

**Oracle® Health Sciences Empirica Signal and  
Topics**

User Guide

Release 8.0

**E50110-01**

September 2014

E50110-01

Copyright © 2002, 2014, Oracle and/or its affiliates. All rights reserved.

This software and related documentation are provided under a license agreement containing restrictions on use and disclosure and are protected by intellectual property laws. Except as expressly permitted in your license agreement or allowed by law, you may not use, copy, reproduce, translate, broadcast, modify, license, transmit, distribute, exhibit, perform, publish, or display any part, in any form, or by any means. Reverse engineering, disassembly, or decompilation of this software, unless required by law for interoperability, is prohibited.

The information contained herein is subject to change without notice and is not warranted to be error-free. If you find any errors, please report them to us in writing.

If this is software or related documentation that is delivered to the U.S. Government or anyone licensing it on behalf of the U.S. Government, the following notice is applicable:

U.S. GOVERNMENT END USERS: Oracle programs, including any operating system, integrated software, any programs installed on the hardware, and/or documentation, delivered to U.S. Government end users are "commercial computer software" pursuant to the applicable Federal Acquisition Regulation and agency-specific supplemental regulations. As such, use, duplication, disclosure, modification, and adaptation of the programs, including any operating system, integrated software, any programs installed on the hardware, and/or documentation, shall be subject to license terms and license restrictions applicable to the programs. No other rights are granted to the U.S. Government.

This software or hardware is developed for general use in a variety of information management applications. It is not developed or intended for use in any inherently dangerous applications, including applications that may create a risk of personal injury. If you use this software or hardware in dangerous applications, then you shall be responsible to take all appropriate fail-safe, backup, redundancy, and other measures to ensure its safe use. Oracle Corporation and its affiliates disclaim any liability for any damages caused by use of this software or hardware in dangerous applications.

Oracle and Java are registered trademarks of Oracle and/or its affiliates. Other names may be trademarks of their respective owners.

Intel and Intel Xeon are trademarks or registered trademarks of Intel Corporation. All SPARC trademarks are used under license and are trademarks or registered trademarks of SPARC International, Inc. AMD, Opteron, the AMD logo, and the AMD Opteron logo are trademarks or registered trademarks of Advanced Micro Devices. UNIX is a registered trademark of The Open Group.

This software or hardware and documentation may provide access to or information on content, products, and services from third parties. Oracle Corporation and its affiliates are not responsible for and expressly disclaim all warranties of any kind with respect to third-party content, products, and services. Oracle Corporation and its affiliates will not be responsible for any loss, costs, or damages incurred due to your access to or use of third-party content, products, or services.

# Table of Contents

Release notes and other documents .....	1
Before you begin.....	3
Prerequisites and usage notes .....	3
Multiple sessions .....	4
Dialog boxes.....	4
Adobe® Acrobat® Reader .....	4
ZIP file utility .....	4
Microsoft Excel .....	5
SAS System Viewer .....	5
Base SAS .....	5
Built-in reports.....	5
Copy to Clipboard feature.....	5
Getting started .....	7
About the Empirica™ Signal application.....	7
Data mining runs.....	7
Run results .....	7
Querying and reporting .....	8
Drug profiles.....	8
Topics .....	8
Signal detection methods .....	10
What Do Data Mining Statistics Do? .....	10
Statistical Association vs. Causal Relationship .....	10
Prioritizing with Rankings or Thresholds .....	10
Using Ranking .....	10
Choosing a Threshold.....	11
Other Factors to Consider .....	11
What are the Data Mining Statistics?.....	11

How Does the Method Cope with Statistical Uncertainty? .....	12
Can the Method Adjust for Confounding? .....	12
Why Do Statistics for Significance Matter? .....	13
Using Significance Scores .....	13
Comparing Significance and Association Scores .....	13
Benefits: Automated, Objective Analysis .....	14
Costs: False Alarms .....	14
Summary: Comparing Signal Detection Methods .....	15
Improving Statistical Algorithms .....	15
Data Mining Bibliography .....	15
Data mining FAQs .....	17
Why data mining? .....	17
Interpretation of results .....	17
Counts .....	18
EB05 and EB95 .....	19
Threshold EB05 .....	20
False positives and negatives .....	20
Signaling sensitivity .....	21
Working with new drugs and small samples sizes .....	22
Stratification and subsets .....	22
Cross-drug comparisons .....	23
Combining reports in a single data mining analysis .....	24
Data issues .....	24
Comparing EBGM values .....	25
Logging into the Empirica Signal application .....	26
Changing your password .....	27
Setting user preferences .....	28
General user preferences .....	28
Preferences for selecting and viewing run results .....	29

Preferences for creating runs .....	30
Preferences for viewing drug profiles .....	31
Preferences for viewing signals.....	32
Preference for topics .....	32
Specifying settings .....	34
Options for managing users .....	34
Options for monitoring the system.....	34
Options for administering the system.....	34
Options for configuring the system .....	34
Navigating with tabs.....	36
Using Empirica Signal commands .....	37
Using Help.....	38
Sending feedback.....	39
Exiting the Empirica Signal application .....	40
Common tools .....	41
Selecting values from a list.....	41
Selecting a single value.....	41
Selecting multiple values .....	41
Filtering available values .....	42
Selecting hierarchy terms.....	44
Browsing terms .....	44
Reviewing terms.....	45
Searching for terms .....	45
Selecting terms .....	49
Selecting table columns .....	51
Selecting entries .....	52
Special characters .....	53
Match string syntax .....	53
Specifying a SQL WHERE clause.....	55

Text variables .....	55
Numeric variables.....	56
Date variables.....	56
Column names .....	56
SQL functions .....	57
Publishing objects .....	59
Saving an object to a topic .....	60
Timestamped data.....	61
Specifying an As Of date .....	61
Using projects.....	62
Tables.....	63
About tables .....	63
Navigating between pages.....	63
Finding text .....	63
Vertical scrollbars .....	63
Column descriptions .....	63
Sorting the table .....	64
Arranging table columns .....	65
Printing a table .....	67
Downloading data .....	68
Drilldown.....	71
Drilling down .....	71
Viewing a list of cases.....	72
Creating a case series from drill-down information .....	73
Transferring cases to a case series .....	74
Viewing case details .....	75
Case ID links .....	76
Data configurations .....	77
Selecting a data configuration.....	77

Example.....	77
Viewing data configuration variables.....	79
Specifying an As Of date .....	80
Data configuration and object compatibility .....	81
Data mining runs.....	81
Saved lists.....	81
Queries and reports .....	81
Case series (not query-based) .....	82
Deleted data configurations .....	82
Saved lists.....	83
About saved lists.....	83
Saved Lists page.....	84
General activities.....	84
Row-specific activities .....	84
Field descriptions—Saved List page.....	84
Creating or editing a saved list.....	86
Adding saved lists in bulk .....	88
Viewing or printing a saved list .....	89
Setting permissions for a saved list .....	90
Saved List information .....	91
Working with drug profiles.....	93
About drug profiles and layouts.....	93
Drugs page .....	94
General activities.....	94
Selecting drugs for a drug profile .....	95
Selecting a drug profile layout .....	96
Printing or copying charts (Drugs tab) .....	98
Linking to an outside URL.....	99
Managing drug profile layouts .....	100

Managing existing drug profile layouts .....	100
Creating a new drug profile layout.....	101
Saving a drug profile layout.....	104
Adding a chart to a drug profile layout .....	105
Ordering charts in a drug profile layout.....	107
Renaming a drug profile layout .....	108
Chart types and options .....	109
Working with chart options .....	109
Sector map graph (Drugs tab) .....	110
Bar graph (Drugs tab) .....	113
Confidence interval graph (Drugs tab) .....	114
Nested confidence interval graph (Drugs tab) .....	115
Cumulative map graph (Drugs tab) .....	117
Reports (Drugs tab).....	119
Examples .....	119
Creating data mining runs .....	121
About data mining runs.....	121
Viewing existing data mining runs .....	123
Data mining run options .....	123
Row menu options .....	124
Data Mining Runs page .....	125
General activities.....	125
Row-specific activities .....	125
Field descriptions—Data Mining Runs page .....	125
Creating a data mining run .....	128
Defining a database restriction.....	130
About custom terms .....	132
Defining custom terms.....	133
Creating a query from an existing query .....	135



Refining a query .....	136
Selecting values .....	136
Matching a text string .....	136
Specifying ranges .....	137
Specifying report IDs .....	137
Creating an MGPS run .....	138
About MGPS runs .....	138
MGPS computations .....	139
Item variables .....	139
Drug-event combination scores .....	139
Interaction scores .....	140
Custom terms and synthetic values .....	140
PRR computations .....	142
Default PRR computations .....	142
Counts based on drug-event combinations .....	143
Drug of interest in comparator set .....	143
Yates correction .....	143
Stratified PRR computation .....	144
ROR computations .....	145
ROR computations .....	145
Counts based on drug-event combinations .....	145
Stratified ROR computations .....	146
Reference .....	146
Selecting variables for an MGPS run .....	147
Using stratification variables .....	148
Example .....	148
Defining subsets .....	150
Using a subset variable .....	150
Example .....	150

Selecting a subset variable .....	153
Defining subset values .....	154
Defining subset labels .....	156
Default labels.....	156
Specifying data mining parameters.....	157
Creating a logistic regression run .....	161
About logistic regression runs .....	161
Logistic regression computations.....	163
Logistic Regression .....	163
Estimating odds ratios for multiple risk factors .....	165
Specifying predictors .....	166
Logistic regression models: standard and extended .....	167
Logistic regression log files .....	171
Selecting variables for logistic regression .....	173
Selecting events for logistic regression.....	174
Specifying drugs for logistic regression .....	176
Viewing interactions .....	179
Defining data mining run options.....	180
Naming a data mining run .....	181
Submitting a data mining run .....	182
MGPS run parameters .....	182
Logistic regression run parameters .....	184
Managing data mining runs.....	186
Renaming a data mining run.....	186
Viewing details of a data mining run .....	187
MGPS runs.....	187
Logistic regression runs.....	189
Viewing jobs for a data mining run .....	191
Viewing job details for a data mining run .....	193

Canceling or deleting a data mining run .....	194
Which runs you can cancel or delete .....	194
Re-running a data mining run .....	196
Viewing data mining results.....	199
About data mining run results.....	199
Viewing a data mining results table .....	200
Finding and selecting a data mining run .....	202
Specifying results criteria .....	204
Selecting data mining results criteria .....	204
Dimensions and patterns.....	207
Dimensions.....	207
Patterns .....	208
Looking up drug names.....	210
Viewing results tables .....	211
Data mining results for MGPS runs .....	211
Data mining results for logistic regression runs .....	217
Results Table .....	217
Covariates Table .....	218
Interactions Table.....	218
Precision of displayed values in data mining results .....	221
Relative reporting ratio measures .....	221
Expected values .....	221
Probability values .....	221
Creating a case series from a results table .....	222
Viewing results graphs .....	224
Choosing a data mining results graph .....	224
Graphs for 2D results.....	226
Graphs for 3D results.....	228
Working with results graphs .....	229

Setting graph cutpoints and palette choices .....	231
Bar graphs.....	233
About bar graphs .....	233
Viewing a bar graph .....	235
Confidence interval graphs.....	237
About confidence interval graphs .....	237
Viewing a confidence interval graph.....	239
Discrete map graphs .....	242
About discrete map graphs .....	242
Viewing a discrete map graph .....	244
Cumulative map graphs.....	247
About cumulative map graphs.....	247
Viewing a cumulative map graph.....	249
Nested confidence interval graphs .....	252
About nested confidence interval graphs .....	252
Viewing a nested confidence interval graph .....	254
Hierarchy graphs .....	256
About hierarchy graphs .....	256
Viewing a hierarchy graph .....	258
Overlap graphs.....	260
About overlap graphs.....	260
Viewing an overlap graph .....	261
Sector maps .....	263
About sector maps .....	263
Viewing a sector map .....	265
Zooming in on a sector map .....	268
Viewing sector map statistics .....	269
Working with queries .....	271
About queries .....	271

Queries page .....	273
General activities.....	273
Row-specific activities .....	273
Field descriptions—Queries page .....	273
Creating a query from an existing query .....	275
Viewing existing queries.....	276
Creating a query .....	278
Defining query conditions.....	278
Specifying query logic.....	280
Logical operators.....	280
Set operators.....	280
Operator priority .....	280
Examples .....	281
Null values .....	286
Previewing a query.....	288
Saving a query .....	289
Running a query .....	290
Selecting query values.....	291
Matching a text string .....	291
Specifying ranges .....	291
Specifying report IDs .....	291
Viewing query results .....	293
Viewing a query .....	294
Renaming a query .....	295
Working with case series.....	297
About case series .....	297
Query-based case series.....	297
Viewing existing case series.....	299
General activities.....	299

Action menu options .....	299
Case Series page .....	301
General activities.....	301
Row-specific activities .....	301
Field descriptions—Case Series page.....	302
Viewing cases in a case series.....	304
Case series options.....	304
Reviewing case details .....	306
Using the PRR calculator .....	308
Selecting a case series for PRR computation .....	311
Renaming a case series.....	312
Copying a case series .....	313
Combining case series .....	315
Creating a case series .....	316
Creating or editing a query-based case series .....	316
Saving a case series .....	318
Creating an empty case series .....	319
Manually adding cases to a case series .....	320
Transferring cases to a case series .....	321
Creating a case series from drill-down information .....	322
Case series background processing.....	323
About background processing .....	323
About background processing job queues.....	324
About background processing job status .....	325
Viewing background processing job status.....	326
Cancelling a background processing job .....	327
Working with reports .....	329
About reports .....	329
Report structure.....	330

Viewing existing report definitions .....	331
Viewing report batch runs .....	333
Truncating a Report Batch Run .....	334
Report Definitions page.....	335
General activities.....	335
Row-specific activities .....	335
Field descriptions—Report Definitions page .....	336
Report background processing .....	337
About background processing .....	337
About background processing job queues .....	338
About background processing job status .....	339
Viewing background processing job status.....	340
Cancelling a background processing job .....	341
Creating report definitions .....	342
Selecting a case series for a report.....	342
Creating or editing a report definition .....	343
Error messages .....	345
Editing report columns.....	346
Adding rows and columns to a report definition .....	346
Specifying column attributes variables .....	347
Specifying a data source in a report.....	349
Specifying content details.....	350
Aggregation methods for text or date variables .....	351
Aggregation methods for numeric variables .....	352
Naming a report definition.....	354
Specifying variable breakdowns.....	355
Defining breakdown details.....	355
Report performance with breakdown details.....	356
All column .....	356

Example.....	357
Defining breakdown by distinct values .....	358
Example.....	358
Defining breakdown by individual values .....	359
Example.....	360
Editing individual value labels .....	362
Defining breakdown by grouped values .....	363
Cutpoints .....	365
Defining date cutpoints .....	366
Existing report definitions and date variables .....	366
Adding additional rows .....	366
Defining breakdown by cutpoints.....	367
Viewing column statistics .....	368
Defining breakdown by query values .....	369
Specifying report attributes/descriptors .....	370
Editing report attributes .....	370
Setting up report drill-down.....	371
Specifying report restrictions .....	372
Editing report descriptors .....	373
Previewing a report .....	375
Using XML to create a report definition.....	376
Viewing a report.....	377
Working with report data.....	377
Managing report rows .....	378
Sorting the report.....	378
Renaming a report definition .....	379
Copying a report definition .....	380
Built-in reports .....	381
Age Group: Gender [N] – Summary: Counts by Age Group by Gender .....	381



Drugs and Events – Detail: ISR, Gender, Age (years), Generic Drugs, Events .....	381
Outcome [%] – Summary: Percentages by Outcome .....	381
Report Type: SOC [N] – Summary: Counts by Report Type by SOC .....	382
Route of Administrations [N,%] – Summary: Counts and Percentages by Route of Administration .....	382
Sample Counts – Compares a variety of report counts .....	383
SOC [%] – Summary: Percentages by SOC .....	383
SOC/HLGT/HLT [N] – Summary: Counts by SOC, HLGT and HLT .....	384
Source [N, %] – Summary: Counts and Percentages by Source .....	384
Sources and Outcomes – Detail: ISR, Gender, Age (years), Source(s), Serious? and Outcome(s) .....	385
Year: Report Type/Seriousness [N] – Summary: Counts by Year by Report Type/Seriousness .....	385
Creating interactive reports .....	387
About interactive reports.....	387
Interactive report definitions.....	387
Valid report definitions .....	387
Creating or editing an interactive report definition .....	388
Interactive Reports page.....	391
General activities.....	391
Row-specific activities .....	391
Field descriptions—Interactive Reports page .....	392
Deleting an interactive report definition .....	393
Viewing a report definition.....	394
About all cases summary reports .....	395
Example.....	395
Creating an all cases summary report output.....	397
Defining a query for an interactive report definition .....	398
Breakdown details .....	399
Creating a query from an existing query .....	400
Running a query .....	401

Creating a report definition file.....	402
Input file .....	403
Viewing report outputs.....	405
Viewing existing report outputs.....	405
General activities.....	406
Action menu options .....	406
Creating a report output .....	408
Saving a report output.....	409
Working with a report output.....	410
Working with report data.....	410
Managing report rows .....	410
Sorting the report output.....	411
Renaming a report output .....	412
Viewing report graphs .....	413
Working with report graphs .....	413
Report graph types.....	415
Graph display options .....	416
Aggregate bar graphs.....	417
About aggregate bar graphs .....	417
Viewing an aggregate bar graph.....	418
Detail bar graphs.....	420
About detail bar graphs.....	420
Viewing a detail bar graph.....	423
Box plot graphs .....	424
About box plots.....	424
Viewing a box plot.....	426
Scatter plot graphs .....	428
About scatter plots .....	428
Viewing a scatter plot .....	430

Managing signals.....	433
About signal management.....	433
Working with drug-event combinations .....	434
Drug-Event Combinations page.....	434
General activities.....	434
Row-specific activities .....	436
Field descriptions—Drug-Event Combinations page .....	436
Filtering comments on the Drug-Event Combinations page .....	440
Filtering drug-event combinations using a SQL WHERE clause.....	441
Viewing age group breakdown for a drug-event combination .....	442
Viewing gender breakdown for a drug-event combination.....	443
Viewing interactions for a drug-event combination .....	444
Suppressing a drug-event combination .....	446
Associating a topic with a drug-event combination .....	447
Assigning a reviewer.....	449
Adding a private comment.....	450
Similar combinations.....	451
Similar Combinations dialog box .....	451
General activities.....	451
Row-specific activities .....	451
Field descriptions—Similar Combinations dialog box.....	452
Viewing signals for similar drug-event combinations .....	453
View signal history.....	454
Available drug-event combination statistics .....	454
Field descriptions—Statistical score.....	454
Field descriptions—Review information for the drug-event combination .....	455
Field descriptions—Review information for the drug-event combination .....	455
Viewing signal history for a drug-event combination .....	457
Document review .....	458

Document review for a drug-event combination .....	458
Comment on a drug-event combination.....	458
Suppress drug-event combination .....	458
Topic association with a drug-event combination .....	459
Documenting your review.....	460
Managing signal views .....	461
Viewing existing signal views .....	461
Row-specific activities .....	462
Selecting signal views.....	463
Default view .....	463
Review period view.....	463
Modified views .....	463
Renaming a signal view .....	465
Organizing signal views.....	466
Saving a signal view .....	467
Working with drug overviews .....	469
Viewing drug overviews .....	469
General activities.....	470
Row-specific activities .....	470
Adding and editing a drug .....	472
Entering a drug note.....	474
Viewing a drug note .....	475
Performing auto-assignment .....	476
About automatic assignment of reviewers .....	476
How reviewers are distributed over drugs .....	476
Overriding automatic assignments.....	477
Automatically assigning reviewers .....	478
Viewing or modifying automatic assignments.....	479
Working with drug-event combination comments .....	480

Drug Comments page .....	480
General activities.....	480
Row-specific activities .....	481
Field descriptions—Drug Comments page .....	481
Viewing detailed comments for a drug .....	483
Field descriptions—View Drug Comments page.....	483
Adding a comment to multiple combinations.....	485
Adding a private comment.....	486
Using sector maps .....	487
Viewing a sector map (Signals tab) .....	487
Setting display options for a sector map (Signals tab).....	489
Zooming in on a sector map .....	491
Viewing sector map statistics.....	492
Working with topics .....	493
About topics .....	493
Topics page .....	495
General activities.....	495
Row-specific activities .....	495
Field descriptions—Topics page .....	495
Sections of the Topic page.....	498
Sections .....	498
Field descriptions—Topic General Information .....	500
Viewing a topic .....	501
Editing a topic.....	502
Adding a topic.....	503
Selecting a work team .....	506
Linking topics .....	508
Adding and viewing comments.....	509
Viewing or adding comments for a topic .....	509

Viewing or adding comments for an action.....	509
Viewing or adding comments for an attachment .....	510
Reopening a topic.....	512
Working with attachments .....	513
Working with attachments.....	513
Viewing Attachments .....	513
Adding an attachment column to the Topics page .....	514
Row menu activities.....	514
Editing and deleting attachments.....	515
Saving an object to a topic .....	516
Signal objects types .....	517
Save to Topic dialog box .....	518
Field descriptions—Save to Topic dialog box .....	518
Adding a document-style attachment.....	520
Selecting a topic .....	522
Editing an attachment.....	524
Viewing source details for an attachment .....	525
Viewing tabular data.....	526
Working with topic actions.....	527
Working with topic actions.....	527
Viewing Topic Actions.....	527
Editing topic actions.....	528
Topic Action page.....	529
Sections .....	529
Field descriptions—Action General Information .....	530
Viewing a topic action .....	532
Adding a topic action .....	533
Editing a topic action .....	535
Reopening an action .....	536

Viewing topic reports .....	537
About topic reports.....	537
Standard Reports .....	537
Predefined Oracle BI EE reports.....	537
Generating topic reports .....	538
Generating a standard topic report .....	538
Generating a predefined topic report in Oracle Business Intelligence Enterprise Edition (Oracle BI EE).....	538
Predefined OBIEE topic reports .....	540
Action State Timelines.....	540
Actions by Status .....	540
Actions by Topic .....	541
Attachments in Topics.....	542
Topic Counts by Work Team/User.....	543
Topic State Timelines.....	544
Topics by State .....	544
Topics by State report .....	546
General activities.....	546
Field descriptions—Topics by State report.....	546
Topics by Action Due Date report .....	548
General activities.....	548
Field descriptions—Topics by Action Due Date .....	548
Creating a topic PDF or ZIP file.....	550
Selecting attachments for a topic PDF or ZIP file .....	550
Selecting content attributes for a topic PDF or ZIP file.....	552
Viewing source data .....	555
About source data .....	555
Source database tables .....	557
Examples of base tables .....	557
Source database tables preparation .....	558

- Resulting source database tables..... 558
- Viewing a data source table..... 560
  - Data Source Tables..... 560
- Setting viewing options for a data source table ..... 562
- Filtering a data source table ..... 564
- Empirica Signal administration ..... 565
  - Managing users ..... 565
  - About user administration ..... 565
  - User permissions..... 566
    - Superusers ..... 568
      - Managing user profiles ..... 570
  - Viewing existing user profiles..... 570
  - Adding or editing a user profile ..... 571
  - Assigning roles to a user profile ..... 573
  - Assigning permissions to a user profile ..... 574
    - Managing users ..... 575
  - Viewing existing users ..... 575
  - Changing user passwords..... 577
- Empirica Signal and Oracle single sign-on usernames ..... 578
- Adding and editing a user..... 579
- Applying a user profile ..... 582
- Assigning roles to a user ..... 583
- Assigning permissions to a user ..... 584
- Renaming users ..... 585
- Deleting a user ..... 586
  - Managing user roles..... 587
- Predefined user roles ..... 587
- Viewing existing user roles ..... 589
- Creating a user role..... 590



Editing a user role .....	591
Deleting a user role .....	592
Managing login groups .....	593
Viewing existing login groups.....	593
Creating a login group .....	594
Editing a login group.....	596
Deleting a login group.....	598
Managing work teams .....	599
About work teams .....	599
Work team permissions.....	600
Permissions that can be assigned to work teams .....	600
Administer Work Team permission.....	601
Default work team permissions .....	601
Viewing existing work teams.....	603
Adding or editing a work team .....	605
Assigning permissions to work team members .....	606
Managing LDAP users .....	607
Configuring Empirica Signal for use with LDAP .....	607
LDAP Properties .....	609
Importing LDAP users .....	612
Refreshing LDAP users .....	613
Using single sign-on.....	614
About single sign-on .....	614
Configuring single sign-on .....	615
Single Sign-On Configuration Checklist.....	615
Renaming users .....	617
Managing data configurations .....	618
About data configurations.....	618
Data configuration tables.....	619

Example of data configuration.....	620
Viewing existing data configurations .....	621
• Data configuration options .....	621
Row menu options .....	622
Viewing a data configuration.....	623
Data configuration options.....	623
Row menu options.....	623
Data configuration and variables information .....	624
Data configuration information .....	624
Data configuration variable information .....	625
Defining data configurations.....	627
Adding a data configuration .....	627
Additional configuration activities .....	629
Connecting to an Oracle account .....	630
Specifying a drill-down map table.....	631
Selecting a drilldown map table.....	631
Creating a drilldown map table.....	631
Editing a drilldown map table .....	632
Copying a drilldown map table .....	633
Drilldown information types .....	633
Selecting an Oracle table or column.....	636
Narrative text .....	637
Concatenation of narrative text .....	637
Narrative text spanning multiple rows .....	637
Source description table.....	639
Content of the source description table .....	639
Timestamped data .....	640
Drug and event hierarchies.....	641
Specifying hierarchy versions for timestamped data .....	642

Unique values table .....	644
Adding or editing a data configuration variable.....	645
Validating data configurations.....	651
Validation process .....	652
Situations that generate error or warning messages .....	652
Publishing multiple data configurations .....	654
Importing data configurations.....	655
Editing a data configuration .....	656
Copying a data configuration .....	658
Deleting a data configuration .....	659
Transforming data .....	661
About data transformations .....	661
Transformation options .....	661
Transformation results .....	662
Mapping text values .....	663
Text mapping process .....	663
Changing only the hierarchy .....	664
Generating results for mapped values .....	665
Adding a mapped variable to the configuration.....	666
Comparing custom terms and mapped text values .....	668
Defining variable cutpoints .....	669
Converting date values .....	672
Viewing column statistics .....	674
Excluding synthetic values.....	675
Managing aliases .....	677
About aliases .....	677
Viewing existing aliases .....	678
Manage Alias page options.....	679
Row menu options.....	679

Adding or editing an alias .....	680
Managing drug profile configurations.....	681
About drug profile configurations.....	681
Setting up drug profiles .....	682
Required permissions .....	682
Setting up the Drug Profiles feature .....	682
Refreshing data for a drug profile .....	685
Viewing existing drug profile configurations .....	687
Drug profile configuration options.....	687
Row menu options.....	687
Viewing a drug profile configuration.....	689
Adding or editing a drug profile configuration.....	691
Referencing data mining runs and aliases .....	691
Available drugs list .....	692
Saving a drug profile configuration .....	693
Renaming a drug profile configuration.....	694
Defining the Links menu.....	695
Managing topic workflow configurations .....	696
Topic workflow configurations .....	696
Setting up the topics feature .....	697
Manage Topic Workflow Configurations page .....	698
General activities.....	698
Row-specific activities .....	698
Field descriptions—Manage Topic Workflow Configurations page.....	698
Adding topic workflow configurations .....	700
Copying a topic workflow configuration .....	700
Definitions in the sample topic workflow configuration .....	701
Basic configuration options .....	701
Field definitions: topics .....	701

Field definitions: actions .....	702
Field definitions: attachments .....	702
Topic states .....	703
Topic field accessibility .....	703
Action states.....	704
Action field accessibility.....	704
Attachment field accessibility .....	704
Adding a topic workflow configuration .....	705
Importing a workflow configuration account.....	706
Editing a topic workflow configuration .....	707
Field descriptions—Edit Workflow Configuration page .....	707
Deleting a topic workflow configuration .....	710
Create PDF .....	712
Create PDF for topic workflow configuration.....	712
Creating a PDF for a topic workflow configuration .....	713
Export topic workflow configurations .....	714
Export topic workflow configuration .....	714
Exporting a topic workflow configuration .....	716
Import topic workflow configurations.....	717
Import topic workflow configuration.....	717
Importing a topic workflow configuration file.....	718
Managing fields .....	719
Fields.....	719
Manage Fields page .....	720
General activities.....	720
Row-specific activities .....	720
Field descriptions—Manage Fields page .....	720
Adding a field .....	723
Editing a field .....	725

- Viewing a field ..... 726
- Deleting a field ..... 727
- Identifying a field as a filter field ..... 728
- Adding a drop-down list field ..... 730
- Adding linked fields ..... 733
  - Add the first, parent, field..... 733
  - Add the second, subsidiary, field ..... 734
  - Define the parent-child values..... 735
- Adding a multi-selection list field ..... 736
- Constraining field values by work team ..... 738
  - Add the field to a topic workflow configuration ..... 738
  - Define the values ..... 739
  - Set site options ..... 739
- Display order for fields and field values ..... 741
- Modifying the display order for a field ..... 742
  - Managing field values..... 743
- Viewing valid values for a field ..... 743
  - Define Field Values options ..... 744
  - Row menu options ..... 744
- Adding and editing valid values for a field..... 745
- Uploading a table of valid values ..... 746
  - Create the table of values..... 746
  - Upload the table of valid values..... 746
- Modifying the display order for field values ..... 748
  - Managing field access..... 749
- Managing topic field accessibility by state..... 749
- Managing action field accessibility by state ..... 751
- Managing attachment field accessibility by type ..... 753
  - Managing workflow states..... 755

Topic states.....	755
Manage Topic States page.....	756
General activities.....	756
Row-specific activities .....	756
Field descriptions—Manage Topic State page .....	756
Adding a topic state.....	758
Editing a topic state.....	759
Viewing a topic state .....	760
Deleting a topic state.....	761
Action states .....	762
Manage Action States page .....	763
General activities.....	763
Row-specific activities .....	763
Field descriptions—Manage Action State page .....	763
Adding an action state .....	765
Editing an action state .....	766
Viewing an action state .....	767
Deleting an action state .....	768
Managing email notification rules.....	769
Manage Email Notification Rules page .....	769
General activities.....	769
Row-specific activities .....	769
Field descriptions—Manage Email Notification Rules page .....	769
Adding an email notification rule .....	771
Editing an email notification rule .....	772
Deleting an email notification rule .....	773
Inserting a field variable into email notification .....	774
About topic templates .....	775
Manage Topic Templates page .....	775

General activities.....	775
Row-specific activities .....	775
Field descriptions—Manage Topic Templates page .....	775
Adding a topic template .....	777
Selecting a work team for topic template .....	779
Topic Template page .....	781
Sections .....	781
Field descriptions—Topic Template General Information .....	782
Viewing a topic template .....	783
Editing a topic template .....	784
Copying a topic template.....	785
Deleting a topic template .....	786
About topic template action.....	787
Topic Template Action page.....	787
Sections .....	787
Field descriptions—Template Action General Information .....	788
Adding a topic template action .....	789
Viewing a topic template action.....	790
Editing a topic template action .....	791
Managing signal configurations.....	792
About signal configurations.....	792
Manage Signal Configuration page.....	793
General activities.....	793
Row-specific activities .....	793
Field descriptions—Manage Signal Configurations page .....	793
Editing a signal configuration .....	795
Field descriptions—Edit Signal Configuration page .....	795
Editing the columns on the Drug-Event Combinations page .....	797
Field descriptions—Edit Drug-Event Combinations Column dialog box.....	797



Adding a signal comment type .....	798
Field descriptions—Add/Edit Comment Type dialog box .....	798
Editing a signal comment type .....	800
Field descriptions—Edit Comment Type Table dialog box .....	800
Deleting a signal comment type .....	802
Changing the sort order of a signal comment type.....	803
Adding a review period .....	804
Editing a review period .....	805
Deleting a review period .....	806
Changing the sort order of a review period .....	807
Configuring the columns that appear on the Drug Overviews page .....	808
Field descriptions—Edit Drug Overview Column dialog box.....	808
Editing the view that corresponds to a column on the Drug Overviews page .....	809
Mapping reviewers to users .....	810
Maintaining data mining runs .....	811
Managing data mining run storage .....	811
Row menu options .....	811
Exporting data mining run data .....	812
Importing data mining run data .....	813
Marking the data mining run as archived.....	814
Moving a data mining run.....	815
Changing user default data mining runs .....	816
Creating a run definition file .....	817
Managing the server .....	818
Viewing currently logged in users .....	818
About auditing .....	819
Viewing the user activity audit trail.....	821
Viewing the server status .....	823
Viewing free disk space.....	824

Setting site options .....	825
Field descriptions—Site Options page .....	825
Sending a message to all users .....	830
Manually restarting the listener process .....	831
Appendices.....	833
A: MGPS independence model.....	833
MGPS independence model.....	833
2D results.....	833
3D results.....	833
B: Hierarchy tables .....	835
Using hierarchy tables .....	835
Glossary.....	837
Index.....	843

## Release notes and other documents

To display a page where you can access Empirica™ Signal release notes, data release notes (if applicable), and customer-specific information (if applicable), click [here](#). These documents are provided as PDF (Portable Document Format) files. To view these documents, you must have Adobe® Acrobat® Reader installed on your computer. Adobe Acrobat Reader is freely distributed software for viewing and printing PDF files, and is available at [www.adobe.com](http://www.adobe.com).

---

**Note:** If you have popup blocking software installed on your PC, it may prevent the PDF files from displaying. You may need to disable your popup blocking software before displaying PDF files.

---



## Before you begin

### Prerequisites and usage notes

The Empirica Signal application requires Microsoft® Internet Explorer (IE) browser, version 8.0, 9.0, or 10.0.

You can configure IE to print graphs and other outputs, such as case details, that use color and download data.

#### To configure IE:

1. Open Internet Explorer browser.
2. From the **Tools** menu, select **Internet Options**.
3. On the **Advanced** tab, scroll down to the **Printing** section.
4. Check **Print background colors and images**. This setting allows the Empirica Signal application to print the color key along with a graph, and the shading for table column headers and grid lines.
5. In the **Security** section, clear the **Do not save encrypted pages to disk** check box so that the application can download data.
6. Click **OK**.

Due to a limitation in IE, when you download data you may not be able to use the **Open** button in the File Download dialog box. If you encounter problems opening a file, use the Save option and then open the saved file. Or, you can clear Internet Explorer's cache.

#### To clear the cache:

1. Open the Internet Explorer browser.
2. From the **Tools** menu, select **Internet Options**.  
The Internet Options dialog box appears.
3. On the **General** tab, and in the **Browsing history** section, click **Delete...**  
The Delete Browsing History dialog box appears.
4. Select the check box next to each category of information you want to delete.
5. Click **Delete**.
6. Close the Internet Explorer browser.

Because the appearance of many pages presented by the Empirica Signal application relies on choices made on previous pages, Oracle recommends that you do not use the browser's **Back** button. Choices made on other pages may not be captured appropriately. To make navigation between pages easier, while providing accurate information on each page, **Back** links appear on many application pages. It is preferable to use these **Back** links, and tabs, to navigate.

## Multiple sessions

Do not run more than one session of the application using multiple browser sessions or several tabs in the same browser.

## Dialog boxes

Some features of the application and its online help system rely on the use of dialog boxes. If you have pop-up blocking software installed, it might prevent these dialog boxes from opening.

### To turn off the pop-up blocker:

1. Open the Internet Explorer browser.
2. From the **Tools** menu, select **Pop-up Blocker**, and then select **Turn On Pop-up Blocker** to toggle it off.

### To allow pop-up windows only for the website on which you run the application:

1. Open the Internet Explorer browser.
2. From the **Tools** menu, select **Pop-up Blocker**, and then select **Pop-up Blocker Settings**.

The Pop-up Blocker Settings dialog box appears.

3. Add the Empirica Signal website to the list of allowed sites.

## Adobe® Acrobat® Reader

For certain features in Empirica Signal, you can download to a Portable Document Format (PDF) file. To do so, you must install Adobe Acrobat Reader on your computer. Adobe Acrobat Reader is freely distributed software for viewing and printing PDF files, and is available at [www.adobe.com](http://www.adobe.com).

You also need Adobe Acrobat Reader to view any PDF files that may be provided as links in this help system.

A PDF file that you create for a [topic](#) might include links to open ZIP files that are attached to the topic. Security features in Adobe Acrobat Reader might prevent you from opening a ZIP file from within the PDF file. See the Adobe website for instructions on modifying this behavior.

If you are using Adobe Acrobat Reader 6.x, you might need to set link options correctly to view certain types of attachments from within a topic PDF file.

## ZIP file utility

If you create ZIP archive files when downloading data, you must have a ZIP file compression and extraction utility, such as WinZip, installed on your computer. WinZip is available at [www.winzip.com](http://www.winzip.com). You must also associate the file extension .zip with the ZIP file utility.

---

**Note:** If your PC runs Windows XP, you do not need to install a ZIP file utility.

---

## Microsoft Excel

If you plan to download data to Microsoft Excel®, make sure that Excel is installed on your computer.

## SAS System Viewer

To view files that you create by downloading data to SAS Version 5 transport files (.xpt files), you need the SAS® System Viewer. The SAS® System Viewer is freely distributed software for viewing and printing .xpt files, and is available at [www.sas.com](http://www.sas.com).

## Base SAS

To use files that you create by downloading data to SAS data step definition files (.sas files), you need Base SAS®. Base SAS® is a third-party application that you can purchase at [www.sas.com](http://www.sas.com).

## Built-in reports

To run the [built-in reports](#) delivered with the Empirica Signal application, you must set up a data stub, as described in *AERS (1q03: S) Configuration Installation Instructions* (located in the Data\_Stub folder on the installation CD).

## Copy to Clipboard feature

Depending on security settings in Internet Explorer, a warning such as, "Do you want to allow this webpage to access your Clipboard?", might appear when you click the **Copy to Clipboard** link. This question can be avoided by adding the Empirica Signal URL to the browser's trusted sites.





## Getting started

### About the Empirica™ Signal application

The Empirica™ Signal application is a web-based analysis environment for generating statistical scores for combinations of drugs and events in a drug safety database, and for detecting signals (unexpected associations of drugs and events). The source data may be public data, such as the data in the Adverse Event Reporting System (AERS); Vaccine Adverse Event Reporting System (VAERS); WHO Vigibase ADR (Adverse Drug Reaction) databases; or your organization's proprietary drug safety database.

Once an Oracle safety database is set up, you define [data configurations](#) in the Empirica Signal application to specify the source data available for data mining, and how it can be used. For example, if the source data includes both trade names and generic names for drugs, the data configuration can specify that data mining be performed using generic names only.

### Data mining runs

Once you have created data configurations, you can perform data mining runs. A data mining run extracts data from the source and applies a statistical algorithm to generate signal scores. The Empirica Signal application offers different algorithms as options for [data mining runs](#):

- **Multi-item Gamma Poisson Shrinker (MGPS)**—For MGPS data mining runs, the run creator can indicate a variety of parameters, such as the number of ways in which drugs and events are combined. For example, a run can generate scores for combinations of up to five values, enabling the study of drug interactions and medical syndromes. Users can specify a database restriction to specify cases to include in a run.
- **Proportional Reporting Ratios (PRR) and Reporting Odds Ratios (ROR)**—You can include computations of PRR and ROR in an MGPS run. PRR computation relates to drug-event combinations, only, in two-dimensional data mining runs. In two-dimensional data mining runs, the application computes the ROR only for drug-event combinations.
- **Logistic Regression (LR)**—These data mining runs model how the probability of an event appearing in an adverse event report depends on multiple predictors (both demographic factors and the presence/absence of various drugs), which can be important for obtaining unbiased results in the presence of polytherapy.

Data mining runs in the Empirica Signal application generate scores that identify potential signals. Your organization determines whether those scores represent true signals.

### Run results

Once a run is completed and published for use by other Empirica Signal users, reviewers can view the resulting signal scores in tabular or graphical format. They can [select criteria](#) to choose results for review and sort the results as needed. Reviewers can also choose a variety of options for displaying the table or graph. If a hierarchy is available, representing different levels for drug or event terms, reviewers can specify terms at any of these hierarchical levels before reviewing results. For example, a reviewer can view the scores for

combinations of a particular drug and any event in a particular MedDRA System Organ Class (SOC), the highest level in the MedDRA event hierarchy.

If appropriate site options and permissions are set up, Empirica Signal users can [drill down](#) from run results to view the list of cases involved. For example, the combination of DrugA and EventB has a high signal score and there are 12 cases with that drug-event combination. The reviewer can drill down to view a list of those 12 cases, and then drill down to detailed information about any of those cases.

Reviewers can also print tables or graphs of results and download them for use in applications such as Microsoft Excel (.xls, .csv) or Microsoft Word (.rtf).

[Signal management](#) is an optional feature in the Empirica Signal application to view disproportionality analysis statistics for successive updates of safety data, allowing monitoring and evaluating of changes in safety signals over time.

## Querying and reporting

You can [query](#) the source data based on criteria that you specify. You can save the query results as a [case series](#), which is a list of cases of interest.

In addition to [reports](#) that are delivered with the Empirica Signal application, you can construct your own reports by specifying which variables to include as columns and which variables determine report rows. There are two types of reports:

- Regular reports, which are non-interactive and are run against cases in a case series.
- [Interactive reports](#), which are based on a specified query for which you can supply values when running the report.

---

**Note:** A special type of interactive report is the [All Cases Summary report](#), which is used for drug profiles.

---

## Drug profiles

On the Drugs tab, you can view drug profiles, which are presentations of statistical and other information about one or more selected drugs. Depending on how the drug profile feature is set up, you can view existing charts or create your own. Drug profiles are made up of charts, which can be either of the following:

- A graph based on the results of a data mining run.
- A graph or table based on a report output.

A drug profile layout is a saved collection of charts, as well as their placement and display options.

## Topics

On the Topics tab, you can organize and track tables, graphs, and documents related to particular subject matter. For example, issues identified through various means, such as automated signal detection, literature review, regulatory requests, and so on, can be saved as attachments to a topic.

You can set up topics to follow workflow through different states, such as Initial, Reviewed, and Closed. You can also assign topics to users and make them visible to [work teams](#).

## Signal detection methods

---

**Note:** This information was excerpted from the WebVDME Newsletter, Volume 2, Issue 2 (Autumn 2005). WebVDME is the previous name of the Empirica Signal application.

---

What benefits can signal detection methods bring to the pharmacovigilance effort, and what are the costs? How can different methods be compared and assessed? What do data mining statistics do? The information in this article is intended to help non-statisticians understand similarities and differences between the statistical algorithms that are used for safety data mining. It can also help reframe these concerns into new questions that can make your evaluation and implementation of signal detection methods more effective.

### What Do Data Mining Statistics Do?

Data mining is the process of applying statistical algorithms to a database, resulting in the generation of statistical values or scores. As part of a pharmacovigilance effort, these scores can alert safety evaluators to potential safety issues, including actual safety signals.

At Oracle, we believe that data mining statistics yield information that safety evaluators can use to help prioritize investigations. Whether a pharmacovigilance group uses data mining or not does not change the need for experienced medical professionals to perform careful evaluations to determine causal relationships between drugs and adverse events.

What data mining statistics do is indicate the strength of the association between a drug of interest and an event in the reporting database: the higher the score, the stronger the statistical association.

### Statistical Association vs. Causal Relationship

While a strong association (high score) may indicate a causal relationship between the drug and the event, it could also be the result of some other circumstance: some examples include an AE that is an indication for the drug (known as “reverse causality”), or a drug-event combination that has been subject to media attention and that has a higher reporting rate than would otherwise occur as a result (often called “publicity effects”). A strong association can also indicate a causal relationship that is already known and labeled.

So, while a high score may serve as an alert to a previously undetected problem, medical knowledge is crucial to the interpretation of data mining results.

### Prioritizing with Rankings or Thresholds

When used with a large database, such as the public FDA AERS data, data mining statistics help users sort through several million potential combinations of drugs and events. Even a hypothetical pharmacovigilance department with an unlimited staff and budget, that could investigate every possible drug-event relationship for causality, could use data mining statistics to help them determine which reviews to undertake first.

### Using Ranking

A straightforward way to prioritize investigations using statistical scores would be to start with the highest score generated and work down through the list to the lowest score. Outside of our hypothetical big-bucks department, practical considerations mean that the number of investigations must be limited: a prioritization approach that ranks scores might result in investigations into the top 10, 250, or 10,000 scores, whatever number is feasible for a group's resources.

## Choosing a Threshold

Another way to limit the number of investigations is to choose one score as a threshold. Any score that exceeds this predetermined threshold alerts reviewers to a potential signal for investigation. Unlike the cutoff for ranking, the number of scores above the threshold will fluctuate over time. But, like ranking, departments can select a threshold score that makes the best use of their resources while helping prioritize investigations.

## Other Factors to Consider

Regardless of whether ranking or a threshold is used for the scores, some reports are likely to be prioritized ahead of any others: a safety evaluator wouldn't have to wait for a high data mining score to flag just one new report of Torsade de pointes, QT prolongation, Stevens-Johnson syndrome, or a similar sentinel event as a high priority for investigation. Serious events in general are likely to need investigation earlier than less serious events. To meet this need for different prioritization levels, a low threshold could be set for sentinel events, a slightly higher one for other serious events, and a third threshold for all other events.

Problems in nonscientific public safety databases, including the biases that result from under reporting, over reporting, and publicity effects, have been widely discussed. When working with signal scores generated from these databases, a higher threshold (or set of thresholds) might be used than when working with a smaller, more controlled and complete company database.

For departments that use ranking as the prioritization method, the relative reliability of the sequencing or ordering of the scores produced by a method may be a consideration. When a threshold is used, any score above that threshold is examined, while with ranking, the highest scores should reflect the strongest associations.

Other considerations, including company goals, the medical knowledge and safety evaluation experience of individual evaluators, and other tools available for the pharmacovigilance effort, also contribute to the prioritization effort.

## What are the Data Mining Statistics?

Some of the data mining statistics that are widely used for signal detection are:

- EBGm – Empirical Bayes Geometric Mean
- IC – Information Component
- PRR – Proportional Reporting Ratio
- ROR – Reporting Odds Ratio

Each of these statistics is the result of a different statistical algorithm. All of the algorithms were designed to uncover the same type of information: a disproportionately high

occurrence of reports for an event and drug, when compared to reports for that event in the entire database. As a result, for large sample sizes, the score that each of these statistics produces for any given drug-event combination is likely to be similar.

---

**Note:** The sample size (N) generally is defined as large if there are 20 or more instances of a drug-event combination in the database.

---

Drugs that are new to the market, or that are prescribed to a small number of patients, may have a small presence in the database. For these drugs, the N may be quite low, which tends to make scores calculated for their drug-event combinations low also.

Some data mining algorithms include statistical techniques that compensate for disparate sample sizes in the safety database and the extreme scores that can result.

### **How Does the Method Cope with Statistical Uncertainty?**

The PRR and ROR statistics do not in themselves indicate a level of certainty or uncertainty due to a small sample size. Rather, each drug-event combination is often accompanied by an additional statistic, a chi squared test statistic, and its corresponding p (significance) value. When you assess a PRR or ROR value, you are supposed to suspect the reliability of large values unless the chi squared value is very large (or, equivalently, the p value is very small). However, there is no clear rule for evaluating a large PRR value that has a moderate p value. Similarly, there is no rule for adjusting for the “multiple comparisons” problem, in that you are focusing on the few largest values of PRR or ROR out of millions that may have been computed in a data mining run.

The algorithms that calculate IC and EBGM address both statistical variability due to small N and multiple comparisons by using a technique called “Bayesian shrinkage.” This statistical technique results in a single relative reporting ratio (with confidence limits) that is easier to interpret directly without the added complexity of a separate chi squared or p value. Reporting ratios that are based on small counts (and that are therefore less reliable) are “shrunk” or moved toward the value 1 using an appropriate Bayesian probability formula. The set of EBGM scores across all drug-event combinations is more restricted than the set of unshrunk scores, so focusing on more extreme EBGM scores is less likely to lead to overestimates of the true reporting ratios than would searching for the largest values of PRR or ROR. The IC method has a similar advantage.

The Bayesian shrinkage technique primarily affects estimates of drug-event reporting ratios based on small counts or small expected counts (that is, when reports mentioning either the drug or the event are quite rare in the database.) Other statistical issues, such as confounding, can cause biased relative reporting ratios even for more frequent drug-event combinations.

### **Can the Method Adjust for Confounding?**

When data mining scores are calculated, adjustments can be made for “confounding” variables. Confounding variables occur in any database that is not completely random. In a drug safety database, for example, a drug that is administered only to the elderly, or only to male subjects, or that is new on the market, has the subject’s age group or gender or the report’s receipt year (or all three) as a confounding variable.

The presence of confounding variables in the data can result in high scores for drug-event combinations that otherwise would not have a strong statistical association. For example, a

drug that is generally prescribed for women over 50, and an event that occurs more frequently for women over 50, may well result in a high score for the combination of that drug and event, based only on the coincidence of the gender and age group involved.

Statistical techniques are available to adjust for confounding variables: for example, a technique called Mantel-Haenszel stratification (used in MGPS) divides the database into groups, one for each value that the variable in question has in the database, and then recalculates an overall score. When a technique like stratification is used, the result is often a lower score (and investigational priority) for a drug-event combination that is affected by a confounding variable, while the effect is minimal on scores for combinations that are not subject to confounding.

### **Why Do Statistics for Significance Matter?**

Each of the data mining statistics listed above, IC, EBGM, PRR, and ROR, indicate the strength of the association between a drug and an event. Each one can also have associated scores that indicate the statistical significance (or uncertainty) of the relationship. As mentioned above, for the PRR and ROR statistics, the chi-squared test of statistical significance can be used to calculate a p value. Unfortunately, the chi squared and p values are in different units than are the basic reporting ratio values, making it hard to interpret them all together. The algorithms for EBGM and IC represent statistical uncertainty with confidence limits, which are less likely to be misinterpreted.

Calculations for significance incorporate information about the sample size. The p value indicates the likelihood that such a large reporting ratio could occur by chance alone if the drug and the event are completely unrelated, but does not provide information about what range of reporting ratios are most likely. A confidence interval shows what range of reporting ratios are consistent with the data. A small N results in a wide confidence interval: the larger the N, the narrower the confidence interval.

### **Using Significance Scores**

A pharmacovigilance group might choose to prioritize investigations based on scores for statistical significance, rather than for association, to avoid following up potential associations that could have arisen merely by chance. However, using a PRR or ROR p value to rank associations may result in excessive focus on drugs and events that are common overall in the database. This may occur because frequently reported drugs and events may have reporting ratios that are only slightly greater than 1, but have very tiny p values. Investigating these drug-event combinations can potentially eclipse larger reporting ratios for less-frequently reported drugs or events.

Both the statistical significance and the reporting ratio can contribute to a prioritization system. This is easier to accomplish with confidence limits than with p values. Ranking drug-event combinations by their lower confidence limits (for MGPS, by using EB05 rather than EBGM) provides an extra layer of protection against false alarms due to chance fluctuation (beyond that afforded by the Bayesian shrinkage discussed above).

### **Comparing Significance and Association Scores**

Comparing the scores for both types of statistics can also be revealing. This illustration shows two drug-event combinations that have identical EB05 scores. The higher EBGM score for the first combination, however, indicates a stronger likelihood of an association than the

EBGM score for the second combination. This graph also gives an indication of the relative number of reports in the database for each combination: Combination 1 has fewer reports than Combination 2, since its confidence interval is relatively wide.



Some pharmacovigilance groups may find it effective to prioritize investigations based on both significance and association scores, rather than relying on only one score. For example, a threshold of  $EBGM > 2$  AND  $EB05 > 1$  could be used. This is roughly equivalent to the common recommendation for PRR, which requires  $PRR > 2$  AND  $N > 2$  AND  $\chi^2 > 4$ .

### Benefits: Automated, Objective Analysis

Signal detection methods are an independent and automated process for assessing all of the drug-event combinations in a safety database, which may contain millions of records. Using these statistics can provide earlier warning than methods that rely on human knowledge, skill, and intuition, and reduce the amount of effort needed to discover signals in safety data.

The value of using a signal detection method is highest when scores alert pharmacovigilance professionals to previously unknown, unexpected, or uncharacteristic events that happen more frequently in combination with one drug than with most all other drugs. These objectively produced alerts can then be evaluated using other pharmacovigilance tools to determine the possibility of a causal relationship.

### Costs: False Alarms

When a pharmacovigilance group uses data mining scores to prioritize investigation, resources may be spent investigating “false positives,” or high scores that do not, in fact, indicate a relationship or causal relationship.

Conversely, a “false negative” can occur when a low score is calculated for a drug-event combination that is, in fact, causally related. Errors of both types can occur with any signal detection method.

If data mining scores are used alone to determine investigational priorities, the group is faced with a conundrum: if you investigate fewer high scores to reduce false positives, you may also increase the number of false negatives. The need for efficiency must be balanced against the cost of missing any true signals.

Fortunately, pharmacovigilance professionals have access to other tools to help make the best choices they can for the situations they need to address. Impact analysis, tracking changes in scores over time, and the “other factors to consider” described above can help a department make the best use of the information that the statistical scores are designed to give them.



## Summary: Comparing Signal Detection Methods

One way to assess the comparative value of different signal scores is to evaluate the results of different algorithms when used to data mine the same database. When setting up such a test, these questions can act as guidelines for the comparison:

- Is the same minimum sample size used by all of the algorithms?
- Is stratification used for all of the algorithms? What confounding variables were selected?
- Are the scores selected for comparison all scores for statistical association, or are they all scores for statistical significance?
- How many signal scores does each algorithm generate over all?
- Is the same threshold used for all scores?

It may be difficult to know how many true signals there are in the database used for the test. If the number is known, then the number of false positives and false negatives produced by each algorithm can also be compared.

## Improving Statistical Algorithms

With WebVDME 5.0, Oracle introduced a new statistical method for evaluation of database disproportionately ratios: Logistic Regression. This statistical technique is intended to support focused investigations into possible polypharmacy effects. Logistic Regression currently alerts WebVDME users to potential signals in cases where the scores calculated by other algorithms do not adjust for confounding by polypharmacy or cloaking. Oracle is also researching the potential for this statistical technique to serve as a database screening tool.

## Data Mining Bibliography

The following articles can provide additional information and detail.

Faich G. Department of Health and Human Services, Food and Drug Administration. Risk Management Public Workshop: Pharmacovigilance Practices and Pharmacoepidemiologic Assessment. Transcript of April 11, 2003: 53-65 [online]. Available from URL: [www.fda.gov/cder/meeting/RMtranscript3.doc](http://www.fda.gov/cder/meeting/RMtranscript3.doc) [Accessed 2005 Sep 12]

Clark JA, Klinecicz SL, Stang PE. Spontaneous Adverse Event Signaling Methods: Classification and Use with Health Care Treatment Products. *Epidemiologic Reviews* 2001; 23 (2): 191-210

DuMouchel W. Bayesian data mining in large frequency tables, with an application to the FDA Spontaneous Reporting System (with discussion). *The American Statistician* 1999; 53 (3): 177-202

DuMouchel W, Pregibon D. Empirical Bayes screening for multi-item associations. In: Conference on Knowledge Discovery in Data. Proceedings of the seventh ACM SIGKDD international conference on Knowledge discovery and data mining. 2001 Aug 26-29; San Francisco (CA). New York: ACM Press, 2001: 67-76

Fram DM, Almenoff JS, DuMouchel W. Empirical Bayesian data mining for discovering patterns in post-marketing drug safety. In: Conference on Knowledge Discovery in Data.

Proceedings of the ninth ACM SIGKDD international conference on knowledge discovery and data mining. 2003 Aug 24-27; Washington, D.C. New York: ACM Press, 2003: 359-368

Hauben M, Reich L. Safety related drug-labelling changes: findings from two data mining algorithms. *Drug Saf* 2004; 27(10):735-44

Lilienfeld DE. A challenge to the data miners. *Pharmacoepidemiology and Drug Safety* 2004 Dec; 13 (12): 881-884

van Puijenbroek EP, Bate A, Leufkens HGM, Lindquist M et al. A comparison of measures of disproportionality for signal detection in spontaneous reporting systems for adverse drug reactions. *Pharmacoepidemiology and Drug Safety* 2002; 11: 3-10

## Data mining FAQs

### Why data mining?

---

**What is the primary motivation for applying statistical data mining to the AERS database?**

- 1 The Empirica Signal application acts as a screening device to sort through several million potential drug/event combinations. You can use the application to prioritize tasks and decide what is random noise versus associations that need further investigation. The output is available as new questions are raised.
- 

**How might the availability of a safety data mining system affect the way that safety evaluators go about doing their work?**

- 2 The data mining feature identifies and investigates potential problems in spontaneous safety data. You can use data mining to identify potential signals, prioritize pharmacovigilance activities, and complete evidence-based reviews.
- 

### Interpretation of results

---

**How can you determine that you are seeing more of some AE than expected for a particular drug when you do not know the number of prescriptions filled for that drug (the denominator)?**

- 1 The technique of disproportionality analysis, upon which the Empirica Signal application is based, uses all reports that mention a drug as a surrogate for the exposure.
- 

**Does the lack of exposure data make it impossible to differentiate between a relatively safe drug that reports few events and another drug that reports more events?**

- 2 The method looks at particular adverse events rather than overall reporting rate. If prescription data is available, then overall reporting rate is worth looking at. In most circumstances, however, the method is less biased than a reporting rate for a particular AE.
- 

**Does the fact that you do not know the reporting rate for a drug and/or event (for example, what percentage of true drug-related adverse events are actually reported to FDA) create a problem in obtaining quantitative estimates of drug-event association?**

- 3 The fact that the reporting rate is unusually high or low for a particular drug does not affect the results as long as the reporting rate for that drug is uniformly high or low across all events. An unusually high or low reporting rate for a particular event does not affect the results as long as the reporting rate for that event is uniformly high or low across all drugs. It is possible that publicity about a particular problem with a drug might cause the report rates for particular drug-event combinations to increase without corresponding increases in the overall report rates for the drug or the event. If that happens, the corresponding associations from disproportionality methods, such as MGPS, becomes biased upward.
-

## Counts

### Where does the notion of an expected count come from?

Observed counts for each drug-event combination of interest:

	Drug of interest	All other drugs
<b>Event of interest</b>	a=N	b
<b>All other events</b>	c	d

Expected counts (E):

	Drug of interest	All other drugs
<b>Event of interest</b>	$E(a) = \frac{(a+b)(a+c)}{(a+b+c+d)}$	$E(b) = \frac{(a+b)(b+d)}{(a+b+c+d)}$
<b>All other events</b>	$E(c) = \frac{(c+d)(a+c)}{(a+b+c+d)}$	$E(d) = \frac{(c+d)(b+d)}{(a+b+c+d)}$

The quantity E(a) is the number of drug-event combinations of interest that would be expected if the event of interest appears in reports independently of the drug of interest.

Observed count / Expected count = Relative Reporting Ratio ( $N/E = RR$ ).

Do not confuse the use of RR as an abbreviation for Relative Reporting Ratio in the Empirica Signal application with the concept of relative risk, which cannot be estimated from spontaneous report frequencies. Relative Reporting Ratio is also different from reporting rate, which can only be estimated if you know both the number of reported and unreported events. RR in the context of data mining of a spontaneous report database is the ratio of the number of occurrences of the drug-event combination of interest to the expected number if the proportion of reports with that event among reports involving that drug were the same as the overall proportion in the database. RR is a disproportionality measure.

### What does it mean if the expected count is less than 1?

- 2 Based on the total number of reports separately for the drug and event, it is expected, statistically, that there would be less than one report of the combination if the drug and event are not associated. The expected count (E) for a drug-event combination can be less than 1 when either the number of reports for the drug, or the number of reports for the AE, is small. It is common for E to be less than 1 (sometimes even  $E < .001$ ) for a rarely reported drug combined with a rarely reported event. This causes the ratio  $N/E$  to fluctuate wildly when N goes from 0 to 1 or more.

### How does the EBGm statistic differ from the concept of an observed count (for a drug-event combination) divided by an expected count?

- 3 EBGm is an improved estimate of the Relative Reporting Ratio (RR). Technically, EBGm is defined as the exponential of expectation value of  $\log(RR)$ , where, in this case, the

probabilities determining expected value are not based on assuming independence of drugs and events, but are based on statistical measures of the dependencies exhibited in the database overall and for each drug-event combination. (In Bayesian terminology, this is called the posterior distribution.) EBGM has the property that it is nearly identical to N/E when the counts are moderately large, but it shrinks towards the average value of N/E (typically  $\sim 1.0$ ) when N/E is unreliable, because of instability issues with small counts.

The posterior probability distribution also supports the calculation of lower and upper 95% confidence limits (EB05, EB95) for the relative reporting ratio.

## EB05 and EB95

### Explain the meaning of EB05 and EB95.

The Empirica Signal application distinguishes between the observed value of  $RR = N/E$  and the true value of the Relative Reporting Ratio that would be observed if a much larger database (so large that sampling error would be negligible) were to be drawn from the same conceptual population of reports. This unknown quantity, sometimes abbreviated as true RR or true N/E, can be bounded probabilistically:

- 1
  - EB05 is a value such that there is about a 5% probability that the true value of N/E lies below it.
  - EB95 is a value such that there is about a 5% probability that the true value of N/E lies above it.

The interval from EB05 to EB95 is the 90% confidence interval. The confidence interval is a way to describe the uncertainty in an estimate due to small sample size (the larger the number of reports, the narrower the confidence interval). EB05 and EB95 describe the probability distribution for the correct answer. For example, an EB05 of 3 means that there is a 95% chance that the true Relative Reporting Ratio is at least 3.

### What is the relationship of other safety data mining report statistics, such as the Proportional Reporting Ratio, the Reporting Odds Ratio, and the Information Component, to EBGM (EB05, EB95)?

These different disproportionality statistics all get at basically the same things, and the values for each in any given situation are likely to be similar, provided the sample size is large.

- 2
 

MGPS allows the use of stratification for elimination of some confounding effects, so it will typically provide lower and more realistic scores if there is a confounding variable involved, such as age or gender, compared to a statistic that does not involve stratification. (Randomized trials are the only way of being sure there is no confounding in a dataset.)

You can specify whether or not you want to calculate Proportional Reporting Ratios (PRR) and Reporting Odds Ratios (ROR) for a data mining run. Further, for a data mining run that is stratified, the PRR and ROR calculations can also be computed using stratification.

- 3
 

**When we apply data mining to evaluate the significance of many different drug-event combinations, are we making a multiple comparison? Does this cause problems?**

Multiple comparisons refers to searching out the largest association (such as the largest

value of N/E among a large number of drug-event pairs) in a database and then evaluating it statistically as if that drug-event pair had been the focus of the study before looking at the data. Bayesian shrinkage estimates shrink (modify the estimate of N/E towards 1 based on a theoretically sound statistical method) and the raw values of N/E so that all values of EB05 have the same 95% chance of being no larger than the true RR (Relative Reporting Ratio), even if you search out the largest value of EB05 in the output table.

---

## Threshold EB05

---

**If MGPS yields a ranked list of associations according to the EBGM signal score, what threshold should be used for determining that an association is an alert that warrants further investigation?**

- 1 There is no absolute threshold. An alert is an indication that there may be a signal. Where to put the cut-off point demanding further investigation is a business decision that is based, among other considerations, on the nature of the data, seriousness of the AE, available resources, and other signal discovery mechanisms.
- 

**Why has the threshold EB05 > 2 been recommended?**

- 2 Although the threshold EB05 > 1 might meet a typical definition of statistical significance, there are many biases in spontaneous report data and costs to following up each alert. Therefore, Oracle suggests you use a somewhat higher threshold. The value 2 is a round number that is often reasonable for relatively rare AEs. (For a rare AE, a doubling of the number of reports may not be a large absolute increase.)

For further discussion, see:

Szarfman A, Machado SG, O'Neill RT. *Use of screening algorithms and computer systems to efficiently signal higher-than-expected combinations of drugs and events in the US FDA's spontaneous reports database.* Drug Saf. 2002;25(6):381-92.

---

**If there is a drug-event combination with an EB05 greater than my chosen threshold (for example, EB05>2), what can I say with certainty about the relationship between the drug and the event? Are they definitely related? Are they causally related?**

- 3 This value suggests only that there is a statistical association between this drug and event. The association may indicate a causal relationship or a reverse causal relationship; that is, the AE is an indication for the drug. It may indicate a relationship that is already labeled, or it may indicate a relationship that is not clinically significant for other reasons. The most frequent explanation is that there is a third variable common to both the drug and the event, often related to the drug's indication (confounding by indication).

You should conduct further investigation, including reading the label, doing a literature review, or, at the very least, expert evaluation of the individual medical records leading to the series of reports, to determine whether they seem causally related. Additional studies, such as clinical trials or case control studies, may be warranted in some cases.

---

## False positives and negatives

---

- 1 **What is meant by alerts potentially being false positives?**
-

A false positive occurs when any signaling system, such as the EBGM or EB05 value, exceeds a pre-set threshold (such as  $EB05 > 2$ ), while, in reality, the drug is either not related to the event or is related, but not causally.

### **What is meant by alerts potentially being false negatives?**

- 2 A false negative occurs when any signaling system, such as the EBGM or EB05 value, did not exceed a pre-set threshold (such as  $EB05 > 2$ ), while, in reality, the drug is causally related to the event.

### **How do I set up an alerting system that gives hardly any false positives and hardly any false negatives. Is this possible?**

No. While the chances of finding false positives or false negatives can be reduced, you cannot eliminate them. It is possible to decrease the chances of finding false positives or false negatives by improving the current statistical algorithms with the addition of extra information, such as stratification, or by improving the data collection itself. Otherwise, any decrease in false positives is automatically accompanied by an increase in false negatives, and vice versa.

- 3 There are two possible reasons for a false positive: there actually is no correlation between the drug and event, or there is a correlation, but it is not causal. The first can be dealt with to some degree statistically (although there will always be unresolved uncertainty for small sample sizes). The second is not a statistical issue, and can only be dealt with through medical knowledge.

Similarly, a false negative can be due to a small sample or be the result of masking from another signal. Given a hypothesis based on medical knowledge you can reduce the masking. Oracle is experimenting with techniques for providing clues about when such masking may be occurring.

A third reason for either a false positive or a false negative is that you are using the wrong threshold.

## **Signaling sensitivity**

### **What is meant by the sensitivity and specificity of signaling systems?**

Sensitivity is defined as the percentage of truly causal associations that are identified by the alerting system. Low sensitivity means a high number of false negatives. For example, in a database with counts for 10,000 drug-event pairs where 1,000 of the pairs have a truly causal relationship, if MGPS identifies 700 out of the 1,000 true associations, the sensitivity of MGPS is  $700/1000$  or 70%. This calculation assumes that the true status of every drug-event pair is known. You have to have a gold standard.

- 1 Specificity indicates the percentage of noncausal (including nonexistent) associations for which the system does not show an alert. Low specificity means a high false positive rate. If MGPS declares that 3,000 of the 99,000 non-causal pairs are associated, that is a  $96,000/99,000 = 97\%$  specificity rate or a 3% false-positive rate. Again, this calculation assumes that you know the actual negatives.

Because there is no gold standard in most pharmacovigilance situations, you cannot usually estimate the values of sensitivity and specificity very well. Sometimes, the gold standard is whether a reaction is on the label. This is problematical. It is a difficult and subjective task to transform the language on a label into an accurate and complete list of MedDRA terms. The label itself may be wrong or incomplete.

**If EB05 is large, does that mean that you can be 95% sure that there is a true signal?**

- 2 No, you can only be 95% sure that an association this large will hold up as the database becomes larger and larger. When  $EB05 > 2$ , almost all the false positives are due to noncausal associations that are reliably likely to continue as more data is collected, such as events being related to indications for the drugs, or publicity effects. A large EB05 rules out mere statistical fluctuation, but not other spurious causes of the association. Thus, medical knowledge is very important for interpretation of data mining results.

---

**If my threshold for signaling is  $EB05 > 2$ , is a drug-event combination with an  $EB05 < 2$  definitely not a signal?**

- 3 The application distinguishes between an alert that occurs when a data mining statistic exceeds a predetermined threshold and a signal that might be declared upon review of all relevant information. Since there can easily be strong evidence of causality from other information in the absence of a data mining alert,  $EB05 < 2$  would not rule out the possibility of a signal. Considering the data mining results, you would require  $EB95 < 1$ , rather than  $EB05 < 2$ , to say that there is strong statistical evidence against a positive association between the drug and the event. Remember, all of the values of true RR that lie within the interval ( $EB05, EB95$ ) are reasonably compatible with the observed data.

---

**Are there any guidelines regarding the smallest N (for a drug-event combination) for which you can get a meaningful signal score?**

- 4 It is not necessary to take the sample size into account. The methodology does that. In practice, however, the built-in conservatism of the MGPS methodology, and the choice of threshold, prevents  $EB05 > 2$  when analyzing AERS data unless N is at least 3. This suggests that reducing the threshold to  $EB05 > 1$  might be advised as part of screening for very serious adverse events, if you want to be warned whenever the first two reports show up significantly earlier than expected for a new drug.

---

**Working with new drugs and small samples sizes**

- 1 **If a drug is new and only has a handful of reports (e.g., 50) overall in the AERS database, can useful data mining signals be obtained?**

Yes, the EB05 statistic takes the sample size into account.

- 2 **What about the case of an event term for which there is a small number of reports (<100) overall?**

Yes, the EB05 statistic takes the sample size into account.

---

**Stratification and subsets**

**What is the difference between stratification and subsetting?**

- 1 Stratification is a way of normalizing data to eliminate confounding by some variable or variables. You generally stratify by age group, gender, and receipt year. The Empirica Signal application calculates the expected count separately for each stratum, then sums those counts and uses this total expected count for the RR and EBGM calculations. This



process can be used, for example, to deal with confounding due to a drug being administered only to the elderly or only to males, or to the drug being new on the market. This process is often called adjustment for confounding variables in the epidemiology literature. Other possible confounding variables are not generally available in AERS data.

Subsetting is a way of repeating the entire data mining analysis using different subsets of the database. Subsets are typically used to study how the strength of a drug-event association evolved over time, but can also be used to compare strength of associations for different age or gender subsets. For each subset, the application calculates the observed count and expected count, then uses those values to calculate a separate RR and EBG value for each subset. Different subsets of the reports can be overlapping or non-overlapping, depending on how the subset run parameters are specified.

---

**Is it meaningful to compare signal scores across subsets (e.g., signal scores for males versus signal scores for females)?**

- 2 Yes. Non-overlapping confidence intervals can alert you to the possibility of a gender difference in response to the drug.
- 

**Cross-drug comparisons**

---

**Under what circumstances might it be meaningful to compare signal scores across different drugs?**

- 1 Non-overlapping confidence intervals can alert you to the possibility of a difference between the safety profiles of the drugs. Alternately, if the confidence intervals overlap a lot, the signal scores can help corroborate evidence that there is no difference.
- 

**What are the advantages and disadvantages of including concomitant medications (as well as suspect drugs) in the data mining analysis?**

- 2 An advantage of including concomitant medications is that you can eliminate the bias from physicians who pre-determined the suspect drugs. Each drug will be weighted equally. In addition, including both concomitant and suspect drugs provides a larger background case set for each drug and may reveal associations unsuspected by the reporter.
- A disadvantage is that potentially valuable judgments from physicians regarding which drug(s) is/are suspect are not taken into account.
- More research is needed to understand whether it is advantageous to include concomitant drugs in an MGPS analysis. Because logistic regression analysis is specifically designed to assess the results of polytherapy, Oracle advises always using a data configuration that includes concomitant drugs in logistic regressions.
- 

**What are the advantages and disadvantages of fully breaking apart combination drugs into their component ingredients for purposes of data mining?**

- 3 An advantage is that the number of unique drugs in the database becomes much smaller, and the counts of each unique ingredient are higher. It is also easier to implement drug classification.
- A disadvantage is that ingredients are equally weighted no matter whether they were part of combination drugs or not.
-

---

## Combining reports in a single data mining analysis

---

### **Is it acceptable to combine foreign and domestic reports in a single data mining run?**

- 1 Yes, although there is only a small proportion of foreign reports (12%) in the FOI FDA AERS+SRS data. WHO data contains approximately 50% cases reported in the US and 50% with foreign sources. It is possible to specify that report source (US/non-US) be used as an additional stratification variable, which may help protect from biases due to differential reporting rates in US and non-US reports.

---

### **Is it acceptable to combine health professional and consumer reports in a single data mining analysis?**

- 2 It can be interesting to compare the two to see whether there is a significant difference. It is not clear that consumer reports are more likely to give false positives or negatives than health professional reports, given that the application examines disproportional reporting as opposed to absolute numbers.  
Subsetting by the report source or occupation code of the reporter allows comparison of values calculated for reports by consumers to those reported by health care professionals. Also, you can use stratification on these variables to eliminate the possibility of confounding based on report source.

---

### **Is it acceptable to combine serious and non-serious adverse events in a single data mining analysis? What if some drugs have non-serious reports entered into AERS and others you are interested in, for purposes of comparing signal scores, do not?**

- 3 Yes, although AERS contains mostly serious events. Including large numbers of non-serious events probably improves the performance of the system, since some analyses have shown that the ratios of non-serious event reports are a reasonable surrogate for the exposure ratios. If, for some reason, non-serious reports have been suppressed to a much greater degree for some drugs than for others, the result would be to bias comparisons of alerting scores across the two sets of drugs.

---

## Data issues

---

### **What is the meaning of a drug showing a positive alerting score with a particular event sometimes being confounded by polytherapy?**

- 1 If a drug is typically co-prescribed with another drug that causes a particular event, then the first drug is statistically associated with the event as well.

---

### **What is the impact of cloaking, where a very strong association with one drug masks your ability to see a moderately strong association with another drug?**

- 2 If a drug has a very strong association with a given event, this may mean that it accounts for a relatively large proportion of the reports for that event in the database. This would tend to raise the expected value for this event for all drugs and, thus, mask the signal (lower observed / expected) for another drug.

---

### **If a potential signal of interest may be spread across multiple MedDRA Primary Terms (different reporters may choose to use slightly different terminology to**

---

**describe essentially the same effect), will this reduce the ability to see the signal of interest?**

Yes, this is possible, although significant associations for several of the possible PTs are a good indication of something real. If you suspect that this spreading is happening, then it is possible in the Empirica Signal application to map the suspect PTs into a new pseudo PT, called a custom term, to look at the combined score. Alternatively, data mining analysis can be based on MedDRA HLT or HLTG, rather than PT.

**MGPS essentially compares the safety profile (relative frequency of different AEs) of each drug against a background comparator of all drugs. Would it be better to choose a more narrowly defined background? For example, to understand the profile of Cerivastatin, why not limit the background to all other statins?**

- 4 Given that noise is a surrogate for exposure, the bigger the denominator, the better. Oracle performed an experiment to look into this; the results showed more noise with smaller databases. To compare a drug against others in its class to see differences, look at the EB05 scores for each of the drugs run against the entire background. Looking at a drug against its own class also means that it is unlikely that you would find a previously unknown class effect.

**Are data mining results skewed by publicity effects?**

- 5 This can occur, and it is one of the possible causes to consider when doing case evaluation of the potential signals.

## Comparing EBGM values

**When comparing different EBGM values, if a given drug D has an EBGM signal score of 4.0 for event E1 and 8.0 for event E2, is it correct to say that the risk of E2 appears to be twice as high?**

- 1 No. At most, you could say (if the confidence interval was very narrow) that the drug had 4 times as many reports for E1 as expected and 8 times as many reports for E2 as expected. To estimate risks you have to know about reporting rates and exposure rates, neither of which are estimable from spontaneous reporting data alone.

**What about comparing EBGM values across two drugs? Suppose, for event E, drug D1 has an EBGM score of 10 and drug D2 has an EBGM score of 20. Is the risk of the event twice as high with drug D2 as with drug D1?**

- 2 Confidence intervals can be used for comparisons, provided they do not overlap. In this example, the interpretation is that the association between D2 and the event is twice as high as the association between D1 and the event. But associations can differ for reasons unrelated to causation.

**What do EBGM scores < 1 signify?**

- 3 A score of EBGM < 1 indicates that the drug-event combination is occurring less frequently than expected statistically. If EBGM were < 1 and N were high, this might indicate a possible therapeutic effect.

## Logging into the Empirica Signal application

You log in to the Empirica Signal application with the username and password that your site administrator provided. If your site administrator has enabled single sign-on, you can log in to the application using your single sign-on username and password. When you log in, the application authenticates your username using a case-insensitive match. For example, **jkelly** and **JKelly** both resolve to the **jkelly** username.

---

**Note:** Prior to logging in to the Empirica Signal application, configure your Internet Explorer browser for printing color and downloading, as described in [Prerequisites and usage notes](#).

---

### To log in initially:

1. Open Internet Explorer.
2. Navigate to the URL provided by your site administrator.
3. Log in using your Empirica Signal username or Oracle single sign-on username.

### To log in using your Empirica Signal username:

1. In the **Username** field, enter the username provided by your site administrator. The username field is not case sensitive. You can enter your username in uppercase, lowercase, or mixed case.
2. In the **Password** field, enter your user password. The initial password provided by your site administrator is case sensitive. You must enter your password using the same case (upper, lower, or mixed) that was used when the password was defined. Oracle recommends that you then [change your password](#) immediately.

If a message appears stating that your password is due to expire, click **Click here** to change your password. If you do not to change your password, the warning message appears each time you log in, until your password expires and you are forced to change it.

3. Click **Log In** or press **Enter** .

The page you set to display initially when you log in to the Empirica Signal application in [user preferences](#) appears.

---

**Note:** Do not open more than one Empirica Signal session at the same time.

---

### To log in using your single sign-on username:

- If you are currently logged in via single sign-on, no login page appears. You can access Empirica Signal without re-entering your username and password.
- If you are not currently logged in via single sign-on, the Single Sign-on Login page appears. Enter your single sign-on username and password, and then click **Log In**.

## Changing your password

Each username has an associated password. You can change your own password at any time. For example, you might want to change it periodically for security reasons. A user who has the Administer Users permission can also change your password. For example, if you have forgotten your password, that user can set a new password for you.

If your password is due to expire, a warning message appears when you log in. Click the link in the message and go to step 3, below.

---

**Note:** If you log in to the Empirica Signal application using a single sign-on username and password, you cannot change your password in Empirica Signal.

---

1. At the top of any page, click **Settings**.

2. Click **Change Password**.

The Change Password page appears.

---

**Note:** The **Change Password** link is unavailable if you log in to Empirica Signal using a single sign-on username and password.

---

3. In the **Old Password** field, enter your current password.

4. In the **New Password** field, enter a new password. Site options determine the required password length and the types of characters allowed (alphabetic, numeric, non-alphanumeric, lowercase, uppercase, and so on). There may be restrictions on the re-use of old passwords.

To log in to the Empirica Signal application, you must enter your exact password in the correct case (upper, lower, or mixed).

5. In the **Confirm Password** field, re-enter your new password.

6. Click **Change Password**.

The Empirica Signal application updates your password. The next time you log in, you must use your new password. The password expiration period, if one has been set as a site option, begins for the new password.

## Setting user preferences

A user preference is a setting activated at log in that customizes the Empirica Signal application for your username. Your user preference settings have no effect on any other Empirica Signal users.

---

**Note:** If you have permission to create user profiles, you can also set user preferences for a user profile.

---

1. At the top of any page, click **Preferences**.  
The Set User Preferences page appears.
2. Modify the user preferences.
3. Click **Save**.

### General user preferences

The following user preferences apply to all users and take effect immediately unless otherwise noted:

Preference	Description
<b>Preferences for dates and times</b>	
Time Zone	From the <b>Time Zone</b> drop-down list, select the time zone to be used for server datetimes that are displayed in the Empirica Signal application for your username. This user preference has no effect on the source safety data (for example, an event date shown in case details) or on the display of As Of dates for <a href="#">timestamped data</a> .
<b>Preferences for logging in</b>	
On login, display this page	From the drop-down list, choose a page to display automatically when you log in to the Empirica Signal application. The available options may depend on your <a href="#">user permissions</a> , as well as Empirica Signal site options set for your organization.
Show table scrollbars on left	Select this check box to display vertical scrollbars on the left side (instead of the right side) of tables of information. <b>Note:</b> This option does not take effect until the next time you log in.
<b>Preferences for Query Wizard</b>	
Show case count by default on preview page	Select to show the count of cases on the Preview Query page. On the <a href="#">Define Query page</a> , select Display Case Count in Query Preview. Computation of the case count can be time-consuming. Display it only when necessary. <b>Note:</b> This preference appears only if appropriate <b>Allow Case Count</b>

on **Query Preview Page** check box of site option has been enabled.

---

### Preferences for downloading data

---

Default download file type	From the drop-down list, select the file type you use most frequently to <a href="#">download data</a> .
----------------------------	----------------------------------------------------------------------------------------------------------

---

### Preferences for viewing graphs

---

Graph color palette	From the drop-down list, set a default color scheme for the <a href="#">graph key</a> for graphs based on the results of data mining runs. (This preference has no effect on graphs based on report data.)
---------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

---

### Preferences for viewing case details

---

Days to retain visited status for case ID link	Specify the number of days that an underlined case ID that you can click to view case details appears in a different color. This preference applies to case IDs for only your username and to all data associated with configurations within the same database group. The default number of days, which is used if you leave the number of days empty, is 45. If you specify 0 as the number of days, the color of a visited link does not change. This preference affects only data associated with data configurations that are in database groups. See <a href="#">Case ID Links</a> .
------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Wrap Wide Tables	Check to wrap table displays on the Case Details page. Wrapping tables makes the vertical display longer. Not wrapping tables makes the horizontal display wider and can necessitate scrolling to the right to see all columns in the tables.
------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Show Table of Contents	Check to show a table of contents on the <a href="#">Case Details page</a> . The table of contents consists of links that jump to the data displayed on the page.
------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------

---

### Preferences for selecting and viewing run results

---

**Note:** These preferences are available only to users with the View Data Mining Results permission.

When you set the following user preferences, they take effect immediately.

Preference	Description
Default Run	From the drop-down list, select a data mining run to appear by default in the Run Name field on the <a href="#">Select Criteria page</a> when you go to the Data Mining Results page for the first time in an Empirica Signal session. You can select any run listed on your Data Mining Runs page. You can also specify <Last Used> or <No Run>.
Display Only Results with score-type Scores Over number	Specify a default minimum score for viewing results of a data mining run for the first time. The score type and value that you specify appear on the Select Criteria page as a default, but you can change them as needed before reviewing results. You can set a

default minimum for:

- **EBGM**—Applies to MGPS runs only.
- **EB05**—Applies to MGPS runs only.
- **N**—Applies to run results for any type of data mining run (however, does not apply to the tables of results for covariates or interactions if they are produced for a logistic regression run).

This preference affects only run results that you have never viewed. Once you have viewed a run, the setting that you choose on the Select Criteria page is used for that run until you change it.

If you select a statistic other than N, a default of LROR>0 is used for logistic regression run results.

Enable Adverse Event Hierarchy Browser	Check to browse and select terms from the <a href="#">hierarchy</a> for tasks that require you to select event values. For an event variable that is set up in the <a href="#">data configuration</a> to have an associated hierarchy, the Select <hierarchy> Terms link appears for these tasks; for example, Select MedDRA Terms.
Enable Drug Hierarchy Browser	Check to browse and select terms from the <a href="#">hierarchy</a> for tasks that require you to select drug values. For a drug variable that is set up in the <a href="#">data configuration</a> to have an associated hierarchy, the Select <hierarchy> Terms link appears for these tasks; for example, Select ATC Terms.
Include SQL WHERE Clause for Advanced Results Selection	Check to enable use of a SQL WHERE clause for <a href="#">selecting results criteria</a> on the Select Criteria page. To view all advanced options, click Show Advanced on the Select Criteria page.

## Preferences for creating runs

**Note:** These preferences are available only to users with the Create Data Mining Run permission.

When you set the following user preferences, they take effect immediately.

<b>Preference</b>	<b>Description</b>
Minimum Count	Specify a default for the Minimum Count field on the <a href="#">Data Mining Parameters page</a> . You can override this default as needed.
Replace Missing Values with	Specify text to represent missing values for variables in the results of data mining runs that you execute. For example, if you set this preference to ^missing^ the results table shows ^missing^ for any item that has no value in the database. You cannot use spaces or the following characters in your replacement string: * \ " : / ? > <



This preference affects only the appearance of run results, and not the source data. When you access source data, as when drilling down from a case series, missing values display as blank.

The Job Details page for a run's extraction job (accessible from the Jobs for Run page) shows the value that was in effect for missing data for the run.

---

**Note:** Other users who view results of a run that you executed will also see the missing value that was set as your user preference at the time you executed the run.

---

Exclude associations if items are of the same type (all drugs, all events)	Check to include a default for a field on the <a href="#">Data Mining Parameters page</a> when you create a new MGPS data mining run. You can override this default as needed. The recommended setting is checked. Checking this preference improves time and space utilization because fewer results are loaded into the results table.
----------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

---

## Preferences for viewing drug profiles

---

**Note:** These preferences are available only to users with the View Drug Profiles permission.

---

When you set the following user preferences, they take effect immediately.

Preference	Description
Drug Profile Configuration	From the drop-down list, select the drug profile configuration. Drug profile configuration determines the source of graphs and reports that you can add as charts to a drug profile layout. You must set this preference to access the Drugs tab. Available drug profile configurations are those that you created or that are published to you. (If you have the Administer Users permission, they also include unpublished configurations created by users in your login group.)
Drug Profile Layout	From the drop-down list, select the drug profile layout, the name of a saved collection of charts, as well as their placement and display options. Layouts are not associated with a particular drug profile configuration. Available layouts are those that you created or that are published to you. (If you have the Administer Users permission, they also include unpublished layouts created by users in your login group.) Use this setting in the following situations: <ul style="list-style-type: none"> <li>• You have not previously used a drug profile layout on the Drugs tab.</li> <li>• You delete the layout you were last using and then return to the Drug Profile page without having selected a layout.</li> <li>• You click a drug name on the Drug Overviews page on the Signals tab.</li> </ul>

---

## Preferences for viewing signals

If your organization uses the [signal management](#) component of the Empirica Signal application, there are additional user preferences. If you set the following user preferences, they take effect the next time you log in.

---

**Note:** These preferences are available only to users with the View Signal Management permission.

---

When setting Default Signal Group, Show only Drugs where I am Reviewer, and Default Signal Drug, make sure that you use compatible settings. If the defaults are not compatible, only the most restrictive default is used. For example, if you specify both a default group and a default drug that is not in that group, only the default drug is applied.

Preference	Description
Signal Management Configuration	From the drop-down list, select a <a href="#">signal configuration</a> . Available signal configurations are those that you created or that are published to you. If you set the preference to --, the signal configuration associated with your login group is used.
Default Signal Group	From the drop-down list, select a group to be used as the default in the Group field on the Drug Overviews page, Drug-Event Combinations page, and the Drug Comments page. An en dash (–) indicates All.
Show only Drugs where I am Reviewer	If you check this preference, your username appears by default in the Reviewer field on the Drug Overviews page, Drug-Event Combinations page, and the Drug Comments page.
Default Signal Drug	From the drop-down list, select a drug to be used as the default in the Drug field on the Drug Overviews page, Drug-Event Combinations page, and the Drug Comments page. The characters, --, indicate All. A None option is also available. If there are a large number of drugs available, you can click Select Drug to <a href="#">select a drug</a> (instead of selecting it from a drop-down list).
Allow SQL WHERE Clause on Signals tab	Check to enable the user of a SQL WHERE clause to restrict rows that appear on the Drug Overviews page, Automatic Assignments page, Drug-Event Combinations page, and Drug Comments page. If this preference is checked, the Columns link for the tables becomes Columns and Rows.

## Preference for topics

---

**Note:** This preference is available only to users with the Manage Topic Workflow Configurations permission.

---

If you set the following user preference, it takes effect the next time you log in.

Preference	Description
Topic Workflow Configuration	<p data-bbox="456 289 1409 380">From the drop-down list, select a topic workflow configuration. Available topic workflow configurations are those that you created or that are published to you.</p> <p data-bbox="456 401 1409 590">This setting overrides the association between your login group and a topic workflow configuration. For example, if your login group is associated with configuration A, but you specify configuration B as the preference, configuration B is in effect the next time you log in. The override is intended to facilitate testing of configurations that you create or edit.</p> <p data-bbox="456 611 1409 669">If you set the preference to –, the topic workflow configuration associated with your login group is used.</p> <hr/> <p data-bbox="456 701 1409 837"><b>Note:</b> If you select a topic workflow configuration that requires each topic to be visible to one and only one work team, you must also define membership in a work team and assign appropriate <a href="#">work team permissions</a>.</p>

## Specifying settings

When you click the **Settings** command at the top of any page, the Settings page appears. Your [user permissions](#) determine the options available on the Settings page. For most users, this page includes only the following options:

- [Change Password](#)
- [Remove Visited Status for Case ID Links](#)
- [Manage Saved Lists](#)
- [About](#)

Depending on your user permissions, the options listed below might be available.

### Options for managing users

- [Edit Users](#)
- [Edit User Profiles](#)
- [Edit Roles](#)
- [Edit Login Groups](#)
- [Edit Work Teams](#)

### Options for monitoring the system

- [View Currently Logged In Users](#)
- [View User Activity Audit Trail](#)
- [View Server Status](#)
- [View Free Space](#)
- [View Batch Report Queue](#)

### Options for administering the system

- [Set Site Options](#)
- [Send Message to All Users](#)
- [Restart Listener](#)
- [Manage Run Storage](#)
- [Change User Default Runs](#)

### Options for configuring the system

- [Manage Configurations](#)
- [Manage Aliases](#)
- [Manage Drug Profile Configurations](#)
- [Manage Signal Configurations](#)

- [Manage Reviewer-User Mapping](#)
- [Manage Topic Workflow Configurations](#)

## Navigating with tabs

You use a set of tabs to navigation through the [Empirica Signal](#) application and access features. Only those features for which you have the appropriate [permission](#) appear as tabs.

Tab	Description
Home	The content of this page can be customized to meet the needs of your company, team, or project. For example, the Home tab may provide links to pertinent information about data mining projects. There may be multiple versions of the Home tab, each associated with a different group of users.  For information about customizing the Home tab, see <a href="#">Editing a Login Group</a> .
Drugs	View drug profiles, which are presentations of graphs and reports related to one or more drugs.
Data Mining Runs	Create and manage <a href="#">data mining runs</a> .
Data Mining Results	View the <a href="#">statistics</a> that result from a data mining run in tabular or graphical format.
Queries	View the <a href="#">Query Library</a> , which includes saved queries of source data. You can view the queries or use them elsewhere in the application.
Case Series	Access <a href="#">case series</a> , which are lists of selected cases of interest.
Reports	Define and display <a href="#">reports</a> based on source data.
Signals	Use the optional <a href="#">signal management</a> component to evaluate and track safety signals over time.
Topics	Use <a href="#">topics</a> to organize and track tables, graphs, and documents related to particular subject matter.

**Note:** If you use a particular tab more than others, you might want to display that tab following logging in. For more information, see [user preferences](#).

## Using Empirica Signal commands




The following commands appear in the upper right corner of all Empirica Signal pages:

<b>Command</b>	<b>Use this command to:</b>
Preferences	<a href="#">Set user preferences</a> for your Empirica Signal username; for example, dates and times, viewing run results, and so on.
Settings	Go the Settings page, where you can change your password, manage <a href="#">saved lists</a> , and perform other activities, depending on your user permissions. Activities related to user and system administration also appear on the Settings page.
Feedback	<a href="#">Send feedback</a> (such as comments, suggestions, or feature requests) to an email address that is specified by your site administrator.
Exit	<a href="#">Exit the Empirica Signal</a> application.
Help	Open the <a href="#">online help</a> .

## Using Help

The Empirica Signal online Help system provides information about pages and tabs, procedures for performing Empirica Signal activities, and conceptual and instructional topics. The help system is context-sensitive; that is, if you click the **Help** link on an Empirica Signal page, information about that page appears.

- Help topics include underlined links that you can click to display more information.
  - Help topics remain open until you close them. You can leave the Help open in the background while you are using the application.
1. Click the **Help** command or click **Help** on an Empirica Signal page. Help for the page that you are viewing appears in a new browser window.
  2. To view the main help page, click **Show Table of Contents** at the top of the help page. The main help window includes a toolbar with the following buttons:

Button	Description
	Display the table of contents for the Help system.
CONTENTS	<ol style="list-style-type: none"> <li>1. In the table of contents, expand a top-level entry in the table of contents by clicking either its name or the closed book icon  before its name. The icon changes to .</li> <li>2. Click a topic name or the question mark icon  before its name to display the topic in the right-hand side of the Help window.</li> </ol>
GLOSSARY	Display a list of Empirica Signal terms. Click a glossary term to display a definition in the bottom left corner of the window.
SEARCH	To find help topics containing a particular word or phrase, type in the word or phrase and click <b>GO</b> . Click a listed topic to display it.
INDEX	<p>Display an alphabetized list of index entries for the Help system. Select a keyword from the list, or type a keyword in the field above the index entries. To go to the first occurrence of an index entry starting with particular characters, type the characters.</p> <p>When you click an index entry, if only one help topic is associated with the index entry, that topic is appears. If multiple topics are associated with the entry, a popup window shows the topics and you can select one.</p>
BACK	Display the previous help topic.



## Sending feedback

Oracle welcomes your comments, problem reports, suggestions, or requests about the Empirica Signal application. You send feedback to an email address that is specified as a site option.

1. At the top of any page, click **Feedback**.
2. In the **Subject** field, enter the subject of your message.
3. In the **Please enter your comments** text box, type the text of your message.
4. Click **Send**.
5. When informed that your message has been sent, click **Continue**.

The user who is set up to receive feedback receives an email message. In the email message:

- The date and time of the message is the date and time at which you clicked **Send**.
- The From line shows the email address associated with the username with which you are logged in.
- The Subject line shows the text you entered in the subject line of the feedback.
- Above your comments is a line identifying the application and your full name.

## Exiting the Empirica Signal application

You should ensure that you exit the Empirica Signal application before closing your browser. If you close your browser without exiting, your session continues to run for some time before the automated timeout and may use system resources unnecessarily.

You can exit the Empirica Signal application, however, while background processing jobs are running. Background processing jobs are not affected by your logout, and continue running after you exit the application.

If you logged in using your single sign-on username and password, exiting the Empirica Signal application may log you out of your single sign-on environment, or from Empirica Signal only, depending on your Empirica Signal configuration.

1. Click the **Exit** command at the top of any Empirica Signal page.

A message appears, indicating that you are logged out of the application.

If you logged in using your single sign-on username and password and your site administrator specified a custom logout page, that page appears.

2. To log in to Empirica Signal again, with the same or a different username, click the link provided on the logout page.

---

**Note:** From outside of the Empirica Signal application, your system administrator can specify the number of minutes before automated session timeout occurs for Empirica Signal users. The session timeout occurs if you have not performed any action within the time period, regardless of whether or not a job you initiated, such as a data mining run, is running in the background.

---

## Common tools

### Selecting values from a list

One of the ways that the Empirica Signal application facilitates your work is to provide lists of accepted values for many functions. These values appear in alphanumeric order in a dialog box and often include an All option as well as individual values.

### Selecting a single value

If the dialog box includes a list of available values but no list of selected values, you can select only one value.

- Click a value to highlight it and then click **OK**.

---

**Note:** When you highlight a single value, the full value is displayed as pop-up text. This enables you to see the full value in case the displayed value is cut off because of its length.

---

### Selecting multiple values

1. To select values from a list, click **Select Available Values**.

A dialog box appears.

If the dialog box includes a list of available values and a list of selected values, you can select multiple values (up to 1,000 values).

2. To select values, you highlight and move them as follows:
  - To highlight a value, click it.
  - To highlight multiple non-contiguous values, hold down the Ctrl key while clicking each value.
  - To highlight multiple contiguous values, click a value, hold down the Shift key, and click another value. Values between and including those values are highlighted.
  - To remove highlighting from a value, hold down the Ctrl key while clicking the selected value.
  - To move values back and forth between the list of all values and the list of selected values, you can double-click a highlighted value or use the arrow keys as follows:

Button	Use To
->	Move highlighted values from the list of all values to the list of selected values.

->>	Move all values from the list of all values to the list of selected values.
<-	Move highlighted values from the list of selected values to the list of available values.
<<-	Move all values from the list of selected values to the list of available values.

- If up and down arrows are available for the list of selected values, you can use them to order the selected values. For example, when specifying breakdown details in a report definition, you can order the selected values as you want them to appear in the report.
3. When you are satisfied with the selected values, click **OK**.

---

**Note:** In some contexts, you can click **Save As List** to [create a saved list](#) of values for future use.

---

### Filtering available values

You can filter the available values if the **Show Filter Options** link appears.

1. Click **Show Filter Options**.
2. In the **Filter** field, type a value on which to filter the available values.
3. Specify filtering options:
  - **Case-sensitive**—If checked, the application lists only available values exactly matching the case (upper, lower, or mixed) of your entry in the Filter field.
  - **Show values**—From the drop-down list, select **Starting with Filter** to list available values that start with your entry in the Filter field. Select **Containing Filter** to include any values containing the specified filter in any position. Select **Ending Filter** to list values that end with the entry in the Filter field.

If there are more than 100 possible values in total (regardless of filter options), the following additional options are available:

- **Minimum filter length**—Select the minimum number of characters you must enter in the Filter field before any available values will be listed. (0 indicates no minimum.)
- **Maximum values to show**—Select the maximum number of available values to be listed. If the maximum number is  $n$ , the first  $n$  matching values found in the list appear. Note that as you move values to the Selected Values list, more values appear in the Available Values list.

A message informs you if any values have been filtered out of the Available Values list by the Maximum values to show field.

---

**Note:** If network performance is not good, avoid using No Limit. This can be slow when used with Generic\_Name, for example, since there are thousands of values.

---

## Selecting hierarchy terms

Adverse events and drugs can be associated with a dictionary, thesaurus, or other standardized terminology that organizes terms into a hierarchical structure. For example, adverse event terms may be associated with a version of the Medical Dictionary for Regulatory Activities (MedDRA), and drugs may be associated with the WHO Anatomical Therapeutic Chemical (ATC) classification system. The hierarchical terms and their relationships are stored in a special account, then associated with variables in [data configurations](#).

To select specific drug or event values for a variable, you can click the **Select Available Values** link to view and [select values from an alphabetized list](#). If the drug or event variable has an associated hierarchy, another link appears so that you can browse through the hierarchy. For example, you can click **Select MedDRA Terms** to browse for Preferred Terms (PT) in the hierarchy. The variable must be set up in the data configuration and you must check the [user preference](#), Enable Adverse Event Hierarchy Browser or Enable Drug Hierarchy Browser.

---

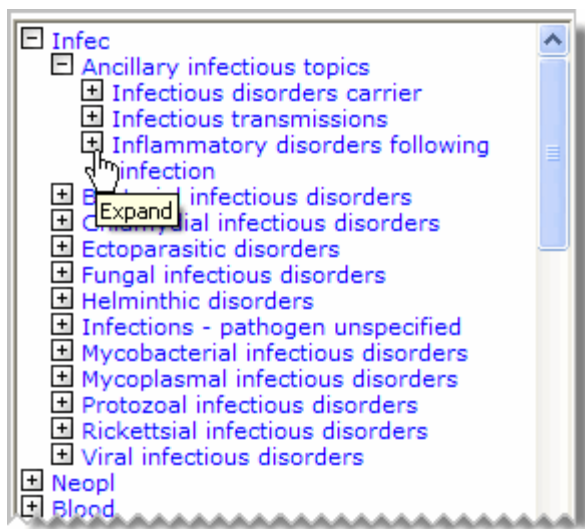
**Note:** The name of the hierarchy associated with the variable appears as part of this link. For example, for a drug variable, **Select ATC Terms** appears. This help system uses **Select <hierarchy> Terms** as a general reference to this link.

---

When you click **Select <hierarchy> Terms**, the Hierarchy Browser dialog box opens and enables you to [browse](#) the hierarchy and [review](#), [search for](#), and [select](#) terms at the appropriate level of the hierarchy.

## Browsing terms

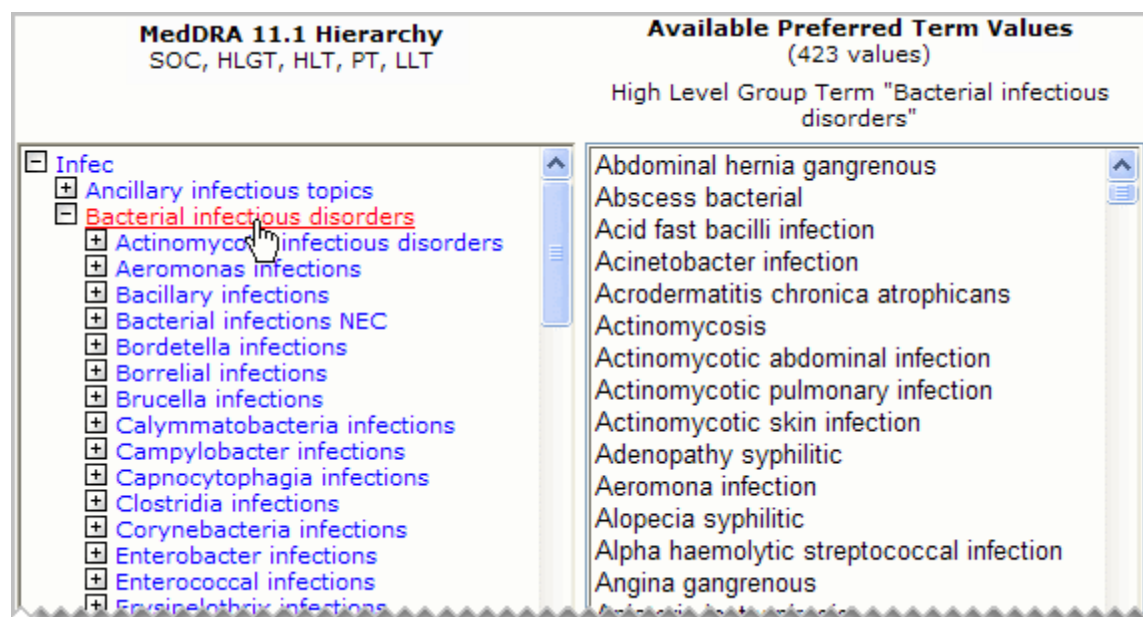
The section on the left of the Hierarchy Browser lists the terms at the highest, most general level of the hierarchy. For example, System Organ Class (SOC) terms appear for the MedDRA hierarchy, and Level 1 terms appear for the ATC hierarchy. To expand the list to show terms at the next level, click the  icon next to a term. Repeat to expand the list to show terms at all levels through the lowest, most specific level in the hierarchy. Click  to collapse sections of the list.



When you use your mouse to move the cursor over terms in this list, an underline appears if you can click on a term to review and, potentially, select terms at the appropriate level of the hierarchy.

## Reviewing terms

The Available <level> Values section in the center of the Hierarchy Browser lists terms at the level of the hierarchy that you are browsing. For example, if you are browsing for PTs, the Available <level> Values section lists all of the PTs in the hierarchy below the term you clicked. If you click on a Higher Level Group Term (HLGT), all of the PTs under that HLGT appear for review.




---

**Note:** Not every term at every hierarchical level shown on the left can be clicked. For example, if you select MedDRA PTs, you cannot click on a lower level term (LLT) to review or select PTs above that LLT in the hierarchy.

---

## Searching for terms

Another way to find and review terms at the hierarchical level of interest is to enter text in the **Match** field at the bottom of the window and click **Search**. (The Match field is not case sensitive.) The list of Available <level> Values appears on the right and contains all terms that match your text at the appropriate hierarchical level. The hierarchy section on the left also refreshes; only terms at the top-most hierarchical level appear, and each term that has a matching term in its path appears in *italics*.

**MedDRA 11.1 Hierarchy**  
SOC, HLGT, HLT, PT, LLT

Showing "dislocation" within hierarchy:

- Infec
- Neopl
- Blood
- Immun
- Endo
- Metab
- Psych
- Nerv
- Eye*
- Ear*
- Card
- Vasc
- Resp
- Gastr
- Hepat
- Skin
- Musc*
- Renal
- Preg
- Repro
- Cong*
- Genrl

**Available Preferred Term Values**  
(12 values)

Results for search of terms matching "dislocation":

- Congenital knee dislocation
- Device dislocation
- Dislocation of joint prosthesis
- Dislocation of sternum
- Dislocation of vertebra
- Intraocular lens dislocation
- Joint dislocation
- Joint dislocation pathological
- Joint dislocation postoperative
- Joint dislocation reduction
- Lens dislocation
- Vertebra dislocation reduction

**Match:**

When you click  next to an italicized term, the hierarchy expands all of the levels for that term to show the complete path to the term that matches. Italics appear at every level in the path to assist you in following the path to the matching term or terms. **Boldface** highlights the actual match.



**MedDRA 11.1 Hierarchy**  
SOC, HLGT, HLT, PT, LLT

Showing "dislocation" within hierarchy:

- Psych
- Nerv
- Eye
  - Anterior eye structural change, deposit and degeneration*
    - Anterior chamber structural change, deposit and degeneration
    - Cataract conditions
    - Conjunctival structural change, deposit and degeneration
    - Corneal structural change, deposit and degeneration
    - Iris and ciliary body structural change, deposit and degeneration
    - Lens structural change, deposit and degeneration (excl cataracts)*
      - Acquired lenticonus
      - Anterior capsule contraction
      - Aphakia
      - Aphakia congenital
      - Fibrin deposition on lens postoperative
      - Intraocular lens **dislocation***
        - IOL **dislocation**
        - Intraocular lens **dislocation**
        - Intraocular lens luxation

**Available Preferred Term Values**  
(12 values)

Results for search of terms matching "dislocation":

- Congenital knee dislocation
- Device dislocation
- Dislocation of joint prosthesis
- Dislocation of sternum
- Dislocation of vertebra
- Intraocular lens dislocation
- Joint dislocation
- Joint dislocation pathological
- Joint dislocation postoperative
- Joint dislocation reduction
- Lens dislocation
- Vertebra dislocation reduction

**Match:**

Alternatively, you can click a term in the Available <level> Values list to expand the hierarchy section to show the primary path for that term. The  icon indicates the primary path.

**MedDRA 11.1 Hierarchy**  
SOC, HLT, HLT, PT, LLT

Showing paths for "Intraocular lens dislocation":

- Inj&P
  - Administration site reactions
  - Bone and joint injuries
  - Chemical injury and poisoning
  - Injuries NEC
  - Injuries by physical agents
  - Medication errors
  - Procedural and device related injuries and complications NEC*
    - Anaesthetic complications
    - Cardiac and vascular procedural complications
    - Device component findings
    - Device malfunction events
    - Device related complications
    - Endocrine procedural complications
    - Eye and ear procedural complications*
      - Anterior capsule contraction
      - Capsular block syndrome
      - Cataract operation complication
      - Ciliary zonular dehiscence
      - Corneal graft rejection
      - Ear canal stenosis postoperative
      - Ear operation complication
      - Elschnig's bodies
      - Eye operation complication
      - Fibrin deposition on lens postoperative
      - Floppy iris syndrome
      - Intraocular lens dislocation*
        - IOL dislocation

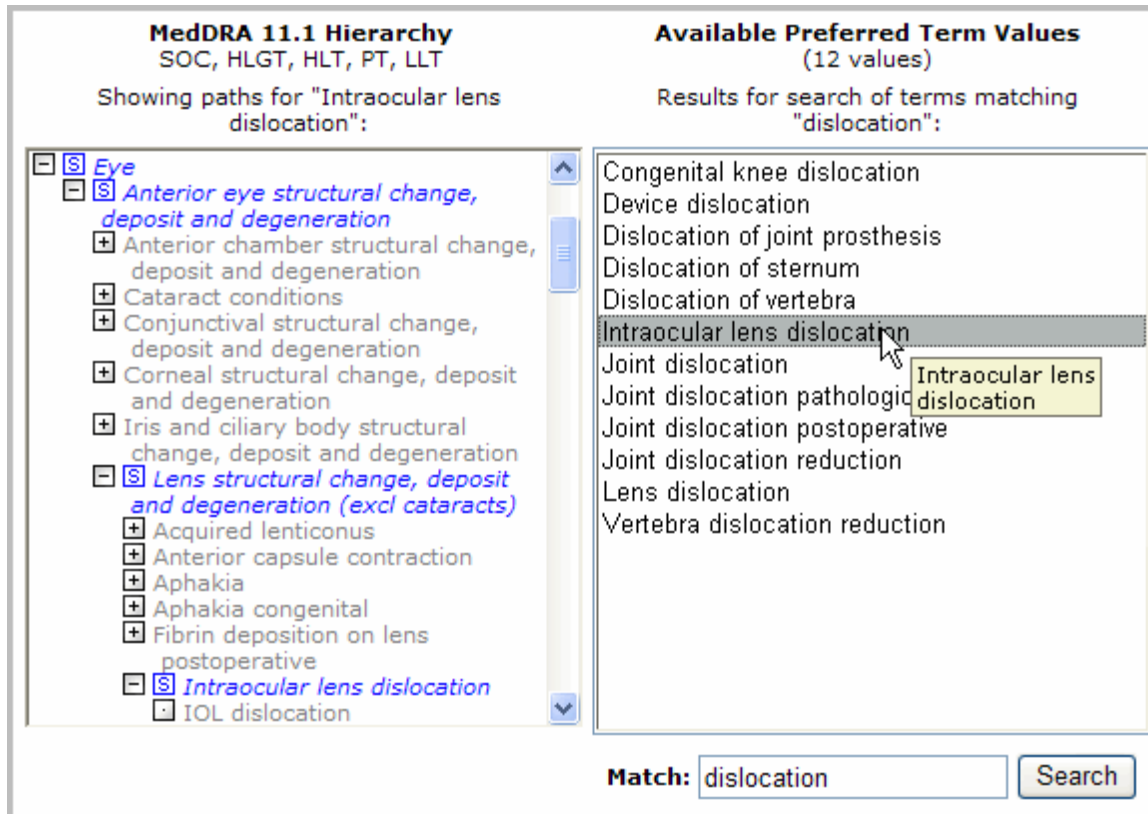
**Available Preferred Term Values**  
(12 values)

Results for search of terms matching "dislocation":

- Congenital knee dislocation
- Device dislocation
- Dislocation of joint prosthesis
- Dislocation of sternum
- Dislocation of vertebra
- Intraocular lens dislocation
- Joint dislocation
- Joint dislocation pathological
- Joint dislocation postoperative
- Joint dislocation reduction
- Lens dislocation
- Vertebra dislocation reduction

Match:

If the term also has a secondary path in the hierarchy, that path also expands and marked by the symbol . You can scroll through the hierarchy to review any alternate paths for the term.

**Notes:**

- When you click a term in the Available <level> Values list, its full name appears as pop-up text. This enables you to see the complete value in case the displayed value is cut off because of its length.
- Terms that appear in the hierarchy multiple times appear only once in the Available <level> Values list.
- The terms shown in this dialog box are from the special account that contains hierarchy data. As a result, custom terms do not appear in the hierarchy list, and cannot match entered search values.

**Selecting terms**

After you review terms in the Available <level> Values list, you can make selections. To select values, you highlight and move them as follows:

- To highlight a value, click it.
- To highlight multiple non-contiguous values, hold down the Ctrl key while clicking each value.
- To highlight multiple contiguous values, click a value, hold down the Shift key, and click another value. Values between and including those values are highlighted.
- To remove highlighting from a value, hold down the Ctrl key while clicking the selected value.

When your selections are complete, click **OK**. The window closes and you return to the task you were performing.

To create a [saved list](#) of terms for future use, click **Save As List**.

MedDRA® is a registered trademark of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).  
MedDRA® the Medical Dictionary for Regulatory Activities terminology is the international medical terminology developed under the auspices of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

## Selecting table columns

When specifying a SQL WHERE Clause, you can click **Show Columns** to display the Select Table Columns window listing variables (columns) that you can include in the WHERE clause. To insert a variable into the WHERE clause, click the column name.

## Selecting entries

1. Find the entry in the list. If a Match field is available, type a string and click **Find**.

All entries containing that string are listed; the matching does not distinguish between cases (upper, lower, mixed). See below for tips on how to search for entries using the Match field.

2. To list all entries again, click **Show All**.

---

**Note:** When an entry is highlighted in the list, you can go to the next occurrence of an entry starting with a character that you type. For example, you can highlight the first entry in the list and type "H" to go to the first entry starting with "H".

---

3. To highlight an entry, click the entry in the list.

4. You can also do the following:

- Highlight multiple non-contiguous entries: hold down the **Ctrl** key while clicking each entry.
- Highlight multiple contiguous entries: click an entry, hold down the **Shift** key, and click another entry.
- Entries between and including those entries are highlighted.
- Remove highlighting from an entry: hold down the **Ctrl** key while clicking the selected entry.

5. To move entries back and forth between the list of all entries and the list of selected entries, double-click a highlighted entry or use the arrow keys as follows:

<b>Button</b>	<b>Use To</b>
->	Move highlighted entries from the list of all entries to the list of selected entries.
->>	Move all entries from the list of all entries to the list of selected entries.
<-	Move highlighted entries from the list of selected entries to the list of available entries.
<<-	Move all entries from the list of selected entries to the list of available entries.

If **Clear** is available, you can click it to clear out the list of selected entries.

6. If up and down arrows are available for the list of selected entries, you can use them to order the selected entries. For example, when specifying breakdown details in a report definition, you can order the selected entries as you want them to appear in the report.

7. When you are satisfied with the selected entries, click **OK**. (In some contexts, the button may instead be **Save** or **Copy**.)

## Special characters

To search for the following special characters, you must precede each special character with a backslash (\):

+  
\*  
?  
.  
\  
(  
)  
[  
]

Example	Description
NAUSEA \+ VOMITING	NAUSEA + VOMITING
\(R\) ELBOW PAIN	(R) ELBOW PAIN

## Match string syntax

In the Match field, you can use the following syntax:

Syntax	What Is Matched	Syntax Example	Found by Example
^	Letter(s) at the beginning of a value.	^V	VERTIGO VOMITING  Does not find SEVERE VOMITING.
\$	Letter(s) at the end of a value.	on\$	AGITATION DEPRESSION  Does not find ANEMIA IRON DEFIC.
.	Any single character.	D.stonia	DYSTONIA
[abcdef]	Any character included in the set.	[gq]	All terms that have any of the letters g or q, including:  ANGINA FREQUENT URINATION
\b	A word boundary in a	\bDr	ABNORMAL DREAMS

	term.		DRY MOUTH
\s	White space in a term.	en\s	PATHOGEN RESISTANCE SUDDEN INFANT DEATH SYNDROM
		\sen	ABDO ENLARGE



## Specifying a SQL WHERE clause

At certain places in the application, you can specify a SQL WHERE clause to restrict rows of a table or report. When specifying a SQL WHERE clause, do not enter the word WHERE. The application adds WHERE internally to the start of the condition that you enter. For example, to view all results for which EBGM is greater than 5, type EBGM > 5.

To connect conditions, use AND or OR. For example:

- N > 5 AND EBGM > 8
- EBGM > 5 OR EBGMDIF > 6

If you provide a SQL expression with incorrect syntax or unsupported SQL functions, an error message appears at the top of the page when you save the expression. Common errors are a wrong or misspelled column name, and unclosed or mismatched parentheses.

The way in which a variable is stored in the Oracle database determines how you can search for it.

## Text variables

If a variable is stored as a text field in the Oracle database, you must enclose the text string in single quotes. Capitalization within the quoted string must match the text string in the database exactly.

To find a value that includes a single quotation mark, or apostrophe, precede the quotation mark or apostrophe with another single quotation mark in the quoted string. For example, to find Bell's palsy for the PT variable, type PT like 'Bell''s palsy'.

You can use any valid SQL operators, including the following commonly used operators:

Operator	Meaning	Example
LIKE	matches	SUBSET LIKE 'F'
NOT	is not the condition that follows	SUBSET NOT LIKE 'F'

% is a wildcard character that you can use in a text string after LIKE; it matches any characters in its position, as follows:

Type of Match	Example
Exact match	ITEM1 LIKE 'Asthma NOS'
Starts with specified string	ITEM1 LIKE 'As%'
Includes specified string	ITEM1 LIKE '%th%'

Ends with specified string      ITEM1 LIKE '%NOS'

---

## Numeric variables

If a variable is stored as a number field in the Oracle database, you can use any valid SQL operators, including the following commonly used operators:

Operator	Meaning	Example
=	is equal to	EBGM = 3
!= or <>	is not equal to	EBGM != 3 EBGM <>3
>	is greater than	EBGM > 98.6
>=	is greater than or equal to	EBGM >= 98.6
<	is less than	EBGM < 8.5
<=	is less than or equal to	EBGM <= 8.5
BETWEEN	is between (includes both 6.5 and 8.0)	EBGM BETWEEN 6.5 AND 8.0

## Date variables

If a date variable is stored as a text field in the Oracle database, you can search for it as you would search for any text string.

If a date variable is stored as a date field in the Oracle database, you can use the Oracle function TO\_DATE to change a text string to an Oracle date. Then you can use the same operators as for numeric variables. For example, if you want to find RCVD\_DATE dates later than 2000-01-17. You specify:

```
RCVD_DATE > TO_DATE('2000-01-17', 'yyyy-mm-dd', 'NLS_DATE_LANGUAGE = American')
```

If you do not specify a time, the time is considered to be midnight of the specified date.

## Column names

To select table columns (variables) to include in the WHERE clause, click **Show Columns** in the Columns and Rows window.

When using a SQL WHERE clause to select criteria for run results that you are viewing or to filter a source table that you are viewing, avoid referring to the drug or event variables or related hierarchy terms. The actual column names in the underlying table are not the same as the labels for fields on the Select Criteria page or as the column headers in the results table. The actual column names are ITEM1, ITEM2, etc.

---

**Note:** The alphabetical order of prefixes defined in the configuration for the drug and event variables determines whether the variables are ITEM1 or ITEM2. For example, if the prefix for the drug variable is D and the prefix for the event variable is E, the drug variable is ITEM1 because D is first alphabetically.

---

## SQL functions

The Empirica Signal application supports the following SQL functions in WHERE clauses:

acos	length	soundex
ascii	lower	sqrt
asciiStr	last_day	substr
asin	ln	tan
atan	log	tanh
atan2	lpad	to_date
BitAnd	ltrim	to_dsinterval1
Ceil	mod	to_multi_byte
Chr	months_between	to_number
Compose	new_time	to_single_byte
concat	next_day	to_timestamp
convert	power	to_timestamp_tz
cos	remainder	translate
cosh	replace	tz_offset
decompose	round	abs
dump	rpadd	to_ymininterval
exp	rtrim	add_months
floor	sign	upper

initcap	sin	vsize
from_tz	sinh	to_char
instr		

**Note:**

The following are the caveats of the SQL functions:

- Functions with no parameters are permitted (for example, sysdate)
- Functions with optional arguments (for example, to\_date) require ALL arguments

## Publishing objects


Publication of an object, such as a data mining run or report output, is a way to make it available to other users. By default, the publication level of every newly created object is Private.

---

**Note:** Users without the Administer Users permission can publish only objects they have created. Users with the Administer Users permission can publish objects that they or any users in their login group created.

---

### To publish an individual object:

1. Select the row menu () for the object, and then click **Publish**.

The Publish <object> page appears and includes publication status information such as the run, who owns it, and the publication level.

---

**Note:** If no publication status appears, the object has been published to a different login group than yours by a superuser.

---

2. If you are a superuser, you can publish an object to multiple login groups. In the Publish to Login Groups drop-down list, click or Ctrl+click to select login groups.

If you publish to –All– and later add a new login group, the object is published automatically to the new login group.

3. Click **Publish**.

The object is published to all of the users who are in your login group.

4. To remove publication for a login group, click **Remove** for it.

5. If the Publication Level is Public, you can click **Make Private to make it private, and vice versa**.

### To publish multiple objects:

Certain types of objects, including report definitions and outputs, allow selection of multiple rows.

- After selecting rows for the objects that you want to publish, click **Publish**.

The objects are published to other users who are in your login group.

---

**Note:** If you are a superuser, you can publish objects to multiple login groups. Select the objects, then click **Publish**. Click or Ctrl+click to select login groups, then click **Publish**.

---

You cannot remove publication for multiple objects at the same time. To remove publication, do so for the individual objects as described above.

## Saving an object to a topic

To save objects as an attachment for an existing or a new topic, do the following:

1. On the page where the object appears, click **Save to Topic**.

The Save to Topic dialog box appears.

---

**Note:** For a graph on the Data Mining Results tab or Reports tab, the **Links** check box must be selected for the **Save to Topic** link to appear below the graph.

---

When you save tabular data, such as run results:

- Only the first **n** rows of the displayed tabular data can be saved, where **n** is determined by a [site option](#). A message is displayed if not all the rows are saved. The number of saved rows and the total number of rows appear when you rest the cursor on the attachment name.

---

**Note:** On the Drug-Event Combinations page, you can select rows, so the first **n** selected rows are saved.

---

- You might want to select different columns before you save. Only the currently displayed columns appear by default when the attachment is viewed. However, the application stores all available columns with the attachment. To customize the columns shown when viewing the attachment within the topic, click **Columns** and select the columns.

2. Enter the information into the fields [shown](#). For more information, see [Save to Topic dialog box](#).

3. Click **OK**.

If you have created a new topic, it is assigned to you by default. You can edit the topic as needed.

---

**Note:** Your administrator may establish a maximum size for the Empirica Signal tables that you can attach with a [site option](#). If you attempt to save a larger table an error message informs you of the defined limit.

---

After you add an attachment, you can view or edit it when you view or edit the topic or action to which it is attached. See [Working with attachments](#).

---

**Note:** Changes to, or deletions of, the original object do not affect the attachment. For example, if you save report output as an attachment to a topic and then that report output is deleted, the topic attachment remains unchanged.

---

## Timestamped data

Timestamping is a technique for representing multiple versions of the same [source data](#) within one database. The source data must include dates (VALID\_START and VALID\_END columns) that can be used to determine the period for which each record is valid. This enables the Empirica Signal application to reconstruct data for different periods of time. As a result, you can base data mining runs, queries, and case series on source data *as of* a date that you specify. This date is referred to as the As Of date.

In the data mining run, query, or case series, data is used if the following is true:

VALID\_START (if present) <= Specified As Of Date < VALID\_END (if present)

For example, suppose that the source data includes the following DRUGS table, where an edit occurred for case ID 100:

CASE_ID	DRUG	ROUTE	VALID_START	VALID_END
100	DrugA	IV	01-01-2005	06-01-2005
100	DrugA	ORAL	06-01-2005	

- If a run is performed as of 2/1/2005, the Route for DrugA is IV.
- If a run is performed as of 7/1/2005, the Route for DrugA is ORAL.
- If a run is performed as of 6/1/2005, the Route for DrugA is ORAL.

## Specifying an As Of date

On pages where you specify an As Of date, a default date appears. You can change the date to another date that is within the range determined by the [source description table](#) for the data configuration.

## Using projects

A project in the Empirica Signal application is an organizational tool (similar to a folder) that allows you to group certain objects for reference and retrieval purposes. On the Empirica Signal pages that list objects (such as data mining runs, queries or case series), you can select a project to filter the list to only objects in that project. Projects have no effect on any computations.

When creating an object, you can assign it to a project; for example:



The screenshot shows a form with two radio button options. The first option, "Add to existing project:", is selected and followed by a dropdown menu currently showing "Unassigned". The second option, "Add to a new project named:", is followed by an empty text input field.

You can either select an existing project or create a new project. The list of existing projects includes projects for objects that you created or that are published to you. You can also choose not to use projects at all. By default, objects are unassigned.

---

**Note:** A project remains available until all objects associated with it have been deleted.

---



## Tables

### About tables

Many of the Empirica Signal pages present information in a tabular format. To work with the table, you can use the following options:



To	Click this link	Help topic
Select, arrange, sort, and filter the columns that display in the table.	<b>Columns</b> or <b>Columns and Rows</b>	<a href="#">Arranging table columns</a>
Print the contents of the table.	<b>Print</b>	<a href="#">Printing a table</a>
Download the contents of the table to a variety of file formats.	<b>Download</b>	<a href="#">Downloading data</a>

The Empirica Signal application saves the display choices that you make for a particular table. Your choices remain in effect for that table throughout your subsequent Empirica Signal sessions, until you make different choices.

### Navigating between pages

To specify how many rows should display at a time, enter a number in the **Rows per Page** field and press **Enter**. In general, you can display up to 10,000 rows on each page. The default number of rows is typically 50, but may vary for different Empirica Signal pages.

To go to another page, you can do the following:

- To view the next page, click .
- To view the previous page, click .
- To view a specific page, type a number in the **Page** field and press the **Enter**.

### Finding text

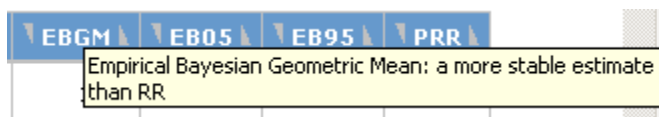
To find specific text on a page, from the browser Edit menu, click **Find**. For efficiency, you may want to set the Rows per Page to a large number before using the Find feature.

### Vertical scrollbars

A site option determines whether vertical scrollbars for tables of information are always on the left side, always on the right side, or determined by the [user preference](#) Show table scrollbars on left side.

### Column descriptions

In some tables, when you rest the cursor on a column heading, a description of the column appears:



## Sorting the table

You can sort a table by up to three columns. The current sort order appears above the table. You can sort a column as follows:

- To sort in Ascending order, click . To sort in descending order, click .
- Click **Columns** or **Columns and Rows**. (See [Arranging table columns.](#))

When you click or to sort a column, that column is the primary sort order. For example, suppose that the current sort order is Generic\_Name, PT, and EBGM (desc):

57 rows Sorted by Generic\_Name, PT, EBGM desc Rows Per Page:  Page

	Generic_Name	PT	EBGM	EB05	EB95
	Niacin And Vitamin B1 And Vitamin B2	Abdominal pain	2.123	0.933	4.501

If you decide to sort by EB05 in descending order, click the down arrow in that column heading. The sort order becomes:

57 rows Sorted by EB05 desc, Generic\_Name, PT Rows Per Page:  Page

	Generic_Name	PT	EBGM	EB05	EB95
	Niacin And Vitamin B1 And Vitamin B2	Tremor	2.579	1.002	14.636

Note that:

- The last sort order you specify becomes the primary sort order.
- Other columns continue to be used for sorting (secondary and third sort orders).
- For most tables, empty columns appear first, if you sort in ascending order, and last, if you sort in descending order. On the [Drug Overviews page](#), the Drug-Event Combinations page, and the [Drug Comments page](#), empty columns always appear last, regardless of the sort order.

If you want to clear a sort order or explicitly specify levels of sorting, do so in the Columns (or Columns & Rows) dialog box. For example, you can change the above sort order as follows:

### Column Sort Order:

EB95	▼	Desc	▼
PT	▼	Asc	▼
Generic_Name	▼	Asc	▼

57 rows Sorted by EB95 desc, PT, Generic\_Name Rows Per Page:  Page

	Generic_Name	PT	EBGM	EB05	EB95
	Niacin And Vitamin B1 And Vitamin B2	Tremor	2.579	1.002	14.636

## Arranging table columns

For Empirica Signal pages that present information in a tabular format, you can:

- Select the columns to include in the table.
- Reorder the columns.
- Sort the rows in the table using the values in up to three different columns.

On some pages, you can also filter rows in the table by [specifying a SQL WHERE clause](#).

1. Click **Columns**.

The Columns dialog box appears.

---

**Note:** If your [user preference](#) is set to allow a SQL WHERE clause on tabs, the link is **Columns and Rows**.



---

2. To select columns that you want to include in the table, move them from the **Available Columns** list to the **Selected Columns** list. See [Selecting entries](#).

For data mining results, you can check **Show All Columns** to list all possible columns in the Available Columns list. Otherwise, only columns that are considered most likely to be needed are in the Available Columns list.

If a table includes a lot of columns or the columns contain long values, the entire table may not fit across your browser window. Scroll to the right to see the rest of the table.

3. To change the order in which columns display in a table, in the **Selected Columns** list, click the column name and:

- Click  to move the column up in the list.
- Click  to move the column down in the list.

4. To move multiple columns, hold down the Ctrl key while you click the column names and then use the up or down arrows.

---

**Note:** For most tables, rows with empty cells appear first when you sort that column in ascending order, and last if you sort in descending order. On the [Drug Overviews page](#), the Drug-Event Combinations page, and the [Drug Comments page](#), empty columns are always displayed last, regardless of the sort order.

---

5. If you want to replace your choices with the Empirica Signal defaults, click **Reset**. The table columns and sorting return to the default values.

6. Specify the sort order.

If you sorted the table by clicking arrows next to column headings, that sort order appears in the Column Name and Sort Order fields. Otherwise, the Column Sort Order fields are empty. To specify a sort order:

- A. From the **Column Name** drop-down lists, select a column name for up to three columns.
- B. From the **Sort Order** drop-down list, select **Asc** (ascending order: A-Z, 1-9) or **Desc** (descending order: Z-A, 9-1).

If the link was **Columns and Rows** (instead of Columns), you can [specify a SQL WHERE clause](#) to filter rows of the table. You can click **Show Columns** to insert variable names into the Where clause.

7. Additional options may also appear for specific tables, or if you have specific user permissions. For example, for data mining results, you can check an option to use the current layout (table arrangement) as the default the first time you view results of any run of the same type and dimension.
8. If you have the Administer Users [permission](#), you have the option to make the current layout the default for all of the users in your login group. This replaces the default table layout supplied by the application with your current layout for any user who has not yet arranged that table.
9. Click **OK**.

For your username (and across your Empirica Signal sessions), the application saves your arrangement of columns and rows and uses it as a default for the specific table, until you change the arrangement.

## Printing a table

1. Set up the displayed table as you want it to appear when printed. The table prints with the same columns and sort order as the displayed table.

2. To print the entire table, click **Print**.

or

If you want to print only the data on the currently displayed page of the table, from the browser File menu, select **Print**. (This option is available only if the table appears in an Internet Explorer window and not a separate dialog box.)

The Windows Print window appears.

Optionally, change the orientation of the paper (Portrait or Landscape) and make other printing choices. If all displayed columns do not print in Landscape mode, you can remove columns from the table before printing it.

3. Select a printer.
4. Click **Print**.

## Downloading data

When working with a table, you can download the information to various types of files. When [viewing case details](#), you can download the details to an Excel spreadsheet or a Rich Text Format file.

You can set your [user preference](#), **Default download file type**, to a file type to be used by default. When downloading, however, you can override the default by selecting another file type as needed.

---

**Note:** For floating-point numbers that are downloaded, the precision of the numbers is accurate to the level of precision in the numbers, as displayed in the Empirica Signal application.

---

1. Make sure you have [arranged table columns](#) as you want them.

2. Click **Download**.

The Download dialog box appears.

3. In the **Base filename** field, enter a filename. Do not include an extension. Oracle recommends that you use a filename that identifies the content of the download.

---

**Note:** With Internet Explorer 8.0, 9.0, 10.0, the application automatically replaces any spaces in the filename with an underscore ( \_ ).

---

4. Click one of the following file types. For some types of information, only certain file types are available.

File Type	Description
Comma-separated file (.csv)	Text file in which values are separated by a comma. Can be used as input to or output from Microsoft Excel.  <b>Note:</b> Leading zeroes in values are not retained when you download to a .csv file.
Tab delimited file (.txt)	Plain text file. Typically, the file extension .txt is associated with a text editor, such as Microsoft Notepad.
Excel spreadsheet (.xls)	Spreadsheet file that can be opened by Microsoft Excel. You must have Microsoft Excel installed on your computer. If you try to download a table of more than 65,535 rows, a message warns you that this exceeds the capacity of Excel.  When you download case details to an Excel spreadsheet, a separate worksheet is used for each of the different types of data shown on the Case Details page. Each worksheet is limited to 65,535 rows.  <b>Note:</b> If dates are not displayed appropriately in Excel, you might

	need to change the display format in Excel.
SAS Version 5 transport (.xpt)	Industry-standard SAS transport file, as defined for SAS Version 5 (XPORT format).
SAS data step definition (.sas)	SAS data step file, which can be used by SAS software to create a native SAS dataset.
Rich Text Format (.rtf)	Available only for downloading case details. File that includes formatting and layout information, as well as the data. Typically, this file type is associated with Microsoft Word.
Portable Document Format (.pdf)	File that includes formatting and layout information, as well as the data. This option requires the Adobe Acrobat Reader.

---

**Note:** When you are downloading case details, only the Excel spreadsheet (.xls) or Word Rich Text Format (.rtf) formats are available.

---

5. In the **Limit to** field, you can enter the number of rows that you want to download (instead of downloading the entire table). For example, if you specify 1000, only the first 1,000 rows of the table download. Keep in mind that the way in which the table is sorted determine which rows are downloaded. If you do not fill in the Limit to field, all rows of the table download.

The number of rows per page of the displayed table has no effect on downloading. For example, the table includes 100 rows and 25 rows appear per page. If you download the entire table, all 100 rows download.

---

**Note:** When you download case details, Oracle recommends that you do not limit the number of rows. The limit applies to each type of data. For example, if you limit the download to two rows, only the first two drugs and the first two adverse events for the case are downloaded.

---

6. If you check **Create a Zip archive file for download**, the application creates a file with the extension .zip to hold the file that contains the downloaded table. You must have a ZIP file compression and extraction utility, such as WinZip, installed on your computer, as described in [Prerequisites and usage notes](#).

The zip file also includes an id.txt file that provides the name of the user who downloaded the table and the date and time of the download.

---

**Note:** When you download data from a report, you can also include a report definition file and analysis files. The report definition is an XML representation of the report. The analysis files include an analysis description file and an analysis script file (if defined for the report).

---

7. Click **OK**.

The File Download dialog box opens and you can choose to open or save the file.

---

**Note:** When you download data mining results or reports, the application includes notes in the download (to all file types except .xpt and .sas) if they appeared at the time of the download.


---



## Drilldown

### Drilling down

On many Empirica Signal pages, the count (N) of cases is a link that you can click to display a menu with drilldown options:

	NIACIN	Flushing	<a href="#">20</a>	12.2	8.30	17.5
	NIACIN	Headache Nos	<div style="border: 1px solid blue; background-color: #e6e6fa; padding: 5px;"> <a href="#">View Cases</a>  <a href="#">Create Case Series</a>  <a href="#">Transfer to Case Series</a>  <a href="#">Download Cases</a>  <a href="#">Download Case Details</a>  <a href="#">Reports</a> </div>			2.27
	NIACIN	Myalgia				4.26
	NIACIN	Pruritus Nos				3.38
	NIACIN	Rhabdomyolysis				7.55

In graphs, you can click an element (such as a bar or cell) of the graph to display the menu.

**Note:** If you are displaying multiple graphs on the same page, and you click a graph element before all the graphs have appeared, you cannot display the popup menu and the rest of the graphs are not displayed.

You can select the following options for the cases that make up the count or are represented by the graph element:

Options	Click to
View Cases	<a href="#">View a list of cases.</a>
Create Case Series	<a href="#">Create a case series.</a> For <a href="#">timestamped data</a> , the As Of date of the case series will be that of the object you are viewing.
Transfer to Case Series	<a href="#">Transfer the list of cases</a> to an existing case series.
Download Cases	<a href="#">Download the list of cases.</a>
Download Case Details	<a href="#">Download case details</a> for the cases to an Excel spreadsheet or a Word Rich Text Format File. You can download case details only if the appropriate site option has been set. (When viewing a particular case, you can also download case details for that one case.)
Reports	<a href="#">View a report</a> for the cases. You can run only one report definition at the same time. Report definitions appear only if they are <a href="#">compatible</a> with the data configuration for the object that you are viewing.

## Viewing a list of cases

When you have [drilled down](#) to a list of cases, the Cases page shows the list in a tabular format. The variable representing the case ID is the first column of the table. Other information in the table is customizable and is determined by the [data configuration](#).

See [About tables](#) for information about viewing, printing, or downloading tables or changing the way data appears in the table on the Cases page.

The application retrieves the data that appears on the Cases page from the source data. Therefore, it does not include [custom terms](#) or values created by [data transformations](#).

From the count (N) drill-down menu, you can do the following:

- If the appropriate site option has been set, you can [view case details](#) for a single case in the list. Click the **case ID** link in the case list. The Case Details page appears. For information about how visited case ID links change color, see [Case ID links](#).
- To [create a case series](#) containing the case IDs, click **Create Case Series**. For [timestamped data](#), the As Of date of the case series is that of the object you were viewing when you drilled down.
- To [transfer the list of cases](#) to an existing case series, click **Transfer to Case Series**.
- To [download case details](#) for all cases in the list to an Excel spreadsheet or a Word Rich Text Format File, click **Download Case Details**. You can download case details only if the appropriate site option has been set. (When viewing a particular case, you can also download case details for that one case.)
- To [view a report](#) for the cases, click **Reports**. Report definitions appear only if they are [compatible](#) with the data configuration for the object that you were viewing.

To [save the list of cases as an attachment to a topic](#), click the **Save to Topic** link (available if the Topics feature has been set up).

## Creating a case series from drill-down information

On pages and in reports that display a list of cases identified by case ID, you can save the list of cases for future use. The named and saved list of cases is referred to as a *case series*. You can also [transfer cases](#) to an existing case series.

1. When viewing a list of cases, click **Create Case Series**. Alternatively, click a **count (N)** of cases in a table or click an element of a graph, and then click **Create Case Series** from the row menu.  
  
The Create Case Series page appears.
2. In the **Name** field, type a name for the new case series. The name does not need to be unique, although Oracle recommends that you use a unique name.
3. In the **Description** field, enter a description of the case series. A default description, which you can modify, might appear.
4. To add the case series to a [project](#), click **Add to existing project** and select the project from the drop-down list of projects associated with objects that you created or that are published to you.
5. To create a new project and assign the case series to it, click **Add to a new project named** and type a project name.
6. Click **Create**.

## Transferring cases to a case series

On pages and in reports that display a list of cases identified by case ID, you can transfer cases to an existing case series. You can also [create a new case series](#) containing the cases.

For [timestamped data](#), when cases are transferred to a case series, the application uses the As Of date associated with the target case series to determine whether the cases are legitimate to add. For example, if the As Of date of the case series is 06/15/2010 and the case ID 1554 did not exist until 07/01/2010, if you try to add case ID 1554 to the case series, it is not added because it did not exist on 06/15/2010.

1. When viewing a list of cases, click **Transfer to Case Series**. Alternatively, click a **count (N)** of cases in a table or click the element of a graph, and then click **Transfer to Case Series** from the row menu.

The Transfer to Case Series page appears.

Available case series are those that are based on data configurations that are [compatible](#) with that of the object you are viewing.

2. Click the row for the case series that you want to select, and then click **OK**.

The application adds the case IDs to the case series if they were not already in it. A message states how many cases were added to the case series.

---

**Note:** It is possible, but not recommended, to transfer cases that do not meet query criteria to a query-based case series. If the query is executed again, the transferred cases are dropped if they do not meet the query criteria.

---

## Viewing case details

When a case ID appears as a link anywhere in the application, you can click the link to drill down to case details. The Case Details dialog box provides information about the case, presented as a set of tables showing source data for the case. At a minimum, the following information appears:

- Case Information (demographic information).
- Reported Drug/Vaccines.
- Reported Events/Symptoms.

There might also be additional information about reported outcomes, case report sources, narrative text, and so on.

If specified by the [data configuration](#), a description of source data appears below the case details. For example: **Source Data:** AERS data as of 4th quarter 2004 from NTIS Public Release loaded on 2005-04-18.

---

**Note:** The application retrieves the data that appears as case details from the source data. Therefore, [custom terms](#) or values created by [data transformations](#) do not appear.

---

1. Click a **case ID**.  
The Case Details dialog box appears.
2. If you have set your [user preference](#) to show a table of contents for case details, there is a Contents section at the top of the page. It includes links that you can click to jump to the various types of data on the page. (If the case has no data of that type, clicking the link has no effect.)
3. To print case details, click **Print**.
4. To [download case details](#) to an Excel spreadsheet or a Word Rich Text Format File, click **Download**.
5. To [save the case details as an attachment to a topic](#), click **Save to Topic** (available if the topics feature has been set up).

The Case Details dialog box might include a link at the top to go to a third-party application showing further information about the case.

## Case ID links

When a case ID appears as a link anywhere in the application, you can click the link to drill down to case details. Once you have clicked a case ID link, the color of the link changes. This color change:

- Applies to only your username and across your Empirica Signal sessions.
- Lasts for the number of days that you have set as your [user preference](#), Days to retain visited status for case ID links.
- Applies across all activities within the application.
- Applies to data associated with all [data configurations](#) in the same database group (an attribute of a configuration).

For example, two data mining runs are based on data configurations in the same database group. When viewing results for one run, you drill down to a list of cases and then click the case ID, 1435. The color of case ID 1435 changes, indicating that you have visited the case ID. You log out, log back in, and view a case series that includes case ID 1435 and is based on the second data configuration. Case ID 1435 appears in the changed color, indicating that you have visited it.

Note:

- The user preference, Days to retain visited status for case ID links, applies to case ID links that you visit after you set the preference.
- The visited status is reset each time you visit a case ID link. For example, suppose that your user preference is set to 5. On Day 2, you click a case ID link. The link visited status is retained for 5 days beginning with Day 2. You visit the case ID link again on Day 3. The link visited status now is retained for 5 days beginning with Day 3. Then you change the user preference to 10. On Day 9, you view a list of cases that includes the case ID. The case ID link is the original color again because 6 days have passed since Day 3. When you click the link, the user preference is reset, so the visited status is retained for 10 days (the new preference setting) from Day 9.
- If you do not want case ID links to change color when they are visited, you can set your user preference to retain the visited status of case IDs to 0 days.
- If the data is associated with a data configuration that is not in a database group, the color of visited case ID links never changes.

To remove the visited status of all your case ID links at any time, click **Settings** and then click **Remove Visited Status of Case ID Links**.

## Data configurations

### Selecting a data configuration

A data configuration is a group of variables representing items (database table columns) in the source data. In several places in the Empirica Signal application, such as when creating a data mining run or query, you must select a data configuration to indicate which source data is used. You can select the data configuration from a list of data configurations to which you have access. If you do not know the name of the data configuration, you can browse a descriptive list of data configurations and select one. When you select a data configuration, it remains selected until you select a different one.

Lists of available configurations typically show only compatible configurations. See [Data configuration and object compatibility](#) for more information.

1. Next to the Configuration field, click **Browse**.

The Select Configuration dialog box appears and provides the following information about each data configuration to which you have access:

Column	Description
ID	Internal identifier of the data configuration.
Name	Name of the data configuration.
Description	Description of the data configuration.
Account	Name of the Oracle account in which the data configuration resides.

See [About tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

2. Click the row for the data configuration that you want to select.
3. Click **OK**.

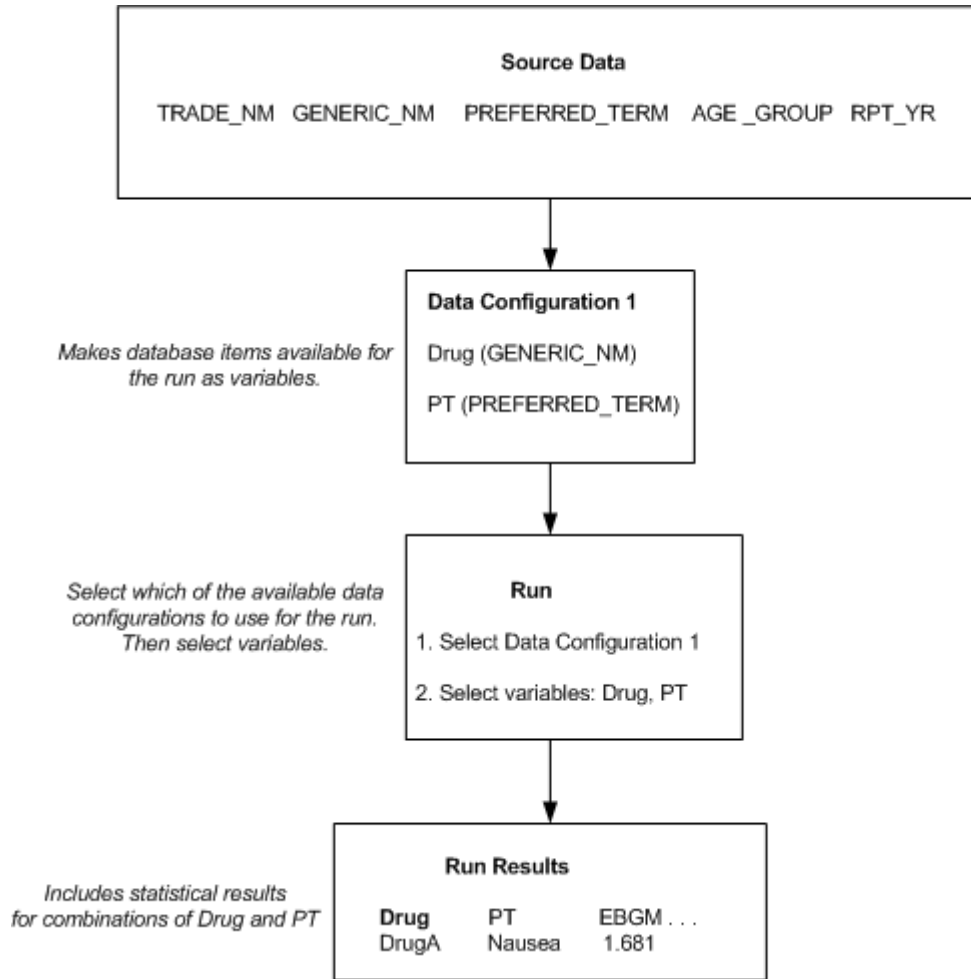
---

**Note:** Some data configurations are set up to support [timestamped data](#). If you select this type of data configuration during certain activities, you must specify an As of date. See [Specifying an As Of date](#).

---

### Example

Suppose that the source data contains all the items shown in the following example. The data configuration specifies GENERIC\_NM and PREFERRED\_TERM as the items to be available in a data mining run. If the data configuration renames GENERIC\_NM and PREFERRED\_TERM to Drug and PT, when you create a run, you select Drug and PT as the items to study. The run results show you scores for combinations of Drug and PT values.





## Viewing data configuration variables

For certain activities, you must select a data configuration. If you are not certain which data configuration to use, viewing the variables in the data configurations can help you determine which data configuration to use.


- On the [Select Configuration dialog box](#), click the row menu () for a data configuration, and then click **Show Variables**.

The Configuration Variables page provides the following information about each variable in the data configuration:

Column	Description
Variable	Name of the variable.
Description	Description of the variable.
Variable Type	Displays the variable type of the variable. For descriptions of the variable types, see <a href="#">Adding or editing a data configuration variable</a> .
Data Transform	Type of <a href="#">data transformation</a> , if any, associated with the variable.

## Specifying an As Of date

During some activities, if you select a data configuration that supports timestamped data, the Select 'As Of' Date page appears and you must specify an As Of date and time. See [Timestamped data](#) for more information.

1. If you want to use the displayed date, click **Latest date**.  
or  
Click **Other** and enter a date in mm/dd/yyyy format.  
or  
Click  to display a calendar and select a date.
2. Enter a time in hh:mm:ss am/pm format.
3. Click **Next**.

## Data configuration and object compatibility

The Empirica Signal application checks the compatibility of data configurations with other data configurations or other objects. For example, when you re-run a data mining run using a different configuration, the application checks that the configuration you specified is compatible with the original configuration used.

Compatibility-checking for various types of objects is as follows.

### Data mining runs

---

**Note:** Two variables match if they have the same variable name, the same variable type and subtype, and the same settings for use as a subset variable or stratification variable.

---

When re-running a data mining run, you can select from configurations with variables that match all variables in the original run's configuration. The configurations must also have the same setting for whether the database is timestamped.

### Saved lists

---

**Note:** Two variables match if they have the same name, selection type, and Oracle data type.

---

When selecting a saved list, you can select from lists where the variable referenced by the saved list has a matching variable in the configuration associated with the object on which you are working.

### Queries and reports

---

**Note:** Two variables match if they have the same name (ignoring underscores and spaces), selection type, and Oracle data type.

---

- When listing reports for a selected case series, the application lists only reports based on configurations with variables that match the variables in the configuration of the selected case series.
- When listing reports for cases that appear when you drill down on a count, the application lists only reports where the variables used by the report match variables in the configuration of the object from which you are drilling down.
- When running a query, you can select from configurations with variables that match all variables referenced by the query.
- When creating a query-based interactive report, you can select from queries where all referenced variables have a matching variable in the report configuration.
- When defining a custom term or database restriction, you can select from queries where all referenced variables have a matching variable in the run configuration.
- When running a query-based interactive report, you can select from configurations with variables that match the union of all variables referenced by the query and all variables referenced by the report.

- When running an All Cases Summary report, you can select from configurations with variables that match all variables referenced by the report.

### **Case series (not query-based)**

---

**Note:** Two variables match if they have the same name and selection type.

---

When transferring cases to a case series, you can select from case series based on configurations with variables that match variables in the configuration of the object from which you are transferring cases.

### **Deleted data configurations**

---

**Note:** Two variables match if they have the same name (ignoring underscores and spaces), selection type, and Oracle data type.

---

When deleting a configuration, you can transfer certain types of objects to another data configuration with variables that match the all variables referenced by the objects.

## Saved lists

### About saved lists

A saved list is a list of up to 1,000 drug or event terms that have been grouped together and saved. Once you have created a saved list, you can refer to the list instead of specifying the individual terms. For example, if you have saved antipsychotic drugs in a list, you can refer to that list elsewhere when you need a list of antipsychotic drugs.

In most places where you can select values for a drug or event variable (for example, when selecting criteria to view data mining run results), you can create a saved list from the values that you have selected. You can also create or edit saved lists by selecting the Settings link at the top of a page and clicking **Manage Saved Lists**.

## Saved Lists page

On the Saved Lists page, you can view saved lists that you have created or for which you have the edit permission. The page displays saved lists created by all users in your login group if you have the Administer Users permission.

### General activities

The following links appear at the top of the page and affect the entire page:

- [Create Saved List](#)
- [Add Lists In Bulk](#)
- Back
- [Columns](#)
- [Print](#)
- [Download](#)

The following filters appear at the top of the page and affect the rows displayed in the table:

- [Project](#)
- [Configuration](#)

### Row-specific activities

The following menu options are available from the row menu, located in the leftmost column of the table, and affect an individual row in the table:

- [View](#)
- [Edit](#)
- [Set Permissions](#)
- Delete

### Field descriptions—Saved List page


Field	Description
Name	Name of the saved list.
Description	Description of the saved list.
Project	Name of the project to which the saved list is assigned.
Configuration	Name of the data configuration on which the saved list is based. If the saved list is based on a run, the name of the data configuration used by the run appears.
Created By	Name of the user who created the saved list.

Created On	Date and time the saved list was created.
# of Terms	Number of terms included in the saved list.
ID	Identifier the application automatically assigns when the saved list is created. Each saved list ID is unique and is not re-used if you delete the saved list.
List Type	Type of variable to which the saved list is attached. Possible values are Drug, Event, and Item.
Modified	Date and time when the saved list was last modified.
Modified By	Name of the user who last modified the saved list.
Variable	Name of the variable for which the saved list contains terms.

## Creating or editing a saved list

Most dialog boxes from which you can select values for drug or event variables, such as when browsing and selecting terms from a [hierarchy](#), include a **Save As List** button to create a saved list from the values that you have selected.

You can also create a saved list from scratch and edit a saved list.

1. From the top of a page, click the **Settings** link.  
The Settings page appears.
2. Click **Manage Saved Lists**.  
The Saved Lists page appears.
3. To create a saved list, click **Create Saved List**.  
or  
To edit a saved list, click the row menu () for a saved list, and then click **Edit**.  
The Saved List dialog box appears.
4. In the **Name** field, enter the name for the list.
5. In the **Description** field, enter a description of the list.
6. Assign the saved list to a [project](#).
  - A. To assign the saved list to an existing project, click **Add to existing project** and select a project from the drop-down list of projects associated with objects that you created or that are published to you.
  - B. To create a new project and assign the saved list to it, click **Add to a new project named** and enter a project name.
7. From the **Configuration** drop-down list, select a configuration, or click **Browse** to browse for a configuration.
8. From the **Associated Variable** drop-down list, select a variable to associate with the saved list. The list includes variables that have a Variable Type of Drug, Event, or Generalized Item in the data configuration.
9. Enter values for the saved list.
  - Click **Select Available Values**. A list of terms for the selected variable appears.  
For more information, see [Select values from the list](#).
  - Click **Select ATC Terms** or **Select MedDRA Terms** (if the selected variable has an associated hierarchy). See [Selecting hierarchy terms](#).



- Type in terms (or copy them from elsewhere and paste them in). For example, you can include custom terms that were used in a data mining run.

---

**Note:** Oracle recommends that you select terms instead of typing them to minimize the possibility of spelling and capitalization errors. Separate terms with commas. The application searches for terms that match uppercase and lowercase exactly as typed.

---

When you enter terms, consider the following:

- If a term contains double quotation marks or a comma, the application encloses the term in double quotation marks automatically. For example: "Rash, disseminated."
- If a term contains a double quotation mark or a backslash, you must precede it with a backslash. For example, "Cold\\flu" for Cold\flu or "\"Terrible\" headache" for "Terrible" headache. If you do not precede it with a backslash, the application removes the backslash automatically.

10. To verify that the specified values match values in the source data, check **Validate list when saving**. If any of the terms do not have a matching value in the source data, an error message appears and the unmatched values appear at the end of the list. If you clear **Validate list when saving**, you can use the saved list even if it did not pass validation.

---

**Note:** If you create a saved list by saving values during viewing of data mining results, the list might include custom terms. For the custom terms, no matches are found in the source data. However, matches are found when the saved list is used to select drugs or events to view data mining results that include those custom terms.

---

11. Click **Save**.

The Saved Lists page appears.


The saved list is available when you [select results criteria](#) for a run that is based on the same data configuration or create a query using the variable with which the saved list is associated. To make your list available to other users, [set permissions](#) for it.

## **Adding saved lists in bulk**

On the [Saved Lists page](#), the **Add Lists in Bulk** option enables you to add multiple saved lists at the same time. You can use this feature only if you are a superuser. If you are interested in using this feature, contact Oracle.

## Viewing or printing a saved list

You can view or print the variables and terms included in a saved list. For more information about saved lists, see [About saved lists](#).

1. On the [Saved Lists page](#), select a saved list and click ()
2. To view a saved list, click **View**.

The Saved Lists dialog box opens displaying the variables and terms included in the saved list.


or

To print the terms and other information for the saved list, click **Print** to access the Windows Print window.

3. To return to the [Saved Lists page](#), click **Close**.

## Setting permissions for a saved list

Users with the Read permission can [select a saved list](#) for use during certain activities. Users with the Edit permission can select the saved list, as well as edit, modify permissions for, or delete the saved list on the Saved Lists page.

1. On the [Saved Lists page](#), click  for the selected saved list, and then click **Set Permissions**.

The Saved Lists Permissions dialog box appears. There are two sections. The Group Permissions applies to your login group. The Individual Permissions section includes individual users in your login group. Superusers see all login groups.

The permissions you can select are No Access, Read, or Edit.

2. To grant permissions to a [login group](#), click **No Access**, **Read**, or **Edit**. The selected permission applies to all members of the login group.
3. To grant permissions to individual users in your login group, in the **Individual Permissions** section, click **No Access**, **Read**, or **Edit** next to each username.

User permissions for a saved list are determined by settings for both the individual user and the user's login group. For example, if the individual user has Read access but that user's login group has Edit access, the user has Edit access.

4. Click **Save**.

## Saved List information

A saved list can contain up to 1,000 drugs or event terms. In activities where you need to specify values for a drug, event, or item variable, you can select a saved list instead of selecting values individually.

Your available saved lists are ones you have created, or ones you have been given Read or Edit permission. They must also be [compatible](#) with the data configuration of the object with which you are working.

To select a saved list, click the row for the saved list, and then click **OK**.

The Select Saved List page provides the following information about each saved list. See [Field descriptions—Saved List page](#) for more information.



## Working with drug profiles

### About drug profiles and layouts

A **drug profile** is the presentation of statistical and other information about one or more drugs. A drug profile layout is a saved collection of charts, as well as their placement and display options. A chart can be either of the following:

- A graph based on the results of a data mining run
- A graphical or tabular report based on source data, showing distribution of cases by such variables as gender and age

Charts in a drug profile layout can be for the same or different drugs. For example, a layout might include charts for the drug that you are studying and for comparator drugs.

Drug profile layouts are available on the Drugs tab. If you have appropriate permissions, you can create new drug profile layouts.

To use drug profiles, you must have the View Drug Profiles permission and you must set a drug profile configuration as a user preference. The drug profile configuration determines which data mining runs are the source of charts that can be added to a drug profile layout. For information on setting up the drug profiles feature, see [Setting up drug profiles](#).

## Drugs page

On the Drugs page, you can view a drug profile. Drug profiles are presentations of graphs and reports related to one or more drugs. From this page, you can select a drug, work with layouts, which are saved collections of charts, and view FDA and NIH label information.

### General activities

The following menus appear at the top of the page and affect the entire page:

- Drug
  - [Select](#)
  - Recent
- Layout
  - [Select](#)
  - Create
  - [Add Chart](#)
  - View
    - Reset
    - Stack
    - Tile
    - [Order](#)
    - Slide Show
  - [Save](#)
  - [Save to Topic](#)
  - [Print](#)
  - Recent
- Links
  - FDA Label Information
  - NIH Label Information

If you click the [Manage Layouts](#) link, the Drug Profile Layouts page appears.



## Selecting drugs for a drug profile

Drug names in the title bars of charts end with one of the following suffixes:

- (G) – Generic name
- (T) – Trade name
- (I) – Ingredient

The primary drug is shown in the blue bar of the Drug Profile page. The comparator drugs are the drugs for which other chart windows appear in the current layout.

1. Click the **Drug** tab.

The Drug Profile page appears.

2. From the Drug menu, click **Select**.

The Select Drugs dialog box appears.

There is a **Primary Drug** field and, if the layout includes chart windows for different drugs, there are **Comparator Drug** fields.

3. Optionally, click **Recent** in the **Drug** menu and select from primary drugs for which you viewed charts recently.

---

**Note:** The Drug menu is available only if you are viewing a layout that has been saved at least once.

---

4. From the **Primary Drug** or **Comparator Drug** drop-down lists, select the type of drug (Generic, Trade, or Ingredient) that you want to specify. Any or all of the drug types might be available.

---

**Note:** If you remove the comparator drug, charts for the drug are not displayed although they are still part of the layout, unless you save the layout without them.

---

5. In the drug name field, type a drug name or click **Select** to [select a drug from a list](#).

---

**Note:** The list of available drugs that you can select on the Drug menu is determined by an algorithm described in [Adding or editing a drug profile configuration](#).

---

6. If you want to select the drugs with which the layout was last saved by you or another user, click **Reset**.

7. When you are satisfied with the drug selections, click **OK**.

## Selecting a drug profile layout

1. Select the **Drugs** tab.

The Drug Profile page appears. The last drug profile layout used for your last selected primary drug appears, unless one of the following is true:

- The last drug profile layout you used was deleted.
- A drug profile layout has never been used.
- The Drug Profile page was accessed by clicking a drug name on the [Drug Overviews page](#) on the Signals tab.

In these cases, the layout is determined by your **Drug Profile Layout** user preference.

2. To select a layout, from the **Layout** menu, click **Select**.

The Select Drug Profile Layout dialog box appears.

The Select Drug Profile Layout dialog box provides the following information about each layout:

Column	Description
Name	Name of the layout. Available layouts are those that you created or that are published to you. If you have the Administer Users permission, available layouts are published or unpublished layouts created by any users in your login group.
Description	Description of the layout.
Created By	Name of the user who created the layout.
Created	Date and time when the layout was created.
Modified By	Name of the user who last modified the layout.
Modified	Date and time when the layout was last modified.

3. Click the radio button of the layout.

or

To select from layouts that you viewed recently, click **Layout** and then click **Recent**.

4. Click **OK**.

The drug profile layout appears.

- The primary drug for the layout that you are currently viewing becomes the primary drug for the selected layout. If you modify the layout, an asterisk appears after the layout name in the blue bar at the top of the page.
- If the layout uses only one drug, it appears with the primary drug from the last layout you viewed.
- If the layout uses multiple drugs, you must specify the primary and comparator drugs. By default:
  - The primary drug is from the last layout that you viewed.
  - The comparator drugs are those that you used the last time you viewed that particular layout. If you never viewed the layout before, the comparator drugs are from the original definition of the layout.

## Printing or copying charts (Drugs tab)

### To print a chart:

1. Configure Internet Explorer to print background colors and images. See [Prerequisites and usage notes](#) for more information.
2. With the Internet Explorer Page Setup option, set up the print options, including headers and footers that you want to use for graphs. Note that you can enter "&p" to show the page number and "&P" to show the total number of pages. For example, you can enter "Page &p of &P" as the page footer. A single chart may span multiple pages, so it is recommended that you include page numbers in the header or footer of your printouts.
3. To print a single chart, under the chart, click **Print**.  
  
or  
  
To print all charts in the layout, from the **Layout** menu, click **Print**.  
  
A preview of the printed chart appears in the Drug Profile dialog box and the Internet Explorer Print window appears.
4. Select print options from the **General** tab and **Options** tab.
5. Click **Print**.

### To copy a chart:

1. Display the chart.
2. Under the chart, click **Copy**.
3. Open the document to which you want to add the chart.
4. Paste in the chart using the **Paste** command for that application.

## Linking to an outside URL

By default, the application links to NIH label information and FDA label information for the drug associated with the current chart window. Your organization can [define the Links menu](#) by changing the default links or adding other links.

1. Click the **Drug** tab.  
The Drug Profile page appears.
2. From the **Links** menu, click a URL outside of the application.  
A separate browser window opens and the selected URL appears.

## Managing drug profile layouts

### Managing existing drug profile layouts

The Drug Profile Layouts page lists layouts that you created or that are published to you. If you have the Administer Users permission, the page also lists unpublished layouts created by any users in your login group.

1. Click the **Drugs** tab.


The Drug Profile page appears.

2. Click **Manage Layouts**.

The Drug Profile Layouts page appears and provides the following information about each drug profile layout:

<b>Column</b>	<b>Description</b>
Name	Name of the layout.
Description	Description of the layout.
Created By	Name of the user who created the layout.
Created	Date and time when the layout was created.
Modified By	Name of the user who last modified the layout.
Modified	Date and time when the layout was last modified.

See [About tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

3. If you click the row menu () for a drug profile layout, you can do the following:

- To view or select the layout, click **Select**.

The layout appears on the Drug Profile page.

- To rename a layout that you created, click **Rename**.
- To publish a layout, click **Publish**.
- To delete a layout that you created, click **Delete**.

## Creating a new drug profile layout

1. Click the **Drugs** tab.

The Drug Profile page appears.

2. From the **Layout** menu, click **Create**.

The Drug Profile page is cleared and the blue bar shows the layout name as **Not Saved\***.

---

**Note:** The Create menu is enabled if you have the Create Drug Profile Layouts [permission](#).

---

3. From the **Layout** menu, click **Add Chart**.

---

**Note:** Unless you have the Create Drug Profiles Layouts permission, you will not be able to save the layout with the new chart.

---

The Add Chart dialog box appears.

4. From the **Drug Type** drop-down list, select **Generic**, **Ingredient**, or **Trade**. Any or all of these values might be available, depending on the [drug profile configuration](#) that you are using.

5. In the **Drug Name** field, type a drug name.

or

Click **Select** to [select a drug from a list](#).

The list of available drugs depends on the chart that is currently highlighted in the list of available charts. For a report chart, available drugs are determined by the [data configuration](#) associated with the report output on which the chart is based. For a data mining results graph, available drugs are from the corresponding data mining results.

---

**Note:** The set of drugs included in logistic regression results is typically smaller than the set of drugs in MGPS results. Graphs for logistic regression results will be available only if the selected drug was included in the model or added explicitly during creation of the run.

---

Click **OK**.

For more information, see [Selecting values from a list](#).

6. Select a chart. The chart types that are available depend on the data mining runs and report outputs referenced by the drug profile configuration that you are using. Possible chart types are as follows:

---

**Data Source**

**Chart Types**

---

	<a href="#">Sector map graph</a>
	<a href="#">EBGM graph</a>
	<a href="#">EBGM confidence interval</a>
MGPS 2D Run	<a href="#">ROR graph</a>
	<a href="#">ROR confidence interval graph</a>
	<a href="#">PRR graph</a>
MGPS 3D Run	<a href="#">Nested confidence interval graph</a>
MGPS 2D by Year Run	<a href="#">Cumulative map graph</a>
	<a href="#">LROR graph</a>
LR 2D Run	<a href="#">LROR confidence interval graph</a>
Reports	<a href="#">Distribution by &lt;variable-name&gt;</a> , where <variable-name> may be gender, outcome, and so on.

7. Click **OK**.  

The chart appears. If the selected drug is not in the run results or report output that is the source for the selected chart, the chart cannot be displayed.

In some cases, a chart window appears but displays a message that the chart cannot be displayed with your current display options. If you click **Options** below the chart and modify the display options, you might be able to display the chart.
8. To select multiple charts, repeats steps 6 and 7.
9. To order the selected charts, from the **Layout** menu, click **View**.
10. Select a view option:
  - **Stack**—Stagger the charts. Part of each chart window is visible so you can click to bring that chart window forward.
  - **Tile**—Show all chart windows without any overlap.
  - **Order**—Order charts in the layout. The order affects only printing and the slide show mode.
  - **Slide Show**—View each chart on its own page.
11. In Slide Show mode, use the following keys:

Key	Description
-----	-------------



Esc	Exit slide show mode and return to the Drug Profile page.
Home	Go to the first chart in the layout.
Up arrow, Page Up, or left arrow	Go to the previous chart in the layout.
Down arrow, Page Down, or right arrow	Go to the next chart in the layout.
End	Go to the last chart in the layout
Ctrl (or Shift) + Home	Go to the top of the current chart.
Ctrl (or Shift) + Up arrow, Page Up, or left arrow	Scroll up in the current chart.
Ctrl (or Shift) + Down arrow, Page Down, or right arrow	Scroll down in the current chart.
Ctrl (or Shift) + End	Go to the bottom of the current chart.

For additional chart ordering options, see [Ordering charts in a drug profile layout](#).

12. To save the updated layout, from the **Layout** menu, click **Save**.

or

To add the currently displayed charts as a single PDF attachment to a topic, click **Save to Topic**. The notes of each chart are included, even if not currently displayed.

## Saving a drug profile layout

When a drug profile layout has been modified but not yet saved, an asterisk appears after the layout name in the blue bar at the top of the Drug Profile page. If the layout has never been saved, the layout name shows as "Not Saved\*".

1. From the **Layout** menu, click **Save**. (This option is available if you have the Create Drug Profile Layouts permission.)

If you have modified a layout and you try to navigate away without saving it, the application prompts you to save the layout. Click **OK**.

The Save Layout As dialog box appears.

2. If you have modified a layout that you created (or if you have the Administer Users permission and you have modified a layout that someone in your login group created), you can check Replace existing. If you check this option, you cannot modify the layout name or description. If you want to rename a layout, use the Rename option on the [Drug Profile Layouts page](#).
3. In the Layout name field, type a name for the layout. Keep in mind that the layout is not associated with a particular [drug profile configuration](#). You might want to avoid identifying a data source in the layout name or description.
4. Optionally, enter a description of the layout to differentiate this layout from other layouts.
5. Click **OK**.

When the application saves a layout, currently displayed chart windows are saved as part of the layout. Even if a chart window shows a message that the chart cannot be displayed with the current options, the chart window is saved. Additionally, the drugs associated with the saved charts are saved as the primary drug and comparator drugs (if any).

---

**Note:** Only displayed chart windows are saved as part of a layout. For example, an existing layout includes a sector map for DrugA. You change the drug profile configuration to point to different run results that do not include DrugA. When you view the layout, a message tells you that the drug is not in the run results. No chart window appears. If you save the layout again, the DrugA sector map will not be part of the layout.

---

## Adding a chart to a drug profile layout

1. Click the **Drug** tab.  
The Drug Profile page appears.
2. Select a drug profile layout.
  - A. From the **Layout** menu, click **Select**.
  - B. From the **Select Drug Profile Layout** dialog box, click the radio button of the layout and click **OK**.

or

  - A. From the **Layout** menu, click **Recent**.
  - B. From the list of recent layouts, click a layout.

The drug profile layout appears.

3. From the **Layout** menu, click **Add Chart**.

---

**Note:** Unless you have the Create Drug Profiles Layouts permission, you will not be able to save the layout with the new chart.

---

The Add Chart dialog box appears.

4. From the **Drug Type** drop-down list, select **Generic**, **Ingredient**, or **Trade**. Any or all of these values might be available, depending on the [drug profile configuration](#) that you are using.
5. In the **Drug Name** field, type a drug name.

or

Click **Select** to [select a drug from a list](#).

The list of available drugs depends on the chart that is currently highlighted in the list of available charts. For a report chart, available drugs are determined by the [data configuration](#) associated with the report output on which the chart is based. For a data mining results graph, available drugs are from the corresponding data mining results.

---

**Note:** The set of drugs included in logistic regression results is typically smaller than the set of drugs in MGPS results. Graphs for logistic regression results will be available only if the selected drug was included in the model or added explicitly during creation of the run.

---

Click **OK**.

For more information, see [Selecting values from a list](#).

- Select a chart. The chart types that are available depend on the data mining runs and report outputs referenced by the drug profile configuration that you are using. Possible chart types are as follows:

Data Source	Chart Types
MGPS 2D Run	<a href="#">Sector map graph</a>
	<a href="#">EBGM graph</a>
	<a href="#">EBGM confidence interval</a>
	<a href="#">ROR graph</a>
	<a href="#">ROR confidence interval graph</a>
MGPS 3D Run	<a href="#">Nested confidence interval graph</a>
MGPS 2D by Year Run	<a href="#">Cumulative map graph</a>
LR 2D Run	<a href="#">LROR graph</a>
	<a href="#">LROR confidence interval graph</a>
Reports	<a href="#">Distribution by &lt;variable-name&gt;</a> , where <variable-name> may be gender, outcome, and so on.

- Click **OK**.  
The chart appears. If the selected drug is not in the run results or report output that is the source for the selected chart, the chart cannot be displayed.  
In some cases, a chart window appears but displays a message that the chart cannot be displayed with your current display options. If you click **Options** below the chart and modify the display options, you might be able to display the chart.
- To select multiple charts, repeats steps 6 and 7.
- When you have finished adding charts, from the **Layout** menu, click **Save**.  
If you have modified a layout, the Save Layout As dialog box appears. Enter the information and click **OK**. For more information, see [Saving a drug profile layout](#).





## Ordering charts in a drug profile layout

You can specify the order in which you want to print charts or display them in slide show mode. The order does not affect the displayed layout.

1. From the **Layout** menu, click **View**, and then click **Order**.


The Order Charts dialog box appears.

2. Use the arrow buttons to specify the order in which charts are displayed in slide show mode or printed:

Arrow	Description
	Move the chart to become the first one.
	Move the chart to before the previous chart.
	Move the chart to after the next chart.
	Move the chart to become the last one.

3. To remove a chart from the layout, select it and click **Remove**.
4. To find a particular chart in the layout, select the chart name and click **Find**.
5. When you are finished reordering charts, click **OK**.

## Renaming a drug profile layout

1. Click the **Drugs** tab.  
The Drug Profile page appears.
2. Click **Manage Layouts**.
3. Click the row menu () for the layout, and then click **Rename**.
4. In the **Name** field, type a name for the layout. Keep in mind that the layout is not associated with a particular drug profile configuration. You may want to avoid identifying a data source in the layout name or description.
5. Optionally, in the **Description** field, type a description of the layout to differentiate layouts.
6. Click **OK**.

## Chart types and options

### Working with chart options

Click an option at the bottom of a chart to perform the following actions:

- To redraw the chart as a table, bar graph, or pie chart, click **Options**. From the Chart Options dialog box, select the chart type and click **OK**.
- To display the notes about the chart below the chart, click **+Notes**. To hide the notes, click **-Notes**.
- To display a key below the chart, click **+Key**. To hide the key, click **-Key**.
- [To print a chart](#), click **Print**. A preview of the printed chart appears in the Drug Profile dialog box and the Internet Explorer Print dialog box opens for you to select print options and click **Print**.

---

**Note:** If you want to print all charts in the layout, from the Layout menu, click **Print**.

- [To copy a chart](#), click **Copy**. Open the document to which you want to add the chart and use that application's **Paste** function.
- To determine the default color used for graphs, set the user preferences, **Graph Color Palette**. You can [modify the graph](#) key for your current session on the Choose Graph page for data mining run results.
- To resize the chart, click the diagonal lines in the lower right corner and drag the right and bottom borders to the desired size.

## Sector map graph (Drugs tab)

A sector map is a visual presentation of data for a selected drug across all System Organ Classes (SOCs). Each System Organ Class (SOC) is represented by a large tile in the sector map. Smaller tiles within each SOC tile represent Preferred Terms (PTs).

PTs are ranked in descending order of values of the statistic (EBGM, EB05, Chi-statistic, or PRR) that you choose. A color key indicates relative ranking. You can also list the ranked PTs below the sector map. (You must include the key in the graph to display both the color key and the list of ranked PTs.)

---

**Note:** The primary path of a PT determines where it appears in the sector map. If a PT is not in the event hierarchy associated with the data mining run results, it appears in a SOC tile named Unknown.

---

The list of ranked PTs below the sector map includes the following information:

Column	Description
Rank	Ranking of the term (combined with the drug) according to values of the statistic you have configured the sector map to use (via the Color controlled by option).
SOC	SOC containing the term.
Term (PT)	Specific PT.
EBGM, EB05, Chi-statistic, or PRR	Value of the statistic you have configured the sector map to use (via the Color controlled by option).

- To set options for the graph, click **Options**. Specify the following options and click **OK**. The options apply to the specific chart, and are saved as part of the layout.

Option	Description
Color controlled by	Name of the statistic whose values will be ranked and used for coloring the sector map tiles. Available values are those computed by the data mining run and may include EBGM, EB05, Chi-statistic (signed), and PRR.
Term box size controlled by	<p>One of the following options indicating what controls the size of PT tiles:</p> <ul style="list-style-type: none"> <li><b>Relative importance of term</b>—Bases the size of PT tiles on an algorithm that determines the relative public health impact of PTs. Using a recent version of AERS data, the public health impact for a PT is computed as: (number of times the PT occurs in serious cases) * (proportion of cases with that PT that are serious or fatal). A higher Public Health Impact score corresponds</li> </ul>



to a larger tile in the sector map. Because size is based on the number of cases of the PT alone (not the number of cases that have the PT and a particular drug), the tile size is stable over sector maps for different drugs.

- **All terms have equal size**—All PT tiles have the same size.

---

**Note:** For PTs that are new in the MedDRA version associated with the AERS data used to assess public health impact, the tile size cannot be determined. Such PTs are represented as small tiles.

---

Display maximum intensity at signal score of	All tiles for which scores are above this value are displayed at the maximum-intensity color as shown in the color key below the graph.
Use gray-scale instead of colors	Use shades of gray instead of colors in the graph.
Show low scores in green for color graph	Check to show low scores in varying shades of green. Clear to show low signal scores in black.  <b>Note:</b> This setting has no effect if you display the sector map in gray-scale.
Omit rare terms used fewer than __ times in AERS	Number indicating how many times a PT must be in the AERS database (the same one used for Relative importance of term) for that PT to be shown in the sector map.  <b>Note:</b> The notes for a sector map indicate any rare terms that are omitted because of this restriction.
Group by HLT	Within a SOC tile, group in the same rectangular area the tiles for PTs that are in the same HLT. If you also group by HLGT, the tiles for PTs are grouped by HLT within each HLGT.
Group by HLGT	Within a SOC tile, group in the same rectangular area the tiles for PTs that are in the same HLGT.
List __ top scores	Number indicating how many (up to 1000) terms with the top scores are ranked and listed below the sector map. The score is the statistic selected for Color controlled by.  If multiple terms have the same score, each term is counted separately. For example, suppose that you enter 20 as the limit. If the 20th row has a score that other terms after that also have, those additional terms are shown as well.  The list below the sector map appears when you display the key.
Show top score indexes	If checked, tiles in the sector map are numbered to show their rank, up to the number of scores specified in List __ top

scores. For this option to take effect, there must be a value specified for List \_\_\_ top scores".

---

2. If you point to a PT tile, the MedDRA PT, HLT, HLGT, and SOC appears. The following information for the combination of the drug and the term that the tile represents also appears:
  - **N**—Observed number of cases with drug-event combination.
  - **EBGM**—Empirical Bayesian Geometric Mean. A more stable estimate than RR; the so-called shrinkage estimate.
  - **EB05**—A value such that there is approximately a 5% probability that the true Relative Ratio lies below it.
  - **PRR**—Proportional Reporting Ratio. The PRR and Chi-statistic are available only if the data mining run was set up to compute PRR.
  - **Chi-statistic**—Chi-statistic associated with PRR. (If EBGM < 1, the Chi-statistic is expressed as a negative number, indicating that the drug-event combination is more rare than expected). The Chi-statistic is the signed square root of Chi-square.

For information about these statistics, see [MGPS computations](#) or [PRR computations](#).

3. To [zoom in](#) on a particular SOC, click anywhere on the SOC tile and select **Zoom** from the menu that appears.
4. If you click a tile for which N is at least 1, you can then [drill down](#) to a list of cases for the tile or [view statistics](#) for the tile.

## Bar graph (Drugs tab)

Bar graphs provide a straightforward way to display the items most closely associated with a selected drug, showing the strength of association by plotting each computed statistical score as the length of a horizontal bar.

For information about statistics in the graph, see [MGPS computations](#), [ROR computations](#), [PRR computations](#), or [Logistic regression computations](#).

- To set options for the graph, click **Options**. Specify the following options and click **OK**. The options apply to the specific chart, and are saved as part of the layout.

Option	Description
N at least	Display only combinations with an observed count (N) of at least the specified number.
At most _____ associations	Display no more than the specified number of combinations. You can display up to 200 combinations. If combinations are excluded because of this limit, a message appears below the graph.
<score> at least	Display only combinations with a score (EBGM, LROR, PRR, or ROR) of at least the specified number.
<score> at least	Display only combinations with a lower confidence limit (EB05, LR05, ROR05) of at least the specified number.
Bar length controlled by	Indicate whether you want bars to show in descending order by: <ul style="list-style-type: none"> <li>N (observed count).</li> <li>The score (EBGM, LROR, PRR, or ROR).</li> <li>The lower confidence interval score (EB05, LR05, ROR05).</li> </ul>
Bar color controlled by	Indicate whether bar color should be controlled by: <ul style="list-style-type: none"> <li>EBGM, LROR, PRR, or ROR, as defined by the graph key.</li> <li>EB05, LR05, ROR05, as defined by the graph key.</li> <li>A single color for all graph bars.</li> </ul>
Order by bar length	Show the bars of the graph in descending order based on bar length.
Order by item	Show the bars of the graph in alphabetical order.

- You can point to a bar of the graph to display statistics for the combination represented by the bar.
- If you click on a bar, you can then [drill down](#) to a list of cases for the bar.

## Confidence interval graph (Drugs tab)

Confidence interval graphs are similar to bar graphs but also include a confidence interval or error bar superimposed on each bar to show the 5% and 95% confidence limits.

For information about statistics in the graph, see [MGPS computations](#), [ROR computations](#), [PRR computations](#), or [Logistic regression computations](#).

- To set options for the graph, click **Options**. Specify the following options and click **OK**. The options apply to the specific chart, and are saved as part of the layout.

Option	Description
N at least	Display only combinations with an observed count (N) of at least the specified number.
At most _____ associations	Display no more than the specified number of combinations. You can display up to 200 combinations. If combinations are excluded because of this limit, a message appears below the graph.
<score> at least	Display only combinations with a score (EBGM, LROR, or ROR) of at least the specified number.
<score> at least	Display only combinations with a lower confidence limit (EB05, LR05, ROR05) of at least the specified number.
Bar color controlled by	Indicate whether bar color should be controlled by: <ul style="list-style-type: none"> <li>• EBGM, LROR, or ROR, as defined by the graph key.</li> <li>• EB05, LR05, ROR05, as defined by the graph key.</li> <li>• A different color for each bar in the graph.</li> <li>• A single color for all graph bars.</li> </ul>
Order by bar length	Show the bars of the graph in descending order based on bar length.
Order by item	Show the bars of the graph in ascending alphabetical order.
Show N at end of confidence interval	Display the value of N at the end of each confidence interval bar.

- You can point to a bar of the graph to display statistics for the combination represented by the bar.
- If you click on a bar, you can then [drill down](#) to a list of cases for the bar.

## Nested confidence interval graph (Drugs tab)

To help you investigate possible drug interactions, the nested confidence interval graph displays sets of confidence intervals. In each set, the first confidence interval is for the three-way combination of drug, drug, and event, and subsequent confidence intervals are for the two-way combinations. In each confidence interval bar, the EB05 value is at the left end, the EBG value is the dot on the bar, and the EB95 value is at the right end. A confidence interval bar is highlighted if its INTSS value is greater than the limit that you specify as a display option. For more information about INTSS, see [interaction scores](#).

To conserve space in labeling, the drug indicated in the title bar of the graph window is referred to by the label "Drug" in the graph.

The key below the graph indicates INTSS values represented by the confidence interval bars.

- To set options for the graph, click Options. Specify the following options and click OK. The options apply to the specific chart, and are saved as part of the layout.

Option	Description
N at least	Display only those drug-drug-event combinations with an observed count (N) of at least the specified number.
At most _____ combinations	Display no more than the specified number of drug-drug-event combinations. You can display graphs for up to 200 combinations. If combinations are excluded because of this limit, a message appears below the graph.
Order by	The value of the score that you select here for the drug-drug-event combinations is used to sort the graphs. For example, if you select INTSS, the graph with the highest INTSS value for the drug-drug-event combination appears first.
Axis Type	Select either Linear or Log (logarithmic). When you use a logarithmic axis, the confidence intervals for the two-way combinations may appear more clearly.
Highlight confidence intervals where INTSS >	Enter the INTSS value above which confidence interval bars will be highlighted.
Show N at end of confidence interval	Display the value of N at the end of each bar.
Use gray-scale instead of colors	Use shades of gray instead of colors in the graph.

2. You can point to a line in the graph to display statistics for the combination represented by the line. Long drug or event terms may end in an ellipsis in the label on the graph itself; in this case, you can point to the line to see the full terms.
3. If you click on a line of the graph, you can then [drill down](#) to a list of cases for the line.

## Cumulative map graph (Drugs tab)

Cumulative map graphs provide a way to compare strength of associations between a selected drug and events across multiple subsets, which are typically based on a continuous variable such as year. See [Using a subset variable](#) for more information.

The map graph on the Drugs tab shows data for all subsets included in the data mining run.

For information about statistics in the graph, see [MGPS computations](#).

1. To set options for the graph, click **Options**.
2. Specify the following options and click **OK**. The options apply to the specific chart, and are saved as part of the layout.

Option	Description
N at least	Display only combinations with an observed count (N) of at least the specified number.
EBGM at least	Display only combinations with an EBGM score of at least the specified number.
EB05 at least	Display only combinations with an EB05 value of at least the specified number.
At most _____ associations	Display no more than the specified number of combinations. You can display up to 200 combinations. If combinations are excluded because of this limit, a message appears below the graph.
Show value of	In each cell of the grid, display the numeric value of N (observed), EBGM, or EB05. You can also select Leave blank to display a grid without labels. Cells with no occurrences are empty.
Color by	Indicate whether the cell color should be controlled by: <ul style="list-style-type: none"> <li>• EBGM, according to the graph cutpoints and palette.</li> <li>• EB05, according to the graph cutpoints and palette.</li> <li>• No color.</li> </ul>
Order by first occurrence of	Indicates how to order drug-event combinations in the graph, based on descending order of N, EBGM, or EB05 values. This ordering is applied to combinations for the first subset. If the maximum number of combinations is not reached, the ordering is applied to combinations for the second subset, and so on until the maximum number of combinations is reached. (The maximum number of combinations is determined by the At most ___ associations option.)  For example, suppose that the graph shows values of EBGM and has at most six combinations. You order by the first occurrence of EBGM > 2. Combinations are ordered in descending order of EBGM as follows:

Combination	Subset1	Subset2	Subset3
DrugA-EventB	EBGM=3.1	EBGM=1.1	
DrugA-EventD	EBGM=2.7		EBGM=2.4
DrugA-EventA	EBGM=2.0	EBGM=3.8	EBGM=1.4
DrugA-EventC	EBGM=1.5	EBGM=2.6	EBMG=2.8
DrugA-EventE	EBGM=0.5	EBGM=2.5	EBGM=0.8
DrugA-EventF		EBGM=1.1	EBGM=2.1

3. You can point to a cell of the graph to display statistics for the combination represented by the cell. Long drug or event terms may end in an ellipsis in the label on the graph itself. In these cases, you can point to the cell to see the full terms.
4. If you click on a cell of the graph, you can then [drill down](#) to a list of cases for the cell.



## Reports (Drugs tab)

The reports that you can add as charts to a drug profile are based on report output generated by an [all cases summary report](#). If the report output uses a breakdown variable such as gender, you can add a report chart showing distribution by that variable.

N represents a count of unique cases with at least one occurrence of the row value. Percentages are computed as N divided by the total of N for all rows in the report chart. The percentage values are meaningful only for demographic data, such as gender, where there is one row value per case, so the total of N is the total of unique cases. In this context, the percentage is for the number of cases with the row value out of the total number of cases.

If there are multiple row values (for example, outcomes) per case, the total of N for all rows is the number of non-unique cases. Thus, percentage values are the number of cases with the row value out of the number of non-unique cases with any of the row values. This is not likely to be a meaningful statistic.

1. To set options for the report chart, click **Options**.
2. Specify whether you want to view the report chart as a table, a bar graph, or a pie chart, and then click **OK**.
3. For a table or bar graph, you can click on a cell or bar and [drill down](#) to a list of cases.

## Examples

In the following report chart, each case can be counted for only one row. The total of N represents the unique number of cases, which is 4352. The percentage of unique cases for gender F is 918/4352, which is 21.09.

Gender	N	%
F	<a href="#">918</a>	21.09
M	<a href="#">3227</a>	74.15
U	<a href="#">207</a>	4.76
NULL	0	0.0

Options +Notes Print Copy

In the following report chart, each case can be counted for multiple rows. The total of N (4776) for all rows is more than the unique number of cases (4532). Thus, the % is not based on a count of unique cases.

Outcome	N	%
Congenital Anomaly	<a href="#">37</a>	0.77
Died	<a href="#">394</a>	8.25
Disabled	<a href="#">285</a>	5.97
Hospitalized	<a href="#">2278</a>	47.7
Life-threatening	<a href="#">366</a>	7.66
None	0	0.0
Other	<a href="#">1034</a>	21.65
Recovered	0	0.0
Required Intervention to Prevent Permanent Damage	<a href="#">382</a>	8.0
Treated with Rx Drug	0	0.0
NULL	0	0.0

Options +Notes Print Copy

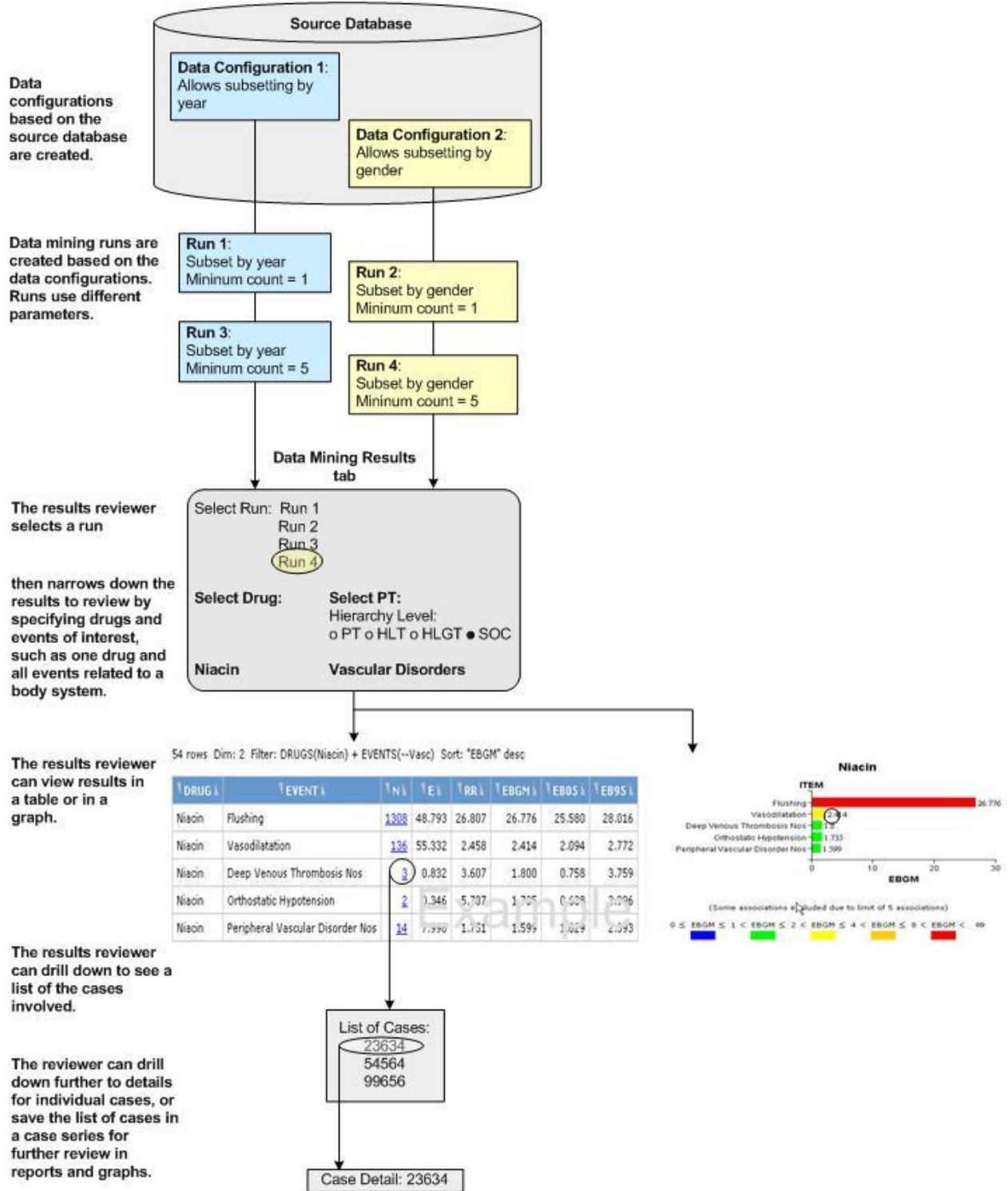
## Creating data mining runs

### About data mining runs

A data mining run is a three-step process: 1) extraction of data from source data; 2) application of statistical algorithms to the extracted data; and 3) generation of statistical values. When these statistical values, or scores, exceed a predetermined threshold, they alert reviewers to a potential safety signal. The two types of data mining runs are [MGPS runs](#) and [logistic regression runs](#).

Data mining runs are batch jobs that the Empirica Signal application submits to a queue for processing. Depending on the number of processors on the Empirica Signal server, it is possible for several data mining runs to run at the same time. The run submitter can request that the run be performed immediately, when a processor is available, or at a scheduled date and time. When a user submits a data mining run, the run appears on the Data Mining Runs tab and can be published to other users, even if it has not started running. A user can also cancel, delete, or rerun a data mining run. The data mining runs that appear on the Data Mining Runs tab and the tasks that you can perform for specific runs depend on your [user permissions](#) and the publication level of runs.

To create a data mining run, you must [select a data configuration](#) that determines the source data on which the run is based. You can base multiple runs on the same configuration. You then specify the type of run and other run parameters. When the run is complete, the application displays the results in tabular or graphical format. When reviewing the results, users with appropriate permissions can [drill down](#) on counts to view case details.



## Viewing existing data mining runs

The Data Mining Runs page provides information about existing [data mining runs](#) and enables you to define new runs if you have the required permission.

For the selected project and data configuration, the [Data Mining Runs page](#) lists runs that you created or that are published to you. If you have the Administer Users permission, the page also lists unpublished runs created by any users in your login group.

1. Click the **Data Mining Runs** tab.  
The Data Mining Runs page appears.
2. From the **Project** drop-down list, select a specific project, or select -- to include all projects.
3. From the **Configuration** drop-down list, select a [data configuration](#), or select -- to include all configurations.


The selected data mining runs appear. See the [Data Mining Runs page](#) for information about each run.

## Data mining run options

- To [create a new data mining run](#), click **Create Run**.
- To print, download, delete, or [publish](#) multiple runs, click **Select Rows**. You can then check the rows for the runs on which you want to act. You can also click **Select All** to check all rows (or **Clear All** to uncheck all rows). Then click the action that you want to perform on the selected rows.
- If you want to delete a run that is currently running or has not yet started running, you must cancel the run before deleting it. When you delete a run, any case series associated with the run are retained, but they no longer have an associated run.
- To [create a run definition file](#) that you can use to execute the MGPS or logistic regression data mining run from outside of the application, click **Create Definition File**. This option is available to superusers only. For more information about executing data mining runs externally, contact Oracle.
  - To [view the jobs for a run](#) or research why an error occurred, click **View Jobs for Run**.
  - To [view details about a run](#), click **View Run Details**.
  - To [publish a run](#) that you have created, click **Publish**. If you have the Administer Users permission, you can publish a run created by any user in your login group.
  - You can publish a run as soon as the run is submitted. It does not need to be complete for you to publish it. However, you might want to review the run results before making them available to other users.

See [About tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

## Row menu options

Click the row menu () for a run, to perform the following actions:

- To [view results](#) of a completed run, click **View Results**.
- To [rename a run](#) or change its project assignment, click **Rename**.

---

**Note:** When you rename a run that is the target of an [alias](#), the name of the alias target is updated.

---

- To [delete a run](#) that has completed or has been cancelled, click **Delete**. If you have the Administer Users permission, you can delete a run created by any user in your login group.

---

**Note:** When you delete a run that is associated with an alias, the target status of the alias becomes Broken.

---

- To [cancel a run](#) that is pending or in progress, click **Cancel**. If you have the Administer Users permission, you can cancel a run created by any user in your login group.
- To [re-run](#) a data mining run with the same or new parameters, click **Re-run**.

---

**Note:** Empirica Signal version 7.1 included significant enhancements to logistic regression computations. As a result, logistic regression runs created prior to the installation of 7.1 cannot be re-run.

---

## Data Mining Runs page

On the Data Mining Runs page, you can view information about existing [data mining runs](#) and define new runs if you have the required permission.

### General activities

The following links and filters appear at the top of the page and affect the entire page:

- [Create Run](#)
- [Columns](#)
- [Print](#)
- [Download](#)
- [Select Rows](#)
- [Project drop-down list](#)
- [Configuration drop-down list](#)

The following links appear at the top of the page when the page is in the Select Rows mode. The links affect the multiple data mining runs:

- [Print](#)
- [Download](#)
- [Delete](#)
- [Publish](#)
- Select All
- Clear All
- Back


### Row-specific activities

The following menu options are available from the Row menu, located in the left-most column of the table, and affect an individual row in the table:

- [Rename](#)
- Cancel (Available prior to completion)
- [Delete](#) (Available for completed runs)
- [Re-run](#)
- [Create Definition File](#) (Available only if superuser)
- [View Jobs for Run](#)
- [View Run Details](#)
- [Publish](#)

### Field descriptions—Data Mining Runs page

The Data Mining Runs page provides the following information about each run:

<b>Field</b>	<b>Description</b>
Name	Name of the run, as defined when the run was created or renamed.
Description	Description of the run, as entered when the run was created or renamed.
Project	Name of the project to which the data mining run is assigned.
Configuration	Name of the data configuration on which this data mining run is based.
Created By	Name of the user who created the run.
Status	<p>This column is empty until all component jobs of the run are complete. If all of the jobs complete successfully, the run is complete and the status in this column is Completed.</p> <p>If any job for the run fails, the run has failed and the status in this column is Error Occurred. To learn more about the error, click  for that run and select <b>View Jobs for Run</b> to review the error message on the <a href="#">Jobs for Run page</a>.</p> <p>If the run was cancelled, the status in this column is Cancelled.</p>
Archived	The Archived flag was set to yes (by a user with appropriate permissions) to indicate that the run data was <a href="#">exported</a> for the purpose of archiving it.
Created	Date and time when the run was created.
Data As Of	Applies to <a href="#">timestamped data</a> . The run uses data as of this date and time.
End Date	Date and time when the run ended. This column is empty until all of the run's component jobs are complete.
ID	Identifier assigned automatically to the run when the run was submitted. Each run ID is unique and is not re-used if the run is deleted.
Run Type	The type of run: MGPS or LR (Logistic Regression).
Size	<p>Size of the complete results table.</p> <p><b>Note:</b> When downloaded, the Size value appears in bytes. For example, 302.5M downloads as 317194240 (302.5 x 1024 x 1024).</p>
Start Date	<p>Date and time when the run started. For a scheduled run, the start date may be substantially later than the submission date of the run.</p> <p><b>Note:</b> If a run that you submitted does not start when expected, Empirica Signal may be processing other runs. Not all runs may be</p>



visible to you.

---

## Creating a data mining run

To create a data mining run, you start by selecting the type of run and the data configuration to use. After these selections, you specify a series of parameters that tell the application how to restrict or combine data, and which types of statistics to compute. You then submit the run and it is executed in batch mode. When the run is complete, you can view the results in tabular or graphical format.

---

**Note:** If you have exceeded the disk space quota for your username, an error message appears when you attempt to create a run. To proceed, delete one or more of your existing runs or contact your system administrator to increase your quota.

---

1. Click the **Data Mining Runs** tab.  
The Data Mining Runs page appears.
2. Click **Create Run**.  
The Create Data Mining Run page appears.
3. Select the type of run to create:  
MGPS data mining run  
Logistic regression data mining run
4. For a logistic regression run, you also select the type of logistic regression computation to perform: Extended uses the best alpha computational model, Standard uses 0.5 as the alpha value for every response. For more information, see [Logistic regression computations](#).

---

**Note:** Once you have selected a run type and continued to the next page, you cannot change the run type.

---

5. [Select a data configuration](#). The configuration references source data and determines which variables you can select for use in the run. Click **Browse** to select from a descriptive list of data configurations.

---

**Note:** For a logistic regression data mining run, Oracle recommends a data configuration that includes concomitant drugs, such as an AERS S+C configuration. For more information, see [Logistic regression computations](#).

---

6. To limit the run to cases that meet specified criteria only, check **Define database restriction**.
7. Click **Next**.

The page that displays next depends on the selections you have made so far:

If you selected a data configuration that supports [timestamped data](#), the Select As Of Date page appears so that you can [specify the As Of date](#).

If you checked Define Database Restriction, the [Define Database Restriction page](#) appears.

For an MGPS run, the [Select Variables page](#) appears.

For a logistic regression run, the [Select Variables page](#) appears.

## Defining a database restriction

A database restriction is a means of limiting which cases in the source data are included in a data mining run (MGPS or logistic regression) by specifying or selecting a query. Data mining statistics are based only on cases that meet the criteria of the query. For example, you can limit a data mining run to only cases that have been reported by health professionals. A data mining run can have only one database restriction.

A database restriction limits cases, not records. For example, if you base a database restriction on a query that finds a particular drug, the application includes each case involving the drug in the run. Because there may be multiple drugs per case; however, the application includes drugs other than the particular drug in the run.

When defining a database restriction, you can create a new [query](#) or use an existing query. When defining a new query, you have the option to save it to the Query Library. You can then use it to define database restrictions for other data mining runs.

When you re-run a run, the application applies the same database restriction. You cannot switch run types. Thus, if you plan to use a particular database restriction for different run types, make sure that you save the query you define for the database restriction for the first run you set up. Then you can select that query as the database restriction for the other run type(s).

1. Click the **Data Mining Runs** tab.  
The Data Mining Runs page appears.
2. Click **Create Run**.  
The Create Data Mining Run page appears.
3. Select the [type of run to create](#):  
MGPS data mining run  
Logistic regression data mining run
4. Select a [data configuration](#).
5. Check **Define database restriction**.
6. Click **Next**.  
The Define Database Restriction page appears.

To create a database restriction by defining a new query, click **Create Using Query Wizard**. The [Define Query page](#) appears. You can save the new query to the Query Library so that you can re-use it for other runs. For more information, see [Defining a query](#).

or

To create a database restriction based on an existing query, click **Create from Existing Query**. The [Select Query from Library page](#) appears. Subsequent changes

to the query in the library will not affect the database restriction. For more information, see [Selecting a query](#).

The screen refreshes and displays the query you created or selected in the Query field. If you click **Edit Query**, the Define Query page appears and you can change query variables, values, and logic.

---

**Note:** If you saved the query to the library and then you edit it from this page, your changes are not saved to the library.

---

## About custom terms

A custom term is a pseudo-value specified in a data mining run for inclusion in cases that meet specified criteria. When you perform data mining, the Empirica Signal application acts as if the custom term is present for those cases and generates statistics for the custom term. Custom terms are defined and used within the context of data mining runs, and do not affect the source data.

You can define multiple custom terms in a data mining run. The application adds the suffix, (Custom Term), to the term that you specify.

A typical use of custom terms is to group together similar terms for drugs or events as a way to prevent the signal dilution that may occur when similar, but not the same, terms are used in reporting. For example, you can create the custom term Hepatic Terms to group the following PTs: Coma hepatic, Hepatic encephalopathy, Hepatic failure, Hepatorenal failure, and Hepatorenal syndrome. The data mining run then computes statistics for Hepatic Terms as if it is a PT in the source data, although the custom term is not added to the source data. The data mining run also computes statistics for the constituent PTs.

When estimating the shrinkage parameters for EBGm scores, MGPS does not consider custom terms. The raw RR scores for combinations involving custom terms are shrunk by the Bayesian formula, but they do not participate in the determination of the formula itself. For more information, see [MGPS computations](#).

---

**Note:** For another way of mapping values to a term for use in a data mining run, See [Mapping text values](#). For information on the differences between these features, see [Comparing custom terms and mapped text values](#).

---

Custom terms are defined using queries. Reports that match the query condition are considered to have the pseudo value. When defining a new query, you have the option to save it to the Query Library. You can then use it to define custom terms for other data mining runs.

When you re-run a run, the same custom terms are used in the run. However, you cannot switch run types. Thus, if you plan to use a custom term for different run types, make sure that you save the query you define for the custom term for the first run you set up; then you can select that query as the custom term for the other run type(s).

## Defining custom terms

When you define a custom term, you create a new [query](#) or use an existing query to determine which cases meet the criteria for the term. When defining a new query, you have the option to save it to the Query Library. You can then use it to define custom terms for other data mining runs.

When you re-run a run, the application uses the same custom terms in the run. However, you cannot switch run types. Thus, if you plan to use a custom term for different run types, make sure that you save the query you define for the custom term for the first run you set up. Then you can select that query as the custom term for the other run type(s).

1. Click the **Data Mining Runs** tab.  
The Data Mining Runs page appears.
2. Click **Create Run**.  
The Create Data Mining Run page appears.
3. Select the [type of run to create](#):
  - MGPS data mining run
  - Logistic regression data mining run
4. Select a [data configuration](#).
5. Click **Next**.  
The Select Variables page appears.
6. Select your variables and check **Define custom terms**. For information about variable selection, see [Selecting variables for an MGPS run](#) or [Selecting variables for a logistic regression](#).
7. Click **Next**.  
The Define Custom Terms page appears.
8. Click **Create Custom Term**.  
The Create Custom Term page appears.
9. In the **Name** field, enter the name of the custom term.  
If a custom term name includes an invalid character, the application changes it automatically, and a message appears to inform you of the change. Invalid characters are replaced with a pound sign (#). Invalid characters for this field are:
  - Invalid filename characters: \, /, <, :, >, |, ?, \*, ", &, and null
  - Control characters
  - Non-ASCII characters

10. In the **Item Variable** field, select the variable to which the custom term will be assigned. Available variables are those that you selected as item variables for the MGPS data mining run, or as the Event or Drug variable in a logistic regression data mining run. A variable is not available if it is mapped via a [data transformation](#) or is associated in the data configuration with a hierarchy table (rather than a hierarchy account).

11. To create a custom term by defining a new query, click **Create Using Query Wizard**. The [Define Query page](#) appears. You can save the new query to the Query Library so that you can re-use it for other runs. For more information, see [Defining a query](#).

or

To create a custom term based on an existing query, click **Create from Existing Query**. The [Select Query from Library page](#) appears. Subsequent changes to the query in the library will not affect the custom term. For more information, see [Selecting a query](#).

The screen refreshes and displays the query you created or selected in the Query field. If you click **Edit Query**, the Define Query page appears and you can change query variables, values, and logic.

---

**Note:** If you saved the query to the library and then you edit it from this page, your changes are not saved to the library.

---

12. If the data configuration selected for an MGPS run specifies a [drug or event hierarchy](#), you can select an existing term that has the primary path that you want to associate with the custom term. Next to **Hierarchy Path**, click **Select <hierarchy> Term** to view the [hierarchy](#). If you select a term, the results table includes its hierarchy values for the custom term. If you do not select a term, the results table does not include hierarchy values for the custom term.

The term that you select to indicate the primary path is always a PT (Preferred Term), even if the variable for which you are creating a custom term is a HLT, HLTG, or SOC. The option to specify a hierarchy path applies only to MGPS runs, and has no effect on logistic regression runs.

To remove a previously specified hierarchy path click **Clear Hierarchy Values**. (Before changing a hierarchy path, you should clear the hierarchy path.)

---

**Note:** Custom terms do not appear, and are not available for selection, from the hierarchy.

---

13. When you are satisfied with the custom term, click **OK**.

The new custom term appears on the Define Custom Terms page.



## Creating a query from an existing query

The Select Query from Library page appears if you choose to use an existing [query](#) when defining a custom term, database restriction, or query-based interactive report. The queries must have been created by you or published to you. (If you have the Administer Users permission, you can select from published or unpublished queries created by any user in your login group.)

Once you use an existing query for a custom term, database restriction, or query-based interactive report, subsequent changes to the query in the library do not affect the custom term, database restriction, or report.

1. Select **Create from Existing Query**.

The Select Query from Library dialog box appears.

2. From the **Project** drop-down list, select a specific [project](#), or select -- to include all projects.
3. From the **Configuration** drop-down list, [select the data configuration](#), or select -- to include all configurations. Available queries are those that are [compatible](#) with the data configuration for the data mining run (if you are creating a custom term or database restriction) or report definition (if you are creating a report).
4. From the **Origin** drop-down list, select one of the following values:
  - **Query**—The query was created and saved from the Queries page.
  - **Case Series**—The query was created and saved during the creation of query-based case series on the Case Series tab.
  - **Custom Term**—The query was created and saved during the creation of a custom term for a data mining run.
  - **Restriction**—The query was created and saved during the creation of a database restriction for a data mining run.
  - **Interactive Report**—The query was created and saved during the creation of an interactive report.
5. Click the radio button of the row for the query that you want to select.
6. Click **Next**.

If you are defining a custom term or database restriction, the Refine Query page appears. Optionally, you can [refine the query](#). For more information, see [Refining a query](#).

## Refining a query

To refine a [query](#) to create a database restriction or custom term, you specify values for variables that are included in the query.

1. From the Select Query from Library page, [select the query](#) and click **Next**.  
The Refine Query dialog box appears.
2. Specify values for query variables.  
  
If all operators in the query are the same; that is, they are all AND, all OR, all INTERSECT, or all UNION, you do not need to specify values for every variable. If you do not specify a value for a variable and you clear Include Null values for the variable, then the application ignores that variable. If any operators differ, you need to specify values for all query variables.  
  
The way in which you specify values depends on the type of variable. For more information, see [Selecting query variables](#).
3. To include null (empty) values along with the other values that you specify for a variable, check **Include Null values**. For more information, including how the NOT operator works if you include null values, see [Specifying query logic](#).
4. Click **OK**.

## Selecting values

- If the Select <hierarchy> Terms link appears for a variable, click it to select terms from the [hierarchy](#). For example, if an event variable is associated with a MedDRA version and your [user preference](#), Enable Adverse Event Hierarchy Browser, is checked, you can click **Select MedDRA Terms**.
- To [select values from a list](#), click **Select Available Values**.
- To refer to a [saved list](#) of terms, click **Select Saved List**. You can specify a saved list that uses the same data configuration as the query.

---

**Note:** You can also type in values separated by a comma. However, it is preferable to select values from a list. If you type in a value that contains a comma, you must enclose the value in double quotation marks (for example, "Diabetes, Type II"). If you type in a value that includes a backslash or double quotation mark, you must precede the backslash or double quotation mark with a backslash (for example, Cold\\flu).

---

- To [look up a drug name](#) for a drug variable, click **Trade/Generic Lookup**. You can find the generic name for a drug (if you only know its trade name) or vice versa. (This link is available if the data configuration's source data included trade name-generic name mapping.)

## Matching a text string

If the options **Contains**, **Starts with**, **Ends with**, or **Equals** appear for a variable, enter a text string and click a radio button to indicate the type of matching. You can also check **Ignore capitalization** to retrieve matching values regardless of upper or lower case.

### Specifying ranges

For numeric or date variables, specify a range by entering values in the **From** and **To** fields. Values equal to or greater than the From value and equal to or less than the To value are found. If you leave the From field empty, there is no lower bound. If you leave the To field empty, there is no upper bound.

Enter date values in the format appropriate for your locale or use the calendar icon to select a date. The application uses the Oracle `TO_DATE` function to change the entered date to an Oracle date. For example, if you enter `03/26/2008` in the From field for the `FDA_DATE` variable, in the SQL generated, `FDA_DATE >= to_date ('2008-03-26 00:00:00', 'yyyy-mm-dd hh24:mi:ss')`.

If you do not specify a time, the time is considered to be midnight of the specified date.

---

**Note:** If a date variable is stored as a text field in the Oracle database, you can search for it as you would search for any text string.

---

### Specifying report IDs

For a variable specified with the type Report ID in the data configuration, you can enter a string of report IDs separated by commas.

## Creating an MGPS run

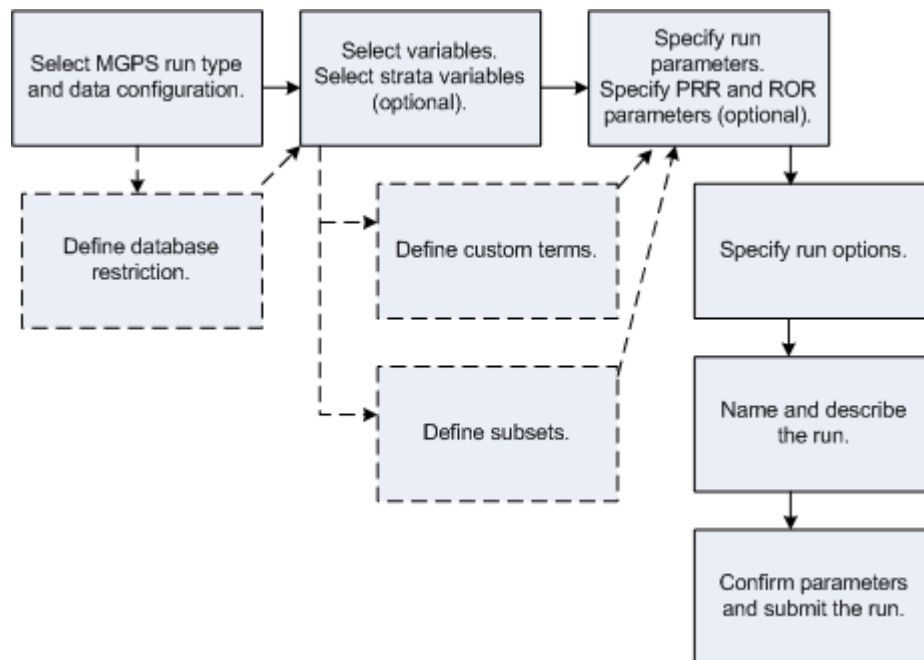
### About MGPS runs

The main statistical scores computed by an MGPS run are EBG<sub>M</sub>, EB<sub>05</sub>, EB<sub>95</sub>, representing the Empirical Bayes Geometric Mean and the 90% confidence interval from 5% to 95%. The application calculates these scores for each combination of items (such as drugs and events) included in the run. The data configuration that you select determines the items that are available for selection in the run.

Optionally, you can include computations of Proportional Reporting Ratios (PRR) and Reporting Odds Ratios (ROR) in an MGPS run.

When you define an MGPS run, you select the items to combine and for which to generate scores. You typically select a drug (or vaccine) variable and an event (or symptom) variable. You can also select items, such as gender, age group, or report receipt year, for the purposes of [subsetting](#) or [stratification](#). You can define a [database restriction](#) to limit which cases in source data to include in the run, and [custom terms](#), to select cases meeting specified criteria.

The execution of an MGPS run includes the following steps. Dotted lines represent optional steps.



As a [data mining parameter](#), you can restrict which results from the run to retain. For example, you can keep only results for drug-event combinations that include certain drugs and certain events. Restricting results does not affect the statistical computations. The application performs the statistical computations first and then keeps only results that meet the restriction.

## MGPS computations

For technical information about MGPS computations, you can click [MGPS Technical Summary](#) to display a PDF document of that title. You must have Adobe® Acrobat® Reader installed, as described in [Prerequisite and usage notes](#).

The analytical core of the Empirica Signal application is a high-performance implementation of the MGPS (Multi-Item Gamma Poisson Shrinker) algorithm. MGPS is based on the metaphor of the market basket problem, in which a database of transactions (adverse event reports) is mined for the occurrence of interesting (unexpectedly frequent) itemsets. For example, these itemsets can represent simple drug-event pairings, or more complex combinations of multiple drugs and events representing interactions and/or syndromes. Interestingness is related to the factor by which the observed frequency of an itemset differs from a nominal baseline frequency.

For each itemset in the database, a Relative Reporting Ratio (RR) is defined as the observed count (N) for that itemset divided by the expected count (E). MGPS allows for the possibility that the database may contain heterogeneous strata with significantly different item frequency distributions occurring in the various strata. To avoid concluding that an itemset is unusually frequent just because the items involved individually all tend to occur more frequently in a particular stratum (Simpson's paradox), MGPS uses the Mantel-Haenszel approach of computing strata-specific expected counts and then summing over the strata to obtain a database-wide value for the expected count.

To improve upon the estimation of true value for each RR (especially for small counts), the empirical Bayesian approach of MGPS assumes that the many observed values of RR are related in that they can be treated as having arisen from a common super population of unknown, true RR-values. The method assumes that the set of unknown RR values is distributed according to a mixture of two parameterized Gamma Poisson density functions, and the parameters are estimated from a maximum likelihood fit to the data. This process provides a prior distribution for all the RRs, and then the Bayes rule can be used to compute a posterior distribution for each RR. Since this method improves over the simple use of each N/E as the estimate of the corresponding RR, it can be said that the values of N/E borrow strength from each other to improve the reliability of every estimate.

The improved estimates of RR are actually derived from the expectation value of the logarithm of RR under the posterior probability distributions for each true RR.

If you select [subset variables](#) for the run, MGPS computations are performed for each subset. If you select [stratification variables](#) for the run, the MGPS computations are modified to use stratification.

## Item variables

When you create an MGPS run, you select item variables. Typically, the item variables represent drugs and events. The counting and estimation that the MGPS computation performs divides the combinations of the selected item types into separate itemsets, based on the combinations possible for the number of dimensions in the run. For the two items D and E in a three-dimensional run, MGPS performs computations on the itemsets DD, DDD, DE, DDE, DEE, EE, and EEE.

## Drug-event combination scores

For a combination of drug and event (a two-dimensional or 2D combination), the signal score is the EBGM (Empirical Bayes Geometric Mean) value.

EBGM is defined as the exponential of the expectation value of  $\log(\text{true RR})$ . EBGM has the property that it is nearly identical to N/E when the counts are moderately large, but is shrunk towards the average value of N/E (typically  $\sim 1.0$ ) when N/E is unreliable because of stability issues with small counts. The posterior probability distribution also supports the computation of lower and upper 95% confidence limits (EB05, EB95) for EBGM, which is an estimate of the relative reporting ratio.

## Interaction scores

Computations for combinations of dimensions greater than 2 focus on measuring and scoring cross-item type combinations, but allow any observed dependence within item types to be fit completely without generating a score. The only exception to this is during the analysis of a homogeneous itemset, such as three events (E1,E2,E3) where all items are of the same type and in which case high EBGM scores do alert reviewers to a potential within-item type association. Thus, for a mixed-type 3D combination like (D1,D2,E1), the values of EBGM, EB05 and so on measure how many times more frequently the pair (D1,D2) occurs with E1 than would be expected if the pair (D1,D2) were independent of E1, without making any statement about whether the drugs D1 and D2 appear in the same reports more frequently than independence would predict.

---

**Note:** In the 7.3 release, the maximum number of dimensions in a run was limited to 3 due to the difficulty in interpreting the results of higher-dimension runs, and the amount of server space and processing time required for the computations. Higher-dimension runs completed prior to 7.3 remain available for review.

---

The signal score for a 3D combination is the INTSS (Interaction Signal Score) value, which is essentially a way of measuring the strength of a higher-order association above and beyond what would be expected from any of the component pairs of items of different types. INTSS is computed as follows:

$$\text{INTSS} = \text{EB05} / \text{EB95MAX}$$

where:

- EB05 is the conservative estimate score for the 3D combination.
- EB95MAX is the highest EB95 score found for the component pairs of items of different types.

An INTSS of greater than 1 indicates a stronger association than is found for the component pairs of items.

---

**Note:** Typically, it would not be concluded that the potential interaction was interesting unless the EB05 score for that DDE combination is large (for example, over 1.5 or 2.0).

---

To support backward compatibility with versions of the application prior to 5.0, signal scores based on the independence model are still computed for dimensions higher than 2. These values are stored in columns ending in `_IND`. See [MGPS independence model](#).

## Custom terms and synthetic values

When estimating shrinkage parameters for EBGM scores, MGPS does not consider the following:

- Custom terms.
- [Excluded synthetic values](#), such as Standardized MedDRA Queries (SMQs), that have been defined for the appropriate [data configuration variable](#).

The raw RR scores for combinations involving custom terms and the excluded synthetic values are shrunk by the Bayesian formula, but they do not participate in the determination of the formula itself.

---

**Note:** Users creating a data mining run do not need to take any additional steps to exclude custom terms or already-excluded synthetic values.

---

## PRR computations

When [specifying data mining parameters](#) for a run, you can perform PRR and ROR computations. For information about ROR, see [ROR computations](#).

The Proportional Reporting Ratio (PRR) computation relates to drug-event combinations, only, in two-dimensional data mining runs. If you specify a dimension of 3 for the run, the application computes PRR only for the 2D pairs; that is, the drug-event combinations, but not the combinations of one drug and two events, two drugs and one event, three drugs, or three events.

### Default PRR computations

If you check **Base counts on cases rather than drug-event combinations** but no other PRR options, the application computes PRR as follows. If you select a [subset variable](#) for the run, the application computes PRR separately for each subset.

- Assume that observed counts of cases with drug-event combinations are named a through d as follows:

	Specific drug	All other drugs
Specific event	a	b
All other events	c	d

- a is the number of cases with the specific event and the specific drug.
  - b is the number of cases with the specific event but not the specific drug.
  - c is the number of cases with the specific drug but not the specific event.
  - d is the total number of cases with neither the specific event nor the specific drug.
- The PRR for the combination of a particular drug and particular event is computed as follows:

$$\text{PRR} = (a / (a + c)) / (b / (b + d))$$

If  $b=0$  (and the **Include drug of interest** checkbox is not checked), then the formula is adjusted to avoid the possibility of division by zero:

$$\text{PRR} = ((a+0.5) / ((a+0.5) + (c+0.5))) / ((b+0.5)/((b+0.5) + (d+0.5)))$$

- For each cell in the table in step 1, the application computes the expected count as follows:

	Specific drug	All other drugs
Specific event	$E(a) = ((a+b)(a+c))/(a+b+c+d)$	$E(b) = ((a+b)(b+d))/(a+b+c+d)$



All other events	$E(c) = \frac{((c+d)(a+c))}{(a+b+c+d)}$	$E(d) = \frac{((c+d)(b+d))}{(a+b+c+d)}$
------------------------	-----------------------------------------	-----------------------------------------

4. The application computes the chi-square of PRR (PRR\_CHISQ) for the combination of a particular drug and particular event as follows, where E represents the expected count under the assumption of no relationship between drugs and events:

$$\text{PRR\_CHISQ} = ((a-E(a))^2)/E(a) + ((b-E(b))^2)/E(b) + ((c-E(c))^2)/E(c) + ((d-E(d))^2)/E(d)$$

The P-values for Chi-square values are also computed. The P-value is the probability that Chi-square would be as large as the value for PRR\_CHISQ by chance alone if there were no causal relationship or consistent association between the drug and the event.

---

**Note:** If any of E(a), E(b), E(c), or E(d) is zero, the Chi-square and P-value cannot be computed and are defined arbitrarily as -1.

---

## Counts based on drug-event combinations

By default, the PRR computation counts the occurrence of cases. On the Data Mining Parameters page, if you clear **Base counts on cases rather than drug-event combinations**, then a through d represent counts of drug-event combinations. If a case has more than one drug or event, the case supplies several drug-event combinations to the computation. This option is not recommended, especially if data mining results include [custom terms](#) or Standardized MedDRA Queries (SMQs).

If you select [stratification variables](#) for the data mining run, the application checks **Base counts on cases instead of drug-events combinations** automatically and cannot be cleared. The [PRR calculator](#) also always bases counts on cases.

## Drug of interest in comparator set

On the Data Mining Parameters page, if you check **For PRR, include drug of interest in the comparator set**, then PRR is computed as:

$$\text{PRR} = (a / (a + c)) / ((a + b) / (a + b + c + d))$$

## Yates correction

On the Data Mining Parameters page, if you check **Apply the Yates correction in computing the value of chi-square**, then PRR\_CHISQUARE is computed as:

$$\text{PRR\_CHISQ} = ([\max(0, |a - E(a)| - 0.5)]^2)/E(a) + ([\max(0, |b - E(b)| - 0.5)]^2)/E(b) + ([\max(0, |c - E(c)| - 0.5)]^2)/E(c) + ([\max(0, |d - E(d)| - 0.5)]^2)/E(d)$$

---

**Note:**  $|a - E(a)| = |b - E(b)| = |c - E(c)| = |d - E(d)|$  for every 2x2 table. This formula can also be expressed as:

---

$$\text{PRR\_CHISQ} = (1/E(a) + 1/E(b) + 1/E(c) + 1/E(d)) [\max(0, |a - E(a)| - 0.5)]^2$$

If you select stratification variables for the data mining run, this option is available only if you do not check **Use stratified computation for PRR and ROR**.

### Stratified PRR computation

Even if you select stratification variables for the data mining run, Oracle does not recommend using stratified computation for PRR and ROR. However, on the Data Mining Parameters page you have the option to check **Use stratified computation for PRR and ROR**. The PRR computation is performed as follows.

If there are  $K$  strata, then for stratum  $k$  ( $k = 1, 2, \dots, K$ ), let  $a_k, b_k, c_k, d_k$  be the four cell counts in stratum  $k$ , and let

- $M1k = a_k + b_k$
- $M0k = c_k + d_k$
- $N1k = a_k + c_k$
- $N0k = b_k + d_k$
- $T = M0k + M1k = N0k + N1k = a_k + b_k + c_k + d_k$

$$PRR = (\sum_k a_k N0_k / T_k) / (\sum_k b_k N1_k / T_k)$$

---

**Note:** If the run uses subsetting, only those strata that contain cases for a given subset are used in the PRR computation for that subset.

---

The Chi-square statistic for stratified PRR is computed as:

$$PRR\_CHISQ = \sum_k (a_k - N1_k * M1_k / T_k)^2 / \sum_k ((N0_k * N1_k * M0_k * M1_k) / ((T_k - 1) * T_k^2))$$

---

**Note:** For instances where the denominator in the PRR or the chi-square formulas would be zero, the computation adds  $0.5/K$  to  $a_k, b_k, c_k,$  and  $d_k$ , where  $K$  is the number of strata.

---

## ROR computations

When [specifying data mining parameters](#) for a run, you can specify that PRR and ROR computations be performed. For information about PRR, see [PRR computations](#).

In two-dimensional data mining runs, the application computes the Reporting Odds Ratio (ROR) only for drug-event combinations. If you specify a dimension of 3 for the run, the application computes ROR only for the 2D pairs. This means that the ROR is computed for the drug-event combinations, but not for the combinations of one drug and two events, two drugs and one event, three drugs, or three events.

## ROR computations

---

**Note:** If you select a [subset variable](#) for the run, the applications computes ROR separately for each subset.

---

Assume that observed counts of drug-event pairs are named a through d, as follows:

	<b>Specific drug</b>	<b>All other drugs</b>
Specific event	a	b
All other events	c	d

- a is the number of cases with the specific event and the specific drug.
- b is the number of cases with the specific event but not the specific drug.
- c is the number of cases with the specific drug but not the specific event.
- d is the total number of cases with neither the specific event nor the specific drug.

The ROR for the combination of a particular drug and particular event is computed as:

$$\text{ROR} = ad/bc$$

The 90% confidence interval is defined by:

$$\text{ROR}_{05} = \text{elog}(\text{ROR}) - 1.645 \times \text{sqrt}(V)$$

$$\text{ROR}_{95} = \text{elog}(\text{ROR}) + 1.645 \times \text{sqrt}(V)$$

where:  $V = 1/a + 1/b + 1/c + 1/d$

In cases where division by zero would arise, 0.5 is added to each of a, b, c and d.

## Counts based on drug-event combinations

By default, the ROR computation counts the occurrence of cases. On the Data Mining Parameters page, if you clear **Base counts on cases rather than drug-event combinations**, a through d represents counts of drug-event combinations. If a case has more than one drug or event, the case supplies several drug-event combinations to the computation. Oracle does not recommend this option, especially if data mining results include custom terms or Standardized MedDRA Queries (SMQs).

If you select [stratification variables](#) for the data mining run, the application automatically checks **Base counts on cases instead of drug-events combinations** and cannot be cleared.

## Stratified ROR computations

If you select [stratification variables](#) for the data mining run, Oracle does not recommend using stratified computation for PRR and ROR. However, on the Data Mining Parameters page you do have the option to check **Use stratified computation for PRR and ROR**. The application computes stratified ROR. Assume that a, b, c and d are counts of drug-event pairs for a given stratum.

$$\text{ROR} = \Sigma^R / \Sigma^S$$

where:

- $R = ad/T$
- $S = bc/T$
- $T = a + b + c + d$
- The sums are taken over all strata.

The 90% confidence interval is defined by:

- $\text{ROR}_{05} = \text{elog}(\text{ROR}) - 1.645 \times \text{sqrt}(V)$
- $\text{ROR}_{95} = \text{elog}(\text{ROR}) + 1.645 \times \text{sqrt}(V)$

where:

- $V = \Sigma PR / 2(\Sigma R)^2 + \Sigma(PS + QR) / 2\Sigma R\Sigma S + \Sigma QS / 2(\Sigma S)^2$
- $P = (a+d)/T$
- $Q = (b + c)/T$

---

**Note:** In cases where division by zero would arise,  $0.5/K$  is added to each of a, b, c and d for each stratum, where K is the number of strata.

---

## Reference

Robins J, Greenland S, Breslow N. A General Estimator for the Variance of the Mantel-Haenszel Odds Ratio. *American Journal of Epidemiology* 1986; 124: 719-23.

## Selecting variables for an MGPS run

When you select a configuration and perform an MGPS run, you select variables to use in the run. A variable is a data item in the source data referenced by the configuration that you selected for the data mining run. Typically, an MGPS data mining run includes a drug (or vaccine) variable and an event (or symptom) variable.

---

**Note:** Before creating a data mining run, set your [user preference](#), **Replace Missing Values with**, with a value to insert if the subset variable is missing from the source data.

---

1. On the Select Variables page, select at least one **Item variable**. To study drug-event combinations, you typically select two or more items that are listed as Drug or Event variables. To select a variable, click its name. You can also do the following:
  - Select multiple non-contiguous variables by holding down the Ctrl key while clicking each variable.
  - Select multiple contiguous variables by clicking a variable, holding down the Shift key, and clicking another variable. Variables between and including those variables are selected.
  - Deselect a variable by holding down the Ctrl key while clicking the variable.

2. If you want to use [stratification](#), select one or more **Stratification variables**. You cannot select the same variable as both an item variable and a stratification variable.

A warning message appears if there are more than 500 values for all selected stratification variables. Too many stratification values can cause reduced sensitivity in the EBGm and EB05 statistics. To avoid this reduced sensitivity, the number of cases divided by the number of unique stratification values should be at least 100. For example, if there are 5,000 cases in the source data, there should not be more than 50 strata values.

3. To define custom terms, check **Define custom terms**.
4. To define subsets, check **Define subsets**.
5. Click **Next**.

If you checked **Define custom terms**, the [Define Custom Terms page](#) appears. For more information, see [Defining custom terms](#).

If you checked **Define subsets**, the [Select Subset Variable page](#) appears. For more information on subsets, see [Using a subset variable](#).

If you did not select **Define custom terms** or **Define subsets**, the [Data Mining Parameters page](#) appears. See [Specifying data mining parameters](#).

## Using stratification variables

Item values can be associated in an [MGPS data mining run](#) because they are associated jointly with other variables, such as gender or age. To minimize the occurrences of this type of spurious association, use stratification variables in the results of an MGPS run.

For example, Drug X is generally prescribed for women above age 50 and Event Y also occurs more frequently for women above age 50. A data mining run indicates a strong association between Drug X and Event Y, based on the coincidence of the gender and age groups involved. To minimize the occurrence of this type of association, stratify the data mining run by Gender and Age Group. To do this, Gender and Age Group must be available as stratification variables in the configuration.

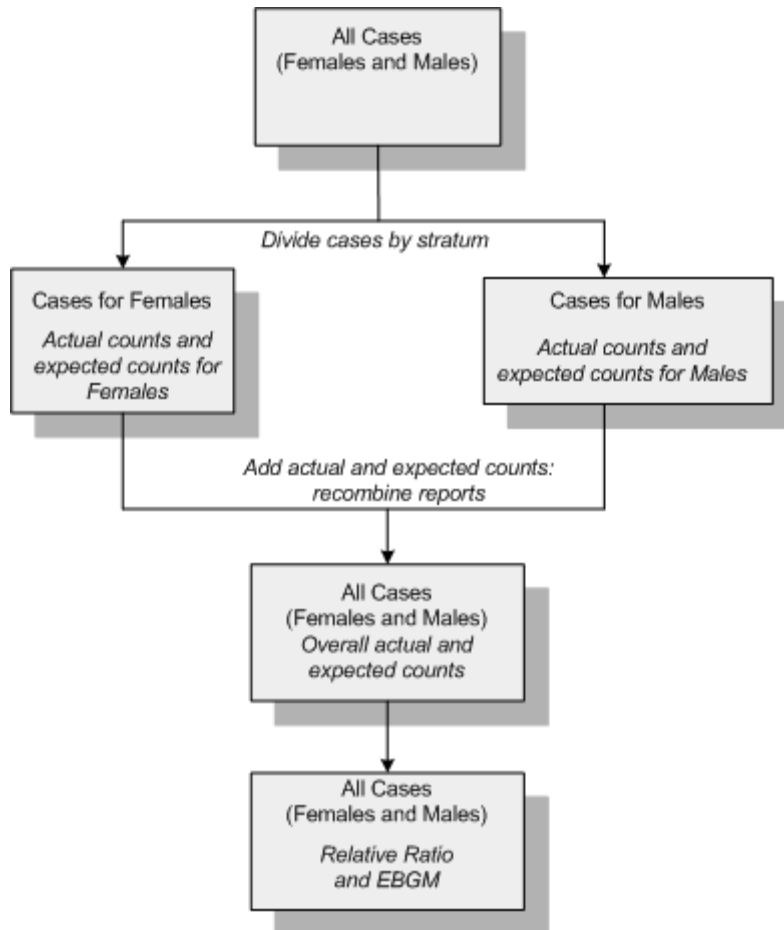
Stratification divides all cases into groups, based on one or more variables, for the computation of expected values (E). The Empirica Signal application sums these expected values across all of the strata to provide a single expected value for all of the cases in the background. This has the effect of adjusting the expected value (and the other statistics computed with E, including the Relative Reporting Ratio (RR) used in the MGPS computation) for the effects of such covariates as age, gender, and receipt year. In this way, you can perform data mining across the entire background set, yet still be protected from false results that can come from coincidental association with age, gender, and so on. With stratification, there is one set of results (as opposed to the multiple result sets generated by a [subset variable](#)).

Like item variables, stratification variables map to columns in the safety database. You cannot select the same variable as both an item variable and a stratification variable at the same time.

If you select stratification variables for your MGPS data mining run, and also choose to compute [PRR](#) (Proportional Reporting Ratios) and [ROR](#) (Reporting Odds Ratios), you can specify stratification to apply to those computations as well.

### Example

The following example shows how reports are divided and then recombined during data mining when you use the stratification variable Gender:



## Defining subsets

### Using a subset variable

When you use a subset variable for an [MGPS data mining run](#), the Empirica Signal application divides source data into separate backgrounds, one for each value of the subset variable, and performs a separate run for each of those different backgrounds. You use subsets to study how the strength of a combination of variables evolved temporally. You can also use subsets to study the strength of variable combinations for age differences, gender differences, and so on. For example, to review separate signal scores for males and for females, you subset the data mining run by gender. Two separate sets of statistics result, one set computed against the background of cases involving males and the other against the background of cases with females.

You can select only one [subset variable](#) for a data mining run. That variable must have only one value for each case in the database. For example, indication, route, or dose cannot be used directly as subset variables because any case with more than one drug has multiple values for these variables, one for each reported drug. After selecting a subset variable, choose which values of that variable to use for subsetting. The application generates a set of results for each subset.

---

**Note:** You cannot select the same variable as both an [item variable](#) and a subset variable.

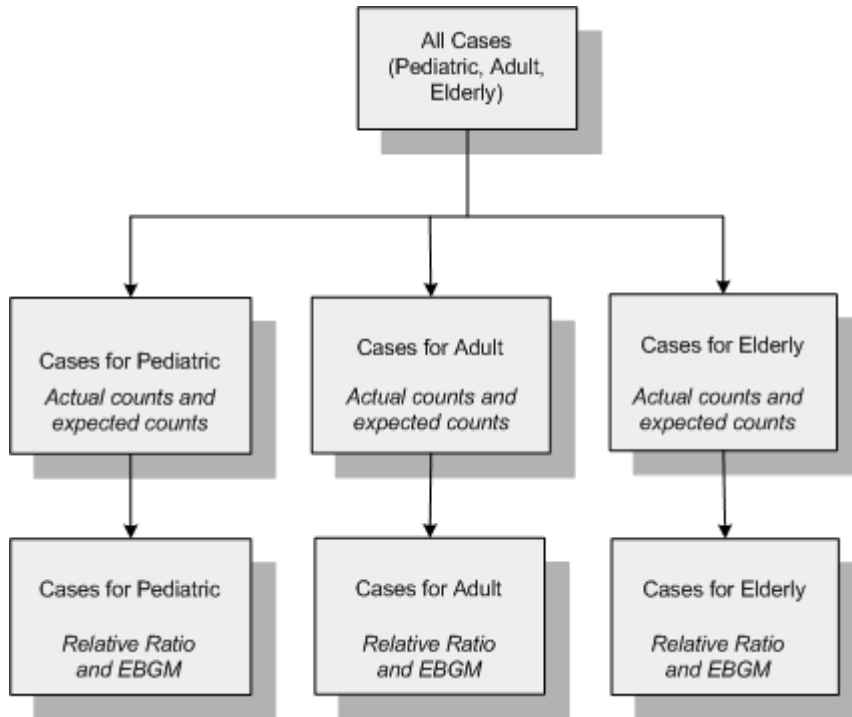
---

### Example

The database contains information on the age of patients reporting adverse reactions. The age has been categorized as Pediatric, Adult, and Elderly, and stored in a variable named AgeGroup. To compare associations of variables for different age categories, you can select AgeGroup as the subset variable (assuming that AgeGroup has been made available as a subset variable by the configuration).

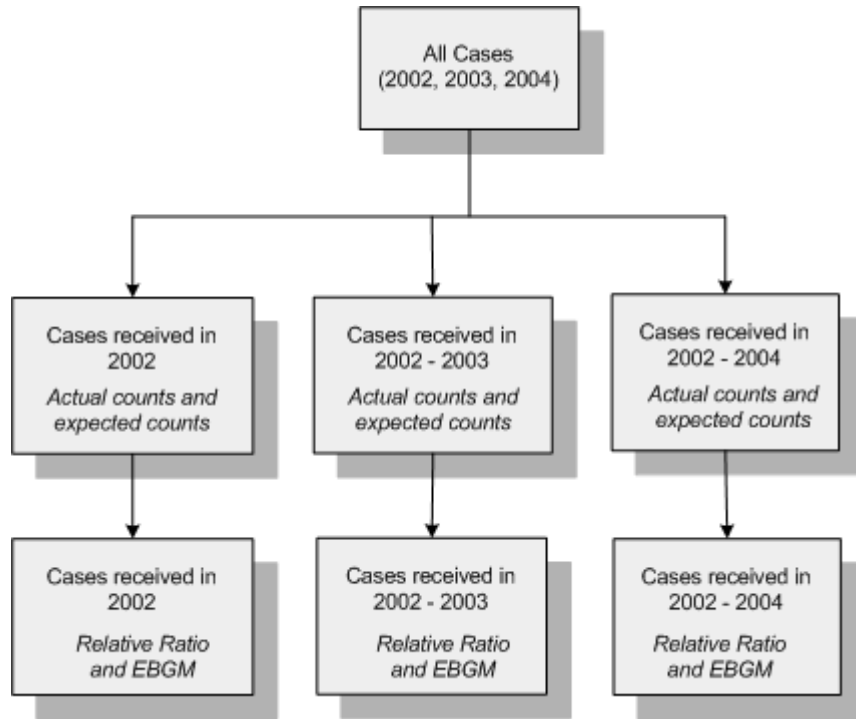
With subsetting, the application computes expected counts, Relative Ratio, and EBGm for each subset separately:





For a data mining run that uses cumulative subsets, there is one set of results for each subset and the computations to determine results for each subset include data from all previous subsets. A previous subset may or may not be previous chronologically. For more information, see [Defining subset values](#). Typically, a variable used for cumulative subsetting represents a time period.

For example, suppose that you use Report Year as the subset variable and the possible report years are 2002 through 2004:



## Selecting a subset variable

To use [subsetting](#) in an MGPS data mining, you must select a subset variable.

1. On the [Select Variables page](#), select **Item** and, optionally, select **Stratification** variables.
2. Check **Define subsets**.
3. Click **Next**.

The Select Subset Variable page appears. If you also checked **Define custom terms** on the Select Variables page, the Select Subset Variable page appears after you add custom terms.

4. From the **Subset variable** list, select the variable to use for subsetting.  
  
You can select only one subset variable, and you cannot select the same variable to be both an item variable and a subset variable in the same data mining run.
5. Click **Next**.  
  
The [Define Subset Values page](#) appears.
6. Continue with [Defining subset values](#).

## Defining subset values

When you have selected a [subset variable](#) for an MGPS run, you must specify subsets, with each subset representing one or more values of the subset variable. For example, if you use Received Year as the subset variable, you can create one subset for each year except 1998, 1999, and 2000, which you group together into one subset. The application generates a set of data mining results for each subset that you specify.

The source of subset values is either the source database or values that have been defined by [data transformations](#) in the data configuration. For example, if the source database contains report received dates, the creator of a configuration can transform the received dates into years, half-years, or quarter-years.

If a value for the subset variable is missing from the source data, the value of your [user preference](#), **Replace Missing Values with**, appears in place of a value.

---

**Note:** When specifying subsets, keep in mind that there is an iteration of MGPS for each subset. The more subsets you specify, the longer the MGPS run takes.

---

1. [Select a subset variable](#).

The Define Subset Values page appears. The Available Values list shows values of the variable in the source data.

2. Use the arrow keys to move values from the **Available values** list to the **Subset values** list:

Button	Use To
=>	Create a single subset containing all values that are selected in the Available values list, for example, one subset for 1998,1999,2000.
->	Create a subset for each of the values that is selected in the Available Values list, for example, a separate subset for each of 2007 and 2008.

3. To include data from all previous subset categories in the results for each subset, check **Subsets will be cumulative**. Typically, a cumulative subset variable represents an ordinal value, such as report year. A non-cumulative subset variable may represent a categorical value, such as age group.
4. If you checked **Subsets will be cumulative**, click one of the following under **Subsets will be ordered**:
  - As listed—Generates data mining results for subsets in the order of the subsets.
  - As reverse of listed—Generates data mining results for subsets in the reverse of the specified sort order.

The sort order is important for cumulative subsetting. The computations to determine results for each subset include data from all previous subsets. (The sort order also affects the order of columns in map graphs.) For example, the listed order of subsets is:

- 2004
- 2005
- 2006

If you use cumulative subsets (as listed), there are subsets for:

- 2004
- 2004 and 2005 combined
- 2004, 2005, and 2006 combined

If you reverse the listed order, there are subsets for:

- 2006
- 2005 and 2006 combined
- 2004, 2005, and 2006 combined

See [Defining subset labels](#) for more examples.

5. Click **Next**.
6. Continue with [Defining subset labels](#).

## Defining subset labels

1. After you have [defined subset values](#) and clicked **Next**, the Define Subset Labels page appears.
2. In the **Label** field, optionally, replace the default label with a different label. There must be a label for each subset.

---

**Note:** If a label includes an invalid character or space, the application changes it automatically and a message appears to inform you of the change. The application replaces invalid characters with a pound sign (#) and spaces with an underscore (\_).

---

Invalid characters for this field are:

\*, \, ", :, /, ?, >, <, &, |, \t, \r, \n, ^, \$, @, and '

plus any non-ASCII characters.

3. Click **Next**.  
The [Data Mining Parameters page](#) appears.
4. Continue with [Specifying data mining parameters](#).

## Default labels

When you define subsets, the application assigns default labels. You can change the default labels as needed. For a list of subset values, the default name is:

<first value>..<last value>

Default labels depend on whether the subsets are cumulative and the order of the subsets, the listed order or the reverse orders. The table shows default labels for different types of subsets:

Subsets As Listed on Define Subset Values page	Default Labels for Non-Cumulative Subsets	Default Labels for Cumulative Subsets	Default Labels for Cumulative Subsets in Reverse Order of Listed
1998	1998	1998	2000..2006
1999	1999	1998-1999	1999-2000..2006
2000, 2001, 2002, 2003, 2004, 2005, 2006	2000..2006	1998-2000..2006	1998-2000..2006

## Specifying data mining parameters

After you have selected variables for data mining, the Data Mining Parameters page appears.

1. In the **MGPS parameters** section, in the **Specify highest dimension** field, select the highest [dimension](#) (2 or 3) for which to perform statistical computations.

A dimension refers to the number of ways in which items will be combined during a run. For example, if you specify 3 as the highest dimension, then the run results include one-dimensional, two-dimensional, and three-dimensional combinations of items.

If you specify a highest dimension greater than 2 and the run has a minimum count of less than 5 and/or uses cumulative subsetting, a warning message appears. In these situations, the results table takes a very long time to generate and can be very large in size.

---

**Note:** Three dimensional runs require very large amounts of space for intermediate storage and to save the final results (potentially hundreds of gigabytes). Use of other data mining parameters, including the minimum count, to reduce the computational effort required for these runs, and restricting results to those results you plan to analyze, is strongly recommended.

---

2. In the **Specify minimum count** field, specify the number of cases in which the combination of items must occur in the data for the combination to be included in MGPS statistical computations. The purpose of the minimum count is to decrease computational time and space requirements. The higher the minimum count, the shorter the computational time.

In the run results, only combinations with at least the specified minimum count appear. For example, if you specify a minimum count of 5, only combinations that occur in at least 5 cases appear.

When specifying a minimum count, consider whether or not you are using a subset variable. For example, suppose that the subset categories are report years 2005, 2006, and 2007 and that there are 4 drug-event combinations for DrugA+Rash in 2005, 3 new ones in 2006, and 5 new ones in 2007. If the minimum count is 5, only the 2007 results show any DrugA+Rash combinations. If you are using cumulative subsetting, both 2006 and 2007 show DrugA+Rash combinations.

---

**Note:** You can set your [user preference](#), **Minimum Count**, to supply a default setting for this field.

---

3. If the run's [data configuration](#) is set up to use a [drug or event hierarchy](#), you can check **Include drug/event hierarchies' primary paths in run results** to include hierarchy levels in the results. For example, if the data mining run is for drug and PT, and the MedDRA Version 12.0 hierarchy is being used, the results include the HLT, HLG, and SOC representing the PT's primary path in MedDRA Version 12.0.

4. Optionally, check **Include calculations for PRR and ROR** in the run. If you check this option, you can also check other options under **PRR and ROR Parameters** (available if both a drug and event variable are selected).

- For information about Proportional Reporting Ratios (PRR) options, see [PRR computations](#).
- For information about Reporting Odds Ratios (ROR) options, see [ROR computations](#).

5. To take into account item types during MGPS processing, select **Fit separate distributions for the different item type combinations** check box.

When selected, this parameter takes into account item types during MGPS processing. N, E, and RR values are not affected, but EBGM and other statistical values are affected. The statistical values for each combination are based on the counts and statistical computations of other occurrences of the same type of combination. For example, in computing EBGM values for Drug+Event combinations, only the distribution of RR values for Drug+Event combinations is considered. The distributions of RR values for Drug+Drug or Event+Event combinations are not considered.

If cleared, MGPS processing does not take item types into account.

---

**Note:** This parameter does not affect the computation of PRR or ROR.

---

6. In the **Restrictions of results** section, specify the values to retain for display.

The fields under **Restrictions of Results** affect only which results the application retains after the data mining is complete. They do not affect the [source data](#) used by the data mining run.

If you check **Exclude associations if items are of the same type (all drugs, all events)**, the run computes statistics for combinations of items of the same type; however, the results that you can view include only combinations of items of different types. With these parameters in use, time and space utilization improves because fewer results load into the results table. Thus, these fields can be useful to users with limited quotas. The fields that restrict the results that are saved include the following:

Field	Description
EBGM >=	You can check none, some, or all four of these check boxes and supply an integer or floating point number as a limit. Combinations for which the value is less than the specified limit are not kept in the results. This limit considers all combination types that are included in the results table.
EB05 >=	
N >=	
PRR >=	
<hr/> <p><b>Note:</b> You can also restrict displayed results based on these values on the Specify Criteria page when you are viewing results.</p> <hr/>	



Top combinations based on <EBGM or EB05>	If a number is entered, only the highest scoring combinations of the specified statistic are kept in the results.
Exclude associations if items are of the same type (all drugs, all events)	<p>If checked, the results table includes only combinations of at least one drug and at least one event. If cleared, the results table includes combinations of all items, even if they are of the same type (for example, Drug+Drug+Drug combinations). Oracle recommends that you select this parameter.</p> <p>You can define a default setting for this check box with the <a href="#">user preference</a>, Exclude associations if items are of the same type (all drugs, all events).</p>
Keep only results that include the following values of	<p>For each item variable in the run, you can select specific terms to limit the results kept to combinations of at least one of the specified drugs (if any) and at least one of the specified events (if any). If you do not select terms, results for all values of the item variables are kept.</p> <p>For example, you keep only results for the drug DrugA and the events Rash and Vertigo. Statistical computations include all drug and event values; however, the saved results include combinations only if the following criteria are met:</p> <ul style="list-style-type: none"> <li>• If there are drugs in the combination, at least one of them is DrugA.</li> <li>• If there are events in the combination, at least one of them is Rash or Vertigo.</li> </ul> <p>If the Select &lt;hierarchy&gt; Terms link appears for a variable, click it to select terms from the <a href="#">hierarchy</a>. For example, if an item variable is associated with a MedDRA version and your <a href="#">user preference</a>, Enable adverse event hierarchy browser, is checked, you can click Select MedDRA Terms.</p>
	<p><b>Note:</b> If you created custom terms for the run, they do not appear in the hierarchy.</p>
	<p>To <a href="#">select values from a list</a>, including custom terms, click Select Available Values.</p>
	<p>To refer to a <a href="#">saved list</a> of terms, including custom terms, click Select Saved List.</p>
	<p><b>Note:</b> You can also type in values separated by a comma. However, it is preferable to select values from a list. Only exact matches, including the case (upper, lower, or mixed), are found. If you type in a value that contains a comma, you must enclose the value in double quotation marks (for example, "Diabetes, Type II"). If you type in a value that includes a backslash or double quotation mark, you must precede the backslash or double quotation mark with a backslash (for example, Cold\\flu).</p>

To [look up a drug name](#), click Trade/Generic Lookup. You can find the generic name for a drug (if you only know its trade name) or vice versa. (This link appears if the data configuration source data includes trade name-generic name mapping.)

---

7. Click **Next**.  
The [Run Options page](#) appears.
8. Continue with the Run Options page.

## Creating a logistic regression run

### About logistic regression runs

Logistic regression is a statistical tool for modeling how the probability of a response depends on the presence of multiple predictors, or risk factors. In the Empirica Signal application, the predictors are drugs and, optionally, covariates such as report year, gender, or age group, and the responses are adverse events.

The main statistical scores computed for the predictors and responses in a logistic regression run are LROR, LR05, and LR95, representing the Logistic Regression Odds Ratio and the 90% confidence interval (LR05, LR95). The scores from a logistic regression run, when compared to the results of an MGPS run, can help identify confounding or masking effects.

To create a logistic regression run, you select a data configuration and one drug variable (the predictor) and one event variable (the response) variable to combine for score generation. You can also explicitly specify drug and event values to include in the computation. Because the logistic regression computation assesses the results of polytherapy, selecting configurations that include concomitant as well as suspect drugs, and drug variables, such as Single Ingredient, that treat combination drugs as if the patient had taken separate drugs, are recommended.

You can also select one or more other variables, such as gender, age group, and report receipt year, as covariates (additional predictor variables) for the computation. Each value of a covariate is used in the logistic regression computation as its own predictor, except for the value with the highest frequency among all reports in the analysis, which is used as the standard to which the other values are compared. For example, if you select Gender as a covariate and Gender has the unique values F, M, and U, with M occurring most frequently, computations are made for the two predictor values GENDER\_F and GENDER\_U. For the relatively rare situations in which the covariate value that occurs most frequently overall, such as M, does not occur in combination with a certain event, such as Uterine cancer, then the value occurring most frequently with that event is used instead. Logistic regression is then performed with drug values and these covariate values as predictors for each response.

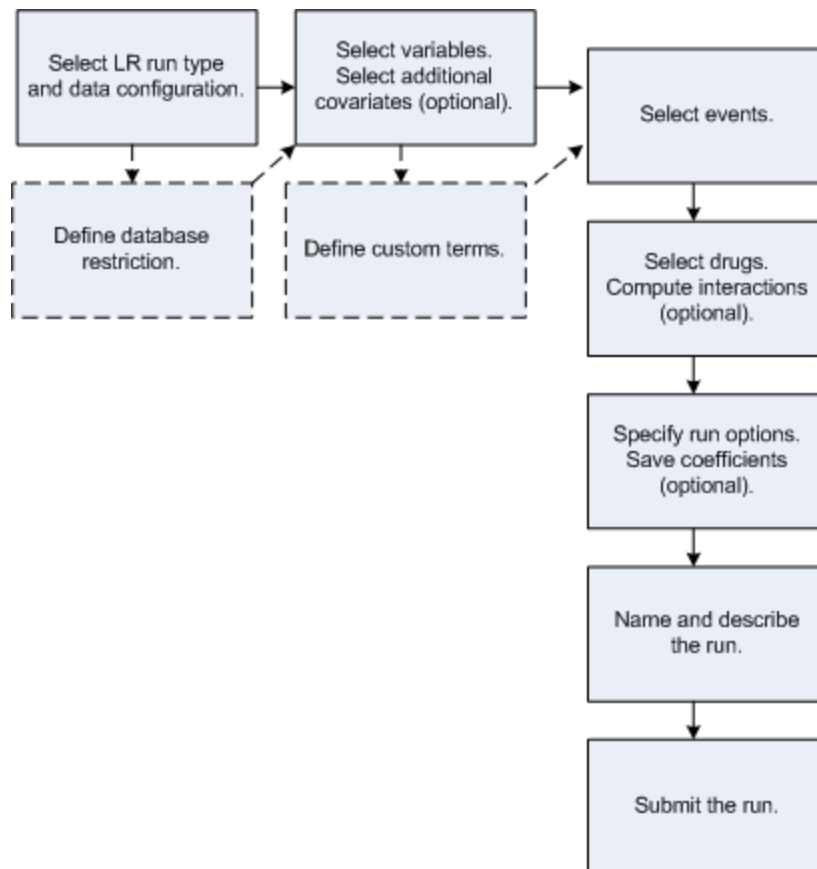
For more information about logistic regression computations, see [Logistic regression computations](#).

In addition to [selecting the variables](#) for the run, you also have options to:

- Use either [extended logistic regression](#), which includes the computation of the best alpha value to use for each response, or standard logistic regression, which uses 0.5 as the alpha value for every response.
- Define a [database restriction](#), which limits the cases in the source data that are included in the run.
- Define [custom terms](#), which are pseudo-values.
- Specify [events](#) of interest for the run.
- Explicitly supply [drugs](#) and/or provide the application with guidelines (minimum number of occurrences with the event, total number of drugs to include) for selecting drugs that occur frequently with specified events.

- Include computations for interactions, such as drug+drug+event or drug+covariate+event, for each response.
- Include the computed coefficients and standard errors of the run in the lr\_coefficients.log [log file](#).

The execution of a logistic regression run includes the following steps. Dotted lines represent optional steps.



## Logistic regression computations

The Empirica Signal application offers two types of logistic regression: standard logistic regression and extended logistic regression. In standard logistic regression, users select an LR type of Standard on the [Create Data Mining Run](#) page. Extended logistic regression is performed when user select LR type of Extended.

Both models describe the relative weight of the presence of various drugs and other factors in a report in predicting the occurrence of a particular adverse event in the same report, but they provide different methods for **fitting** the model.

- In the standard model, computations always use the same alpha value of 0.5. When the probability of an AE occurring is small, as in the case of a relatively rare AE, the result of the standard computation is an assumption that drug effects are more multiplicative than additive. If this assumption is false, logistic regression is likely to detect associations correctly, but the relative effects of drugs may not be correct. The standard model is equivalent to the logistic regression method found in statistics textbooks.
- The extended logistic regression model allows an extended family of **link** functions that connect the estimated coefficients to the event probabilities. Whereas, the standard model assumes that this link function is the well-known S-shaped logistic curve, the extended model allows other shapes of curves, if another curve in the family fits the data better. The family is parameterized by the scalar alpha, where  $0 < \alpha < 1$ , and where  $\alpha = 0.5$  corresponds to the standard logistic. An interpretation of alpha is that value of the fitted event probability where the curve has a point of inflection, meaning that the curve is linear there and so the effects of multiple predictors are additive in the neighborhood of  $P(\text{response event}) = \alpha$ . When the extended model option is chosen, the system estimates the **maximum likelihood** value of alpha and uses that value to form model predictions.

To compare scores calculated by each of these models, you can re-run a logistic regression data mining run that used one of these models and change only its **LR type**, name, and description for the second run.

The alpha value calculated for each response is available for review in the `lr_coefficients.log` file produced by the run. To review this file, go to the Data Mining Runs tab and from the Actions menu for the completed run, select **View Jobs for Run**. On the Jobs for Run page, click the **LR\_<number>\_0** job, then at the bottom of the Job Detail page click **lr\_coefficients.log**.

## Logistic Regression

Logistic regression has long been a standard statistical tool for modeling how the probability of an event (the response) depends on multiple predictors. The estimated coefficients can be interpreted as the logarithm of an odds ratio. Especially for medical applications, where so much of statistical analysis consists of analysis of  $2 \times 2$  frequency tables, the odds ratio, the simple  $ad/bc$  ratio, where (a, b, c, d) are the familiar counts in the  $2 \times 2$  table examining the association of two values, has become a preferred measure of association. The preference for expressing associations in terms of odds ratios developed because the odds ratio is invariant to the choice of sampling plan of a study.

For example, consider a prospective study in which 1,000 patients are either exposed to a drug or not and then followed for signs of an adverse event such as irregular heartbeat. The data might look like this:

	<b>Irregular</b>	<b>Normal</b>	<b>Total</b>
<b>Drug</b>	a=300	b=700	1000
<b>No Drug</b>	c=100	d=900	1000
<b>Total</b>	400	1600	2000

The risk ratio is  $(300/1000)/(100/1000)$ , which equals 3.00.

The odds ratio is  $(300/700)/(100/900)$ , which equals 3.86.

The risk ratio and the odds ratio are both large compared to the null hypothesis value of 1 that would be expected if there were no association between drug and irregular heartbeat. In other words, the probability (chance, risk) of irregular heartbeat is 3.00 times greater for patients taking the drug than for those not taking the drug. The odds (in favor) of irregular heartbeat are 3.86 times greater for patients taking the drug. This corresponds to a conversion between probabilities and odds. If a probability is  $p$ , the odds are  $p/(1-p)$ , or if the odds are  $X:1$  the probability is  $X/(X+1)$ . Thus, odds of 3:1 mean that the probability is  $3/4 = 0.75$  and vice versa.

Consider now a retrospective study that has determined whether or not all those with irregular heartbeat took the drug, involving the same 400 patients as in the above table, but only 400 other patients with normal heartbeat are sampled instead of 1600. Without bias, the results looks like the following table, in which the Irregular column of the table is unchanged, and the counts in the Normal column have been divided by 4.

	<b>Irregular</b>	<b>Normal</b>	<b>Total</b>
<b>Drug</b>	300	175	475
<b>No Drug</b>	100	225	325
<b>Total</b>	400	400	800

The risk ratio is  $(300/475)/(100/325)$ , which equals 2.05.

The odds ratio is  $(300/175)/(100/225)$ , which equals 3.86.

Note that the risk ratio has changed from 3.00 in the first table to 2.05 in the second table, while the odds ratio is unchanged at 3.86 in both tables. The odds ratio as a measure of association is invariant to multiplying either a row or a column of the 2x2 table by a constant. If the risk factor and the adverse event are each rare, then the risk ratio and the odds ratio are almost the same.

Consider the following table, where the Irregular column and the Drug row of the first table above have each been divided by 10 (so that the Irregular-Drug cell is reduced by a factor of  $10 \times 10 = 100$ ).

	<b>Irregular</b>	<b>Normal</b>	<b>Total</b>
<b>Drug</b>	3	70	73
<b>No Drug</b>	10	900	910
<b>Total</b>	13	970	983

The risk ratio is  $(3/73)/(10/910)$ , which equals 3.74.

The odds ratio is  $(3/70)/(10/900)$ , which equals 3.86.

Note that the risk ratio is now quite close to the still unchanged odds ratio of 3.86.

In many instances, a relatively small fraction of the population as a whole is exposed to a risk factor for an adverse event, and a relatively small fraction of the population actually suffers the adverse event. In such cases, you can loosely interpret the odds ratio as if it were a multiplier of the probability of the event rather than a multiplier of the odds of the event, since if  $p$  is small,  $p/(1-p) \sim p$ , so probabilities and odds are about the same. In such a case, even though you might have collected data that misestimates the proportion of those suffering the event by some unknown multiplier, and/or your data over- or under-samples those exposed to the risk by some other unknown factor, the odds ratio in your observed table may be a better estimate of the population risk ratio than the risk ratio computed from your 2x2 table, because the odds ratio is robust to bias in the row and column reporting rates. It is possible for a flawed data collection process to cause an excess frequency in just one cell of a table, without a corresponding increase in the other cell of its row or column. In that case, no measure of association from your data table is able to accurately measure the true association in the population.

### **Estimating odds ratios for multiple risk factors**

It is common to collect data retrospectively when patients have been exposed to multiple risk factors. In such cases, you want obtain a measure of association between an adverse event and each of the risk factors, and separate out the associations with each risk factor. This can be a difficult task, especially when there are many risk factors that occur in multiple combinations across patients. No method of analysis is guaranteed to provide a best solution to this problem and, in fact, there may be no best answer, since interactions among the risk factors can create great ambiguities as to the interpretation of any association measures. However, ignoring such difficulties, the most common approach to this problem is logistic regression, which uses a multifactor analysis to compute a separate odds ratio for each risk factor.

In the ideal application of logistic regression, the odds ratio associated with multiple risk factors is the product of the estimated odds ratios for each of the risk factors being considered. For example, if one risk factor is being over age 65 (odds ratio = 1.5) and another is taking a particular drug (odds ratio = 2.0), then the logistic regression model assumes that the odds of having the adverse event are  $(1.5)(2.0) = 3.0$  times as great for those over 65 who take the drug, compared to those under 65 who do not take the drug. The assumption that every risk factor's association with the adverse event can be summarized in a single odds ratio, and that simply multiplying them can describe the associations of multiple risk factors with the adverse event, is usually an oversimplification. Nevertheless, logistic regression has proven to be a very useful tool for summarizing

associations among multiple risk factors and an event, and for finding those factors that seem to be consistently associated with the event no matter what other factors are present.

A typical logistic regression analysis produces a prediction equation of the form:

$$\log_e[p/(1-p)] = B_0 + B_1(\text{Factor 1}) + B_2(\text{Factor 2}) + B_3(\text{Factor 3}) + B_4(\text{Factor 4})$$

For example:

$$\log_e[p/(1-p)] = -5.0 + 1.1(\text{Age} > 65) + 0.6(\text{Gender Male}) + 0.3(\text{Drug 1}) + 0.8(\text{Drug 2})$$

where  $\log_e[p/(1-p)]$  is the natural log of the odds of observing the adverse event, and the coefficients  $B_0, B_1, \dots$  are estimated from the database. The odds ratios for each factor are the exponentials of the coefficients. Therefore, in this example, the over 65 year age group has an odds ratio of  $e^{1.1} = 3.00$  for the adverse event, males have an odds ratio of  $e^{0.6} = 1.82$ , and users of the two drugs have odds ratios of  $e^{0.3} = 1.35$  and  $e^{0.8} = 2.23$ , respectively. The implicit assumption is that the combined odds ratio would be  $(3.00)(1.82)(1.35)(2.23) = 16.4$  for males over 65 taking both drugs, compared to females under 65 taking neither drug. However, even when these complex associations are not estimated very exactly, the coefficients and their corresponding odds ratios often are good estimates of the relative overall strength of association of each factor with the adverse event. In this example, the association with age is greater than that of gender or of either drug.

Including potentially highly associated covariates in the computation is important, because otherwise the logistic regression might be subject to confounding due to the leftout covariates. For example, assume that (age > 65) was not in the model and that Drug1 was almost exclusively taken by the elderly in the database. In that situation, the estimated coefficient for Drug1 increases, since Drug1 is, in effect, a partial proxy for being elderly. The result might be an odds ratio for Drug 1 estimated to be 2 or 3 rather than the value 1.35 estimated when the variable (age > 65) is in the model, resulting in an inflated estimate of the association of Drug1 with the adverse event.

## Specifying predictors

In general, it is important to include all covariates that might be associated with the adverse event as predictors in the logistic regression equation. For analysis of adverse event databases, Oracle recommends including covariate variables for age groups, gender, and report year, and explicitly including drugs that occur very frequently with the event. Drugs that occur most frequently with the event are, by their very frequency, more likely to be confounded with other drugs of interest in the database, and thereby cause biases if they are left out of the model. The logistic regression user interface makes it easy to enter all drugs in the data that occur more than a set number of times with the response event automatically, up to the defined maximum number of drugs allowed, including the drugs specifically requested.

Covariates must be categorical (stratification) variables having at least  $K > 1$  categories, and every category value ( $K$ ) must have at least one report with the response event present to be included. The covariate category having the most reports across all reports in the analysis is viewed as the standard for the odds ratio of each of the other categories. If there are  $K$  categories for a covariate, there will be  $K-1$  coefficients for that covariate, with a corresponding odds ratio for each coefficient. For example, if the categories for the Gender covariate are M, F, and U (for unknown), and if F is the most common gender category, then the output will only have odds ratios for M and for U. The odds ratio for M is the



estimated reporting odds ratio comparing M to F, and the odds ratio for U is the estimated reporting odds ratio comparing U to F. Selecting the most common category to be used as the standard is arbitrary, but it allows you to interpret an odds ratio of 1 for a category as meaning that the selected category can be pooled with the most frequent category.

The logistic regression analysis provides a standard error for each coefficient that can be used to produce a confidence interval for each coefficient. The 90% confidence interval (CI) is computed as:

$$(\text{estimated coefficient}) \pm 1.645 * (\text{standard error of coefficient})$$

Taking the exponential of the endpoints of the coefficient CI produces a CI for the associated odds ratio. These are then labeled (LR05, LR95) in the logistic regression output tables.

To handle the relatively rare situation in which the most common category of a covariate has no reports with the response event (such as the most common gender category F and the event Prostate cancer), for that response a different category is selected as the most common. The computation does not leave out the gender covariate entirely in these situations as the confounding of gender with drugs taken primarily by one gender would distort the LOR estimates.

Each logistic regression data mining run generates a text file, [lr.log](#), that identifies the most common category found for each covariate. If any events in the run used a different category, the most common category for that event is noted.

### Logistic regression models: standard and extended

Logistic regression (without explicit interaction terms) assumes that odds ratios (OR) are multiplicative in the presence of polypharmacy; that is, logistic regression predicts that a drug with OR=3 combined with a drug with OR=4 produces an OR=3\*4=12 for the event of interest when both drugs are reported together. This simple relation holds for the OR scale but, for the probability scale, the predicted combined effect of risk factors is more complex. When the probabilities of events are in a middle range of 0.2 to 0.8, the joint effect of two risk factors on probabilities (according to standard logistic regression) is more additive than multiplicative.

For example, if the base rate (probability) for an event is 20%, the rate after applying an OR of 3 is 43%; the rate after applying an OR of 4 is 50%; and the rate after applying an OR of 12 is 75%. Compare these three rates to the original rate both as rate differences and as rate ratios:

Base rate = 0.20	Rate difference	Rate ratio_____
Risk factor with OR=3:	.43 - .20 = .23	.43/.20 = 2.15
Risk factor with OR=4:	.50 - .20 = .30	.50/.20 = 2.50
Both factors with OR=12:	.75 - .20 = .55	.75/.20 = 3.75

Thus, the combination of the two risk factors (if the odds ratios multiply) is more nearly additive than multiplicative on the probability scale, since .23 + .30 = .53 is close to .55, whereas 2.15\*2.50 = 5.38 is not as close to 3.75.

On the other hand, suppose the base rate were 0.002, which is more in the range of most adverse event probabilities. In this case, applying odds ratios of 3, 4, and 12 results in probabilities of 0.0060, 0.0079, and 0.0234, respectively. Comparing rate differences to rate ratios in the low base rate example:

Base rate = 0.0020	Rate difference	Rate ratio_____
Risk factor with OR=3:	.0060 - .0020 = .0040	.0060/.0020 = 3.00
Risk factor with OR=4:	.0079 - .0020 = .0059	.0079/.0020 = 3.95
Both factors with OR=12:	.0234 - .0020 = .0214	.0234/.0020 = 11.7

In this case, the effect of both factors is more multiplicative than additive on the probability scale, since  $.0040 + .0059 = .0099$  is not as close to  $.0214$ , whereas  $3.00 * 3.95 = 11.85$  is close to  $11.7$ .

In summary, logistic regression makes the following assumptions: the joint risk of two risk factors is nearly additive on the probability scale if the base rate is relatively large (e.g., about 0.2), but is nearly multiplicative if the base rate is very small (e.g., about 0.002). When modeling spontaneous reports, you are considering relative reporting ratios in a database of reports rather than risk. The question remains, which is more likely to fit spontaneous report ratios better? an additive model or a multiplicative model? Since most individual adverse events occur in a very small proportion of spontaneous reports, applying standard logistic regression fits the data well if the multiplicative model is approximately true.

To allow for the possibility that a nearly additive model for spontaneous report ratios might fit better than a nearly multiplicative model, the Empirica Signal application provides an alternative model called extended logistic regression. This family of models has a parameter, denoted  $\alpha$  (alpha), that specifies the region of near-additivity to be centered at an arbitrary base rate. If  $\alpha = 0.5$ , then extended logistic regression reduces to standard logistic regression. If you select the extended option, then the system performs an estimation of the best coefficients for each of many values of  $\alpha$ , and selects the value of  $\alpha$  that gives the best fit to the observed data.

If the estimated value of  $\alpha$  is near 0.5, this means that the standard logistic regression fits the data (that is, predicts the presence or absence of the response for individual reports) about as well as the extended logistic model. In practice, if the estimate of  $\alpha$  is between 0.4 and 0.6, then the odds ratio estimates for individual predictors is close to the corresponding estimates for standard logistic regression. In such a case, for simplicity in explaining your methodology to someone unfamiliar with extended LR, use the standard LR estimates. Another approach to choosing between standard and extended LR is to compare the difference ( $\alpha - 0.5$ ) to the standard error of  $\alpha$ . You can compute:

$$(Z\text{-score for } \alpha) = (\alpha - 0.5) / (\text{standard error of } \alpha)$$

If the Z-score is less than -3 or greater than +3, there is strong statistical evidence that extended LR fits the data better than standard LR.

The estimates of  $\alpha$  and their standard errors (separate estimates for each response value in the run) can be found in the [Logistic regression coefficients log file](#) (lr\_coefficients.log) that is produced for each logistic regression data mining run.

It is difficult to say in advance whether extended LR fits any particular data much better than standard LR. Different response events give different choices. It takes more computation time to find the best fitting  $\alpha$ , so, if you want to get quicker answers for hundreds or thousands of response events, selecting standard LR accomplish that. But, in most situations, the estimation and examination of the values of  $\alpha$  and its standard errors, using extended LR, are recommended. If the data being used in the LR is voluminous, the standard error of  $\alpha$  may be very small; perhaps just 0.01 or even smaller. Then, even if  $\alpha$  is near 0.5, there may be strong evidence that it is not exactly 0.5. For example, if  $\alpha = 0.41$ , standard error = 0.005, then the Z-score is 18, but the individual estimated odds ratios do not differ much from those of standard LR.

Two caveats apply to this model selection problem. First, even if one model fits the spontaneous reports better, there is still no guarantee that the resulting estimated odds ratios for each drug are valid estimates of the prospective risk to takers of the drug of an adverse reaction. Second, even in terms of fit to the relative reporting ratios, the better fitting model is not necessarily a perfect guide to which of the many drugs in the regression model are truly significant. If there are 100 drugs in the model, it may be that extended logistic regression fits better than standard logistic regression because it models the polytherapy effects involving 80 of the drugs better, while modeling those involving the other 20 drugs worse. That is, many of the drugs may combine in their effects additively, while others combine multiplicatively (or, in some more complicated combining formula), so that neither model can estimate the effects of every drug reliably. As statisticians often say, "no model is perfect, but many are useful."

The extended model is technically described as a binomial regression with a different link function. Suppose that  $z = B_0 + B_1X_1 + B_2X_2 + \dots$  is the linear combination used for prediction, where the Bs are coefficients and the Xs are predictors. The standard logistic regression defines the probability of event occurrence as  $p(z)$ , where:

$$p(z) = 1/(1 + \exp(-z))$$

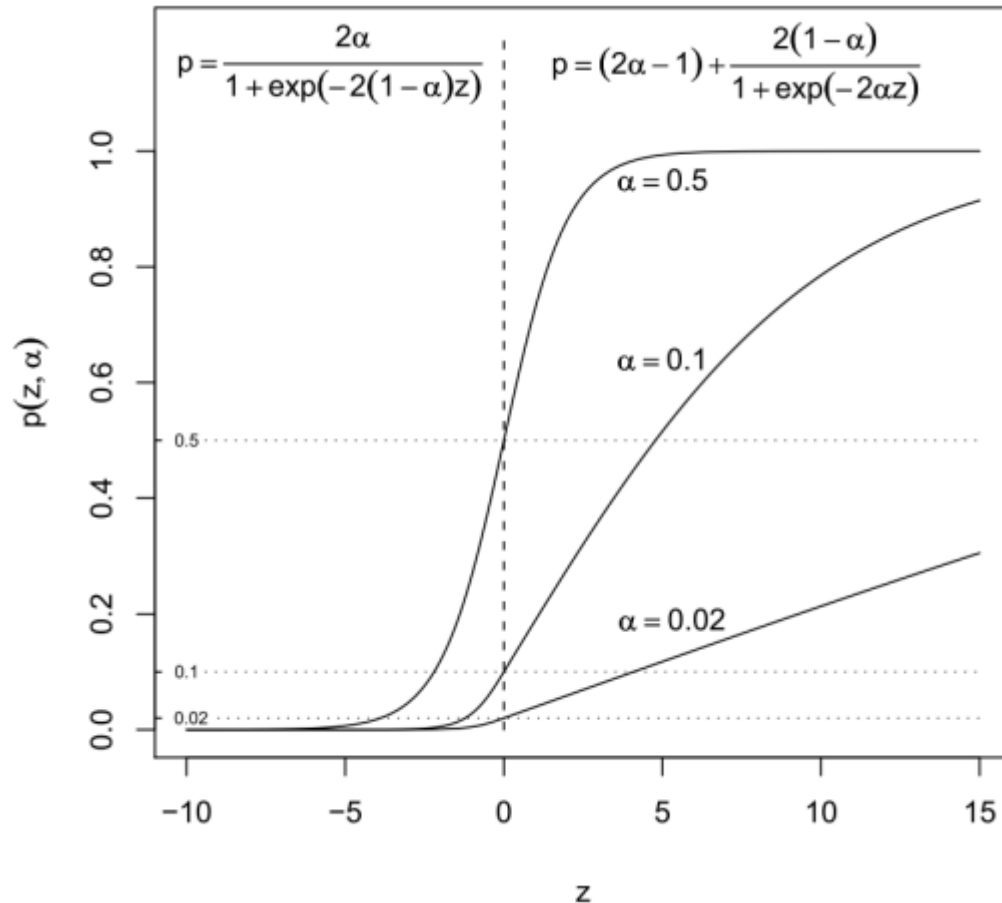
Extended logistic regression uses the formula:

$$p(z, \alpha) = 2\alpha / [1 + \exp(-2(1 - \alpha)z)] \quad \text{for } z \leq 0$$

$$p(z, \alpha) = 2\alpha - 1 + 2(1-\alpha) / [1 + \exp(-2\alpha z)] \quad \text{for } z \geq 0$$

Note that  $p(z, \alpha)$  reduces to  $p(z)$  when  $\alpha = 1/2$ . Also,  $p(z, \alpha)$  and its first two derivatives with respect to  $z$ ,  $p'(z, \alpha)$  and  $p''(z, \alpha)$ , are each continuous, and, evaluated at  $z=0$ , for every  $\alpha$ ,  $p(0; \alpha) = \alpha$ ,  $p'(0; \alpha) = \alpha(1-\alpha)$ , and  $p''(0; \alpha) = 0$ .

A two-dimensional plot of the probability distribution function of the extended logistic regression computation follows:



For a predictor  $X$  whose standard LR coefficient is  $B$ , the odds ratio comparing the probabilities of the event at  $X = 0$  versus  $X = 1$  is  $OR = e^B$ . In the case of extended logistic regression with estimated link parameter  $\alpha$ , the odds ratio is defined as:

$$OR = \frac{p(z_0 + B, \alpha)}{p(z_0, \alpha)} \frac{1 - p(z_0, \alpha)}{1 - p(z_0 + B, \alpha)}$$

Where  $p_0 = (\# \text{ response events}) / (\# \text{ Reports})$  [proportion of reports with the response event] and  $z_0$  is the solution to the equation  $p(z_0 + B, \alpha) = p_0$ .

This formula for OR reduces to  $e^B$  when  $\alpha = 1/2$ . The 90% confidence intervals for OR are computed by replacing  $B$  in the above formula by  $B \pm 1.645 \cdot \text{standard error}(B)$ , analogous to the procedure for standard logistic regression.

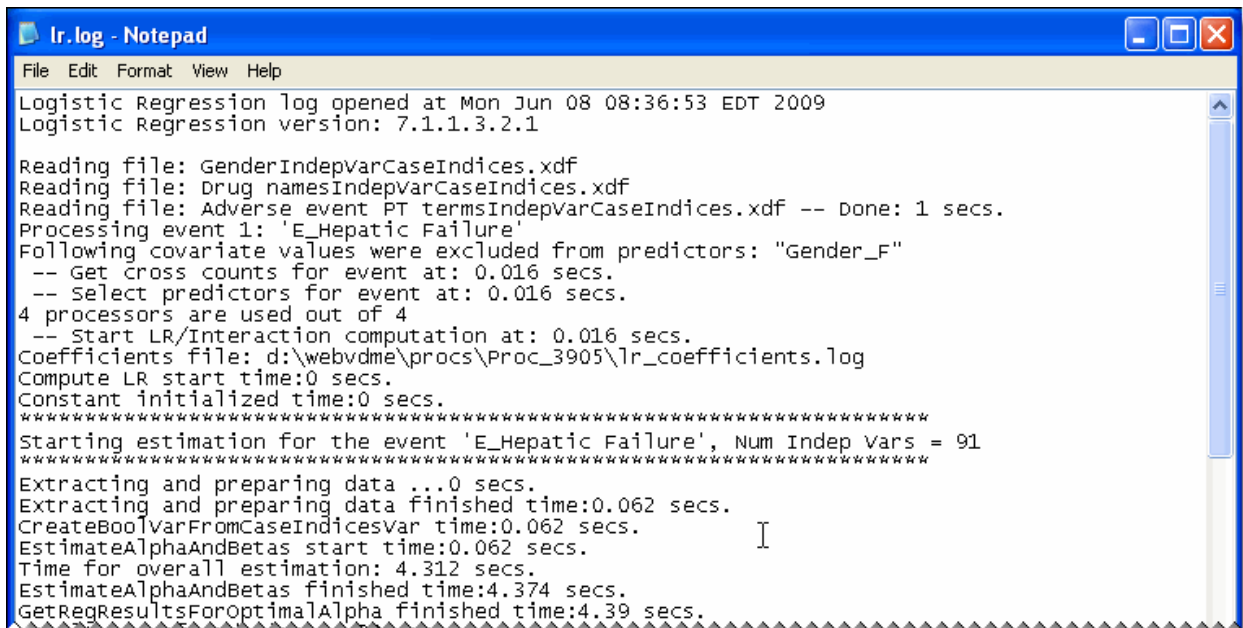
Each logistic regression data mining run generates a tab-delimited [log file](#), `lr_coefficients.log`, with the alpha value computed for each response and its standard error. When you [define options](#) for the run, you can check **Save coefficients** to include the coefficient and standard error calculated for each predictor and response in this log.

For more information about logistic regression, see any intermediate-level statistics or biostatistics textbook, such as *Statistical Methods in Epidemiology* by HA Kahn and CT Sempos, Oxford U Press, 1989.

## Logistic regression log files

Logistic regression data mining runs produce log files to provide information on run processing. These text files are available for download on the [Job Detail page](#) for the LR job in the run.

The lr.log file identifies the most frequently occurring value for each covariate variable in the run, such as the value F for the Gender variable. The value that occurs most frequently is determined based on all reports in the analysis. If any of the events in the run were not reported in combination with the most frequently occurring value for a covariate, the application notes the value used in its place for that event.



```

lr.log - Notepad
File Edit Format View Help
Logistic Regression log opened at Mon Jun 08 08:36:53 EDT 2009
Logistic Regression version: 7.1.1.3.2.1

Reading file: GenderIndepvarCaseIndices.xdf
Reading file: Drug namesIndepvarCaseIndices.xdf
Reading file: Adverse event PT termsIndepvarCaseIndices.xdf -- Done: 1 secs.
Processing event 1: 'E_Hepatic Failure'
Following covariate values were excluded from predictors: "Gender_F"
-- Get cross counts for event at: 0.016 secs.
-- select predictors for event at: 0.016 secs.
4 processors are used out of 4
-- Start LR/Interaction computation at: 0.016 secs.
Coefficients file: d:\webvdme\procs\Proc_3905\lr_coefficients.log
Compute LR start time:0 secs.
Constant initialized time:0 secs.
*****
Starting estimation for the event 'E_Hepatic Failure', Num Indep Vars = 91
*****
Extracting and preparing data ...0 secs.
Extracting and preparing data finished time:0.062 secs.
CreateBoolVarFromCaseIndicesVar time:0.062 secs.
EstimateAlphaAndBetas start time:0.062 secs.
Time for overall estimation: 4.312 secs.
EstimateAlphaAndBetas finished time:4.374 secs.
GetRegResultsForOptimalAlpha finished time:4.39 secs.
  
```

The lr.log file also provides information on convergence for each response and, if necessary, the reason that an event specified for the run was not included in the computation.

The lr\_coefficients.log file contains the best alpha value computed for each response in an extended logistic regression data mining run. For standard logistic regression runs, the value 0.5 is always used as the alpha.

When you [define the run options](#) for a logistic regression data mining run, if you check **Save coefficients**, the application includes coefficient and standard error values computed for each predictor and response in the run in this file.

The following example shows the first few rows in an lr\_coefficients.log file that has been downloaded and opened in Microsoft Excel:

A	B	C	D	E
ROW_NUM	Predictor	Response	Coeff	Std Error
	<Alpha>	Hepatic Failure	0.00949967	0.0420202
1	<Intercept>	Hepatic Failure	-1.0337	0.0520001
2	M	Hepatic Failure	0.2783	0.0651565
3	U	Hepatic Failure	0.0270971	0.122427
4	ABACAVIR	Hepatic Failure	-1.08111	0.540372
5	ACETAMINOPHEN	Hepatic Failure	1.35481	0.182878
6	ACYCLOVIR	Hepatic Failure	0.35271	0.472137

Note that the value of  $B_0$  is labeled <Intercept> in the Predictor column, and the value of  $\alpha$  is labeled in that column. The computed value of  $\alpha$  appears in the Coeff column.

For more information on logistic regression, see [Logistic regression computations](#).

## Selecting variables for logistic regression

After you have specified that you want to perform a logistic regression run and selected the LR type and a [data configuration](#), you select the drug (predictor) and event (response) variables to use in the run. You also have the option to select one or more variables as covariates (additional predictors).

1. On the Select Variables page, click one variable in the **Event variable** list and one variable in the **Drug variable** list.

Available variables are those that are defined as event variables or drug variables in the [data configuration](#), and that do not have associated [data transformations](#).

---

**Note:** To treat combination drugs as if the subject had taken separate drugs, select a variable, such as Single Ingredient, as the drug variable.

---

2. You can also select one or more variables in the **Additional covariates** list. Available variables are those that are defined as [stratification variables](#) in the data configuration, and that do not have associated data transformations. (To identify a variable as a stratification variable, edit the variable in the [data configuration](#).)

Typically, a logistic regression run includes one or more additional covariates as predictors. Otherwise, the logistic regression can be subject to confounding due to potentially highly associated covariates being left out. Recommended covariates for an AERS-based configuration include the AgeGroup4, Gender, and Subset\_Year variables.

To select one variable, click its name. To select multiple variables as covariates:

- Select multiple non-contiguous variables by holding down the Ctrl key while clicking each variable.
- Select multiple contiguous variables by clicking a variable, holding down the Shift key, and clicking another variable. Variables between and including those variables are selected.
- To deselect a variable, hold down the Ctrl key while clicking the variable.

---

**Note:** AERS data includes the variables STANDARD\_STRATA and STANDARD\_STRATA\_INIT. These variables are not available as covariates in logistic regression runs.

---

3. To set up a [custom term](#) for this data mining run, check **Define custom terms**.

4. Click **Next**.

The Select Events page appears.

5. Continue by [selecting event values](#). If you checked **Define Custom Terms**, the [Define Custom Terms page](#) appears first.

## Selecting events for logistic regression

When defining a logistic regression run, you specify values (that is, responses) for the event variable that you are investigating with the run on the Select Event Values page. The application computes separate results for each specified event value.

The run computes values for an event only if it finds a sufficient number of reports. Results are not produced for an event if either of the following situations exists:

- For all drugs explicitly included in the run no reports are found with the event and, in addition, the drugs that do occur in combination with the event most frequently do not meet the specified minimum number of occurrences for inclusion. (For more information on specifying drug values see [Specifying drugs for logistic regression.](#))
- For the covariate variables selected for the run, the number of reports that include the event and each of the possible covariate values averages less than 10. This is determined as follows:
  - $10 * \text{the total number of possible values for all covariate variables that occur with this event} > \text{count of reports for the event.}$

If an event is specified for the run but results are not produced, one of these reasons appears in the [lr.log file](#) produced for the run.

If you specify a single event and that event is not found in the data used in the run, the run fails and an error appears on the Jobs for Run page. If you specify multiple events and any one of them is not found, the run fails and a message appears in the error log. You can access the lr.log and the error log from the [Job Detail page](#).

Typically, logistic regression data mining runs do not include every possible drug+event combination. Instead, they are generally used to focus on specific medically related adverse events (response values) and drugs of interest (predictors). For some investigations, you may wish to compute scores for all adverse events in the selected data configuration (after database restrictions are applied).

---

**Note:** When selecting events, keep in mind that there is a logistic regression computation for each response value. The more events you select as responses, the longer the LR run takes

---

- To select individual event terms from the [hierarchy browser](#), click **Select <hierarchy> Terms.**

This option appears if your [user preference](#), **Enable Adverse Event Hierarchy Browser**, is checked. (For more information, see [Drug and event hierarchies.](#))

or

To [select values from a list](#), click **Select Available Values.**

or

To refer to a [saved list](#) of terms, including custom terms, click **Select Saved List.**



If you created a custom term for the event variable in the run, the application includes it by default in the list of selected event values. If you remove it, the custom term is not be included in run results.

- To include all of the events in the configuration in your run, select the **Select all available values** check box.

Click **Next** to open the Select Drugs page, and continue with [specifying drug values](#).

## Specifying drugs for logistic regression

For a logistic regression run, you define the number of predictor values (that is, how many drugs) to include in computations for each of the events you select for the run. You also define the minimum number of reports in which a selected event must occur in combination with a drug for that drug to be included. Optionally, you can supply a list of drug values to include in the run.

Using these values, the Empirica Signal application determines what drugs to include for each event in the run, including any explicitly specified drug values and selecting additional drugs that occur in combination with each run event frequently, based on the defined total number of drugs and the minimum number of occurrences.

- If you explicitly specify fewer drug values than the defined total number, the application finds additional drugs in the configuration to make up the difference. The application uses the defined minimum to limit the possible set of drugs to include in the run to those found most frequently in combination with each of the selected run events. For each event, only drugs found in combination at least that number of times are included.
- Each of the drug values that you explicitly supply are included in the run, even if they do not meet the specified minimum for a given run event. (However, the drug+event combination must occur at least once to be included.) If you supply more drug values than the defined total number to include in the run, the Empirica Signal application orders the drug values alphabetically and includes only the first <total number> from the list.

For example, assume that you specified a single event, Rash, for the logistic regression run. You keep the default, 10, as the minimum number of cases in which the drugs must occur, and you explicitly include DrugD. With the following drugs in the data configuration, and occurrences of Rash and each drug, the run computes scores for Rash and the shaded drugs only:

<b>Drug</b>	<b>Number of Cases in which Drug Occurs in Combination with Rash</b>
DrugA	11
DrugB	10
DrugC	5
DrugD	1
DrugE	0

Oracle recommends that you include drugs that occur most frequently with an event, as computational biases can result if they are left out. For more information, see [Logistic regression computations](#).

1. On the Select Drugs page, enter the minimum number of cases in which a drug must occur in combination with an event to be included in the logistic regression run. This minimum must be 5 or greater. The default is 10.

2. Enter the maximum number of drugs to include in the run. The default is 100.

---

**Note:** When defining the number of drugs, keep in mind that the run computes a logistic regression for each predictor value. The more drugs you include as predictors, the longer the LR run takes.

---

3. You can also specify drugs of interest to include in the run (even if the number of reports with both the event and the drug is less than the minimum specified, but greater than 0).

To select event terms from the [hierarchy browser](#), click **Select <hierarchy> Terms**.

This option appears if your [user preference](#), **Enable Adverse Event Hierarchy Browser**, is checked. (For more information, see [Drug and event hierarchies](#).)

or

To [select values from a list](#), click **Select Available Values**.

or

To refer to a [saved list](#) of terms, including custom terms, click **Select Saved List**.

or

To [look up a drug name](#), click **Trade/Generic Lookup**. You can find the generic name for a drug (if you only know its trade name) or vice versa. (This link is available if the data configuration's source data included trade name-generic name mapping.)

If you created a [custom term](#), it is included by default in this list of specified drug values. If you remove it from this list, your custom term is not be included in run results.

4. To include the computation of interaction scores in the logistic regression run, check **Compute interactions**.

When an analysis of predictor interactions is requested, the Empirica Signal application generates a [table](#) that has a row for every possible triple of the form (item1, item2, response), where each item can be either a drug or a covariate category that is in the model specification for the particular response.

The purpose of each row of the table is to examine the count, N, of times the response event was present across all cases where both item1 and item2 are present, and to compare it to the predicted count, E, for those cases that has been estimated by the standard or extended logistic regression computation for that response. The table enables you to compare the observed and fitted response frequencies when both items are present against the individual LROR values for each of the two predictor items.

5. Click **Next**.

The Run Options page appears.

6. Continue to [define run options](#).

---

**Note:** Run size varies depending on the parameters you define. A message displays if your specifications will result in a very large run. You can reduce the number of drugs to include in the run on this page, or click Back to reduce the number of events to include.

---

## Viewing interactions

Each row in the table presents two predictor values, which appear in the columns labeled Item1 and Item2, and a response, which appears in the column labeled for the selected event variable, such as PT.

---

**Note:** You can also include columns in the table that indicate the type of variable selected: the P\_Item1 and P\_Item2 columns contain either D, to indicate the drug variable, or the name of a covariate variable.


---

The scores appearing for each predictor1+predictor2+response combination include LROR1 (LROR for predictor1+response) and LROR2 (LROR for predictor2+response), which are repeated from the main results table. They reappear in the interactions table as a reminder of the individual predictor disproportionalities with the response.

The table displays the following information:

- **N\_TOT**—The total number of times the pair of predictor items appeared together, irrespective of the responses.
- **INT\_LOF (lack of fit interaction ratio)**— A Bayesian “shrunk” version of N/E. For example, if INT\_LOF = 2, then the response seems to be appearing with this pair of predictor items 2 times as frequently as the standard or extended logistic regression model formula indicates. That is, the model doesn’t “fit” well when these items are both present.
- **INT\_REGR**—Compares the standard or extended logistic regression expected adverse event frequency when both items are present to the expected frequency when only the item (of the two) having the larger LROR is present. That is, if INT\_REGR = 2, then the regression model predicts that the response is 2 times as likely when both items are present than when just the more associated item is present.
- **INT\_TOT = INT\_REGR x INT\_LOF**—Shows the combined relative effect of having both items present versus having the more associated item present.

## Defining data mining run options

1. On the Run Options page, specify when to perform the run.
  - To perform the run right away, click **Run as soon as possible**.
  - To schedule the run for a future date or time, click **Do not run until** and enter a date in mm/dd/yyyy format, or click  to display a calendar and select a date. Also enter a time in hh:mm:ss am/pm format. The scheduled date and time appear on the [Jobs for Run page](#) that you can access from the Data Mining Runs tab.

For example, you may wish to schedule an MGPS run that has a highest dimension of 3, or a logistic regression that includes all events, so that it begins after the normal workday is over and the computational time required is less likely to affect other requests.

2. To receive email notification when the run is complete (as successful or failed), check **Email me when complete** and specify one or more email addresses (separated by commas). By default, the address (or addresses) associated with your Empirica Signal username appears. If you want to change the address that is associated with your username, see your site administrator.
3. If you are assigned the Save Intermediate Files permission, a **Save intermediate data files** check box appears. Check this option to save Intermediate data files produced during a data mining run, including files such as item dictionaries and count files. If you save intermediate data files, you can view or download them from the [Jobs for Run page](#). These files may be useful in understanding the processing that occurred or in troubleshooting errors.
4. For a logistic regression run, check **Save coefficients** to include the coefficient and standard error values computed for each predictor+response combination in the run in the lr\_coefficients.log file. You can view or download this tab-delimited text file by viewing [jobs for the run](#).

For more information, see [Logistic regression coefficients log file](#).

5. Click **Next**.
6. Continue with [naming the run](#).

---

**Note:** Information you provide on the Run Options page applies to the current session only. The next time you log in to Empirica Signal, run options are reset to the defaults.

---

## Naming a data mining run

After you [define run options](#) you name the data mining run.

1. In the **Run name** field, type the name of the run. The name does not need to be unique, although Oracle recommends that you use a unique name.  
  
The Empirica Signal application assigns a unique run ID to each run.
2. In the **Description** field, enter a description of the run. Oracle recommends that you provide an informative description of the run so that users who view run results know which run to use.
3. Assign the run to a [project](#).
  - To assign the run to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.
  - To create a new project and assign the run to it, click **Add to a new project named** and enter a project name.
4. Click **Next**.
5. Continue with [submitting the run](#).

## Submitting a data mining run

After [naming a data mining run](#) that you are creating, you confirm run parameters and submit the run.

1. On the Confirm Run Parameters page, review the parameters chosen for your run to make sure that they are correct. Different parameters display for [MGPS runs](#) and [LR runs](#).
2. To change any parameters, click **Back** until you are on the appropriate page and make the necessary changes. Then click **Next** until you are back on the Confirm Run Parameters page

3. When you are satisfied with the run parameters, click **Submit**.

The application notes that the run has been submitted.

4. Click **Continue**.

The run status appears on the Data Mining Runs page. To monitor the progress of a run, you can [view jobs for the run](#).

All data mining runs are batch jobs, which continue to run on the Empirica Signal server even if you log out of the application. The next time you log in to the Empirica Signal application, you can check on the Data Mining Runs tab to determine if your run has completed. If you selected the **Email me when complete** run option, the application notifies you by email when your run completes.

### MGPS run parameters

Field	Description
Type	MGPS.
Name	Name supplied for the run.
Description	Description supplied for the run.
Project	The name of the project to which the run is assigned.
Configuration	Name of the <a href="#">data configuration</a> used for the run.
Configuration description	Description of the data configuration used for the run.
As of date	<a href="#">As Of date</a> for the run, if the run is for <a href="#">timestamped data</a> .
Database restriction	<a href="#">Database restriction</a> , if any, associated with the run.



Item variables	Names of the <a href="#">item variables</a> to be used in the run.
Drug Hierarchy	The name and version of the drug hierarchy used by this run if the data configuration specifies a drug hierarchy.
Event Hierarchy	The name and version of the event hierarchy used by this run if the data configuration specifies an event hierarchy.
Custom terms	<a href="#">Custom terms</a> , if any, specified for the run.
Stratification variables	<a href="#">Stratification variables</a> , if any, to be used for the run.
Subsets	<a href="#">Subset variable</a> , if any, as well as whether the subsets are cumulative, the order of subsets, and the subset labels and values.
Highest dimension	The maximum number of ways in which items are combined. See <a href="#">Specifying data mining parameters</a> .
Minimum count	Minimum number of cases in which a combination of items must occur in order for the combination to be included in the run's MGPS computations. See <a href="#">Specifying data mining parameters</a> .
Calculate PRR	Indicates whether <a href="#">PRR computations</a> are included in the run.
Calculate ROR	Indicates whether <a href="#">ROR computations</a> are included in the run.
Base counts on cases	For a run that includes PRR and ROR computations, indicates if counts are based on cases rather than drug-event combinations.
Use "all drugs" comparator	For a run that includes PRR computations, indicates whether the drug of interest are included in the comparator set.
Apply Yates correction	For a run that includes PRR computations, indicates whether the Yates correction is applied.
Stratify PRR and ROR	For a run that includes PRR and ROR computations, indicates whether the PRR or ROR computations are stratified.
Fill in hierarchy values	Indicates whether the <a href="#">run option</a> to use hierarchy information was checked.
Limit results to	Limitations, if any, on which results will be kept based on statistical thresholds or specified values of item variables. See <a href="#">Specifying data mining parameters</a> .
Exclude single itemtypes	Indicates whether the run excludes combinations of items of the same type. See <a href="#">Specifying data mining parameters</a> .
Fit separate distributions	Indicates the run's setting for the advanced parameter to fit separate distributions for the different item type combinations.

Save intermediate files	Indicates whether intermediate processing files for the run are saved. See <a href="#">Defining data mining run options</a> .
Source database	Information about the source data (from the <a href="#">source description table</a> ).
Scheduled to run	Date and time at which the run is scheduled to be run. See <a href="#">Defining data mining run options</a> .


### Logistic regression run parameters

Field	Description
Type	LR. For runs completed prior to the installation of Empirica Signal version 7.1, LR (Legacy) appears.
Name	Name supplied for the run.
Description	Description supplied for the run.
Project	The name of the project to which the run is assigned.
LR type	Indicates the algorithm type selected for the run: standard or extended. See <a href="#">Logistic regression computations</a> . For runs completed prior to the installation of Empirica Signal version 7.1, an Extended logistic regression field appears instead, with a Yes or No value.
Configuration	Name of the <a href="#">data configuration</a> used for the run.
Configuration description	Description of the configuration used for the run.
As of date	<a href="#">As Of date</a> for the run, if the run is for <a href="#">timestamped data</a> .
Database restriction	<a href="#">Database restriction</a> , if any, associated with the run.
Item variables	Names of the run's selected <a href="#">event and drug variables</a> .
Custom terms	<a href="#">Custom terms</a> , if any, specified for the run.
Covariates	Variables, if any, selected as <a href="#">covariates</a> for the run.
Drug values	Explicitly specified values of the drug variable included in the run, even if they do not meet the minimum number of times a drug must occur in combination with specified events.
Event values	Values of the event variable used in the run.

Minimum count	Minimum number of cases in which a drug must occur in combination with specified events in order to be included in the run (except for drugs specifically selected as Drug values). See <a href="#">Selecting drugs for logistic regression</a> .
Number of events	Number of event values specified.
Save intermediate files	Indicates whether intermediate processing files for the run are saved. See <a href="#">Defining data mining run options</a> .
Run interactions	Indicates whether the run calculates statistics for two predictors (such as drug+drug or drug+covariate) and a response.
Save coefficients	Indicates whether the lr_coefficients.log file produced for the run include the coefficient and standard deviation values calculated for the run.
Source database	Information about the source data (from the <a href="#">source description table</a> ).
Scheduled to run	Date and time at which the run is scheduled to be run. See <a href="#">Defining data mining run options</a> .



## Managing data mining runs

### Renaming a data mining run

1. Click the **Data Mining Runs** tab.  
The Data Mining Runs page appears.
2. Select the row menu () for the run and click **Rename**.  
The Rename Run page appears.
3. In the **Run name** field, enter a new name for the run. The name does not need to be unique, although Oracle recommends that you use a unique name.
4. In the **Description** field, enter a new description. Oracle recommends that you provide an informative description of the run so that users who view run results know which run to use.
5. Assign the run to a [project](#).
  - To assign the run to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.
  - To create a new project and assign the run to it, click **Add to a new project named** and enter a project name.
6. Click **OK**.

## Viewing details of a data mining run

You can view run details in any of the following ways:

- On the [Data Mining Runs page](#), click  for a run, and then click **View Run Details**.
- On the [Select Criteria page](#) for run results, click **View Run Details** for the selected run.
- On the [Jobs for Run page](#), click **View Run Details**.
- On the [Select Run page](#), click  for a run, and then click **View Run Details**.

Different information appears for [MGPS runs](#) and [LR runs](#).

### MGPS runs

The Detail for Run dialog box provides the following information about an MGPS run:

Field	Description
ID	Automatically assigned, unique numeric identifier of the run.
Type	MGPS.
Name	Name supplied for the run.
Description	Description supplied for the run.
Project	The name of the <a href="#">project</a> to which the run is assigned.
Configuration	Name of the <a href="#">data configuration</a> used for the run.
Configuration description	Description of the configuration used for the run.
As of date	<a href="#">As Of date</a> for the run, if the run is for <a href="#">timestamped data</a> .
Database restriction	<a href="#">Database restriction</a> , if any, associated with the run.
Item variables	Names of the <a href="#">item variables</a> used in the run.
Custom terms	<a href="#">Custom terms</a> , if any, specified for the run.
Stratification variables	<a href="#">Stratification variables</a> , if any, used for the run.
Subsets	<a href="#">Subset variable</a> , if any, as well as whether the subsets are cumulative, the order of subsets (if cumulative), and the subset labels and values.

Drug Hierarchy	If the data configuration specifies a drug hierarchy, the name and version of the drug hierarchy used by this run.
Event Hierarchy	If the data configuration specifies an event hierarchy, the name and version of the event hierarchy used by this run.
Highest dimension	The maximum number of ways in which items are combined. See <a href="#">Specifying data mining parameters</a> .
Minimum count	Minimum number of cases in which a combination of items must occur for the combination to be included in the MGPS computations for the run. See <a href="#">Specifying data mining parameters</a> .
Calculate PRR	Whether or not the run includes <a href="#">PRR computations</a> .
Calculate ROR	Whether or not the run includes <a href="#">ROR computations</a> .
Base counts on cases	For a run that includes PRR and ROR computations, indicates if counts are based on cases rather than drug-event combinations.
Use "all drugs" comparator	For a run that includes PRR computations, whether or not the comparator set includes the drug of interest.
Apply Yates correction	For a run that includes PRR computations, whether or not the Yates correction is applied.
Stratify PRR and ROR	For a run that includes PRR and ROR computations, whether or not the PRR or ROR computations are stratified.
Fill in hierarchy values	Indicates whether the <a href="#">run option</a> to use hierarchy information was checked.
Limit results to	Limitations on which results are kept based on statistical thresholds or specified values of item variables. See <a href="#">Specifying data mining parameters</a> .
Exclude single itemtypes	Indicates whether combinations of items of the same type were excluded from run results. See <a href="#">Specifying data mining parameters</a> .
Fit separate distributions	Indicates the setting for the advanced parameter to fit separate distributions for the different item type combinations.
Save intermediate files	Whether or not intermediate processing files for the run were saved. See <a href="#">Defining data mining run options</a> .
Created by	Name of the user who created the run.
Created on	Date and time at which the run was submitted.
User	Your username (name of the user who is viewing run details).

Source database Information about the source data (from the [source description table](#)).

---

## Logistic regression runs

The Detail for Run dialog box provides the following information about a logistic regression run:


Field	Description
ID	Automatically assigned, unique numeric identifier of the run.
Type	LR. For runs completed prior to the installation of Empirica Signal version 7.1, LR (Legacy) appears.
Name	Name supplied for the run.
Description	Description supplied for the run.
Project	The name of the <a href="#">project</a> to which the run is assigned.
LR type	The logistic regression used for the run, either <a href="#">extended or standard</a> .
Configuration	Name of the <a href="#">data configuration</a> used for the run.
Configuration description	Description of the data configuration used for the run.
As of date	If the run is for <a href="#">timestamped data</a> , <a href="#">As Of date</a> for the run.
Database restriction	<a href="#">Database restriction</a> , if any, associated with the run.
Item variables	Names of the selected <a href="#">event and drug variables</a> .
Custom terms	<a href="#">Custom terms</a> , if any, specified for the run.
Covariates	Variables, if any, selected as <a href="#">covariates</a> for the run.
Drug values	Explicitly specified values of the drug variable included in the run, even if they do not meet the minimum number of times a drug must occur in combination with specified events.
Event values	Values of the event variable used in the run.
Minimum count	Minimum number of cases in which a drug must occur in combination with specified events to be included in the run (except for drugs explicitly specified as Drug values). See <a href="#">Specifying drugs for logistic regression</a> .

Run interactions	Whether or not the run calculates statistics for two predictors (such as drug+drug or drug+covariate) and a response.
Save coefficients	Whether or not the lr_coefficients.log file produced for the run includes the coefficient and standard deviation values calculated for the run.
Save intermediate files	Whether or not intermediate processing files for the run were saved. See <a href="#">Defining data mining run options</a> .
Created by	Name of the user who created the run.
Created on	Date and time at which the run was submitted.
User	Your username (name of the user who is viewing run details).
Source database	Information about the source data (from the <a href="#">source description table</a> ).



## Viewing jobs for a data mining run

The Jobs for Run page presents information about the batch jobs that make up a run and provides access to input and output files for the jobs. The name and owner of the run appears at the top of the page. If a run is scheduled for future processing, the scheduled date and time appear.

- For runs that are in progress, this page refreshes automatically until the run completes successfully or an error causes a job to fail.
  - As the jobs in a run are performed, the Status column indicates Completed or displays the error that caused that job to fail. If any of the jobs in a run fail, the status of the run is Error Occurred.
1. On the [Data Mining Runs page](#), click the row menu () for a run, and then click **View Jobs for Run**.

The Jobs for Run page appears. The Jobs for Run page provides the following information about each job:

Column	Description
ID	Automatically assigned unique ID of the job. IDs of deleted runs are not re-used.
Name	<p>The name of each job, including a descriptor followed by the number of the run. The jobs included in the run differ for MGPS and LR runs, as follows.</p> <p>An <a href="#">MGPS run</a> includes the following jobs:</p> <ul style="list-style-type: none"> <li>• extract—Extracts data from the source database. The run ID follows the job name.</li> <li>• mgps—Applies the MGPS algorithm to the extracted data to produce scores. The run ID and 0 follow the job name.</li> <li>• Post_Process—Creates unique value tables for the drugs and events that appear in the run results (for use by the results table) and adds column indexes to the output table. There is only one post-process job. The run ID and 0 follow the job name.</li> </ul> <p>A <a href="#">logistic regression run</a> includes the following jobs:</p> <ul style="list-style-type: none"> <li>• LR_extract—Extracts data from the source database. The run ID follows the job name.</li> <li>• LR—Calculates logistic regression scores. The run ID and 0 follow the job name. Click the name of this job to download the <a href="#">log files</a>. These include the tab-delimited lr_coefficients.log file, which contains alpha values computed for every event in an Extended LR run; and, if selected as a <a href="#">run option</a>, the coefficients and standard errors for each predictor+response combination; and the lr.log file, which lists the most common values found for run covariates and summarizes convergence for each response.</li> <li>• LR_Post_Process—Creates unique value tables for the drugs and events that appear in the run results (for use by the results table)</li> </ul>

and adds column indexes to the output table. There is only one post-process job. The run ID and 0 follow the job name.


Description	The text, <b>Part of Run</b> , followed by the run ID.
Server	The value, <b>Any</b> , appears if the next available listener can perform the job. If multiple listeners are in use and the MGPS or logistic regression run is submitted externally using a <a href="#">run definition file</a> , a listener can be specified to perform each job and the unique ID of the listener appears.
Created	Server date and time when the extraction or base job was created. For a run that is scheduled and may be queued for processing after other runs, the creation of the extraction or base job may be substantially later than the creation date of the run itself.
Start Date	Server date and time when the job was started.  Note: Once an extraction completes, there is internal preparation of the extraction for the mgps or LR job. If you submit two runs, it is possible for the extraction job of the second run to start before the mgps or LR job of the first run.
End Date	Server date and time when the job ended.
Runnable	The value remains NO for each job until the preceding job is complete; then the value becomes YES.
Status	The column remains empty until the job has completed or failed. If the job completes successfully, the status is Completed. If the run is canceled when the job is being performed, the status is Canceled. An error message (and red background) appears if the job failed.

2. To [view details](#) about the run (such as which configuration was used) and the parameters of the run, such as subsetting information, click **View Run Details**.
3. To [view job detail](#), such as the job parameters, and to access input and output files for jobs, click the name of the job.
4. To [view source tables](#), click **Sources** (if you are a superuser).
5. To return to the Jobs for Run page, click **Back**.

## Viewing job details for a data mining run

The Job Detail page provides a list of parameters used for a component job in a data mining run, and a list of input and output files produced by the selected job. Certain files are always saved and available from this page, while other files are saved and available only if the run creator checked **Save intermediate data files** on the [Run Options page](#).

- An error log file called job\_job-id\_log-id.log is produced for each extract or LR\_extract job. This log contains the date and time that error logging began and messages about any errors that occurred. For LR runs, this log also includes a line for each process in the run.
- The [lr\\_coefficients.log file](#) is produced for each LR job. This file contains the computed best alpha value for each response in an extended LR computation, and also includes the coefficient and standard error values computed for each predictor-response combination if the run creator checked **Save coefficients** on the [Run Options page](#).
- The [lr.log file](#) is produced for each LR job. This file identifies the most common value for each covariate in the run and summarizes convergence for each response.
- For the mgps job, the datamine.log file shows the version of the MGPS engine that you used. For the LR job in a logistic regression run, the lr.log file shows the version. The version number is helpful to know when communicating with Oracle about issues related to the data mining run.

1. On the [Data Mining Runs page](#), click the row menu () for a run, and then click **View Jobs for Run**.

The Jobs for Run page appears.

2. From the **Name** column, click the job.

The Job Detail page appears.

3. To download a file, from the Job Parameters section, click the input or output filename.

The Windows File Download dialog box appears.

4. You can open the file or save it. If the file is zipped, you must have a ZIP file compression and extraction utility, such as WinZip, installed on your computer, as described in [Prerequisites and usage Notes](#).

## Canceling or deleting a data mining run

At any point before a data mining run has completed, you can cancel the run. A canceled run remains on the Data Mining Runs page and can be re-run as is or with modifications. For example, suppose there are several runs in the queue. You need the one that was most recently submitted to run first. You can cancel all runs except the most recently submitted one. Later, you can re-run the canceled runs.


When a run has completed, the run status becomes either Complete or Error Occurred, and you can delete the run. You can also delete a run that has been canceled (the run status is Canceled). Data mining runs can take up a significant amount of server space. Deleting runs that are no longer needed frees up this space for other processes.

---

**Note:** To learn more about the error that caused a run to fail, review the information on the [Jobs for Run page](#).

---

### To cancel a data mining run:

1. On the [Data Mining Runs page](#), click the row menu () for a run, and then click **Cancel**.

The Cancel option is available as soon as the run is submitted. You can cancel a run that is currently running or that is scheduled to run in the future.

2. At the message asking if you want to cancel the run, click **OK**.

The status of the run changes to Canceled. You can delete or [re-run the run](#).


### To delete a data mining run:

- Before deleting a run, you might want to make sure that it is not referenced by any [drug profile configurations](#) or [signal configurations](#), because such references are removed.

---

**Note:** If you want to delete multiple runs at the same time, on the [Data Mining Runs page](#), click **Select Rows**.

---

1. On the Data Mining Runs page, click  for a run, and then click **Delete**.

The Delete option is available only when the run has a status of Completed, Error Occurred, or Canceled. If you want to delete a run that is currently running or is scheduled to run in the future, you must cancel it first.

2. At the message asking if you want to delete the run, click **OK**.

Any case series associated with the run are retained, but they no longer have an associated run.

When you delete a run that is associated with an alias, the target status of the alias becomes Broken.

## Which runs you can cancel or delete

You can always cancel or delete the data mining runs that you have created, even if your username does not have the Delete Any Run permission.

You can cancel or delete runs created by any users in your login group if you have the Delete Any Run permission.


## Re-running a data mining run

Once a data mining run has been submitted, it can be re-run as is or with modified parameters. For example, you need an MGPS run with 5 as the Minimum Count, and another MGPS run with all of the same data mining parameters but with 10 as the Minimum Count. Once you have submitted the first run, instead of creating a new run and supplying all of the same selections again, except for the minimum count, you can re-run and change one parameter.

You can re-run any of the data mining runs that appear on your Data Mining Runs tab, including runs created by other users and runs that are currently running, completed successfully, failed, were canceled, or have not started. You can also re-run runs that are themselves re-runs. Note that:

- You cannot change the run type when re-running a run. For example, you cannot change from an MGPS run to a logistic regression run.
- To learn more about the error that caused a run to fail, review the Status column on the [Jobs for Run page](#).
- The re-run option is not available for logistic regression runs created prior to the installation of Empirica Signal version 7.1, which included significant enhancements to logistic regression computations.

When you re-run a data mining run, the application treats it as an independent run that is not associated with the original run; you are the owner of the new run. The run uses all parameters and options used for the original run (including the [As Of date](#) of the run, if the data configuration supports [timestamped data](#)) unless you explicitly modify them. In addition, the re-run uses the [user preference](#), **Replace Missing Values with**, setting that was in effect for the run creator when the original run was created.

1. On the [Data Mining Runs page](#), click the row menu () for the run, and then click **Re-run**.

The Re-Run page appears and displays the configuration used for the original run.

2. To select a different data configuration, from the **Configuration** drop-down list of [compatible data configurations](#), [select a data configuration](#).
3. To limit the run to only cases meeting specified criteria, check **Add Database Restriction**.
4. Click **Next**.

If you added or modified a database restriction, the [Define Database Restriction](#) page appears. Otherwise, the Run Options page appears.

5. [Modify run options](#) as needed. You can also click **Back** to review all of the selections made for the original run and modify them as needed. For more information, see [Defining run options](#).

---

**Note:** The run uses all of the variables, values, and parameters selected for the original run unless you modify them in the new run. For example, if there was a custom term for the original run, it is used as is unless you modify it. Keep in mind that any changes made to queries on the Queries tab have no effect on database

restrictions or [custom terms](#) that were part of the original run. During the re-run, you must modify the database restriction or custom term, if needed, including reselecting a query that was modified on the Queries tab.

---

6. Click **Next**.

The Name Data Mining Run page appears.

7. In the **Run name** field, enter a name for the run. The name of the run does not need to be unique, although Oracle recommends that you use a unique name. The Empirica Signal application assigns a unique run ID to each run.
8. In the **Description** field, optionally enter a description. Oracle recommends that you provide an informative description of the run so that users who view run results know which run to use.
9. Optionally, assign the run to a [project](#).
  - To assign the run to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.
  - To create a new project and assign the run to it, click **Add to a new project named** and enter a project name.

10. Click **Next**.

The Confirm Run Parameters page appears.

11. On the Confirm Run Parameters page, review the parameters chosen for your run to make sure that they are correct. Different parameters display for [MGPS runs](#) and [LR runs](#).
12. If you want to change any parameters, click **Back** until you are on the appropriate page and make the necessary changes. Then click **Next** until you are back on the Confirm Run Parameters page
13. When you are satisfied with the run parameters, click **Submit**.

The application notes that the run has been submitted.

14. Click **Continue**.

The run status appears on the Data Mining Runs page. To monitor the progress of a run, you can [view jobs for the run](#).

15. Check the Data Mining Runs tab to determine when your run has completed.





## Viewing data mining results

### About data mining run results

Each [data mining run](#) produces a set of results that you can review in tabular or graphical format. Run results are the scores that indicate the strength of the association between the variables, such as drug and event, included in the run.


You view results on the Data Mining Results page after selecting results criteria (for example, drugs or events of interest). You can view the results of runs that you have created or that are published to you. If you have the Administer Users permission, you can also view the results of any run, published or unpublished, created by any user in your login group.

When reviewing results, you can [drill down](#) on counts to view case details if you have appropriate permissions.

## Viewing a data mining results table

1. Click the **Data Mining Runs** tab.

The [Data Mining Runs page](#) appears.

2. Click the row menu () for the run, and then click **View Results**.

or

Click the **Data Mining Results** tab.

The [Select Criteria page](#) appears.


3. From the **Run name** drop-down list, select the run you want to view. (Your [user preference](#), **Default Run**, determines which run, if any, is selected by default.) You can also click **Browse** next to the Run name field to [find and select a run](#).

4. Specify selection criteria on the Select Criteria page, then click **View Results Table**.

The results table shows only run results that meet the selection criteria that you specified. There is one row for each combination identified during data mining; for example, each Drug+Event combination in an MGPS 2D run or logistic regression run, or each Drug+Drug+Event in an MGPS 3D run. The results of the statistical computations performed for that combination are shown in columns of the table.

For a description of each column that you can include on the Results Table page see [Data mining results for MGPS runs](#) or [Data mining results for logistic regression runs](#).

See [About tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table. If you change the table display, you have the option to make the new layout the default for any other results you view for runs of the same type (MGPS or logistic regression) and dimension (2D or 3D).

5. Select one or more options from the links at the top of the page.
  - To display a description of the column, rest the cursor on any column heading.
  - To [drill down](#) to a listing of cases for a row, either click  for a row, or click the value in the **N** column.
  - To change your [selection criteria](#) and view a different set of results, click **Select Criteria**.
  - To view a graphical representation of the results, click **Choose Graph** and [choose a graph type](#). You can view data mining run results graphically for logistic regression runs and for two- or three-dimensional drug-event combinations in MGPS runs.

- To [create a case series](#) containing all cases for which there are rows in the displayed table, click **Add to Case Series**. This option is available when the results table contains 20 or fewer rows.
- To show information about the data mining run, click **Show Notes**. The notes appear below the results table, and are included if you print or download table data. For more information on the information that appears, see [Viewing details of a data mining run](#). Click **Hide Notes** to remove the notes.
- To view scores calculated for covariate(s) (if defined for a logistic regression run), click **View Covariates**. A table of covariate results appears in a separate window. See [Data mining results for logistic regression runs](#).

---

**Note:** Only the drug and event values specified as data mining results criteria are used to define the results that appear in the Covariates Table. Other criteria, such as a Limit to value, do not apply to this table.

---

- To view interaction scores calculated for a logistic regression run (if selected as a run parameter), click **View Interactions**. A table of interaction scores appears in a separate window. See [Data mining results for logistic regression runs](#).

---

**Note:** Only the drug and event values specified as data mining results criteria are used to define the results that appear in the Interactions Table. Other criteria, such as a Limit to value, do not apply to this table.

---

- To [save the results as an attachment to a topic](#), click **Save to Topic** (available if the topics feature has been set up).

## Finding and selecting a data mining run

You can use various run characteristics to easily locate a run.

1. Select the **Data Mining Results** tab.  
The Select Criteria page appears.
2. Next to the **Run name** field, click **Browse**.  
The Select Run dialog box appears.
3. From the drop-down lists in the **1. Choose Characteristics** section, specify the characteristics of the runs to select. Select -- to include all runs.

Run Characteristic	Description
Database Group	Database group containing the data configuration that was used for the run.
Data As Of	Run As Of date. If blank, the run is not for <a href="#">timestamped data</a> and has no As Of date.
Event Variable	Event variable used by the run.
Drug Variable	Drug variable used by the run.
Concomitant Drugs	Select Exclude for runs based on a data configuration that is set up to exclude concomitant drugs. Select Include for runs based on a data configuration that is set up to include concomitant drugs, such as an AERS (S + C) configuration.
Dimension	For an MGPS run, the highest dimension specified for the run when the run was created. For an LR run, select 2 for runs that did not compute interactions and 3 for runs that did compute interactions.
DB Restriction	If a database restriction was used for the run, select Yes. If no database restriction was used for the run, select No.
Subset Variable	Subset variable used for the MGPS run. A run can have only one subset variable. If blank, no subset variable was used for the run.
Subset Type	If cumulative subsetting was used for the MGPS run, select Cumulative. If non-cumulative (discrete) subsetting was used for the run, select Non-cumulative. If no subsetting was used for the run, the drop-down list is blank.
Strata Variables	Stratification variable used for the MGPS run. The same run can have multiple stratification variables. If blank, no stratification

variable was used for the run.


Min Count	For an MGPS run, the minimum count specified for the run. For an LR run, the minimum number of times a drug must occur in combination with a specified event to be included in the run.
Configuration	Name of the data configuration used for the run.
Project	Name of the <a href="#">project</a> for which the run was created.
Run Type	MGPS for an MGPS run; LR for a logistic regression run.

For example, to work with an MGPS run that uses Gender for stratification, choose MGPS as the run type and Gender as the stratification variable. Only runs that have both those characteristics appear in the table.

**Note:** If there are no existing runs with a certain characteristic, you cannot choose that characteristic. For example, if there are no logistic regression runs, LR is not available for Run Type.

- In the **2. Select Run** section, to [view a description of a run](#), click the row menu () and then click **View Run Details**.

The application displays the run details of the selected run. For more information, see [Viewing run details](#).

- To choose a run, click  for that run, and then click **Select**.
- Click **Reset** if you want to reset all criteria to -- (All).

To change the way columns display in this table, or for information on finding text, printing, or downloading, see [About tables](#).

## Specifying results criteria

### Selecting data mining results criteria

To view data mining results, you specify criteria such as the drugs and events to include in the table or graph of results on the Select Criteria page.

1. Click the **Data Mining Results** tab.  
The Select Criteria page appears.
2. From the **Run name** drop-down list, select a data mining run, or click **Browse** to [view all runs and select a run](#).
3. To [view details](#) about the selected run, click **View Run Details**. Click **Close** to close the detail dialog box for the run.
4. Specify one or more drugs and one or more events. Only exact matches, including the case (upper, lower, or mixed), are found in the run results.
5. To specify item variable values, use one or more of the following options:
  - If a variable has an associated hierarchy of terms and your [user preference](#) enables use of the hierarchy, you can click **Select <hierarchy-name> Terms** and [select terms from the hierarchy](#). Custom terms used in the run are not in the hierarchy.

If the run option to store the primary paths of terms in run results was used, you can search for terms at various levels of the hierarchy. Click the radio button for the level at which you want to search. If you select terms at a higher level than the level of the term used in the run, you see results only for terms that have that higher level in their primary path.

- To [select values from a list](#), click **Select Available Values**. The available values include custom terms used in the run.
- To use a [saved list](#) of terms, click **Select Saved List**. A saved list can include custom terms.
- In the text boxes, you can also type in values separated by a comma. If you type in a value that contains a comma, you must enclose the value in double quotation marks (for example, "Diabetes, Type II"). If you type in a value that includes a backslash or double quotation mark, you must precede the backslash or double quotation mark with a backslash (for example, Cold\\flu). To minimize the possibility of spelling and capitalization errors, however, Oracle recommends selecting values from lists.

---

**Note:** Drugs or events that have a missing (null) value in the source data have the value of the [user preference](#), **Replace missing value with**, that was in effect for the user who created the run. (Your own user preference does not affect run results generated by another user.)

---

- To [look up a drug name](#), click Trade/Generic Lookup. You can find the generic name for a drug (if you only know its trade name) or vice versa. (This link is available only if the mapping of trade/generic names has been defined as part of preparing source data.)

6. To include only scores that exceed a minimum threshold value, use the **Limit to** field to select a statistic and supply that minimum number. For a description of the statistics that you can use to limit results, see [Data mining results for MGPS runs](#) or [Data mining results for logistic regression runs](#).

For example, to review only MGPS run results with an EB05 score greater than 2, select EB05 and supply 2. The application uses the setting as the default (for results that you have not yet viewed) until you change it.

**Notes:**

- If you provide a limit for an MGPS run and then view a graph, the application applies the limit to the highest dimension in the graph only. For a sector map graph, the limit is ignored.
- When you view one-dimensional run results for an MGPS run, the application ignores this limit unless you specify a limit for the N statistic.
- This limit does not apply to sector map graphs or to the tables of covariate and interaction results for a logistic regression run.

To supply defaults for this statistic and value the first time you look at results for a run, you can set the [user preference](#), **Display Only Results with <score-type> Scores Over <number>**. If you select a statistic other than N, a default of LROR > 0 is used for logistic regression runs.

7. To select additional criteria, click **Show Advanced**. This link is available if additional fields can be used to limit the results to display. (If you do not generally use these fields you can click **Hide Advanced**.)
- For an **MGPS run In the Dimension** field, select a [dimension](#) to limit the results that appear. You can select 1, up to the highest dimension included in the run, or All to display results for all of the dimensions included in the run. By default, the dimension is the highest dimension that was selected when the data mining run was created. You can change the dimension to less than the default. The number of Pattern fields that appear depends on the number in the Dimension field.

- The **Subset** field appears if the run used [subsetting](#) and at least two subset categories were specified for the run. Select the subset for which you want to view results, or select All to display results for all subsets.
  - In the **Pattern** fields, specify a pattern such as Drug+Event. See [Dimensions and patterns](#).
  - If your **user preference, Include SQL WHERE Clause for Advanced Results Selection**, is checked, you can [specify a SQL WHERE clause](#) to restrict which run results you view. You can reference any of the columns that can be displayed in the results table, regardless of whether they are currently included in the display. To view the complete list of columns, click the Columns link above the results table. The SQL WHERE clause entered here is ignored if you view a table of covariates or interactions for a logistic regression run, or when you view a sector map graph.
8. If you want to remove your selections from the fields on this page, click **Clear All**.
  9. Click **View Results Table** to view a results table or click **Choose Graph** to [choose a graph type](#) to display. To view a graph, you must specify at least one drug or one event. For MGPS runs, you can view results graphically for two-, or three-dimensional drug-event combinations.

---

**Note:** When you view results for a logistic regression run, all criteria defined on this page are used to select the combinations that appear in the results table. However, only the drug and event values specified, if any, are used to define the results that appear in the Covariates Table and Interactions Table.

---



## Dimensions and patterns

On the [Select Criteria page](#), you can specify the dimension and pattern for an MGPS run as criteria for viewing data mining results. To display these controls, click **Show Advanced**.

### Dimensions

The dimensions in a run are the number of ways in which items combine to generate scores. When [specifying data mining parameters](#) for MGPS runs, the run creator specifies the highest dimension to compute. The run results include combinations of all dimension combinations, from 1 to the specified highest dimension. For example, a two-dimensional (2D) data mining run performed for drug and event item variables produces scores for the following combinations:

Drug (1D)

Event (1D)

Drug+Drug (2D)

Drug+Event (2D)

Event+Event (2D)

where

Drug and Event represent the names of the item variables used for the data mining run.

---

**Note:** One-dimensional results are useful to determine the total count (N) for a drug or event. Other statistics are not generated for 1D results, and you cannot display graphs for 1D results.

---

A 3D run for the same drug and event item variables produces results for these combinations:

Drug (1D)

Event (1D)

Drug+Drug (2D)

Drug+Event (2D)

Event+Event (2D)

Drug+Drug+Drug (3D)

Drug+Drug+Event (3D)

Drug+Event+Event (3D)

Event+Event+Event (3D)

When specifying criteria to view data mining results, you can indicate the number of dimensions to view. You can include 1 dimension up to the highest dimension included in the run. To include all dimensions, select **All**. The default is the highest dimension included in the run. If you change the default number of run dimensions, consider changing the default pattern for the run.

---

**Note:** Combinations of two or more dimensions that include only multiple drugs or only multiple events (such as Drug+Drug or Event+Event) are only included in the results table if the run creator specified (on the [Data Mining Parameters page](#)) that results for items of the same type should be kept.

---

## Patterns

You select a pattern to define the item types (such as drugs and events) to appear in the results table or graph. The default pattern depends on the number of dimensions in the run. The following table shows the default pattern for each dimension. Drug and Event represent the names of the item variables used for the data mining run.

<b>Dimensions</b>	<b>Default Pattern</b>
1D	Drug
2D	Drug+Event
3D	Drug+Any Drug+Event

The results table or graph includes results only for the selected pattern. You can change the types of items supplied by the default pattern as needed. The following table describes the options for the pattern fields:

<b>Option</b>	<b>Description</b>
<variable-name>	Lists each item variable used in the data mining run; for example, Generic_Name and PT. (Item variables can also represent other types of data, such as Gender or Age_Group.) For any pattern that includes <variable-name>, you can specify terms for the variable. If you specify terms, the results table displays only those terms and the scores calculated for them; otherwise, the results table displays all values for the <variable-name>.
Any <variable-name>	Lists each of the item variables used in the data mining run with the prefix Any; for example, Any Trade_Name and Any PT. These pattern options allow you to display results for specified terms as though you had supplied an OR between those terms. For example, if you choose the pattern PT+PT and specify the terms Headache and Rash, the results table displays only rows that contain both Headache and Rash. However, if you choose the pattern PT+Any PT, then specify Headache and Rash, the results table displays rows that contain either Headache or Rash.

## Any Item

The Any Item option is a wildcard that represents any of the other item variables in the run. You can use Any Item in a pattern for a 3D run that uses the Generic\_Name and PT item variables. When you choose the pattern Any Generic\_Name+Any Item+PT and specify the term DrugA, the results table displays DrugA+Event+Event combinations and also DrugA+Drug+Event combinations.

---

## Looking up drug names

The application provides an easy way for you to find the generic drug name associated with a trade name that you provide, or the trade name associated with the generic name that you provide. This feature is available only if the mapping of trade and generic names has been defined as part of preparing source data for use in the application. For more information, see your [data release notes](#).

1. Click the **Data Mining Results** tab.  
The Select Criteria page appears.
2. Click Trade/Generic Lookup.  
The Search for Trade/Generic Name dialog box appears.
3. In the **Search String** field, type a drug name. You can use the % sign as a wildcard character to match zero or more characters in that position. This field is not case-sensitive; for example, if you enter F%IC ACID, both Folic acid and Folinic acid match even though they use mixed case.
4. Click **Search**.  
The first 100 drug names (in either the GENERIC\_NAME or TRADE\_NAME column) that start with, end with, or include the text string are listed.
5. To sort the results by generic or trade name, click the up or down arrows next to the column name.
6. To dismiss the dialog box, click **Cancel**.

## Viewing results tables

### Data mining results for MGPS runs

Data mining results for an MGPS run display in the table columns listed below. By default, the table includes a limited set of columns. To include more columns in the results table, click **Columns**, and then check **Show All Columns**. For information about viewing, printing, or downloading tables or changing the way data displays in the table see [About tables](#).


You can rest the cursor on a column heading to display a description of the column.

The following columns are available for inclusion in the results table for an MGPS run. For information on the columns available for a logistic regression run refer to [Data mining results for logistic regression runs](#). For additional information, see [About MGPS runs](#) and [Precision of displayed values](#).

Column	Description
<variable-name>	<p>Each variable on which data mining was performed. Typically, there is a drug variable and an event variable.</p> <p>If the run used <a href="#">drug or event hierarchies</a>, the Empirica Signal application adds a column for each hierarchy level above the term for which data mining was performed to the results table. The primary path in the hierarchy is represented in these columns. For example, if the event variable is PT, the results include HLT, HLGT, and SOC columns showing the primary path of the PT.</p> <p>When you display results for more than two dimensions, the application identifies columns for variables of the same type by adding a numeric suffix to the column name. For example, when you display results for the pattern D+E+E, you see:</p> <pre>PT1   HLT1   HLGT1  SOC1   PT2    HLT2   HLGT2  SOC2</pre> <hr/> <p><b>Note:</b> For runs with three dimensions, these columns cannot be used to sort the results table. The actual column names in the underlying table are not the same as the labels for fields on the Select Criteria page or as column headers in the results table. The actual column names are ITEM1, ITEM2, and so on.</p>
DIM	Dimension. The number of items combined.

E	<p>The expected number of cases with the combination. For a 2-dimensional (2D) run, computed as:</p> $(\text{Observed \# cases with ITEM1} / \text{Total \# cases}) \times (\text{Observed \# cases with ITEM2} / \text{Total \# cases}) \times \text{Total \# cases}$ <p>For a stratified MGPS run, calculated as total of expected values for all the strata, where the expected number of cases for each stratum is computed as:</p> $(\text{Observed \# cases with ITEM1 for stratum} / \text{Total \# cases for stratum}) \times (\text{Observed \# cases with ITEM2 for stratum} / \text{Total \# cases for stratum}) \times \text{Total \# cases for stratum}$ <p>Overall Expected = Total of Expected values for all strata</p> <p>When <math>E &lt; .001</math>, displays in scientific notation.</p> <p>For a 3-dimensional (3D) MGPS run, the calculations include ITEM3. For 3D runs, the calculation of E depends on the mix of item types in the set of items. If the set of items includes at least two different types and also includes at least two items of the same type (such as D+D+E), then E is the result of <a href="#">MGPS interaction</a> calculations. In this model, E incorporates observed within-item-type associations, and uses only the assumption of cross-item-type independence in the computation of E.</p>
EB05	<p>There is approximately a 5% probability that the true Relative Ratio lies below this value.</p>
EB95	<p>There is approximately a 5% probability that the true Relative Ratio lies above this value.</p> <p>The interval from EB05 to EB95 is the 90% confidence interval.</p>
EBGM	<p>Empirical Bayesian Geometric Mean. A more stable estimate than RR. This so-called shrinkage estimate is computed as the geometric mean of the posterior distribution of the true Relative Ratio.</p>
EBMAX	<p>Applies to runs with more than 2 dimensions. For each 3D itemset, EBMAX is the largest 2D EBGM among all included cross-item-type 2D combinations. If the itemset is homogeneous, so that there are no included cross-item-type combinations, EBMAX is the largest EBGM among all the included 2D combinations. The 2D combination for which <math>\text{EBGM} = \text{EBMAX}</math> is specified by the columns MAXITEM1 and MAXITEM2.</p>
EXCESS	<p>A conservative estimate of how many extra cases were observed above what was expected. Computed as:</p> $(\text{EB05} - 1) \times E$
EXCESS2	<p>Applies only to runs with more than 2 dimensions. A conservative estimate of how many extra cases were observed over what was expected assuming that only a single cross-item interaction is present. Computed as:</p> $E \times \text{EB95MAX} * (\text{INTSS} - 1) = E * (\text{EB05} - \text{EB95MAX})$ <p>where EB95MAX is the largest 2D EB95 among all included cross-item-</p>

type combinations.

F	Applies only to runs created by Oracle, with the advanced parameter, <b>Do comparative analysis</b> , selected.
ID	Identifies the unique row number assigned as Oracle loads data from the run's output files.
INTSS	Interaction Signal Score. Applies only to 3D runs. Essentially, this is a way of measuring of the strength of a higher-order association above and beyond what would be expected from any of the component pairs of items of different types. Computed as: EB05 / EB95MAX where EB95MAX is the largest 2D EB95 among component pairs of items of different types.
JOB_ID	The identifier assigned by the listener to the sub-job in the run.
MAXITEM1	First item determining the 2D combination for which EBGM = EBMAX.
MAXITEM1P	Prefix, if any, assigned to the variable MAXITEM1.
MAXITEM2	Second item determining the 2D combination for which EBGM = EBMAX.
MAXITEM2P	Prefix, if any, assigned to the variable MAXITEM2.
N	Observed number of cases with the combination of items. You can click the value of N to display a menu from which you can <a href="#">drill down</a> to view or download case information or run reports. (The same options are available when you click  for the row.)
P_<variable-name>	Prefix, if any, assigned to the variable in the <a href="#">data configuration</a> on which the run is based. The alphabetical ordering of prefixes determines which of the underlying ITEM column names is used for each of the item variables in the results table. For example, if the prefix for the drug variable is D and the prefix for the event variable is E, values for the drug variable appear in the ITEM1 column and values for the event variable in the ITEM2 column.
P_VALUE	For runs that include the calculation of PRR, the probability that chi-square is as large as or larger than the value in the PRR_CHISQ column by chance alone if there is no causal relationship or consistent association between the drug and the event. Small values display in scientific notation.
PRR	For runs that include the calculation of PRR, the <a href="#">Proportional Reporting Ratio</a> for the combination of a particular drug and particular event.

PRR_A	For runs that include the calculation of PRR, the observed count for the combination of a particular drug and particular event. This can be the number of combinations or number of cases, depending on the PRR options used in the run.
PRR_B	For runs that include the calculation of PRR, the observed count for the combination of a particular event and all other drugs. This can be the number of combinations or number of cases, depending on the PRR options used in the run.
PRR_C	For runs that include the calculation of PRR, the observed count for the combination of a particular drug and all other events. This can be the number of combinations or number of cases, depending on the PRR options used in the run.
PRR_D	For runs that include the calculation of PRR, the observed count for the combination of all other drugs and all other events. This can be the number of combinations or number of cases, depending on the PRR options used in the run.
PRR_CHISQ	For runs that include the calculation of PRR, the chi-square of PRR. For more information, see <a href="#">PRR computations</a> .
Q	Intermediate computation in the calculation of EBGM. Defined as the posterior probability that the combination is in component 1 of the mixture prior distribution estimated by the empirical Bayes algorithm.
ROR05	For runs that include the calculation of ROR, the lower 5% confidence limit for ROR.
ROR95	For runs that include the calculation of ROR, the upper 5% confidence limit for ROR. The interval from ROR05 to ROR95 is the 90% confidence interval.
ROR	For runs that include the calculation of ROR, the Reporting Odds Ratio. Computed as: $\text{ROR} = (\text{PRR\_A} * \text{PRR\_D}) / (\text{PRR\_B} * \text{PRR\_C})$ With stratification, ROR is computed as a weighted average of the ROR within each stratum. For more information, see <a href="#">ROR computations</a> .
ROW_NUM	Identifies the row number assigned in one of the output files. The value in this column may not be unique in the results table for a given run.
RR	Relative Ratio. (The same as N/E.) Observed number of cases with the combination divided by the expected number of cases with the combination. This is a sampling estimate of the true Relative Ratio (that would be observed if the database were much larger, but drawn from the same conceptual population of reports) for the particular combination of drug and event. RR is computed as: Observed # cases with ITEM1+ITEM2 pair / Expected # cases with



ITEM1+ITEM2 pair

For a stratified MGPS run, RR is computed as:

Observed # cases with ITEM1+ITEM2 pair for all strata / Final Expected # cases with ITEM1+ITEM2 pair

For a 3D MGPS run, the computations include ITEM3.

---

SUBSET	If an MGPS run includes a subset variable to categorize ( <a href="#">subset</a> ) results, displays the label for the subset that applies to each combination.
--------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------

---

Data in the following columns (ending in \_IND) are computed using the [MGPS independence model](#) and are provided to support runs completed in versions of the Empirica Signal application prior to version 5.0:

Column	Description
E_IND	<p>The expected number of cases with the combination, as calculated by the MGPS independence model. Computed as:</p> $(\text{Observed \# cases with ITEM1} / \text{Total \# cases}) \times (\text{Observed \# cases with ITEM2} / \text{Total \# cases}) \times \text{Total \# cases}$ <p>For a stratified MGPS run, calculated as total of expected values for all the strata, where the expected number of cases for each stratum is computed as:</p> $(\text{Observed \# cases with ITEM1 for stratum} / \text{Total \# cases for stratum}) \times (\text{Observed \# cases with ITEM2 for stratum} / \text{Total \# cases for stratum}) \times \text{Total \# cases for stratum}$ <p>Overall Expected = Total of Expected values for all strata</p> <p>When E_IND &lt; .001, displays in scientific notation.</p> <p>For a 3D MGPS run, the calculations include ITEM3.</p>
E2D_DIV_E_IND	Ratio computed as: E2D_IND/E_IND
E2D_DIV_F_IND	Ratio computed as: E2D_IND/F
E2D_IND	The expected count based on the all-2-factor log linear model.
EB05_IND	A value such that there is approximately a 5% probability that the true Relative Ratio lies below it, where Relative Ratio is defined by the MGPS independence model.
EB95_IND	<p>A value such that there is approximately a 5% probability that the true Relative Ratio lies above it, where Relative Ratio is defined by the MGPS independence model.</p> <p>The interval from EB05_IND to EB95_IND may be considered to be the 90% confidence interval.</p>
EBGM_IND	Empirical Bayesian Geometric Mean, as computed by the MGPS independence model. A more stable estimate than RR; the so-called

	shrinkage estimate.
EBGMDIF_IND	<p>Applies to 3D runs. Essentially, this is a way of measuring of the strength of a higher-order association above and beyond what would be expected from previously computed component two-factor associations. Computed by the MGPS independence model as:</p> $EBGM\_IND - E2D\_IND/E\_IND$
EXCESS_IND	<p>A conservative estimate of how many extra cases were observed above what was expected. Computed by the MGPS independence model as:</p> $(EB05\_IND - 1) \times E\_IND$
EXCESS2_IND	<p>Applies to 3D runs. An estimate of how many extra cases were observed over what was expected using the all-2-factor model. Computed by the MGPS independence model as:</p> $(EBGM\_IND \times E\_IND) - E2D\_IND$ <p>where E2D_IND is the expected count based on the all-2-factor log linear model.</p>
RR_IND	<p>Relative Ratio computed by the MGPS independence model. (The same as N/E_IND.) Observed number of cases with the combination divided by the expected number of cases with the combination. This may be viewed as a sampling estimate of the true value of observed/expected for the particular combination of drug and event. RR is computed as:</p> $\text{Observed \# cases with ITEM+ITEM2 pair} / \text{Expected \# cases with ITEM1+ITEM2 pair}$ <p>For a stratified MGPS run, RR is computed as:</p> $\text{Observed \# cases with ITEM1+ITEM2 pair for all strata} / \text{Final Expected \# cases with ITEM1-ITEM2 pair}$ <p>For a 3D MGPS run, the computations include ITEM3.</p>

## Data mining results for logistic regression runs

Data mining results for a logistic regression run display in the results table using the columns listed below. If the run includes one or more covariate variables, click **View Covariates** above the results table to see results specifically for the [covariates](#). If the run includes the computation of interactions, click **View Interactions** to see results specifically for [interactions](#).

By default, a limited set of columns is included in each of these tables. To include more columns in the results table, click **Columns** above the table and, optionally, check **Show All Columns**. For information about viewing, printing, or downloading tables or changing the way data displays in the table, see [About tables](#).

You can rest the cursor on a column heading to display a description of the column.

### Results Table

The following columns are available for inclusion in the results table for a logistic regression run. For information on the columns available for an MGPS run, see [Data mining results for MGPS runs](#). For additional information, see [Logistic regression computations](#) or [Precision of displayed values](#).

Column	Description
<predictor variable>	Logistic regression runs include a drug variable (the predictor) and an event variable (the response). The results table includes a column with the name of each variable selected for the run; for example, Single Ingredient and PT.
<response variable>	Logistic regression runs can also include covariate variables as predictors. If the run includes covariates, click <b>View Covariates</b> to review results for each covariate-event pair.
N	Observed number of cases with the combination of items. You can click the value of <b>N</b> to display a menu from which you can <a href="#">drill down</a> to view or download case information or run reports.  <b>Note:</b> On the Covariates table, the value of <b>N</b> is not hyperlinked.
E	The expected number of cases with the combination, computed as: (Observed # cases with predictor/Total # cases ) x (Observed # cases with response/Total # cases) x Total # cases When E < .001, displays in scientific notation.
RR	Relative Ratio. Observed number of cases with the combination divided by the expected number of cases with the combination. (The same as N/E.) This is a sampling estimate of the true Relative Ratio (that would be observed if the database were much larger, but drawn from the same conceptual population of reports) for the particular combination of predictor and response and ignoring the LR adjustments for covariates and other drugs.

LROR	Logistic Regression Odds Ratio. Estimated odds ratio relating occurrence of response to occurrence of predictor, adjusting for other predictors.
LR05	Lower 5% confidence limit for the logistic regression odds ratio.
LR95	Upper 95% confidence limit for the logistic regression odds ratio. The interval from LR05 to LR95 is the 90% confidence interval.
JOB_ID	The identifier assigned by the listener to the sub-job in the run.
ID	Identifies the unique row number assigned as Oracle loads data from the run's output files.
ROW_NUM	Identifies the row number assigned in one of the run's output files. The value in this column does not have to be unique in the results table for a given run.

### Covariates Table

For logistic regression runs that include computations for covariates, such as gender, age group, or report receipt year, you can view a results table for each covariate-event combination. The rows in this table reflect the scores calculated for each event and each possible value for the covariates of the run, with the exception of the value that occurs most frequently. (The value that occurs most frequently for each covariate is used as the standard for the odds ratio calculated for each of the other values.) For example, if you use Seriousness as a covariate and Seriousness has the unique values YES and NO, with NO occurring most frequently, this table only includes rows for YES in combination with each event.

**Note:** Only the event values specified as [results criteria](#) apply to the table of covariate results.

In addition to the columns shown in the results table, the following additional columns are available in the table of covariate results:

Column	Description
P_ITEM	The name of the selected covariate variable, such as Gender or Seriousness.
ITEM	The value of the covariate, such as M, F, or U for a covariate of Gender, or YES or NO for a covariate of Seriousness.

### Interactions Table

For logistic regression runs that include the computation of interactions, you can view a results table of scores calculated for each predictor+predictor+response (drug+drug+event, drug+covariate+event, or covariate+covariate+event).

Only the drug(s) and event(s) you selected as [criteria](#) to view the results of the logistic regression apply to the table of interaction results. To include only scores that exceed a minimum threshold value in this table, click the Columns and Rows link above the table and use the Limit to field to select a statistic and supply that minimum number. By default, this limit is set to  $N > 0.0$ : to include rows in this table for reports in which the Item1 value and Item2 value did *not* occur with the event value, you must change this limit to a negative number such as  $N > -1.0$ .

If your [user preference](#), **Include SQL WHERE Clause for Advanced Results Selection**, is checked, you can also specify a SQL WHERE clause. For example, to view only rows that have a certain drug name as a value for either the first or second predictor, enter a SQL WHERE clause of `ITEM1='<drug name>' OR ITEM2='<drug name>'`.

The following columns are available in the table of interaction results:

Column	Description
P_ITEM1	For the value that appears in the ITEM1 column, either provides the name of the covariate variable or the configuration prefix for drug (D).
ITEM1	The value of the first predictor in the interaction. This value can be a covariate (if the run included one or more covariates) or a drug.
P_ITEM2	For the value that appears in the ITEM2 column, provides the configuration prefix for drug (D) or the name of the covariate variable.
ITEM2	The value of the second predictor in the interaction. This value can be a drug or a covariate (if the run included multiple covariates).
<response variable name>	Event (response) variable selected for the run, such as PT.
N	Observed number of cases with the combination of all three values (ITEM1, ITEM2, response). You can click the value of N to display a menu from which you can <a href="#">drill down</a> to view or download case information or run reports.
N_TOT	Observed number of cases in the data that have both ITEM1 and ITEM2. To specify a SQL WHERE clause that includes this column, use the underlying column name of INTSS.
E	The predicted value of N based on LR without interactions: the sum, over all N_TOT reports that have both ITEM1 and ITEM2, of the predicted probability of the response using the LR prediction formula. When $E < .001$ , displays in scientific notation.
INT_LOF	Empirical Bayes shrinkage estimate of additional interaction due to lack of fit to the LR model, based on the ratio $N/E$ . To specify a SQL WHERE clause that includes this column, use the underlying column name of EXCESS2.

INT_REGR	<p>Predicted ratio of probability of the response given both ITEMS, divided by probability given worst ITEM, if LR model is correct.</p> <p>To specify a SQL WHERE clause that includes this column, use the underlying column name of EXCESS.</p>
INT_TOT	<p>Total interaction, computed as <math>INT\_REGR * INT\_LOF</math>.</p> <p>To specify a SQL WHERE clause that includes this column, use the underlying column name of LROR.</p>
INT05	<p>Lower 5% confidence limit for INT_TOT.</p> <p>To specify a SQL WHERE clause that includes this column, use the underlying column name of LR05.</p>
INT95	<p>Upper 95% confidence limit for INT_TOT.</p> <p>To specify a SQL WHERE clause that includes this column, use the underlying column name of LR95.</p>
LROR1	<p>Logistic regression odds ratio relating the response event to ITEM1.</p> <p>To specify a SQL WHERE clause that includes this column, use the underlying column name of PRR_A.</p>
LROR2	<p>Logistic regression odds ratio relating the response event to ITEM2.</p> <p>To specify a SQL WHERE clause that includes this column, use the underlying column name of PRR_B.</p>
JOB_ID	The identifier assigned by the listener to the sub-job in the run.
ID	Identifies the unique row number assigned as Oracle loads data from the output files of the run.
ROW_NUM	Identifies the row number assigned in one of the output files of the run. The value in this column may not be unique in the results table for a given run.

## Precision of displayed values in data mining results

This topic covers the precision with which various computed numeric columns in the data mining results table appear. Note that the full precision of numeric values is present in the underlying database.

There are three types of computed numeric columns to consider: relative reporting ratio measures, expected values, and probability values.

### Relative reporting ratio measures

- Numeric values with an absolute value > 10 have one digit to the right of the decimal point.
- Numeric values between 1 and 10 have two digits to the right of the decimal point.
- Numeric values less than 1 appear as 0.xxx with three digits after the decimal.
- Scientific notation is not used.

MGPS columns of this type: EB05, EB95, EBG, INTSS, PRR, ROR05, ROR95, ROR, RR, EBMAX, RR\_IND, EB05\_IND, EB95\_IND, EBG\_IND, EBGMDIF\_IND, E2D\_DIV\_E\_IND, E2D\_DIV\_F\_IND.

Logistic regression columns of this type: RR, LROR, LR05, LR95 in the tables for Results and Covariates, INT\_REGR, INT\_LOF, INT\_TOT, INT05, INT95 in the Interactions table

### Expected values

- Numeric values with an absolute value > 10 have one digit to the right of the decimal point.
- Numeric values between 1 and 10 have two digits to the right of the decimal point.
- Numeric values between .01 and 1 appear as 0.xxx with three digits after the decimal.
- Numeric values less than .01 are expressed as scientific notation with four significant figures.

Columns of this type: E, F, EXCESS, EXCESS2, PRR\_CHISQ, E\_IND, EXCESS\_IND, EXCESS2\_IND, E2D\_IND.

### Probability values

- Numeric values between .001 and 1 are displayed as 0.xxxx with four digits after the decimal.
- Numeric values less than .001 are expressed as scientific notation with four significant figures.


(In the event that a value is 1 or greater, it will display with two digits to the right of the decimal point.)

Columns of this type: P\_VALUE, Q.

## Creating a case series from a results table

If a results table has 20 or fewer rows, you can create a new case series containing the case IDs of cases represented. You can also add the case IDs to an existing case series that was created from results of the same data mining run.

If you create a case series from the results of a data mining run for [timestamped data](#), the case series has the same As Of date as the data mining run.

1. Click the **Data Mining Runs** tab.  
The [Data Mining Runs page](#) appears.
2. Click the row menu () for the run, and then click **View Results**.  
The [Select Criteria page](#) appears.  
or  
Click the **Data Mining Results** tab.  
The [Select Criteria page](#) appears.
3. From the **Run name** drop-down list, select the run. (Your [user preference](#), **Default Run**, determines which run, if any, is selected by default.) You can also click **Browse** next to the Run name field to [find and select a run](#).
4. Specify selection criteria on the [Select Criteria page](#), then click **View Results Table**.  
The Results Table page appears.
5. On the [Results Table page](#), click **Add to Case Series**.  
If there are more than 20 rows in the results table, an error message appears. Click **Continue** and change your selection criteria to restrict results to 20 or fewer rows.  
If there are existing case series created from results of the same data mining run, the Add Cases from Selected Results page appears.
6. Click **Select** for a case series.  
The cases are added to the selected case series.  
or  
If there are no existing case series created from results of the same run, or if you click **New Case Series**, the Create Case Series page appears.
7. In the **Name** field, type a name for the case series. The name does not need to be unique, although Oracle recommends that you use a unique name.
8. The name of the run appears by default in the Description field as the description of the case series. Edit the description as necessary.



9. To add the case series to an existing project, click **Add to existing project** and select the project from the drop-down list.
10. To add the case series to a new project, click **Add to new project named** and type the name of the project.
11. Click **Save**.

The Case Series page appears listing the case series.

## Viewing results graphs

### Choosing a data mining results graph

1. Click the **Data Mining Results** tab.  
The Select Criteria page appears.
2. In the **Run Name** field, [select the run](#) from the drop-down list. You can also click **Browse** next to the Run Name field to [find and select a run](#).
3. Specify at least [one drug term](#) or one event term. For graphs to be available, you can specify no more than 200 drug terms or 200 event terms.

#### Notes:

- The limit of 200 is based on terms that are actually in the results.
- The limit of 200 is the number of terms remaining after applying restrictions on the Select Criteria page. For example, If you specify 300 PTs and  $EBGM > 5$ , and there are fewer than 200 drug-event combinations for which  $EBGM > 5$ , graphs are available.
- You can display a sector map only if you specify no more than 5 drugs (that are actually in the results). The limit of 5 applies regardless of restrictions on the Select Criteria page.
- For MGPS runs, if you select the terms at a higher level in the hierarchy than the level at which data mining was performed (for example, you specify an HLGT and data mining was performed on PTs), typically the run includes more than 200 PTs.

4. Click **Choose graph**.

The Choose Graph page appears, listing graph types that are suited to the data mining run and your selection criteria..

The following headings appear:

- **Review a drug and its associations with other items (drugs or events)**— These graphs focus on a particular drug or drugs that you specified on the Select Criteria page. For example, suppose that you are interested in all the events associated with DrugA. You select DrugA on the Select Criteria page and then choose a graph in order to review results for the events associated with DrugA.
- **Review an event and its associations with other items (drugs or events)**—These graphs focus on a particular event or events that you specified on the Select Criteria page. For example, suppose that you are interested in all

the drugs associated with Event1. You select Event1 on the Select Criteria page and then choose a graph in order to review results for the drugs associated with Event1.

---

**Note:** If you are viewing results of a three-dimensional run and you specify 2 as the dimension (on the [Select Criteria page](#)), you can view graphs for the two-dimensional combinations in the results.

---

5. If you want to [modify the graph key](#) (for all graphs), click **Set Graph Cutpoint and Palette Choices**.

The Graph Cutpoints and Palette Choices page appears. See [Setting graph cutpoints and color choices](#) for more information.

6. Click **Save** to return to the Choose Graph page.

7. Choose a graph type and click its link.

A graph display options page appears for the selected graph type.

8. Specify graph display options and click **Display**. For information about setting display options, see:

- [Viewing a bar graph](#)
- [Viewing a confidence interval graph](#)
- [Viewing a discrete map graph](#)
- [Viewing a cumulative map graph](#)
- [Viewing a nested confidence interval graph](#)
- [Viewing a hierarchy graph](#)
- [Viewing an overlap graph](#)
- [Viewing a sector map graph](#)

The graph appears on the right side of the page.

## Graphs for 2D results

For two-dimensional results (for example, Drug+Event), the graph types are described in the following table. The graph types are available for MGPS runs. Some are available for logistic regression runs.

Graph	Description								
<a href="#">Bar graph</a>	<p>Available for MGPS and logistic regression run results. A horizontal bar graph with one bar for each combination. Use this graph type to plot EBGM, PRR, ROR, and LROR scores.</p> <p><b>Note:</b> If the run includes subsetting, the graph label includes (for a Single Subset).</p> <table border="1"> <thead> <tr> <th>Link Name</th> <th>Run Type</th> </tr> </thead> <tbody> <tr> <td>EBGM</td> <td>MGPS</td> </tr> <tr> <td>ROR</td> <td>MGPS with ROR</td> </tr> <tr> <td>LROR</td> <td>Logistic regression</td> </tr> </tbody> </table>	Link Name	Run Type	EBGM	MGPS	ROR	MGPS with ROR	LROR	Logistic regression
Link Name	Run Type								
EBGM	MGPS								
ROR	MGPS with ROR								
LROR	Logistic regression								
<a href="#">Confidence interval bar graph</a>	<p>Available for MGPS and logistic regression run results. A horizontal bar graph with one bar for each combination, showing confidence intervals based on the EB05-EBGM-EB95, ROR05-ROR-ROR95, or LR05-LROR-LR95 values. Suitable for studying scores and related confidence intervals.</p> <p><b>Note:</b> If the run includes subsetting, the graph label includes (for a Single Subset).</p> <table border="1"> <thead> <tr> <th>Link Name</th> <th>Run Type</th> </tr> </thead> <tbody> <tr> <td>EB05-EBGM-EB95</td> <td>MGPS</td> </tr> <tr> <td>ROR05-ROR-ROR95</td> <td>MGPS with ROR</td> </tr> <tr> <td>LR05-LROR-LR95</td> <td>Logistic regression</td> </tr> </tbody> </table>	Link Name	Run Type	EB05-EBGM-EB95	MGPS	ROR05-ROR-ROR95	MGPS with ROR	LR05-LROR-LR95	Logistic regression
Link Name	Run Type								
EB05-EBGM-EB95	MGPS								
ROR05-ROR-ROR95	MGPS with ROR								
LR05-LROR-LR95	Logistic regression								
<a href="#">Discrete map graph</a>	<p>Available for results of MGPS runs that use discrete (non-cumulative) subsets. A map graph (discrete) displays a colored grid showing combinations of items (drugs or events) with a drug or event, where each column of the grid reflects the data in a different subset. The subsets were defined as non-cumulative (discrete) in the data mining run.</p> <p>This graph is suitable for comparing strength of association between different subsets. For example, to compare scores for the individual years of 1998, 1999, and 2000, or for the genders Female, Male, and</p>								

Unknown.

Link name: **Map Graph showing Multiple Discrete Subsets.**

---

[Cumulative map graph](#)

Available for results of MGPS run results that use cumulative subsets. A map graph (cumulative) displays a colored grid showing combinations of items (drugs or events) with a drug or event, where each column of the grid reflects the data in a subset. The subsets were defined as cumulative in the data mining run.

This graph is suitable for studying the change in association strength over time. For example, to observe scores for 1998, 1998 through 1999, and 1998 through 2000.

Link name: **Map Graph showing Cumulative Subsets.**

---

[Sector map graph](#)

Available for MGPS runs that include PT as an item variable and for which you have selected drugs to view results. A sector map graph for data mining results is a visual presentation of data for a particular drug across all System Organ Classes (SOCs). Sector map graphs are available if you select up to five drugs on the Specify Criteria page. The application ignores event selections for the sector map graph.

Link name: **Sector Map for Specified Drugs(s) and All Events.**

**Note:** If the run includes subsetting, the link name includes (for a Single Subset).

---

## Graphs for 3D results

For three-dimensional results (for example, Drug+Drug+Event), the available graph types are described in the following table. These graph types are available for MGPS runs only.

<b>Graph</b>	<b>Description</b>
<a href="#">Hierarchy graph</a>	<p>Columns of colored cells, where the rows represent 2-way and 3-way combinations. This graph is suitable for studying multiple-item combinations such as drug interactions or syndromes.</p> <p>The hierarchy graph uses INTSS values. The independence model hierarchy graph, which uses EBGMDIF_IND values, is for compatibility with releases prior to WebVDME 5.0.</p> <p>Link name: Hierarchy Graph showing Interaction . . .</p>
<a href="#">Overlap graph</a>	<p>A table of colored cells, where the rows represent 2-way and 3-way combinations. Same content as hierarchy graph, but formatted differently.</p> <p>The overlap graph uses INTSS values. The independence model overlap graph, which uses EBGMDIF_IND values, is for compatibility with releases prior to WebVDME 5.0.</p> <p>Link name: Overlap Graph showing Interaction . . .</p>
<a href="#">Nested confidence interval graph</a>	<p>Sets of confidence intervals. In each set, the first confidence interval is for the 3D combination for the specified pattern. Subsequent confidence intervals in the set are for 2D combinations. Uses INTSS values.</p> <p>Link name: Nested Confidence Interval Graph showing Interaction . . .</p>

## Working with results graphs

The following display options are available for most graphs of data mining results:

Option	Check to
Popup	Display each graph in an individual window. If you have popup blocking software installed on your PC, it may prevent these windows from opening. You may want to disable your popup blocking software.
Key	Display a color key below the graph to show which value each graph element (such as a bar or region of the graph) represents. You can <a href="#">modify the graph key</a> as needed.
Notes	Display notes about the graph.
Links	<p>Show the following:</p> <ul style="list-style-type: none"> <li>• For some graphs, information about what a graph component (such as a bar, cell, or region) represents, or statistics for the component, that appears when you point to that component.</li> <li>• A menu that allows you to <a href="#">drill down</a> when you click a graph component.</li> <li>• <b>Print</b> and <b>Copy to Clipboard</b> links.</li> <li>• <b>Save to Topic</b> link (if <a href="#">Topics</a> has been configured to offer this feature).</li> <li>• For some graphs, links to download graph data.</li> </ul>

### To print a graph:

1. Configure Internet Explorer to print background colors and images. See [Prerequisites and usage notes](#) for more information.
2. With the Internet Explorer Page Setup option, set up the print options, including the headers and footers that you want to use for graphs. Note that you can enter &p to show the page number and &P to show the total number of pages. For example, you can enter Page &p of &P. A single graph may span multiple pages, so it is recommended that you include page numbers in the header or footer of your printouts.
3. Check or clear **Key** and **Notes**, depending on whether you want to include the graph key or notes in the printout.
4. Clear **Links**.
5. Click **Print**.  
The Internet Explorer Print dialog box appears.
6. Select the orientation of the paper (Portrait or Landscape) and make other choices.
7. Select a printer.

8. Click **Print**.

**To copy a graph:**

1. Check or clear **Key** and **Notes**, depending on whether you want to include the graph key or notes in the copy.
2. Click **Copy to Clipboard**.
3. Open the document to which you want to add the graph(s), and use the **Paste** command for that application.

**To download graph data to Microsoft Excel:**

You can download data that appears in the graph to Microsoft Excel.

1. See [Prerequisites and usage notes](#) for information about configuring Internet Explorer for downloading.
2. Check **Links**.
3. Click **Download Data for Graph(s) to Excel**.

The File Download dialog box appears.

4. Indicate whether you want to open the file or save the file to your computer.


The file always downloads to a comma-separated (.csv) file. If you open the file from within the application, the file always opens in Excel. If you save the file and open it from your desktop, the file opens in the application associated (in Microsoft Windows) with the file extension CSV.



## Setting graph cutpoints and palette choices

The graph cutpoints define the ranges of values associated with different colors in the graph. The graph palette is the spectrum of colors used for graphs based on the results of data mining runs (including charts on the Drugs tab) during your current session. You can set a default palette as your [user preference](#), **Graph color palette**.

**Note:** Neither cutpoints nor color settings have any effect on the sector map graph, graphs that are based on report data, or graphs on the Signals tab.

1. On the [Data Mining Runs page](#), click the row menu () for the run, and then click **View Results**.

or

Click the **Data Mining Results** tab.

The Select Criteria page appears.

2. Select a run and click **View Graph**. For more information, see [Choosing a data mining results graph](#).

The Choose Graph page appears.

3. Click Set Graph Cutpoint and Palette Choices.

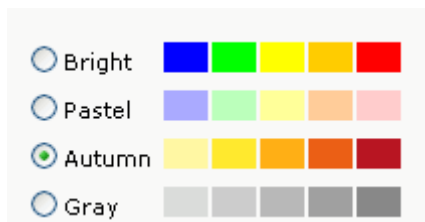
The Graph Cutpoints and Palette Choices page appears.

4. To change the cutpoints or minimum/maximum limits for a particular score range, enter an integer or floating point number in each of the four range fields for a score such as EBGM, PRR, or INTSS. For example:

0 ≤ EBGM ≤ 2.5 < EBGM ≤ 5 < EBGM ≤ 7.5 < EBGM ≤ 10 < EBGM

If you are unsure about the meaning of a score, see [Data mining results for MGPS runs](#) or [Data mining results for logistic regression runs](#).

5. To change the color palette, click one of the following radio buttons:



6. Your choices result in ranges with corresponding color gradations, as in the following example that uses the Autumn palette:



7. Click **Save**.

Changes to the cutpoints and palette take effect immediately and apply to all graphs for your current session. The next time you log in, the cutpoints are reset to defaults and the palette is reset according to your user preference **Graph color palette**.

## Bar graphs

### About bar graphs

Bar graphs provide a straightforward way to display the items most closely associated with a specified drug or event, showing the strength of association by plotting each computed statistical score as the length of a horizontal bar. A bar graph is available for two-dimensional results of MGPS data mining runs or logistic regression runs. You can choose a bar graph to display the following scores:

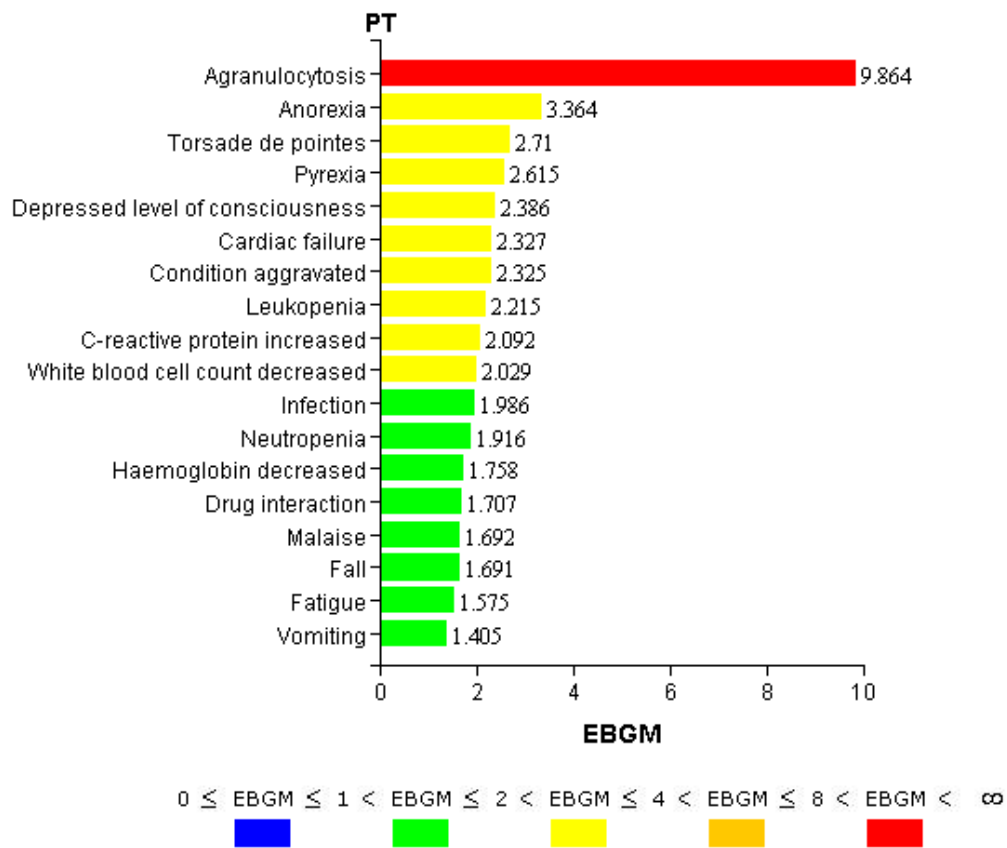
- EBGM, EB05, or N for an MGPS data mining run.
- PRR, if computed for an MGPS data mining run.
- ROR, ROR05, or N, if computed for an MGPS data mining run.
- LROR, LR05, or N for a logistic regression run.

The graph key indicates the statistical ranges that determine the bar colors. On the Choose Graph page, you can [modify the graph key](#) (specifically, the cutpoints and colors).


If the Notes check box is checked when you display the graph, a Notes section provides information about the selection criteria and display options used for the graph.

The following example is a two-dimensional data mining run, with the drug Aprindine selected:

**Drug=Aprindine (Subset: [1968-85]-[2007])**



## Viewing a bar graph

- Click the **Data Mining Runs** tab.  
The [Data Mining Runs page](#) appears.
- Click the row menu () for the run, and then click **View Results**.  
or  
Click the **Data Mining Results** tab.  
The [Select Criteria page](#) appears.
- From the **Run name** drop-down list, select the run you want to view. (Your [user preference](#), **Default Run**, determines which run, if any, is selected by default.) You can also click **Browse** next to the Run name field to [find and select a run](#).
- Type at least one drug or event.
- Click **Choose Graph**.  
The [Choose Graph page](#) appears.
- Select a bar graph.
- On the Bar Graph page, specify restrictions, which are applied in addition to any restrictions that you specified on the [Select Criteria page](#):

Restriction	Description
N at least	Display only combinations with an observed count (N) of at least the specified number.
At most _____ associations	Display no more than the specified number of combinations. You can display up to 200 combinations. If combinations are excluded because of this limit, a message appears below the graph.
<score> at least	Display only combinations with a score (EBGM, LROR, PRR, or ROR) of at least the specified number.
<score> at least	Display only combinations with a lower confidence limit (EB05, LR05, ROR05) of at least the specified number.
Subset	Available only if you selected <b>All</b> on the Select Criteria page. The available subsets are all those selected during run creation. Bar graphs show data for only one subset. To view data for all subsets in a single graph, click <b>View as a Map Graph Showing Discrete Subsets</b> or <b>View as a Map Graph Showing Cumulative Subsets</b> below the graph.

8. Specify the following display options:

<b>Display Option</b>	<b>Description</b>
Bar length controlled by:	<p>Indicate whether you want bars to show in descending order by:</p> <ul style="list-style-type: none"> <li>• N (observed count).</li> <li>• The score (EBGM, LROR, PRR, or ROR).</li> <li>• The lower confidence interval score (EB05, LR05, ROR05).</li> </ul>
Bar color controlled by:	<p>Indicate whether bar color should be controlled by:</p> <ul style="list-style-type: none"> <li>• EBGM, LROR, PRR, or ROR, as defined by the graph key.</li> <li>• EB05, LR05, or ROR05, as defined by the graph key.</li> <li>• A single color for all graph bars.</li> </ul>
Order by bar length	Check to show the bars of the graph in descending order based on bar length.
Order by item	Check to show the bars of the graph in alphabetical order.

9. Click **Display**.  
The bar graph appears.
10. You can point to a bar of the graph to display statistics for the combination represented by the bar.
11. Click a bar in the graph to display a menu. If you are displaying multiple graphs on the same page, do not click any graph until all the graphs appear.
  - A. To display the cases underlying the bar, click **View Cases** to [drill down](#) to a list of cases for the bar.
  - B. To create a case series from the cases comprising the bar, click **Create Case Series**.
  - C. To transfer to a different case series, click **Case Series**.
  - D. To download the cases from the bar, click **Download Cases**.
  - E. To download case details of the bar, click **Download Case Details**.
  - F. To run a report about the bar, click **Reports**.
  - G. To [save the graph as an attachment to a topic](#), click **Save to Topic**. (This option is available if **Links** is checked and the topics feature has been set up.) The graph is attached in a PDF file.

See [Working with results graphs](#) for information about links below the graph.

## Confidence interval graphs

### About confidence interval graphs

Confidence interval graphs are similar to bar graphs but also include a confidence interval or error bar superimposed on each bar to show the 5% and 95% confidence limits. A confidence interval graph is available for two-dimensional MGPS results and logistic regression results. You can choose a confidence interval graph to display the following scores:

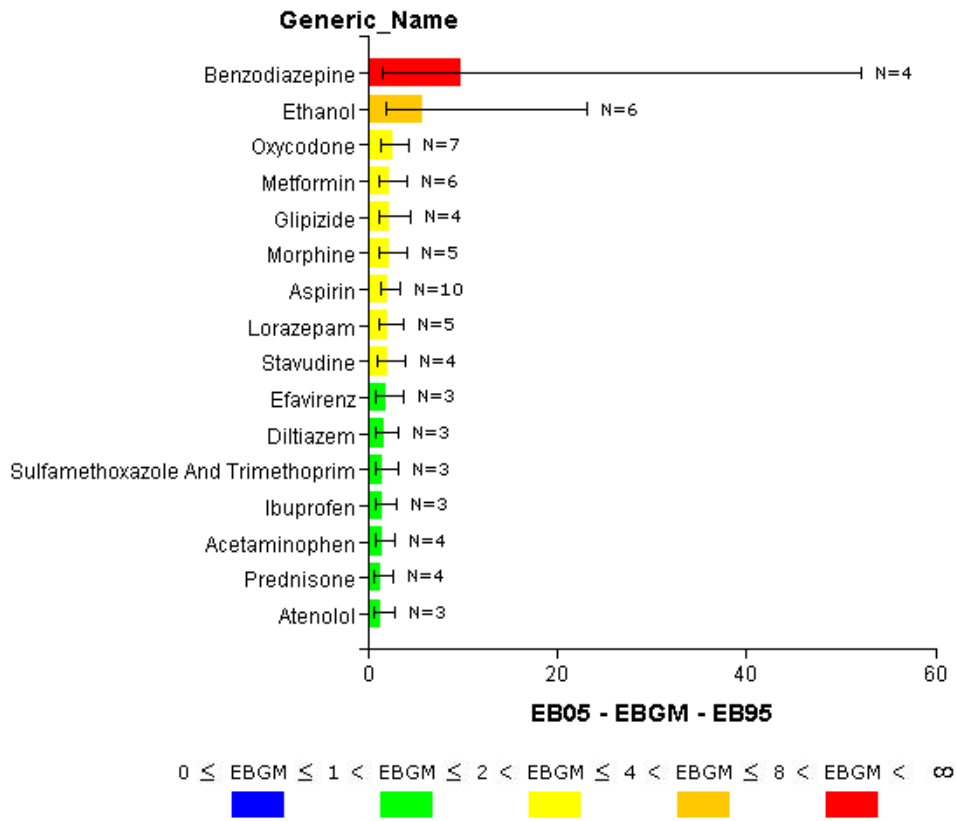
- EB05-EBGM-EB95 for an MGPS data mining run.
- ROR05-ROR-ROR95 for Reporting Odds Ratio computations, if computed by the MGPS data mining run.
- LR05-LROR-LR95 for a logistic regression run.

The graph key shows the statistical ranges that determine the bar colors. You can [modify the graph key](#) (specifically, the cutpoints and colors) on the Choose Graph page.

If the Notes check box is selected when you display the graph, a Notes section appears, and provides information on the selection criteria and display options used for the graph.


The following example is for a two-dimensional data mining run, with the Anion gap abnormal event selected:

**Event=Anion gap abnormal (Subset: [1968-85]-[2007])**





## Viewing a confidence interval graph

- Click the **Data Mining Runs** tab.  
The [Data Mining Runs page](#) appears.
- Click the row menu () for the run, and then click **View Results**.  
or  
Click the **Data Mining Results** tab.  
The [Select Criteria page](#) appears.
- From the **Run name** drop-down list, select the two-dimensional MGPS or Logistic Regression run you want to view. (Your [user preference](#), **Default Run**, determines which run, if any, is selected by default.) You can also click **Browse** next to the Run name field to [find and select a run](#).
- Type at least one drug or event.
- Click **Choose Graph**.  
The [Choose Graph page](#) appears.
- Select a confidence interval graph.
- On the Confidence Interval Graph page, specify restrictions, which will be applied in addition to any restrictions that you specified on the [Select Criteria page](#):

Restriction	Description
N at least	Display only combinations with an observed count (N) of at least the specified number.
At most _____ associations	Display no more than the specified number of combinations. You can display up to 200 combinations. If combinations are excluded because of this limit, a message appears below the graph.
<score> at least	Display only combinations with a score (EBGM, LROR, or ROR) of at least the specified number.
<score> at least	Display only combinations with a lower confidence limit (EB05, LR05, ROR05) of at least the specified number.
Subset	Available only if you selected <b>All</b> on the Select Criteria page. The available subsets are all those selected during run creation. Confidence interval graphs show data for only one subset. To view data for all subsets in a single graph, click <b>View as a Map Graph Showing Discrete Subsets</b> or <b>View as a Map Graph Showing</b>

### Cumulative Subsets.

8. Specify the following display options:

Display Option	Description
Bar color controlled by:	<p>Check to specify how to control bar color:</p> <ul style="list-style-type: none"> <li>• EBGM, LROR, or ROR, as defined by the graph key.</li> <li>• EB05, LR05, or ROR05, as defined by the graph key.</li> <li>• A different color for each bar in the graph.</li> <li>• A single color for all graph bars.</li> </ul>
Order by bar length	Check to show the bars of the graph in descending order based on bar length.
Order by item	Check to show the bars of the graph in alphabetical order.
Show N at end of confidence interval	Display the value of N at the end of each confidence interval bar.

9. Click **Display**.
- The confidence interval graph appears.
10. You can point to a bar of the graph to display statistics for the combination represented by the bar.
11. Click a bar in the graph to display a menu. If you are displaying multiple graphs on the same page, do not click any graph until all the graphs appear.
- To display the cases underlying the bar, click **View Cases** to [drill down](#) to a list of cases for the bar.
  - To create a case series from the cases comprising the bar, click **Create Case Series**.
  - To transfer to a different case series, click **Case Series**.
  - To download the cases from the bar, click **Download Cases**.
  - To download case details of the bar, click **Download Case Details**.
  - To run a report about the bar, click **Reports**.
  - To [save the graph as an attachment to a topic](#), click **Save to Topic**. (This option is available if **Links** is checked and the topics feature has been set up.) The graph is attached in a PDF file.

See [Working with results graphs](#) for information about links below the graph.



## Discrete map graphs

### About discrete map graphs

Discrete map graphs provide a way to compare strength of associations between specified drugs and events across multiple discrete (non-cumulative) subsets. See [Using a subset variable](#) for more information. A discrete map graph is available for two-dimensional MGPS results of data mining runs that use non-cumulative subsets.

---

**Note:** Map graphs show data for multiple subsets. To view data for only a specified subset, click **View as a Bar Graph Showing a Single Subset** or **View as a Single-Subset Bar Graph with Confidence Intervals**.

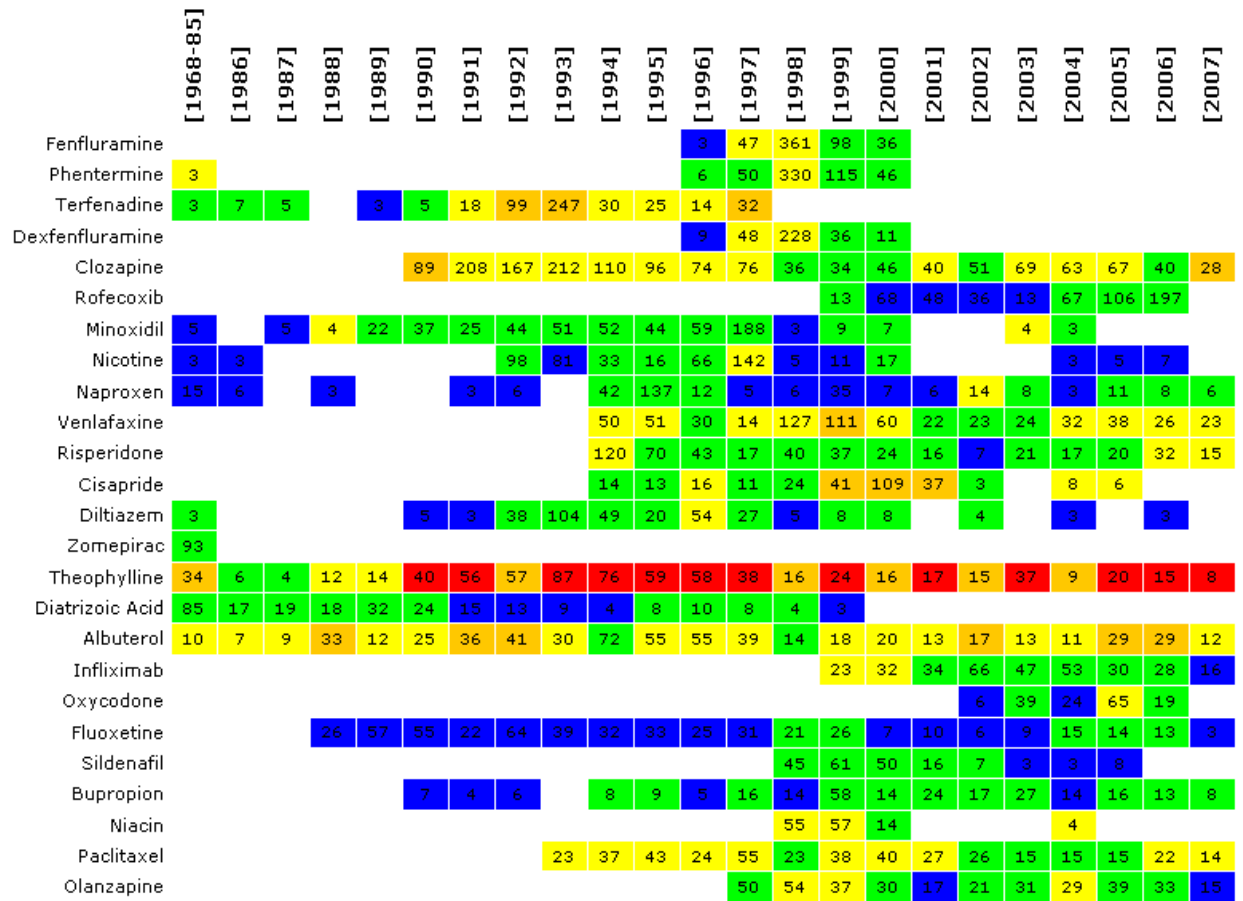
---

The graph key indicates the statistical ranges that determine the cell colors. You can [modify the graph key](#) (specifically, the cutpoints and colors) on the Choose Graph page.

If the **Notes** check box is selected when you display the graph, a Notes section provides information on the selection criteria and display options used for the graph.

The following example is for a two-dimensional data mining run, with the Tachycardia event selected :


Event=Tachycardia



(Some associations excluded due to limit of 25 associations)



## Viewing a discrete map graph

1. Click the **Data Mining Runs** tab.  
The [Data Mining Runs page](#) appears.
2. Click the row menu () for the run, and then click **View Results**.  
or  
Click the **Data Mining Results** tab.  
The [Select Criteria page](#) appears.
3. From the **Run name** drop-down list, select the two-dimensional MGPS run that uses non-cumulative subsets that you want to view. (Your [user preference](#), **Default Run**, determines which run, if any, is selected by default.) You can also click **Browse** next to the Run name field to [find and select a run](#).
4. Type at least one drug or event.
5. Click **Choose Graph**.  
The [Choose Graph page](#) appears.
6. Select a discrete map graph.
7. On the Discrete Map Graph page, specify restrictions, which will be applied in addition to any restrictions that you specified on the [Select Criteria page](#):

Restriction	Description
N at least	Display only combinations with an observed count (N) of at least the specified number.
At most _____ associations	Display no more than the specified number of combinations. You can display up to 200 combinations. If combinations are excluded because of this limit, a message appears below the graph.
EBGM at least	Display only combinations with an EBGM score of at least the specified number.
EB05 at least	Display only combinations with an EB05 score of at least the specified number.

8. Specify the following display options:

Display Option	Description
Select by and	In each cell of the grid, display the numeric value of N (observed),

show value of	EBGM, or EB05. Cells with no occurrences are empty.																															
Color by	<p>Indicates whether the cell color should be controlled by:</p> <ul style="list-style-type: none"> <li>• EBGM, according to the graph cutpoints and palette.</li> <li>• EB05, according to the graph cutpoints and palette.</li> <li>• No color.</li> </ul>																															
Order by high value in any subset	<p>Depending on your selection for <b>Select by and show value of</b>, orders the combinations in the graph in descending order of N, EBGM, or EB05 across all subsets.</p> <p>For example, if the graph contains values of EBGM and has at most six combinations. order by the high value in any subset. The application orders combinations in descending order of EBGM as follows:</p> <table border="1"> <thead> <tr> <th>Combination</th> <th>Subset1</th> <th>Subset2</th> <th>Subset3</th> </tr> </thead> <tbody> <tr> <td>DrugA-EventA</td> <td>EBGM=2.0</td> <td>EBGM=3.8</td> <td>EBGM=1.4</td> </tr> <tr> <td>DrugA-EventB</td> <td>EBGM=3.1</td> <td>EBGM=1.1</td> <td></td> </tr> <tr> <td>DrugA-EventC</td> <td>EBGM=1.5</td> <td>EBGM=2.6</td> <td>EBGM=2.8</td> </tr> <tr> <td>DrugA-EventD</td> <td>EBGM=2.7</td> <td></td> <td>EBGM=2.4</td> </tr> <tr> <td>DrugA-EventE</td> <td>EBGM=0.5</td> <td>EBGM=2.5</td> <td>EBGM=0.8</td> </tr> <tr> <td>DrugA-EventF</td> <td></td> <td>EBGM=1.1</td> <td>EBGM=2.1</td> </tr> </tbody> </table>				Combination	Subset1	Subset2	Subset3	DrugA-EventA	EBGM=2.0	EBGM=3.8	EBGM=1.4	DrugA-EventB	EBGM=3.1	EBGM=1.1		DrugA-EventC	EBGM=1.5	EBGM=2.6	EBGM=2.8	DrugA-EventD	EBGM=2.7		EBGM=2.4	DrugA-EventE	EBGM=0.5	EBGM=2.5	EBGM=0.8	DrugA-EventF		EBGM=1.1	EBGM=2.1
Combination	Subset1	Subset2	Subset3																													
DrugA-EventA	EBGM=2.0	EBGM=3.8	EBGM=1.4																													
DrugA-EventB	EBGM=3.1	EBGM=1.1																														
DrugA-EventC	EBGM=1.5	EBGM=2.6	EBGM=2.8																													
DrugA-EventD	EBGM=2.7		EBGM=2.4																													
DrugA-EventE	EBGM=0.5	EBGM=2.5	EBGM=0.8																													
DrugA-EventF		EBGM=1.1	EBGM=2.1																													
Order by item	Sort combinations in the graph in ascending order of item name across all subsets.																															

9. Click **Display**.  
The discrete map graph appears.
10. You can point to a cell of the graph to display statistics for the combination represented by the cell. Long drug or event terms may end in an ellipsis in the label on the graph itself; in this case, you can point to the cell to see the full terms.
11. Click a cell in the graph to display a menu. If you are displaying multiple graphs on the same page, do not click any graph until all the graphs appear.
  - A. To display the cases underlying the cell, click **View Cases** to [drill down](#) to a list of cases for the bar.
  - B. To create a case series from the cases comprising the cell, click **Create Case Series**.
  - C. To transfer to a different case series, click **Case Series**.

- D. To download the cases from the cell, click **Download Cases**.
- E. To download case details of the cell, click **Download Case Details**.
- F. To run a report about the cell, click **Reports**.
- G. To [save the graph as an attachment to a topic](#), click **Save to Topic**. (This option is available if **Links** is checked and the topics feature has been set up.) The graph is attached in a PDF file.

See [Working with results graphs](#) for information about links below the graph.



## Cumulative map graphs

### About cumulative map graphs

Cumulative map graphs provide a way to compare strength of associations between specific drugs and events across multiple subsets, which are typically based on a continuous variable, such as Year. A cumulative map graph is available for two-dimensional MGPS results of data mining runs that use cumulative subsets.

For more information on subset variables, see [Using a subset variable](#).

---

**Note:** Map graphs show data for multiple subsets, starting with the first subset for which results exist. To view data for a specific subset, click **View as a Bar Graph Showing a Single Subset** or **View as a Single-Subset Bar Graph with Confidence Intervals**.

---

The graph key shows the statistical ranges that determine the cell colors. You can [modify the graph key](#) (specifically, the cutpoints and colors) on the Choose Graph page.

If the Notes check box is selected when you display the graph, a Notes section provides information on the selection criteria and display options used for the graph.

The following example is for a two-dimensional data mining run, with the Tachycardia event selected:


Event=Tachycardia

	[1968-85]	[1968-85]-[1986]	[1968-85]-[1987]	[1968-85]-[1988]	[1968-85]-[1989]	[1968-85]-[1990]	[1968-85]-[1991]	[1968-85]-[1992]	[1968-85]-[1993]	[1968-85]-[1994]	[1968-85]-[1995]	[1968-85]-[1996]	[1968-85]-[1997]	[1968-85]-[1998]	[1968-85]-[1999]	[1968-85]-[2000]	[1968-85]-[2001]	[1968-85]-[2002]	[1968-85]-[2003]	[1968-85]-[2004]	[1968-85]-[2005]	[1968-85]-[2006]	[1968-85]-[2007]
Zomepirac	93	94	94	94	94	94	94	94	94	94	94	94	94	94	94	94	94	94	94	94	94	94	94
Diatrizoic Acid	85	102	121	139	171	195	210	223	232	236	244	254	262	266	269	270	270	270	271	271	271	271	271
Chymopapain	52	53	53	53	54	56	56	56	56	56	56	56	56	56	56	56	56	56	56	56	56	56	56
Terbutaline	50	54	56	64	64	68	75	79	82	85	89	97	104	106	106	109	112	113	115	116	116	116	116
Imipramine	47	56	62	65	69	81	87	95	102	105	108	112	115	120	122	123	125	127	129	131	136	139	140
Metaproterenol	47	74	92	103	112	129	138	144	149	154	155	156	156	156	156	156	156	157	157	157	157	159	159
Lidocaine	41	62	71	81	83	85	89	99	114	118	124	133	137	148	163	173	182	188	198	203	209	219	227
Amoxapine	38	44	48	48	50	50	50	50	51	51	51	51	52	57	57	59	59	60	60	60	60	61	61
Amitriptyline	37	40	47	49	52	55	59	76	84	89	94	99	107	115	129	145	158	168	186	196	222	234	241
Theophylline	34	40	44	56	70	110	166	223	310	386	445	503	541	557	581	597	614	629	666	675	695	710	718
Prazosin	31	40	40	43	45	47	47	48	50	50	50	51	51	54	54	54	54	54	54	54	54	54	54
Epinephrine	30	30	31	32	33	38	41	43	46	50	52	64	66	66	70	73	75	77	80	84	91	93	93
Ritodrine	29	46	57	65	74	78	78	82	89	98	98	101	102	104	107	115	120	121	121	121	121	121	121
Cimetidine	29	36	43	46	46	50	52	53	57	63	71	92	100	102	105	108	109	109	110	112	113	113	113
Benzylpenicillin	27	27	29	29	30	31	31	32	32	33	35	35	35	35	35	35	35	35	35	35	35	35	35
Nifedipine	26	31	38	42	48	57	59	62	70	83	94	100	109	119	133	141	142	144	150	152	158	167	169
Haloperidol	26	26	28	31	32	34	42	48	55	65	76	89	98	107	128	148	159	164	169	177	186	196	200
Pethidine	25	29	31	33	35	43	43	46	54	61	65	71	75	77	79	83	85	85	89	89	91	91	91
Hydralazine	24	24	24	24	27	29	29	31	33	34	35	35	35	36	36	36	36	36	37	37	38	38	38
Alprazolam	24	29	41	53	58	63	69	81	91	105	117	128	137	142	146	156	157	159	165	167	178	185	190
Maprotiline	23	23	23	24	28	29	30	30	30	33	35	35	35	37	37	37	37	40	42	43	44	44	44
Propranolol	23	33	42	47	51	59	63	63	70	78	89	95	102	106	113	116	118	121	127	128	131	133	135
Trazodone	23	30	40	44	49	59	66	70	74	84	86	90	97	99	105	109	119	122	127	135	146	148	150
Cyclobenzaprine	20	23	26	26	29	30	30	32	35	41	42	46	52	56	57	61	62	62	66	70	77	80	85
Iothalamate	20	28	36	44	55	66	71	77	80	87	87	92	95	95	96	97	97	97	97	97	97	97	97

(Some associations excluded due to limit of 25 associations)



## Viewing a cumulative map graph

- Click the **Data Mining Runs** tab.  
The [Data Mining Runs page](#) appears.
- Click the row menu () for the run, and then click **View Results**.  
or  
Click the **Data Mining Results** tab.  
The [Select Criteria page](#) appears.
- From the **Run name** drop-down list, select the two-dimensional MGPS runs with cumulative subsets run that you want to view. (Your [user preference](#), **Default Run**, determines which run, if any, is selected by default.) You can also click **Browse** next to the Run name field to [find and select a run](#).
- Type at least one drug or event.
- Click **Choose Graph**.  
The [Choose Graph page](#) appears.
- Select a cumulative map graph.
- On the Map Graph (Cumulative) page, specify restrictions, which will be applied in addition to any restrictions that you specified on the [Select Criteria page](#):

Restriction	Description
N at least _____	Display only combinations with an observed count (N) of at least the specified number.
EBGM at least _____	Display only combinations with an EBGM score of at least the specified number.
EB05 at least _____	Display only combinations with an EB05 value of at least the specified number.
At most _____ associations	Display no more than the specified number of combinations. You can display up to 200 combinations. If combinations are excluded because of this limit, a message appears below the graph.

- Specify the following display options:

Display Option	Description
Show value of	In each cell of the grid, display the numeric value of N (observed),

EBGM, or EB05. You can also select **Leave blank** to display a grid without labels. Cells with no occurrences are empty.

- Color by
- Check to specify how to color graph cells:
- EBGM, according to the graph cutpoints and palette.
  - EB05, according to the graph cutpoints and palette.
  - No color.

Indicates how to order drug-event combinations in the graph, based on descending order of N, EBGM, or EB05 values. The application applies this ordering to combinations for the first subset. If the maximum number of combinations is not reached, the application applies the ordering to combinations for the second subset, and so on, until the maximum number of combinations is reached. (The maximum number of combinations is determined by the **At most \_\_\_ associations** option.)

For example, the graph shows values of EBGM and has at most six combinations. You order by the first occurrence of EBGM > 2. The combinations in descending order of EBGM are as follows:

Order by first occurrence of

<b>Combination</b>	<b>Subset1</b>	<b>Subset2</b>	<b>Subset3</b>
DrugA-EventB	EBGM=3.1	EBGM=1.1	
DrugA-EventD	EBGM=2.7		EBGM=2.4
DrugA-EventA	EBGM=2.0	EBGM=3.8	EBGM=1.4
DrugA-EventC	EBGM=1.5	EBGM=2.6	EBMG=2.8
DrugA-EventE	EBGM=0.5	EBGM=2.5	EBGM=0.8
DrugA-EventF		EBGM=1.1	EBGM=2.1

9. Click **Display**.  
The cumulative map graph appears.
10. You can point to a cell of the graph to display statistics for the combination represented by the cell. Long drug or event terms may end in an ellipsis in the label on the graph itself; in this case, you can point to the cell to see the full terms.
11. Click a cell in the graph to display a menu. If you are displaying multiple graphs on the same page, do not click any graph until all the graphs appear.
  - A. To display the cases underlying the cell, click **View Cases** to [drill down](#) to a list of cases for the bar.
  - B. To create a case series from the cases comprising the cell, click **Create Case Series**.

- C. To transfer to a different case series, click **Case Series**.
- D. To download the cases from the cell, click **Download Cases**.
- E. To download case details of the cell, click **Download Case Details**.
- F. To run a report about the cell, click **Reports**.
- G. To [save the graph as an attachment to a topic](#), click **Save to Topic**. (This option is available if **Links** is checked and the topics feature has been set up.) The graph is attached in a PDF file.

See [Working with results graphs](#) for information about links below the graph.

## **Nested confidence interval graphs**

### **About nested confidence interval graphs**

To help you investigate possible drug interactions or multi-event syndromes, the nested confidence interval graph displays sets of confidence intervals.

In each set, the first confidence interval is for the 3D combination for the specified pattern (such as Drug+Drug+Event). Subsequent confidence intervals in the set are for the 2D combinations (such as Drug+Event).

In each confidence interval bar, the EB05 value is at the left end, the EBG value is the dot on the bar, and the EB95 value is at the right end. The application highlights a confidence interval bar if its INTSS value is greater than the limit that you specify as a display option. For more information about INTSS, see [interaction scores](#).

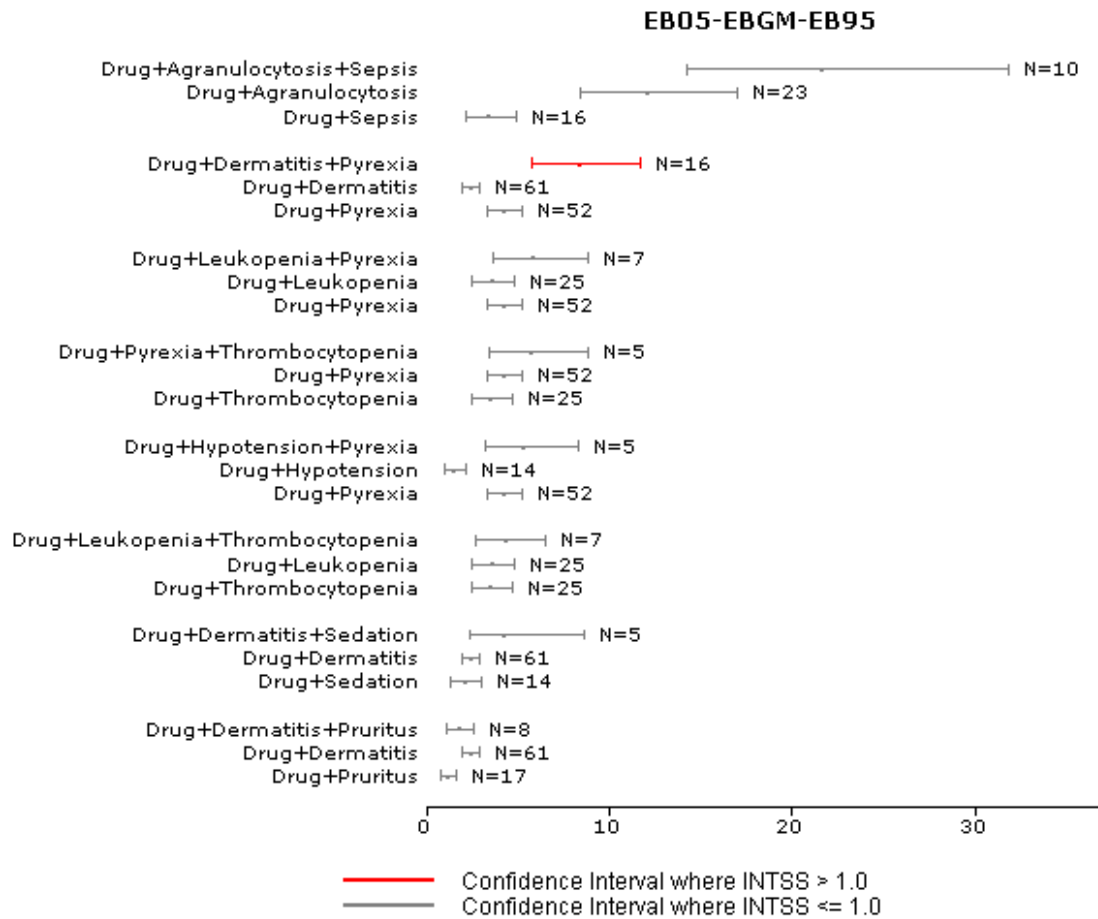
To conserve space in labeling, the drug or event name indicated above the graph is referred to by the label Drug or Event in the graph. In the example below, Drug means Aminoglutethimide.

The key below the graph indicates INTSS values represented by the confidence interval bars. Settings on the [Graph Cutpoints and Palette Choices page](#) do not affect this graph type.


If Notes is checked when you display the graph, a Notes section provides information about the selection criteria and display options used for the graph.

The following example shows a nested confidence interval graph for a three-dimensional data mining run, with the drug Aminoglutethimide selected. The confidence interval for the 3D combination of that drug and two events appears first, followed by confidence intervals for the specified drug and each of the component events.

**Drug= Aminoglutethimide**



## Viewing a nested confidence interval graph

1. Click the **Data Mining Runs** tab.  
The [Data Mining Runs page](#) appears.
2. Click the row menu () for the run, and then click **View Results**.  
or  
Click the **Data Mining Results** tab.  
The [Select Criteria page](#) appears.
3. From the **Run name** drop-down list, select the three-dimensional MGPS run. (Your [user preference](#), **Default Run**, determines which run, if any, is selected by default.) You can also click **Browse** next to the Run name field to [find and select a run](#).
4. Type at least one drug or event.
5. Click **Choose Graph**.  
The [Choose Graph page](#) appears.
6. Select a nested confidence interval graph.
7. On the Nested Confidence Interval Graph page, specify restrictions, which will be applied in addition to any restrictions that you specified on the [Select Criteria page](#). These restrictions apply to combinations of 3 dimensions in the graph.

Restriction	Description
N at least	Display only combinations with an observed count (N) of at least the specified number.
At most _____ combinations	Display no more than the specified number of combinations. You can display graphs for up to 200 combinations. If combinations are excluded because of this limit, a message appears below the graph.
Subset	Available only if you selected <b>All</b> on the Select Criteria page. The available subsets are all those selected during run creation.

8. Specify the following display options:

Display Option	Description
Order by	The application sorts the combinations by the value of the score that you select. For example, if you select INTSS, the 3D combination with the highest INTSS value appears first.



Axis Type	Select either Linear or Log (logarithmic). When you use a logarithmic axis, the confidence intervals for the lower-level combinations appear more clearly.
Highlight confidence intervals where INTSS >	Enter the INTSS value above which confidence interval bars are highlighted.
Show N at end of confidence interval	Check to display the value of N at the end of each bar.
Use gray-scale instead of colors	Check to use shades of gray instead of colors in the graph.

9. Click **Display**.  
The nested confidence interval graph appears.
10. You can point to a bar of the graph to display statistics for the combination represented by the bar. Long drug or event terms may end in an ellipsis in the label on the graph itself; in this case, you can point to the bar to see the full terms.
11. Click a bar in the graph to display a menu. If you are displaying multiple graphs on the same page, do not click any graph until all the graphs appear.
  - A. To display the cases underlying the bar, click **View Cases** to [drill down](#) to a list of cases for the bar.
  - B. To create a case series from the cases comprising the bar, click **Create Case Series**.
  - C. To transfer to a different case series, click **Case Series**.
  - D. To download the cases from the bar, click **Download Cases**.
  - E. To download case details of the bar, click **Download Case Details**.
  - F. To run a report about the bar, click **Reports**.
  - G. To [save the graph as an attachment to a topic](#), click **Save to Topic**. (This option is available if **Links** is checked and the topics feature has been set up.) The graph is attached in a PDF file.

See [Working with results graphs](#) for information about links below the graph.

## Hierarchy graphs

### About hierarchy graphs

Hierarchy graphs highlight situations in which there are interaction effects (such as drug interactions or event syndromes), where the score for an interaction or syndrome is not predicted by the scores of its components. The score for an interaction is INTSS, which is calculated as the EB05 score for the combined drugs or events divided by the highest EB95 score found for an individual component drug or event. The graph is built within the context provided by the drug or event specified on the Select Criteria page. A hierarchy graph is available for three- dimensional results of MGPS data mining runs.

The key below the graph shows the statistical ranges that determine the cell colors. The ranges are for EBGGM and INTSS values. On the Choose Graph page, you can [modify the graph key](#) (that is, the cutpoints and colors).

If Notes is checked when you display the graph, a Notes section provides information about the selection criteria and display options used for the graph.

The following example is for a three-dimensional data mining run, with the drug Tilidine selected. The scores for the two-way interactions between that drug and a single event appear in the left column. The scores for three-way interactions, between the drug and two events, appear in the right column.

## Drug=Tilidine

Item A	Drug + Item A (EBGM)	Item B	Drug + Item A + Item B (INTSS)
Arthralgia	1.725	+ Oedema peripheral	0.692
Asthenia	1.1	+ Dizziness	0.547
Blister	5.692	+ Mucosal erosion	0.385
		+ Stevens-Johnson syndrome	0.586
		+ Toxic epidermal necrolysis	0.637
C-reactive protein increased	5.23	+ Pneumonia	0.421
Dizziness	0.993	+ Asthenia	0.547
Erythema	2.022	+ Oedema peripheral	0.591
Mucosal erosion	21.16	+ Blister	0.385
		+ Stevens-Johnson syndrome	0.377
Nausea	1.034	+ Vomiting	0.468
Oedema peripheral	1.762	+ Arthralgia	0.692
		+ Erythema	0.591
Pneumonia	1.877	+ C-reactive protein increased	0.421
Pyrexia	1.699	+ Toxic epidermal necrolysis	0.514
Stevens-Johnson syndrome	4.663	+ Blister	0.586
		+ Mucosal erosion	0.377
		+ Toxic epidermal necrolysis	0.603
Toxic epidermal necrolysis	14.314	+ Blister	0.637
		+ Pyrexia	0.514
		+ Stevens-Johnson syndrome	0.603
Vomiting	1.25	+ Nausea	0.468


EBGM key applies to cells in the left column

 $0 \leq \text{EBGM} \leq 1 < \text{EBGM} \leq 2 < \text{EBGM} \leq 4 < \text{EBGM} \leq 8 < \text{EBGM} < \infty$ 


INTSS key applies to cells in the right column

 $0 \leq \text{INTSS} \leq 1 < \text{INTSS} \leq 2 < \text{INTSS} \leq 4 < \text{INTSS} \leq 8 < \text{INTSS} < \infty$ 


## Viewing a hierarchy graph

1. Click the **Data Mining Runs** tab.  
The [Data Mining Runs page](#) appears.
2. Click the row menu () for the run, and then click **View Results**.  
or  
Click the **Data Mining Results** tab.  
The [Select Criteria page](#) appears.
3. From the **Run name** drop-down list, select the three-dimensional run you want to view. (Your [user preference](#), **Default Run**, determines which run, if any, is selected by default.) You can also click **Browse** next to the Run name field to [find and select a run](#).
4. Type at least one drug or event.
5. Click **Choose Graph**.  
The [Choose Graph page](#) appears.
6. Select a hierarchy graph.
7. On the Hierarchy Graph page, specify restrictions, which will be applied in addition to any restrictions that you specified on the [Select Criteria page](#). These restrictions apply to combinations of the highest dimension in the graph.

Restriction	Description
N at least	Display only combinations with an observed count (N) of at least the specified number.
At most _____ associations	Display no more than the specified number of combinations. You can display up to 200 combinations. If combinations are excluded because of this limit, a message appears below the graph.
Subset	Available only if you selected <b>All</b> on the Select Criteria page. The available subsets are all those selected during run creation.

8. Specify the following display options:

Display Option	Description
Show value of	Select <b>N</b> or <b>EBGM/INTSS</b> as the statistic to show in cells. You can also leave cells blank.  For 3D run results, the EBGM score applies to the two-way combinations, which appear in the cells in the left column. The

INTSS score applies to the three-way combinations, which appear in the right column.

---

**Note:** If the data mining run results do not include items of the same type (an option during run creation), statistics do not appear for items of the same type (such as a drug+drug or event+event combination).

---



---

Color by	Check to specify how to color graph cells: <ul style="list-style-type: none"> <li>• EBG/INTSS</li> <li>• No color</li> </ul>
----------	------------------------------------------------------------------------------------------------------------------------------

---

9. Click **Display**.  
The hierarchy graph appears.
10. You can point to a cell of the graph to display statistics for the combination represented by the cell. Long drug or event terms may end in an ellipsis in the label on the graph itself; in this case, you can point to the cell to see the full terms.
11. Click a cell in the graph to display a menu. If you are displaying multiple graphs on the same page, do not click any graph until all the graphs appear.
  - A. To display the cases underlying the cell, click **View Cases** to [drill down](#) to a list of cases for the cell.
  - B. To create a case series from the cases comprising the cell, click **Create Case Series**.
  - C. To transfer to a different case series, click **Case Series**.
  - D. To download the cases from the cell, click **Download Cases**.
  - E. To download case details of the cell, click **Download Case Details**.
  - F. To run a report about the cell, click **Reports**.
  - G. To [save the graph as an attachment to a topic](#), click **Save to Topic**. (This option is available if **Links** is checked and the topics feature has been set up.) The graph is attached in a PDF file.

See [Working with results graphs](#) for information about links below the graph.

## Overlap graphs

### About overlap graphs


Overlap graphs highlight situations in which there are interaction effects (such as drug interactions or event syndromes), where the score for an interaction or syndrome is not predicted simply by the scores of its components. The score for the interaction or syndrome is shown as INTSS, which is computed as the EB05 score for the combined drugs or events divided by the highest EB95 score found for the component drugs or events. The graph is built within the context provided by the drug or event specified on the Select Criteria page. An overlap graph is available for three- dimensional results of MGPS data mining runs.

The key below the graph shows the statistical ranges that determine the cell colors. The ranges are for EBGm and INTSS values. On the Choose Graph page, you can [modify the graph key](#) (that is, the cutpoints and colors).

If Notes is checked when you display the graph, a Notes section provides information about the selection criteria and display options used for the graph.

The following example is for a three-dimensional data mining run, with the event Flushing selected on the Select Criteria page. The scores for the two-way interactions between that event and a single drug appear in the cells in the first column and the first row of the graph. The scores for three-way interactions between the event and two drugs appear in the remainder of the graph (in the center and in the rest of the bottom row and right column).

## Viewing an overlap graph

- Click the **Data Mining Runs** tab.  
The [Data Mining Runs page](#) appears.
- Click the row menu () for the run, and then click **View Results**.  
or  
Click the **Data Mining Results** tab.  
The [Select Criteria page](#) appears.
- From the **Run name** drop-down list, select the three-dimensional run you want to view. (Your [user preference](#), **Default Run**, determines which run, if any, is selected by default.) You can also click **Browse** next to the Run name field to [find and select a run](#).
- Type at least one drug or event.
- Click **Choose Graph**.  
The [Choose Graph page](#) appears.
- Select an overlap graph.
- On the Overlap Graph page, specify restrictions, which will be applied in addition to any restrictions that you specified on the [Select Criteria page](#). These restrictions apply to combinations of the highest dimension in the graph.

Restriction	Description
N at least	Display only combinations with an observed count (N) of at least the specified number.
At most _____ associations	Display no more than the specified number of combinations. You can display up to 200 combinations. If combinations are excluded because of this limit, a message appears below the graph.
Subset	Available only if you selected <b>All</b> on the Select Criteria page. The available subsets are all those selected during run creation.

- Specify the following display options:

Display Option	Description
Show value of	Select <b>N</b> or <b>EBGM/INTSS</b> as the statistic to show in cells. You can also leave cells blank. For 3D run results, the EBGM score applies to the two-way

combinations, which appear in the cells in the left column. The INTSS score applies to the three-way combinations, which appear in the remainder of the graph (in the right column).

---

**Note:** If the data mining run results do not include items of the same type (an option during run creation), statistics do not appear for items of the same type (such as a drug+drug or event+event combinations).

---

---

Color by  Check to specify how to color graph cells:

- EBG/INTSS
- No color

---

9. Click **Display**.  
The overlap graph appears.
10. You can point to a cell of the graph to display statistics for the combination represented by the cell. Long drug or event terms may end in an ellipsis in the label on the graph itself; in this case, you can point to the cell to see the full terms.
11. Click a cell in the graph to display a menu. If you are displaying multiple graphs on the same page, do not click any graph until all the graphs appear.
  - A. To display the cases underlying the cell, click **View Cases** to [drill down](#) to a list of cases for the cell.
  - B. To create a case series from the cases comprising the bar, click **Create Case Series**.
  - C. To transfer to a different case series, click **Case Series**.
  - D. To download the cases from the cell, click **Download Cases**.
  - E. To download case details of the cell, click **Download Case Details**.
  - F. To run a report about the cell, click **Reports**.
  - G. To [save the graph as an attachment to a topic](#), click **Save to Topic**. (This option is available if **Links** is checked and the topics feature has been set up.) The graph is attached in a PDF file.

See [Working with results graphs](#) for information about links below the graph.



## Sector maps

### About sector maps

A sector map for data mining results is a visual presentation of data for a particular drug across all System Organ Classes (SOCs). A large tile represents each System Organ Class (SOC) in the sector map. Smaller tiles within each SOC tile represent Preferred Terms (PTs). A sector map graph is available for two-dimensional results of MGPS data mining runs.

The application ranks PTs in descending order of values of the statistic (EBGM, EB05, Chi-statistic, or PRR) that you choose. A color key indicates relative ranking. You can also list the ranked PTs below the sector map.

---

**Note:** The primary path of a PT determines where it appears in the sector map. If a PT is not in the event hierarchy associated with the configuration, it appears in a SOC tile named Unknown.

---

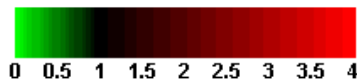
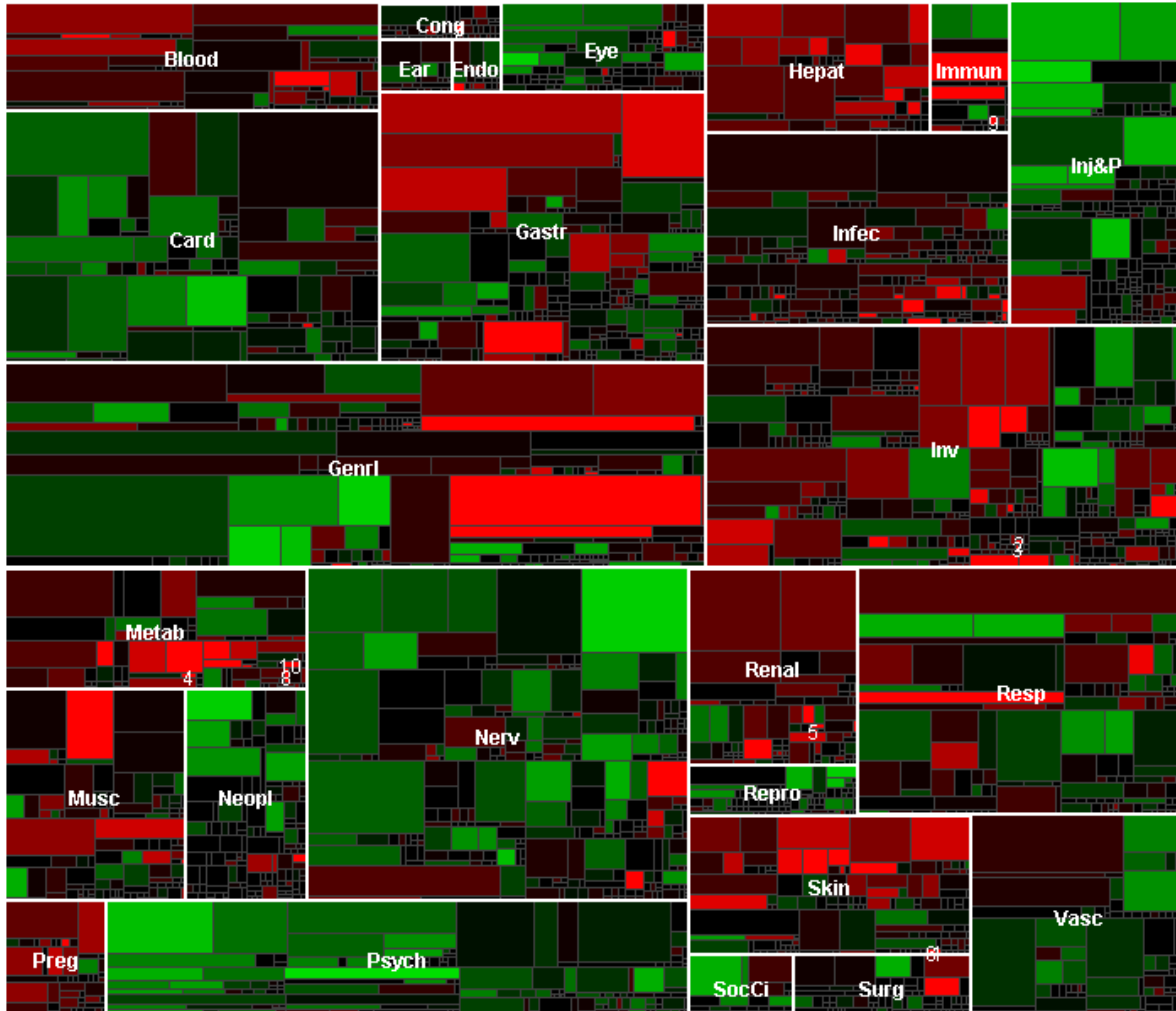
The list of ranked PTs below the sector map includes the following information:

Field	Description
Rank	Ranking of the term (combined with the drug) according to values of the statistic you have configured the sector map to use (via the Color controlled by option).
SOC	SOC containing the term.
Term (PT)	Specific PT.
EBGM, EB05, Chi-statistic, or PRR	Value of the statistic you have configured the sector map to use (via the Color controlled by option).

If Notes is checked when you display the graph, a Notes section provides information about the selection criteria and display options used for the graph.


The following example is for a two-dimensional data mining run, with the drug Abacavir selected on the Select Criteria page:

**Drug=Abacavir**



Rank	SOC	Term (PT)	EBGM
1	Skin	Lipoatrophy	58.070
2	Inv	Viral mutation identified	27.037
3	Inv	Viral load increased	26.720
4	Metab	Hyperlactacidaemia	26.526
5	Renal	Fanconi syndrome acquired	26.160
6	Skin	Lipodystrophy acquired	21.570
7	Cong	Trisomy 21	19.346
8	Metab	Mitochondrial cytopathy	18.923
9	Immun	Immune reconstitution syndrome	18.546
10	Metab	Hypophosphataemia	18.243

## Viewing a sector map

1. Click the **Data Mining Runs** tab.  
The [Data Mining Runs page](#) appears.
2. Click the row menu () for the run, and then click **View Results**.  
or  
Click the **Data Mining Results** tab.  
The [Select Criteria page](#) appears.
3. From the **Run name** drop-down list, select the two-dimensional MGPS run you want to view. (Your [user preference](#), **Default Run**, determines which run, if any, is selected by default.) You can also click **Browse** next to the Run name field to [find and select a run](#).
4. Type at least one, but no more than five, drug names
5. Click **Choose Graph**.  
The [Choose Graph page](#) appears.
6. Select a sector map graph.
7. On the Sector Map page, specify the following display options:

Column	Description
Subset	Available only if you selected <b>All</b> on the <a href="#">Select Criteria page</a> . The available subsets are all those selected during run creation.
Color controlled by	Name of the statistic whose values will be ranked and used for coloring the sector map tiles. Available values are those computed by the data mining run and include EBGGM, EB05, Chi-statistic (signed), and PRR.
Term box size controlled by	The factor that controls the size of PT tiles: <ul style="list-style-type: none"> <li>• <b>Relative importance of term</b>—Bases the size of PT tiles on an algorithm that determines the relative public health impact of PTs. Using a recent version of AERS data, the application computes the public health impact for a PT as: (number of times the PT occurs in serious cases) * (proportion of cases with that PT that are serious-or-fatal). A higher Public Health Impact score corresponds to a larger tile in the sector map. Because size is based on the number of cases of the PT alone (not the number of cases that have the PT and a</li> </ul>

particular drug), the tile size is stable over sector maps for different drugs.

---

**Note:** For PTs that are new in the MedDRA version associated with the AERS data used to assess public health impact, the application cannot determine the tile size. The application represents these PTs as small tiles.

---

- **All terms have equal size**—All PT tiles have the same size.

Display maximum intensity at signal score of ___	Displays all tiles for which scores are above this value at the maximum-intensity color, as shown in the color key below the graph.
Use gray-scale instead of colors	Use shades of gray instead of colors in the graph.
Show low scores in green for color graph	Check to show low scores in varying shades of green. Clear to show low scores in black.  <b>Note:</b> This setting has no effect if you display the sector map in gray-scale.
Omit rare terms used fewer than ___ times in AERS	Number indicating how many times a PT must be in the AERS database (the same one used for Relative importance of term) for that PT to be shown in the sector map.  <b>Note:</b> The notes for a sector map indicate any rare terms that are omitted because of this restriction.
Group by HLT	Within a SOC tile, group in the same rectangular area the tiles for PTs that are in the same HLT. If you also group by HLGT, the tiles for PTs are grouped by HLT within each HLGT.
Group by HLGT	Within a SOC tile, group in the same rectangular area the tiles for PTs that are in the same HLGT.
List ___ top scores	Number indicating how many (up to 1000) terms with the top scores are ranked and listed below the sector map. The score is the statistic selected for Color controlled by.  If multiple terms have the same score, the application counts each term separately. For example, you enter 20 as the limit. If the 20th row has a score that other terms after that also have, the application shows those additional terms as well.
Show top score indexes	If checked, the application numbers tiles in the sector map to show their rank, up to the number of scores specified in List ___ top scores. For this option to take effect, there must also be a value specified for List ___ top scores.

8. Click **Display**.

9. If you point to a PT tile, the MedDRA PT, HLT, HLGT, and SOC appear. The following information for the combination of the drug and the term that the tile represents also appears:
  - **N**—Observed number of cases with drug-event combination.
  - **EBGM**—Empirical Bayesian Geometric Mean. A more stable estimate than RR; the so-called shrinkage estimate.
  - **EB05 A**—5% probability value that the true Relative Ratio lies below it.
  - **PRR**—Proportional Reporting Ratio. For more information, see PRR computations. The PRR and Chi-statistic are available only if the data mining run was set up to compute PRR.
  - **Chi-statistic**—Chi-statistic associated with PRR. (If EBGM < 1, the Chi-statistic is expressed as a negative number, indicating that the drug-event combination is more rare than expected). The Chi-statistic is the signed square root of Chi-square.
10. To [zoom in](#) on a particular SOC, click anywhere on the SOC tile and select **Zoom** from the menu.
11. If you click a tile for which N is at least 1, you can then [drill down](#) to a list of cases for the tile or [view statistics](#) for the tile.
12. To [save the graph as an attachment to a topic](#), click **Save to Topic**. (This option is available if **Links** is checked and the topics feature has been set up.) The graph is attached in a PDF file.

See [Working with results graphs](#) for information about links below the graph. For best results, print the sector map graph in landscape mode.

### Related topic

[About Sector Map Graphs](#)

## Zooming in on a sector map

If you zoom in on a particular SOC tile in the sector map, data only for that SOC appears in the zoom window.

1. On the sector map, click a SOC tile.
2. From the menu, click **Zoom**.  
A sector map of the selected SOC tile appears.
3. You can perform all the same actions as when [viewing the main sector map](#), except that you cannot zoom in further. Note that the ranking of PTs changes because you are viewing PTs for only one SOC.
4. To close the dialog box, click **Cancel**.

## Viewing sector map statistics

1. On the sector map or in the zoom window, click a PT tile.
2. From the menu, click **Statistics**.

A dialog box appears showing the following statistics for the combination of the drug and event:

- **N**—Observed number of cases.
- **EBGM**—Empirical Bayesian Geometric Mean. A more stable estimate than RR; the so-called shrinkage estimate. For more information, see [MGPS computations](#).
- **EB05**—A 5% probability value that the true Relative Ratio lies below it.
- **PRR**—Proportional Reporting Ratio. For more information, see [PRR computations](#). The PRR and Chi-statistic are available only if the data mining run was set up to compute PRR.
- **Chi-statistic**—Chi-statistic associated with the PRR. (If EBGM < 1, the Chi-statistic is expressed as a negative number, indicating that the drug-event combination is more rare than expected). The Chi-statistic is the signed square root of Chi-square.

3. To close the dialog box, click **Close**.





## Working with queries

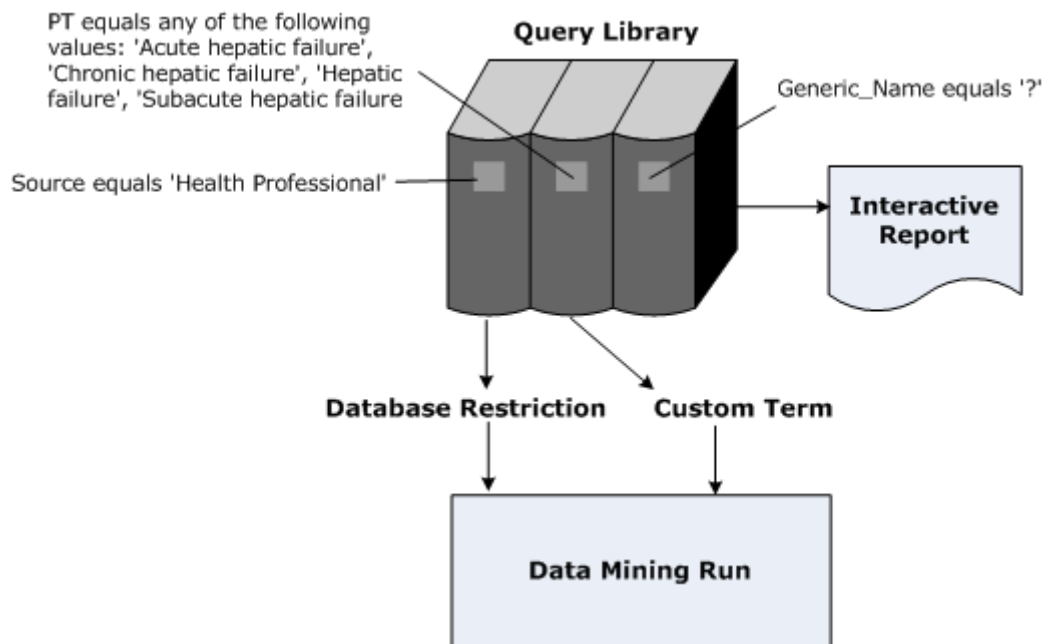
### About queries

A query is the specification of criteria based on variables and values in the [source data](#). When you run a query, the application retrieves cases that match the specified criteria. To create or edit a query, use the Query Wizard to guide you through the steps of selecting variables, selecting values, and specifying query logic.

For variables in a query, values do not need to be predefined. Users can supply values at the time they run the query. For example, you can set up a query to look for cases that include both of two drugs, where the two drugs are specified at the time you run the query.

A query is a dynamic object that is re-applied each time you run the query. If data has changed since the last time you ran the query, the query results can differ. In contrast, a [case series](#) is a saved list of cases.

When creating [database restrictions](#), [custom terms](#), [query-based case series](#), or [interactive reports](#), you can create new queries or use existing queries. The list of existing queries is the Query Library. To use an existing query, you select it from the Query Library. For example, there is an existing query that finds females under age 65. To perform a data mining run based only on females under age 65, you define a database restriction based on that query.



When using an existing query in the process of defining another object, you work with a copy of the query. Modifying the copy does not affect the query in the Query Library. Likewise, changes to the query in the library do not affect the copies of the query associated with any existing objects.

---

**Note:** Because queries run on source data (not data mining results), they do not include [custom terms](#) or values created by [data transformations](#).

---

## Queries page

On the Queries page, you can view information about existing queries and define new queries if you have the Create Queries/Case Series permission.

### General activities

The following links and filters appear at the top of the page and affect the entire page:

- [Create Using Query Wizard](#)
- [Columns](#)
- [Print](#)
- [Download](#)
- [Select Rows](#)
- [Project drop-down list](#)
- [Configuration drop-down list](#)
- Origin drop-down list

The following links appear at the top of the page when the page is in the Select Rows mode. The links affect the multiple queries:

- [Print](#)
- [Download](#)
- Delete
- Select All
- Clear All
- Back

### Row-specific activities

The following menu options are available from the Row menu, located in the left-most column of the table, and affect an individual row in the table:

- [Run](#)
- [Create Case Series](#)
- [View](#)
- [Edit](#)
- [Rename](#)
- [Report](#)
- [Publish](#)
- [Copy](#)
- Delete

### Field descriptions—Queries page

The Queries page provides the following information about each query:

<b>Column</b>	<b>Description</b>
Name	Name of the query.
Description	Description of the query.
Project	Name of the project to which the query is assigned.
Configuration	Name of the data configuration associated with the query.
Created By	Name of the user who created the query.
Created	Date and time when the query was created.
Modified By	Name of the user who last modified the query.
Modified	Date and time when the query was last modified.
ID	Identifier that was assigned automatically to the query when the query was saved. Each query ID is unique and is not re-used if the query is deleted.
Origin	<p>One of the following values:</p> <ul style="list-style-type: none"> <li>• <b>Case Series</b>—The query was created and saved during the creation of a query-based case series on the Case Series tab.</li> <li>• <b>Custom Term</b>—The query was created and saved during the creation of a custom term for a data mining run.</li> <li>• <b>Interactive Report</b>—The query was created and saved during the creation of an interactive report.</li> <li>• <b>Query</b>—The query was created and saved from the Queries page.</li> <li>• <b>Restriction</b>—The query was created and saved during the creation of a database restriction for a data mining run.</li> </ul>

## Creating a query from an existing query

The Select Query from Library page appears if you choose to use an existing [query](#) when defining a custom term, database restriction, or query-based interactive report. The queries must have been created by you or published to you. (If you have the Administer Users permission, you can select from published or unpublished queries created by any user in your login group.)

Once you use an existing query for a custom term, database restriction, or query-based interactive report, subsequent changes to the query in the library do not affect the custom term, database restriction, or report.

1. Select **Create from Existing Query**.

The Select Query from Library dialog box appears.

2. From the **Project** drop-down list, select a specific [project](#), or select -- to include all projects.
3. From the **Configuration** drop-down list, [select the data configuration](#), or select -- to include all configurations. Available queries are those that are [compatible](#) with the data configuration for the data mining run (if you are creating a custom term or database restriction) or report definition (if you are creating a report).
4. From the **Origin** drop-down list, select one of the following values:
  - **Query**—The query was created and saved from the Queries page.
  - **Case Series**—The query was created and saved during the creation of query-based case series on the Case Series tab.
  - **Custom Term**—The query was created and saved during the creation of a custom term for a data mining run.
  - **Restriction**—The query was created and saved during the creation of a database restriction for a data mining run.
  - **Interactive Report**—The query was created and saved during the creation of an interactive report.
5. Click the radio button of the row for the query that you want to select.
6. Click **Next**.

If you are defining a custom term or database restriction, the Refine Query page appears. Optionally, you can [refine the query](#). For more information, see [Refining a query](#).

## Viewing existing queries

The Queries page provides information about existing [queries](#) and enables you to define new queries.

For the selected project and data configuration, the Queries page lists queries that you have created or that are published to you. If you have the Administer Users permission, the page also lists unpublished queries created by any users in your login group.

1. Click the **Queries** tab.

The Queries page appears and lists your queries and queries published to you.

2. Filter the list as necessary.

- From the **Project** drop-down list, select the [project](#) for which you want to view queries or -- to include all projects.
- From the **Configuration** drop-down list, select the [data configuration](#) for which you want to view queries or -- to include all configurations.
- From the **Origin** drop-down list, select the origin of the queries you want to view.-- to include all types.


The selected queries appear. See the [Queries page](#) for information about the queries.

3. See [About tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.


4. To print, download, or delete multiple queries, click **Select Rows**. You can then check the rows for the queries on which you want to act. You can also click **Select All** to check all rows (or **Clear All** to uncheck all rows). Then click the action that you want to perform on the selected rows.

5. To create a query, click **Create Using Query Wizard**.

The Select Configuration page appears.

6. If you click the row menu () for any query, you can do the following:

- To run the query, click **Run** and select a data configuration.
- To run the query and create a case series from the query results, click **Create Case Series**. You select a data configuration, review variables and values, and optionally change the name, description, and project assignment before saving the case series.
- To view the query logic, click **View**. This option shows the variables and values that make up the query, as well as the logic.

- To run the query and then run a report against cases found by the query, click **Report** and select a data configuration. After you run the query, the Report Definitions page appears.
  - To copy a query, click **Copy**. Then provide a name for the copy and save it.
7. If you click  for a query that you created, you can do the following:
- To edit the query, click **Edit**. You can click **Back** to select a different data configuration.
  - To rename the query, click **Rename**. You can also change its description or assign it to a different project.
  - To publish a query, click **Publish**. (If you have the Administer Users permission, you can publish a query created by any user in your login group.)
  - To delete a query, click **Delete**. At the message asking if you want to delete the query, click **OK**. The query is deleted and no longer appears on your Queries tab.

---

**Note:** Editing or deleting a query has no effect on any case series, database restrictions, custom terms, or interactive reports that were created using the query.

---

## Creating a query

### Defining query conditions

When you create or edit a query, the Define Query page appears. On the Define Query page, you specify conditions and link them with operators. For information about operators, see [Specifying query logic](#).

1. Click the **Queries** tab.  
The Queries page appears and lists your queries and queries published to you.
2. Click **Create Using Query Wizard**.  
The Select Configuration page appears.
3. From the Configuration drop-down list, select a [data configuration](#). You can click **Browse** to select from a descriptive list of data configurations.
4. Click **Next**.  
The [Define Query page](#) appears.
5. Click **Select Variables**.  
The Select Variables dialog box appears.  
If you need more information about variables, click **Show Variables**. The Configuration Variables dialog box appears, showing a description of each variable.
6. From the **All Variables in all Tables** list, [select one or multiple variables](#) on which to base conditions. For more information, see [Selecting values from a list](#).
7. Click **OK**.  
The Define Query page appears.
8. A field for each variable you selected appears on the Define Query page. If you point to the field name, a description of the field appears. The application assigns a number to each variable. When you specify query logic, you use that number to refer to the condition that is based on that variable.
9. If you are creating or editing a query from the Queries tab or for an interactive report, you can specify values for each variable in the query. When running the query, you can change the specified values or enter values (if none were provided in the original query).

or

If you are creating or editing a query in the process of defining a database restriction, custom term, or case series, you must specify values for each variable or remove the variable.



The way in which you specify values depends on the type of variable. For more information, see [Selecting query variables](#).

10. Each condition that you specify must be referenced by the query logic. If you are not going to reference a condition, you must remove the condition from the query. To remove a condition, click [**X**] in the upper right corner of the box containing the variable. (After deleting a condition, you might need to respecify values for variables in the other conditions.)

---

**Note:** You can include the same variable in the query multiple times. For example, cases for which the subject's age is between 17 and 25 or above 65. You include the AGE variable and set it to 17-25; include the AGE variable again and set it to above 65; then connect the variables with the OR operator.

---

11. After adding all variables that you need for specifying conditions, specify query logic by clicking **Edit**. For more information, see [Specifying query logic](#).
12. Click **OK**.

---

**Note:** If you add or delete another query variable after this step, the query logic is reset to a default.

---

13. If your [user preferences](#) include **Show case count by default on preview page**, you can check **Display Case Count in Query Preview**. This option requires that you have specified values for all variables in the query. The next page, which is the Preview Query page, shows the count of cases. Computation of the case count can be time-consuming, so Oracle recommends that you display it only when necessary.
14. To save the query to the library (the Queries page), check **Add Query to Library**. This option is available when you are defining a new query for a database restriction, custom term, or interactive report or creating a query-based case series. The query has the same name as the case series.

If you add the query to the library, it is separate from the database restriction, custom term, interactive report, or case series. Subsequent modifications of the query in the library have no effect on the database restriction, custom term, interactive report, or case series.

15. Click **Next**.  
The [Preview Query page](#) appears.

## Specifying query logic

When you specify conditions in a query, they are connected using default operators. You can modify the operators as needed. When specifying query logic, you refer to conditions by the numbers that were assigned automatically to the variables on which the conditions are based. For example, the query logic **1 AND 2** means **Condition 1 AND Condition 2**.

1. On the [Define Query page](#), click **Edit**.  
The Edit Logic window appears.
2. Type in logical operators, set operators, and parentheses as needed.
  - The conditions in a query must be joined by the AND, OR, INTERSECT, UNION, or MINUS operator. The NOT operator is available to negate a condition (for example, 1 AND NOT 2).
  - Each condition must be referenced by the query logic at least once. You can refer to the same condition multiple times in a query. For example, you can specify: (1 AND NOT 2) OR 2.
3. Click **OK**.

## Logical operators

Logical operators act on individual rows of source data tables. You can use the following logical operators between conditions:

- **AND**—Find cases for which both conditions occurred simultaneously.
- **OR**—Find cases for which either of the conditions occurred.

You can use the logical operator NOT to negate a condition. (You cannot use NOT alone to connect conditions.)

## Set operators

Set operators act on sets of cases that are retrieved by the conditions on each side of the set operator. You can use the following set operators between conditions:

- **INTERSECT**—Find cases that are in both sets.
- **UNION**—Find cases that are in either set.
- **MINUS**—Find cases that are in the set to the left of the operator, and subtract from that list the cases that are in the set to the right of the operator.

Sometimes it is possible to specify the same query using either logical operators or set operators. It is preferable to use logical operators because they are more efficient.

## Operator priority

When the application interprets the query expression, it applies operators in the following order:

- NOT
- AND
- OR
- INTERSECT, UNION, MINUS (same priority)

The only restriction on how logical and set operators can interact is that logical operators cannot act on the results of set operators. For example, the following query is invalid: 1 AND (2 INTERSECT 3).

You can use parentheses to change the way in which a query expression is interpreted. If you do not use parentheses explicitly, the query is interpreted as if there are parentheses, based on the default order of operators.

For example, suppose the query is:

1 AND 2 OR 3 INTERSECT 4

With no supplied parentheses, the application reads the query as:

((1 AND 2) OR 3) INTERSECT 4

If you use parentheses, the meaning of the query is different:

1 AND (2 OR 3) INTERSECT 4

## Examples

You specify the following conditions:

The image shows three dialog boxes for specifying query conditions:

- 1 DRUG**: A list box containing "Thiamine" and a "Select" button. Below the list box is an unchecked checkbox labeled "Include Null values".
- 2 DRUG**: A list box containing "Niacin" and a "Select" button. Below the list box is an unchecked checkbox labeled "Include Null values".
- 3 DOSE**: Two input fields labeled "From:" (containing "20") and "To:". Below the input fields is an unchecked checkbox labeled "Include Null values".

In the following examples, the query logic does not always refer to all three conditions. When you create a query within the Empirica Signal application, the query logic must reference all conditions in the query.

---

**Note:** A condition can refer to multiple values. For example, you can include the DRUG variable once and select Thiamine and Niacin as one condition. The example includes the DRUG variable twice to illustrate complex logic.

---

If the source data includes cases A through G with the following data:

<b>CASE_ID</b>	<b>DRUG</b>	<b>DOSE</b>
A	Thiamine	25
A	Niacin	15
B	Thiamine	15
B	Niacin	25
C	Calcium	15
D	Thiamine	15
E	Thiamine	25
F	Niacin	25
G	Calcium	25

### **1 AND 3**

The query retrieves cases with rows in which Thiamine occurred and DOSE  $\geq$  20 for that row:

A

E

### **1 OR 3**

The query retrieves cases with rows in which either Thiamine occurred or DOSE  $\geq$  20 for any DRUG:

A

B

C

D

E

F

G

If you use OR between variables from different tables, only cases that are in each of those tables are retrieved. For example, if a query specifies that Death Date from the DEMO table is within a specified range OR Outcome from the OUTCOME table is Died OR PT from the REACTION table is Death, the application retrieves only cases that meet the criteria and are in all three tables. You can use set operators instead of logical operators. For example, replace OR with UNION in the query to find DEMO table cases with Death Date within the range plus OUTCOME table cases where the Outcome is Died plus REACTION table cases where the PT is Death.

### **1 AND 2**

No cases are retrieved because no one row for a case can have both Thiamine and Niacin for a DRUG.

You can use the set operator INTERSECT if you want to find cases with both Thiamine and Niacin. See the 1 INTERSECT 2 example.

### **1 AND 2 OR 3**

The query retrieves cases with rows in which Thiamine occurred and, for that row, Niacin occurred (not possible, because a row can have only one DRUG), or DOSE  $\geq$  20 for any DRUG:

A

B

E

F

G

### **1 AND (2 OR 3)**

The query retrieves cases with rows in which Thiamine occurred and, for the same row, either Niacin occurred (not possible, since a row can have only one DRUG) or DOSE  $\geq$  20:

A

E

### **1 AND NOT 3**

The query retrieves cases with rows in which Thiamine occurred and DOSE is not  $\geq$  20 for that row:

B

D

### **NOT 1 AND 3**

The query retrieves cases with rows in which Thiamine did not occur and DOSE  $\geq$  20:

B

F

G

**NOT (1 AND 3)**

The query retrieves cases with rows in which Thiamine with DOSE  $\geq$  20 did not occur:

A

B

C

D

F

G

**NOT 1 AND NOT 3**

The query retrieves cases with rows in which Thiamine did not occur and, for the DRUG that occurred, DOSE is not  $\geq$  20:

A

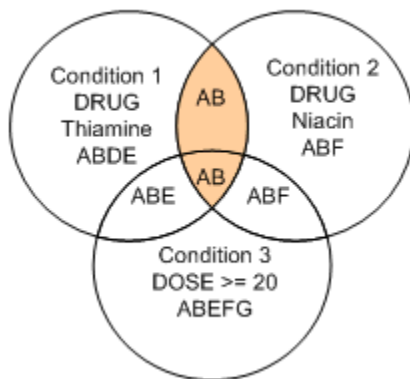
C

**1 INTERSECT 2**

The query finds the intersection of the two sets:

A

B

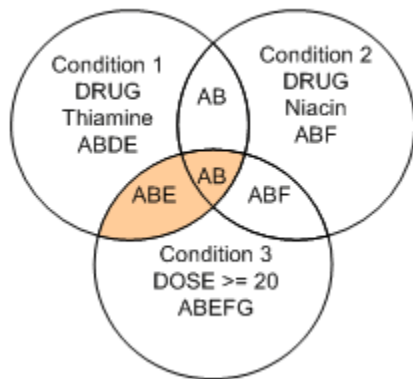


**1 INTERSECT 3**

The query finds the intersection of the two sets:

- A
- B
- E

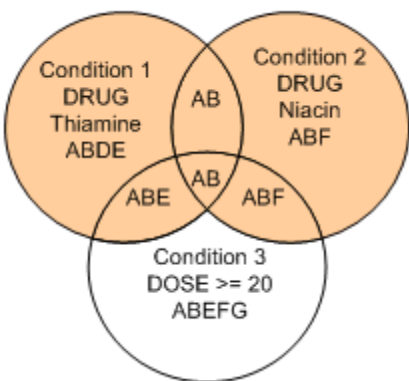
Note that for case B, there is no occurrence of Thiamine where DOSE  $\geq$  20, but case B was in the set created by Condition 3 as well as the set created by condition 1, so the query retrieves it.



### 1 UNION 2

The query finds the union of the two sets:

- A
- B
- D
- E
- F



### 3 MINUS 1

The query finds the cases that remain when cases in set 1 are removed from set 3:

F

G

### 1 INTERSECT 2 AND 3

The query finds the following case:

B

### 1 UNION 2 AND 3

The query finds the following cases:

A

B

D

E

F

### Null values

If you check **Include Null values** for a condition, the condition finds cases with rows for which the condition is true or the variable referenced by the condition is null. If you precede the condition with NOT, the condition finds cases with rows for which the condition is not true or the variable referenced by the condition is not null.

For example, suppose that the source data has four null values for DOSE (indicated by empty cells in the following table):

CASE_ID	DRUG	DOSE
A	Thiamine	
A	Niacin	15
B	Thiamine	
B	Niacin	25
C	Calcium	
D	Thiamine	15
E	Thiamine	25
F	Niacin	



G	Calcium	25
---	---------	----

---

If you specify the condition `DOSE >= 20` and check **Include Null values**, the application finds the following cases:

- A
- B
- C
- E
- F
- G

When you specify that values for a query should include nulls and then you precede the condition with the NOT operator, the query retrieves cases with rows for which the condition is not true and the variable used in the condition is not null.

If you specify NOT 3 (meaning not condition 3, which is `DOSE >= 20`) and you have checked **Include Null values**, the following cases are found:

- A
- D

## Previewing a query

1. On the [Define Query page](#), click **Next**.

The Preview Query page appears, providing the following information:

- The data source, which is the name of the data configuration on which the query is based.
- The logic of the query and a description of each condition in the query.

---

**Note:** If query values were not specified for a variable, the value for the variable appears as ?.

---

The number of cases to be retrieved by the query (if you checked **Display Case Count in Query Preview** on the Define Query page).

2. To preview the query results, click **Preview Cases**.


This option is available only if you specified values for all variables and site option **Allow Case Count on Query Preview page** is enabled.

3. Click **Next**.

To save the query, see [Saving a query](#).

If you are not satisfied with the query, click **Back** and then modify the query as needed.

## Saving a query

1. Click the **Queries** tab.  
The Queries page appears and lists your queries and queries published to you.
2. Filter the list as necessary. For more information, see [Viewing existing queries](#).
3. From a row menu () for a query, click **Add Query to Library**.  
The Save Query page appears.
4. In the **Name** field, enter a name for the query. The name does not need to be unique, although Oracle recommends that you use a unique name.
5. In the **Description** field, optionally enter an informative description of the query.
6. To assign the query to an existing [project](#), click **Add to existing project** and select the project from the drop-down list. Only projects associated with objects that you created or that are published to you appear in the list.  
or  
To create a new project and assign the query to it, click **Add to a new project named** and enter a project name.
7. Click **OK**.


## Running a query

When you run a query, the application retrieves a list of cases matching the query criteria.

Each time that you run a query, the application re-executes the query. Even if you do not change values for variables in the query, if the source data changed since the last time you ran the query, the query results can differ from when you last ran the query.

1. Click the **Queries** tab.

The Queries page appears. For more information, see [Queries page](#).

2. Click the row menu () for the query, and then click **Run**.

---

**Note:** When you run an [interactive report](#), you also run a query.

---

3. From the [Configuration](#) drop-down list, [select a data configuration](#) from a list of [compatible data configurations](#). This is the source data against which the query runs.

4. Click **Next**.

The Run Query page appears.

5. Specify values for query variables. For more information, see [Selecting query variables](#).

If the operators in the query are all AND, all OR, all INTERSECT, or all UNION, you do not need to specify values for every variable. If you do not specify a value for a variable and you do not check **Include Null values** for the variable, then the application ignores that variable. If all of the operators in the query are MINUS or if you use a mixture of different operators in the query, you must specify values for every variable.

---

**Note:** You can set up a query-based interactive report to use [query values](#) as breakdown details. If a column or row variable has no breakdown values because you do not supply query values when running the report, the application drops the column or row from the report. If the resulting report has no rows or no columns, you cannot run the report until you supply query values.

---

6. Click **Next**.

If you are running a query from the Queries tab, the query results appear. See [Viewing query results](#).

If you are running a query for an interactive report, the query generates a list of cases against which the report is run. See [Viewing a report](#).

## Selecting query values

The way in which you specify values depends on the type of variable.

- If the **Select <hierarchy> Terms** link appears for a variable, click it to select terms from the [hierarchy](#). For example, if an event variable is associated with a MedDRA account and your [user preference](#), **Enable Adverse Event Hierarchy Browser**, is checked, you can click **Select MedDRA Terms**.
- To [select values from a list](#), click **Select Available Values**.
- To refer to a [saved list](#) of terms, click **Select Saved List**. You can specify a saved list that uses the same data configuration as the query.

---

**Note:** You can also type in values separated by a comma. However, it is preferable to select values from a list. If you type in a value that contains a comma, you must enclose the value in double quotation marks (for example, "Diabetes, Type II"). If you type in a value that includes a backslash or double quotation mark, you must precede the backslash or double quotation mark with a backslash (for example, Cold\\flu).

---

- To [look up a drug name](#) for a drug variable, click **Trade/Generic Lookup**. You can find the generic name for a drug (if you only know its trade name) or vice versa. (This link is available if the data configuration's source data included trade name-generic name mapping.)

## Matching a text string

If the options Contains, Starts with, Ends with, or Equals appear for a variable, enter a text string and select an option to indicate the type of matching. You can also check **Ignore capitalization** to retrieve matching values regardless of upper or lower case.

## Specifying ranges

For numeric or date variables, specify a range by entering **From** and **To** values. Values equal to or greater than the From value and equal to or less than the To value are found. If you leave the From field empty, there is no lower bound. If you leave the To field empty, there is no upper bound.

If a date variable is stored as a date field in the source data, you must enter the date in the format MM/DD/YYYY or use the calendar icon to select a date.

If you do not specify a time, the application considers the time to be midnight of the specified date.

---

**Note:** If a date variable is stored as a text field in the Oracle database, you can search for it as you would search for any text string.

---

## Specifying report IDs

For a variable specified with the type Report ID in the data configuration, you can enter a string of report IDs separated by commas.

Check **Include Null values** to include null (empty) values along with the other values that you specify for a variable, and click **Next**. For more information, including how the NOT operator works if you include null values, see [Specifying query logic](#).

## Viewing query results

When you [run a query](#), the cases retrieved by the query appear on the Cases page. The application lists the cases in a tabular format. The variable representing the Report ID is the first column of the table. Other information in the table is customizable and determined by the [data configuration](#).

See [About tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table on the Cases page.

The application retrieves the data that appears on the Cases page from the source data. Therefore, the Cases page does not include [custom terms](#) or values created by [data transformations](#).


You can do the following on the Cases page:

- If the appropriate site option has been set, you can [view case details](#) for a single case in the list. Click the **case ID** link in the case list. The Case Details page appears. For information about how visited case ID links change color, see [Case ID links](#).
- To [save a case series](#) from the query results, click **Save As Case Series**.
- To [download case details](#) for all cases in the list to an Excel spreadsheet or a Word Rich Text Format file, click **Download Case Details**. You can download case details only if the appropriate site option has been set. (When viewing a particular case, you can also download case details for that one case.)
- To run a report against cases found by the query, click **Report**. The [Report Definitions page](#) appears.
- To [save the query results as an attachment to a topic](#), click **Save to Topic** (available if the topics feature has been set up).


## Viewing a query

This Query Logic dialog box shows the variables and values used in a query, as well as the logic of the query. For more information about query logic, see [Specifying query logic](#).

### To view a query:

1. Click the **Queries** tab.  
The Queries page appears.
2. Click the row menu () for the query, and then click **View**.  
The query logic for the selected query appears.


### To view the query used by a case series:

1. Click the **Case Series** tab.  
The Case Series page appears
2. Click the row menu () , and select a [query-based case series](#).
3. Click **View Query**.  
The query logic for the case series appears.



## Renaming a query

You can rename only those queries that you created.

1. Click the **Queries** tab.  
The Queries page appears.
2. Click the row menu () of the query, and then click **Rename**.  
The Rename Query page appears.
3. In the **Name** field, type a query name. The name does not need to be unique, although Oracle recommends that you use a unique name.
4. In the **Description** field, optionally modify the description of the query.
5. To assign the query to an existing [project](#), click **Add to existing project** and select the project from the drop-down list. Only projects associated with objects that you created or that are published to you appear in the list.  
or  
To create a new project and assign the query to it, click **Add to a new project named** and enter a project name.
6. Click **Save**.  
The Queries page appears, listing the renamed query.



## Working with case series

### About case series

A case series is a list of the case identifiers for cases of interest that you selected and saved; for example, a list of all cases that involved a particular class of drugs administered to patients of a particular demographic profile. From a case series, you can access the details of each case. You also use case series to determine the cases against which to run a report.

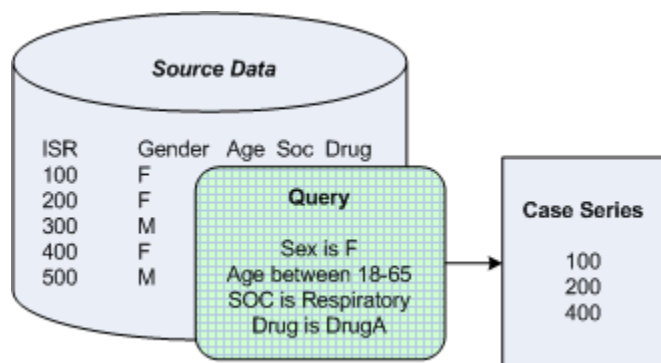
You can create a case series from the Case Series tab, the Queries tab, or from various pages that list case IDs or counts of case IDs (for example, run results, drilldown information, or certain reports).

You can also [manually add](#) or [transfer](#) additional cases to the case series.

Typically, a case series is a static list of cases; however, if you edit and re-execute the query portion of a query-based case series, the application drops any cases that you manually added or transferred to the case series if they do not meet the query criteria.

### Query-based case series

You can use the Query Wizard to define a query that retrieves case IDs from source data on the basis of specified criteria. For example, you can query for cases in which the patient is a female between age 18 and 65 who has experienced events in the Respiratory SOC (System Organ Class) and has taken DrugA.



Use a query-based case series to retrieve and view source data as needed in your review and analysis of data. For example, you can retrieve cases that meet specified criteria, and then run a report against that case series.

Using the Query Wizard, you select variables from the source data, and then select values for each variable. You can use logical operators (AND, OR, and NOT) or set operators (INTERSECT, UNION, and MINUS) between the variables to construct a logical expression. The query retrieves a list of cases. The case series consists of case IDs of those cases. If the query retrieves a case multiple times, its case ID appears once in the case series.

You can add the query portion of a case series to the Query Library (the [Queries page](#)). The query in the Query Library is completely separate from the query that is part of the case series. For example, if you modify the query in the Query Library, the modification does not

affect the case series. If you modify the query portion of a case series, the modification does not affect the query in the library.

## Viewing existing case series

The Case Series page provides information about existing [case series](#) and enables you to define new case series.

For the selected project and data configuration, the Case Series page lists case series that you have created or that have been published to you. If you have the Administer Users permission, the page also lists unpublished case series created by any users in your login group.

1. Click the **Case Series** tab.  
The Case Series page appears.
2. Filter the list as necessary.
  - From the **Project** drop-down list, select the [project](#) for which you want to view case series or -- to include all projects.
  - From the **Configuration** drop-down list, select the [data configuration](#) for which you want to view case series or -- to include all configurations.

The selected case series appears. See the [Case Series page](#) for information about the case series.

## General activities

- For information about viewing, printing, or downloading tables or changing the way data displays in the table, see [About tables](#).
- To print, download, combine, or delete selected case series, click **Select Rows**. You can then check the rows for the case series on which you want to act. You can also click **Select All** to check all rows (or click **Clear All** to uncheck all rows). From the menu, click the action that you want to perform on the selected rows.
- To create a case series by defining a query, click **Create Using Query Wizard**.
- To [create an empty case series](#) to which you manually add case IDs, click **Create Empty Case Series**.
- To compute [Proportional Reporting Ratios](#) (PRR) for a set of previously defined case series, click **PRR Calculator**.


## Action menu options

If you click  for any case series, you can do the following:

- To [view a case series](#), click **View Cases**.
- To view the query for a [query-based case series](#), click **View Query**. This option shows the variables and values that make up the query, as well as the edit logic.
- To [view existing report definitions](#) for the case series, click **Report**.
- To add the query portion of the case series to the [Query Library](#), click **Add Query to Library**. You must have access to the [data configuration](#) on which the case series is

based. If the query is in the Query Library (the Queries page), it is separate from the case series. Subsequent modification or deletion of the query in the library has no effect on the case series.

- To [copy a case series](#), click **Copy**. You must have access to the configuration on which the case series is based. You can copy any case series that you created or that has been published to your login group. If you have the Administer Users permission, you can copy a case series published to any login group.
- To cancel a running or In Queue case series background processing job, click **Cancel**. The Cancel option is available only when a background processing job exists for the case series.

If you click  for a case series that you created, you can do the following:

- To [edit the query portion](#) of a case series that was created with the Query Wizard, click **Edit Query**. You can click **Back** to select a different data configuration.
- If the Cases Added column shows **Yes**, then cases have been transferred or added manually to the case series. If you re-execute the case series, those cases are no longer be part of the case series.

---

**Note:** Your edits to the query portion of the case series have no effect on the query in the Query Library (the Queries page). Likewise, editing or deleting the query in the library has no effect on the case series.

---

- To [rename a case series](#), click **Rename**. You can also change its description or assign it to a different project.
- To [publish a case series](#), click **Publish**. If you have the Administer Users permission, you can publish a case series created by any user in your login group.
- To delete a case series, click **Delete**. When a message asks if you want to delete the case series, click OK. The case series is deleted and no longer appears on your Case Series tab.

---

**Note:** Before deleting a query-based case series, you can save the query portion of the case series with the **Add Query to Library option**.

---

## Case Series page

On the Case Series page, you can view information about existing case series that you have created or that have been published to you. And you can define new case series if you have the Create Queries/Case Series permission.

### General activities

The following links and filters appear at the top of the page and affect the entire page:

- [Create Using Query Wizard](#)
- [Create Empty Case Series](#)
- [PRR Calculator](#)
- [Columns](#)
- [Print](#)
- [Download](#)
- [Select Rows](#)
- [Project drop-down list](#)
- [Configuration drop-down list](#)

The following links appear at the top of the page when the page is in the Select Rows mode. The links affect the multiple cases:

- [Print](#)
- [Download](#)
- Delete
- [Combine Case Series](#)
- Select All
- Clear All
- Back

### Row-specific activities

The following menu options can be available from the Row menu, located in the left-most column of the table, and affect an individual row in the table:


- Cancel
- [View Cases](#)
- [View Query](#)
- [Edit Query](#)
- [Rename](#)
- [Report](#)
- [Publish](#)

- [Add Query to Library](#)
- [Copy](#)
- Delete

To add the query portion of the case series to the [Query Library](#), click **Add Query to Library**. You must have access to the [data configuration](#) on which the case series is based. If the query is added to the Query Library (the Queries page), that query is separate from the case series. Subsequent modification or deletion of the query in the library has no effect on the case series.

To [copy a case series](#), click **Copy**. You must have access to the configuration on which the case series is based. You can copy any case series that you created or that has been published to your login group. If you have the *Administer Users* permission, you can copy a case series published to any login group.

To cancel a **Running** or **In Queue** case series background processing job, click **Cancel**. The Cancel option is available only when a background processing job exists for the case series.

If you click  for a case series that you created, you can do the following:

- To [edit the query portion](#) of a case series that was created with the Query Wizard, click **Edit Query**. You can click **Back** to select a different data configuration.

If the Cases Added column shows Yes, then cases have been transferred or added manually to the case series. If you re-execute the case series, those cases will no longer be part of the case series.

---

**Note:** Your edits to the query portion of the case series have no effect on the query in the Query Library (the Queries page). Likewise, editing or deleting the query in the library has no effect on the case series.

---



- To [rename a case series](#), click **Rename**. You can also change its description or assign it to a different project

## Field descriptions—Case Series page

The Case Series page provides the following information about each case series:


Column	Description
Name	Name of the case series.
Description	Description of the case series.
Project	Name of the project to which the case series is assigned.
Configuration	Name of the data configuration associated with the case series.
# of Cases	Number of cases in the case series.
Created By	Name of the user who created the case series.



Created	Date and time on which the case series was created.
Modified	Date and time when the case series was last modified.
Modified By	Name of the user who last modified the case series.
Status	The current <a href="#">status</a> of the <a href="#">background processing job</a> .
As Of	<p>Applies if the configuration supports <a href="#">timestamped data</a>. The As Of date associated with the case series. If you created the case series when <a href="#">drilling down</a>, this is the As Of date associated with what you were viewing before you drilled down.</p> <p><b>Note:</b> A date and time appear in this column even if the configuration does not support timestamped data. In this case, the date and time is approximately the same as the date and time in the Created column.</p>
Associated Run	<p>Name of the <a href="#">data mining run</a> that generated the results from which the case series was created. If the run associated with a case series is deleted, the application retains the case series but it is no longer associated with the run.</p> <p>If the case series was not created from run results, this column is empty.</p>
Cases Added	<p>One of the following values:</p> <ul style="list-style-type: none"> <li>• <b>Yes</b>—For a query-based case series, cases have been manually added to or transferred to the case series since the query portion of the case series was last executed (by clicking , and then clicking <b>Edit Query</b>.) If you re-execute the query portion of the case series in this way, the manually added or transferred cases are dropped from the case series.</li> <li>• <b>No</b>—For a query-based case series, cases have not been manually added to or transferred to the case series since the query portion of the case series was last executed (by clicking , and then clicking <b>Edit Query</b>.)</li> <li>• <b>NA</b>—Not Applicable because the case series is not based on a query.</li> </ul>
ID	Identifier the application assigned when the case series was created. Each case series ID is unique and is not re-used if the case series is deleted.

## Viewing cases in a case series

The list of cases in a case series does not change if source data changes. However, you can add cases to a case series manually or by transferring cases from a list of cases generated elsewhere in the application.

1. Click the **Case Series** tab.  
The Case Series page appears.
2. Click the row menu () for the case series, and then click **View Cases**.

The Cases page appears.

Because the application retrieves the data from the source data, it does not include [custom terms](#) or values created by [data transformations](#).

The case list appears as a table. The variable representing the case ID is the first column of the table. The [data configuration](#) associated with the case series determines the additional columns that appear. If site option **Allow Case Comment/Review/Exclusion** is enabled, additional columns indicate whether the case has been reviewed or excluded, and whether comments have been added by a reviewer.

See [About tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

## Case series options

- To [review case details](#), click the **case ID** in the first column. When viewing case details, if site option **Allow Case Comment/Review/Exclusion** is enabled, you can mark cases as Reviewed and Excluded and add comments. For more information, see [Reviewing case details](#).

---

**Note:** If you navigate through cases in the Case Details dialog box using Next and Prev, the visited status of the cases on the Cases page is subsequently not updated. To refresh the visited status on the Cases page, manually refresh the cases by pressing F5.

---

- If any cases have been [marked as excluded](#) as part of reviewer input, you can click **Hide Excluded**. Excluded cases are not visible on the Cases page. If you click **Show Excluded**, such cases are visible.
- To [add cases manually](#), click **Manually Enter IDs**.
- To display the [Report Definitions page](#) with the case series selected, click **Report**. If any cases have been [marked as excluded](#) as part of reviewer input, the application does not include them in the report.
- To [download case details](#) for all cases in the list to an Excel spreadsheet or a Word Rich Text Format File, click **Download Case Details**. (When viewing a particular case, you can also download case details for that one case.) The application does not include cases that are marked as excluded and that are hidden at the time of the download.

- To [save the list of cases as an attachment to a topic](#), click **Save to Topic** (available if the topics feature has been set up). The application does not include cases that are marked as excluded and that are hidden at the time you save the list as an attachment.

## Reviewing case details

When viewing a case series from the Case Series page, you can click a case ID to view case details. The Case Details dialog box provides information about the case, presented as a set of tables showing source data for the case. On this dialog box, if site option **Allow Case Comment/Review/Exclusion** is enabled, you can indicate that you have reviewed the case details and provide a comment.

At a minimum, the Case Details page typically includes the following information:

- Case Information (demographic information).
- Reported Drugs/Vaccines.
- Reported Events/Symptoms.

Additional information includes reported outcomes, case report sources, narrative text, and so on.

If specified by the configuration, a description of the source data appears below the case details. For example: Source Data: AERS data as of 4th quarter 2009 from NTIS Public Release loaded on 2010-04-18.


---

**Note:** The application retrieves the case details from the source data. Therefore, [custom terms](#) or values created by [data transformations](#) do not appear.

---

1. Click the **Case Series** tab.

The Case Series page appears.

2. Click the row menu () for the case series, and then click **View Cases**.

The Cases page appears.

3. Click a case ID.

The Case Details dialog box appears.

If you have set your [user preference](#) to show a table of contents for case details, there is a Contents section at the top of the page. It includes links that you can click to jump to the various types of data on the page.

4. In the **Reviewer Input** section at the bottom of the dialog box, you can do the following:

- To indicate that source data for a case has been reviewed, check **Reviewed**.
- If you do not want the case to appear on the Cases page when you hide excluded cases, click **Excluded**.
- In the **Comments** text box, enter comments about the data.

---

**Note:** The Reviewer Input section appears only if the appropriate site option has been set.

---

5. You can also perform the following actions:
  - To print case details, click **Print**.
  - To [download case details](#) to an Excel spreadsheet or a Word Rich Text Format file, click **Download**.
  - To [save the case details as an attachment to a topic](#), click **Save to Topic** (available if the topics feature has been set up).
  - To go to a third-party application showing further information about the case, click the custom link (available only if configured for the data configuration on which the case series is based).
6. To save your changes and close the Case Details dialog box, click **Save**.  
or  
To save your changes and keep the Case Details dialog box open, click **Apply**.
7. To view the case details for another case in the case series, click **Prior** or **Next**.  
These buttons are unavailable for case series that contain 50,000 cases or greater.

## Using the PRR calculator

When creating a data mining run, you can specify that Proportional Reporting Ratio (PRR) and Chi-square should be computed and included in the results for each drug-event combination against a specified background database.

Before you use the PRR calculator, you must specify three case series (based on the same configuration) to represent a background database, the events of interest, and the drugs of interest. For example, to compute PRR for combinations of analgesics and respiratory ailments in women over age 65, use a case series that includes cases for women over age 65, a case series that includes cases for analgesics, and a case series that includes cases involving respiratory ailments.

1. Click the **Case Series** tab.  
The Case Series page appears.
2. [Identify or define the three case series](#) to use.
3. Click **PRR Calculator**.  
The PRR Calculator page appears.
4. From the **Configuration** drop-down list, [select a data configuration](#).
5. For the following types of case series, click **Browse** and [select a case series](#). You must base all three case series on the same configuration.
  - Background Definition Case Series Defines the customized background for the computations.
  - Event Definition Case Series Defines the set of events.
  - Drug Definition Case Series Defines the set of drugs.
6. To define the chi-square calculation method, check or clear **Apply the Yates correction for chi-square**.
7. To define the PRR calculation method, check or clear **Include drug of interest in the comparator set**.
8. Click **Calculate**.  
The observed counts and results appear.
  - Observed counts of cases with drug-event combinations are represented as a, b, c, and d in a 2x2 table as follows:

---

**Note:** When PRR is computed by a data mining run, a, b, c, and d represent counts of drug-event combinations by default. You can select an option to count cases with those combinations instead. However, the PRR calculator always counts cases.

---

Cases	Specific drug	All other drugs
Specific event	a	b
All other events	c	d

- The PRR for the combination of a particular drug and particular event is computed as follows:

$$PRR = (a / (a + c)) / (b / (b + d))$$

If  $b=0$  (and **Include drug of interest in the comparator set** described below is cleared), then the formula is adjusted as follows to avoid the possibility of division by zero:

$$PRR = ((a+0.5) / ((a+0.5) + (c+0.5))) / ((b+0.5)/((b+0.5) + (d+0.5)))$$

If you checked **Include drug of interest in the comparator set**, the application computes PRR as:

$$PRR=(a / (a + c)) / ((a + b) / (a + b + c+ d))$$

- For each cell in the 2x2 table, the expected count is computed as follows:

Cases	Specific drug	All other drugs
Specific event	$E(a) = ((a+b)(a+c))/(a+b+c+d)$	$E(b) = ((a+b)(b+d))/(a+b+c+d)$
All other events	$E(c) = ((c+d)(a+c))/(a+b+c+d)$	$E(d) = ((c+d)(b+d))/(a+b+c+d)$

The chi-square of PRR (PRR\_CHISQ) for the combination of a particular drug and particular event is computed as follows, where E represents the expected count under the assumption of no relationship between drugs and events:

$$PRR\_CHISQ = ((a-E(a))^2)/E(a) + ((b-E(b))^2)/E(b) + ((c-E(c))^2)/E(c) + ((d-E(d))^2)/E(d)$$

If you checked **Apply the Yates correction for chi-square**, PRR\_CHISQUARE is computed as follows:

$$PRR\_CHISQ = ([\max(0, |a - E(a)| - 0.5)]^2)/E(a) + ([\max(0, |b - E(b)| - 0.5)]^2)/E(b) + ([\max(0, |c - E(c)| - 0.5)]^2)/E(c) + ([\max(0, |d - E(d)| - 0.5)]^2)/E(d)$$

**Note:**

$|a - E(a)| = |b - E(b)| = |c - E(c)| = |d - E(d)|$  for every 2x2 table; this formula can also be expressed as:

$$PRR\_CHISQ = (1/E(a) + 1/E(b) + 1/E(c) + 1/E(d)) [\max(0, |a - E(a)| - 0.5)]^2$$

The P-values for chi-square values are also computed. The P-value is the probability that chi-square would be as large as the value for PRR\_CHISQ by chance alone if there were no causal relationship or consistent association between the drug and the event.

---

**Note:** If any of E(a), E(b), E(c), or E(d) is zero, the chi-square and P-value cannot be computed and are defined arbitrarily as -1.

---

9. In the table for observed counts, you can click the value of **N** in a column to display a menu. Click **View Cases** to [drill down](#) to cases that have the specified drugs and specified events.



## Selecting a case series for PRR computation

1. On the [PRR Calculator page](#), select the configuration that you want to use.
2. Next to a case series field, click **Browse**.

The Select Case Series dialog box appears, listing case series that you have created or that have been published to your login group, and that are based on the selected data configuration.

---

**Note:** If you have the Administer Users permission, all published case series based on the selected configuration appear.

---


The following information is provided for each case series:

Column	Description
Name	Name of the case series.
Description	Description of the case series.
Project	The name of the project to which the case series is assigned.
# Cases	Number of cases in the case series.
Configuration	Configuration used by the case series.
Created By	Name of the user who created the case series.
Created	Date and time when the case series was created.
Modified By	Name of the user who last modified the case series.
Modified	Date and time when the case series was last modified.

3. Click the row for the case series that you want to select.
4. Click **OK**.

## Renaming a case series

You can rename only those case series that you created.

1. Click the **Case Series** tab.  
The Case Series page appears.
2. Click the row menu () for a case series, and then click **Rename**.  
The Rename Case Series page appears.
3. In the **Name** field, type a new name for the case series. The name does not need to be unique, although Oracle recommends that you use a unique name.
4. In the **Description** field, leave the description or modify the description of the case series.
5. To assign the case series to an existing [project](#), click **Add to existing project** and select the project from the drop-down list. Only projects associated with objects that you created or that are published to you appear in the list.  
or  
To create a new project and assign the case series to it, click **Add to a new project named** and enter a project name.
6. Click **OK**.  
The Case Series page appears, listing the renamed case series.

---

**Note:** When you rename a case series, the case series name attached to any existing report outputs is not changed.

---

## Copying a case series


One way to create a new [case series](#) is to use an existing case series as the basis for a new one. If you copy a [query-based case series](#), you can then edit the copy to create the new case series.

When you copy a query-based case series, the application uses the query that was in effect at the time of the original case series for the copy. Any indication of cases as Reviewed or Excluded, and any attached comments, are included in the copy of a case series.

---

**Note:** The copy of a case series includes any cases that were [transferred](#) or [added manually](#) to the case series. If you re-execute the query portion of the copy of a query-based case series, however, the application drops those cases from the case series if they do not meet the query criteria.

---

1. Click the **Case Series** tab.  
The Case Series page appears.
2. Click the row menu () for a case series, and then click **Copy**.  
The Copy Case Series page appears.
3. From the **Select a configuration** drop-down list, [select a data configuration](#). By default, the application uses the data configuration associated with the original case series (and you must have permissions to use that configuration). If you are copying a query-based case series, this page does not appear.

---

**Note:** If you select a different data configuration, case IDs that match in both data configurations are copied, but may represent different cases if the source data for the two data configurations differs.

---

4. Click **Next**.
5. In the **Name** field, enter a name for the new case series. The name does not need to be unique, although Oracle recommends that you use a unique name.
6. In the **Description** field, optionally leave or edit the description of the case series.
7. To assign the case series to an existing [project](#), click **Add to existing project** and select the project from the drop-down list. Only projects associated with objects that you created or that are published to you appear in the list.

or

To create a new project and assign the case series to it, click **Add to a new project named** and enter a project name.

8. Click **Save**.

A message tells you that the case series has been copied and shows the names of the original case series (Source), the copy of the case series (Destination), and the number of cases in the two lists:

	Copy Case Series Name	# of Cases
<b>Source:</b>	TEST_series100	16
<b>Destination:</b>	Copy of TEST_series100	16

9. Click **Continue**.

The Case Series page appears, showing the new case series.

---

**Note:** The application does not copy the original publication level to the new case series. You must [publish](#) the new case series if you want others to see it.

---

## Combining case series

If you have the Create Queries/Case Series permission, you can combine two or more case series when you have two or more complex query-based case series. The application copies all cases in the selected case series into a new case series. The application retains the original case series selected. It does not delete the case series selected after copying cases. The application sets the Reviewed and Excluded statuses for all cases to null in the new case series.

To combine case series, the status of the case series that you select must be Completed, and the cases must have the same data configuration. For [timestamped](#) data, the application prompts you to select an As Of date.

1. Click the **Case Series** tab.  
The Case Series page appears.
2. Click **Select Rows** to enter row selection mode.  
Check boxes appear to the left of the case series list.
3. Select the check boxes next to the case series that you want to combine. You must select at least two case series.
4. Click **Combine Case Series**.  
The Combine Case Series page appears.
5. If the case series contains timestamped data, [specify an As Of date](#).
6. In the **Name** field, enter a name for the new case series. The name does not need to be unique, although Oracle recommends that you use a unique name.
7. In the **Description** field, enter an informative description of the combined case series.
8. To assign the case series to an existing [project](#), click **Add to existing project** and select the project from the drop-down list. Only projects associated with objects that you created or that are published to you appear in the list.  
or  
To create a new project and assign the case series to it, click **Add to a new project named** and enter a project name.
9. Click **Create**.  
The application copies the cases into the new case series.

## Creating a case series

### Creating or editing a query-based case series

One way to create a case series is by creating a query and including the cases found by the query in the case series. You can also edit a query-based case series that you have created. To create or edit a query-based case series, you use the Query Wizard, which guides you through the process of selecting variables, selecting values, and specifying query logic.

---

**Note:** If you edit and re-execute the query portion of a query-based case series to which cases have been [transferred](#) or [added manually](#), the application drops those cases from the case series if they do not meet the query criteria.

---

1. Click the **Case Series** tab.

The Case Series page appears.

2. To create a query-based case series, click **Create Using Query Wizard**.


The Select Configuration page appears.

- A. From the **Configuration** drop-down list, [select a data configuration](#). You can click Browse to select from a list of data configurations.

- B. Click **Next**.

The Define Query page appears. See [Defining query conditions](#).

or

To edit a query-based case series that you created, click the row menu () for the case series, and then click **Edit Query**.

The Define Query page appears.

- A. To change the data configuration, on the Define Query page, click **Back**. You can select a different data configuration from a list of available configurations. Available data configurations are those with at least the same variables as the original case series' data configuration. The variables must have the same names and the underlying database columns must have the same Oracle data type.

- B. Click **Next**.

The Define Query page appears.

3. Define or edit the query. For more information, see [Defining a query](#), beginning with Step 6.

The Preview Query page appears.

4. To preview the query results, click **Preview Cases**. This option is available only if you specified values for all variables and your user preference **Show case count by default on preview page** is enabled. For more information, see [Previewing a query](#).
5. Click **Next**.  
The Save Case Series page appears.
6. In the **Name** field, type a new name for the case series. The name does not need to be unique, although Oracle recommends that you use a unique name.
7. In the **Description** field, leave the description or modify the description of the case series.
8. To assign the case series to an existing [project](#), click **Add to existing project** and select the project from the drop-down list. Only projects associated with objects that you created or that are published to you appear in the list.  
  
or  
  
To create a new project and assign the case series to it, click **Add to a new project named** and enter a project name.
9. Click **OK**.  
The application submits the case series to the [background processing job queue](#). For larger datasets, the Background Processing indicator appears next to the **Preferences** link.

---

**Note:** The Background Processing indicator may not appear if you create a case series from a small data set that processes quickly.

---

The Case Series page appears, listing the new or edited case series.

## Saving a case series

1. Create or edit a query. For more information, see [Creating or editing a query-based case series](#) or [Creating an empty case series](#).
2. On the **Save Case Series** page, in the **Name** field, enter a name for the case series. The name does not need to be unique, although Oracle recommends that you use a unique name.
3. In the **Description** field, enter an informative description of the case series.
4. To assign the case series to an existing [project](#), click **Add to existing project** and select the project from the drop-down list. Only projects associated with objects that you created or that are published to you appear in the list.

or

To create a new project and assign the case series to it, click **Add to a new project named** and enter a project name.

5. Click **OK**.

A message tells you that the case series is being saved. If you click **Cancel** at this point or navigate to another page, the application does not create the case series.



## Creating an empty case series

One way to create a case series is to create an empty case series and then manually add (type in or paste in) a list of case IDs, or transfer cases to the empty case series.

1. Click the **Case Series** tab.  
The Case Series page appears.
2. Click Create Empty Case Series.  
The Create Empty Case Series page appears.
3. From the **Select a configuration** drop-down list, select a configuration. You can click **Browse** to select from a list of data configurations.
4. Click **Next**.  
The Create Empty Case Series page appears. If you selected a data configuration that supports [timestamped data](#), the Select As Of page appears first so that you can specify an As Of date.
5. In the **Name** field, enter a name for the case series. The name does not need to be unique, although Oracle recommends that you use a unique name.
6. In the **Description** field, enter an informative description of the case series.
7. To assign the case series to an existing [project](#), click **Add to existing project** and select the project from the drop-down list. Only projects associated with objects that you created or that are published to you appear in the list.  
  
or  
  
To create a new project and assign the case series to it, click **Add to a new project named** and enter a project name.
8. Click **Save**.  
The Case Series page appears, listing the new case series.
9. View the empty case series and [manually add cases](#) to the case series or [transfer cases](#) to the empty case series.


## Manually adding cases to a case series

You can add cases manually from source data to an empty case series or to a case series that already includes cases that you created or has been published to your login group. If you have the Administer Users permission, you can add cases manually to a published or unpublished case series created by any user in your login group.

For [timestamped data](#), when cases are added manually to a case series, the application uses the As Of date associated with the target case series to determine whether the cases are legitimate to add. For example, the As Of date of the case series is 06/15/2010 and case ID 1554 did not exist until 07/01/2010. If you try to add case ID 1554 to the case series, the application does not add it, because the case did not exist on 06/15/2010.

1. Click the **Case Series** tab.

The Case Series page appears.

2. Click the row menu () for the case series to which you want to add cases, and then click **View Cases**.

The Cases page appears.

3. Click **Manually Enter IDs**.

The Append Manually Entered Case IDs dialog box appears.

4. Type or paste in a list of case IDs. Each case must be on a separate line or separated from the next case ID by a comma.

5. Click **Append**.

The application searches the source data for the specified case IDs. The application refreshes the Append Manual Entered Case IDs dialog page with the number of case IDs that you manually entered, the number of case IDs added to the case series, and the total number of cases now included in the case series. If a manually added case ID does not exist in the source data, the application does not add that case ID to the case series.

6. Click **Close**.

---

**Note:** It is possible, but not recommended, to add cases that do not meet query criteria to a query-based case series. If you execute the query again, the application does not include the added cases because they do not meet the query criteria.

---

## Transferring cases to a case series

On pages and in reports that display a list of cases identified by case ID, you can transfer cases to an existing case series. You can also [create a new case series](#) containing the cases.

For [timestamped data](#), when cases are transferred to a case series, the application uses the As Of date associated with the target case series to determine whether the cases are legitimate to add. For example, if the As Of date of the case series is 06/15/2010 and the case ID 1554 did not exist until 07/01/2010, if you try to add case ID 1554 to the case series, it is not added because it did not exist on 06/15/2010.

1. When viewing a list of cases, click **Transfer to Case Series**. Alternatively, click a **count (N)** of cases in a table or click the element of a graph, and then click **Transfer to Case Series** from the row menu.

The Transfer to Case Series page appears.

Available case series are those that are based on data configurations that are [compatible](#) with that of the object you are viewing.

2. Click the row for the case series that you want to select, and then click **OK**.

The application adds the case IDs to the case series if they were not already in it. A message states how many cases were added to the case series.

---

**Note:** It is possible, but not recommended, to transfer cases that do not meet query criteria to a query-based case series. If the query is executed again, the transferred cases are dropped if they do not meet the query criteria.

---

## Creating a case series from drill-down information

On pages and in reports that display a list of cases identified by case ID, you can save the list of cases for future use. The named and saved list of cases is referred to as a *case series*. You can also [transfer cases](#) to an existing case series.

1. When viewing a list of cases, click **Create Case Series**. Alternatively, click a **count (N)** of cases in a table or click an element of a graph, and then click **Create Case Series** from the row menu.  
  
The Create Case Series page appears.
2. In the **Name** field, type a name for the new case series. The name does not need to be unique, although Oracle recommends that you use a unique name.
3. In the **Description** field, enter a description of the case series. A default description, which you can modify, might appear.
4. To add the case series to a [project](#), click **Add to existing project** and select the project from the drop-down list of projects associated with objects that you created or that are published to you.
5. To create a new project and assign the case series to it, click **Add to a new project named** and type a project name.
6. Click **Create**.

## Case series background processing

### About background processing

Background processing allows processes, such as case series, to run without user intervention and interruption, so that you can perform other tasks simultaneously. Uninterrupted background processing also allows you to exit the application without affecting job processing or completion. Background processing is a standard feature and occurs automatically. You do not need to enable background processing.

One background processing job exists per task when you perform any of the following:

- [Create a case series](#) using the Query Wizard.
- [Create a case series from an existing query](#).
- [Edit and save](#) a query-based case series.

---


**Note:** Background processing does not occur for query-based interactive report outputs.

---

## About background processing job queues

A background processing job queue is a temporary container that the application creates on demand when one or more sequential jobs are [awaiting background processing](#). Jobs in the queue run one at a time in the order in which the application added them to the queue. The job queue is specific to your user account, and contains only jobs that you created. You cannot view another user's job queue, even if you are a superuser.

Your queue can hold an unlimited number of jobs. The application adds jobs to your queue when you perform specific case series tasks, as described in [About background processing](#). The application can add jobs while a job is running without interrupting that job.

When a background processing job is running, you can view the job queue and the current status of the jobs in your queue by hovering the Background Processing indicator (). The Background Processing indicator appears next to the **Preferences** link, and remains visible until there are no unprocessed jobs remaining.

You can [cancel](#) **Running** or **In Queue** jobs in your background processing queue from individual cases on the Case Series page. If you are a superuser, you can also cancel other users' jobs from these pages.

## About background processing job status

Case series background processing jobs can have one of the following statuses:

- **In Queue**—Job is awaiting processing.
- **Running**—Job is currently processing.
- **Cancelled**—Superuser or the user who submitted the job cancelled it.
- **Error Occurred**—Job did not finish processing. You may see this status if, for example, the database fails during processing.
- **Completed**—Job finished processing successfully.

Note that:

- You can [cancel](#) In Queue or Running jobs, if necessary, from the Case Series page.
- You cannot restart Error Occurred jobs. To complete the job processing, edit and then save the case series.

## Viewing background processing job status

You can view the current job status for background processing jobs:

- On the [Case Series](#) page, in the **Status** column.
- By hovering over the Background Processing indicator.

For information on background processing job status, see [About background processing job status](#).



## Canceling a background processing job

The **Cancel** action menu command is available for In Queue or Running case series or report outputs in your background processing queue. You can cancel these jobs at any time from the Case Series page, depending on the job type you submitted. You cannot cancel jobs when hovering your mouse over the Background Processing indicator.

If you are a superuser, you can:

- Cancel jobs that you submitted.
- Cancel jobs that other users submitted.

You cancel other users' jobs on the Case Series page.


### To cancel a case series background processing job:

1. Click the **Case Series** tab.

The Case Series page appears.

2. Locate the case series for which you submitted a background processing job. The status in the Status column is Running. If you are a superuser, you can locate the case series that another user submitted.

If necessary, hover your mouse over the Background Processing indicator located next to the **Preferences** link to obtain the case series name from your job queue. You can sort case series by status to locate In Queue or Running jobs.

3. Click the row menu () next to the case series, and click **Cancel**.

The application cancels the job and sets the case series status to Cancelled.



## Working with reports

### About reports

The Empirica Signal application includes a reporting feature that allows you to do the following:

- Run [built-in reports](#) that are delivered with the product. You can use these reports as is, or copy and modify them.
- Retrieve source data and present it in a tabular format.
- View graphs of report data.
- Determine which variables to use to define rows and columns of the report.
- Define break-down variables, such as counts of PTs for males and counts of PTs for females within each age group, at multiple levels.
- Indicate how to aggregate multiple values for variables in the report.
- Create various types of reports, from line listings to summary reports, that show statistics for cross-tabulations of variables.
- Use the drill-down feature to view case details for a report that includes case IDs or counts.
- Create a report definition. A report definition is the specification of the format of a report and restrictions on the data that the report displays. You must have the appropriate permissions to create a report definition and publish it for other users to view.

---

**Note:** Because reports run on source data (not data mining results), they do not include custom terms or values created by [data transformations](#).

---

## Report structure

A report is a tabular display of source data, according to the specifications of a report definition. Because data that appears in a report is source data, the report does not contain [custom terms](#) or values created by [data transformations](#).

A report includes one row for each variable (or combination of variables) that you specify as a row variable in the report definition. For each row, the report includes columns that you identify as column variables in the report definition. Each column is called an analysis variable.

The report definition may include multiple levels of column variables, as in the following example. A variable that groups values for another variable is called a breakdown variable. Any row variable can be a breakdown variable, and the column variable at the top of the report can also be a breakdown variable.

		Body System		
		CARDIOVASCULAR	GASTROINTESTINAL	RESPIRATORY
Age	Sex	Count	Count	Count
		N	N	N
37	F	3	3	2
37	M	7	7	10
38	F	1	1	1
38	M	14	26	15
39	F	2	3	2
39	M	24	40	23
40	F	1	1	1
40	M	28	34	19

## Viewing existing report definitions

A report definition specifies:

- Which variables from the source data appear as columns in the report, and how they are broken down based on other variables.
- Which variable or combination of variables provide unique keys for the report. There is one row in the report for each unique key value (or key value combination).
- How to aggregate multiple values in individual cells.
- The subset of rows that appear in the report, based on conditions specified by a SQL WHERE clause.

For the selected project and data configuration, the [Report Definitions page](#) lists report definitions that you created or that are published to you. If you have the Administer Users permission, the page also lists unpublished report definitions that were created by any user in your login group.

This page lists reports based on data configurations that are [compatible](#) with the data configuration used by the selected case series.

1. Do one of the following:
  - A. Click the **Reports** tab.
  - B. Select a case series. Click the radio button of the selected case series and click **OK**.
  - C. Click **Browse** to display the [Select Case Series page](#).

You must [select a case series](#) before you can run, edit, copy, or delete a report definition (this requirement does not apply to interactive report definitions). If you run the report, it is only for cases in the selected case series.

Or

- A. On the [Cases Series page](#) or the [Queries page](#), click the row menu () for a case series or query, and click **Report**.

The Report Definitions page appears. The names of valid report definitions appear in bold font. A report definition is valid (and, therefore, can be run) if it includes at least one row variable and one column variable, and no error messages appear for the variables.

2. Filter the report definitions as necessary.
  - From the **Project** drop-down list, select the [project](#) for which you want to view report definitions or -- to include all projects.
  - From the **Configuration** drop-down list, select the [data configuration](#) for which you want to view report definitions or -- to include all configurations.

The selected report definitions appears. See the [Report Definitions page](#) for information about the information shown.

See [About tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

## **Viewing report batch runs**

The Report Batch Runs page provides information about reports that are run in batch mode. It is intended for troubleshooting any problems related to batch reports in conjunction with Oracle.

## **Truncating a Report Batch Run**



This feature is intended for use in conjunction with Oracle.



## Report Definitions page

On the Report Definitions page, you can view information about existing report definitions and define new definitions if you have the Create Report Definitions permission.

**Note:** You must select a case series before you can create, edit, copy, or display a report.

- On the Reports Definitions page, click **Browse**.
- On the Queries page, click the row menu () and select **Report**. After you select the configuration and run the query, the Report Definitions page appears.
- On the Case Series page, click  and select **Report**. The Report Definitions page appears.

## General activities

The following links and filters appear at the top of the page and affect the entire page:

- [Create Definition](#)
- [Create Definition from XML](#)
- [Columns](#)
- [Print](#)
- [Download](#)
- [Select Rows](#)
- [Project drop-down list](#)
- [Configuration drop-down list](#)

The following links appear at the top of the page when the page is in the Select Rows mode. The links affect the multiple report definitions:

- [Print](#)
- [Download](#)
- [Publish](#)
- Delete
- Select All
- Clear All
- Back

## Row-specific activities

The following menu options are available from the row menu, located in the left-most column of the table, and affect an individual row in the table:

- [Run](#)
- [Create Output](#)
- [Edit](#)

- [Rename](#)
- [Publish](#)
- [Copy](#)
- Delete

If you have the Create Report permission, Copy option is available for report definitions created by other users. Although you cannot edit such report definitions, you can copy them and modify its copy.

## Field descriptions—Report Definitions page

The Report Definitions page provides the following information about each report definition:

<b>Field</b>	<b>Description</b>
Definition	Name of the report definition. If in bold type, the report definition is valid to run.
Description	Description of the report definition.
Project	Name of the project with which the report definition is associated.
Configuration	Name of the data configuration used by the case series on which the report definition is based.
Created By	Name of the user who created the report definition.
Created	Date and time when the report definition was created. The Created By and Created fields are filled in when the Create Definition page is completed.
Modified	Date and time when the report definition was last modified.
Modified By	Name of the user who last modified the report definition. The Modified and Modified By fields are filled in each time the report definition is saved.
ID	Identifier that was assigned automatically to the report definition when the report definition was saved. Each report definition ID is unique (across all report definitions, regardless of whether or not they are interactive) and is not re-used if the report definition is deleted.
Category	Category of the report (intended only for informational purposes).

## Report background processing

### About background processing

Background processing allows processes, such as reports, to run without user intervention and interruption, so that you can perform other tasks simultaneously. Uninterrupted background processing also allows you to exit the application without affecting job processing or completion. Background processing is a standard feature and occurs automatically. You do not need to enable background processing.

One background processing job exists per task when you perform any of the following:

- [Create output from a report definition.](#)
- [Create an all cases summary report output.](#)
- [Create and edit an interactive report definition.](#)

---


**Note:** Background processing does not occur for query-based interactive report outputs.

---

## About background processing job queues

A background processing job queue is a temporary container that the application creates on demand when one or more sequential jobs are [awaiting background processing](#). Jobs in the queue run one at a time in the order in which the application added them to the queue. The job queue is specific to your user account, and contains only jobs that you created. You cannot view another user's job queue, even if you are a superuser.

Your queue can hold an unlimited number of jobs. The application adds jobs to your queue when you perform specific report tasks, as described in [About background processing](#). The application can add jobs while a job is running without interrupting that job.

When a background processing job is running, you can view the job queue and the current status of the jobs in your queue by hovering the Background Processing indicator (). The Background Processing indicator appears next to the **Preferences** link, and remains visible until there are no unprocessed jobs remaining.

You can [cancel](#) **Running** or **In Queue** jobs in your background processing queue from individual cases from individual report outputs on the Report Outputs page. If you are a superuser, you can also cancel other users' jobs from these pages.

## About background processing job status

Report background processing jobs can have one of the following statuses:

- **In Queue**—Job is awaiting processing.
- **Running**—Job is currently processing.
- **Cancelled**—Superuser or the user who submitted the job cancelled it.
- **Error Occurred**—Job did not finish processing. You may see this status if, for example, the database fails during processing.
- **Completed**—Job finished processing successfully.

Note that:

- You can [cancel](#) In Queue or Running jobs, if necessary, from the Report Outputs page.
- You cannot restart Error Occurred jobs. To complete the job processing, create a new report output from the report definition.

## Viewing background processing job status

You can view the current job status for background processing jobs:

- On the [Report Outputs](#) page, in the **Status** column.
- By hovering over the Background Processing indicator.

For information on background processing job status, see [About background processing job status](#).

## Canceling a background processing job


The **Cancel** action menu command is available for In Queue or Running case series or report outputs in your background processing queue. You can cancel these jobs at any time from the Report Outputs page, depending on the job type you submitted. You cannot cancel jobs when hovering your mouse over the Background Processing indicator.

If you are a superuser, you can:

- Cancel jobs that you submitted.
- Cancel jobs that other users submitted.

You cancel other users' jobs on the Report Outputs page.

### To cancel a report background processing job:

1. Click the **Reports** tab.  
The Report Definitions page appears.
2. Click **Report Outputs**.  
The Report Outputs page appears.
3. Locate the report output for which you submitted a background processing job. The status in the Status column is Running. If you are a superuser, you can locate the report output that another user submitted.
4. If necessary, mouse over to the Background Processing indicator located next to the **Preferences** link to obtain the report output name from your job queue.
5. Click  next to the report output, and click **Cancel**.  
The application cancels the job and sets the report output status to Cancelled.

## Creating report definitions

### Selecting a case series for a report

On the Report Definitions page, you must select a case series before you can run, edit, copy, or delete a report definition. If you run the report, it is only for cases from the selected case series.

---

**Note:** Your case series selection does not affect the Report Outputs page or the Interactive Reports page.

---

Once you select a case series, only report definitions based on data configurations that are [compatible](#) with that of the cases series appear.

1. Click the **Reports** tab.

The Reports Definitions page appears.

2. Accept the case series shown, or click **Browse** to display the Select Case Series page. Click the radio button of the selected case series and **OK**.

The Report Definitions page appears and shows the name of the selected case series and the number of cases in it. Cases [marked as excluded](#) as part of reviewer input are included in the number, but a report that you run does not include those cases.

3. Filter the report definitions as necessary.

- From the **Project** drop-down list, select the [project](#) for which you want to view report definitions or -- to include all projects.
- From the **Configuration** drop-down list, select the [data configuration](#) for which you want to view report definitions or -- to include all configurations.

The selected report definitions appears. See the [Report Definitions page](#) for information about the information shown.



## Creating or editing a report definition

---

**Note:** You must [select a case series](#) before you can run, edit, copy, or delete a report definition (this requirement does not apply to interactive report definitions). If you run the report, it will be only for cases in the selected case series.

---

1. Do one of the following:

- A. Click the **Reports** tab.
- B. Select a case series. Click the radio button of the selected case series, and click **OK**.
- C. Click **Browse** to display the [Select Case Series page](#).

You must [select a case series](#) before you can run, edit, copy, or delete a report definition (this requirement does not apply to interactive report definitions). If you run the report, it is only for cases in the selected case series.

Or

- A. On the [Cases Series page](#) or the [Queries page](#), click the row menu () for a case series or query, and click **Report**.

The Report Definitions page appears. The names of valid report definitions appear in bold font. A report definition is valid (and, therefore, can be run) if it includes at least one row variable and one column variable, and no error messages appear for the variables.

2. To create a report definition, click **Create Definition**.

The Create Definition page appears.

Or

To edit a report definition, click () for the report definition, and click **Edit**.

Alternatively, click **Edit Definition** on the Display Report page.

The Edit Report Columns page appears. Continue with Step 9.

3. In the **Name for Report** field, type a report name. The name does not need to be unique, although Oracle recommends that you provide a unique and meaningful name.

4. In the **Description of Report** field, type a report description that differentiates the report definition from others on the Report Definitions page.

5. Assign the report definition to a [project](#).

- To assign the report definition to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.

- To create a new project and assign the report definition to it, click **Add to a new project named** and enter a project name.
6. Click **Save**.
- The Edit Report Columns page appears. From this page, you can edit the report columns, the [report attributes](#), and the [report descriptors](#).
- The application also saves the report definition and lists it on the Report Definitions page filling in the Created By and Created columns, although you cannot yet run it.
7. [Edit the report columns](#). For more information, see [Editing report columns](#).
8. Optionally, [edit the report attributes](#). For more information, see [Editing report attributes](#).
9. Optionally, [edit the report descriptors](#). For more information, see [Editing report descriptors](#).
10. If you have made changes to a report definition since the last time it was saved, use the following options to:
- Save the report definition without running it. Click **Save**. If you are working on a complex report definition, click **Save** periodically.

---

**Note:** If you edit a report definition that you did not create, the **Save** button does not appear.

---

- Save the report definition with a different name, without running it. Click **Save As**. Provide a name for the new report definition.
  - Save the report definition and run it. For a valid report definition, click **Save & Run**. A report is considered valid if it includes at least one row variable and one column variable, and there are no error messages for the report definition. For a query-based interactive report, a query must be part of the report definition. For an all cases summary interactive report, the definition must conform to certain criteria.
11. If you have not made changes to a report definition since it was last saved:
- To save the report definition with a different name, without running it, click **Save As**. Name the new report definition.
  - To run the report definition, for a valid report definition, click **Run**. A report is considered valid if it includes at least one row variable and one column variable, and there are no error messages for the report definition. For a query-based interactive report, a query must be part of the report definition. For an all cases summary interactive report, the definition must conform to certain criteria.

Each time you save the report definition, the application fills in the Modified and Modified By columns on the Report Definitions page.

## **Error messages**

An error message appears if any of the following are true:

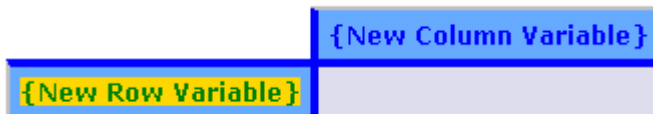
- You have not specified breakdown details for a column breakdown variable that has more than 10 values. (If there are 10 or fewer values, the application automatically uses the values as distinct values for the breakdown variable.)
- You have specified breakdown details for an analysis variable.
- In a SQL WHERE clause for the report definition, one of the variables referenced by the WHERE clause has been removed from the report definition.
- You specified breakdown details as grouped values, but there is at least one group that includes no values.

## Editing report columns

The Edit Report Columns page appears when you create or edit a report definition, or when you click **Report Columns** on one of the report definition pages. On this page, you specify the variables and values (from source data) to define rows and columns in the report, the labels of report columns, and the aggregation method (such as count, percentage, mean, or actual value) to be used to show values in the report.

A report can include columns from multiple tables. The application assumes that the tables can be linked by the case ID. As a result, only tables containing a case ID column are suitable for use with reports.

If you are creating a report definition, a placeholder appears for the variables that define rows and columns for the report in a tabular display:



When specifying columns and rows:

- Click **Save** frequently to save the report, especially when building a complex report definition.
- Click **Preview** to [preview the report](#). (This feature is not available for interactive reports.)
- Click **Undo** to remove the last change you made to the report definition since you last saved the report definition. Click **Redo** to add back the last undone change. You can click Undo and Redo successive times.

## Adding rows and columns to a report definition

The following instructions do not include [changing the labels](#) of row and column variables or changing the [aggregation method](#). These instructions use default labels, which are the variable names, and the default aggregation method (Value).

### To define the first row variable:

1. Click **{New Row Variable}** to highlight it in yellow.
2. To specify the corresponding source data variable, next to **Data Source**, click **Select**.

The [Edit Data Source dialog box](#) appears.

3. Specify a data source. For more information, see [Specifying a data source](#).
4. Click **OK**.

The selected variable appears as the row variable.

**To define the first column variable:**

1. Click **{New Column Variable}** to highlight it in yellow.
2. To specify the corresponding source data variable, next to **Data Source**, click **Select**.  
The [Edit Data Source](#) dialog box appears.
3. Specify a data source. For more information, see [Specifying a data source](#).
4. Click **OK**.  
The selected variable appears as the column variable.

**To add a row variable:**

1. Click the name of an existing row to highlight it in yellow.
2. Click **Insert Left** or **Insert Right**.  
The [Edit Data Source](#) dialog box appears.
3. Specify a data source. For more information, see [Specifying a data source](#).
4. Click **OK**.  
The application adds the new row variable to the report definition.

**To add a column variable:**

1. Click the name of an existing column variable to highlight it in yellow.
2. Click **Insert Left**, **Insert Right**, **Insert Above**, or **Insert Below**.  
The [Edit Data Source](#) dialog box appears.
3. Specify a data source. For more information, see [Specifying a data source](#).
4. Click **OK**.  
The selected variable appears as a column variable.

---

**Note:** For a column breakdown variable, you are required to specify breakdown values. If there are 10 or fewer distinct values for the variable in the source data, the application automatically uses those values as breakdown values. You can modify them as needed. If there are more than 10 distinct values, a message informs you that breakdown details are missing and you must specify them.

---

**Specifying column attributes variables**

1. Add rows and columns as described above.
2. To select an aggregation method for an analysis variable, highlight the variable in the cell.

3. Next to **Content Details** click **Select**.  
The Contents Details dialog box appears.
4. [Specify content details](#). For more information, see [Specifying content details](#).
5. Click **OK**.
6. To select which source values for a variable will appear in the report, highlight the variable in the cell.
7. Next to **Breakdown Details**, click **Select**.  
The Breakdown Details dialog box appears.
8. [Specify breakdown details](#). For more information, see [Defining breakdown details](#).
9. Click **OK**.
  - You can [edit report attributes](#), [edit report descriptors](#), or save or run the report definition. For an interactive report definition, you can [define a query](#).
  - To [view a histogram](#) showing the distribution of values for a numeric variable, click **View Column Statistics**.
  - To delete a variable, highlight the variable and click **Delete**. At the message asking if you are sure you want to delete the variable, click **OK**. You cannot delete the last row variable or last column variable.

## Specifying a data source in a report

In a report definition, the data source of a column variable or row variable is the name of the source database variable from which data will be retrieved for the report. You also specify the label that will identify the variable in the report.

---

**Note:** If a row variable's underlying column has the same name as any column in an analysis variable's table, then a SQL inner join of the same-named columns occurs in addition to the usual join on report ID.

---

1. On the [Edit Report Columns page](#), next to **Data Source**, click **Select**.

The Edit Data Source dialog box appears.

2. In the **Table** field, select the name of the database table that contains the variable that you want to use, or select **All Tables**.

---

**Note:** If you want to look at all cases, use the report ID (that is, the variable of the Report ID type in the configuration) in the demographics table. It is possible that a report has no record in the other tables. If you are not interested in getting all report IDs, but only those that have records in the table from which you are getting other data, use the report ID from that table.

---

3. [Select a variable](#).

4. When you highlight a variable in the list, the Label field shows the variable name by default. You can type in a different label, which appears in the report as the column heading for the variable.

For example, suppose that you use default labels for the `ISR_drug` and `Generic_Name` variables. The column headings in the report look like this:

ISR_drug	Generic_Name
<a href="#">3006552</a>	Amoxicillin

For clarity, you could modify them as follows:

ISR	Drug
<a href="#">3006552</a>	Amoxicillin

5. To change the label, select the default label and change it.
6. Click **OK**.
7. If you chose a numeric value, you can click **View Column Statistics** to display a histogram showing the distribution of values for the variable in the source data.

## Specifying content details

Content details specify how to display values of an [analysis variable](#); that is, the aggregation method for values. For example, you may want to show an actual value, a count of records with a value, a percentage of records with the value, and so on. You can specify multiple aggregation methods for an analysis variable; each aggregation method is represented in the report.

When you add an analysis variable to a report, the term Value appears by default as the aggregation method:

	Case ID
Gender	Value

Value stands for First value, which is the default aggregation method. (It is used when no other aggregation method is selected.) When you change the aggregation method, an abbreviation of that aggregation method appears in the table cell. For example, if you select Count as the aggregation method, N appears in the table cell:

	Case ID
Gender	N

### Notes:

- If the source table for a column or row can include multiple records per case, the count and unique count for the column or row can differ.
  - Percentages in the columns or rows can add up to greater than 100 percent. For example, the breakdown variable is PT severity. Adverse events data can include multiple records per case. Suppose that each of 10 cases has an event with the severity Mild, an event with the severity Moderate, and an event with the severity Severe. The count of cases with each severity is 10. The count of cases with any severity will also be 10. So the percentage of cases with each severity will be 10/10, which is 100%. The total of percentages for each severity would be 300%.
1. On the [Edit Report Columns page](#), highlight the aggregation method that appears in the table cell below the analysis variable. You must click the aggregation method, not the column heading. You can choose more than one aggregation method for a variable.
  2. Next to **Content Details**, click **Select**.  
The Content Details dialog box appears.
  3. Select the desired aggregation methods and percentages. Available aggregation methods depend on the data type of a variable.
  4. Click **OK**.



## Aggregation methods for text or date variables

For an analysis variable with a data type of text or date, check one or more of the following check boxes. The abbreviation appears in the report column heading.

Check box	Abbreviation	Meaning
Count	N	The number of non-NULL values.
Count (Unique)	N (U)	The number of unique non-NULL values.
Row %	Row %	Count of non-unique values for the row and column/Count of non-unique values for the row for all columns. (There must be a column for All.)
Column %	Column %	Count of non-unique values for the column and row/Count of non-unique values for the column for all rows. (There must be a row for All.)
Overall %	Overall %	Count of non-unique values for the column and row/Count of non-unique values for all columns and all rows. (There must be a column for All and a row for All.)
Row % (Unique)	Row % (U)	Count of unique values for the row and column/Count of unique values for the row for all columns. (There must be a column for All.)
Column % (Unique)	Col % (U)	Count of unique values for the column and row/Count of unique values for the column for all rows. (There must be a row for All.)
Overall % (Unique)	% (U)	Count of unique values for the column and row/Count of unique values for all columns and all rows. (There must be a column for All and a row for All.)
All values	ALL	All values, including null values, separated by commas. Null values are shown as blanks, so you may see a list of values like "DrugA, , DrugC".
All values (excluding NULLs)	All	All values except null values, separated by commas.
Unique values	ALL (U)	Unique values (in ascending order), including NULL values, separated by commas. Null values are represented in the list by the string "null".
Unique values (excluding NULL)	All (U)	Unique values (in ascending order), excluding NULL values, separated by commas.

Unique values and counts	ALL (N)	Unique values (in ascending order), including NULL values, separated by commas; after each value is the count of the value. Null values are represented in the list by the string "null".
Unique values and counts (Excluding NULL)	All (N)	Unique values (in ascending order), excluding NULL values, separated by commas; after each value is the count of the value.
First value	Value	First non-NULL value from the database (for the case series or query being used). If you do not specify an aggregation method, this method is used by default.

### Aggregation methods for numeric variables

For an analysis variable with a data type of number, check one or more of the following check boxes. The abbreviation appears in the report column heading.

**Note:** If a case is counted in multiple columns or rows, a count in the All column or row is not necessarily the same as the total of counts in other columns or rows of the report. Also, percentages in the columns or rows can add up to greater than 100 percent.

Check box	Abbreviation	Meaning
Count	N	The number of non-NULL values.
Count (Unique)	N (U)	The number of unique non-NULL values.
Row %	Row %	Count of non-unique values for the row and column/Count of non-unique values for the row for all columns. (There must be a column for All.)
Column %	Col %	Count of non-unique values for the column and row/Count of non-unique values for the column for all rows. (There must be a row for All.)
Overall %	%	Count of non-unique values for the column and row/Count of non-unique values for all columns and all rows. (There must be a column for All and a row for All.)
Row % (Unique)	Row % (U)	Count of unique values for the row and column/Count of unique values for the row for all columns. (There must be a column for All.)
Column % (Unique)	Col % (U)	Count of unique values for the column and row/Count of unique values for the column for all rows. (There must be a row for All.)

Overall % (Unique)	% (U)	Count of unique values for the column and row/Count of unique values for all columns and all rows. (There must be a column for All and a row for All.)
Sum	Sum	The sum of the values.
Mean	Mean	The mean of the values.
Median	Median	The median of the values.
Standard Deviation	SD	The standard deviation of the values.
1st Quartile	Q1	The first quartile of the values.
3rd Quartile	Q3	The third quartile of the values.
Min	Min	The minimum value.
Max	Max	The maximum value.

For example, suppose that a report includes counts like this:

	Severity			
	Mild	Mod	Severe	All
	Case ID	Case ID	Case ID	Case ID
Male	200	300	500	1000
Female	100	600	700	1400
All	300	900	1200	2400

If you replace the counts in the report with row, column, and overall percentages, the report display changes to this:

	Severity											
	Mild			Mod			Severe			All		
	Case ID			Case ID			Case ID			Case ID		
	Row %	Col %	%	Row %	Col %	%	Row %	Col %	%	Row %	Col %	%
Male	200/1000	200/300	200/2400	300/1000	300/900	300/2400	500/1000	500/1200	500/2400	1000/1000	1000/2400	1000/2400
Female	100/1400	100/300	100/2400	600/1400	600/900	600/2400	700/1400	700/1200	700/2400	1400/1400	1400/2400	1400/2400
All	300/2400	300/300	300/2400	900/2400	900/900	900/2400	1200/2400	1200/1200	1200/2400	2400/2400	2400/2400	2400/2400

## Naming a report definition

When you have clicked **Create Definition** on the Report Definitions page or you have clicked **Save As** while editing a report definition, you must name the report definition.

1. In the **Name for Report** field, type a report name. The name does not need to be unique, although Oracle recommends that you provide a unique and meaningful name.
2. In the **Description of Report** field, type a report description that differentiates the report definition from others on the Report Definitions page.
3. Assign the report definition to a [project](#).
  - To assign the report definition to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.
  - To create a new project and assign the report definition to it, click **Add to a new project named** and enter a project name.
4. Click **Save**.

The Edit Report Columns page appears.

The application also saves the report definition and lists it on the Report Definitions page filling in the Created By and Created columns, although you cannot yet run it.

## Specifying variable breakdowns

### Defining breakdown details

Breakdown details are the specification of values for a [breakdown variable](#). If a breakdown variable is a text or date variable, you can define breakdown details using individual selected values, distinct values, or grouped values. If a breakdown variable is a numeric variable, you define breakdown details using cutpoints. For an [interactive report](#), you can define a query whose user-supplied values are used as breakdown details when the report is run.

---

**Note:** If there are 10 or fewer values for a column breakdown value, the application uses them by default as distinct values for the breakdown variable. For a row variable, the application uses all values by default as distinct values for the breakdown variable. You can modify these default breakdowns as needed.

---

1. Click the **Reports** tab.

The Report Definitions page appears.

---

**Note:** You must select a case series before you can run, edit, copy, or delete a report definition. For more information, see [Selecting a case series](#).

---

2. Click **Create Definition**.

The Create Definition page appears.

3. In the **Name for Report** field, type a report name. The name does not need to be unique, although Oracle recommends that you provide a unique and meaningful name.

4. In the **Description of Report** field, type a report description that differentiates the report definition from others on the Report Definitions page.

5. Assign the report definition to a [project](#).

- To assign the report definition to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.
- To create a new project and assign the report definition to it, click **Add to a new project named** and enter a project name.

6. Click **Save**.

The [Edit Report Columns page](#) appears.

7. Next to **Breakdown Details**, click **Select**.

The Breakdown Details dialog box appears.

8. Select the breakdown type by selecting the Every Distinct Value, Individual Values, Grouped Values, or Query Values radio button.
  - To define breakdown details by distinct value, see [Defining breakdown by distinct values](#). The report includes a column or row for every distinct (unique) value of the variable. This option uses the values available at the time you run the report, not at the time you define it.
  - To define breakdown details by individual values, see [Defining breakdown by individual values](#). The report includes a column or row for every value that you select. This option results in a static list of breakdown values that does not automatically adjust to changing source data.
  - To define breakdown details by grouped values, see [Defining breakdown by grouped values](#). The report includes a column or row for every group that you define.
  - To define breakdown details by query values, see [Defining breakdown by query values](#). This choice allows you to [substitute values from the query](#) that is run as part of an [interactive report](#).
  - To define breakdown details for a numeric variable, see [Defining breakdown by cutpoints](#).
9. Click **OK**.

### Report performance with breakdown details

The performance of a report with breakdown details can depend on whether the analysis variable that you use comes from the same source table as the row variables. If the analysis variable is from the same table as the row variables, the performance of a report definition with breakdown details is much faster. This may be important when you are working with a sizeable case series (containing 5,000 or more cases). The speed difference is several orders of magnitude. When possible, select the analysis variable from the same table as the row variables.

### All column

For a breakdown variable, you can include a category for All values. The All column is not based on values for other columns in the report. For example, if the report shows counts, the All column is not a total of counts for the other columns.

In the following example, the same case may have PTs in both the Card SOC and Other SOC:

SOC			
Card	Other	Null	All

Sex	Cases	Cases	Cases	Cases
	N (U)	N (U)	N (U)	N (U)
F	5000	11000	0	12000
M	6000	13000	0	16500

The N (U) value for the All column and F row is not 5000 + 11000. The value in the All column is:

- 4000 who have a PT in the Card SOC and a PT in other SOCs.
- + 1000 who have a PT in the Card SOC only.
- + 7000 (computed as 11000 - 4000) who have a PT in any SOCs except Card.
- = 12000.

### Example

For example, you want a summary of the number of cases for each report type (direct, expedited, and periodic). For your report definition, you set up the FDA Year as the row variable and you specify Report Type as the column variable. You then need to specify the value you want to show for each report type; that is, the [analysis variable](#). You specify CASE\_ID as the analysis variable, label it as Cases, and select the **Count** [aggregation method](#).

FDA Year	Report Type		
	Direct	Expedited	Periodic
	Cases	Cases	Cases
	N	N	N
1997	<a href="#">6</a>	<a href="#">19</a>	<a href="#">25</a>
1998	<a href="#">18</a>	<a href="#">91</a>	<a href="#">111</a>
1999	<a href="#">20</a>	<a href="#">94</a>	<a href="#">159</a>
2000	<a href="#">24</a>	<a href="#">109</a>	<a href="#">116</a>
2001	<a href="#">31</a>	<a href="#">115</a>	<a href="#">118</a>
2002	<a href="#">29</a>	<a href="#">137</a>	<a href="#">15</a>
2003	<a href="#">31</a>	<a href="#">177</a>	<a href="#">31</a>
2004	<a href="#">23</a>	<a href="#">171</a>	<a href="#">83</a>
2005	<a href="#">24</a>	<a href="#">271</a>	<a href="#">44</a>
2006	<a href="#">23</a>	<a href="#">259</a>	<a href="#">48</a>

## Defining breakdown by distinct values

In the Breakdown Details dialog box, if you click **Every Distinct Value**, the report includes a column or row for every distinct (unique) value of the variable. This option uses the values available at the time the report is run, not at the time you define the report.

1. In the [Breakdown Details](#) dialog box, click **Every Distinct Value**.
2. To include a column or row in the report to represent all values for the variable (including null values if **Include a category for Null values** is checked), check **Include a category for ALL selected values**. For reports that display percentages, the report must include a row or column for **All**.

---

**Note:** If a case is counted in multiple columns or rows, a count in the All column or row is not necessarily the same as the total of counts in other columns or rows of the report. Also, percentages in the columns or rows may add up to greater than 100 percent.

---

3. To include a column or row to represent null (missing) values for the variable, check **Include a category for Null values**.
4. Click **OK**.

### Example

In the following example, the **All** row shows the number of cases with any of the Gender values for each Age Group. The **All** column shows the number of cases with any Age Group for each Gender. Also, the **NULL** column shows the number of cases (in this example, none) that have no Age Group for each Gender.

Gender	Age Group										
	00_01	02_04	05_12	13_16	17_45	46_75	76_85	86_above	UNK	NULL	All
	Cases	Cases	Cases	Cases	Cases	Cases	Cases	Cases	Cases	Cases	Cases
	N (U)	N (U)	N (U)	N (U)	N (U)	N (U)	N (U)	N (U)	N (U)	N (U)	N (U)
F	1	2	6	11	1078	1913	99	18	552	0	3680
M	2	3	0	9	540	869	66	9	272	0	1770
U	0	0	0	1	92	60	1	1	47	0	202
All	3	5	6	21	1710	2842	166	28	871	0	5652

---

**Note:** See [Specifying Content Details](#) for information about the behavior of the All row when unique counts are shown for column variables.

---



## Defining breakdown by individual values

In the Breakdown Details dialog box, if you click **Individual Values**, the report includes a column or row for every value that you select. This option results in a static list of breakdown values that does not automatically adjust to changing source data.

---

**Note:** If there are more than 20,000 available values for the breakdown variable, you cannot use a breakdown by individual values.

---

1. In the [Breakdown Details](#) dialog box, click **Individual Values**.
2. To include a column or row to represent null (missing) values for the variable, check **Include a category for Null values**.
3. To include a column or row in the report to represent all selected values for the variable (including null values if **Include a category for Null values** is checked), check **Include a category for ALL selected values**. For reports that display percentages, the report must include a row or column for **All**.

---

**Note:** If a case is counted in multiple columns or rows, a count in the **All** column or row is not necessarily the same as the total of counts in other columns or rows of the report. Also, percentages in the columns or rows may add up to greater than 100 percent.

---

4. To include a column or row for values that are not represented by any other columns, check **Include a category for all unselected values**.
5. From the **All Values** list, select values for the variable.
  - To find a value, you can type a string into the **Find** field, then click **Find**. All values containing that string appear. The matching does not distinguish between cases (upper, lower, mixed). To list all values again, you can click **Show All**.
  - To search for the following special characters, you must precede each special character with a backslash (\): + \* ? . \ ( ) [ ]

---

**Note:** When a value is highlighted in the list, you can go to the next occurrence of a value starting with a character that you type. For example, you can highlight the first value in the list and type H to go to the first value starting with H.

---

6. Highlight one or more values in the list of all values. You can also do the following:
  - To highlight multiple non-contiguous values, hold down the **Ctrl** key while clicking each value.
  - To highlight multiple contiguous values, click a value, hold down the **Shift** key, and click another value. Values between and including those values are highlighted.

- To remove highlighting from a value, hold down the **Ctrl** key while clicking the selected value.
- To move values back and forth between the list of all values and the list of selected values, you can double-click a highlighted value or use the arrow keys as follows:

<b>Button</b>	<b>Use To</b>
->	Move highlighted values from the list of all values to the list of selected entries.
->>	Move all values from the list of all values to the list of selected values.
<-	Move highlighted values from the list of selected values to the list of available values.
<<-	Move all values from the list of selected values to the list of available values.

- If **Clear** is available, you can click it to clear out the list of selected values.
  - If up and down arrows are available for the list of selected values, you can use them to order the selected values as you want them to appear in the report.
7. From the **Breakdown values order** field, select the breakdown values order.
    - To sort the values in ascending order, click **Sorted**.
    - To show values in the order in which they appear in the Selected Values list, click **Listed order**.
  8. When you are satisfied with the Selected Values list, click **OK**.

The Edit Report Columns page shows the selected values. Click **Save** to save your report definition so far.
  9. To [edit value labels](#) for breakdown values, in the **Breakdown Details** section, click **Edit Labels**.

The Edit Labels dialog box appears. For more information, see [Editing individual value labels](#).
  10. Click **OK**.

## Example

The following example shows a report in which three different SOCs were selected:

Gender	SOC		
	Card	Cong	Infec
	Cases	Cases	Cases
	N	N	N
F	<a href="#">13</a>	0	<a href="#">20</a>
M	<a href="#">11</a>	0	<a href="#">27</a>
U	<a href="#">1</a>	<a href="#">1</a>	<a href="#">2</a>

In the following example, the **All** row shows the number of cases with any of the Gender values for each SOC. The **All** column shows the number of cases with any of the SOCs for each Gender. The **Null** column shows the number of cases (in this example, none) with no SOC for each Gender. All SOCs that are not any of the three selected SOCs are represented by the **Other** column:

Gender	SOC					
	Card	Cong	Infec	NULL	All	Other
	Cases	Cases	Cases	Cases	Cases	Cases
	N	N	N	N	N	N
F	<a href="#">13</a>	0	<a href="#">20</a>	0	<a href="#">33</a>	<a href="#">424</a>
M	<a href="#">11</a>	0	<a href="#">27</a>	0	<a href="#">38</a>	<a href="#">301</a>
U	<a href="#">1</a>	<a href="#">1</a>	<a href="#">2</a>	0	<a href="#">4</a>	<a href="#">24</a>
All	<a href="#">25</a>	<a href="#">1</a>	<a href="#">49</a>	0	<a href="#">75</a>	<a href="#">749</a>

---

**Note:** See [Specifying content details](#) for information about the behavior of the **All** row when unique counts are shown for column variables.

---

## Editing individual value labels

If you define breakdown details using individual values, the default labels for values are the exact values from the source data. You can modify the labels that appear in the report. Editing the labels has no effect on the source data.

---

**Note:** When you add reports as charts on the Drugs tab, the configuration variable name is always used in the reports, instead of any specified labels from the report definition (the all cases summary interactive report).

---

1. On the [Edit Report Columns page](#), in the **Breakdown Details** section, click **Edit Labels**.

The Edit Labels dialog box appears. Each value that you have selected appears in the **Value** column.

2. In the **Label** field for any of the values, type in a different label.
3. Click **OK**.

The modified labels are shown on the Edit Report Columns page.

## Defining breakdown by grouped values

If you click Grouped Values in the Breakdown Details window, the report will include a column or row for every group that you define. This option results in a static list of breakdown values that does not automatically adjust to changing source data.

---

**Note:** If there are more than 20,000 available values for the breakdown variable, you cannot use a breakdown by grouped values.

---

1. In the [Breakdown Details window](#), click **Grouped Values**.
2. Next to the **Groups** field, click **New**.  
A message asks for the new group's name.
3. Enter a name for the new group, and click **OK**.
4. To include a column or row to represent null (missing) values for the variable, check **Include a category for Null values**.
5. From the **All Values** list, select values to include in the group.
  - To highlight multiple non-contiguous values, hold down the **Ctrl** key while clicking each value.
  - To highlight multiple contiguous values, click a value, hold down the **Shift** key, and click another value. Values between and including those values are highlighted.
  - To remove highlighting from a value, hold down the **Ctrl** key while clicking the selected value.
  - To move values back and forth between the list of all values and the list of selected values, you can double-click a highlighted value or use the arrow keys as follows:

Button	Use To
->	Move highlighted values from the list of all values to the list of selected entries.
->>	Move all values from the list of all values to the list of selected values.
<-	Move highlighted values from the list of selected values to the list of available values.
<<-	Move all values from the list of selected values to the list of available values.

- If **Clear** is available, you can click it to clear the list of groups.

- If up and down arrows are available for the groups, you can use them to order the selected groups as you want them to appear in the report.
6. Create other groups and select values to be included in them. Make sure that each group includes at least one value.
  7. From the **Breakdown values order** field, select the breakdown values order:
    - A. To sort the values in ascending order, click **Sorted**.
    - B. To show values in the order in which they appear in the Selected Values list, click **Listed order**.
  8. To rename or delete groups, on the Breakdown Details dialog box to the right of the Groups box, click **Rename** or **Delete**.
  9. To include a column or row to represent null (missing) values for the variable, check **Include a category for Null values**.
  10. To include a column or row in the report to represent all selected values for the variable (including null values if **Include a category for Null values** is checked), check **Include a category for ALL selected values**. For reports that display percentages, the report must include a row or column for **All**.

---

**Note:** If a case is counted in multiple columns or rows, a count in the All column or row is not necessarily the same as the total of counts in other columns or rows of the report. Also, percentages in the columns or rows may add up to greater than 100 percent.

---

11. To include a column or row for values that are not represented by any other columns, check **Include a category for all unselected values**.
12. When you are satisfied with the groups and other options, click **OK**.

The Edit Definition page shows the selected values. Click **Save** to save your report definition so far.

---

**Note:** You cannot save the report definition if all groups are empty (that is, have no values in them). If some groups are empty, the report definition is saved and the empty groups are ignored.

---

## Cutpoints

If you are defining breakdown details for a numeric variable, you must define cutpoints. Cutpoints are consecutive, user-defined value ranges that categorize data for both numeric and date variables. You use cutpoints to subset data, which allows you to group specific portions of data that are of interest to your organization. You define cutpoints for both numeric and date variables when you define breakdown details in a report definition.

For example, suppose that you want to create a report definition that includes the number of deaths that occurred:

- Before 2009
- During 2009
- After 2009

You could then define the following cutpoints for the Death Date variable in the Breakdown Details dialog box:

The screenshot shows a web-based dialog box titled "Breakdown Details" with the subtitle "Define Cutpoints for Variable DEMO\_AERS.DEATH\_DATE (Death date)". The dialog contains a table with two columns: "Value" and "Label". The table has several rows, with the first three rows containing data and the rest being empty. The first row shows "VALUE <= 12/31/2008" with the label "2008 and before". The second row shows "12/31/2008 < VALUE <= 12/31/2009" with the label "2009". The third row shows "12/31/2009 < VALUE" with the label "2010 and after". Below the table, there are two checkboxes: "Include a category for NULL values" and "Include a category for ALL selected values", both of which are unchecked. At the bottom of the dialog, there are "Save" and "Cancel" buttons. The status bar at the bottom of the browser window shows the URL "http://datamine78.north.pf.com/signal\_dev1/ctModalContainer.jsp?vinc" and "Local intranet".

	Value	Label
	VALUE <= 12/31/2008	2008 and before
12/31/2008	< VALUE <= 12/31/2009	2009
12/31/2009	< VALUE	2010 and after

Include a category for NULL values

Include a category for ALL selected values

Save Cancel

http://datamine78.north.pf.com/signal\_dev1/ctModalContainer.jsp?vinc Local intranet

You can define cutpoints for both row variables and column variables in report definitions.

---

**Note:** You can also define cutpoints when you specify a data transformation for a data configuration variable. For more information, see [Defining variable cutpoints](#).

---

With the numeric variable highlighted on the [Edit Report Columns page](#), you can click **View Column Statistics** to [view a histogram](#) of variable values.

## Defining date cutpoints

You define cutpoints for date variables in report definition breakdown details as you would define cutpoints for numeric variables. When you define cutpoints for dates, you must ensure that you enter dates in the format **MM/DD/YYYY**. You must ensure that you enter non-breaking and consecutive date ranges. You cannot set cutpoints with gaps in the ranges.

In defining cutpoints, you may encounter the following cases:

- Cutpoints appear in the report output in alphabetical order by label name, rather than chronological date order.
- The **Save** button may become inaccessible. To correct the situation, place the cursor in the last available **Value** field, and then press <Tab> until you reach the **Save** button.

## Existing report definitions and date variables

Prior to Empirica Signal 7.3.337, you specified breakdown details for date variables by Individual Values or by Grouped Values. Report definitions created prior to Empirica Signal 7.3.337 continue to maintain the previous date variable functionality. To define breakdown details by cutpoints for these reports, you must delete the date variables, and then re-add them to the reports.

For information on deleting variables from breakdown details, see [Editing report columns](#).

## Adding additional rows

When you define cutpoints, a limited number of rows are available for date and label entry. Should you require additional rows, do the following:

1. Click **Save**.  
The Breakdown Details dialog box closes.
2. Click **Select** next to the Breakdown Details field.  
The Breakdown Details dialog box reopens with additional rows available.



## Defining breakdown by cutpoints

If you are defining breakdown details for a numeric variable, you must define cutpoints. To define cutpoints, you specify ranges of numbers by indicating their boundaries. This option uses the values available at the time the report is run, not at the time you define the report.

With the numeric variable highlighted on the [Edit Report Columns page](#), you can click **View Column Statistics** to [view a histogram](#) of variable values.

1. In the [Breakdown Details](#) dialog box, in the first value field (after **VALUE <=**), enter the maximum value for the first category.
2. Enter a label for the value.
3. In the next row, in the **Value** field, enter the maximum value for the second category. (The cutpoint values must be in ascending order.)
4. Enter a label.
5. Continue defining categories until you are ready to define the last category.
6. For the last category, enter only a label. Do not enter a value. This is the label for all values greater than the previous cutpoint.
7. To include a column or row to represent null values for the variable, check **Include a category for NULL values**.
8. To include a column or row to represent all values for the variable (including null values if **Include a category for NULL values** is checked), check **Include a category for ALL selected values**. For reports that display percentages, the report must include a row or column for **All**.
9. When you are satisfied with the cutpoints, click **Save**.

The Edit Report Columns page shows the selected values. Click **Save** to save your report definition so far.

## Viewing column statistics

When you are [adding a column](#) for a numeric variable to a report definition on the Edit Data Source dialog box, or [defining cutpoints](#) for a numeric or date variable in a data configuration on the Cutpoints for Variable dialog box, you can click **View Column Statistics** to view information about the distribution of values for the variable in the source data.

The Column Value Statistics dialog box appears.

The following information is provided for numeric and date variables:

- **A histogram**—A graph of grouped (binned) data showing frequency distribution. The x-axis represents values from the source data and the y-axis represents counts of cases. A shaded rectangular block in the graph represents each bin. A bin is a range of x-axis values. The top of each block indicates the count of cases for the bin.
- **Minimum**—Minimum value.
- **Maximum**—Maximum value.
- **Distinct Values**—Number of distinct values.
- **Total Values**—Total number of values.

The following additional information is provided for date variables:

- **Average**—Average value.
- **Standard Deviation**—Standard deviation of values.
- **Variance**—Variance of values.

When you point to a block in the histogram, the following information appears:

- The range of x-axis values for the bin.
- The cumulative count of cases with that range of values.
- The cumulative percentage of cases with that range of values.

To close the Column Value Statistics dialog box, click **Close**.

## Defining breakdown by query values

When you [create an interactive report definition](#), you define a query that will be run when the report is run. The report is run against the cases found by the query. You can set up a breakdown variable to use user-specified query values as the breakdown details. For example, you can define a report that uses user-specified values for Outcome as breakdown values.

---

**Note:** You cannot define breakdown by query values for numeric or date variables.

---

1. In the [Breakdown Details](#) dialog box, click **Query Values**.
2. To include a column or row to represent null (missing) values for the variable, check **Include a category for NULL values**.
3. To include a column or row in the report to represent all the values provided to the query, including null values, check **Include a category for ALL selected values**. For reports that display percentages, the report must include a row or column for **All**.

---

**Note:** If a case is counted in multiple columns, a count in the All column is not necessarily the same as the total of counts in other columns of the report.

---

4. To include a column or row for values that are not represented by any other columns, check **Include a category for all unselected values**.
5. Click **OK**.

Make sure that the query for the report definition includes the breakdown variable.

## Specifying report attributes/descriptors

### Editing report attributes

1. While editing a report definition pages, click the **Report Attributes** option.  
The Edit Report Attributes page appears.
2. To disable [drill-down](#) for column variables in the report, click **Generate drill-down Information**, then change the value of the field to **No**.  
This option is not available for an all cases summary interactive report.

---

**Note:** When generated, drill-down information increases the amount of memory used for report output. For large reports, this option should be set to No.

---
3. To [specify report restrictions](#), click **Restrict by SQL WHERE Clause**.  
The Restrict by SQL WHERE Clause page appears. Only cases that meet the criteria of the Where clause that you specify are included in the report.
4. Type the **SQL WHERE clause**.
5. To see the columns defined for the report, click **Show Columns**.

---

**Note:** To know the list of supported SQL functions, see [SQL functions](#).

---
6. Click **Apply**.  
You can [edit column attributes](#), [edit report descriptors](#), or save or run the report definition. For an interactive report definition, you also can [define a query](#).

## Setting up report drill-down

If drill-down is allowed for reports, users can [drill down](#) on report column variables that show counts of cases, or on elements of graphs based on such reports. If the running of a report generates an out-of-memory error, you can turn off drill-down in the report definition and try running the report again. When drilldown is off, less memory is used to run the report; however, the report may take longer to run.

---

**Note:** For an all cases summary report, this option on the Edit Report Attributes page is not available. However, on the Drugs tab, users are able to drill down on charts based on the output of this type of report.

---

1. On the [Edit Report Attributes page](#), click **Generate drill-down Information**.
2. To allow drill-down in reports, click **Yes** (the default). To disallow drill-down, click **No**.

---

**Note:** Even if you click **No**, users can drill down to case details from a case ID that appears as a row variable in a report.

---

## Specifying report restrictions

You can restrict a report to data that meets a specified condition by using a SQL WHERE clause. For example, you might want the report to include only males who reside in the United States and are between 18 and 55 years old. The application applies the report restriction, if specified, after generating the report, but before displaying the report.

For an interactive report, the query run as part of the report determines which cases are included in the report. A SQL restriction, on the other hand, acts on the data for those cases. For example, suppose you want a report that shows drug counts for only suspect drugs. If you include a suspect drug indicator as a query variable, the report runs against all cases including suspect drugs. Some of these cases might also have non-suspect drugs. However, you could specify a SQL restriction to include only suspect drugs in the report.

---

**Note:** Columns of the type CLOB are truncated in reports. Therefore, if a column referenced in the restriction has the type CLOB (as is typical with narrative text), the application applies the restriction to the truncated values for that column.

---

1. On the [Edit Report Attributes page](#), click **Restrict by SQL WHERE Clause**.  
The Restrict by SQL WHERE Clause page appears.
2. Click **Show columns**.  
The Select Table Columns dialog box appears listing the column names and types.
3. Click the name of the column to include in the WHERE clause.
  - Note the column type, so that you know what syntax is valid for that column in the WHERE clause.
  - On the Restrict by SQL WHERE Clause page, the column you selected appears in the SQL WHERE clause field in square brackets. The Select Table Columns page remains open, so that you can select other columns.
4. In the **SQL WHERE clause** field, complete the SQL condition. You might, for example, select the AGE column (placing AGE into the field), and then type ">=65" to restrict the report to patients who are at least 65.
5. When you are satisfied with the WHERE clause, click **Apply**.

If the SQL syntax is valid, the Edit Report Attributes page appears, showing the SQL WHERE clause and the number of rows that meet the criteria of the WHERE clause.

or

If there are errors in the SQL syntax, an error message appears when you try to run the report.

---

**Note:** To know the list of supported SQL functions, see [SQL functions](#).

---

## Editing report descriptors

1. On a Report Definitions page, such as Edit Report Columns, Edit Report Attributes, or Edit Report Descriptors, click the **Report Descriptors** radio button.

The Edit Report Descriptors page appears.

2. View or modify the information shown.

Column	Description
Name of Report	Name of the report definition.
Description of Report	Description of the report definition.
Category	Category of the report definition, either Ad Hoc or Standard. The category is for informational purposes. You can display it as a column on the Report Definitions page, the Interactive Reports page, or the Report Outputs page.
Built-in	This field is available for superusers only. It is for use by Oracle when creating built-in report definitions, which are predefined reports supplied with the Empirica Signal application and available if the appropriate data configuration has been set up during installation. For more information, see <a href="#">Built-in reports</a> .
Type	<p>Applies to interactive reports only. One of the following values:</p> <ul style="list-style-type: none"> <li>• <b>Query-based</b>—Indicates a report definition that includes a query. Users can provide values to the query when the report is run.</li> <li>• <b>Summary of all cases</b>—Indicates a report definition that includes all cases and can be used by a drug profile configuration. Reports that can be added as charts on the Drugs tab are based on this type of report.</li> </ul> <p>If you are a superuser, this field can also show a customer-specific report that has been provided by Oracle.</p>
Project	<p>You can assign the report to an existing project by clicking <b>Add to existing project</b> and selecting the project from the drop-down list containing projects associated with objects that you created or that are published to you.</p> <p>To create a new project and assign the report to it, click <b>Add to a new project named</b> and enter a project name.</p>
Status	<p>Ready or Under Development.</p> <p>If the report definition can be run, the application applies the Ready status denoting that the report definition is valid. A report definition is</p>

valid if it has at least one row variable, at least one column variable, and no error messages appear for report variables. For a query-based report, a query must be part of the report definition. For an all cases summary report, the definition must conform to certain [criteria](#).

If the report definition is not ready to be run, the application assigns it the status Under Development.

Configuration	Description of the source data of the report definition.
XML	This field is available for superusers only. You can copy and paste this XML to <a href="#">create a report using XML</a> .

3. Click **Save**.



## Previewing a report

On the [Edit Report Columns page](#), when creating or editing a report definition (except an interactive report definition), you can click **Preview** to check that the report definition is set up as you want it before you save or run the report. The Report Preview page shows data for only the first 10 cases of the selected case series or the first 10 cases found by the query.

You can preview only a valid report definition. A report definition is valid if it includes at least one row variable and one column variable, and there are no error messages displayed on the Edit Report Columns page.

## Using XML to create a report definition

Each report definition is stored internally as XML (eXtensible Markup Language). Superusers can create definitions using XML.

1. Log into the Empirica Signal application as a superuser.
2. Obtain the XML that you want to use. You can copy the text from the XML field on the [Edit Report Descriptors page](#).

---

**Note:** Copied XML for a non-interactive report can only be used to create a non-interactive report. Copied XML for an interactive report can only be used to create an interactive report.

---

3. On the [Report Definitions page](#), click **Create Definition from XML**.  
The Create from XML page appears.
4. Provide the following information. The values that you specify appear on the Report Definitions page or Interactive Reports page, where users can sort by them.




Column	Description	Notes
Name	Name of the report.	Required.
Description	Description of the report.	
Category	Category containing the report. By default, this value is Ad Hoc. Alternatively, you can select Standard.	Required.
Creator	Name of the user who created the report.	Read-only.
Data	Applies to (non-interactive) report definitions only. Specifies the configuration on which the currently selected case series is based.	Read-only.
Configuration for Report	Applies to interactive report definitions only. Specifies the configuration to supply source data when the report is run.	Required.
Status	Under Development status indicates that the report is not ready to be run until you have saved it.	Read-only.

5. In the **XML Definition** field, paste in the copied XML.
6. Click **Save**.

If you want to assign the report definition to a project, edit the report definition to provide a project name on the Edit Report Descriptors page.

## Viewing a report

There are several ways to run a report. Choose one of the following:

- On the Report Definitions page, select a case series. Select the row menu () for the report definition, and select **Run**.
- When editing a report definition, click **Save & Run** or **Run**.
- On the Interactive Reports page, click  for an interactive report, and then click **Run**.
  - For a query-based interactive report, you must [select a data configuration](#) and [run a query](#). The application runs the query and the report against source data for that data configuration. The report is run against only cases that meet the query criteria.
  - When you view a query-based report from the Interactive Reports page, you select a data configuration against which to run a query. The source data for the report is the set of cases in the selected data configuration that match the report's query.
- On the Queries page, click  for a query, and then click **Report**.
- Drill down to the Cases page, and click **Report**.
- You can [drill-down](#) on a count or graph element elsewhere in the application to run a report definition against cases that make up the count or are represented by the graph element.



The application runs the report and displays the report output.

## Working with report data





- If you have the Create Report Definitions permission, you can click **Edit Definition**. The Edit Report columns page appears and you can modify the definition as needed.
- To [save report output](#) so it can be viewed later, click **Save Output**. (This option is not available if you are running a report definition after drilling down.) You can also run a report definition and save its output in a single step. For more information, see [Creating a Report Output](#).
- To create a new case series containing cases in the report, click **Create Case Series**. This option is available only if the case IDs in the first column of the report contains links.
- To show the report data in a graph format, click **Choose Graph**.
- To [save the report as an attachment to a topic](#), click **Save to Topic** (available if the topics feature has been set up).

- To [print the](#) report, click **Print**.
- To [download report data](#), click **Download**. The column names are created from the labels in the report definition, followed by the breakdown specifications.
- To show descriptive information below the report, click **Show Notes**.

### Managing report rows

- To specify how many rows should display at a time, enter a number in the **Rows per Page** field and press the **Enter** key. You can display up to 999 rows on each page.
- To go to another page, you can do the following:
  - To view the next page, click .
  - To view the previous page, click .
  - To view the specific page, enter a number in the Page field and press the Enter key.
- To find specific text on a page, select **Find** on the browser's (Internet Explorer's) Edit menu. For efficiency, you may want to set the Rows per Page to a large number before using the Find feature.

### Sorting the report

- You can sort a report by up to three columns of the report. The current sort order appears above the report. You can sort a column as follows:
  - To sort in ascending order, click .
  - To sort in descending order, click .
- When you click  or  to sort a column, that column is used for the primary sort order. The previous primary sort order (if any) becomes the secondary sort order. The previous secondary sort order (if any) becomes the tertiary sort order.

---


**Note:** In displayed reports, sorting is case-insensitive.

---

- Underlined counts (N) are links. Click the number to display a menu from which you can [drill-down](#). If specific case IDs appear in the report as a link, click a case ID to [view case details](#).

## Renaming a report definition

You can rename only those report definitions that you created.


1. On the [Report Definitions page](#) or Interactive Reports page, select the row menu () for the report definition, and then click **Rename**.

The Rename Definition page appears.

2. In the **Name for Report** field, type a name. The name does not need to be unique, although Oracle recommends that you use a unique name.
3. In the **Description of Report** field, enter an informative description of the report definition.
4. Assign the report definition to a [project](#).
  - To assign the report definition to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.
  - To create a new project and assign the report definition to it, click **Add to a new project named** and enter a project name.
5. Click **Save**.

## Copying a report definition

If you cannot edit a report definition, you can copy it and modify the copy as needed.

1. On the [Report Definitions page](#), select the row menu () for the report definition, and then click **Copy**.  
  
The Copy Definition page appears.
2. In the **Name for Report** field, type a report name. The name does not need to be unique, although Oracle recommends that you provide a unique and meaningful name.
3. In the **Description of Report** field, type a report description that differentiates the report definition from others on the Report Definitions page.
4. Click **Save**.
  - If you want to assign the report definition to a project, edit the report definition to provide a project name on the Report Descriptors page.
  - [Edit](#) the copy of the report definition as needed.

## Built-in reports

The Empirica Signal application includes a set of built-in report definitions that you can run from the Report Definitions page. You can also copy them and modify the copies as needed. Only a superuser can edit the original built-in reports.

**Note:** The built-in reports are available only if a data stub has been set up as described in AERS (1q03: S) Configuration Installation Instructions (located in the Data\_Stub folder on the installation CD).

Examples of the built-in reports follow. Each heading shows the report name and description.

### Age Group: Gender [N] – Summary: Counts by Age Group by Gender

Age Group	Gender		
	Female	Male	Unknown
	Reports	Reports	Reports
0 - 17	<a href="#">181</a>	<a href="#">197</a>	0
18 - 64	<a href="#">2701</a>	<a href="#">2014</a>	0
65 - above	<a href="#">1211</a>	<a href="#">800</a>	0
Unknown	<a href="#">509</a>	<a href="#">319</a>	0

### Drugs and Events – Detail: ISR, Gender, Age (years), Generic Drugs, Events

ISR	Gender	Age (yrs)	Generic Drug(s)	Event(s)
			All (U)	All
<a href="#">3004472</a>	F	101	Lorazepam	Respiratory distress
<a href="#">3083084</a>	F	102	Amoxicillin And Clavulanate	Rash papular
<a href="#">3085155</a>	F	101	Ciprofloxacin	Rash erythematous, Rash papular
<a href="#">3087389</a>	M	102	Cetirizine	Rash pruritic
<a href="#">3134950</a>	F	102	Spironolactone	Abnormal behaviour, Hyponatraemia, Malaise, Renal impairment
<a href="#">3166701</a>	M	101	Glipizide	Myocardial infarction
<a href="#">3212555</a>	F	102	Risperidone	Agitation, Drug abuser, Sedation
<a href="#">3218324</a>	F	102	Azithromycin	Death
<a href="#">3271545</a>	F	101	Pethidine	Injection site inflammation, Injection site reaction

### Outcome [%] – Summary: Percentages by Outcome

Outcome	Reports
	Col % (U)
Congenital Anomaly	1.14
Died	23.32
Disabled	20.04
Hospitalized	78.46
Life-threatening	13.35
Other	48.33
Required Intervention to Prevent Permanent Damage	8.8
All	100

**Report Type: SOC [N] – Summary: Counts by Report Type by SOC**

Report Type	SOC
	All (N)
DIR	Blood (174), Card (297), Cong (4), Ear (155), Endo (21), Eye (304), Gastr (905), Genrl (1315), Hepat (100), Immun (51), Infec (407), Inj&P (198), Inv (1034), Metab (316), Musc (607), Neopl (40), Nerv (1480), Preg (5), Psych (1583), Renal (242), Repr (135), Resp (538), Skin (466), SocCi (125), Surg (36), Vasc (237)
EXP	Blood (5810), Card (18140), Cong (1066), Ear (1537), Endo (763), Eye (4360), Gastr (23214), Genrl (22621), Hepat (4815), Immun (1232), Infec (14287), Inj&P (8018), Inv (33338), Metab (8872), Musc (13685), Neopl (2484), Nerv (23570), Preg (519), Psych (16524), Renal (6973), Repr (2091), Resp (16540), Skin (7735), SocCi (1333), Surg (2175), Vasc (7610)
PER	Blood (83), Card (134), Cong (4), Ear (103), Endo (14), Eye (190), Gastr (960), Genrl (1232), Hepat (39), Immun (28), Infec (334), Inj&P (258), Inv (660), Metab (208), Musc (629), Neopl (23), Nerv (961), Psych (1104), Renal (147), Repr (86), Resp (454), Skin (424), SocCi (53), Surg (24), Vasc (122)

**Route of Administrations [N,%] – Summary: Counts and Percentages by Route of Administration**



Route of Administration	Drugs	
	N	Col %
AURICULAR (OTIC)	13	0.08
BUCCAL	3	0.02
CUTANEOUS	2	0.01
DENTAL	1	0.01
ENDOSINUSIAL	1	0.01
EPIDURAL	11	0.07
INTRA-ARTERIAL	10	0.06
INTRA-ARTICULAR	1	0.01
INTRA-UTERINE	14	0.09
INTRACEREBRAL	1	0.01
INTRADERMAL	4	0.03
INTRAMUSCULAR	214	1.35
INTRAPERITONEAL	7	0.04
INTRATHECAL	23	0.15
INTRATHORACIC	3	0.02

**Sample Counts – Compares a variety of report counts**

SOC	ISR_demog		ISR_reac		PT		PT
	N	(U)	N	(U)	N	(U)	ALL (N)
Card	4875	4875	18571	4875	18571	218	[Truncated] AV dissociation (2), Accelerated idioventricular rhythm (1), Acquired cardiac septal defect (2), Acute coronary syndrome (93), Acute left ventricular failure (2), Acute myocardial infarction (338), Acute right ventricular failure (1), Agonal rhythm (1), Angina pectoris (464), Angina unstable (318), Aortic valve calcification (17), Aortic valve disease (34), Aortic valve disease mixed (3), Aortic valve incompetence (240), Aortic valve prolapse (2), Aortic valve sclerosis (83), Aortic valve stenosis (85), Arrhythmia (366), Arrhythmia neonatal (1), Arrhythmia supraventricular (38), Arteriosclerosis coronary artery (245), Arteriospasm coronary (20), Arteritis coronary (1), Atrial fibrillation (608), Atrial flutter (93), Atrial hypertrophy (15), Atrial septal defect acquired (2), Atrial tachycardia (44), Atrial thrombosis (8), Atrioventricular block (49), Atrioventricular block complete (53), Atrioventricular block first degree (120), Atrioventricular block second degree (25), Bifascicular block (6), Bradyarrhythmia (13), Bradycardia (415), Bradycardia foetal (2), Bradycardia neonatal (5), Bundle branch block (37), Bundle branch block bilateral (4), Bundle branch block left (136), Bundle branch block right (159), Cardiac amyloidosis (3), Cardiac aneurysm (23), Cardiac arrest (425), Cardiac arrest neonatal (3), Cardiac asthma (1), Cardiac discomfort (1), Cardiac disorder (475), Cardiac failure (301), Cardiac failure acute (18), Cardiac failure chronic (11), Cardiac failure congestive (956), Cardiac failure high output (4), Cardiac fibrillation (7), Cardiac flutter (30), Cardiac hypertrophy (9), Cardiac perforation (1), Cardiac pseudoaneurysm (1), Cardiac sarcoidosis (1), Cardiac tamponade (28), Cardiac valve disease (141), Cardiac valve vegetation (9), Cardiac ventricular disorder (6), Cardio-respiratory arrest (245), Cardio-respiratory arrest neonatal (3), Cardio-respiratory distress (2), Cardiogenic shock (85), Cardiomegaly (721), Cardiomyopathy (231), Cardiomyopathy acute (1), Cardiomyopathy alcoholic (2), Cardiopulmonary failure (24), Cardiotoxicity (11), Cardiovascular deconditioning (2), Cardiovascular disorder (205), Carditis (1), Chordae tendinae rupture (2), Conduction disorder (25), Congestive cardiomyopathy (68), Cor pulmonale (27), Cor pulmonale acute (2), Cor pulmonale chronic (1), Coronary artery aneurysm (2), Coronary artery dilatation (1), Coronary artery disease (945), Coronary artery dissection (2), Coronary artery embolism (4), Coronary artery insufficiency (8), Coronary artery occlusion (214), Coronary artery perforation (1), Coronary artery restenosis (47), Coronary artery stenosis (209), Coronary artery thrombosis (22), Coronary ostial stenosis (5), Cyanosis (208), Diabetic cardiomyopathy (1), Diastolic dysfunction (109), Dilatation atrial (214), Dilatation ventricular (119), Dissecting coronary artery aneurysm (1), Dressler's syndrome (8), Electromechanical dissociation (40), Endocardial disease (4), Endocardial fibrosis (3), Endocarditis noninfective (3), Eosinophilic myocarditis (5), Extrasystoles (85), Foetal arrhythmia (2), Foetal heart rate deceleration (5), Foetal heart rate disorder (3), Heart valve calcification (1), Heart valve incompetence (16), Heart valve stenosis (1), Hepatojugular reflux (6), Hyperdynamic precordium (3), Hyperkinetic heart syndrome (5), Hypertensive cardiomegaly (3), Hypertensive cardiomyopathy (11), Hypertensive heart disease (90), Hypertrophic cardiomyopathy (11), Intracardiac thrombus (35), Ischaemic cardiomyopathy (125), Left atrial dilatation (1), Left ventricular failure (68), Left ventricular hypertrophy (5), Long QT syndrome (3), Low cardiac output syndrome (5), Malignant hypertensive heart disease (1), Microvascular angina (1), Mitral valve calcification (54), Mitral valve disease (68), Mitral valve disease mixed (3), Mitral valve incompetence (679), Mitral valve prolapse (87), Mitral valve sclerosis (14), Mitral valve stenosis (22), Myocardial calcificati...

**SOC [%] – Summary: Percentages by SOC**

SOC	Preferred Terms
	Col %
Blood	2.26
Card	6.92
Cong	0.4
Ear	0.67
Endo	0.3
Eye	1.81
Gastr	9.35
Genrl	9.38
Hepat	1.85
Immun	0.49
Infec	5.6
Inj&P	3.16
Inv	13.05

### SOC/HLGT/HLT [N] – Summary: Counts by SOC, HLGT and HLT

SOC	HLGT	HLT	Reports	Preferred Terms
			N	N
Blood	Anaemias nonhaemolytic and marrow depression	Anaemias NEC	<a href="#">2</a>	<a href="#">2</a>
Blood	Anaemias nonhaemolytic and marrow depression	Marrow depression and hypoplastic anaemias	<a href="#">1</a>	<a href="#">1</a>
Blood	Coagulopathies and bleeding diatheses (excl thrombocytopenic)	Coagulopathies	<a href="#">1</a>	<a href="#">1</a>
Blood	Haemolyses and related conditions	Anaemias haemolytic NEC	<a href="#">1</a>	<a href="#">1</a>
Blood	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	<a href="#">1</a>	<a href="#">1</a>
Card	Cardiac arrhythmias	Rate and rhythm disorders NEC	<a href="#">3</a>	<a href="#">4</a>

### Source [N, %] – Summary: Counts and Percentages by Source

Source	Reports	
	N	Col %
Company Representative	<a href="#">269</a>	2.22
Consumer	<a href="#">1703</a>	14.07
Distributor	<a href="#">42</a>	0.35
E-Submission	<a href="#">3207</a>	26.5
Foreign	<a href="#">996</a>	8.23
Health Professional	<a href="#">3479</a>	28.74
Literature	<a href="#">485</a>	4.01
Other	<a href="#">1209</a>	9.99
Study	<a href="#">710</a>	5.87
User Facility	<a href="#">3</a>	0.02
All	<a href="#">12103</a>	100

**Sources and Outcomes – Detail: ISR, Gender, Age (years), Source(s), Serious? and Outcome(s)**

ISR	Gender	Age (yrs)	Source(s)	Serious?	Outcome(s)
			All		All
<a href="#">1000000728</a>	F	58	Health Professional, Company Representative	YES	Died, Hospitalized, Life-threatening
<a href="#">1000000786</a>	F		Other	YES	Other
<a href="#">1000000790</a>	F		Other	YES	Other
<a href="#">1000001289</a>	F		Other	YES	Other
<a href="#">1000001339</a>	F		Other	YES	Other
<a href="#">1000001393</a>	F		Other	YES	Other
<a href="#">1000001714</a>	F	69	Study	YES	Died, Life-threatening, Hospitalized

**Year: Report Type/Seriousness [N] – Summary: Counts by Year by Report Type/Seriousness**

FDA Year	Serious?					
	No			Yes		
	Report Type			Report Type		
	Direct	Expedited	Periodic	Direct	Expedited	Periodic
	Reports	Reports	Reports	Reports	Reports	Reports
1997	0	0	0	0	<a href="#">27</a>	<a href="#">2</a>
1998	0	<a href="#">1</a>	0	<a href="#">9</a>	<a href="#">245</a>	<a href="#">6</a>
1999	<a href="#">1</a>	0	<a href="#">2</a>	<a href="#">2</a>	<a href="#">63</a>	<a href="#">1</a>
2000	0	<a href="#">3</a>	0	<a href="#">12</a>	<a href="#">609</a>	<a href="#">3</a>
2001	<a href="#">2</a>	<a href="#">2</a>	<a href="#">2</a>	<a href="#">19</a>	<a href="#">349</a>	<a href="#">5</a>
2002	0	<a href="#">2</a>	<a href="#">2</a>	<a href="#">28</a>	<a href="#">430</a>	<a href="#">10</a>
2003	<a href="#">1</a>	0	<a href="#">2</a>	<a href="#">44</a>	<a href="#">630</a>	<a href="#">23</a>
2004	0	<a href="#">4</a>	<a href="#">11</a>	<a href="#">53</a>	<a href="#">866</a>	<a href="#">39</a>
2005	0	<a href="#">1</a>	<a href="#">5</a>	<a href="#">63</a>	<a href="#">1464</a>	<a href="#">85</a>
2006	<a href="#">1</a>	<a href="#">4</a>	<a href="#">10</a>	<a href="#">51</a>	<a href="#">1947</a>	<a href="#">31</a>
2007	<a href="#">3</a>	<a href="#">1</a>	<a href="#">9</a>	<a href="#">46</a>	<a href="#">685</a>	<a href="#">16</a>

## Creating interactive reports

### About interactive reports

The application provides three types of interactive reports:

- **Query-based**—Reports are based on a query for which you can provide values. The application runs the report against the cases found by the query. You can use the query values as breakdown details in the report.
- **Summary of all cases**—Reports include all cases and generates a report output that can be used as the source data for the tables and graphs in drug profiles.
- **Customer-specific**—Reports provided by Oracle.

### Interactive report definitions

An interactive report definition specifies:

- Variables from the source data to appear as columns in the report. The definition also specifies how data is broken down based on other variables.
- A variable or combination of variables that provide unique keys for the report. The report has a row for each unique key value, or key value combination.
- How to aggregate multiple values in individual cells.
- The subset of rows to appear in the report, based on conditions specified by a SQL WHERE clause.
- Queries for query-based interactive reports.

### Valid report definitions

The names of valid report definitions appear in boldface type. A report definition is valid if it includes at least one row variable and one column variable, and no error messages appear for report variables. For a query-based report, a query must be part of the report definition. For an all cases summary report, the definition must conform to certain [criteria](#).

## Creating or editing an interactive report definition

1. Click the **Reports** tab.


The Report Definitions page appears.

2. Click **Interactive Reports**.

The [Interactive Reports page](#) appears.

3. To create an interactive report definition, click **Create Definition**.

or

To edit an interactive report definition, click the row menu () for the interactive report definition, and then click **Edit**. Alternatively, click **Edit Definition** on the [Display Report page](#).

The Create Definition page appears. Continue with Step 9.

---

**Note:** If you are a superuser, the Edit option is available for customer-specific reports provided by Oracle; however, any changes to these reports should be made by Oracle.

---

4. From the **Configuration** drop-down list, [select a data configuration](#) to indicate the source data on which to base the report. You can click **Browse** to select from a descriptive list of data configurations.
5. In the **Name** field, type a report name. The name does not need to be unique, although Oracle recommends that you provide a unique and meaningful name.
6. In the **Description** field, type a description that differentiates the report definition from others on the Interactive Report Definitions page.
7. Assign the report definition to a [project](#).
  - To assign the report definition to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.
  - To create a new project and assign the report definition to it, click **Add to a new project named** and enter a project name.
8. From the **Type** drop-down list, select one of the following options for the report type (if you are a superuser). The types always include Query-based and Summary of all Cases. Customer-specific reports also appear in the list.
  - **Query-based**—Create an interactive report definition that includes a query. Users can provide values to the query when the report is run.

- **Summary of all Cases**—Create a report output that includes all cases and can be used by a drug profile configuration. Reports that can be added as charts on the Drugs tab are based on this type of report.

---

**Note:** Once you leave the Create Definition page, you cannot change the report type.

---

9. Click **Save**.

For a query-based interactive report, the Edit Report Query page appears. You must [define a query](#). (If you are editing the report definition, click the **Query** option.)

or

For a Summary of all Cases interactive report, the Edit Report Columns page appears. If you are defining an all cases summary report, the report definition is not valid until certain requirements have been met. See [About All Cases Summary reports](#).

The Edit Report Columns page appears. From this page, you can edit the report columns, the [report attributes](#), and the [report descriptors](#).

The application also saves the interactive report definition and lists it on the Interactive Report Definitions page filling in the Created By and Created columns, although you cannot yet run it.

10. [Edit the report columns](#). For more information, see [Editing report columns](#).

When defining breakdown details for a report variable that you included in the query for the report, you can specify that the breakdown details will be the values provided for the query variable when the report is run. See [Defining breakdown by query values](#).

11. Optionally, [edit the report attributes](#). For more information, see [Editing report attributes](#).

12. Optionally, [edit the report descriptors](#). For more information, see [Editing report descriptors](#).

13. If you have made changes to an interactive report definition since the last time it was saved, save the interactive report definition without running it by clicking **Save**. If you are working on a complex report definition, click **Save** periodically.

---

**Note:** If you edit a report definition that you did not create, the **Save** button does not appear.

---

or

To save the interactive report definition with a different name, without running it, click **Save As**. Provide a [name for the new report definition](#).

or

Save the interactive report definition and run it. For a valid report definition, click **Save & Run**. A report is considered valid if it includes at least one row variable and one column variable, and there are no error messages for the report definition. For a query-based interactive report, a query must be part of the report definition. For an all cases summary interactive report, the definition must conform to certain [criteria](#).

14. To run the report definition, for a valid report definition, click **Run**. A report is considered valid if it includes at least one row variable and one column variable, and there are no error messages for the report definition. For a query-based interactive report, a query must be part of the report definition. For an all cases summary interactive report, the definition must conform to certain [criteria](#).
  - If you run the report, you must [select a data configuration](#) to indicate the source data against which the report will be run.
  - To run a query-based report, you must also [run the query](#). The report will be run against cases that meet the query criteria.
  - To run an all cases summary report, you must [specify report parameters](#).

Each time you save the report definition, the application fills in the Modified and Modified By columns on the Interactive Reports page.



## Interactive Reports page

On the Interactive Reports page, you can view interactive report definitions that you created or were published to you for select projects and data configurations. This page also lists all published and unpublished interactive report definitions created by users in your login group, if you have the Administer Users permission.

### General activities

The following links appear at the top of the page and affect the entire page:

- [Create Definition](#)
- [Create Definition from XML](#)
- [Columns](#)
- [Print](#)
- [Download](#)

---

**Note:** The **Create Definition from XML** link is only available for users with the superuser permission.

---

The following filters appear at the top of the page and affect the report definition list:

- [Project](#)
- [Configuration](#)

### Row-specific activities

The following menu options are available from the row menu, located in the leftmost column of the table, and affect an individual row in the table:

- Run
- [Create Output](#)
- [Create Definition File](#)
- [Edit](#)
- [Rename](#)
- [Copy](#)
- [Publish](#)
- [Delete](#)

#### Notes:

- The **Create Output** row menu appears for a valid all cases summary report and allows you to save its output.
- The **Copy** row menu only appears if you have the Create Report permission. This option is available for report definitions created by other users. You cannot edit such report definitions, but you can copy and modify them.


**Field descriptions—Interactive Reports page**

<b>Field</b>	<b>Description</b>
Definition	Name of the interactive report definition.
Description	Description of the interactive report definition.
Project	Name of the project that the interactive report definition is associated.
Configuration	Name of the data configuration that the interactive report definition is based on.
Created By	Name of the user who created the interactive report definition.
Created	Date and time when the interactive report definition was created. The Created By and Created fields are filled in when the Create Definition page is completed.
Modified	Date and time the interactive report definition was last modified.
Modified By	Name of the user who last modified the interactive report definition. The Modified and Modified By fields are filled in each time the report definition is saved.
ID	Identifier that was assigned automatically to the interactive report definition when it was saved. Each report definition ID is unique across all report definitions and is not reused if the report definition is deleted.
Category	Category of the report. The category is intended only for informational purposes.
Type	Type of report. For example, Query-based or Summary of all Cases.

## Deleting an interactive report definition

1. Click the Reports tab, and click **Interactive Reports**.

The Interactive Reports page appears.

2. Select the row menu () , and select **Delete**.

A message box appears to confirm the deletion.

3. Click **OK**.

The Interactive Reports page refreshes with the updated list. Any report that was created using the deleted report definition remains accessible on the Report Outputs page.

## Viewing a report definition

1. Click the Reports tab, and then click **Interactive Reports**.

The Interactive Reports page appears.

---

**Note:** You do not need to select a case series to work with these reports. If a case series is selected, it is not used for the interactive report.

---

2. Select the row menu () , and click any of the [actions](#).

To view an interactive report, click **Run**.

---

**Note:** For a query-based report or an all cases summary report, you must [select a data configuration](#) from a list of [compatible data configurations](#).

---

3. For a query-based report, you must also run the query.
4. For an all cases summary report, you must [specify report parameters](#).

## About all cases summary reports

An all cases summary report runs on all cases in a specific data configuration. You can select report outputs from this report type in the Report Output field in a [drug profile configuration](#). You can also add a report chart to a drug profile layout for each breakdown variable in the report definition.

To create this type of report, you [create an interactive report](#), and then select the report type **Summary of all cases**. The report definition is not valid until all of the following criteria are true:

- There is only one row variable.
- The row variable is based on a [data configuration variable](#) with the variable type Drug and the variable subtype Generic, Ingredient, or Trade.  
To support reports for all three subtypes on the Drugs tab, you can create a different All Cases Summary report for each of the three subtypes.
- Breakdown variables are based on variables for which the Oracle data type of the underlying database column is VARCHAR2 or CHAR.
- The Every Distinct Value radio button is selected in breakdown details for the row variable.
- There is at least one column breakdown variable.
- Each column contains both a [breakdown variable](#) and an [analysis variable](#).

Oracle recommends that the breakdown variable and the analysis variable be from the same source table. You cannot use a continuous variable as a breakdown variable.

The breakdown details for each column breakdown variable are:

- The Every Distinct Value radio button is selected.
- The Include a category for NULL values check box is selected.
- The Include a category for ALL selected values is deselected.

The content detail for the analysis variable is specified as Count (Unique).

If the report does not meet all criteria, a message appears below the report, indicating that the report is not valid. The exception to this is that the check for the drug variable subtype is not performed until you run the report.

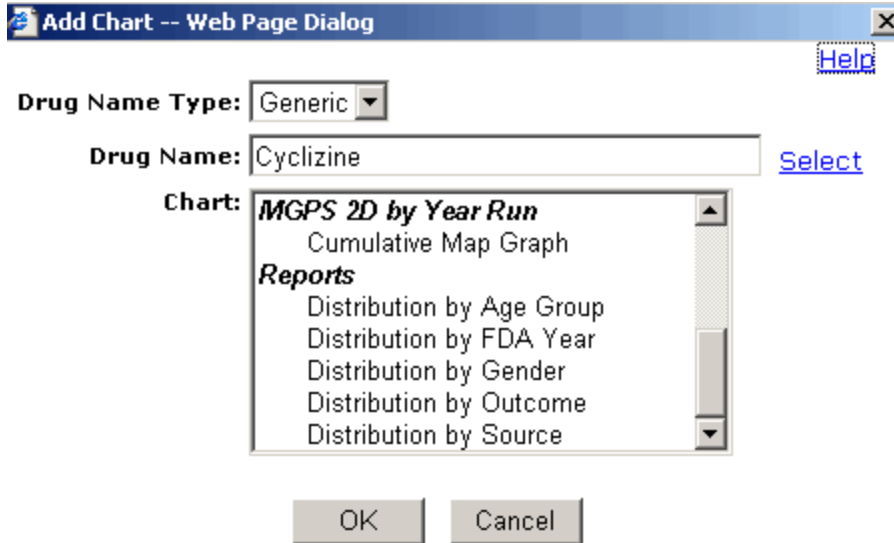
### Example

The following example shows a report definition for an All Cases Summary report:

	Gender	FDA Year	Outcome	Age Group	Source
	ISR_demog	ISR_demog	ISR_outcome	ISR_demog	ISR_report_source
<b>Generic_Name</b>	N (U)	N (U)	N (U)	N (U)	N (U)


Available report charts in a drug profile include Distribution of <variable-name>, where <variable-name> is the label of the breakdown variable from the report definition. The label may differ from the variable name.

Report output for this report definition makes the following report charts available to add to a drug profile layout:



## Creating an all cases summary report output

You can run an [all cases summary](#) report definition and save its output in a single step.

1. Click the **Reports** tab.  
The Report Definitions page appears.
2. Click **Interactive Reports**.  
The [Interactive Reports page](#) appears.
  - A. Click the row menu () for the all cases summary report definition, and then click **Create Output**.  
The Create Output page appears. The Create Output option is available only for All Cases Summary interactive reports.
3. From the **configuration** drop-down list, [select a configuration](#). The report runs against source data for the selected data configuration.  
When you save the report output, the application verifies that the selected data configuration has a Drug type variable with a subtype of Generic, Trade, or Ingredient.
4. In the **Name for Output** field, enter a name for the saved output. The name does not need to be unique, although Oracle recommends that you provide a unique and meaningful name.
5. In the **Output Description** field, enter a description of the saved output that differentiates the report output from entries on the Report Outputs page.
6. From the **Output Category** drop-down list, select **Ad Hoc** or **Standard**. The application uses the category for organizing reports and the category is not related to report availability. You can include a column showing report categories on the Report Outputs pages.
7. Assign the report output to a [project](#).
  - To assign the report output to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.
  - To create a new project and assign the report output to it, click **Add to a new project named** and enter a project name.
8. Click **Save**.

The application submits the report output to your [background processing job queue](#), and the Background Processing indicator appears next to the Preferences link.

## Defining a query for an interactive report definition

A query-based interactive report has a query associated with it. When the user runs the report, the user specifies values for the variables in the query. The application then runs the report against cases that meet the criteria of the query.

1. Click the **Reports** tab.  
The Report Definitions page appears.
2. Click **Interactive Reports**.  
The [Interactive Reports page](#) appears.
3. Click **Create Definition**.  
The Create Definition page appears.
4. From the **Configuration** drop-down list, [select a data configuration](#) to indicate the source data on which to base the report. You can click **Browse** to select from a descriptive list of data configurations.
5. In the **Name** field, type a report name. The name does not need to be unique, although Oracle recommends that you provide a unique and meaningful name.
6. In the **Description** field, type a description that differentiates the report definition from others on the Interactive Report Definitions page.
7. Assign the report definition to a [project](#).
  - To assign the report definition to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.
  - To create a new project and assign the report definition to it, click **Add to a new project named** and enter a project name.
8. Click **Save**.  
The Edit Report Query page appears.  
You can also display the page by clicking **Query** on other pages of the interactive report definition.
9. To create a new query using the Query Wizard, click **Create Using Query Wizard**.  
The [Define Query page](#) appears. For more information, see [Defining a query](#).  
or  
To create a query based on an existing query, click **Create from Existing Query**.



The [Select Query from Library page](#) appears. Subsequent changes to the query in the library do not affect the report. For more information, see [Defining a query](#).

The defined query appears on the Edit Report Query page in the **Query field**.

---

**Note:** If you saved the query to the library and then you edit from this page, your changes are not saved to the library. If the query includes a variable that you want to use as a breakdown variable in the report, remember to set up the breakdown details to use query values.

---

## Breakdown details

If you want user-specified values from a query to be used as breakdown details for a report column or row, you must do both of the following:

- Include the breakdown variable in the query.
- Specify **Query Values** for the variable's breakdown details.

If you set up a breakdown variable to use query values but you do not include the variable in the query that is part of the report definition, the application cannot determine the breakdown values. If a column or row variable has no breakdown values, the application drops it when running the report. If this results in a report without rows or columns, the report cannot be run.

If you include a breakdown variable in the query but do not set up the breakdown variable to use query values, the application uses any values that a user specifies for the query to select cases to include in the report, but does not use those values as breakdown details. For example, the query is for generic name and generic name is a breakdown variable with **Every Distinct Value** specified for breakdown details. If the user specifies DrugA as the query value, the report includes only cases with DrugA, and it includes a column for each value of generic name for those cases.

## Creating a query from an existing query

The Select Query from Library page appears if you choose to use an existing [query](#) when defining a custom term, database restriction, or query-based interactive report. The queries must have been created by you or published to you. (If you have the Administer Users permission, you can select from published or unpublished queries created by any user in your login group.)

Once you use an existing query for a custom term, database restriction, or query-based interactive report, subsequent changes to the query in the library do not affect the custom term, database restriction, or report.

1. Select **Create from Existing Query**.

The Select Query from Library dialog box appears.

2. From the **Project** drop-down list, select a specific [project](#), or select -- to include all projects.

3. From the **Configuration** drop-down list, [select the data configuration](#), or select -- to include all configurations. Available queries are those that are [compatible](#) with the data configuration for the data mining run (if you are creating a custom term or database restriction) or report definition (if you are creating a report).

4. From the **Origin** drop-down list, select one of the following values:

- **Query**—The query was created and saved from the Queries page.
- **Case Series**—The query was created and saved during the creation of query-based case series on the Case Series tab.
- **Custom Term**—The query was created and saved during the creation of a custom term for a data mining run.
- **Restriction**—The query was created and saved during the creation of a database restriction for a data mining run.
- **Interactive Report**—The query was created and saved during the creation of an interactive report.

5. Click the radio button of the row for the query that you want to select.

6. Click **Next**.

If you are defining a custom term or database restriction, the Refine Query page appears. Optionally, you can [refine the query](#). For more information, see [Refining a query](#).


## Running a query

When you run a query, the application retrieves a list of cases matching the query criteria.

Each time that you run a query, the application re-executes the query. Even if you do not change values for variables in the query, if the source data changed since the last time you ran the query, the query results can differ from when you last ran the query.

1. Click the **Queries** tab.

The Queries page appears. For more information, see [Queries page](#).

2. Click the row menu () for the query, and then click **Run**.

---

**Note:** When you run an [interactive report](#), you also run a query.

---

3. From the [Configuration](#) drop-down list, [select a data configuration](#) from a list of [compatible data configurations](#). This is the source data against which the query runs.

4. Click **Next**.

The Run Query page appears.

5. Specify values for query variables. For more information, see [Selecting query variables](#).

If the operators in the query are all AND, all OR, all INTERSECT, or all UNION, you do not need to specify values for every variable. If you do not specify a value for a variable and you do not check **Include Null values** for the variable, then the application ignores that variable. If all of the operators in the query are MINUS or if you use a mixture of different operators in the query, you must specify values for every variable.

---

**Note:** You can set up a query-based interactive report to use [query values](#) as breakdown details. If a column or row variable has no breakdown values because you do not supply query values when running the report, the application drops the column or row from the report. If the resulting report has no rows or no columns, you cannot run the report until you supply query values.

---

6. Click **Next**.

If you are running a query from the Queries tab, the query results appear. See [Viewing query results](#).

If you are running a query for an interactive report, the query generates a list of cases against which the report is run. See [Viewing a report](#).

## Creating a report definition file

If you are a superuser, you can create a report definition file from a valid All Cases Summary report.

1. Click the Reports tab, and click **Interactive Reports**.

The Interactive Reports page appears.

2. Select the row menu () , and click **Create Definition File**.

The Create Definition File page appears.

3. From the **Configuration** drop-down list, select a data configuration to indicate the source data on which to base the report. You can click **Browse** to select from a descriptive list of data configurations.

4. In the **Name for Output** field, type a report name.

5. In the **Output Description** field, type a description.

6. Assign the report definition to a project.

Only the **Add to existing project:** option should be used. If the selected project, based on its ID, exists on the instance in which the report is run, the report output is placed in that project. If the project doesn't exist on the instance in which the report is run, the output can go into the Unassigned project. The **Add to new project named:** has no affect.

7. Click **Save**.

The [Input File](#) page appears. The page displays the content that you can use in a report definition file.

## Input file

You can copy the content of the Input File page into a text file and save the file using the extension **.in**. You can then place the file in the input folder of the application server in order to be processed by the Empirica Signal application. The input folder is located in the path defined by `temp_dir` in `webvdme.properties`.

The input file (report definition file) contains the following information.

Line in the Report Definition File	Description
<code>#datetime</code>	Date and time of creation of the report definition file. The comments are preceded by #.
<code>ACTION=CREATE REPORT</code>	Represents the type of batch file. Reports appear as <code>CREATE REPORT</code> . Data mining runs appear as <code>CREATE RUN</code> .
<code>Description</code>	Description of the report definition used with Create Definition File.
<code>Name</code>	Name of the report definition used with Create Definition File.
<code>Owner</code>	Owner of the report definition used with Create Definition File.
<code>Project_id</code>	Project ID of the report definition used with Create Definition File. The Report Batch Runs page relies on the project ID.
<code>Type</code>	0
<code>Report.classname</code>	<code>com.lincolntechnologies.webvdme.reports.batch.RunAllCasesReportProc</code>
<code>Report.configuration</code>	Configuration on which the report runs. If the configuration does not exist when the batch report is run, an error message displays: <b>Configuration named '&lt;configuration name&gt;' does not exist</b>
<code>Report.name</code>	Name of the report definition used with Create Definition File. The same name will appear in the Definition column of Report Output.  <b>Note:</b> For consistency in report outputs that rely on a report definition coming from another instance, the <code>report.name</code> should match the value of <code>Name\="All Drug Summary Report"</code> in XML.
<code>Report.output_name</code>	Name entered on the Create Definition File page. This name is

	used as Output in the Report Output table.
<code>Report.output_description</code>	Description entered on the Create Definition File page. This description is used as Description in the Report Output table.
<code>Report.project_id</code>	ID of an existing project selected on the source server. It can be used as a filter on the Report Batch Runs page.  If the file is to be used on an instance other than the one on which it was created, it is unlikely that the ID is on the receiving server. Omit or assign 0.
<code>Report.reportid</code>	Report ID of the report definition used with Create Definition File. This line should be removed in order to force use of the XML referenced by <code>report.reportxml</code> , especially if the file is to be used on an instance other than the one on which it was created.
<code>Report.reportxml</code>	XML of the report definition used with Create Definition File.

The following additions can be made to the file.

<b>Line in the Report Definition File</b>	<b>Description</b>
<code>report.Project\ Name</code>	If the specified project name exists on the server on which report is ultimately run, the report output is placed in that project. Else, the report output is assigned to project with ID matching <code>report.project_id</code> .
<code>report.Alias\ Names</code>	Report Output Alias .If the Report Output Alias exists, it is updated with <code>Report.output_name</code> . If the Report Output Alias does not exist, it is created and assigned the specified value.

## Viewing report outputs

### Viewing existing report outputs

A report output is the result of applying a report definition to the cases in a selected case series or found by a query, and saving the result. A report output is static. If there is a change in a report definition or the set of cases against which the report was run to produce the output, you can run the report again and save another report output.

When you run a report, you can name and save the output. You can view the saved output without any need to rerun the report. Once report output is saved, it remains available until you explicitly delete it. Modification or deletion of the report definition, or of the case series or query on which the report was based, do not affect the saved report output.

For the selected project and data configuration, the Report Outputs page shows report outputs that you have created or that are published to you. If you have the Administer Users permission, the page also lists published and unpublished report outputs created by any users in your login group.

1. Click the **Reports** tab.  
The Report Definition page appears.
2. Click **Report Outputs**.  
The Report Outputs page appears.
3. From the **Project** drop-down list, select the [project](#) for which you want to view report outputs or -- to include all projects.
4. From the **Configuration** drop-down list, select the [data configuration](#) from which you want to view report outputs or -- to include all configurations.

The selected report outputs appear.

The application provides the following information about each report output:

Column	Description
Output	Name of the saved output.
Description	Description of the saved output, if provided.
Project	Name of the project associated with the report output.
Configuration	Name of the data configuration used by the case series or query to run the report definition.
Case Series	Applies to non-interactive reports. Name of the case series for which the report was run.

Created By	Name of the user who saved the report output.
Created	Date and time when the report output was saved.
Status	The <a href="#">current status</a> of the <a href="#">background processing job</a> .
As Of	As Of date of the case series or query for which the report definition was run. Appears only if the data configuration supports <a href="#">timestamp data</a> .  For output from an interactive report: As Of date selected when the report was run.
Category	Category of the report. The category is for informational purposes.
Definition	Name of the report definition.
ID	Identifier that was assigned automatically to the report output when the report output was saved. Each report output ID is unique and is not re-used if the report output is deleted.

## General activities

- For information about viewing, printing, or downloading tables or changing the way data displays in the table, see [About tables](#).
- To print, download, delete, or [publish](#) multiple report outputs, click **Select Rows** and check the report outputs on which you want to act.
- To check all rows, click **Select All** (or **Clear All** to uncheck all rows), then click the action that you want to perform on the selected rows.

## Action menu options

If you click  for a report output, you can do the following:

- To view the report output, click **View**.
- To rename the report output that you created, click **Rename**.

---

**Note:** When you rename a report output that is the target of an alias, the application updates the name of the alias target

---

- To cancel a Running or In Queue report output background processing job, click **Cancel**.  
The Cancel option is available only when a background processing job exists for the report output.
- To publish a report output that you created, click **Publish**.
- To delete a report output that you created, click Delete and, at the prompt asking if you want to delete the report output, click **OK**.

Before deleting a report output, make sure that it is not referenced by any drug profile configurations, because the application will remove these references.




---

**Note:** When you delete a report output that is associated with an alias, the target status of the alias becomes Broken.

---

## Creating a report output

You can run a report definition and save its output in a single step.

1. On the [Report Definitions page](#), click **Browse**.  
The Select Case Series page appears.
2. [Select a case series](#), and then click **OK**.  
The Report Definitions page re-appears.
3. Locate the report definition for which you want to create output.
4. Click the row menu () for the report definition, and then click **Create Output**.  
The Create Output page appears.
5. In the **Name for Output** field, type a name for the saved output. The name does not need to be unique, although Oracle recommends that you provide a unique and meaningful name.
6. In the **Output Description** field, enter a description of the saved output that differentiates the report output from entries on the Report Outputs page.
7. From the **Output Category** drop-down list, select **Ad Hoc** or **Standard**. The application uses the category for organizing reports and the category is not related to report availability. You can include a column showing report categories on the Report Definitions and Report Outputs pages.
8. Assign the report output to a [project](#).
  - To assign the report output to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.
  - To create a new project and assign the report output to it, click **Add to a new project named** and enter a project name.
9. Click **Save**.  
The Empirica Signal application submits the report output to your [background processing job queue](#), and the Background Processing indicator appears next to the **Preferences** link.

---

**Note:** The Background Processing indicator may not appear if you create a report output from a small data set that processes quickly.

---

## Saving a report output

If you are displaying a report that you ran from the [Report Definitions page](#), you have the option to save the output so that it can be viewed later without regenerating the report.


1. On the [Display Report page](#), click **Save Output**.  
The Save Output page appears.
2. In the **Name for Output** field, type a name for the saved report. The name does not need to be unique, although Oracle recommends that you provide a unique and meaningful name.
3. In the **Output Description** field, enter a description of the saved output that differentiates the report output from entries on the Report Outputs page.
4. From the **Output Category** drop-down list, select **Ad Hoc** or **Standard**. The application uses the category for organizing reports and the category is not related to report availability. You can include a column showing report categories on the Report Definitions and Report Outputs pages.
5. Assign the report output to a [project](#).
  - To assign the report output to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.
  - To create a new project and assign the report output to it, click **Add to a new project named** and enter a project name.
6. Click **Save**.  
The application saves the report output. Modification or deletion of the report definition does not affect the saved report output.

---

**Note:** The current sort order of a report is not saved as part of the report output.

---

## Working with a report output

1. Click the **Reports** tab.  
The Report Definition page appears.
2. Click **Report Outputs**.  
The Report Outputs page appears.
3. From the **Project** drop-down list, select the [project](#) for which you want to view report outputs or -- to include all projects.
4. From the **Configuration** drop-down list, select the [data configuration](#) from which you want to view report outputs or -- to include all configurations.  
The selected report outputs appear.
5. Select the row menu () for a report output, and click **View**.  
The Display Output page appears.

If the report includes an underlined count (N) of cases, the count is a link that you can click to display a menu from which you can [drill down](#). If specific case IDs appear underlined in the report, you can click a case ID to [view case details](#).



## Working with report data

- To [choose a graph](#) to show data in the report, click **Choose Graph**.
- To [save the report output as an attachment to a topic](#), click **Save to Topic** (available if the topics feature has been set up).
- To [print the table](#) (that is, the report), click **Print**.
- To [download report data](#), click **Download**. The column names will be created from the labels in the report definition, followed by the breakdown specifications.
- To show descriptive information below the report, click **Show Notes**.

## Managing report rows

To specify how many rows should display at a time, enter a number in the **Rows per Page** field and press the **Enter** key. You can display up to 999 rows on each page.



To go to another page, you can do the following:



- To view the next page, click .
- To view the previous page, click .
- To view the specific page, enter a number in the **Page** field and press the **Enter** key.

- To find specific text on a page, you can select **Find** on the browser's (Internet Explorer's) **Edit** menu. For efficiency, you might want to set the Rows per Page to a large number before using the **Find** feature.

### Sorting the report output

You can sort a report output by up to three columns. The current sort order appears above the report output. You can sort a column as follows:

- To sort in ascending order, click .
- To sort in descending order, click .


When you click  or  to sort a column, that column is the primary sort order. The previous primary sort order (if any) becomes the secondary sort order. The previous secondary sort order (if any) becomes the tertiary sort order.

---

**Note:** In displayed report outputs, sorting is case-insensitive.

---

## Renaming a report output

1. Go to the Reports tab and click **Report Outputs**.
2. On the Report Outputs page, click the row menu () for the report, and then click **Rename**.  
The Rename Output page appears.
3. Modify the report name, description, category, or project. For more information, see [Saving report output](#).
4. Click **Save**.

The following information also appears but you cannot modify it:

<b>Column</b>	<b>Description</b>
Configuration	Name of the data configuration for which the report definition was run.
Case Series	Name of the case series for which the (non-interactive) report was run.
Report Definition	Name of the report definition that was run to create the output.

## Viewing report graphs

### Working with report graphs

1. On the **Display Report** or the **Display Output** page, click **Choose Graph**.  
The Choose Graph page appears. Only those graph types that are appropriate for the report data appear.
2. Click the graph type.
  - For information about aggregate bar graphs, see [About aggregate bar graphs](#).
  - For information about detail bar graphs, see [About detail bar graphs](#).
  - For information about box plots, see [About box plots](#).
  - For information about scatter plots, see [About scatter plots](#).

The options page for the selected graph type appears.
3. Specify the options for the selected graph type.
  - For information about aggregate bar graphs, see [Viewing an aggregate bar graph](#).
  - For information about detail bar graphs, see [Viewing a detail bar graph](#).
  - For information about box plots, see [Viewing a box plot](#).
  - For information about scatter plots, see [Viewing a scatter plot](#).
4. Click **Display**.  
The selected graph appears.

#### To print a graph:

1. Click **Print**.  
The Internet Explorer Print dialog box appears.
2. Select print options. For more information, see [Prerequisites and usage notes](#).
3. Click **Print**.

#### To save the graph as an attachment to a topic:

- Click **Save to Topic**. The graph is attached as a PDF file.

---

**Note:** This option is available only if the Topics feature has been set up.

---

#### To copy a graph:

1. At the bottom of the graph, click **Copy to Clipboard**.

2. Open the document to which you want to add the graph(s), and **Paste** the graph into that document.



## Report graph types

When displaying a report or report output, you have the option to view a graphical representation of the report data. On the Display Report or the Display Output page, when you click **Choose Graph**, the Choose Graph page appears. Different graphs are available depending on the types of columns in the report, as follows:

Graph Type	Report Variables
<a href="#">Aggregate bar graph</a>	All column variables or all column variables except one are numeric. The case ID does not need to be in the report. Link name: Bar graph (where rows are aggregate values).
<a href="#">Detail bar graph</a>	The row variable in the report is the case ID. Link name: Bar graph (where rows are detail records).
<a href="#">Box plot</a>	The row variable in the report is the case ID. At least one column variable is numeric. Link name: Box plot (where rows are detail records).
<a href="#">Scatter Plot</a>	The row variable in the report is the case ID. At least two column variables are numeric. Link name: Scatter plot (where rows are detail records).

**Note:** A numeric variable is one for which source data is numeric or a numeric value such as count or percentage is specified as content detail.

The [graph key](#) and color palette that you set for graphs based on data mining results does not affect the report graphs. The report graphs appear in color unless you choose the display option, **Use gray-scale instead of colors**.

## Graph display options

The following display options are available for most report-based graphs:

Option	Check to
Use gray-scale instead of colors	Use shades of gray instead of colors in the graph.
Popup	Display each graph in an individual window. If you have popup blocking software installed on your PC, it may prevent these windows from opening. You may want to disable your popup blocking software.
Key	Display a color key below the graph to show which value each graph element (such as a bar or region of the graph) represents.
Notes	Display notes about the graph. The notes are the same as for the displayed report.
Links	<p>Show the following:</p> <ul style="list-style-type: none"> <li>• Information about what a graph component (such as a bar, cell, or region) represents, or statistics for the component, that appear when you point to that component.</li> <li>• A menu that allows you to <a href="#">drill down</a> when you click a graph component.</li> <li>• Print and Copy to Clipboard links.</li> <li>• A Save to Topic link (if <a href="#">Topics</a> has been configured).</li> </ul>

## Aggregate bar graphs

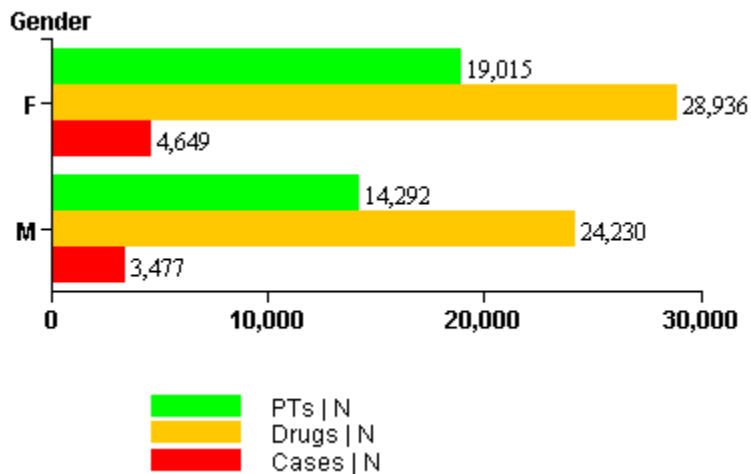
### About aggregate bar graphs

In an aggregate bar graph, the row variable of the report appears on the y-axis. Each numeric column variable in the report appears on the x-axis. A key appears below the graph describing each bar.

For example, a report includes counts of PTs, drugs, and cases for each gender:

Gender	PTs	Drugs	Cases
	N	N	N
F	19015	28936	<a href="#">4649</a>
M	14292	24230	<a href="#">3477</a>

Depending on the [display options](#) that you specify, the graph might look like this:



## Viewing an aggregate bar graph

For an overview of aggregate bar graphs, see [About aggregate bar graphs](#).

1. On the [Choose Graph page](#), select **Bar graph (where rows are aggregate values)**.

The Aggregate Bar Graph page appears.

2. Specify the following display options:

Option	Description	Notes
Labels X and Y	Label the x-axis and y-axis to clarify what is represented by the axes.	Required.
Show counts at the ends of bars	Show case counts at the end of bars in the graph.	If the report shows numeric values that are not case counts and you check this option, the values are shown instead of counts.
Transpose rows and columns	Switch the roles of the rows and columns in displaying the graph.	
Use gray-scale instead of colors	Use shades of gray instead of colors in the graph.	
Popup	Display each graph in an individual window. If you have popup blocking software installed on your PC, it may prevent these windows from opening. You may want to disable your popup blocking software. For details, see <a href="#">Graph display options</a> .	

3. Click **Display**.

The application creates the graph using the specified display options. These options apply only to this graph.

4. To see the exact values represented by a bar in the graph, point to the bar.

If you click a bar, you can [drill down](#) to cases for the bar. If you are displaying multiple graphs on the same page, do not click any graph until all the graphs appear.

For information about copying, printing, or saving a graph as an attachment to a topic, see [Working with report graphs](#).

## Detail bar graphs

### About detail bar graphs

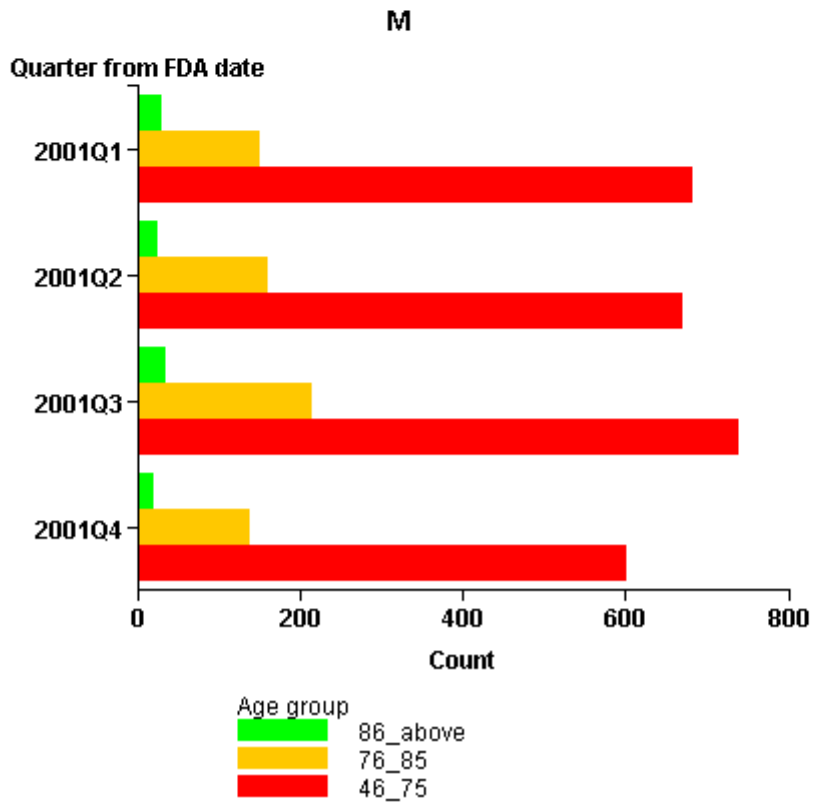
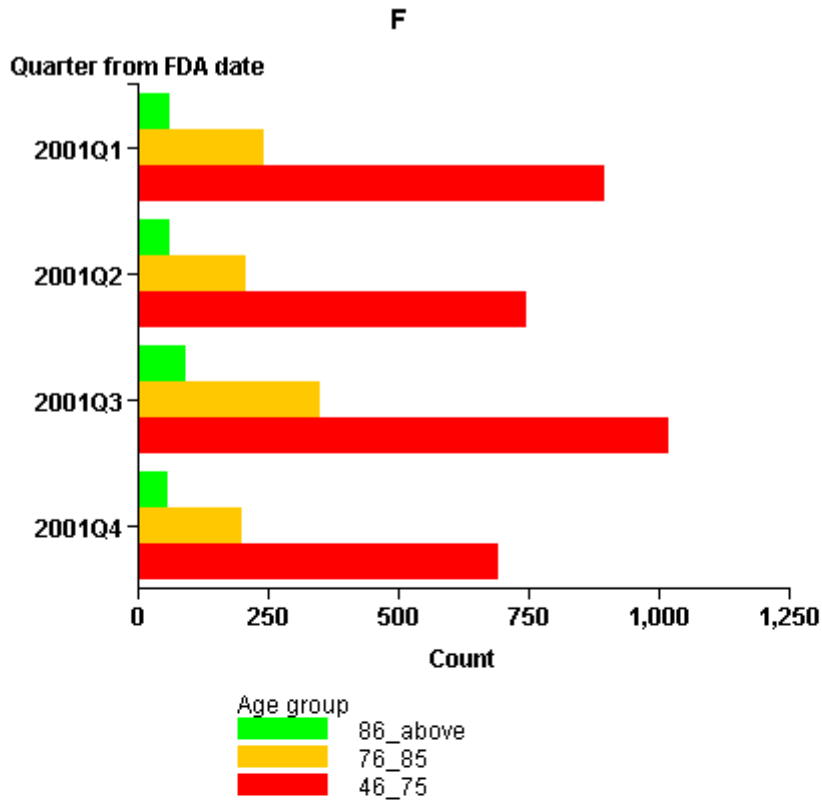
With a detail bar graph, you determine the row variables and column variables of the report that appear on the y-axis, and the subject counts that appear on the x-axis. There is a subject count for each primary variable that you select as a display option. You can break down the case counts for the primary variable by specifying a secondary variable. If you specify a secondary variable, a graph key indicates the meaning of each bar.

You can also create multiple graphs, one for each value of a row or column variable that you specify as a subset variable.

For example, a report shows gender, age group, and quarter from FDA date for each case ID:

Case ID	Gender	Age group	Quarter from FDA date
<a href="#">3639704</a>	M	46_75	2001Q1
<a href="#">3640323</a>	M	46_75	2001Q1
<a href="#">3640348</a>	F	46_75	2001Q1
<a href="#">3640453</a>	M	46_75	2001Q1
<a href="#">3640497</a>	M	46_75	2001Q1
<a href="#">3640690</a>	M	46_75	2001Q1

Depending on the [display options](#) that you specify, the graph might look like this, where **Gender** is the subset variable, **Quarter from FDA date** is the primary variable, and **Age Group** is the secondary variable:







## Viewing a detail bar graph

For an overview of detail bar graphs, see [About detail bar graphs](#).

1. On the [Choose Graph page](#), select **Bar graph (where rows are detail records)**.  
The Detail Bar Graph page appears.
2. From the **Subset Variable (for multiple graphs)** drop-down list, select a subset variable. There creates one graph for each value of the selected variable.
3. From the **Primary Variable (bar groups)** drop-down list, select a primary variable to appear on the x-axis.
4. From the **Secondary Variable (bars within groups)** drop-down list, select a secondary variable (optional). Each bar in the graph represents a value of the secondary variable, as identified by the color key below the graph.
5. Specify the following display options:

Option	Description	Notes
Labels X and Y	Label the x-axis and y-axis to clarify what is represented by the axes.	Required.
Show counts at the ends of bars	Show case counts at the end of bars in the graph.	
Use gray-scale instead of colors	Use shades of gray instead of colors in the graph.	
Popup	Display each graph in an individual window. If you have popup blocking software installed on your PC, it may prevent these windows from opening. You may want to disable your popup blocking software. For details, see <a href="#">Graph display options</a> .	

6. Click **Display**.  
The application creates the graph using the specified display options. These options apply only to this graph.
7. To see the exact values represented by a bar in the graph, point to the bar.  
If you click a bar, you can [drill down](#) to cases for the bar. If you are displaying multiple graphs on the same page, do not click any graph until all the graphs appear.  
For information about copying, printing, or saving a graph as an attachment to a topic, see [Working with report graphs](#).

## Box plot graphs

### About box plots

A box plot (also known as a box-and-whisker plot) is the plotting of data points against horizontal and vertical axes to show the distribution of a continuous variable. In a box plot:

- The box represents the middle 50% or so of the numeric values.
- A horizontal line within the rectangle represents the median of all values (specifically, the value that is exactly in the middle of all values).
- The top end of the box represents the upper quartile (specifically, the median of the ordered set of values that is greater than the overall median).
- The bottom end of the box represents the lower quartile (specifically, the median of the ordered set of values that is less than the overall median).

The interquartile range, which is the difference between the upper quartile and the lower quartile, is a measure of the spread of the distribution. The relative distances of the upper and lower quartiles from the median describe the shape of the distribution of data.

In the box plot:

- The whisker above the box plot extends from the upper quartile to the highest actual value that is within the (75th percentile + 1.5 \* (interquartile range)).
- The whisker below the box plot extends from the lower quartile to the lowest actual value that is within the (25th percentile - 1.5 \* (interquartile range)).
- Outliers are plotted as individual points in the graph. An outlier is considered to be a value that falls outside of the upper or lower whisker.

---

**Note:** Points in a box plot are jittered (displayed at small random offsets from the center line). This ensures that if two records have the same value, a point is likely to be displayed for each of them.

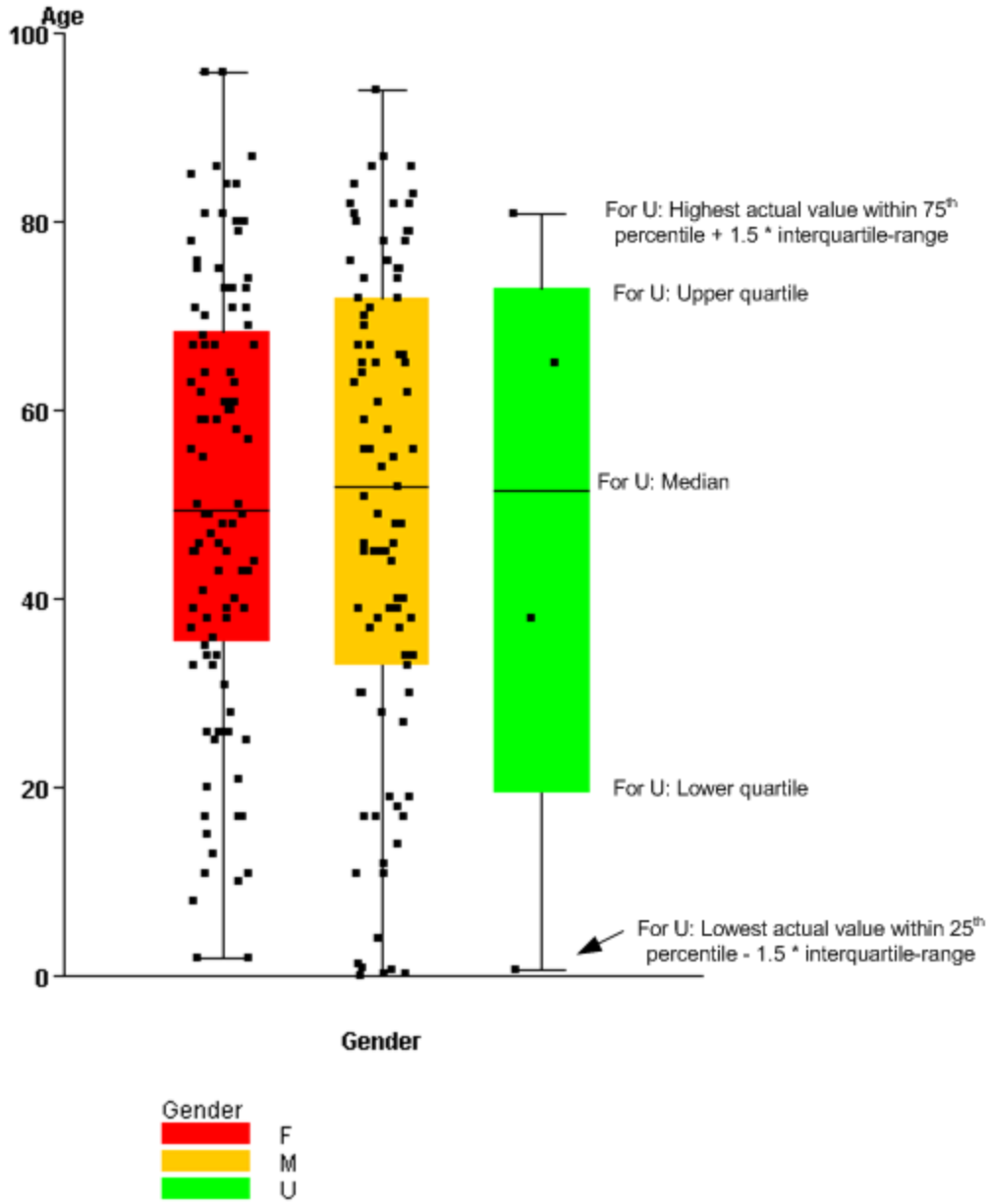
---

Several box plots might be shown in a single graph if you select a secondary variable. If so, a key appears below the box plot to relate the individual box plots to the values of the secondary variable.

For example, a report shows age and gender for each case ID:

Case ID	Age	Gender
<a href="#">3015459</a>	21	F
<a href="#">3017292</a>	56	M
<a href="#">3017527</a>	34	M
<a href="#">3017866</a>	64	F
<a href="#">3017945</a>	80	M

Depending on the [display options](#) that you specify, the graph might look like this:



## Viewing a box plot

For an overview of box plots, see [About box plots](#).

1. On the [Choose Graph page](#), select **Box plot (where rows are detail records)**.  
The Box Plot page appears.
2. From the **Subset Variable (for multiple graphs)** drop-down list, select a subset variable. The application creates one graph for each value of the selected variable.
3. From the **Primary Variable (defines individual boxplots)** drop-down list, select a primary variable from a list of numeric variables in the report definition. Each point in the box plot represents a value of the primary variable.
4. From the **Secondary Variable (defined boxplot groups)** drop-down list, select a secondary variable (optional). Each box represents a value of the secondary variable, as identified by the color key below the graph.
5. Specify the following display options:

Option	Description	Notes
Labels X and Y	Label the x-axis and y-axis to clarify what is represented by the axes.	Required.
Show all points as overlay	Show all points on the box plot. If cleared, only points outside the upper and lower whiskers are shown.	Points in a box plot are jittered, so that if two records have the same value, a point is likely to be displayed for each of them.
Use gray-scale instead of colors	Use shades of gray instead of colors in the graph.	
Popup	Display each graph in an individual popup window. If you have popup blocking software installed on your PC, it may prevent these windows from opening. You may want to disable your popup blocking software. For details, see <a href="#">Graph display options</a> .	

6. Click **Display**.  
The application creates the graph using the specified display options. These options apply only to this graph.  
For information about copying, printing, or saving a graph as an attachment to a topic, see [Working with report graphs](#).

7. If you point to a region of the graph, the following information appears:
  - The region of the box (Upper Outlier, Upper Whisker, Upper Box, Lower Box, Lower Whisker, or Lower Outlier).
  - The value of the secondary variable, if any.
  - The count of data points for the primary variable (and secondary variable, if any) for that region of the box.

The count may be more than the number of cases because there may be more than one data point for the same case. For example, a case might have multiple adverse events, where each adverse event is a separate data point.

8. If you click a region (Upper Outlier, Upper Whisker, Upper Box, Lower Box, Lower Whisker, or Lower Outlier) of the graph, you can [drill down](#) to cases for that region. If you are displaying multiple graphs on the same page, do not click any graph until all the graphs are displayed.

If a case has a value on the boundary between any regions (not including the Upper Outlier or Lower Outlier regions), the case ID is included when you drill down on either of the regions. Cases with values on the boundary of the Upper Whisker or Lower Whisker are not included when you drill down on the Upper Outlier or Lower Outlier regions.

## Scatter plot graphs

### About scatter plots

A scatter plot is the plotting of data points against horizontal and vertical axes to show the correlation between two or more continuous variables. You select a variable to plot against the x-axis of the scatter plot, and one or two variables to plot against the y-axis.

You can select a variable by which to subset data. For example, you can view a different scatter plot for each adverse event.

If you want to use a color key to associate each dot on the graph with a particular value, you can specify an inner breakdown variable. For example, to determine the particular case ID associated with each dot, you can use the case ID as the inner breakdown variable.

Note that:

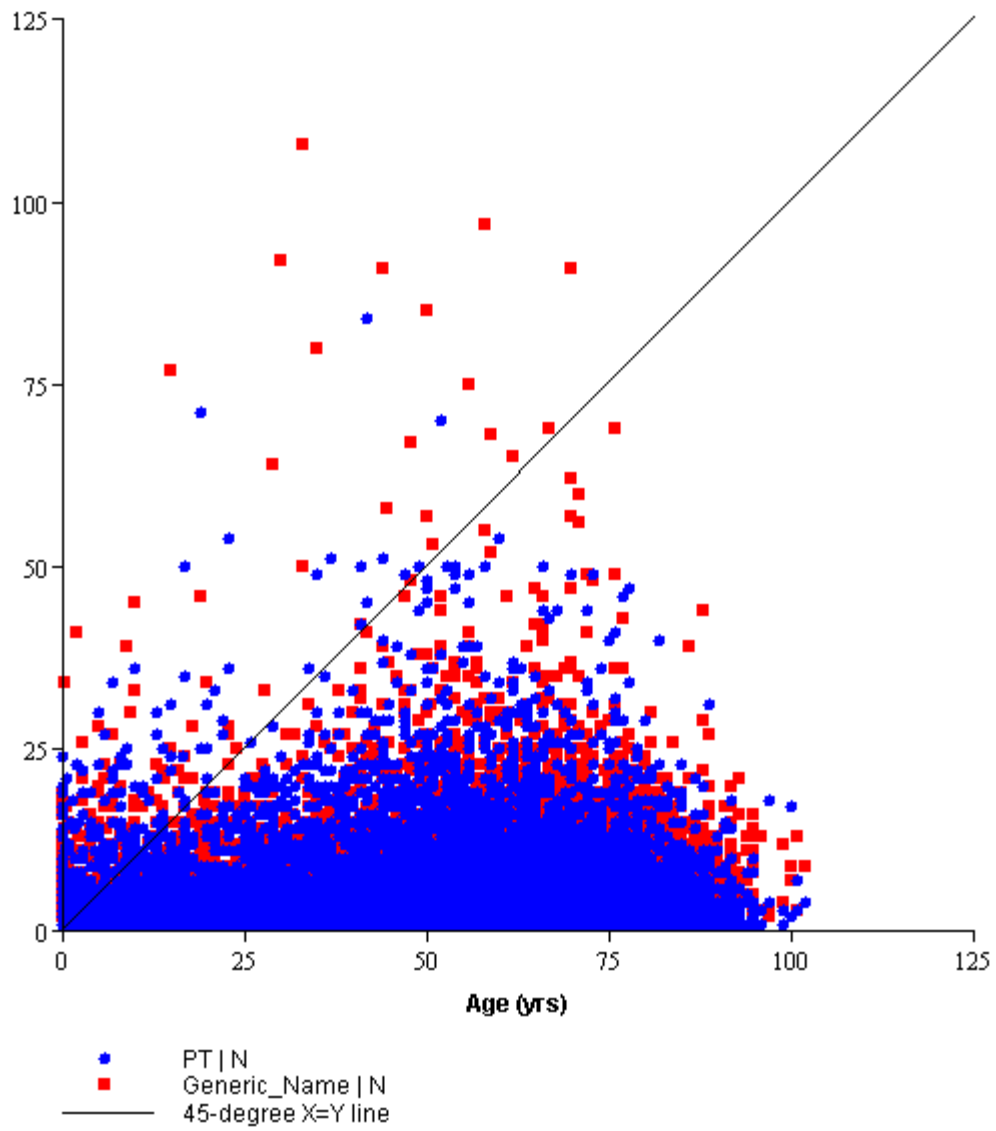
- No data point is plotted for a record if either the X variable or the Y variable is empty.
- If you select two y-axis variables, each of them uses a different shape, as shown in the color key below the scatter plot.
- If the X and Y values for one record coincide with the X and Y values for another record, the two data points are plotted in the same position. It is not possible to distinguish whether that data point represents one record or several records.

The color key below the scatter plot shows which value of the inner breakdown variable each dot represents.

For example, a report shows age, count of PTs, and count of drugs for each case ID:

Case ID	Age (yrs)	Count of PTs	Count of Drugs
<a href="#">4367534</a>	34	4	1
<a href="#">4370243</a>	43	10	8
<a href="#">4371214</a>	53	6	2

Depending on the [display options](#) that you specify, the graph might look like this:



## Viewing a scatter plot

For an overview of scatter plots, see [About scatter plots](#).

1. On the [Choose Graph page](#), click **Scatterplot**.  
The Scatterplot page appears.
2. From the **Subset Variable** drop-down list, select a subset variable.  
The application creates one scatter plot for each value of the subset variable.
3. Select an **X variable**; that is, a numeric variable to be plotted against the x-axis.
4. Select a **Y variable**; that is, a numeric variable to be plotted against the y-axis.
5. You can select another **Y variable**. Each of the two Y variables are plotted against the y-axis. Each Y variable corresponds to a different-shaped point, as shown in the key below the scatter plot.
6. You can also select a text variable as an inner breakdown variable. The color key associates each point on the scatter plot with a particular value of the inner breakdown variable.
7. Specify the following display options:

Option	Description
Labels X and Y	Label the x-axis and y-axis to clarify what is are represented by the axes.
Include linear regression lines	Include a linear regression line to identify trends in the data.
Include 45-degree line and matched axes	Include a 45-degree line in the scatter plot. This is useful if you are plotting two similar variables and you are interested in the differences.
Use gray-scale instead of colors	Use shades of gray instead of colors in the graph.
Popup	Display each graph in an individual window. If you have popup blocking software installed on your PC, it may prevent these windows from opening. You may want to disable your popup blocking software. For details, see <a href="#">Graph display options</a> .

8. Click **Display**.  
The application creates the graph using the specified display options. These options apply only to this graph.



9. To [drill down](#) to case information, point to the graph, click, and hold down the mouse button while you draw a red rectangle around the data points for which you want to drill down. When you release the mouse button, a menu appears and you can drill down. Note that a single point in the graph may represent several data points.

---

**Note:** If you are displaying multiple graphs on the same page, do not try to drill down until all the graphs are displayed.

---

For information about copying, printing, or saving a graph as an attachment to a topic, see [Working with report graphs](#).



## Managing signals

### About signal management

Signal management facilitates the ongoing monitoring of safety signals by enabling you to view disproportionately analysis statistics for successive updates of safety data. Oracle prepares the signal management data from a combination of the results from multiple data mining runs.

On the Signals tab, you can do the following:

- View quantitative and objective measurements of related reporting frequency of safety signals over time.
- Identify, evaluate, and track safety signals.
- Associate a lead topic with one or more drug-event combinations in order to enable workflow and follow up of a potential signal.

A signal set is a compilation of signals for drug-event combinations that have a particular characteristic, such as All, Foreign, and so on, from a group of data mining runs. During data preparation, multiple signal sets are defined to meet your organization's requirements.

On the [Drug Overviews page](#), you enter and view drug notes and view [sector maps](#) showing PTs for a drug. If you have appropriate permissions, you manage monitored drugs and reviewers. On the Drug-Event Combinations page, you view signals and other information about combinations. On the [Drug Comments page](#), you view counts of comment types and topics assigned to drug-event combinations for each drug and access the comments.

To use signal management, you must have the View Signal Management [permission](#) and a [signal configuration](#) must be associated with your login group. Some signal management features may not be available at your organization or to your login group. Signal management offers a number of options that your organization may or may not use, either for your entire site or for a specific signal configuration. These include:

- Integration with topics, allowing you to associate a lead topic with one or more drug-event combinations.
- A site option to drill-down to case details and narratives to perform manual review of event causality or clinical assessment of case reports.
- A signal configuration option to assign a review period, such as monthly, semi-annually, or annually, to each drug. This allows you to review safety signal data for the period of time that is most appropriate for each drug, rather than reviewing data for the same period of time for every drug.
- A site option for entering detailed, free-text comments for a drug-event combination, in addition to selecting a standardized comment from a predefined list.
- A signal configuration option to specify whether each comment is public, and can be viewed by all users, or private. Private comments can be viewed only by the comment author or a superuser, or by all users after data for a drug-event combination that is attached to a [topic](#).

## Working with drug-event combinations

### Drug-Event Combinations page

On the Drug-Event Combinations page, you can view the statistical information about each drug-event combination, including the EBGM and PRR for each drug-event combination, over cumulative time periods. In addition, the page contains information that your organization chose to include (for example, trending information about changes in the statistics over time). This information varies depending on how signal management has been configured for your organization. For a drug-event combination, you can access information that can help determine causal association. For example, you can view age and gender distribution, reporting frequency, and combinations for the same HLT, HLGT, or SOC.

---

**Note:** The drug-event combinations can include custom terms and terms from the source data.

---

If, for a drug-event combination, there are statistics from multiple signal sets, the statistics columns typically have names that identify the signal sets. If signal management is integrated with topics, the table includes columns for Topic Name and Topic State.

---

**Note:** Statistics, such as EBGM and PRR, are provided for the signal sets and time periods. If there is no value of N for the signal set and time period, no statistics are available.

---

### General activities

The following links appear at the top of the page and affect the entire page:

- [Select View](#)
- [Filter By Comments](#)
- [Save As View](#)
- [Manage Views](#)
- [Columns](#) (or Columns and Rows, depending on the user preference)
- [Print](#)
- [Download](#)
- Select Rows

The following links appear at the top of the page when the page is in the Select Rows mode. The links affect the selected drug-event combinations:

- [Print](#)
- [Download](#)
- [Create Case Series](#)
- [Transfer to Case Series](#)
- Reports

- [Save to Topic](#) (if Topics has been configured for your organization)
- [Document Review](#)
- [Add Private Comment](#) (Appears if the signal management configuration is supported)
- Select All
- Clear All
- Back

The following filters appear at the top of the page and affect the entire page.

- Group
- Reviewer
- Drug
- SOC

You can limit the drug-event combinations that appear in the table by using the filters. For example, you might want to see only drugs that are assigned to you for review, or only one drug. You can set user preferences for default values to appear in the Group, Reviewer, and Drug filters. If you select a drug group, the Reviewer and Drug filters are affected as follows:

- In the Reviewer filter, you can select reviewers assigned to drugs in the specified drug group. You can also select reviewers, if any, that have been assigned to drug-event combinations for drugs in the group.
- In the Drug filter, you can select only drugs in the specified drug group and, if a reviewer is specified, only drugs to which that reviewer is assigned and drugs from drug-event combinations to which that reviewer is assigned. If there are a large number of drugs available, you can click **Select Drug** to select a drug.

In the Group, Reviewer, or Drug filters, select — to include **all**. Note that a warning message appears if all filters are set to —, no WHERE clause exists, and no filtering by comments are specified. This is to prevent inadvertently displaying all drug-event combinations, which can have a negative performance impact. For the Drug filter, you can also specify **None**.

For example, consider the following drugs:

<b>Group</b>	<b>Reviewer</b>	<b>Drug</b>
A	User1	Acetaminophen
A	User2	Aspirin
I	User2	Iron
N	User1	Niacin

Your group, reviewer, and drug selections have the following effect:

<b>Selected group</b>	<b>Selected reviewer</b>	<b>Selected drug</b>	<b>Combinations with any of these drugs are listed</b>
A	User2	-	Aspirin
A	-	-	Acetaminophen, Aspirin
-	User2	-	Aspirin, Iron

Reviewers can be assigned to drug-event combinations as well as to drugs. Thus, when you select a reviewer, you see all drug-event combinations assigned to the reviewer, in addition to any combinations that appear because of drug assignments. If you see a combination because it is assigned to you, you also see all combinations for the drug (even if the drug itself is not assigned to you).

For example, suppose that User1 is assigned to the drug Niacin, and User2 is assigned to the combination of the drug Niacin and the event Flushing. If you select User2, you see all combinations that include Niacin, even though User1 is assigned to Niacin.

### Row-specific activities

The following menu options are available from the row menu, located in the left most column of the table, and affect an individual row in the table:

- [Document Review](#)
- [Edit Topic](#) (Appears if a Topic is associated with the combination and you have View Topics permission)
- [Add Private Comment](#) (Appears if the signal management configuration is supported)
- [View Signal History](#)
- [View Similar Combinations](#)
- [Assign Reviewer](#)
- [View Interactions](#)
- [View Age Group Breakdown](#) (Depending on how signal management is configured, there might be multiple links for different signal sets)
- [View Gender Breakdown](#) (Depending on how signal management is configured, there might be multiple links for different signal sets)

### Field descriptions—Drug-Event Combinations page

In this page, you can view the statistical information for each drug-event combination.

<b>Column</b>	<b>Description</b>
Drug	Name of the drug.

Event	Name of the Preferred Term (PT).
HLGT	Name of the High Level Group Term (HLGT) that contains the PT.
HLT	Name of the High Level Term (HLT) that contains the PT.
SOC	Abbreviated name of the System Organ Class (SOC) containing the PT.
SOC Desc	Description of the SOC that contains the PT
Comment	<p>Most recent comment, if any, entered for the drug-event combination. To review the detailed comments (if any) place the cursor over the comment.</p> <p>Comments can be added to a drug-event combination when you review the summary for the combination or when you filter the combination. You can also select multiple combinations and add the same comment to all of them.</p>
Comment Date	Date and time the most recent comment was added.
Topic Name	<p>If the signal management configuration has been integrated with topics, the topic name associated with the drug-event combination.</p> <p>If you have permission to view the topic, the name appears as a hyperlink, and when clicked, the topic appears in view mode.</p>
Topic State	If the signal management configuration has been integrated with topics, the current topic state for the topic associated with the drug-event combination.
Private Comment	The most recent private comment you entered for the combination. To review the detailed comments (if any) place the cursor over the private comment. This column appears if the private comments feature is enabled in the signal configuration.
Private Comment Date	Date and time the most recent private comment was added. This column appears if the private comments feature is enabled in the signal configuration.
Filter	<ul style="list-style-type: none"> <li>• <b>YES</b>—The drug-event combination is suppressed.</li> <li>• <b>NO</b>—The drug-event combination was suppressed, and was included again. If this column is empty, the combination has never been filtered.</li> </ul>
Reviewer	Name of the reviewer, if any, assigned to the drug-event combination. This column does not show reviewers who have been assigned to the drug.
N, Nsince	<p>The following counts may appear:</p> <p>N is the total count of cases (with the drug-event combination) from the earliest start date of the source data (EARLIEST_ASOFDATE value in the <a href="#">source description table</a>) up through the indicated time period.</p>
<p><b>Note:</b> For combinations that include new drugs, the N column is typically</p>	

empty for older time periods. Also, if drug or event term was recorded, the N column might be empty for combinations that include the previous drug or event term.

The Nsince column displays the count of new or significantly changed cases (with the drug-event combination) since the indicated time period through the latest end date of the source data (ASOFDATE in the source description table). If there are no new or changed cases for a combination, the column is empty.

The following table shows how N and Nsince relate to the indicated time period.

Count	From	Through
N	Earliest start date of the source data (EARLIEST_ASOFDATE value in the <a href="#">source description table</a> )	Indicated time period
Nsince	Indicated time period	Latest end date of the source data (ASOFDATE in the source description table)

You can click the values in the N or Nsince columns to display a menu that you can use to drill-down to cases that make up the count.

EBGM	Empirical Bayesian Geometric Mean for the drug-event combination. The EBGM is a more stable estimate than RR (Relative Ratio); the so-called shrinkage estimate, computed as the geometric mean of the posterior distribution of the true Relative Ratio. For more information, see <a href="#">MGPS computations</a> .
EB05	For the drug-event combination, a value such that there is approximately a 5% probability that the true Relative Ratio lies below it. The interval from EB05 to EB95 may be considered to be the 90% confidence interval.
EB95	For the drug-event combination, a value such that there is approximately a 5% probability that the true Relative Ratio lies above it. The interval from EB05 to EB95 may be considered to be the 90% confidence interval.
PRR_CHISQ	Chi-square of PRR for the drug-event combination.
PRR	Proportional Reporting Ratio for the drug-event combination. For more information, see <a href="#">PRR computations</a> .
PVALUE	For the drug-event combination, the probability that chi-square would be as large as or larger than the value in the PRR_CHISQ column by chance alone if there were no causal relationship or consistent association between the



drug and the event. Small values display in scientific notation.

---

ROR	Reporting Odds Ratio for the drug-event combination. Without stratification, computed as: $(PRR\_A \times PRR\_D) / (PRR\_B \times PRR\_C)$ With stratification, computed as a weighted average of ROR within each stratum. For more information, see <a href="#">ROR computations</a> .
ROR05	For the drug-event combination, the lower 5% confidence limit for ROR. The interval from ROR05 to ROR95 may be considered to be the 90% confidence interval.
ROR95	For the drug-event combination, the upper 5% confidence limit for ROR. The interval from ROR05 to ROR95 may be considered to be the 90% confidence interval.

---

**Note:** Depending on how signal management is set up for your organization; a Link column may appear containing a hyperlink to a third-party application.

---

## Filtering comments on the Drug-Event Combinations page

You can filter drug-event combinations by the comments applied to drug-event combinations. The filter is not part of the view, but is applied across views until you change it. If a drug-event combination does not appear for the current view, you cannot show it by filtering by comments.

If the signal configuration has the private comments feature set up, you choose between filtering based on **Public** comments entered by any user or **Private** comments entered only by yourself.

If rows have been filtered using a SQL WHERE clause in the Column and Rows window, the text **Rows are filtered** appears above the table of drug-event combinations. If rows have also been filtered by comments, the text instead reads **Rows are filtered by <private> comments**. You can place your mouse on that text to see a tooltip with the SQL WHERE clause, if any, that is in effect

1. Click the **Signals** tab.  
The Drug-Event Combinations page appears.
2. Click **Filter By Comments**.
3. If the signal configuration supports private comments, from the menu, select the type of comment:
  - To filter by comments entered by all users, click **Public**.
  - To filter by comments that only you entered, click **Private**.

If you select Public, the Signal Comments Filter dialog box appears.

If you select Private, the Signal Private Comments Filter dialog box appears.

4. Select the check box of one or more comments, or to include all comments, click **Select All**.
5. Click **OK**.

The application displays only those combinations that include the selected comments and meet the condition of the signal view. The text, **Rows are filtered by <private> comments**, appears above the table of drug-event combinations.

## Filtering drug-event combinations using a SQL WHERE clause

You can set your user preference, **Allow SQL WHERE Clause on Signals Tab**, to allow use of a SQL WHERE clause to restrict rows that appear on the Drug-Event Combinations page. If this preference is checked, the Columns link on the Drug-Events Combinations page is replaced by a Columns and Rows link.

1. Click the **Signals** tab.

The Drug-Event Combinations page appears.

2. Click **Columns and Rows**.

The Columns & Rows dialog box appears.

3. From the **Available Columns** list, select one or more columns and move them to the **Selected Columns** list.

If you use a SQL WHERE clause, you must refer to the names of columns in the underlying database table, which might not be the same as the column names that appear on the page.

4. For the columns shown, specify the column names and sort order.

- From the **Column Name** drop-down list, select the name.
- From the **Sort Order** drop-down list, select **Asc**, to sort in ascending order, or **Desc**, to sort in descending order.

5. To use the layout as the default for your login group, select the **Use current layout as login group default** check box.

6. In the **Where Clause** text box, type or paste the SQL WHERE clause.

To include a column in the WHERE clause, click **Show Columns** and click the column name from the **Select Table Columns** dialog box.

7. Click **OK**.

The text, **Rows are filtered**, appears above the table of drug-event combinations. Hover over the text to see the SQL WHERE clause that is in effect.


## Viewing age group breakdown for a drug-event combination

The breakdown of case data by age group for a drug-event combination is represented in a bar graph. Data represented in the graph includes all available data up through the current time period and is for the designated signal set. You cannot view the age group breakdown if there is no value of N.

The x-axis of the bar graph represents the percent of the total number of cases with the drug-event combination. The y-axis represents each value of Age Group. For each value of Age Group, there are two bars that are differentiated by the color key below the graph. The bars represent the following:

- **Drug**—Cases with the drug for the current time period. The total number of cases with the drug for the current time period appears in the color key.
- **Drug+Event**—Cases with the drug-event combination for the current time period. The total number of cases with the drug-event combination for the current time period appears in the color key.

If there are no cases including the drug-event combination for a particular age group, 0 appears instead of a bar. Cases with NULL values for an age group are represented by a bar for NULL values.

1. On the **Drug-Event Combinations** page (or the [Similar Combinations page](#)), click the row menu () for the combination, and then click **View Age Group Breakdown**.

The Breakdown by Age Group dialog box appears.

If there are multiple signal sets for which you can view an age group breakdown, the signal set is identified in the link name.

2. To [save the graph as an attachment to a topic](#), click **Save to Topic** (available if the topics feature has been set up).

The graph is attached to a PDF file.

3. To close the Breakdown by Age Group dialog box, click **Cancel**.

For information about copying or printing a graph, see [Working with results graphs](#).


## Viewing gender breakdown for a drug-event combination

The breakdown of case data by gender for a drug-event combination is represented in a bar graph. Data represented in the graph includes all available data up through the current time period and is for the designated signal set. You cannot view the gender breakdown if there is no value of N.

The x-axis of the bar graph represents the percent of the total number of cases with the drug-event combination. The y-axis represents each value of Gender. For each value of Gender, there are two bars that are differentiated by the color key below the graph. The bars represent the following:

- **Drug**—Cases with the drug for the current time period. The total number of cases with the drug for the current time period appears in the color key.
- **Drug+Event**—Cases with the drug-event combination for the current time period. The total number of cases with the drug-event combination for the current time period appears in the color key.

If there are no cases including the drug-event combination for a particular gender, 0 appears instead of a bar. Cases with NULL values for gender are represented by a bar for NULL values.

1. On the **Drug-Event Combinations** page (or the [Similar Combinations page](#)), click the row menu () for the combination, and then click **View Gender Breakdown**.

The Breakdown by Gender dialog box appears.

If there are multiple signal sets for which you can view a gender breakdown, the signal set is identified in the link name.

2. To [save the graph as an attachment to a topic](#), click **Save to Topic** (available if the topics feature has been set up). The graph will be attached in a PDF file.
3. To close the dialog box, click **Cancel**.

For information about copying or printing a graph, see [Working with results graphs](#).


## Viewing interactions for a drug-event combination

Information about an event and drug interactions is represented as a nested confidence interval graph of EB05-EB95 confidence intervals and EBGM values for two drugs and the event. Data represented in the graph includes all available data up through the current time period. The signals were generated by a particular run that was set up for the purpose of viewing interactions.

For each combination of two drugs and the event, the graph displays a series of confidence intervals, with the highest dimension shown first. The first confidence interval is for Event+Drug+Drug. The other two confidence intervals are for Event+Drug. You can compare the strength of the interaction between the two drugs and the event with the strength of the interaction between the individual drugs and the event.

In each confidence interval bar, the EB05 value is at the left end, the EBGM value is the dot on the bar, and the EB95 value is at the right end. The count (N) of cases with the combination is also shown at the end of each bar. Bars are colored according to the color key below the graph. To indicate a possible interaction, the confidence interval for the Event+Drug+Drug combination displays in red when the INTSS (Interaction Signal Score) value is greater than a predefined threshold that is set when signal management is configured. For more information about INTSS, see [interaction scores](#).

Note that:

- The Event+Drug+Drug combinations are shown in descending order of their INTSS values.
  - To conserve space in labeling, the event from the drug-event combination is referred to by the label, Event, in the graph.
  - Below the graph, there may be additional text provided by a site option.
1. On the **Drug-Event Combinations** page (or the [Similar Combinations page](#)), click the row menu () for a combination, and then click **View Interactions**.

The Interactions dialog box appears.

---

**Note:** A message informs you if there are no combinations of the drug and another drug with the event. Depending on how your signal management data was prepared, this option might not be available at all for some drug-event combinations or there may be multiple links for different runs.


---

2. If you point to a confidence interval, the names of the event and the two drugs appear. The following information for the Event+Drug+Drug combination also appears:
  - **N**—Observed number of cases with this Event+Drug+Drug combination.
  - **EBGM**—Empirical Bayesian Geometric Mean. A more stable estimate than RR; the so-called shrinkage estimate. For more information, see [MGPS computations](#).

- **EB05**—A value such that there is approximately a 5% probability that the true Relative Ratio lies below it.
  - **EB95**—A value such that there is approximately a 5% probability that the true Relative Ratio lies above it.
  - **INTSS**—Interaction Signal Score. A way of measuring of the strength of a higher-order association above and beyond what would be expected from any of the component pairs of items of different types.
  - **EXCESS2**—A conservative estimate of how many extra cases were observed over what was expected assuming that only a single cross-item interaction is present.
3. To work with the cases represented by any of the confidence intervals, you can click the bar to see an action menu of options.
  4. To [save the graph as an attachment to a topic](#), click **Save to Topic** (available if the topics feature has been set up). The graph is attached to a PDF file.  
  
For information about copying or printing a graph, see [Working with results graphs](#).
  5. To close the Interactions dialog box, click **Close**.

## Suppressing a drug-event combination

You can suppress a drug-event combination so that it is not included on the Drug-Event Combinations page. For example, if you determine that a drug-event combination has already been reviewed, you might want to suppress that combination.

1. Click the **Signals** tab.  
The Drug-Event Combinations page appears.
2. Click the row menu () for the drug-event combination, and then click **Document Review**.  
The Document Review dialog box appears.
3. From the **Comment** drop-down list, select the comment.
4. To suppress a comment for the drug-event combination, select the **Suppress drug-event combination** check box.


If at least one comment in the signal management configuration is set to **Is Suppress Reason? = Yes**, the Suppress drug-event combination check box appears

If the selected comment is **Is Suppress Reason = Yes**, or if the drug-event combination is already suppressed, the **Suppress drug-event combination** check box is already enabled.

5. In the **Detailed comment** text box, enter a detailed comment (optional).
6. If the associated topic is displayed, you can change it by clicking **Change**. Complete the **Topic Association** section of the Document Review dialog box. For more information, see [Associating a topic with a drug-event combination](#).
7. Click **OK**.




## Associating a topic with a drug-event combination

1. Click the **Signals** tab.  
The Drug-Event Combinations page appears.
2. Click the row menu () for the drug-event combination, and then click **Document Review**.  
The Document Review dialog box appears.
3. In the **Topic Association** section, do one of the following:
  - A. If you do not want to associate a topic with the drug-event combination, select **None**.
  - B. To associate an existing topic with the drug-event combination, select **Existing topic** and type the topic name.  
or  
To select a topic from a list, click **Browse**.  
The Select Topic dialog box appears.
    - i. Click the radio button of the desired topic.
    - ii. Click **OK**.  
  
The Document Review dialog box appears with the selected topic name in the text field.
    - iii. Click **OK**.  
  
The selected topic is associated with the drug-event combination, and the drug-event combination row is added as an attachment to that topic.
  - C. To associate a new topic with a drug-event combination, select **New topic**, and do the following:
    - i. From the **Topic template** drop-down list, select a topic template, or click **Browse** to select a topic template from the Select Topic Template dialog box.
    - ii. In the **Topic name** field, type a name for the new topic.
    - iii. In the **Topic description** field, type a description for the new topic.
    - iv. Optionally, assign the new topic to a [project](#).

- To assign the topic to an existing project, click **Add to existing project**, and select the project from the drop-down list of projects associated with objects that you created or that are published to you.
- To create a new project and assign the topic to it, click **Add to a new project named**, and type a project name.

4. Click **OK**.

## Assigning a reviewer


1. Click the **Signals** tab.  
The Drug-Event Combinations page appears.
2. Click the row menu () for a combination, and then click **Assign Reviewer**.  
The Assign Reviewer dialog box appears for the selected drug-event combination.
3. From the **Reviewer** drop-down list, select the reviewer.  
You can also select no reviewer (--) to remove an assignment. Available reviewers for assignment are those in login groups to which the signal configuration is published. This assignment does not overlap with the reviewer assignments to drugs. For example, if User1 is assigned to the drug Niacin, you can assign User2 to the combination of the drug Niacin and event Flushing.
4. Click **OK**.  
The reviewer name appears on the Drug-Event Combinations page.

## Adding a private comment

You can add a private comment to a drug-event combination on the Drug-Event Combinations page if the signal management configuration allows private comments.

1. Click the **Signals** tab.

The Drug-Event Combinations page appears.

2. Click the row menu () for a drug-event combination, and then click **Add Private Comment**.

The Add Private Comment dialog box appears.

3. From the **Comment** drop-down list, select a predefined comment.
4. In the **Detailed comment** text box, enter a detailed comment (optional). This option is available if the appropriate site option has been set.
5. Click **OK**.

The private comment appears for the drug-event combination.

---

**Note:** The private comment is visible to only you and superusers.

---

## Similar combinations

### Similar Combinations dialog box

On the Similar Combinations dialog box, you can view the statistical information for combinations involving the same drug and the same HLT, HLGT, or SOC as that of the PT in the original combination. You can also view all combinations for the drug.

For example, if you are viewing signals for the combination of Ascorbic Acid and Chest Pain, you might also want to view combinations of Ascorbic Acid and any PT that is in the same HLGT as Chest Pain.

### General activities

The following links appear at the top of the dialog box and affect the entire dialog box:

- [Columns](#)
- [Print](#)
- [Download](#)
- [Save to Topic](#)

In addition, the **Show events within field** drop-down list contains levels of the MedDRA hierarchy.

---

**Note:** If the data have been prepared to use SMQ terms, signal management might be set up so that when you are viewing a drug-event combination involving an SMQ, your choices in this field are PTs for SMQ (which shows combinations for PTs related to the SMQ) or ALL.

---

### Row-specific activities

The following options are available from the row menu, located in the leftmost column of the table, and affect an individual row in the table:

- [Document Review](#)
- [Edit Topic](#)
- [Add Private Comment](#)
- [View Signal History](#)
- [Assign Reviewer](#)
- [View Interactions](#)
- [View Age Group Breakdown](#)
- [View Gender Breakdown](#)

The **Edit Topic** row menu appears if the combination includes an associated topic that you have permission to edit.

The **Add Private Comment** row menu appears if private comments are supported in your signal management configuration.


### **Field descriptions—Similar Combinations dialog box**

The Similar Combinations dialog box contains the same set of columns as displayed in the Drug-Event Combinations page. For more information, see [Drug-Event Combinations page](#).

## Viewing signals for similar drug-event combinations

1. Click the **Signals** tab.

The Drug-Event Combinations page appears.

2. Select the row menu () for the drug-event combination you want to view, and select **View Similar Combinations**.

The Similar Combinations dialog box appears. The dialog box displays the same columns and uses the same sort order and review period as the selected on the Drug-Event Combinations page. However, the rows are not restricted by the SQL WHERE Clause that may be part of the view or if filtered by comments.

3. In the **Show events within field**, select any of the following events:
  - HLT (default)
  - HLGT
  - SOC

If you select **ALL**, all events for the drug are listed.

---

**Note:** If the data has been prepared to use SMQ terms, signal management might be set up so that when you view a drug-event combination involving an SMQ, your choices in are PTs for SMQ (which shows combinations for PTs related to the SMQ) or ALL.

---

4. Select the row menu, and select any of the [actions](#).

You can perform the same actions as on the Drug-Event Combinations page. You can also click a count (N or Nsince) of cases to display a menu that you can use to drill down to cases that make up the count.

## View signal history

### Available drug-event combination statistics

For each drug-event combination, you can review a summary of statistics presented in a trend graph and a histogram.

The trend graph is a confidence interval graph in which the x-axis represents dates and the y-axis represents EBGGM values for the drug-event combination. In the line for each time period:

- The point represents the EBGGM value.
- The lower end represents the EB05 value.
- The upper end represents the EB95 value.

The histogram that appears below the trend graph shows reporting frequency for the drug-event combination. The x-axis represents dates and the y-axis represents counts of cases that contain the drug-event combination.

### Field descriptions—Statistical score

The statistical score that might appear for each drug-event combination includes the following rows:

Field	Description
EB05	A value such that there is approximately a 5% probability that the true Relative Ratio lies below it. The interval from EB05 to EB95 might be considered to be the 90% confidence interval.
EB95	A value such that there is approximately a 5% probability that the true Relative Ratio lies above it. The interval from EB05 to EB95 might be considered to be the 90% confidence interval.
EBGM	Empirical Bayesian Geometric Mean. A more stable estimate than RR; the so-called shrinkage estimate, computed as the geometric mean of the posterior distribution of the true Relative Ratio. For more information, see <a href="#">MGPS computations</a> .
N	Observed number of cases with the combination of items.
PRR	Proportional Reporting Ratio for the combination of a particular drug and particular event.
PRR_CHISQ	Chi-square of PRR. For more information, see <a href="#">PRR computations</a> .
ROR05	Lower 5% confidence limit for ROR.



ROR95 Upper 5% confidence limit for ROR. The interval from ROR05 to ROR95 might be considered to be the 90% confidence interval.

ROR Reporting Odds Ratio. Computed as:  

$$\text{ROR} = (\text{PRR\_A} * \text{PRR\_D}) / (\text{PRR\_B} * \text{PRR\_C})$$
 With stratification, ROR is computed as a weighted average of the ROR within each stratum. For more information, see [ROR computations](#).

### Field descriptions—Review information for the drug-event combination

The review information for the drug-event combination includes the following columns:

Field	Description
Date	Date and time when the comment was added. The comments are ordered by the date they were added, with the most recently added comment appearing first.
Created By	Name of the user who added the comment. The user name appears even if the user has been deleted.
Filtered	<ul style="list-style-type: none"> <li>• <b>Yes</b>, if you added the comment when the drug-event combination was suppressed.</li> <li>• <b>No</b>, if you added a public comment when you were documenting your review, or when you un-suppressed the drug-event combination.</li> <li>• Empty (blank), for private comments.</li> </ul>
Private	<p>If the signal management configuration allows private comments, displays <b>Yes</b> to identify private comments and <b>No</b> to identify public comments.</p> <p><b>Note:</b> A superuser can review both public and private comments entered by all users.</p>
Comment	The predefined comment added to the combination.
Detailed Comment	The optional free text description added with the comment. This column appears only if the corresponding site option has been set.

### Field descriptions—Review information for the drug-event combination

If signal management is integrated with topics, the table also includes the following columns:

Field	Description
-------	-------------

Topic  
Name (ID)      Topic name and ID associated with the drug-event combination.

---


Topic  
Association      Activity involving the associated topic. Values include Created, Removed or Modified.

---

## Viewing signal history for a drug-event combination

1. Click the **Signals** tab.

The Drug-Event Combinations page appears.

2. Click the row menu () of a drug-event combination, and then click **View Signal History**.

The Signal History dialog box appears and includes the following information.

- The name of the drug and event (PT) and the HLT, HLGT, and SOC that include the PT.
- A trend graph that shows the EBG, EB05, and EB95 values over time.
- A histogram that shows the total count of cases with the drug-event combination over time.
- Statistical scores for the PT and HLT and SOC, if available. The statistics that are displayed depends on the signal management configuration.
- A list of comments for the drug-event combination. If signal management is integrated with topics, the list also includes topic associations.

---

**Note:** If the [signal configuration](#) includes public and private comments, the list includes all public comments by any user and all of your private comments. The list for a Superuser includes all comments regardless of author or type. If the signal configuration does not include private comments, all comments by any user appear in the list.

---

The detailed information about the drug-event combination might include multiple signal sets.

3. From the **Signal set** drop-down list, select the signal set for which you want to view a history, or select **All** to include all data.

You can select up to two different signal sets at a time to display graphs for each of them.

4. To save the signal history as an attachment to a topic, next to the signal set, click **Save to Topic**.

The signal set graphs and statistics are attached to a PDF file.

5. When you have finished viewing the signal history, click **Close**.

## Document review

### Document review for a drug-event combination

In the Document Review dialog box, you can document the disposition of the drug-event combination. If your site has integrated Signal Management with topics, you can associate a topic with the combination.

### Comment on a drug-event combination

The **Comment** drop-down list contains all the comments that are defined in the signal management configuration, where one of the following is true:

- Is Review Summary Reason? = Yes
- Is Suppress Reason? = Yes

If no comment yet exists for the drug-event combination, then the **Comment** drop-down list displays **<Select a comment>**. If you want to clear the existing comment, from the **Comment** drop-down list, select **<Clear Comment>**.

When you clear a comment, a new blank comment is added and the drug-event combination has no comments. The No Comment column on the [Drug Comments page](#) counts the drug-event combination as having no comment attached. All previous comments are retained and can be viewed on the View Signal History dialog box and when viewing [detailed comments](#) for a drug.

In addition, you can include additional information in the **Detailed comment** text field.

---

**Note:** The **Detailed comment** text field appears only if the **Allow Free Text Signal Comments** site option is enabled.

---

### Suppress drug-event combination

A drug-event combination can be suppressed to not be included on the Drug-Event Combinations page. For example, if you determine that a drug-event combination has already been reviewed, you may want to suppress that combination.

There is a view that includes only suppressed (previously referred to as filtered) drug-event combinations so they can be easily identified.

If a drug-event combination has been suppressed, the Filter column shows **YES**. If the combination was suppressed and then unsuppressed, this column shows **NO**. If the combination has never been suppressed, this column is empty.

You can suppress a comment for a drug-event combination by selecting the **Suppress drug-event combination** checkbox. The **Suppress drug-event combination** checkbox appears if at least one comment in the signal management configuration is set as **Is Suppress Reason? = Yes**. It is enabled if you selected a comment with **Is Suppress Reason? = Yes**.

## Topic association with a drug-event combination

If signal management is integrated with topics, then you can associate a topic with a given drug-event combination in the Document Review dialog box. If the integrated topic workflow configuration differs from the workflow configuration used on the Topics tab, the Document Review dialog box includes the topic workflow configuration name that is integrated with signal management.

---

**Note:** A drug-event combination can be associated with only one topic at a time. However, you can change or remove the currently associated topic. The history of previously associated topics is visible in the Comments and Topic Associations table that appears on the View Signal History dialog box.

---

You can select any of the following during the review:

- **None**—Use this option if you do not want to associate any topic with the drug-event combination. This is the default option if no topic has been associated with the drug-event combination. If you select this option, comments and detailed comments are still logged but no topic is associated with the drug-event combination.
- **Existing topic**—Use this option if you want to associate an existing topic with the drug-event combination. As you type characters into this field, a drop-down list of matching topic names is displayed. You can click **Browse** to select from a list of existing topics. Available topics are those that you can edit. Available topics include ones you created, topics assigned to you, or topics that have been made visible to a work team you are in.

If you select this option, comments and detailed comments are logged along with a topic association. The drug-event combination is saved to the existing topic as an attachment.

- **New topic**—Use this option to create a new topic and associate it with a drug-event combination. If topic templates are available, the new topic can be based on the topic template that you select from the **Topic template** drop-down list. In addition, you can click **Browse** to select from a list of existing topic templates. Available topic templates are those that have been made visible to a work team that you are in.


The comments and detailed comments are logged along with a topic association. The drug-event combination is saved to the new topic as an attachment. When you click **OK**, the Topic page is displayed and you can edit the associated topic.

If a topic is already associated with a drug-event combination, the Document Review dialog box displays the associated topic name along with the **Change** link. To view the information about the associated topic in the Topic Association section, click **Change**.

Another user can edit a topic while you are associating that topic with a drug-event combination, however, if the other user closes or deletes the topic during this time, you are prevented from making the association, and an appropriate error message is displayed.

## Documenting your review

You can add a detailed comment to the drug-event combination.

1. Click the **Signals** tab.  
The Drug-Event Combinations page appears.
2. Click the row menu () for the drug-event combination, and then click **Document Review**.  
The Document Review dialog box appears.
3. From the **Comment** drop-down list, select a comment. For more information, see [Document review for a drug-event combination](#).
4. To suppress the drug-event combination, click the **Suppress drug-event combination** check box. For more information, see [Suppressing a drug-event combination](#).
5. In the **Detailed comment text box**, type the text of the comment.  
This option is available if the **Allow Free Text Signal Comments** site option is enabled. If the selected comment is configured with **Requires Detailed Comment = Yes**, you are required to enter a detailed comment.
6. If the signal management configuration is integrated with topics, you can work with an associated topic. To change an existing associated topic, click **Change**. Complete the Topic Association section of the Document Review dialog box. For more information, see [Associating a topic with a drug-event combination](#).
7. Click **OK**.

## Managing signal views

### Viewing existing signal views

A signal view specifies the following for the Drug-Event Combinations page:

- Which columns are included, and in what order.
- The sort order of columns.
- The SQL WHERE clause that selects drug-event combinations.

1. Click the **Signals** tab.

The Drug-Event Combinations page appears.

2. Click **Manage Views**.


The Manage Signal Views page appears and provides the following information about each signal view that you created. If you have the Manage Signal Views permission, the page also lists views created by other users in your login group, as well as views published to you.

Column	Description
Name	Name of the signal view.  <b>Note:</b> If the signal configuration has the review period feature set up, each view name should include the length of the review period, such as New Cases (3 months) and New Cases (6 months).
Description	Description of the signal view.
Category	The grouping for the view, such as Drug Alerts or Supplemental. The category defines the view's location in the Select View menu on the Drug-Event Combinations page.  View categories are customized for the requirements of each organization.
Modified	Date and time when the signal view was last modified.
Created By	Name of the user who created the signal view.
Created On	Date and time when the signal view was created.
Review Period	The period of time for data in the view, such as the last 3 months, 6 months, or 1 year. Appears if the signal configuration has the review period feature set up.

3. To [organize signal views](#) that is, to specify how they will appear in the **Select View** menu on the Drug-Event Combinations page, click **Organize Views**.

(This option is available only if you have the Manage Signal Views permission.)

### **Row-specific activities**

If you click the row menu () for a signal view, you can do the following:

- To [rename a view](#), click **Rename**.
- To [publish](#) a view, click **Publish**. (This option is available only if you have the Manage Signal Views permission.)
- To delete a view, click **Delete** and then click **OK**.

For information about viewing, printing, or downloading tables or changing the way data displays in the table, see [About tables](#).



## Selecting signal views

A signal view specifies which columns are included on the Drug-Event Combinations page, the sort order of columns, and the SQL WHERE clause (if any) that applies selection criteria to drug-event combinations. If the signal configuration uses the review period feature, each view is also associated with a review period.

Typically, an organization has predefined standard views. You can select from views that are published to you and views that you have created. If you have the Manage Signal Views permission, you can also select views created by any users in your login group. If you select a single drug, the application uses the view assigned as the default for that drug.

1. Click the **Signals** tab.  
The Drug-Event Combinations page appears.
2. Filter the combinations by group, reviewer, drug, or SOC as desired. For more information, see [Drug-Event Combinations page](#).
3. Above the table, click the **Select View** menu.
  - If views are assigned to categories, or if review periods are used, the Select View menu cascades; that is, it offers additional submenus depending on your menu choice. If a down or up arrow appears above or below the list of views, use it to scroll through the list.
  - If no views are assigned to categories, a View field that you can use to select from a list of views appears.

### Default view

When you click **Select View**, and then select **Default** from the menu or the View field, the application uses the default view for any single drug you select. If no default view for the drug exists, but there is a default view for signal management, the application uses that default view.

The application also uses the default view for signal management if the Group, Reviewer, and Drug fields are set so that the application finds multiple drugs.

### Review period view


If the signal configuration uses the review period feature and you select a view that has a different review period than the drug, a warning message appears and informs you that the SQL WHERE clause for the view was removed.

### Modified views

If you have modified a view, an asterisk appears after the view name in the blue bar at the top of the page. Your changes remain in effect for your current session until

you select a different view, group, reviewer, or drug. If you want to retain your changes to the view, you must save the view.

## Renaming a signal view

1. On the **Drug-Event Combinations** page, click **Manage Views**.  
The Manage Signal Views page appears.
2. Click the row menu () for a signal view, and then click **Rename**.  
The Rename Signal View page appears. In addition to the information you can change in the steps below, the Rename Signal View page shows the following information about the view:
  - The ordered list of columns included on the Drug-Event Combinations page.
  - The sort order for Drug-Event Combinations page.
  - The SQL WHERE clause, if any, that selects the drug-event combinations to appear on the Drug-Event Combinations page.
3. In the **View name** field, enter a new view name.
4. In the **Description** field, enter an informative description of the view.
5. Optionally, change the **Category** assignment for the view.
  - To add the view to an existing category, select **Add existing category** and select the view from the drop-down list.
  - to add a new category, select **Add a new category named** and type the category name in the text box.
6. Optionally, change the **Review period** for the view by selecting it from the **Review period** drop-down list. This option is available if the signal configuration has the review period feature set up.
7. Click **Save**.

## Organizing signal views

You can define the order of view categories, and the views within each category.

---

**Note:** The category Unassigned always appears last in the list of categories.

---

1. Click the **Signals** tab.  
The Drug-Event Combinations page appears.
2. Click **Manage Views**.  
The Manage Signal Views page appears.
3. Click **Organize Views**. (This option is available only if you have the Manage Signal Views permission.)  
The Organize Views dialog box appears.
4. To specify the order in which categories appear, in the **Category** list, click a category name, then click the up and down arrow keys.  
  
or  
  
To specify the order of the views assigned to a category, click a category, then, in the **Views** list, click a view name, then click the up and down arrow keys.  
  
or  
  
To reorder the views, click the up and down arrow keys next to the Views list.
5. When you are satisfied with the order of the categories and of the views in each category, click **OK**.

## Saving a signal view

A signal view specifies the following for the Drug-Event Combinations page:

- Which columns are included.
- The sort order of columns.
- The SQL WHERE clause (if any) that applies selection criteria to drug-event combinations.

If the signal configuration uses the review period feature, you can associate each signal view with a review period. When you save the view, you can assign it to a category. These categories populate the Select View menu.

1. On the **Drug-Event Combinations** page, [arrange the table](#) as you would like it to appear in the view.

2. Click **Save As View**.

The Save As View page appears.

3. If you have modified an existing view that you created (or if you have the Manage Signal Views permission), check **Replace existing**.

If you check this option, you cannot modify the view name. If you want to rename a view, use the Rename option on the [Manage Signal Views page](#).

When you create a signal view, the name, description, and category of the currently selected view display by default. You can change them as needed.

4. In the **Name for view** field, enter a name for the signal view.

---

**Note:** If the signal configuration has the review period feature set up, each view name should include the length of the review period; for example, New Cases (3 months), New Cases (6 months), New Cases (1 year), and so on.

---

5. In the **Description of view** text box, enter a description of the signal view. The description appears only on the Manage Signal Views page.

6. Optionally, assign the view to a category. The category determines the view's location on the [Select View menu](#).
  - To assign the view to an existing category, click **Add to existing category** and select a category that you created from the drop-down list.
  - To create a new category and assign the view to it, click **Add to a new category named** and enter a category name. The category name must be unique for the signal configuration.

See [Organizing signal views](#) for information about ordering categories and ordering views within categories.

7. If the signal configuration has the review period feature set up, select a review period for the view to identify the period of time for the data in the view, such as the last 3 months, 6 months, or 1 year, or select Unassigned.

8. Click **OK**.

The application saves the view and the Drug-Event Combinations page appears using that view.

## Working with drug overviews

### Viewing drug overviews

The Drug Overviews page lists drugs that are being monitored using signal management capabilities. Your organization can monitor all or some of the drugs for which cases exist in the results of data mining runs that generated the signal scores.

1. Click the **Signals** tab.
2. Click **Drug Overviews**.  
The Drug Overviews page appears.
3. To filter the list, make selections from the **Group**, **Reviewer**, and **Drug** drop-down lists to limit the number of rows that appear on this page, or select --to include all groups, reviewers, or drugs.

---

**Note:** If you select a reviewer who is assigned to a drug-event combination but not to the drug itself, the drug that is part of that drug-event combination will be listed.

---

The Drug Overviews page refreshes and includes the following information about each drug being monitored. The columns of information that appear depend on how signal management is set up at your organization. Columns that can be included on the Drug Overviews page include the following:

Column	Description
DRUG	Name of the drug. The drug names in this column may be links if your <a href="#">user preferences</a> for Drug Profile Configuration and Drug Profile Layout are both set (and if this feature is set up as part of the drug profile configuration). When you click a drug name, the Drugs tab appears using the layout specified as your user preference. The drug is considered to be the primary drug for the layout and, if the layout is for multiple drugs, you can select comparator drugs.
Group	Name of the group associated with the drug.
<count type>	One or more columns show the number of cases in which the drug has a certain characteristic, such as New reports, Serious adverse events, or Fatal outcomes. The columns that appear are customized to the requirements of each organization. The case count in each <count type> column is a link that you can click to display the Drug-Event Combinations page for the drug using its associated view. If the signal configuration has the review period option enabled, the case count in each of these columns reflects the number of cases with that characteristic for the drug's last review period. As a result, when multiple drugs appear on this page, the counts for each one may reflect activity in a

different time period.


Allow Auto	Yes, if Participates in Automatic Assignment is checked in the Add/Edit Drug dialog box for the drug. Otherwise, No.
Entry Date	Date on which the most recent note was entered for the drug.
Review Period	<p>The frequency with which evaluations are expected to take place for this drug, such as every 3 months, 6 months, or 1 year. Typically, the view assigned to the drug is for the same interval so that the scores, counts, and other data shown on the Drug-Event Combinations page for this drug reflect new information received since the last review.</p> <p>This column appears if the signal configuration has the review period feature set up.</p>
View Name	Name of the default view to use when this drug is selected in the Drug field on the Drug-Event Combinations page, or when you click a count on this page. If this column is blank, the drug is associated with the default view for signal management.

## General activities

- To [add a drug](#), click **Add Drug**.
- To [assign drugs to reviewers automatically](#), click **Auto-Assign to Reviewers**.
- To [view or modify existing automatic assignments](#), click **Modify Automatic Assignments**.

**Note:** You can assign reviewers to drugs and add, edit, or delete drugs only if you have the Administer Signal Management permission.

## Row-specific activities

If you click  for a drug, you can do the following:

- To [enter a drug note](#), click **Enter Note**.
- To [view all notes for the drug](#), click **View Notes**.
- To [view a sector map](#) for the drug, click **View Sector Map**.
- To [edit a drug](#), click **Edit**.
- To delete a drug, click **Delete**. Confirm the deletion by clicking **OK**. You cannot delete a drug if there are notes for the drug, or if there are comments for any drug-event combinations that include the drug.

For information about viewing, printing, or downloading tables or changing the way data appears in the table, see [About tables](#).



You can set your user preference **Allow SQL Where Clause on Signals Tab** to allow use of a SQL WHERE clause to restrict drugs that appear on the page. If this preference is checked, the **Columns** link is replaced by **Columns and Rows**. If you use a SQL WHERE clause to restrict drugs that appear on the page, you must refer to the names of columns in the underlying database table, which might not be the same as the column names that appear on the page. To include a column in the WHERE clause, click **Show Columns** in the **Columns and Rows** dialog box, and click the column name.

## Adding and editing a drug

Your organization chooses which drugs to monitor using signal management capabilities. Typically, organizations arrange for Oracle to identify those drugs during preparation of the signal management data.

The Empirica Signal application also provides a way for you to add drugs manually for signal management monitoring, or to edit monitored drugs.

---

**Note:** After a drug is added manually, the next safety data update includes that drug automatically if it is for an AERS-based, VAERS-based, or Vigibase-based signal management implementation. To assure that an added drug for a customer-specific signal management implementation is included in periodic safety data updates, contact Oracle.

---


1. Click the **Signals** tab.

2. Click **Drug Overviews**.

The [Drug Overviews page](#) appears.

3. To add a drug, click **Add Drug**.

or

To edit the overview of a drug, click the row menu () for an existing drug, then click **Edit**.

The Add/Edit Drug dialog box appears.

4. Enter or modify the following information about the drug:

Field	Description
Drug	Unique name of the drug.
Review period	The frequency with which evaluations are expected to take place for this drug, such as every 3 months, 6 months, or 1 year. Required, if the signal configuration has the Review Period feature set up.
Default view	Name of the signal view associated with the drug. When this drug is selected in the Drug field on the Drug-Event Combinations page, this view is used for the drug by default. If there is a default view for signal management, select -- in this field to specify that view. If the signal configuration has the review period feature set up, the view assigned to the drug is typically for the same time interval so that the scores, counts, and other data shown on the Drug-Event Combinations page for this drug reflects information received since the last review.
Drug group	Group associated with the drug. To select an existing group, click

**Select from existing groups** and select from a list of groups. To add a new group, click **Add new group** and type in a group name.

---

**Note:** Drugs, not reviewers, belong to groups.

---

Reviewers  
(optional)

Names of individual reviewers assigned to the drug. Click **Add Reviewers From List** to [select reviewers from a list](#). If the drug is marked as participating in automatic assignment of reviewers, you can specify only one reviewer.

If there is already a reviewer assigned to the drug, you can select no reviewer (--) to remove the assignment.


Reviewers available for assignment are users in login groups to which the signal configuration is assigned.

---

5. If you want the drug to be eligible for automatic assignment of reviewers, check **Participates in automatic assignment**. This check box is available only if the appropriate site option is enabled.
6. Click **Save**.

## Entering a drug note

You can add a note to a drug. For example, you might indicate which issues for the drug are being investigated or which signals for the drug need further evaluation. The application retains previous versions of the drug note as history and can be viewed when you [view drug notes](#).

1. On the [Drug Overviews page](#), click the row menu () for a drug, and then click **Enter Note**.

The Enter Drug Note dialog box appears and includes the drug name and the date and time a note about the drug was last saved.

Default text defined for your configuration, or the text of the most recently entered note, appears. You can modify it as needed.


2. Enter the text of your note.

Depending on how signal management is configured for your organization, there might additional check boxes.

3. Click **Save**.

The note becomes the current note for the drug.

## Viewing a drug note

1. On the [Drug Overviews page](#), click the row menu () for a drug, and then click **View Notes**.

The Drug Notes History dialog box appears and shows the following information about the current note for the drug and previous versions of the note. Notes are ordered by their Entry Date, with the most recent version of the note appearing first in the list.

Column	Description
Drug	Name of the drug.
Entered By	Name of the user who entered the note.
Entry Date	The date that the version of the drug note was entered.

2. Click **View Note** for the version of the note that you want to view.  
The Drug Note dialog box shows that version of the note.
3. If you want to view all notes for the drug, click **Show All Notes**.
4. To close the dialog box, click **Cancel**.

## Performing auto-assignment

### About automatic assignment of reviewers

Reviewers whose names have been added to the signal management components of the application are eligible for automatic assignment to drugs. You can either assign reviewers to drugs when [adding or editing a drug](#), or use a process that automatically assigns selected reviewers to drugs for which there are new cases since an indicated time period.

The automatic assignment process affects only drugs that have been set up to participate in automatic assignment. (You must have checked **Participates in auto-assignment** when adding or editing the drug.) The process looks at drugs for new cases since the time period you select, and allows you to distribute the drugs evenly over selected reviewers. Because these drugs might already have assignments (due to previous cases), the automatic assignment process can result in re-assignments. Drugs for which there are no new cases (since the last period), but that have been set up to participate in automatic assignment, have their reviewer assignments cleared.

The following table shows how assignments of reviewers to drugs that have been set up to participate in automatic assignment are affected by the automatic assignment process:

	Have new cases	Do not have new cases
Already Assigned	Re-assigned if you select them. Retain previous assignments if you do not select them.	Assignments are cleared.
Unassigned	Assigned if you select them. Remain unassigned if you do not select them.	Remain unassigned.

### How reviewers are distributed over drugs

The application does the following during the automatic assignment process:

1. Orders the drugs in ascending order of the number of new cases.
2. For the first drug in the ordered list, assigns the first reviewer in the list of Selected reviewers that you have chosen.
3. For the next drug in the ordered list, assigns the next reviewer in the list of Selected reviewers.
4. Continues to assign drugs until all drugs have been assigned. When the application reaches the end of the list of Selected reviewers, the applications starts again with the first reviewer in the list.

When a drug that is already assigned to a reviewer is re-assigned, no attempt is made to retain the currently assigned reviewer. However, it is possible for the drug to be re-assigned to the same reviewer coincidentally.

You can force a drug that appears in new cases to retain its current assignment by excluding it from the [automatic assignment process](#).

### **Overriding automatic assignments**

At the end of the automatic assignment process, the application displays the automatic assignments that have been made to drugs and you have the opportunity to override assignments. You can also override the automatic assignment for a drug on the [Automatic Assignment page](#) or by editing a drug and changing the reviewer.

## Automatically assigning reviewers

1. Click the **Signals** tab.
2. Click **Drug Overviews**.  
The [Drug Overviews page](#) appears.
3. Click **Auto-Assign to Reviewers** (available only if the appropriate site option is set and you have the Administer Signal Management permission).
4. Select a signal set and time period, and click **Next**. Only time periods for which there are new cases are available to select. If there are no time periods with new cases for a signal set, the signal set is not available to select.
5. [Select reviewers from a list](#), and click **Next**. Available reviewers for assignment are those in login groups to which the signal configuration is published.
6. [Select drugs from a list](#), and click **Next**. Available drugs are those that are marked as allowing participation in automatic assignment and for which there are new cases since the selected time period.
7. Click **Next**.  
The Automatic Assignments dialog box appears, showing the reviewer assignments to be made. The number of new cases for each drug is also shown.
8. Click **Assign**.

You can [review or override automatic assignments](#).




## Viewing or modifying automatic assignments

The Automatic Assignments page provides information about drugs that have been assigned automatically to a reviewer. There is one reviewer per drug. This page does not show assignments that were made manually (when the drug was added or edited).

1. On the [Drug Overviews page](#), click **Modify Automatic Assignments** (available only if the appropriate site option is set up and you have the Administer Signal Management permission).

The Automatic Assignments page appears and provides the following information about each drug that currently has a reviewer (who has been assigned automatically):

Column	Description
Drug	Name of the drug.
Reviewer	Name of the reviewer who has been assigned automatically to the drug.

2. If rows have been filtered using a SQL WHERE clause in the Column and Rows dialog box, the text, **Rows are filtered**, appears above the table. Rest the cursor on that text to see the SQL WHERE clause that is in effect. For more information, see [Filtering drug-event combinations using a SQL WHERE clause](#).
3. To change a reviewer assignment to a drug, click the row menu () for the drug, and then click **Change**. Then select another reviewer and click **OK**. You can also select no reviewer (--) to remove an assignment. Available reviewers for assignment are those in login groups to which the signal configuration is assigned.

## Working with drug-event combination comments

### Drug Comments page

Comments can be added to drug-event combinations when you are [documenting](#) your review for one or multiple combinations.

For each drug, the Drug Comments page shows the count of each different comment type that has been entered for that drug in combination with any event. Only the most recently entered comment for each drug-event combination is included in each count.

If the signal configuration is integrated with topics, the Drug Comments page shows the count, per drug, of topics associated with drug-event combinations in each different topic workflow state.

If the signal configuration has the private comments feature set up, counts appear for either public comments added by any user or the private comments that you have entered. Only the most recently entered comment, either public or private as selected, for each drug-event combination is included in the count. (For a superuser, the counts of private comments include only the most recent private comments you personally entered, not private comments entered by any user.)

You can also view all or a subset of the [detailed comments](#) entered for a drug from the Drug Comments page.

### General activities

The following filters appear at the top of the page and affect the entire page.

- Group
- Reviewer
- Drug

You can limit the drugs that appear in the table by using the filters. You can set user preferences for default values to appear in the Group, Reviewer, and Drug filters. If you select a drug Group, the Reviewer and Drug filters are affected as follows:

- In the Reviewer filter, you can select reviewers assigned to drugs in the specified drug group.
- In the Drug filter, you can only select drugs in the specified drug group. If you specify a reviewer, only drugs to which that reviewer is assigned and drugs from drug-event combinations to which that reviewer is assigned displays.

To include all drugs, in the Group, Reviewer, or Drug filters, select —. You can also specify **None**.

The following links appear at the top of the page and affect the entire page:

- [Columns](#)
- [Print](#)
- [Download](#)

- Select Rows

You can set your [user preference](#), **Allow SQL WHERE Clause on Signals Tab**, to allow use of a SQL WHERE clause to restrict the rows that appear on the page. If this preference is checked, the **Columns and Rows** link replaces the **Columns** link.

If you use a SQL WHERE clause to restrict the rows that appear on the page, refer to the names of columns in the underlying database table, which might not be the same as the column names that appear on the page. To include a column in the SQL WHERE clause, click **Show Columns** in the Columns and Rows dialog box and click the column name.

The following links appear at the top of the page when the page is in the Select Rows mode. The links affect the selected drug comments:

- [Print](#)
- [Download](#)
- [View Comments](#)
- Select All
- Clear All
- Back

The following options appear at the top of the page and affect the entire page:

If Signal Management is integrated with Topics:

- **Show counts of: Public Comments and Topic Associations**—Displays the count of each different comment type that has been entered for that drug in combination with any event and the count of topics associated with each drug-event combination in each Topic State.

If Signal Management is not integrated with Topics:

- **Show counts of: Public comments**—Displays the count of each different comment type that has been entered for that drug in combination with any event.

**If Signal Management supports private comments:**

- **Show counts of: Private Comments**—Displays the count of each different private comment type that has been entered for that drug in combination with any event. For a superuser, the private comments only include the most recent private comments you entered, not private comments entered by any user.

### Row-specific activities

The [View Comments](#) menu option is available from the row menu, located in the left column of the table, and affects an individual row in the table. It allows you to see the detailed comments for combinations involving a particular drug.

### Field descriptions—Drug Comments page

<b>Field</b>	<b>Description</b>
Drug	Drug name.
Group	Group name associated with the drug in the drug.
Comment:No Comment	The number of drug-event combinations that include the drug and do not have a comment.  If a drug-event combination had a comment and the comment was cleared, the combination is considered to have no comment.
Comment:<comment- type>	The number of drug-event combinations that include the drug and have this type of comment. To determine the count, only the (public or private) comment attached most recently to a drug-event combination is used.
Topic:No Topic	The number of drug-event combinations that include the drug and do not have an associated topic.
Topic:<state>	The number of drug-event combinations that include the drug and have an associated topic in this state.

## Viewing detailed comments for a drug

1. Select the Signals tab, and click the **Drug Comments** link.

The Drug Comments page appears.

2. Select the row menu () , and select **View Comments**.

The View Comments dialog box appears.

---

**Note:** On the Drug Comments page, click **Select Rows**, then click **View Comments** to view comments for multiple drugs.

---

3. In the View Comments dialog box, do the following:

- From the **View comments** drop-down list, select **All** or **Most Recent**.
- From the **Comment type** drop-down list, select **Private**, **Public**, or **All**.

Private comments, public comments entered by all users, or both appear. Superusers can see private comments entered by any user.

- Optionally, enter a **Start date**, an **End date**, or both to limit the comments to a specific date range.

4. Click **View Comments**.

The View Drug Comments page appears.

---

**Note:** You can set your user preference to allow the use of an SQL WHERE Clause to restrict drugs that appear on this page. If you select this preference, the **Columns and Rows** link replaces the **Columns** link.

If you restrict drugs, you need to refer to the column names in the underlying database table, which may not match the column names that appear on the page. To include a column in the WHERE Clause, click **Show Columns** in the Columns and Rows pop-up and click the column name.

---

5. To show information about the comments that display, click **Show Notes**. The notes appear below the table and the application includes them if you print or download table data.
6. To exclude the notes. click **Hide Notes**.
7. To save the comments to a topic, click **Save to Topic**.

The comments appear as an attachment to the topic.

## Field descriptions—View Drug Comments page

Field	Description
Drug	Name of the selected drug.

Event	Name of an event that is reported in combination with the drug.
Created	Date and time the comment was added.
Created By	Name of the user who added the comment.
Filtered	<ul style="list-style-type: none"> <li>• If the comment was entered when the drug-event combination was suppressed, <b>Yes</b> appears.</li> <li>• If the comment was entered for a drug-event combination that was not suppressed, <b>No</b> appears.</li> <li>• Empty (blank) for private comments (if the signal configuration has the private comments feature set up).</li> </ul>
Comment	Comment for the drug-event combination.
Private	<p>Appears if the signal configuration has the private comments feature set up.</p> <ul style="list-style-type: none"> <li>• <b>Yes</b>—A private comment.</li> <li>• <b>No</b>—A public comment.</li> </ul>
Detailed Comment	The optional free text added with the comment. This column appears only if the corresponding site option has been set.

## Adding a comment to multiple combinations

1. On the **Drug-Event Combinations** page, click **Select Rows**.
2. Select the check box of one or more drug-event combinations.
3. Click **Document Review**.

The Document Review dialog box appears.

---

**Note:** If the signal configuration supports private comments and you want to add a private comment, click **Add Private Comment** instead of **Document Review**.

---

4. From the **Comment** drop-down list, select a comment.
5. In the **Detailed comment** text box, provide a comment by typing in the text of the comment. This option is available if the appropriate site option has been set.
6. Click **OK**.

The comment is added for all of the selected combinations.


A list of all comments added to a drug-event combination appears in the Comments section of the View Signal History page. You can also view counts of the comments added for combinations involving a drug on the [Drug Comments page](#), or select a drug and view [detailed comments](#).

## Adding a private comment

You can add a private comment to a drug-event combination on the Drug-Event Combinations page if the signal management configuration allows private comments.

1. Click the **Signals** tab.

The Drug-Event Combinations page appears.

2. Click the row menu () for a drug-event combination, and then click **Add Private Comment**.

The Add Private Comment dialog box appears.

3. From the **Comment** drop-down list, select a predefined comment.
4. In the **Detailed comment** text box, enter a detailed comment (optional). This option is available if the appropriate site option has been set.
5. Click **OK**.

The private comment appears for the drug-event combination.

---

**Note:** The private comment is visible to only you and superusers.

---



## Using sector maps

### Viewing a sector map (Signals tab)

A sector map for signal management data is a visual presentation of data for a particular drug across all System Organ Classes (SOCs). Each System Organ Class (SOC) is represented by a large tile in the sector map. Smaller tiles within each SOC tile represent Preferred Terms (PTs). The color, size, and ranking of tiles provide a big picture overview of the adverse event profile of a drug. Data represented in the sector map includes all available data up through the current time period and is for a particular [signal set](#).

You view a sector map for a particular drug. PTs are ranked in descending order of values of the statistic (EBGM, EB05, Chi-statistic, or PRR) that you choose. A color key indicates relative ranking. You can also list the ranked PTs below the sector map.


---

**Note:** The primary path of a PT is used to determine where it appears in the sector map. If a PT is not in the event hierarchy used for the drug-event combinations, it appears in a SOC tile named Unknown.

---

The list of ranked PTs below the sector map includes the following information:

Column	Description
Rank	Ranking of the term (combined with the drug) according to values of the statistic you have configured the sector map to use (via the Color controlled by option).
SOC	SOC containing the term.
Term (PT)	Specific PT.
EBGM, EB05, Chi-statistic, or PRR	Value of the statistic you have configured the sector map to use (via the Color controlled by <a href="#">option</a> ).

- On the [Drug Overviews page](#), click the row menu () for a drug, and then click **View Sector Map**.  
The Sector Map window appears.
- If you want to [set display options for the sector map](#), click **Options** below the sector map.
- If you point to a PT tile, the MedDRA PT, HLT, HLG, and SOC appear. The following information for the combination of the drug and the term that the tile represents also appears:
  - N**—Observed number of cases with term.

- **EBGM**—Empirical Bayesian Geometric Mean. A more stable estimate than RR; the so-called shrinkage estimate. For more information, see MGPS computations.
  - **EB05**—A value such that there is approximately a 5% probability that the true Relative Ratio lies below it.
  - **PRR**—Proportional Reporting Ratio. For more information, see PRR computations.
  - **Chi-statistic**—Chi-statistic associated with PRR. (If EBGM < 1, the Chi-statistic is expressed as a negative number, indicating that the drug-event combination is more rare than expected). The Chi-statistic is the signed square root of Chi-square.
4. To [zoom in](#) on a particular SOC, click anywhere on the SOC tile and select **Zoom** from the menu.
  5. If you click a tile for which N is at least 1, a menu appears and you can [drill down](#) to cases that include the PT represented by the tile or view statistics for the tile.
  6. To [save the graph as an attachment to a topic](#), click **Save to Topic**. (This option is available if **Links** is checked and the Topics feature has been set up.)
  7. To close the Sector Map window, click **Cancel**.

For information about copying or printing a graph, see [Working with results graphs](#). For best results, print the sector map in landscape mode.

## Setting display options for a sector map (Signals tab)

1. On the [Sector Map window](#), click **Options** (below the sector map).  
The Sector Map Options dialog box appears.
2. Change any of the following options:

Column	Description
Color controlled by	Name of the statistic whose values is ranked and is used for coloring the sector map tiles. Possible values are any of the following that are available in the signal management data prepared for your organization: EBGM, EB05, PRR, Chi-statistic (signed).
Term box size controlled by	<p>One of the following options indicating what controls the size of PT tiles:</p> <ul style="list-style-type: none"> <li>• <b>Relative importance of term</b>—Bases the size of PT tiles on an algorithm that determines the relative public health impact of PTs. Using a recent version of AERS data, the public health impact for a PT is computed as: (number of times the PT occurs in serious cases) * (proportion of cases with that PT that are serious or fatal)</li> </ul> <p>A higher Public Health Impact score corresponds to a larger tile in the sector map. Because size is based on the number of cases of the PT alone (not the number of cases that have the PT and a particular drug), the tile size is stable over sector maps for different drugs.</p> <hr/> <p><b>Note:</b> For PTs that are new in the MedDRA version associated with the AERS data used to assess public health impact, the tile size cannot be determined. Such PTs are represented as small tiles.</p> <hr/> <ul style="list-style-type: none"> <li>• <b>All terms have equal size</b>—All PT tiles have the same size.</li> </ul>
Display maximum intensity at signal score of	All tiles for which scores are above this value are displayed at the maximum-intensity color, as shown in the color key below the graph.
Use gray-scale instead of colors	Use only shades of gray in the color key to represent score ranking.
Show low scores in green for color graph	<p>Check to show low scores in varying shades of green. Clear to show low signal scores in black.</p> <hr/> <p><b>Note:</b> This setting has no effect if you display the sector map in gray-scale.</p>

Omit rare terms used fewer than __ times in AERS	<p>Number indicating how many times a PT must be in the AERS database (the same one used for Relative importance of term) for that PT to be shown in the sector map.</p> <hr/> <p><b>Note:</b> The notes for a sector map indicate any rare terms that are omitted because of this restriction.</p>
Group by HLT	<p>Within a SOC tile, group in the same rectangular area the tiles for PTs that are in the same HLT. If you also group by HLGT, the tiles for PTs are grouped by HLT within each HLGT.</p>
Group by HLGT	<p>Within a SOC tile, group in the same rectangular area the tiles for PTs that are in the same HLGT.</p>
List __ top scores	<p>Number indicating how many (up to 1000) terms with the top scores are ranked and listed below the sector map. The score is the statistic selected for <b>Color controlled by</b>.</p> <p>If multiple terms have the same score, each term is counted separately. For example, suppose that you enter 20 as the limit. If the 20th row has a score that other terms after that also have, those additional terms are shown as well.</p>
Show top score indexes	<p>If checked, tiles in the sector map are numbered to show their rank, up to the number of scores specified in <b>List __ top scores</b>. For this option to take effect, there must also be a value specified for <b>List __ top scores</b>.</p>
Key	<p>Display a color key below the graph.</p>
Notes	<p>Display information about graph display options below the graph.</p>
Links	<p>Show the following:</p> <ul style="list-style-type: none"> <li>• Information about what a tile represents when you place the mouse over the tile.</li> <li>• A menu that appears when you click a tile.</li> <li>• A <b>Print</b> link for printing the graph.</li> <li>• A <b>Save to Topic</b> link to save the graph as an <a href="#">attachment to a topic</a> (if the topics feature has been set up)</li> </ul> <p>Before copying a graph (for example, with copy and paste functions), you might want to clear this check box so that links are not included in the copy.</p>

3. Click **OK**.

## Zooming in on a sector map

If you zoom in on a particular SOC tile in the sector map, data only for that SOC appears in the zoom window.

1. On the sector map, click a SOC tile.
2. From the menu, click **Zoom**.  
A sector map of the selected SOC tile appears.
3. You can perform all the same actions as when [viewing the main sector map](#), except that you cannot zoom in further. Note that the ranking of PTs changes because you are viewing PTs for only one SOC.
4. To close the dialog box, click **Cancel**.

## Viewing sector map statistics

1. On the sector map or in the zoom window, click a PT tile.
2. From the menu, click **Statistics**.

A dialog box appears showing the following statistics for the combination of the drug and event:

- **N**—Observed number of cases.
  - **EBGM**—Empirical Bayesian Geometric Mean. A more stable estimate than RR; the so-called shrinkage estimate. For more information, see [MGPS computations](#).
  - **EB05**—A 5% probability value that the true Relative Ratio lies below it.
  - **PRR**—Proportional Reporting Ratio. For more information, see [PRR computations](#). The PRR and Chi-statistic are available only if the data mining run was set up to compute PRR.
  - **Chi-statistic**—Chi-statistic associated with the PRR. (If EBGM < 1, the Chi-statistic is expressed as a negative number, indicating that the drug-event combination is more rare than expected). The Chi-statistic is the signed square root of Chi-square.
3. To close the dialog box, click **Close**.

## Working with topics

### About topics

To manage the process of identifying and investigating drug safety issues, including organizing the collection and interpretation of information from different sources over time, you can create topics. A topic can help you and the other members of your work team track an issue throughout the process of researching and resolving it. You update the progress of the topic through different stages of work using statuses such as Initial, Reviewed, or Completed. You can monitor topics from creation to completion on the Topics tab and by using reports. You can also download all, or a selected subset, of the information stored with a topic at any time to a PDF file.

When you create and edit topics, information is collected using a structured, predefined layout of fields. While a sample, standard layout is provided with Empirica Signal, it is likely that your organization has customized the layout supplied with the application to meet the specific requirements of your organization:

- The fields that store information.
- The values that you can supply for each field.
- The workflow states that you can assign.
- The types of attachments you can add: Empirica Signal objects including run results, graphs, reports, and query results, or website URLs or document files.
- The option to add free text comments.
- The rules for sending automated email notifications triggered when a topic or action is added or modified, a change is made to its workflow state, an action due date is nearing, or the topic is assigned to a different user.

All of these attributes are stored in a topic workflow configuration that is managed by an administrator at your organization. You can design topic workflow configurations to meet the needs of different groups in your organization. For example, a collaborative topic workflow configuration might structure the participation of several members of a work team on every topic, while a separate notebook topic workflow configuration might allow individuals working in another part of your organization to track their own issues over time without the participation of other users. Alternatively, a single topic workflow configuration might allow you to work cooperatively with others on projects using topics and also allow you to track your own issues by setting up topics that you leave assigned just to yourself. If your organization defines more than one topic workflow configuration, the topics that you enter are based on just one of them. As a result, members of different groups in your organization might work with topics in different ways, supplying different types of information or assigning different workflow states.

If your organization uses Signal Management, a topic workflow configuration can be integrated with a Signal Management Configuration. Topics associated with drug-event combinations will be stored and managed in the integrated topic workflow configuration. The integrated topic workflow configuration can differ from the one used on the Topics tab. If distinct, the Save to Topic dialog will display the name of the Topic Workflow Configuration in which a topic is saved.

---

**Note:** When describing topic-related activities, help topics reference the topic workflow configuration supplied with the application.

---

You access topics through the Topics tab. you must have the View Topics [permission](#) and an administrator must set up the topics feature for your use, including assigning a topic workflow configuration to your login group, and, if needed, assigning work team permissions. For information on setting up the topics feature see [Setting up topic workflow](#).



## Topics page

On the Topics page, you can view information about existing topics and add topics, if you have the required permission.

### General activities

The following links and filters appear at the top of the page and affect the entire page:

- [Add Topic](#)
- [Report](#) (available if OBIEE is enabled )
- [Select Rows](#)
- [Columns](#)
- [Print](#)
- [Download](#)
- [Project drop-down list](#)
- Additional drop-down lists, as defined for your organization

The following links appear at the top of the page when the page is in the Select Rows mode. The links affect the multiple topics:

- [Print](#)
- [Download](#)
- [Reports](#)
- Select All
- Clear All
- Back

### Row-specific activities

The following menu options are available from the Row menu, located in the left column of the table, and affect an individual row in the table:

- [View](#)
- [Edit](#)
- [Reopen](#)
- [Create PDF](#)
- [Create ZIP](#)
- Delete

### Field descriptions—Topics page

The Topics page provides information about topics that are visible to a work team of which you are a member. If you have created any topics those topics also appear. The table that

appears might include these standard columns, and additional columns customized for your organization:

<b>Field</b>	<b>Description</b>
ID	Unique identifying number for the topic.
Work teams	The work team(s), if any, to which this topic is visible.
Project	Project, if any, with which the topic is associated.
Name	Name of the topic.
Topic description	Description of the topic.
Current state	The state of the topic in the topic workflow. States are defined by your organization to represent expected workflow stages and are specified in the topic workflow configuration.
Reason for change	Last reason for change, if any, provided for the topic.
Assigned to user	Name of the user to whom the topic currently is assigned.
Keywords	Keywords, if any, associated with the topic. This is the column that is searched if you select a keyword at the top of the page.
Resolution	Last resolution, if any, provided for the topic.
Resolution date	Date and time when a resolution was provided.
Size	Total size of all attachments, including attachments to the topic and to any actions. Also includes attachments that have been deleted from the topic or its actions. (Deleted attachments are retained in the database, although they cannot be accessed from within the application.)
Attachment count	Total count of attachments to the topic and to any of its actions. (Deleted attachments are not included in this count.)
Created	Date and time when the topic was created.
Created By	Name of the user who created the topic.
Modified	Date and time when the topic was last modified. (Interim modifications to the topic are tracked in the History of Topic General Information section of the Topic page.)
Modified By	Name of the user who last modified the topic.



The table may also include columns for custom fields added by your organization.

## Sections of the Topic page

On the Topic page, you can view and edit topic information. The page includes sections in which you can view general information about the topic, topic links, comments, attachments, actions, and history. When the page is in Edit mode, you can also perform activities based on your permissions and topic workflow configuration.

To expand the sections on this page, click **Show All**, or click  for a single section. To hide section details, click  for a section or click **Hide All**.

### Sections


Section	Description	Available actions
Topic General Information	<p>Displays the current field values that describe a topic:</p> <ul style="list-style-type: none"> <li>The fields might be read-only, editable, or required. If a field is required, an asterisk (*) appears next to it and you cannot save the topic until you provide a value for the field.</li> <li>Each field accepts text, numeric, or date values, or provides a list of predefined values that you can select. If a value is not required in the field, you can select <b>(a blank value)</b> to indicate no value for the field. A field that accepts text may also offer a <b>Select Available Values</b> link so you can select one or more values from a list.</li> <li>Arrow icons may appear after the names of a pair of fields to show that they are a linked pair. For example, if fields for MedDRA SOC () and MedDRA HLGT () appear, the arrows indicate that you must select a value for the MedDRA SOC field first and then select a value for the MedDRA HLGT field. You cannot select an HLGT value first: the values available for HLGT depend on the SOC you select.</li> <li>The <b>Visible to work teams</b> field displays a comma-separated list of work teams whose members can use the topic. When the page is in the edit mode, it appears as a list.</li> <li><a href="#">In edit mode</a>, to save changes to the Topic General Information section, click <b>Save</b>. Saved changes are shown as entries in the History of Topic General Information section.</li> </ul> <p><b>Note:</b> The <b>Save</b> button affects only the Topic General Information section of the topic. You do not need to click <b>Save</b> after you work with other sections of this page.</p>	None
Topic Links	Displays information about the topics that are linked to a	<a href="#">View</a>

topic. When the page is in edit mode, you can click **Add Topic Link** to select a topic and link it to this one. For each linked topic, you can click **Remove Link** or **View details** about the linked topic.

A set of filters appear for the section, determined by the Filter attribute on the Topic context fields in the Workflow Configuration. These might include some or all of the following, plus filters customized for your organization:

- **Project**—Includes projects that contain the linked topics.
- **Current state**—Includes current topic states of the linked topics.
- **Assigned to user**—Includes names of users currently assigned to the linked topics.
- **Name**—Includes names for the linked topics.

[Remove Link](#)  
[Columns](#)  
[Print](#)  
[Download](#)

Topic Comments	Displays each comment added to the topic. When in the edit mode, you can click <b>Add Topic Comment</b> to add a comment. You cannot modify or remove a comment.	None
	<b>Note:</b> This section appears only if your topic workflow configuration allows topic comments.	
Topic Attachments	Displays information about each item attached to the topic. Your topic workflow configuration determines the types of attachments you can add, such as files, URLs, free-text notes, or Empirica Signal objects. When in the edit mode, you can click <b>Add Topic Attachment</b> to add a document-style attachment (for example, file, URL, or note).	<a href="#">View</a> <a href="#">View Source Details</a> Comments <a href="#">Edit</a> Delete <a href="#">Columns</a> <a href="#">Print</a> <a href="#">Download</a>
Topic Actions	Displays a list of each specific activity identified for the topic. Actions may reflect research activities, such as literature searches and scheduled meetings, or any other activity you wish to track for the topic. In the edit mode, you can click <b>Add Topic Action</b> to add an action, or click  to edit, add attachments, or add comments.	<a href="#">View</a> <a href="#">Edit</a> Delete <a href="#">Columns</a> <a href="#">Print</a> <a href="#">Download</a>
History of Topic General Information	Displays information on changes that have taken place for the topic. A new row is added to the table each time you click <b>Save</b> in the Topic General Information section.	None <a href="#">Columns</a> <a href="#">Print</a>

---




## Field descriptions—Topic General Information

Depending on your organization's workflow configuration, the following fields appear in this section.

Field	Description
Visible to work team(s)	The work team or teams whose members can view or act on the topic. You can click <b>Browse</b> to select a work team from a descriptive list.
Topic name	Name of the topic.
Current state	<p>State of the topic in the topic workflow. States are specified in the topic workflow configuration to represent your organization's expected workflow for topics.</p> <p>A topic may require all of its associated actions to be in a final state before you can assign a final state to the topic itself. In this case, a message appears if you try to assign a final state to the topic with actions that are not in a final state.</p>
Assigned to user	User to whom the topic is assigned. By default, a topic that you add is assigned to you. If you assign the topic to a different user, that user can view or act on the topic, depending on his or her work team permissions.
Keywords	Free text that you can use to filter the topics that appear in a table, or to search for a topic. There might be many keywords included for the topic.

If another user edits the same topic at the same time, the first one to save the topic will have their changes saved. The second user will get an error indicating the topic has been changed since the edit session began. In some cases, the General Information section of the page becomes visible, allowing the user to print or take a screen shot, so that the information can be re-entered.

## Viewing a topic

1. Click the **Topics** tab.  
The Topics page appears.
2. Click the row menu () for a topic, and then click **View**.  
The Topic page appears. For information on each section of the Topic page, see [Sections of the Topic page](#).  
You can expand and collapse the sections by clicking **Show All** and **Hide All**.
3. View different aspects of a topic by selecting a topic section.
  - A. To display general information about the topic, click **Topic General Information**.
  - B. To display the topics linked to the topic, in the **Topic Links** section, click , and select **View**. The application displays the linked topic in a dialog box.
  - C. To view comments about the topic, click **Topic Comments**.
  - D. To view topic attachments, click **Topic Attachments**. Then click  for an attachment and do any of the following:
    - i. To view the attachment, click **View**.
    - ii. To view details about the topic source, click **View Source Details**.
    - iii. To view comments about the attachment, click **Comments**.
  - E. To display actions for the topic, click **Topic Actions**.
    - i. To view the action, click **View**.
  - F. To view the history of the topic, click **History of Topic General Information**.

## Editing a topic

1. Click the **Topics** tab.

The Topics page appears.

2. Click the row menu () for a topic, and then click **Edit**.

The Topic page appears. For information about the section of the page, see [Sections of the topic page](#).

3. In the Topic General Information section, select values from drop-down lists or type values in the fields.
4. If your changes are complete, click **Save**.

or

You can make changes in the other sections:

- A. In the **Topic Links** section, do any of the following:
  - To select a topic and link it to the current topic, click **Add Topic Link**. Follow the steps in [Linking topics](#).
  - To view a linked topic, click , and then click **View**.
  - To remove a link, click , and then click **Remove Link**.
- B. In the **Topic Comments** section, click **Add Comments** to add a comment.

When a comment is added it cannot be modified or removed. For more information, see [Adding and viewing comments](#).
- C. In the **Topic Attachments** section, click **Add Topic Attachment** to add a document-style attachment (for example, file, URL, or note). For more information, see [Adding a document-style attachment](#).
- D. In the **Topic Actions** section, click **Add Topic Action** to add an action. For more information, see [Adding a topic action](#).

5. Click **Save**.



## Adding a topic

1. Click the **Topics** tab.

The Topics page appears.

2. Click **Add Topic**.

The Add Topic page appears with a set of fields for topic-related information. The specific fields that appear depend on your topic workflow configuration.

---

**Note:** You may also be able to add a new topic when you [save an attachment to a topic](#) from other pages in the application.

---

3. In the **Topic template** field, select a topic template that can provide default values for the Topic General Information and Topic Actions, or click **Browse** to select from a detailed table of topic templates.

The Topic template field is available only if there are templates that have been made visible to a work team in which you are a member

4. In the **Visible to work team** field, [select the work team or teams](#) whose members can view or act on the topic, or click **Browse** to select from a detailed table of work teams. For more information, see [Selecting a work team](#).

Available work teams are those for which you have the edit topics/actions permission. Your topic workflow configuration defines whether you must specify a single work team (from the **Visible to work team** drop-down list) or you can select zero, one, or multiple work teams (from the **Visible to work team** list box).

---

**Note:** If you do not select any work teams, only you are able to view and act on the topic.

---

To select multiple work teams in the list box, hold down the Ctrl key while clicking each work team. Deselect a work team by holding down the Ctrl key while clicking the work team.

5. Specify values for the rest of the fields.
  - Each field is display-only, editable, or required. If a field is required, an asterisk (\*) appears next to it and you cannot save the topic until you provide a value.



---

**Note:** When a topic is created during the process of saving another Empirica Signal object as an attachment, requirements for the initial state are not enforced until the topic is edited.

---

- Each field accepts text, numeric, or date values, or provides a list of predefined values that you can select. If a value is not required in such a field, you can select " " (a blank value) to indicate no value for the field. A field that accepts

text or numeric values might also offer a **Select Available Values** link so that you can [select one or more values from a list](#).

- Arrow icons might appear after the names of a pair of fields to show that they are a linked pair. For example, if fields for MedDRA SOC  and MedDRA HLGT  appear, the arrows indicate that you must select a value for the MedDRA SOC field first and then select a value for the MedDRA HLGT field. You cannot select an HLGT value first. The values available for HLGT depend on the SOC you select.

The fields listed below are standard fields that might appear on the Topic page when you add a topic.

<b>Fields</b>	<b>Description</b>
Topic name	Name of the topic.
Topic description	Description of the topic.
Current state	The state of the topic in the topic workflow. States are defined by your organization to represent the expected workflow, and are specified in the topic workflow configuration.
Assigned to user	User to whom the topic is assigned. By default, a topic that you add is assigned to you. If you assign the topic to a different user, that user can view or act on the topic. Available users are those in all work teams to which the topic has been made visible and who have the Edit Topic/Action work team permission .
Keywords	Free text that you can use to filter (limit) the topics that appear in a table, or to <a href="#">select a topic</a> .

Additional, custom fields might also be available.

6. Optionally, assign the topic to a [project](#).
  - To assign the topic to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.
  - To create a new project and assign the topic to it, click **Add to a new project named** and enter a project name.
7. Do one of the following:
  - A. Click **Save**.

The topic is created and an entry is added to the History of Topic General Information section.

- B. Click **Save & Edit** to continue editing the topic.

## Selecting a work team

A work team is a group of Empirica Signal users who have an interest in a set of topics. When a topic is made visible to a work team, the members of that team can view the topic and any actions defined for it. The topic and its individual actions can also be assigned to different members of the work team. Users with appropriate work team permissions can then edit the topic or action in addition to viewing it.

1. Click the **Topics** tab.

The Topics page appears.

2. Click **Add Topic**.

The Add Topic page appears with a set of fields for topic-related information. The specific fields that appear depend on your topic workflow configuration.

3. Next to the **Visible to work team** field, click **Browse**.

The Browse Work Teams dialog box appears and provides information about each work team for which you have the edit topics/actions permission, in a table that might include these standard columns:

<b>Column</b>	<b>Description</b>
Name	The name of the work team.
Description	Descriptive text about the work team.
Login Group	The name of the login group. Each work team is a subset of a login group.
All Users	Yes, if all users in the login group are members of the work team. No, if users have been individually added to the work team.
Users	The full name and Empirica Signal username of each member of the work team. Blank, if all users in the login group are members of the work team.
Created By	Name of the user who created the work team.
Created	Date and time when the work team was created.
Modified By	Name of the user who last modified the work team.
Modified	Date and time when the work team was last modified.

The table may also include columns for custom fields added by your organization.

4. Click the radio button of the row for the work team that you want to select.

5. Click **OK**.

The Add Topic page appears with the selected work team in the **Visible to work team** drop-down list.

For information about viewing, printing, or downloading tables or changing the way data displays in the table, see [About tables](#).


## Linking topics

When you edit a topic, you can add a cross-reference from that topic to another topic by adding a topic link. After you link two topics, information about the link appears in the Topic Links section when you view or edit either of the topics.


---

**Note:** Your topic workflow configuration defines whether you can link a topic to any other topic, or only to topics that are currently in a final state such as Closed.

---

1. Click the **Topics** tab.  
The Topics page appears.
2. Click the row menu () for the topic, and then click **Edit**.  
The Topic page appears.
3. In the **Topic Links** section, click **Add Topic Link**.  
The Add Topic Link dialog box appears, listing all available topics.
  - Available topics are those that you can edit, which might include those that you created or that have been made visible to a work team of which you are a member. Topics might also be limited to those that are in a final state only (based on your topic workflow configuration).
4. Optionally, limit the display using the lists that appear above the table. For example, select a [project](#) or enter a keyword to list only topics that match the specified project or keyword.
5. Click the radio button of the row for the topic that you want to select.
6. Click **OK**.  
The Topic page appears. The selected topic appears in the Topic Links section.

### To remove a link:

1. Click the **Topics** tab.  
The Topics page appears.
2. Click the row menu () for the topic, and then click **Edit**.  
The Topic page appears.
3. In the **Topic Links** section, click **Remove Link**.
4. To the message asking if you want to remove the link, click **OK**.

## Adding and viewing comments

Your topic workflow configuration might give you the ability to add comments to all, some, or none of the following:

- A topic as a whole.
- Individual topic actions.
- Topic attachments and action attachments.

If this feature is available for one or more of these contexts, when you view a topic, action, or attachment, you can also view all of its comments. When editing a topic, action, or attachment, you can both view and add comments.

---

**Note:** Once you have added a comment, you cannot edit or delete it.

---

### Viewing or adding comments for a topic

You view and add comments about a topic as a whole in the Topic Comments section of the Topic page.


1. Click the **Topics** tab.  
The Topics page appears.
2. To view comments only, click the row menu () for the topic, and then click **View**.  
The Topic page appears. Comments about the topic appear in the Topic Comments section.  
or  
To add a comment, click  for the topic, and then click **Edit**.  
The Topic page appears.
  - A. In the Topic Comments section, click **Add Comment**.  
The Add Comment dialog box appears.
  - B. In the text box, enter the comment.
  - C. Click **Save**.  
The comment appears on the Topic page in the Topic Comments section.

### Viewing or adding comments for an action

You view and add comments about an action in the [Action Comments section of the Topic Action page](#).

1. Click the **Topics** tab.

The Topics page appears.

2. To view action comments only, click the row menu () for the topic, and then click **View**.

The Topic page appears.

- A. In the **Topic Actions** section, click  for the topic action, and then click **View**.

The Topic Action page appears.

- B. Expand the **Action Comments** section to view all comments for an action.

or

To add an action comment, click  for the action, and then click **View**.

The Topic page appears.

- A. In the **Topic Actions** section, click  for the topic action, and then click **Edit**.

The Topic Action page appears.

- B. In the **Action Comments** section, click **Add Comment**.

The Add Comment dialog box appears.

- C. In the text box, enter the comment.

- D. Click **Save**.


The Topic Action page appears. The comment appears in the Action Comments section.

## Viewing or adding comments for an attachment


You work with attachments to a topic, including any comments on those attachments, in the Topic Attachments section of the Topic page. You work with attachments to an action, including any comments on those attachments, in the [Action Attachments section of the Topic Action page](#).

1. Click the **Topics** tab.

The Topics page appears.


2. To view attachment comments only, click the row menu () for the topic, and then click **View**.

The Topic page appears.


- A. In the **Topic Attachments** section, click  for the topic attachment, and then click **Comments**.



The Comments dialog box appears and displays any comments.

To add a comment to an attachment, click  for the topic, and then click **Edit**.

The Topic page appears.

- B. In the **Topic Attachments** section, click  for the topic attachment, and then click **Comments**.

The Comments dialog box appears.

- C. Click **Add Comment**.

The Add Comment dialog box appears.

- D. In the text box, enter the comment.

- E. Click **Save**.


The comment appears in the Comments dialog box.

- F. Click **Close**.

## Reopening a topic

1. Click the **Topics** tab.

The Topics page appears.

2. Click the row menu () for the topic, and then click **Reopen**.

This option is available if the topic is in a final state such as Closed, and your topic workflow configuration includes a transition from that state to another state such as Assigned or Reopened. This option may only be available if you have the work team permission to reopen topics.

3. In the **Current state** field, select a state. Your topic workflow configuration defines the states that can be assigned to a topic that is in a final state.

4. Click **Save**.

The Topics page appears. You can view and edit the topic as needed.

## Working with attachments

### Working with attachments

Depending on your topic workflow configuration, you can attach one or more types of data to topics and actions:

- Empirica Signal objects, such as run results or report output.
- Any type of file, including .doc, .pdf, .ppt, .xls, .xml, .xpt, .gif, .jpg, and .zip formats.
- The URL of a webpage.
- A note.

If you can attach an object, a Save to Topic link appears on the page. You can also add attachments when you edit a topic or action. See [Adding a document-style attachment](#).

When you add any type of attachment, the actual data is saved as part of the topic, so changes to or deletions of the original item have no effect on the topic attachment. For example, if you save data mining run results as an attachment to a topic and then delete the run, the run results remain attached to the topic.

---

**Note:** If you attach a URL to a topic and that URL is later changed, you must edit the attachment to keep the location up to date.

---

### Viewing Attachments

When you view or edit a specific topic or action, you can view or edit all of its attachments. The Topic Attachments section of the Topic page, or the [Action Attachments section of the Topic Action page](#), provides information about each attachment in a table that might include these standard columns:


Column	Description
ID	Unique identifying number for the attachment.
Created By	Name of the user who saved the attachment.
Created	Date and time when the attachment was saved.
Modified By	Name of the user who last modified the attachment, including adding comments to the attachment.
Modified	Date and time modified the attachment was last modified.
Source	Type of data saved as an attachment: file, URL, note, or a brief description of the object.
Attachment name	Name of the attachment. If you rest the cursor on an attachment name, help text describing the

	attachment appears. For tabular data, if only a certain number of rows were saved (as determined by a <a href="#">site option</a> ), the number of rows saved and the total number of rows is shown also.
Attachment description	Description of the attachment.
URL address	The URL attached to the topic or action. Applies to URL attachments only.
File name	The name of the file attached to the topic or action. Applies to file attachments only.
Comments	Number of comments that have been added to the attachment. The number is a link that you can click to <a href="#">view or add comments</a> .

The table might also include columns for custom fields added by your organization. For information about viewing, printing, or downloading tables or changing the way data displays in the table, see [About tables](#).

### Adding an attachment column to the Topics page

When you click the **Topics** tab, you can include an Attachment Counts column in the table to show the total count of attachments to each topic and to its actions. Similarly, on the Topic page for a specific topic, you can include a column for Attachments in the Topic Actions section of the Topic page with a count of attachments to each action.

1. To include an attachment count column on the Topics page, click **Columns**.  
or  
To include an attachment column on the Topic page:
  - A. On the **Topics** page, click row menu () for a topic, and then click **View**.  
The Topic page appears.
  - B. In the **Topic Actions** section, click **Columns**.  
The Columns dialog box appears.
2. Move **Attachment Count** from the **Available Columns** list to the **Selected Columns** list.
3. Click **OK**.

### Row menu activities

If you click the row menu () for an attachment, you can also do the following:

- To view the attachment, click **View**. If the attachment source is tabular Empirica Signal data, it is displayed as a table with Columns, Print, and Download links. The title of the page is the attachment name. Other types of attachments are

downloaded to your computer so that you can view them with an appropriate application. You may need to configure Internet Explorer to download files properly: see [Prerequisites and usage notes](#) for more information.


---

**Note:** Non-tabular Empirica Signal data, such as case details and graphs, are saved in .pdf files. You need Adobe® Acrobat® Reader to view .pdf files. See [Prerequisites and usage notes](#).

---

- To view details about the source of the attachment, click **View Source Details**. The [View Source Details dialog box](#) appears.
- To view comments about the attachment (if attachment comments are enabled in your topic workflow configuration), click **Comments**. The [Comments dialog box](#) appears.

## Editing and deleting attachments

When you edit a topic or [edit an action](#) and you click  for an existing attachment, you can also do the following:

- To [edit the attachment](#), click **Edit**.
- To delete the attachment, click **Delete**. At the message asking if you want to delete the attachment, click **OK**. The attachment is removed from the list of attachments for the topic or action. (Deleted attachments, including their comments, cannot be accessed from within the application, although they are retained in the database.)
- To add a comment about the attachment (if attachment comments are enabled in your topic workflow configuration) click **Comments**. The [Comments dialog box](#) appears and includes an **Add Comment** button.

## Saving an object to a topic

To save objects as an attachment for an existing or a new topic, do the following:

1. On the page where the object appears, click **Save to Topic**.

The Save to Topic dialog box appears.

---

**Note:** For a graph on the Data Mining Results tab or Reports tab, the **Links** check box must be selected for the **Save to Topic** link to appear below the graph.

---

When you save tabular data, such as run results:

- Only the first **n** rows of the displayed tabular data can be saved, where **n** is determined by a [site option](#). A message is displayed if not all the rows are saved. The number of saved rows and the total number of rows appear when you rest the cursor on the attachment name.

---

**Note:** On the Drug-Event Combinations page, you can select rows, so the first **n** selected rows are saved.

---

- You might want to select different columns before you save. Only the currently displayed columns appear by default when the attachment is viewed. However, the application stores all available columns with the attachment. To customize the columns shown when viewing the attachment within the topic, click **Columns** and select the columns.

2. Enter the information into the fields [shown](#). For more information, see [Save to Topic dialog box](#).

3. Click **OK**.

If you have created a new topic, it is assigned to you by default. You can edit the topic as needed.

---

**Note:** Your administrator may establish a maximum size for the Empirica Signal tables that you can attach with a [site option](#). If you attempt to save a larger table an error message informs you of the defined limit.

---

After you add an attachment, you can view or edit it when you view or edit the topic or action to which it is attached. See [Working with attachments](#).

---

**Note:** Changes to, or deletions of, the original object do not affect the attachment. For example, if you save report output as an attachment to a topic and then that report output is deleted, the topic attachment remains unchanged.

---

## Signal objects types

You can save the following signal objects as attachments:

- **Drug Profile**—Collection of charts displayed on the Drugs tab.
- **Data Mining Results**—Tabular results of a data mining run.
- **Data Mining Results Graph**—Graphical results of a data mining run.
- **Query**—Results of a query.
- **Case Series**—Case series.
- **First Level drill-down**—List of cases resulting from drill-down on a count of cases.
- **Cases**—Case details displayed upon drill-down for a particular case.
- **Report Output**—Saved report output or a displayed report for an output that was not saved.
- **Report Graph**—Graph based on a saved report output or on a displayed report for an output that was not saved.

---

**Note:** You can save objects to a topic only if you have been given the [work team permission](#) to add, edit, and delete attachments in open topics/actions.

---

You can save the additional objects if your organization uses the Signal Management module of the application:

- **Drug-Event Combinations**—Combinations selected from the Drug-Event Combinations page.
- **Similar Combinations**—Combinations selected from the Similar Combinations page.
- **Interactions Graph**—Interactions graph for a combination on the Drug-Event Combinations page.
- **Age Group Breakdown**—Age group breakdown graph for a combination on the Drug-Event Combinations page.
- **Gender Breakdown**—Gender breakdown graph for a combination on the Drug-Event Combinations page.
- **Sector Map Graph**—Sector map for a drug on the Drug Overviews page.

---

**Note:** If you save data from a Signal Management table as an attachment and your signal configuration has the private comments feature set up, all of the Signal Management comments, public and private, are attached to the topic and are visible to all users who can view the topic.

---

## Save to Topic dialog box

The Save to Topic dialog box saves tabular data or a graph as an attachment. When you save signal objects to a topic, you either create a new topic with minimal information or add the attachment to an existing topic or one of its actions.

If the topic workflow configuration in use on the Topics tab differs from the integrated workflow configuration used with the Signal Management module, the name of the topic workflow configuration in use on Topics tab appears in the Save to Topic dialog box.

Another user can edit a topic while you are saving an attachment to that topic; however, if the other user closes or deletes the topic during this time, you are prevented from saving the attachment, and an appropriate error message is displayed

---

**Note:** You can save objects to a topic only if you have been given the [work team permission](#) to add, edit, and delete attachments in open topics/actions.

---

### Field descriptions—Save to Topic dialog box

Field	Description
Attachment name	Name of the attachment.
Attachment description	Description of the attachment.
Add to existing topic	<p>You can select an open topic that is visible to a work team of which you are a member. Or you can select a topic that you created.</p> <ul style="list-style-type: none"> <li>You can attach the object to an existing topic. In the <b>Topic name</b> field, type the topic name. When typing into this field, matching topic names appear in the drop-down list as soon as you enter a few characters. Or click <b>Browse</b> to select from a descriptive list of topics.</li> <li>To attach the object to an action, from the <b>Action name</b> drop-down list, select an action name or --none--.</li> </ul>
Create new topic	<p>You can attach an object to a new topic.</p> <ul style="list-style-type: none"> <li>You might be required to select a <b>Visible to work team</b> value from the drop-down list, based on the definitions for your topic workflow configuration. You can also click <b>Browse</b> to select from a descriptive list of work teams.</li> <li>If templates exist, from the <b>Topic template</b> drop-down list, optionally select a template or click <b>Browse</b> to choose from a descriptive list of templates.</li> <li>Type a <b>Topic name</b> and <b>Topic description</b> for the new topic.</li> <li>Optionally, you can assign the new topic to either an existing or new <a href="#">project</a>.</li> </ul>





## Adding a document-style attachment

The [attachment types](#) that you can save with a topic are defined by your topic workflow configuration. If you can save files, URLs, or notes, you add these document-style attachments when you edit a topic or action.

1. Click the **Topics** tab.

The Topics page appears.


2. Click the row menu () for the topic, and then click **Edit**.

The Topic page appears.

3. To add the attachment to a topic, in the **Topic Attachments** section, click **Add Topic Attachment**.

The Add Attachment dialog box appears.

or

To add the attachment to an action, in the **Topic Actions** section, click () for the action, and then click **Edit**.

The Topic Action page appears.

In the [Action Attachments section](#), click **Add Action Attachment**.

The Add Topic Action dialog box appears.

4. Select the attachment type. One or more of the following standard types might be available:
  - URL
  - File
  - Note
5. Enter values in the remaining fields. If a field is required, an asterisk (\*) appears next to it and you cannot save the attachment until you provide a value. The fields that display vary based on the type of attachment selected:
  - For a URL, typically a name and the URL are required, and you can also enter a description. You must enter the protocol (http, https, ftp) when you enter the URL. The application does not add the protocol (such as http://) automatically. Additional fields might also appear.
  - For a file, typically a name and the file name (including its path) are required. Click **Browse** to select the file name and path. You can also enter an attachment

description. Additional fields might also appear. Supported file types include, but are not limited to: .doc, .gif, .jpg, .pdf, .ppt, .xls, .xml, .xpt, and .zip.

- For a note, typically a name is required. You can also enter a more detailed description. Additional fields might also appear. This option is useful for adding a row that is purely descriptive. For example, you can add a note to describe a set of different documents that you are about to add to the topic or action.

6. Click **OK**.

The attachment is added.

---

**Note:** Your administrator can set a [site option](#) for the maximum size of files that you can attach. If you attempt to save a larger file, an error message informs you of the defined limit.

---

7. After you add an attachment, you can view or [edit](#) it when you view or edit the topic or action to which it is attached. See [Working with attachments](#).

---

**Note:** Changes to, or deletions of, the original document do not affect the attachment. For example, if you save a document as an attachment to a topic and then that document is edited, the topic attachment remains unchanged.

---

## Selecting a topic

When [saving an attachment to a topic](#), you can select a topic from a list of existing topics. Available topics are those that you can edit, which may include those that you created, that are assigned to you, or that have been made visible to a work team that you are in.

1. In the **Save to Topic** dialog box, select the **Add to existing topic** option.
2. In the **Topic name** field, enter a few characters of the topic name, and a list of matching topics will appear from which you can select.

Or next to the **Topic name** field click **Browse**. The Select Topic dialog box appears and lists the topics you can select.

3. Optionally, filter the lists using the drop-down lists that appear above the table. (Lists appear above the table if the topic workflow configuration you are using offers this feature.) For example, if you select a [project](#), only topics matching the specified project appear.

The application displays standard information about each topic as follows. Additional columns might appear, depending on the topic workflow configuration for your organization.

Field	Description
ID	The internal identifier assigned to the topic at creation.
Work teams	The work teams to which this topic has been made visible.
Project	The project with which the topic is associated.
Name	Name of the topic.
Topic description	Description of the topic.
Current state	Current state of the topic in the workflow.
Reason for change	Last reason for change provided for the topic.
Assigned to user (topic)	Name of the user to whom the topic is assigned currently.
Keywords	Keywords associated with the topic. This is the column that is searched if you specify keywords at the top of the page.
Resolution	Resolution provided for the topic.
Resolution date	Date and time when a resolution was provided for the topic.
Size	The total size of the topic's attachments.

Created By	Name of the user who created the topic.
Created	Date and time when the topic was created.
Modified By	Name of the user who last modified the topic.
Modified	Date and time when the topic was last modified.

For information about viewing, printing, or downloading tables or changing the way data displays in the table, see [About tables](#).


4. Click the row for the topic that you want to select, and then click **OK**.

The topic name appears in **Add to existing topic** section in the **Topic name** field.


## Editing an attachment

You can modify existing attachment information. You work with attachments on the Topic Attachments section of the Topic page and on the Action Attachments section of the Topic Action page.


### To edit a topic attachment:

1. Edit the topic, and locate the attachment in the [Topic Attachments](#) section of the Topic page.
2. Select the row menu () , and select **Edit**.  
The Edit Attachment dialog box appears.
3. Update values as needed. Required fields are indicated by a red asterisk.  
You can edit the name, description, and any custom fields defined for attachments by your topic workflow configuration.
4. Click **Save**.

### To edit an action attachment:

1. Edit the topic, then edit the action, and locate the attachment in the Action Attachments section of the Topic Action page.
2. Select the row menu () , and select **Edit**.  
The Edit Attachment dialog box appears.
3. Update values as needed. Required fields are indicated by a red asterisk.  
You can edit the name, description, and any custom fields defined for attachments by your topic workflow configuration
4. Click **Save**.


## Viewing source details for an attachment

1. On the Topic Attachments section of the Topic page or on the Action Attachments section of the Action page, click the row menu () , and then click **View Source Details**.  
  
The View Source Details page appears.
2. Review the information about the attachment. For an Empirica Signal object, the page provides information on the object's origin. For a document-style attachment, the complete URL or file name appears.
3. To return to the Topic or Action page, click **Close**.

## Viewing tabular data


The following Empirica Signal tabular data can be saved as attachments to a topic or action:

- Data mining results
- Case series (first level drill-down)
- Report output
- Drug-event combinations
- Drug comments
- Similar combinations

1. On the Topic Attachments section of the Topic page, click the row menu () and then click **View**.

The tabular data appears. The name of the page corresponds to the attachment name.

or

On the Action Attachments section of the Topic Action page, click the row menu () and then click **View**.

By default, only the columns that were included in the table when the attachment was saved appears. However, all available columns are stored with the attachment.

2. Click **Columns** to show other columns.
3. If the source of the table is data mining results, report output, or drug comments:
  - A. Click **Show Notes** to display the notes.
  - B. Click **Hide Notes** to hide the notes.
4. If the source of the table is a case series, the Reviewed, Excluded, and Comments columns refer to whether, on the Case Series tab, the case was marked as reviewed or excluded and whether comments were added to the case.




## Working with topic actions

### Working with topic actions

A topic action is an activity that has been identified as contributing to the understanding or resolution of a topic. Examples of activities that you may track with topic actions include:

- Performing research such as literature searches.
- Scheduling project meetings or milestones.
- Documenting follow-up work.

Like topics, actions store information in a structured set of fields, and are given workflow states to track their progress from creation to completion. An action can be assigned to the same user that is currently assigned to the topic or to a different user.

When you click the row menu () for an action, you can click **View** to view all of the information on the [Topic Action page](#).

### Viewing Topic Actions


When you view a topic, you can view its actions. The Topic Actions section of the Topic page provides information about each existing action in a table that might include these standard columns:

Column	Description
ID	Unique identifying number for the action.
Action name	Name of the action.
Action description	Description of the action.
Action state	Indicates the state of the action in the workflow. States are specified in the topic workflow configuration to represent the expected workflow.
Assigned to user	User to whom the action is assigned.
Planned completion date	Deadline (mm/dd/yyyy) for performing this action. Used to produce the <a href="#">Topics by Action Due Date</a> report, and used as the date for email reminders, if included in your topic workflow configuration
Actual completion date	Date (mm/dd/yyyy) on which the action was completed. Used to produce the <a href="#">Topics by Action Due Date</a> report.
Attachment	Total count of attachments to the topic action. (Deleted attachments

Count	are not included in this count.)
Created By	Name of the user who saved the attachment.
Created	Date and time when the attachment was saved.
Modified By	Name of the user who last modified the action, including adding comments.
Modified	Date and time when the action was last modified.

The table might also include columns for custom fields added by your organization. For information about viewing, printing, or downloading tables or changing the way data displays in the table, see [About tables](#).

## Editing topic actions

When you edit a topic you can work with existing actions and [add actions](#). When you click  for an existing action in the Topic Actions section of the Topic page, you can do the following:

- To update the action click **Edit**. On the [Topic Action page](#) you can modify general information, including the user assignment and state. In other sections of this page, you might be able to add comments or attachments to the action.
- To delete the action, click **Delete**. At the message asking if you want to delete the action, click **OK**. (This option might only be available if you have the work team permission to delete topics/actions.)

The topic action is removed from the table and no further processing can be performed on it.



- To reopen a closed action, click **Reopen**. This option is available if the action is in a final state such as Closed, and your topic workflow configuration includes a transition from that state to another state such as Open or Ongoing. This option is only available if you have the Reopen Topics/Actions work team permission. In the **Action state** field, select a state. Your topic workflow configuration defines the states that can be assigned to an action that is in a final state. Click **Save**. The Topics page appears. You can edit the action as needed.

## Topic Action page

On the Topic Action page, you can view and edit topic action information. The page allows you to view comments, attachments, and the history of the topic action. In Edit mode, you can also perform activities based on your permissions and topic workflow configuration.

To expand the sections on this page, click **Show All**, or click  for a single section. To hide section details, click  for the section or click **Hide All**.

### Sections

Section	Description	Available actions
Action General Information	<p>Displays the current field values that describe the action:</p> <ul style="list-style-type: none"> <li>The fields can be display-only, editable, or required. If a field is required, an asterisk (*) appears next to it and the action cannot be saved until you provide a value for the field.</li> <li>Each field accepts text, numeric, or date values, or provides a list of pre-defined values that you can select. If a value is not required in the field, you can select <b>(a blank value)</b> to indicate no value for the field. A field that accepts text may also offer a <b>Select Available Values</b> link so you can select one or more values from a list.</li> <li>Arrow icons may appear after the names of a pair of fields to show that they are a linked pair. For example, if fields for Country () and State () appear, the arrows indicate that you must select a value for the Country field first and then select a value for the State field. You cannot select a State value first: the values available for State depend on the Country you select.</li> <li>To save changes in the Action General Information section, click <b>Save</b>.</li> </ul> <p><b>Note:</b> The <b>Save</b> button affects only the Action General Information section of the topic. You do not need to click <b>Save</b> after you work with other sections of this page.</p>	None
Action Comments	<p>Displays each comment added to the action. When in the edit mode, you can click <b>Add Comment</b> to add a comment. When a comment is added it cannot be modified or removed.</p> <p><b>Note:</b> This section displays only if your topic workflow configuration allows action comments.</p>	None

Action Attachments	Displays information about each item attached to the action. Your topic workflow configuration determines the types of attachments you can add, such as files, URLs, free text notes, or Empirica Signal objects. When in the edit mode, you can click <b>Add Action Attachment</b> to add a document-style attachment (for example, file, URL, or note).	<a href="#">View Source</a> <a href="#">Details</a> <a href="#">Comments</a> <a href="#">Edit</a> Delete
History of Action General Information	Displays information on changes that have taken place for the action. A new row is added to the table each time you click Save in the Action General Information section.	None

### Field descriptions—Action General Information



Depending on your organization’s workflow configuration, the following field appears in this section.

Field	Description
Action name	Name of the action.
Action description	Description of the action.
Action state	<p>Indicates the state of the action in the workflow. States are defined by your organization to represent the expected workflow and are specified in the topic workflow configuration.</p> <p>A warning message may appear if you try to assign a final state to an action before a comment or attachment has been added.</p>
Assigned to user	<p>User to whom the action is assigned. By default, an action that you add is assigned to you. If you assign the action to a different user, that user can see and act on the action.</p> <p>Available users are those in all work teams of which you are a member.</p>
Planned completion date	Planned date for the completion of the action
Actual completion date	Date the action was completed.




If another user edits the same topic action at the same time, the first one to save the action will have their changes saved. The second user will get an error indicating the action has been changed since the edit session began. The General Information section of the page becomes visible, allowing the user to print or take a screen shot, so that the information can be re-entered.



## Viewing a topic action

1. Click the **Topics** tab.  
The Topics page appears.
2. For a topic, click the row menu () , and then click **View**.  
The Topic page appears.
3. In the Topic Actions section, click  , and then click **View**.  
The Topic Action page appears.

## Adding a topic action

1. Click the **Topics** tab  
The Topics page appears.
2. Click the row menu () for a topic, and then click **Edit**.  
The Topic page appears.
3. In the [Topic Actions section of the Topic page](#), click **Add Topic Action**.  
The Add Topic Action dialog box appears.
4. Specify values for the fields.
  - Each field is display-only, editable, or required. If a field is required, an asterisk (\*) appears next to it and you cannot save the action until you provide a value.
  - Each field accepts text, numeric, or date values, or provides a drop-down list of predefined values that you can select. If a value is not required in such a field you can select " " (a blank value) to indicate no value for the field.
  - Arrow icons may appear after the names of a pair of fields to show that they are a linked pair. For example, if fields for State  and Area Code  appear, the arrows indicate that you must select a value for the State field first and then select a value for the Area Code field. You cannot select an Area Code value first. The values available for Area Code depend on the State you select.

The fields listed below are standard fields that might appear with the same or different field names.

Field	Description
Action name	Identifying name for the action (required).
Action description	Description of the action.
Action state	The progress of the action in the workflow. Action states are defined by your organization to represent expected workflow stages and are specified in the topic workflow configuration.
Assigned to user	User to whom the action is assigned. By default, an action that you add is assigned to you. If you assign it to a different user, that user can view or act on the action.  The users in the drop-down list are users in all of the work teams that you belong to, and to which the topic (as a whole) is visible.

Planned completion date	Date (mm/dd/yyyy) when the action is expected to be complete. Used to produce the <a href="#">Topics by Action Due Date</a> report.
Actual completion date	Date (mm/dd/yyyy) when the action was completed. Used to produce the <a href="#">Topics by Action Due Date</a> report.







Additional, custom fields might also appear.

5. Click **Save**.



The action is created and appears in the Topic Actions section of the Topic page.



## Editing a topic action

1. Click the **Topics** tab.  
The Topics page appears.
2. For a topic, click the row menu () , and then click **Edit**.  
The Topic page appears.
3. In the Topic Actions section, click , and then click **Edit**.  
The Topic Action page appears.
4. In the Action General Information section, change the values in the [fields](#).
5. Click **Save**.
6. To add a comment, in the Action Comments section, click **Add Comments**.  
When a comment is added it cannot be modified or removed.
7. In the Action Attachment section, do any of the following:
  - To add a document-style attachment (for example, file, URL, or note), click **Add Action Attachment**.
  - To view the details of an action attachment, click  for the attachment, and then click **View Source Details**.
  - To add a comment, click  for the attachment, and then click **Comments**.
  - To edit an attachment, click  for the attachment, and then click **Edit**.
  - To delete an attachment, click  for the attachment, and then click **Delete**.  
Confirm the deletion.

## Reopening an action

1. Click the **Topics** tab  
The Topics page appears.
2. Click the row menu () for a topic, and then click **Edit**.  
The Topic page appears.
3. In the Topic Actions section, search for the action in the final state that you want to reopen. Click , and then click **Reopen**.

---

**Note:** The Reopen action appears if Action states include a transition following a Final Action State and your user administrator assigns you the permission, Reopen Topics/Actions.

---

The Action General Information section of the Reopen Topic Action dialog box appears.

4. In the **Action state** drop-down list, select a state.  
The topic workflow configuration determines the available states you can assign.
5. Click **Save**.  
You can view and edit the action as necessary. The action state change is also recorded in the History of Action General Information section on the Topic Action page.

## Viewing topic reports

### About topic reports

Topic reports provide information on topics and topic attachments. There are two types of reports available for topics reporting:

- Standard reports
- Predefined Oracle Business Intelligence Enterprise Edition (Oracle BI EE) reports

### Standard Reports

Standard reports are provided with Empirica Signal and do not require any additional software or configuration. You access standard topic reports from the Topics tab. The following standard reports are available:

- [Topics by State](#)
- [Topics by Action Due Date](#)

### Predefined Oracle BI EE reports

Predefined Oracle BI EE reports are optional topic reports that provide greater detail on topic information. These reports require additional software and are available if your Database Administrator and IT Administrator installed and configured Oracle BI EE and its components. You access the reports in Oracle BI EE from a link on the Topics tab.

The following predefined Oracle BI EE reports are available:

- Action State Timelines
- Actions by Status
- Actions by Topic
- Attachments in Topics
- Topic Counts by Work Team/User
- Topic State Timelines
- Topics by State

For more information on the Oracle BI EE reports, see [Predefined Oracle BI EE Topic Reports](#).

For more information on installing Oracle BI EE and its components and enabling the Oracle BI EE topic reporting feature, see the *Oracle Business Intelligence Empirica Signal and Topics Reporting Configuration Guide*.

## Generating topic reports

In Empirica Signal, you can generate one of two built-in reports. If Oracle Business Intelligence Enterprise Edition (Oracle BI EE) is configured, you can generate OBI EE reports, including one of the pre-defined reports provided by Oracle.

### Generating a standard topic report

1. Click the **Topics** tab  
The Topics page appears.
2. Click **Select Rows**.  
The Topics page refreshes with a check box next to each topic.
3. Select the check box for the topics that you want to include in a report.  
To select all rows, click **Select All**. To de-select all rows, click **Clear All**.

---

**Note:** You can select up to 5000 topics from the Topics page.

---

4. Click **Reports**, and select either of the following reports:
  - [Topics by State](#)
  - [Topics by Action Due Date](#)
5. In the dialog box that appears, make additional specifications:
  - For the Topics by State report, select one or more topic states to include on the report.
  - For the Topics by Action Due Date report, select one or more action completion status date ranges to include on the report. The planned completion date for each action in the selected topics is compared to the current date to determine the action completion status.
6. Click **View Report**.  
The report appears.

### Generating a predefined topic report in Oracle Business Intelligence Enterprise Edition (Oracle BI EE)

The Oracle BI EE reports include only the topics that are visible to you when working on the Topics tab. The report includes the topics that you created and those that are visible to the work teams to which you are assigned.

---

**Note:** You must have at least the BI Consumer user permission and the View Topics permission to access the reports.

---

1. Click the **Topics** tab.

The Topics page appears.

2. Click **Report** next to the **Add Topic** link.

The Oracle BI EE login page appears.

---

**Note:** The **Report** link is available only when your Database Administrator and IT Administrator have completed the Oracle BI EE reporting setup.

---

3. Log in to Oracle BI EE using your Empirica Signal username and password, and click **Sign In**.

The Topics Dashboard appears.

4. Click **Open** next to a report.

If the Topics Dashboard does not appear, do the following to access topic reports:

1. Click **Catalog** at the top of the page.

The **Catalog** tab appears.

2. In the Folders pane, expand Shared Folders.

3. Expand the Topics subfolder.

4. Expand My Dashboard, and click **Topics**.

A list of topic reports appears.

5. Click **Open** next to a report.

## Predefined OBIEE topic reports

Predefined Oracle Business Intelligence Enterprise Edition (OBIEE) reports are available from a link on the Topics tab if your Database Administrator and IT Administrator installed and configured OBIEE and its components.

The following sections describe the predefined reports that are available.

---

**Note:** Options in drop-down lists appear in case-sensitive alphabetical order.

---

### Action State Timelines

Description	Filters for Data Retrieval	Columns
<p>Provides the total elapsed time in days that each Topic Action spent in a specific state. Computes the elapsed time using the Topic Action Modification Date. If this date is unavailable, computes the time using the Topic Action Creation Date.</p> <p>Sorted in order by Topic ID by Action ID by Action Version ID. Action Version ID is not a visible field.</p>	<ul style="list-style-type: none"> <li>Project</li> <li>Topic name</li> <li>Action Name</li> </ul>	<ul style="list-style-type: none"> <li>Project</li> <li>Topic ID</li> <li>Topic Name</li> <li>Action ID</li> <li>Action Name</li> <li>Action States</li> </ul>

#### Sample Report

					Escalated		Init	
					Closed	Init	Closed	Escalated
Project	Topic ID	Topic Name	Action ID	Action Name				
Vaccines	134	Mercury Poisoning	435	Attach Mercury Poisoning info from CDC			2 days	
			436	Attach data mining results				1 day
					3 days			

### Actions by Status

Description	Filters for Data Retrieval	Columns
<p>Provides topic information based on action status.</p> <p>Sorted in order by Action Status by Planned Completion Date by Action Name.</p>	<ul style="list-style-type: none"> <li>Action Status</li> <li>Project</li> <li>Topic Action Modified Date From/To</li> </ul>	<ul style="list-style-type: none"> <li>Action Status</li> <li>Planned Completion Date</li> <li>Action ID</li> <li>Action Name</li> </ul>
<p><b>Note:</b> To ensure that the</p>		

query retrieves all data for a specific day, you should increase the date in the To field by 1 day. For example, to retrieve topics with Action Modified dates from 02/01/2012-02/04/2012, specify a From date of 02/01/2012 and a To date of 02/05/2012.

- Action Description
- Action State
- Action Assigned To
- Action Created By
- Action Created Date
- Actual Completion Date
- Action Modified By
- Action Modified Date
- Topic ID
- Topic Name
- Topic Description
- Topic State
- Project
- Topic Assigned To

### Sample Report (partial)

Action Status	Planned Completion Date	Action ID	Action Name	Action Description	Action State	Action Assigned To	Action Created By	Action Created Date
Closed	2/14/2012 12:00:00 AM	435	Attach Mercury Poisoning info from CDC	Visit cdc website and attach their Mercury poisoning info	Closed	Maria Smith	Maria Smith	2/14/2012 4:52:30 AM
	2/15/2012 12:00:00 AM	436	Attach data mining results	Include results from most recent VAERS data.	Closed	Maria Smith	Jane Doe	2/14/2012 5:09:22 AM
No Due Date		450	Contact physicians participating in post-market trial	Reach out to those pediatricians that are investigating in Trial PGE242	Init	Jane Doe	Jane Doe	3/14/2012 5:26:14 PM

### Actions by Topic

#### Description

Provides topic information based on topic action.  
Sorted in order by Project by Topic Name by Topic Modified Date by Action Name.

#### Filters for Data Retrieval

- Project
- Topic Name
- Topic State
- Action State

#### Columns

- Project
- Topic ID
- Topic Name
- Topic Description
- Topic Created Date
- Topic Modified Date
- Topic State
- Resolution Date

- Search Keywords
- Action Name
- Action Description
- Action State
- Action Assigned To
- Action Status
- Planned Completion Date
- Actual Completion Date

Sample Report (partial)

Project	Topic ID	Topic Name	Topic Description	Topic Created Date	Topic Modified Date	Topic State	Resolution Date	Search Keywords	Action Name	Action Description	Action State
Vaccines	107	MMR and Autism	Follow up on public perception that MMR and Autism are related	1/27/2012 5:49:58 AM	3/14/2012 5:45:00 PM	Assigned			Contact physicians participating in post-market trial	Reach out to those pediatricians that are investigating in Trial PGE242	Init
	134	Mercury Poisoning	Explore mercury poisoning in childhood vaccines	2/2/2012 7:43:03 AM	2/26/2012 9:55:49 PM	Assigned	2/14/2012 12:00:00 AM		Attach Mercury Poisoning info from CDC	Visit cdc website and attach their Mercury poisoning info	Closed
									Attach data mining results	Include results from most recent VAERS data.	Closed

Attachments in Topics

**Description**

Provides topic attachment information.  
Sorted in order by column from left to right.

**Filters for Data Retrieval**

- Project
- Topic Name
- Source
- Topic Modified Date From/To

**Note:** If a topic has not yet been modified, the topic Creation Date is used in topic retrieval.

**Note:** To ensure that the query retrieves all data for a specific day, you should increase the date in the To field by 1 day. For example,

**Columns**

- Project
- Topic ID
- Topic Name
- Source
- Topic Attachment Name
- Topic Attachment Created By
- Topic Attachment Created Date
- Topic Attachment Modified By
- Topic Attachment



to retrieve topics with Topic Modified dates from 02/01/2012-02/04/2012, specify a From date of 02/01/2012 and a To date of 02/05/2012.

Modified Date

## Sample Report

Project	Topic ID	Topic Name	Source	Topic Attachment Name	Topic Attachment Created By	Topic Attachment Created Date	Topic Attachment Modified By
Vaccines	107	MMR and Autism	Note	Note to self	Jane Doe	3/14/2012 5:45:00 PM	
	134	Mercury Poisoning	Data Mining Results Graph	Poisoning and vaccines	Maria Smith	2/6/2012 3:58:59 AM	
	135	Blood transfusions and infection	Data Mining Results	VAERS results of interest on infection	Maria Smith	2/23/2012 6:25:12 PM	
			Data Mining Results Graph	Confidence Interval graph	Maria Smith	2/23/2012 6:26:11 PM	
				Map Graph for infection in vaers data	Maria Smith	2/23/2012 6:28:08 PM	
			File	Dear Provider letter	Maria Smith	2/23/2012 6:19:37 PM	
			Note	Additional concerns	Maria Smith	2/23/2012 6:20:48 PM	
			URL	Presentation from UK National Blood Service	Maria Smith	2/23/2012 6:18:03 PM	

## Topic Counts by Work Team/User

### Description

Provides the number of topics in each state assigned to each user on one or more work teams, and the total number of topics assigned to the work team.

There is one table for each work team.

Sorted in order by work team user.

**Note:** Topics that are visible to a work team but are not assigned to a member of the work team are not included in the Work Team Total.

### Filters for Data Retrieval

- Work Team Name

### Columns

- Topics (count)
- Topic State (one column for each)

**Note:** If no topics are in a given state, the Topic State column does not appear.

## Sample Report

### Biologics

	Topics	Assigned
User		
Jane Doe	1	1
Maria Smith	1	1
<b>Work Team Total</b>	<b>2</b>	<b>2</b>

## Topic State Timelines

Description	Filters for Data Retrieval	Columns
<p>Provides the total elapsed time in days that each topic spent in a specific topic state.</p> <p>Sorted in order by Topic Version ID. Topic Version ID is not a visible field.</p>	<ul style="list-style-type: none"> <li>Project</li> <li>Topic Name</li> </ul>	<ul style="list-style-type: none"> <li>Project</li> <li>Topic ID</li> <li>Topic Name</li> <li>Topic Description</li> <li>Topic State</li> </ul>
<p><b>Note:</b> If the total elapsed time is less than 12 hours, the time period appears as 0 days.</p>		

### Sample Report

Project	Topic ID	Topic Name	Topic Description	Assigned	Escalated	Init
				Closed	Assigned	Assigned
Vaccines	107	MMR and Autism	Follow up on public perception that MMR and Autism are related			2 days
	134	Mercury Poisoning	Explore mercury poisoning in childhood vaccines		3 days	0 days
	135	Blood transfusions and infection		12 days		2 days

## Topics by State

Description	Filters for Data Retrieval	Columns
<p>Provides topic information based on topic state.</p> <p>Sorted in order by State by Project by Topic ID.</p>	<ul style="list-style-type: none"> <li>Topic State</li> <li>Project</li> <li>Topic Modified Date From/To</li> </ul>	<ul style="list-style-type: none"> <li>Topic State</li> <li>Project</li> <li>Topic ID</li> <li>Topic Name</li> <li>Topic Description</li> <li>Topic Assigned To</li> <li>Topic Created By</li> <li>Topic Created Date</li> <li>Topic Modified By</li> <li>Topic Modified Date</li> <li>Resolution</li> <li>Resolution Date</li> </ul>
<p><b>Note:</b> To ensure that the query retrieves all data for a specific day, you should increase the date in the To field by 1 day. For example, to retrieve topics with Topic Modified dates from 02/01/2012-02/04/2012, specify a From date of 02/01/2012 and a To date of 02/05/2012.</p>		
<p><b>Note:</b> If a topic has not yet been modified, the topic Creation Date is used in topic retrieval.</p>		

## Sample Report

Topic State	Project	Topic ID	Topic Name	Topic Description	Topic Assigned To	Topic Created By	Topic Created Date	Topic Modified By	Topic Modified Date	Resolution
Assigned	Vaccines	107	MMR and Autism	Follow up on public perception that MMR and Autism are related	Jane Doe	Maria Smith	1/27/2012 5:49:58 AM	Jane Doe	3/14/2012 5:45:00 PM	
		134	Mercury Poisoning	Explore mercury poisoning in childhood vaccines	Maria Smith	Jane Doe	2/2/2012 7:43:03 AM	Maria Smith	2/26/2012 9:55:49 PM	There was data available on this topic up
		135	Blood transfusions and infection		Maria Smith	Jane Doe	2/2/2012 7:49:17 AM	Maria Smith	2/23/2012 8:17:11 PM	

## Topics by State report

On the Topics by State report, you can view topic information for the selected topics in specified topic states.

### General activities

The following links appear at the top of the page and affect the entire page:

- [Back](#)
- [Columns](#)
- [Print](#)
- [Download](#)

### Field descriptions—Topics by State report

You can view the topic information that includes these standard fields. The page also includes columns for any custom topic fields that your organization adds. The Display Name of each field is used as column headers.

Field	Description
Current state	Indicates the state of the topic in the topic workflow. States are defined by your organization to represent the expected workflow and are specified in the topic workflow configuration.
Topic ID	Unique identifying number for the topic.
Name	Name of the topic.
Resolution	The resolution, if any, provided for the topic.
Resolution date	Date and time when a resolution was provided.
Keywords	Keywords associated with the topic.
Reason for change	Last reason for change, if any, provided for the topic.
Assigned to user	Name of the user to whom the topic is assigned currently.
Topic description	Description of the topic.
Created	Date and time when the topic was created.
Created By	Name of the user who created the topic.
Last Modified	Date and time when the topic was last modified.
Last Modified	Name of the user who last modified the topic.

---

By

---

## Topics by Action Due Date report

On the Topics by Action Due Date report, you can view the topic action information for the selected topics that have actions with a specified completion status. It lists each topic that you selected from the Topics page and that has an action specified in a completion status list.

### General activities

The following links appear at the top of the page and affect the entire page:

- [Back](#)
- [Columns](#)
- [Print](#)
- [Download](#)

### Field descriptions—Topics by Action Due Date

You can view the topic information for the topics that includes these standard fields. The page also includes columns for any custom topic action fields that your organization adds. The Display Name of each field is used as column headers.

Field	Description
Action status	<p>Indicates the completion status of the action in comparison to its planned and actual completion dates. Possible action completion statuses are:</p> <ul style="list-style-type: none"> <li>• Overdue</li> <li>• Due within 7 days</li> <li>• Due within 30 days</li> <li>• Due after 30 days</li> <li>• No due date, and Closed</li> </ul> <p>For example, an action has a planned completion date of September 30th. However, no actual completion date has been entered. If you produce the report on September 25th, this column displays Due within 7 days. However, if you produce the report on October 3rd and there is still no actual completion date, this column displays Overdue.</p> <p>Only statuses specified for the Topics by Action Due Date report are included.</p>
Action name	Name of the action.
Planned completion date	Planned date for the completion of the action.

Actual completion date	Date the action was completed.
Topic ID	Unique identifier of the topic.
Name	Name of the topic.
Topic state	Current state of the topic.
Assigned to user	User to whom the action is assigned.
Topic description	Description of the topic.
Action description	Description of the action.
Action state	Indicates the state of the action in the workflow. States are defined by your organization to represent the expected workflow, and are specified in the topic workflow configuration.
Created	Date and time the action was created.
Created By	Name of the user who created the action.
Last Modified	Date and time when the action was most recently modified.
Last Modified By	Name of the user who last modified the action.


## Creating a topic PDF or ZIP file

### Selecting attachments for a topic PDF or ZIP file

When you create a Portable Document Format (.pdf) file or a compressed .zip file (which contains a .pdf file) for a topic, you select the attachments to include (if any) and then you [select additional content](#) for the included items. The resulting .pdf file contains a section for information about the topic, followed by additional sections for information about each selected attachment.

1. Click the **Topics** tab.

The Topics page appears.

2. Click the row menu () for the topic, and then click **Create PDF** or **Create ZIP**.

The Select Attachments page appears and lists all topic attachments followed by the action attachments for each topic action.

---

**Note:** If the topic does not have any attachments, or you do not wish to include attachments in the .pdf, click **Next**.

---

3. From the **Available list**, choose one or more attachments to include in the .pdf file.

- To include all attachments, click **->>**.
- To select an attachment, in the Available list, click the attachment to highlight it, and then click **->**. The attachment appears in the Selected list. You can also:
  - Highlight multiple non-contiguous attachments. Hold down the **Ctrl** key while clicking each attachment. Click **->**.
  - Highlight multiple contiguous attachments. Click an attachment, hold down the **Shift** key, and click another attachment. Attachments between and including those attachments are highlighted. Click **->**.
  - Remove the highlighting from an attachment. Hold down the **Ctrl** key while clicking the selected attachment.

4. To move attachments back and forth between the list of available attachments and the list of selected attachments, you can double-click a highlighted attachment or use the arrow keys as follows:

Button	Use To
->	Move highlighted attachments from the list of available attachments to the list of selected attachments.



->> Move all attachments from the list of available attachments to the list of selected attachments.

---

<- Move highlighted attachments from the list of selected attachments to the list of available attachments.

---

<<- Move all attachments from the list of selected attachments to the list of available attachments.

---

5. When you are satisfied with the selected attachments, click **Next**.

The [Select Attributes dialog box](#) appears. Continue with [Selecting content attributes for a topic PDF or ZIP file](#).

## Selecting content attributes for a topic PDF or ZIP file

When you create a Portable Document Format (.pdf) file, or a compressed .zip file (which contains a .pdf file) for a topic, you [select the attachments](#) to include, and then you can select additional content to include for those items.

1. On the Select Attachments dialog box, [select the attachments](#) and click **Next**.

The Select Attributes dialog box appears.

This dialog box lists the topic and each attachment that you selected for inclusion. The first row that appears, with Topic - <topic-name> in the Content column, represents the topic as a whole.

2. To include information about the source of an attachment, check **Source Details**.

The .pdf file includes Source Details in the section for that attachment with the help text that appears when you rest the cursor on the name of the attachment on the Topic page. Additionally, if more information is available for the type of attachment, it appears after the attachment in the PDF file.

or

To include source details for every attachment, check the **Source Details** column heading.

3. To include all comments made about the topic as a whole, or about an attachment, check **Comments**.

The .pdf file includes a section for Topic Comments, or a subsection for the attachment's comments.

or

To include comments for the topic and for all of the attachments, check the **Comments** column heading.

4. To include a log of changes made to the topic or an attachment, check **Change Log**.

The .pdf file includes a Topic History section that shows the information from the History of Topic General Information section of the topic, or an attachment-name Log subsection with changes to the attachment.

or

To include a change log for the topic and for all of the attachments, check the **Change Log** column heading.

5. To specify the order in which attachment information will be presented in the .pdf file, click a row to highlight it, then use the following buttons:

Button	Use To
--------	--------

---



Move the attachment information to the top of the PDF file.

---



Move the attachment information up in the PDF file.

---



Move the attachment information down in the PDF file.

---



Move the attachment information to the bottom of the PDF file.

---

**Note:** The section with information about the topic as a whole is always first in the .pdf. You cannot move the Topic - *<topic-name>* row (top row).

---

6. Click **Create PDF** or **Create Zip Archive**.

The application creates the .pdf or .zip file. The .pdf file includes links on the first page to navigate to various sections. Files or URL attachments within the .pdf file are linked to from within the PDF file.

Note that:

- Security features in Adobe Acrobat Reader 7.x might prevent you from opening a .zip file from within the .pdf file. See the Adobe website for instructions on modifying this behavior.
- If you are using Adobe Acrobat Reader 6.x, you might need to set link options correctly to view certain types of attachments.



## Viewing source data

### About source data

The drug safety data to be used in the Empirica Signal application might include:

- Public safety data, such as data from the Adverse Event Reporting System (AERS) or Vaccine Adverse Event Reporting System (VAERS), covered by the Freedom of Information (FOI) Act.
- Subscription data, such as data from Vigibase, the World Health Organization's Adverse Drug Reaction (ADR) database.
- Your company's own safety data.

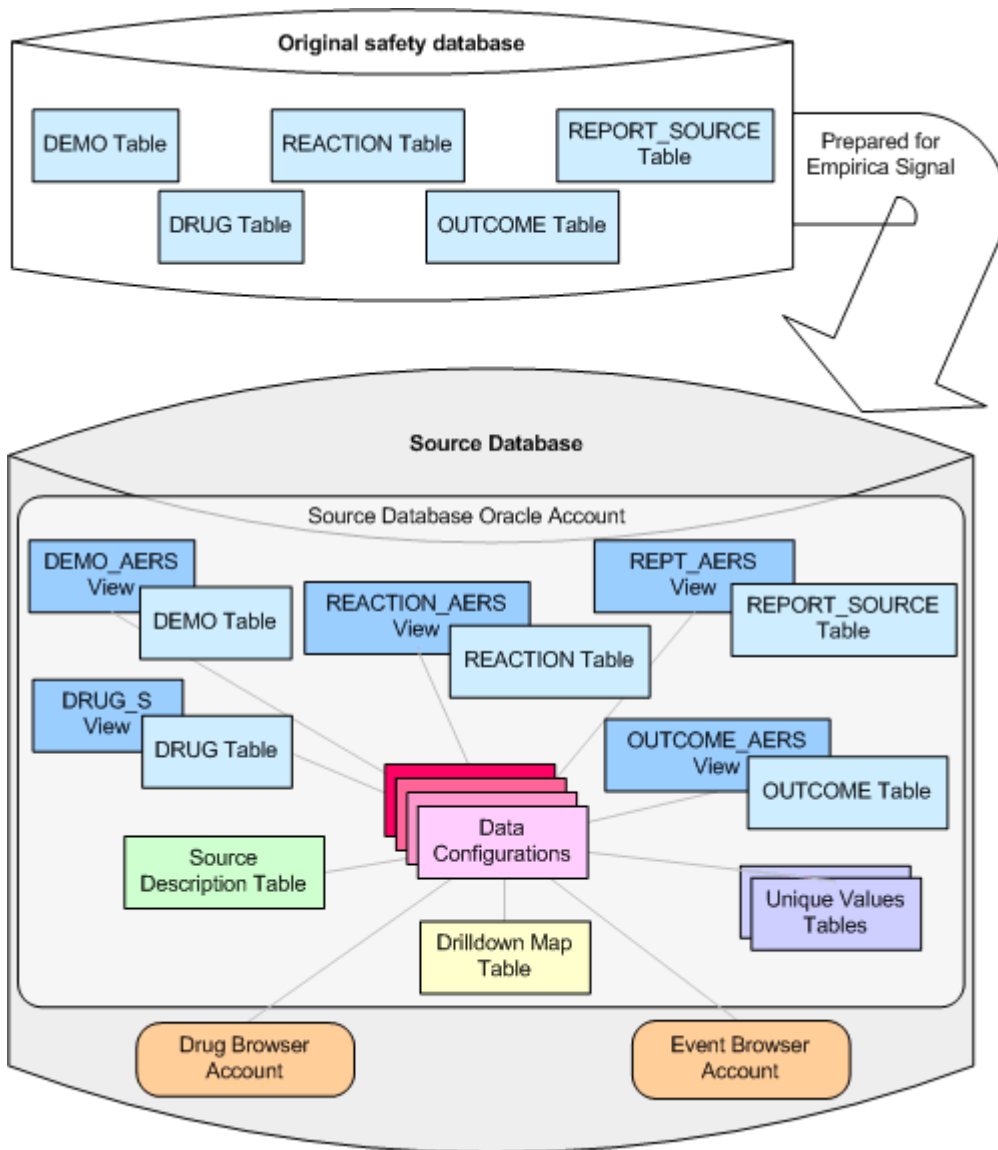
Typically, drug safety data in the original, base tables is [cleaned and prepared](#) for useful data mining. The prepared data is stored in an Oracle database and is the source data used by Empirica Signal.

Each source database resides in a separate Oracle account. In addition to the Oracle tables and views that contain safety data, the source database might include other tables that support the use of source data in the application:

- A [data configuration](#) is a group of variables that correspond to items (database columns) in the source database. There must be at least one data configuration for data mining to be performed. Typically, multiple data configurations are available. For example, there might be a data configuration for SRS+AERS data and a separate data configuration for AERS data (since 1997).
- A [drilldown map table](#) specifies which data appears when users drill down to case information.
- A [source description table](#) provides a description of the source database, such as its name and when it was loaded.
- [Unique values tables](#) enhance performance by listing unique values for variables.

If dictionaries of hierarchical data from a classification system such as the Medical Dictionary for Regulatory Activities (MedDRA) are used, each version of dictionary data is stored in a separate Oracle account. If hierarchy accounts are defined, users can browse for and select event terms or drug terms [in the hierarchy](#).

The following illustration shows the relationship between the original safety database and the Empirica Signal source database:



## Source database tables

Source database tables are the Oracle tables or views that store prepared safety data, which has been cleaned and transformed for data mining. To prepare source database tables, you can use standard Oracle tools or any application that enables you to work with Oracle tables. In preparing the analysis tables, you must:

- Decide how many source database tables or views are needed.
- Ensure that all of the source database tables include an item that links them and can serve as a case identifier in the Empirica Signal application.
- Ensure that, if the source data is [timestamped](#), the source database tables include dates that can be used as start and end dates for data.
- Ensure that the source database tables include the following:
  - An item or items representing the therapeutic product being studied.
  - An item or items representing the event or symptom being studied.
  - Items that allow stratification during a data mining run.
  - Items that allow subsetting during a data mining run.

## Examples of base tables

The base tables are as follows:

### DEMO table:

CASE_ID	GENDER	COUNTRY	REPORT_DATE	BIRTH_DATE
123	M	US	12/01/2001	01/16/1954
138	F	France	01/05/2000	07/01/1965
147	M	Japan	09/17/2001	03/11/1942
154	F	US	10/04/1999	09/07/1966

### ANTIGENS table:

CASE_ID	VAX_NAME	ANTIGEN	VAX_LOT
123	VAX A	ANTIGEN 1	15HR34
123	VAX A	ANTIGEN 2	15HR34
138	VAX B	ANTIGEN 3	49J3
147	VAX C	ANTIGEN 4	97WEO
147	VAX C	ANTIGEN 2	97WEO

154	VAX D	ANTIGEN 3	D90477F6
-----	-------	-----------	----------

**SYMPTOMS table:**

CASE_ID	SYMPTOM	START	STOP	SEVERITY	NARRATIVE
123	Rash	10/30/01	11/25/01	Moderate	Red weeping rash on left side of neck extending from left back of neck over shoulder to left clavicle.
138	Hearing loss	11/14/00	12/05/00	Severe	Total hearing loss, both ears.
147	Rash	09/01/01	09/03/01	Mild	Red weeping rash on right forearm.
154	Vertigo	09/30/99	10/03/99	Severe	After walking block, patient experienced abrupt feeling of spinning and almost fell down.

**Source database tables preparation**

Suppose that the following data is needed for data mining:

- All cases originating in the U.S.
- The year that the case report was received.
- Age groups of patients.
- The symptom duration.

To prepare source database tables, you can do the following:

- Create a DEMO\_ANALYSIS view on the DEMO table. Rename the CASE\_ID to RPT\_ID. Exclude case reports that did not originate in the U.S. Derive AGE\_GROUP from AGE, which is derived from REPORT\_DATE and BIRTH\_DATE.
- Create a VACCINES\_ANALYSIS view on the ANTIGENS table. Exclude case reports that did not originate in the U.S. Rename the CASE\_ID to RPT\_ID.
- Create a SYMPTOMS\_ANALYSIS view on the SYMPTOMS table. Rename the CASE\_ID to RPT\_ID. Exclude case reports that did not originate in the U.S. Derive RCVD\_YR from CASE\_DATE. Derive DUR\_DAYS (symptom duration in days) from START and STOP in the SYMPTOMS table.
- Create a DRILLDOWN view including a RPT\_ID and any fields from the base tables that the user needs to see upon drilling down to case-level information. Exclude case reports that did not originate in the U.S. (This view is not the same as the drilldown map table.)

**Resulting source database tables**



The resulting source database tables (or views) might look like this:

**DEMO\_ANALYSIS view:**

RPT_ID	GENDER	RCVD_YEAR	AGE_GROUP
123	M	2001	40-49
154	F	1999	30-39

**VACCINES\_ANALYSIS view:**

RPT_ID	VACCINE	ANTIGEN	LOT_NO
123	VAX A	ANTIGEN 1	15HR34
123	VAX A	ANTIGEN 2	15HR34
154	VAX D	ANTIGEN 3	D90477F6

**SYMPTOMS\_ANALYSIS view:**

RPT_ID	SYMPTOM	DUR_DAYS	SEVERITY
123	Rash	27	Moderate
154	Vertigo	4	Severe

**DRILLDOWN view:**

RPT_ID	GENDER	VACCINE	SYMPTOM	DUR_DAYS	SEVERITY	AGE_GROUP	NARRATIVE
123	M	VAX A	Rash	27	Moderate	40-49	Red weeping rash on left side of neck extending from left back of neck over shoulder to left clavicle.
154	F	VAX D	Vertigo	4	Severe	30-39	After walking a block, patient experienced abrupt feeling of spinning and almost fell down.


## Viewing a data source table

From within the Empirica Signal application, you can view the data source tables referenced by the [data configuration](#) associated with the currently selected run. For more information, see [About source data](#).

---

**Note:** Only a superuser can view data source tables.

---

1. Click the **Data Mining Runs** tab.  
The [Data Mining Runs page](#) appears.
2. Select the row menu () for a run, and then click **View Jobs for Run**.  
The [Jobs for Run page](#) appears.
3. Click **Sources**.  
The Data Sources page appears.
4. Click the name of the data source table that you want to view.  
The data source table appears.
5. Perform actions on the table:
  - To [set viewing options](#), click **Options**.
  - To [filter the data](#) that you want to view to certain specified characteristics, click **Filter**.
  - To [download](#) the data in the table, click **Download** (available if you have the Download Raw Data permission).

## Data Source Tables

The following data source tables might be available to view:


Table	Description
Complete Results Table	Complete, raw results table, intended for troubleshooting purposes. For most purposes, the results table available from the Data Mining Results tab is more appropriate. This complete results table might contain more columns than you need to see.
Drug Index Table and Event Index Table	Oracle column indexes for drugs and events.
Master Configuration Table	Empirica Signal master data configuration table (named DM_CONFIGS), which stores attributes of all data configurations in all the source databases.

Configuration Table	Table containing information about variables in the specific <a href="#">data configuration</a> that was used for the run.
Drilldown Map Table	The <a href="#">drilldown map table</a> , which defines which information (such as case outcomes or narratives) appears when the results reviewer drills down to case details.
Data Source Description Table	<a href="#">Source description table</a> , which defines information (such as the date the data was loaded) about the source database and appears when the results reviewer drills down to view case details and in the Notes section of tables. This table is available only if it was defined for the data configuration.
Source Database Tables Referenced by Configuration	<a href="#">Source database tables</a> referenced by the data configuration; for example, the demographics, drugs, and events tables.
Hierarchy Tables Referenced by Configuration	Available if an older method was used for setting up drug and event hierarchies by providing hierarchy tables for individual variables in a data configuration, and if the run used hierarchy information. For more information, see <a href="#">Drug and event hierarchies</a> .
Unique Values Tables Referenced by Configuration	<a href="#">Unique values tables</a> referenced by the data configuration that was used for the run.
Source Database Tables Referenced by Drilldown Map	Source database tables referenced by the drilldown map table for the data configuration. For example, the drilldown map table might reference a table containing demographics data, making demographics data available as part of the case details.

## Setting viewing options for a data source table

Viewing options allow you to sort rows as needed and choose which columns to include in a [data source table](#). The options apply to the specific table during your current session. When you exit and log back in, the application resets the options to the default settings.

While setting options, click **Clear** to reset the options to the default settings (except for which columns to include).

1. Click the **Data Mining Runs** tab.  
The [Data Mining Runs page](#) appears.
2. Select the row menu () for a run, and then click **View Jobs for Run**.  
The [Jobs for Run page](#) appears.
3. Click **Sources**.  
The Data Sources page appears.
4. Select a table.  
The selected table appears.
5. Click **Options**.  
The Table Viewing Options page appears.
6. Specify up to three columns by which to sort the table. You can sort on columns, regardless of whether or not the columns appear in the displayed table. You can also sort by clicking the down and up arrows on either side of column headings in the table itself.
  - A. From the **Sort By** drop-down list, select a field to sort by. To sort data in descending order, click the **Descending** check box. Otherwise, results appear in ascending order.
  - B. Within the primary sort, specify up to two additional sort orders by selecting them from the **Then By** drop-down lists. To sort data in descending order, click the **Descending** check box. Otherwise, results appear in ascending order.
7. In the **Rows per page** field, type the number of rows to display per page. (The default is 15.)
8. To show the number of rows and current filter information above the table, check **Show heading**.
9. To show a description of the source database, check **Show notes**. The description comes from the [source description table](#) for the configuration used by the run.
10. To show the SQL WHERE clause that the application used to construct the displayed table, check **Show SQL**.

11. If you want the table to include columns for which no values exist, check **Show empty columns**.
12. From the **Include columns** list, check the columns to include in the table.
13. Click **Save**.

The modified table appears.

## Filtering a data source table

When you filter a [data source table](#), you use a SQL WHERE clause to indicate specific characteristics for the data you want to view. You can access any data that is in the source table. For example, suppose that you are viewing the DEMOG table in the source database, and you want to look at only cases for females. If Gender is stored in the DEMOG table, you can filter by Gender.

1. On the [Data Sources page](#) displaying the [data source table](#), click **Filter**.  
The Specify Filter page appears.
2. In the SQL WHERE clause text box, type a SQL WHERE clause. You can refer to any of the columns listed on the [Table Viewing Options page](#), regardless of whether or not you included them in the displayed table.
3. Click **Apply Filter**. To remove the filter, click **Clear**.  
The filtered data source table appears.

# Empirica Signal administration

## Managing users

### About user administration

Each user must have a username and password with which to log into the Empirica Signal application.

---

**Note:** Empirica Signal provides a way to update user information using [LDAP](#) (Lightweight Directory Access Protocol).

---

- **Permission**—Permissions control which activities users can perform. For example, you can allow certain users to create data mining runs, or some users to view report output but not create report definitions.
- **User role**—A user role is a set of permissions needed by a particular type of user. Each user or user profile can be assigned one or more roles. Permissions can also be assigned individually to users.
- **Login group**—A login group is a group of users. Each login group can have its own version of the Home tab, with links to customer-specific information. When a user publishes an object (such as a query or report), the object is usable by other users in the same login group. (Users with the Administer Users permission can use and act on published or unpublished objects created by other users in the same login group.)
  - If you have the Administer Users permission, you can add, edit, and delete users and user profiles in your login group only. You can also edit your own login group (and its work teams), but you cannot create or delete login groups.
  - If you are a superuser, you can add, edit, and delete users and user profiles in any login group, and you can create, edit, and delete any login groups and user roles.
- **Work team**—A work team is a subset of users in a login group. The same user can be in multiple work teams for the same login group. Work teams are used only in the context of the [topics](#) feature, and are intended to structure the level of access that different users have to topics.
- **User profile**—A user profile is a set of attributes (login group and quota), user roles, permissions, and default user preferences that can be applied to users as a convenience in setting up users. If you do not use a user profile, you must set the attributes, user roles, and permissions for users individually, and individual users must set their own preferences.

## User permissions

The following table shows the user permissions required to perform Empirica Signal activities. You can assign permissions to individual users or to user roles. The application includes several [predefined user roles](#), and you can create additional roles as needed.

**Note:** Objects on which users can perform activities might depend on whether the object is published, and whether the user also has the Administer Users permission. For example, users can view the results of data mining runs that they created or that have been published to their login group. If they have the Administer Users permission, they can view published and unpublished runs created by any user in their login group.

Permission	Activity
<b>-- Safety Data --</b>	
View Raw Safety Database	Drill down to view case details.  <b>Note:</b> Most users should be given this permission, so that they can drill down to case details.
Download Raw Data	Download <a href="#">case series details</a> or data for <a href="#">results graphs</a> .
<b>-- Data Mining --</b>	
View Data Mining Results	View results of a run. Create, edit, or delete a saved list.
Create Data Mining Run	Create a data mining run; re-run a data mining run; rename, cancel, or delete a data mining run that you created; view jobs for a run. Users with this permission can create queries to add a database restriction or custom terms in a run, but they cannot save the queries to the Query Library unless they have the Create Queries/Case Series permission.
Save Intermediate Files	Save intermediate data files created during a data mining run.
Delete Any Run	Cancel or delete runs (published or unpublished) created by other users in your login group.
<b>-- Layouts/Queries/Reports --</b>	
View Topics	View topics on the Topics tab. If the user with this permission is a member of a work team, <a href="#">work team permissions</a> must also be assigned to determine the level of access (view, edit topics and actions, edit attachments, and so on) that the user has to topics.
View Topics across Work Teams	For a user that has the View Topics permission, grants view access to all topics that are visible to any of the work teams in that user's login group. The user does not need to be a member of all work teams, or



to have [work team permissions](#), to read topics, actions, or attachments. (Work team permissions must be granted to provide any additional level of access.)

Hide Queries/Case Series/Reports Tabs	Prevent the navigational tabs for Queries, Case Series, and Reports from displaying for a user, regardless of any other permissions.
View Drug Profiles	View drug profiles on the Drugs tab.
Create Drug Profile Layouts	Create, edit, and manage drug profile layouts on the Drugs tab. Users with this permission also need the View Drug Profile permission.
Create Queries/Case Series	If the user also has the View Raw Safety Database permission, create, copy, edit, rename, or delete a query or case series. Transfer cases to an existing case series.
Create Report Definitions	Create, copy, edit, or delete report definitions. (No special permission is needed to run report definitions.)
Create Report Outputs	Create, edit, copy, or delete report outputs. (No special permission is needed to view report outputs.)
<b>-- OBI EE Reporting --</b>	
BI Consumer	Corresponds to the BI Consumer role in Oracle BI EE. If you implemented the optional Oracle BI EE Topics reporting feature, users must have at least the BI Consumer permission to view the reports.
BI Author	Corresponds to the BI Author role in Oracle BI EE. If you implemented the optional Oracle BI EE Topics reporting feature, assign this permission to Empirica Signal users who have the corresponding BI Author role in Oracle BI EE.
BI Administrator	Corresponds to the BI Administrator role in Oracle BI EE. If you implemented the optional Oracle BI EE Topics reporting feature, assign this permission to Empirica Signal users who have the corresponding BI Administrator role in Oracle BI EE.
<b>-- Signal Management --</b>	
View Signal Management	Perform all activities on the Signals tab except those that also require Manage Signal Views or Administer Signal Management. Users can always manage signal views that they have created.
Manage Signal Views	On the Signals tab, manage signal views created by any users in your login group. (View Signal Management permission is also required for access to the Signals tab.)
Administer Signal	View existing signal configurations and edit components of them.

Management	<p>Map signal reviewers to users.</p> <p>On the Signals tab, view, add, edit, or delete drugs; assign reviewers to drugs or drug-event combinations. (View Signal Management permission is also required for access to the Signals tab.)</p> <p>A user with this permission also needs the Administer Users permission to assign the configuration to a login group.</p>
------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

---

**-- Administration --**

---

Administer Users	<p>View, add, edit, or delete usernames, user profiles, and work teams in your login group. Update user information from LDAP. Send a message to users in the same login group. Arrange table columns and set that layout as the default for your login group. View the User Activity Audit Trail for users in the same login group. View currently logged in users in the same login group.</p> <p>Users with this permission can edit their own login group (and its work teams), but they cannot create or delete login groups.</p> <p>For some activities, users with this permission can act on objects (including unpublished objects) created by users in the same login group.</p>
------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Administer LDAP	Import LDAP Users, Refresh LDAP Users, Change LDAP/Local Authentication.
-----------------	--------------------------------------------------------------------------

Administer Drug Profiles	Create and manage drug profile configurations. (View Drug Profile Layouts is also required for access to the Drugs tab.)
--------------------------	--------------------------------------------------------------------------------------------------------------------------

Manage Configurations	View data configurations. Create, import, copy, validate, or edit a data configuration for which you have the Edit permission. Delete a data configuration that does not have existing runs, case series, saved lists, report definitions, or report outputs associated with it.
-----------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Manage Topic Workflow Configurations	<p>Create and manage topic workflow configurations. (View Topics permission is also required for access to the Topics tab.)</p> <p>A user with this permission also needs the Administer Users permission in order to assign the configuration to a login group, or to define permissions for work team members.</p>
--------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Manage Aliases	Add, edit, and delete aliases.
----------------	--------------------------------

**Superusers**

A user designated as a superuser can perform any activities in the Empirica Signal application, with the following exception: To arrange the columns of a table and define that layout as the default for a login group, the superuser also must have the Administer Users permission.

Only a superuser can perform the following activities:

- Publish an object to multiple login groups.

- Create, edit, or delete [user roles](#).
- Create or delete login groups.
- Restart the listener process.
- Set any [site options](#).
- View the server status.
- View free space.
- Create a report definition using XML.
- Create or edit built-in report definitions.
- Permanently delete a topic workflow configuration.
- Create a run definition file.
- Create a report definition file.
- [Change default runs](#) for users.
- View data source tables for runs.
- Delete any runs.
- Manage run storage.
- View the batch report queue.
- Delete a data configuration that has existing runs, case series, saved lists, report definitions, or report outputs associated with it.
- Add saved lists in bulk mode.

A superuser can act on objects (such as data mining runs) created by any users in any login groups. In contrast, a user with the Administer Users permission (who is not a superuser) only can act on objects that were created by users in the same login group.

## Managing user profiles

### Viewing existing user profiles

A user profile is a set of attributes (login group and quota), user roles, permissions, and default user preferences that can be applied to users. You can set up a user profile and apply it as needed to new or existing users. Once you have applied a user profile to a user, subsequent changes to the user profile do not affect that user.


---

**Note:** If you [set user preferences](#) by applying a user profile to users, those user preferences are defaults that the individual users can override.

---

1. Click **Settings**  
The Settings page appears.
2. In the **Manage Users** section, click **Edit User Profiles**.  
The User Profiles page appears and provides the following information:

Column	Description
User Profile Name	Name of the user profile.
Login Group	Name of the login group associated with the user profile. Appears only if you are a superuser.
Quota	Maximum amount of server space in megabytes (M) that users with the user profiles are permitted to use for creating runs. If this limit is exceeded, users cannot submit new runs (or re-runs). To indicate an unlimited amount of storage space, leave this field blank. If the quota is 0, users cannot create any runs even if the user has appropriate permissions.

3. If you click the row menu () for a user profile, you can do the following:
  - To [edit a user profile](#), click **Edit**.
  - To delete a user profile, click **Delete**. The user profile is deleted, and existing users are not affected.

For information about viewing, printing, or downloading tables or changing the way data displays in the table, see [About tables](#) .

## Adding or editing a user profile

If you modify a user profile, the changes do not apply automatically to existing users to whom the profile has been applied previously. If you want the changes to apply to those users, you need to re-apply the user profile to those users.

1. Click **Settings**.

The Settings page appears.

2. In the **Manage Users** section, click **Edit User Profiles**.

The User Profiles page appears.

3. To add a user profile, click **Add a New User Profile**.

The Add User Profile page appears.

or

To edit a user profile, click the row menu () for a user profile, and then click **Edit**.

The Edit User Profile page appears.

4. Enter or change the following information:

Field	Description
User Profile Name	Name of the user profile.
Quota	Maximum amount of server space in megabytes (M) that users with this user profile are permitted to use for creating runs. If this limit is exceeded, users cannot submit new runs (or re-runs). To indicate an unlimited amount of storage space, leave this field blank. If you enter 0, users cannot create any runs even if the user has appropriate permissions.
Login Group	Name of the login group associated with the user profile. Appears only if you are a superuser. If this field does not appear, the login group for the user profile is the same as your login group.
Enable SSO Login when SSO is configured	Enables single sign-on for users in this profile. You must have <a href="#">completed all single sign-on configuration tasks</a> , including installing and configuring Oracle Access Manager, before selecting this check box.

5. Click **Save**.

The new or modified user profile is saved. Once a user profile has been saved, links to assign roles, permissions, or default user preferences appear on the page.

6. Perform the following optional activities:
  - [Assign roles](#) to the user profile. For more information, see [Assigning roles to a user profile](#).
  - [Assign permissions](#) to the user profile. For more information, see [Assigning permissions to a user profile](#).
  - To [set user preferences](#) for the user profile, click **Preferences**. New users will have these preferences as defaults that they can change as needed. For more information, see [Setting user preferences](#).


---

**Note:** If you do not click **Save** before performing Steps 4, 5, or 6, the changes you made in previous steps are not saved.


---

## Assigning roles to a user profile

A user role is the name of a set of permissions that are needed by a particular group of users (such as data mining results reviewers). The application includes predefined user roles, which can be modified or added to by a superuser. When you create a user profile, you can assign one or more user roles to the user profile.

1. Click **Settings**  
The Settings page appears.
2. In the **Manage Users** section, click **Edit User Profiles**.  
The User Profiles page appears.
3. To [edit a user profile](#), click the row menu () for a user profile, and then click **Edit**.  
The Edit User Profile page appears.
4. Click **Assign Roles**.  
The Assign Roles page appears, listing all user roles.
5. To assign roles to or remove roles from the user profile, check or clear user role check boxes.
6. Click **Save**.

## Assigning permissions to a user profile

1. Click **Settings**  
The Settings page appears.
2. In the **Manage Users** section, click **Edit User Profiles**.  
The User Profiles page appears.
3. To [edit a user profile](#), click the row menu () for a user profile, and then click **Edit**.  
The Edit User Profile page appears.
4. Click **Assign Permissions**.  
The Assign Permissions page appears, listing all permissions for the user profile. See [User permissions](#) for information about which activities are made available by each permission.
5. To assign permissions to the user profile or remove permissions from the user profile, check or clear permission check boxes.
6. Click **Save**.



## Managing users

### Viewing existing users

1. Click **Settings**


The Settings page appears.

2. In the **Manage Users** section, click **Edit Users**.

The Users page appears, listing users who are in the same login group as you. The following information is provided about each username:

Column	Description
User Name	Unique name of the user account.
Name	Full name associated with the username.
Email	Email address associated with the username. This address (or addresses, separated by commas) is the default notification address for runs if the run creator chooses email notification. This address is also used when a user with the Administer Users permission with appropriate permissions sends a message to all users. And it is used when a message is generated by a topic email notification rule.
Login Group	Appears only if you are a superuser. Login group associated with the user.
Authentication	<p>One of the following values:</p> <ul style="list-style-type: none"> <li>• <b>Local</b>—Standard Empirica Signal authentication.</li> <li>• <b>LDAP</b>— LDAP authentication.</li> </ul> <p>For more information, see <a href="#">Configuring Empirica Signal for use with LDAP</a>.</p>
Status	<p>Enabled if the user can log in to the application. Disabled if the user cannot log in.</p> <hr/> <p><b>Note:</b> This value is determined by the Account disabled check box on the Edit User page.</p>
Quota	Maximum amount of server space in megabytes (MB) that the user is permitted to use for creating runs. Blank for users who do not have a quota (that is, unlimited runs permitted).
SSO Login	Enabled if single sign-on authentication is enabled for the user. Disabled if local authentication is used.

3. Perform the following optional activities:

- To [add a user](#), click **Add a New User**.
  - To [import LDAP users](#), click **Import LDAP Users**.
  - To [refresh LDAP users](#), click **Refresh LDAP Users**.
4. If you click the row menu () for a user, you can do the following:
- To [edit a user](#), click **Edit**.
  - To delete a user, click **Delete**. If topics are assigned to the user, you cannot delete the user until you have removed those assignments. Click **Continue**.

For information about viewing, printing, or downloading tables or changing the way data displays in the table, see [About tables](#) .


## Changing user passwords

If you have the Administer Users permission, you can change the passwords of other users in your login group.

---

**Note:** If you are using single sign-on, you cannot change user passwords in the Empirica Signal application. You must use Oracle Access Manager (OAM) to change or reset user passwords.

---

1. Click **Settings**  
The Settings page appears.
  2. In the **Manage Users** section, click **Edit Users**.  
The Users page appears,
  3. Click the row menu () for the user, and then click **Edit**. You can edit only users in the same login group as you.  
The Edit User page appears.
  4. Click **Change Password**.  
The Change Password page appears.
  5. In the **New Password** field, type a new password.  
The site administrator sets the required password length and the types of characters allowed (alphabetic, numeric, non-alphanumeric, lowercase, uppercase). There may be restrictions on the re-use of old passwords.
- 
- Note:** To log into the application, the user's exact password must be entered in the correct case (upper, lower, or mixed).
- 
6. In the **Confirm Password** field, re-enter the same password.
  7. Click **Change Password**.  
The password is updated.  
The password expiration period, if one has been set as a [site option](#), begins for the new password. The next time the user logs in, the user must use the new password.

## **Empirica Signal and Oracle single sign-on usernames**

You create a username for each user who logs in to the Empirica Signal application. When you create usernames, you must ensure that each username is unique. The application converts usernames to lowercase automatically upon creation and, thus, does not allow duplicate usernames that differ only in case. For example, if you create user jkelley and then attempt to create user JKelley, a message appears indicating that the user already exists. The application converts all usernames to lowercase regardless of authentication type.

If you have enabled single sign-on, the Empirica Signal usernames that you create must match their associated single sign-on usernames in Oracle Access Manager. Though users log into the Empirica Signal application using their single sign-on username and password in this instance, you must still supply an Empirica Signal password. You must create Signal passwords according to the Signal password restrictions set by your site administrator, such as minimum length and composition. Empirica Signal usernames and passwords are applicable when a superuser logs in to Empirica Signal natively.

Though Empirica Signal usernames and single sign-on usernames must match, the case can be different. For example, you can create user JKelley in Oracle Access Manager, and user jkelley in Empirica Signal.

## Adding and editing a user

This procedure describes adding and editing Empirica Signal users only. For information on creating single sign-on users in Oracle Access Manager, refer to your Oracle Access Manager documentation.

1. Click **Settings**.

The Settings page appears.


2. In the **Manage Users** section, click **Edit Users**.

The [Users page](#) appears.

3. To add a user, click **Add a New User**.

The Add User page appears. The user will be in the same login group as you.

or

To edit a user, click the row menu () for the user, and then click **Edit**. You can edit only users in the same login group as you.

The Edit User page appears.

4. Enter or change the following information:

Field	Description
Authentication	The user's authentication method. If standard Empirica Signal authentication applies, set to <b>Local</b> . If LDAP authentication applies, set to <b>LDAP</b> .
Username	Unique name (up to 100 characters) of the user account. (You can re-use deleted usernames.) This field appears only if you are creating a new username. Does not apply if LDAP authentication is used.
First Name	First name of the user (up to 64 characters).
Last Name	Last name of the user (up to 64 characters).
Email	Email address of the user. This address (or addresses, separated by a comma) is used: <ul style="list-style-type: none"> <li>• As the default email address if the user chooses to be notified of data mining run completion notification.</li> <li>• When a message is generated by a topic email notification rule.</li> <li>• When you use the <b>Send Message to All Users</b> link on the Settings page.</li> </ul>

	It is recommended that all users have an associated email address.
User Profile	The user profile, or set of attributes (login group and quota), user roles, permissions, and default user preferences that can be applied to users.
Quota	Maximum amount of server space in megabytes (M) that the user is permitted to use for creating runs. If this limit is exceeded, the user cannot submit new runs (or re-runs). To indicate an unlimited amount of storage space, leave this field blank. If you enter 0, the user cannot create any runs even if the user has appropriate permissions.
Login Group	Name of the login group to which the user belongs. Appears only if you are a superuser. If this field does not appear, the login group for the user is the same as your login group.
Password	Password for the user account (up to 64 characters). The password does not need to be unique. Note that users can also modify their own passwords. Follow any recommendations by your organization related to creating secure (hard-to-guess) passwords. You must create passwords according to the password restrictions set by your site administrator. Does not apply if LDAP authentication is used.
Confirm Password	Re-enter the password for the user account to confirm it. Does not apply if LDAP authentication is used.
Superuser	If checked, the user can perform any activities. This check box is available only if you are logged in as a superuser. If you are not a superuser, the label Superuser appears (without a check box) for any previously created superuser.
Password never expires	If checked, the user's password never expires. <b>Note:</b> If a user's password has expired, a message at the top of the Edit User page tells you this when you edit the user. Does not apply if LDAP authentication is used.
User must change password at next login	If checked, the user is required to <a href="#">change the password</a> when next logging in. This option is cleared automatically once the user has changed the password. Does not apply if LDAP authentication is used.
Account locked	If checked, the user cannot log in until you clear the check box. This check box is checked automatically for a user who tries to log in with an incorrect password more than the number of times allowed by the

site option, Number of Attempts Allowed.

Account disabled	<p>If checked, the user account is disabled and the user cannot log in.</p> <hr/> <p><b>Note:</b> When a user's password has expired, the user's account becomes disabled. To allow the user to log in again, you must both assign a new password to the user and re-enable the user's account.</p>
Enable SSO Login when SSO is configured	<p>If checked, enables single sign-on for the user. You can enable single sign-on for both LDAP users and locally authenticated users. This check box is deselected by default.</p> <p>You must have <a href="#">completed all single sign-on configuration tasks</a>, including installing and configuring Oracle Access Manager, before selecting this check box.</p>

5. Click **Save**.

The new or modified user is saved. Once a user has been saved, links to [assign roles](#), [assign permissions](#), or [change the user password](#) appear on the page.

If LDAP is enabled, there are additional options on the Edit User page, as follows.

- To change a user's authentication type from Local to LDAP, click **Change to LDAP Authentication**. Then select an LDAP user. Every place that the username or other information appears, including the User Activity Audit Trail, is updated with new information from the LDAP directory. Note that it is possible for usernames to change as a result of changing the authentication type to LDAP.

---

**Note:** The settings for the user attributes, Password never expires and User must change password at next login, are not relevant to LDAP users.

- To change a user's authentication type from LDAP to Local, click **Change to Local Authentication**. Then enter the Empirica Signal password.

---

**Note:** The settings for the user attributes, Password never expires and User must change password at next login, are cleared for the local username.

- To [refresh an LDAP user](#), click **Refresh from LDAP**.

If you use the topics feature, you also might need to [add the user to one or more work teams](#) and [assign work team permissions](#) to the user.

## Applying a user profile

A user profile is a set of attributes (login group and quota), user roles, permissions, and default user preferences that can be applied to users. (For more details, see [Adding or editing a user profile.](#))


When you apply a user profile to an existing user, the information in the profile replaces any previous settings for the user.

After applying a user profile to a user, you can modify settings further for the user. (However, the changes are lost if you re-apply the profile.)

---

**Note:** Once you have applied a user profile to a user, there is no further association between the user profile and the user. For example, if the user profile is subsequently modified or deleted, users to whom the profile was applied are not affected.

---

1. Click **Settings**  
The Settings page appears.
2. In the **Manage Users** section, click **Edit Users**.  
The [Users page](#) appears.
3. Click the row menu () for the user, and then click **Edit**. You can edit only users in the same login group as you.  
The Edit User page appears.
4. Click **Apply User Profile** (which is available only if there are existing user profiles).  
The Apply User Profile page appears, listing user profiles that are associated with your login group.
5. From the **User Profiles** list, click a user profile to be associated with the user.
6. Click **Save**.

---


**Note:** If you apply a user profile to a user who is currently logged in, any changes that you made to the profile affect that user the next time the user logs in.

---



## Assigning roles to a user

A user role is the name of a set of permissions that are needed by a particular group of users (such as data mining results reviewers). The application includes predefined user roles, which can be modified or added to by a superuser. When you create a user, you can assign one or more user roles to the user. (You can also explicitly [assign individual permissions](#) to the user.)

1. Click **Settings**  
The Settings page appears.
2. In the **Manage Users** section, click **Edit Users**.  
The [Users page](#) appears.
3. Click the row menu () for the user, and then click **Edit**. You can edit only users in the same login group as you.  
The Edit User page appears.
4. Click **Assign Roles**.  
The Assign Roles page appears, listing all user roles.
5. Check or clear check boxes to assign roles to, or remove roles from, the user.
6. Click **Save**.  
The user is assigned the roles and their associated permissions. If you modified the user's roles and the user is currently running the application, the user is not affected by the changes. The changes take effect the next time the user logs in to Empirica Signal.

## Assigning permissions to a user


You can assign additional permissions to the individual user; however, you cannot disable permissions that have been assigned via a user role.

1. Click **Settings**.

The Settings page appears.

2. In the **Manage Users** section, click **Edit Users**.

The [Users page](#) appears.

3. Click row menu () for the user, and then click **Edit**. You can edit only users in the same login group as you.

The Edit User page appears.

4. Click **Assign Permissions**.

The Assign Permissions page appears, listing all permissions. Permissions that have been granted to the user are indicated by selected check boxes.

See [User permissions](#) for information about which Empirica Signal activities are made available by each permission.

5. Check or clear permission check boxes to assign permissions to or remove permissions from the user.

6. Click **Save**.

If you modified the user's permissions and the user is currently running Empirica Signal, the user is not affected by the changes during their current session. The changes take effect the next time the user logs in to Empirica Signal.

## Renaming users

If you are using single sign-on and you rename a user in Signal, you must also rename the user in Oracle Access Manager (OAM). The user names must always be the same. If you migrate to [single sign-on](#) and if any existing Signal usernames do not match the existing single sign-on usernames, you have to rename the Empirica Signal usernames to match.

When you change a username:


- The original username can no longer be used to log into the Empirica Signal application.
- The new username appears throughout the application, including historical activities in the User Activity Audit Trail.
- It is possible to create another user with the same, original username after a rename.
- The application converts usernames to lowercase automatically upon creation and, thus, does not allow duplicate usernames that differ only in case. For example, if you create user jkelley, and then attempt to create user JKelley, an error occurs.

1. Click **Settings**.

The Settings page appears.

2. In the **Manage Users** section, click **Edit Users**.

The [Users page](#) appears.

3. Click the row menu () for the user, and then click **Edit**. You can edit only users in the same login group as you.

The Edit User page appears.

4. Click **Rename User**.

The Rename User page appears.

5. In the **Username** field, type the new username for the user. The name must be unique, and can be up to 100 characters long.

If you are implementing single sign-on, type the single sign-on user name.

6. Click **Save**.

The Edit User page appears with the new username displayed at the top.

If the affected user is currently logged into the application, that user can continue working. Once the user logs out, however, the user must log in using the new username.

## Deleting a user

When you delete a user:

- The username can no longer be used to log into the application. The username, however, is not removed from the database.
- The username remains visible in the User Activity Audit Trail, which allows you to view activities performed by the deleted user. (The username is followed by (deleted).)
- Topic content created by the user will continue to be attributed to the deleted user as will Comments made on Drug-Event Combinations.

Note that:

- When you delete a user, your username becomes the owner of objects that were created by that user. However, for elements within a topic, the username does not change.
- You cannot delete a user if the user is currently assigned to a topic. You must first re-assign the topic (on the Topics tab).
- If you try to delete a user who is currently assigned to a drug-event combination or a drug (on the Signals tab), a list of those assignments appears and a message informs you that the assignments will be removed if you continue with the user deletion.
- It is possible to create another user with the same (original) username as the deleted user.

1. Click **Settings**.

The Settings page appears.

2. In the **Manage Users** section, click **Edit Users**.

The [Users page](#) appears.

3. Click the row menu () for the user, and then click **Delete**.

4. Confirm the deletion by clicking **Yes**.

The user is deleted. If the deleted user is currently logged into the application, that user can continue working. Once the user logs out, however, the user cannot log in again.

## Managing user roles

### Predefined user roles

The Empirica Signal application includes the following predefined user roles, which have one or more user permissions assigned to them. When you assign a role to a user or user profile, all of the permissions for that role are given to the user or user profile.

**Note:** The following table includes only permissions that are assigned to at least one predefined user role. For a description of every permission, see [User permissions](#).

<b>Roles:</b>	<b>Data Mining Run Reviewer</b>	<b>Data Mining Run Designer</b>	<b>Customer Administrator</b>	<b>Report Designer</b>	<b>Report Producer</b>	<b>Signals Reviewer</b>	<b>Empirica Signal Administrator</b>
<b>Permissions:</b>							
View Raw Safety Database	X	X		X	X	X	
Download Raw Data	X	X				X	
View Data Mining Results	X	X					
Create Data Mining Run		X					
Save Intermediate Files		X					
Access Advanced MGPS Features							
Create Drug Profile Layouts		X		X			
Create Queries/Case Series	X	X		X	X	X	

Create Report Definitions		X		
Create Report Outputs		X	X	
View Signal Management				X
Administer Signal Management				X
Administer Users	X			X
Administer Drug Profiles				X
Manage Configurations				X
Manage Topic Workflow Configurations				X
Manage Aliases				X

## Viewing existing user roles

A user role is a set of permissions needed by a particular type of user. The application includes a set of predefined user roles, which you can modify or supplement.

When a user or user profile is created, one or more roles can be assigned to the user or user profile. You can also assign permissions individually and explicitly to a user or user profile. Individually assigned permissions are in addition to any permissions granted by a role.

1. Click **Settings**.

The Settings page appears.

2. In the **Manage Users** section, click **Edit Roles**.

The Edit Roles page appears.

Each role appears, followed by **Edit** and **Delete** links.

- To [edit a user role](#), click **Edit** for the role.
- To [delete a user role](#), click **Delete** for the role.
- To [create a user role](#), click **Create New Role**.

## Creating a user role

1. Click **Settings**.  
The Settings page appears.
2. In the **Manage Users** section, click **Edit Roles**.  
The Edit Roles page appears.
3. Click **Create New Role**.  
The Create New Role page appears.
4. In the **Enter name for a new role** field, type a unique name for the user role.
5. Click **Save**.  
The [Edit Roles page](#) appears for the new user role.
6. Check or clear the **Permissions** check boxes to assign permissions to, or remove permissions from, the user role. See [User permissions](#) for information about which Empirica Signal activities are made available by each permission.
7. Click **Save**.



## Editing a user role

1. Click **Settings**.  
The Settings page appears.
2. In the **Manage Users** section, click **Edit Roles**.  
The Edit Roles page appears.
3. For the user role you want to edit, click **Edit**.  
The [Edit Roles page](#) appears for the user role.
4. Check or clear the **Permissions** check boxes to assign permissions to, or remove permissions from, the user role. See [User permissions](#) for information about which Empirica Signal activities are made available by each permission.
5. Click **Save**.  
If you modify permissions for an existing user role, then users currently logged in and associated with the user role are not affected by the changes during their current session. The changes take effect the next time they log into the application.

## Deleting a user role

1. Click **Settings**.

The Settings page appears.

2. In the **Manage Users** section, click **Edit Roles**.

The Edit Roles page appears.

3. For the user role you want to delete, click **Delete**.

4. When a message asks if you are sure you want to delete the role, click **OK**.

The role is deleted. Users currently logged in with that role can continue with their current session. Once they log out, however, their permissions will no longer include those that had been granted solely through the deleted role.

## Managing login groups

### Viewing existing login groups

A login group is a group of users. A different logo image and Home page can be established for each login group. When a user or user profile is created, a login group must be associated with the user or user profile. If you have the Administer Users permission, you can edit your own login group, but you cannot create or delete login groups.

When a user publishes an object (such as a query or report), the object is usable by other users in the same login group. (Users with the Administer Users permission can use and act on published or unpublished objects created by other users in the same login group.)

Additionally, [work teams](#) based on login groups can be defined for the purpose of sharing [topics](#).

1. Log in to Empirica Signal as a superuser.

2. Click **Settings**.

The Settings page appears.

3. In the **Manage Users** section, click **Edit Login Groups**.

The Edit Login Groups page appears.

Each login group defined appears, followed by Edit and Delete links.

- To [edit a login group](#), click **Edit**.
- To [delete a login group](#), click **Delete**.
- To [create a login group](#), click **Create New Login Group**.

## Creating a login group

1. Log in to Empirica Signal as a superuser. If you are not a superuser but you have the Administer Users permission, the Login Group Settings page appears for your own login group as soon as you click **Edit Login Groups** on the Settings page.
  2. Click **Settings**.  
The Settings page appears.
  3. In the **Manage Users** section, click **Edit Login Groups**.  
The Edit Login Groups page appears.
  4. Click Create New Login Group.  
The Create Login Group page appears.
  5. In the **Enter name for new login group** field, type a unique name for the login group.
  6. Click **Save**.  
The [Login Group Settings page](#) appears for the new login group.
  7. In the **Logo Image** field, enter the name of an image file. (You cannot use a text file.) The image file must exist in the \image subdirectory of the server location in which the application was installed. The application scales any logo image that is not exactly 50 pixels in height to fit within the space allotted for the header. The aspect ratio is maintained so that the width of the image is also scaled.  
  
By default the **Logo Image** field specifies logo.gif (the Empirica Signal logo). If you leave the Logo Image field blank, it is reset automatically to the default.
  8. In the **Home Page** field, enter the name of the file that contains the customized page, in .html format, for the Home page. The .html file must exist in the \customhomes subdirectory of the server location in which the application was installed.  
  
By default the Home Page field specifies home.inc (which says: This area can now be customized.). If you leave the Home Page field blank, it is reset automatically to the default.
  9. From the **Signal Management Configuration** drop-down list, select a [signal configuration](#) from a list of those published to the login group that you are editing.  
  
The **Signals** tab is not available to users unless they are in a login group with an assigned signal configuration and they have the [View Signal Management permission](#).
- 
- Note:** The same signal configuration can be assigned to multiple login groups.
- 
10. From the **Topic workflow Configuration** drop-down list, select a topic workflow configuration from a list of those published to the login group that you are editing.

This will be the topic workflow configuration used on the Topics tab. (If Signal Management is integrated with Topics, the workflow configuration used on the Signals tab is defined in the Signal Management Configuration). A user can make a topic visible to work teams that are based on login groups to which the topic workflow configuration is assigned.

The **Topics** tab is not available to users unless they are in a login group with an assigned topic workflow configuration and they have the View Topics permission. (The exception is that users with the Manage Topic Workflow Configurations permission can set a user preference as another way to make the Topics tab accessible.)

---

**Note:** The same topic workflow configuration can be assigned to multiple login groups.

---

11. Click **Save**.

## Editing a login group

1. Click **Settings**.

The Settings page appears.

2. In the **Manage Users** section, click **Edit Login Groups**.

The Edit Login Groups page appears.

3. Click **Edit** for a login group.

The Login Group Settings page appears.

If you are not a superuser but you have the Administer Users permission, the Login Group Settings page appears for your own login group as soon as you click **Edit Login Groups** on the Settings page.

4. In the **Logo Image** field, enter the name of an image file. (You cannot use a text file.) The image file must exist in the \image subdirectory of the server location to which the application was installed. The application scales any logo image that is not exactly 50 pixels in height to fit within the space allotted for the header. The aspect ratio is maintained so that the width of the image is also scaled.

By default the **Logo Image** field specifies logo.gif (the Empirica Signal logo). If you leave the Logo Image field blank, it is reset automatically to the default.

5. In the **Home Page** field, enter the name of the file that contains the customized page, in .html format, for the Home page. The .html file must exist in the \customhomes subdirectory of the server location to which the application was installed.

By default the Home Page field specifies home.inc (which says: This area can now be customized.). If you leave the Home Page field blank, it is reset automatically to the default.

6. From the **Signal Management Configuration** drop-down list, select a [signal configuration](#) from a list of those published to the login group that you are editing.

---

**Note:** The same signal configuration can be assigned to multiple login groups.

---

7. From the **Topic workflow Configuration** drop-down list, select a topic workflow configuration from a list of those published to the login group that you are editing. A user can make a topic visible to work teams that are based on login groups to which the topic workflow configuration is assigned.

The **Topics** tab is not available to users unless they are in a login group with an assigned topic workflow configuration and they have the View Topics permission. (The exception is that users with the Manage Topic Workflow Configurations permission can set a user preference as another way to make the Topics tab accessible.)

---

**Note:** The same topic workflow configuration can be assigned to multiple login groups.

---

8. Click **Save**.

If you modified settings for an existing login group, then users currently logged in who are associated with the login group are not affected by the changes during their current session. The changes take effect the next time they log in.

## Deleting a login group

1. Log into the application as a superuser.  
If the login group includes usernames (even if they are disabled), you cannot delete the login group unless you first delete those usernames.
2. Click **Settings**.  
The Settings page appears.
3. In the **Manage Users** section, click **Edit Login Groups**.  
The Edit Login Groups page appears.
4. For the login group, click **Delete**.
5. When a message asks if you are sure you want to delete the login group, click **OK**.



## Managing work teams

### About work teams

A work team is a subset of the users who belong to a single [login group](#). Work teams are used only in the context of the [topics](#) feature, and are intended to structure the level of access that different users have to topics.

When adding or editing a topic, users can make the topic visible to a work team or teams. Users can either specify a single work team for a topic or zero, one, or more work teams (as defined by the topic workflow configuration that is in use). Only members of the specified work team(s) can see or act on the topic, and then only in the ways permitted by their assigned work team permissions. (A topic that is not made visible to any work teams can only be viewed and acted on by its creator. For work on these topics, work team permissions are not needed.)

---

**Note:** When assigning work team permissions, note that only users with the View Topics [user permission](#) can access the Topics tab and work with associated topics on the Signals tab. Work team permissions grant different levels of access to the topics on those tabs, but not to the topics feature itself.

---

You can define multiple work teams within the same login group. For example, different work teams can represent various therapeutic areas. A user can be a member of one, several, or none of the login group's work teams.

Users with the Administer Users user permission can add and delete work teams, and edit work teams to specify members and assign work team permissions to them. (One of the work team permissions, Administer Work Team, can be used to give designated members editing access only to a work team.)

## Work team permissions

**Note:** To use the [topics](#) feature and access the Topics tab or work with associated topics on the Signals tab, users must be given the View Topics [user permission](#). Work team permissions give users different levels of access to the topics that appear on those tabs.

### Permissions that can be assigned to work teams

The following permissions can be assigned to the members of a work team. Each permission is independent of the others. For a member to edit a topic, both the View Topics/Actions/Attachments permission and the Edit Topics/Actions permission must be granted to that member. For a member to edit a topic attachment, the View Topics/Actions/Attachments permission and the Add/Edit/Delete Attachments in Open Topics/Actions permission must be granted.

It is possible for one person to be a member of different work teams and have different work team permissions in each one. If a user has access to a topic that is visible to multiple work teams through membership in more than one of those work teams, the least restrictive permissions assigned to the user apply.

Permission	Activity
View Topics/Actions/Attachments	View topics, actions, and attachments to both topics and actions, and create .pdf or compressed .zip files of topic information.  <b>Note:</b> All work team members should be given this permission to allow topic review.
Edit Topics/Actions	Add and edit topics and actions, including adding comments (if enabled by the topic workflow configuration).  <b>Note:</b> This permission does not grant view access to topics or actions. Typically, members also are given the View Topics/Actions/Attachments work team permission.
Add/Edit/Delete Attachments in Open Topics/Actions	Add, edit, and delete attachments to topics and actions, including adding comments (if enabled by the topic workflow configuration).  Grants access to attachments to topics and actions that are in a non-final state, such as Assigned.
Edit Attachments in Closed Topics/Actions	Edit topic or action attachments when the topic is in a final state, such as Closed, and edit action attachments when the action is in a final state.

	<p><b>Note:</b> This permission does not allow members to add comments to attachments.</p>
Reopen Topics/Actions	<p>Reopen topics or actions by changing the state from a final state, such as Closed, to a non-final state, such as Assigned. No other edits are permitted by this permission.</p> <p><b>Note:</b> For the Reopen option to be available for a topic or action, in the topic workflow configuration at least one state also must be defined as a <b>Next possible state</b> for the final state.</p>
Delete Topics/Actions	<p>Delete topics and actions.</p> <p><b>Note:</b> This permission does not grant delete access to attachments.</p>
Administer Work Team	<p>See the section on the <a href="#">Administer Work Team permission</a>.</p>

**Note:** Work team permissions apply only in the context of working with topics and, as a result, are effective only for members who also have the View Topics [user permission](#). Only members with the View Topics user permission can access the Topics tab, where they can add topics and make them visible to a work team (or teams) to initiate collaborative participation. Users who are members of the visible to work team(s) can then view and act on topics as granted by their assigned work team permissions. View Topics [user permission](#) is also required to work with associated topics on the Signals tab.

### Administer Work Team permission

An additional, managerial work team permission is available: Administer Work Team. This work team permission grants members access to a limited subset of the activities that can be performed with the Administer Users user permission. From the **Settings** page, select **Edit Work Teams**. From the **Edit Work Teams** page, members with this permission can:

- Edit work teams to add new members.
- Assign work team permissions to members.
- Specify the values that apply to a given work team for fields with constrained values (see [Constraining field values by work team](#)).

### Default work team permissions

You can assign work team permissions individually to members, or you can define a set of default work team permissions and assign that set to the members of a work team. When a work team is added, each permission is designated as being in the default set for that work team or not, as follows:

Permission	Default
------------	---------

View Topics/Actions/Attachments	Yes
Add/Edit/Delete Attachments in Open Topics/Actions	No
Edit Attachments in Closed Topics/Actions	No
Reopen Topics/Actions	No
Delete Topics/Actions	No
Administer Work Team	No

You can change this set of default permissions so that members are given additional permissions by default. When you add a member to a work team, the permissions in the default set are assigned to that new member automatically. You can edit each member's [assigned permissions](#) as needed.

If you make changes to the default set after it has been assigned to members, the permissions granted to those members by default are updated automatically to match the new default set.

## Viewing existing work teams

1. Click **Settings**.


The Settings page appears.

2. In the **Manage Users** section, click **Edit Work Teams**.

The Edit Work Teams page appears and provides the following information about each work team:

Field	Description
Name	Name of the work team.
Description	Description of the work team.
Login Group	Name of the work team's login group.
All Users	<p>Yes, if the work team is set up to include all users in the login group automatically. When a new user is added to the login group, he or she is also added to the work team and given the default set of work team permissions.</p> <p>No, if users in the login group are selected individually for inclusion in the work team, and are listed in the Users column. New users must be added to the work team manually.</p>
Users	Blank, if all users in the login group are in the work team. Otherwise, lists the name of each work team member.
Created By	Name of the user who created the work team.
Created	Date and time when the work team was created.
Modified By	Name of the user who last modified the work team.
Modified	Date and time when the work team was last modified.
ID	Identifier that was assigned automatically when the work team was created. Each work team ID is unique and is not re-used if the work team is deleted.


The table might also include columns for custom fields added by your organization.

3. Perform the following optional activity: [add a new work team](#). Click **Add Work Team**. Only users with the Administer Users user permission can add work teams. For more information, see [Adding or editing a work team](#).
4. If you click the row menu () for a work team, you can do the following:

- To [edit a work team](#), including adding new members, click **Edit**.
- To [assign work team permissions](#) to members, click **Assign Work Team Permissions**.
- To delete a work team, click **Delete**. At the message asking if you want to delete the work team, click **OK**. Only users with the Administer Users user permission can delete a work team, and a work team cannot be deleted if any topics have been made visible to it.

For information about viewing, printing, or downloading tables or changing the way data displays in the table, see [About tables](#) .

## Adding or editing a work team

1. Click **Settings**.  
The Settings page appears.
2. In the **Manage Users** section, click **Edit Work Teams**.  
The Edit Work Teams page appears
3. To add a new work team, click **Add Work Team**. Only users with the Administer Users user permission can add work teams.  
The Add Work Team page appears.  
or  
To edit a work team, click the row menu () for the work team, and then click **Edit**.  
The Edit Work Team page appears.
4. In the **Name** and **Description** fields, enter or change the name and description of the work team.
5. If you are a superuser, from the **Login group** drop-down list, select the login group from which you want to add users to the work team. If you are not a superuser, this field does not appear and you add users from your own login group to the work team.
6. Do one of the following:
  - To add all users in the login group to the work team, click the **Add all users** radio button. As new users are added to the login group, they are added to the work team and given the default set of work team permissions automatically.
  - To add users in the login group to the work team individually, click the **Select users** radio button. Click **Select Users** to individually [select users](#). As new users are added to the login group, you must add them to this work team manually.
7. Optionally, supply values in any custom fields present for work teams. Custom fields for work teams are defined in a topic workflow configuration, and a superuser must enable these fields for use by [setting site option](#), Topic workflow configuration for work team custom fields.
8. Click **OK**.  
Your changes are saved and you can [assign work team permissions](#) to the members of the work team.


## Assigning permissions to work team members

1. Click **Settings**.

The Settings page appears.

2. In the Manage Users section, click **Edit Work Teams**.

The Edit Work Teams page appears

3. Click the row menu () for the work team, and then click **Assign Work Team Permissions**.

The Assign Work Team Permission page appears.

By default, each new work team member is assigned the default set of permissions and the check box in the Use Default column is checked.

4. To assign permissions individually, clear the Use Default check box then check or clear the check boxes in the row with the user's name.

---

**Note:** You must assign at least one work team permission to each member or the default set of permissions will be assigned.

---

For more information on the access level granted by each permission, see [Work team permissions](#).

5. Click **Save**.

If you modified permissions for a user who is currently logged into the application, the user is not affected by the changes during the current session. The changes take effect the next time the user logs in.



## Managing LDAP users

### Configuring Empirica Signal for use with LDAP

LDAP (Lightweight Directory Access Protocol) is an internet protocol used to look up information stored in a directory on a server. The Empirica Signal application provides a way for you to update user information using LDAP. Thus, user information can be maintained in an LDAP directory and imported into the application. User authentication is performed by LDAP instead of by the standard means of authentication in Empirica Signal.

When user information is stored in an LDAP directory, users can be identified by a unique user attribute that remains constant despite potential username changes in the LDAP directory.

---

**Note:** The Empirica Signal application does not update information in the LDAP directory.

---

You can configure Empirica Signal to use LDAP by editing a properties file template for Active Directory, Sun One Directory, or Oracle Internet Directory. For more information, see your LDAP documentation.

1. Log in to Empirica Signal as a user with the *Superuser* permission. It is recommended that only an administrator perform this configuration.
2. Click **Settings**.  
The Settings page appears.
3. On the Settings page, click **Set Site Options**.
4. Deselect **Enable LDAP** and click **Save**.
5. Navigate to `<INSTALL_DIR>/Signal/WEB-INF/classes`.

---

**Note:** To know the exact value of the `<INSTALL_DIR>`, see Oracle Health Sciences Empirica Signal Installation Guide.

---

6. Copy one of the following properties files that corresponds with your directory type to the same location, and rename it to `ldap.properties`:
  - **template\_ldap\_ad\_kerberosAuth.properties**—Active Directory using kerberos for authentication.
  - **template\_ldap\_ad\_ldapAuth.properties**—Active Directory using ldap for authentication.
  - **template\_ldap\_sunone\_ldapAuth.properties**—Sun One Directory.
  - **template\_ldap\_oid\_ldapAuth.properties**—Oracle Internet Directory.

---

**Note:** After the `ldap.properties` file is created, redeploy the application server using WebLogic Server Administration Console.

---

7. Open the ldap.properties file in a text editor.
8. Replace all placeholders (for example, <HOSTNAME>) with the relevant values. For more information on LDAP Properties, see [LDAP Properties](#).
9. Save your changes.
10. On the Settings page, click **Set Site Options**.
11. Select **Enable LDAP** and click **Save**.
12. On the Settings page, click **Edit Users**.
13. Click **Import LDAP Users** and search for users to verify the LDAP configuration. For more information, see [Importing LDAP Users](#).

## LDAP Properties

For reference, you can use the following properties to configure Empirica Signal application for use with LDAP. Some properties apply only to certain directory types. You configure these properties in the appropriate ldap properties file. For more information, see [Configuring Empirica Signal for use with LDAP](#).

Property	Description
auth.mode	Authentication method. Specify kerberos or ldap.
auth.jndi.java.naming.factory.initial	Implementation class for JNDI LDAP provider used during LDAP user authentication. Specify com.sun.jndi.ldap.LdapCtxFactory.
auth.kerberos.host	Hostname for the Kerberos Key Distribution Center (KDC) used during Kerberos-based user authentication.
auth.kerberos.port	Port for the Kerberos Key Distribution Center (KDC) used during Kerberos-based user authentication.
auth.kerberos.domain	Domain used during Kerberos-based user authentication.
auth.jndi.java.naming.security.protocol	Security protocol used during LDAP-based user authentication. Specify one of the following: <ul style="list-style-type: none"> <li>• none - LDAP</li> <li>• ssl - LDAPS</li> </ul>
auth.jndi.java.naming.provider.url	Hostname and port used during LDAP-based user authentication.
auth.jndi.java.naming.security.authentication	Authentication mode used during LDAP-based user authentication. Specify simple.
search.jndi.java.naming.factory.initial	Implementation class for JNDI LDAP provider used during user search and import. Specify com.sun.jndi.ldap.LdapCtxFactory.
search.jndi.java.naming.security.protocol	Security protocol used during LDAP user search and import. Specify one of the following:

	<ul style="list-style-type: none"> <li>• none - LDAP</li> <li>• ssl - LDAPS</li> </ul>
search.jndi.java.naming.provider.url	Hostname and the port used during LDAP user search and import. When importing users or changing a user to LDAP authentication, all searches begin in the specified root.
search.jndi.java.naming.security.authentication	Authentication mode used during LDAP user search and import. Specify one of the following: <ul style="list-style-type: none"> <li>• none - Anonymous connections.</li> <li>• simple - Search as a specific user.</li> </ul>
search.jndi.java.naming.security.principal	Stores LDAP username that resides in the LdapCredentials key. For more information, see <i>Oracle Health Sciences Empirica Signal Installation Guide</i> .
search.jndi.java.naming.security.credentials	Stores LDAP password that resides in the LdapCredentials key. For more information, see <i>Oracle Health Sciences Empirica Signal Installation Guide</i> .
search.jndi.java.naming.referral	Indicates whether the LDAP provider follows referrals during a user search and import. Specify follow.
search.controls.timelimit	Maximum number of seconds that a query of the LDAP server can take before the LDAP connection times out.
search.controls.countlimit	Maximum number of users that can be received from the LDAP server before the LDAP connection times out.
search.root	LDAP search root used during LDAP user search and import.
search.syncroot	LDAP search root used during LDAP refresh/sync of users. Generally should be the same as search.root.
search.nameAttribute	LDAP attribute which is searched upon in the Import LDAP User page.
search.emailAttribute	LDAP attribute used to populate a Signal user's email address during an import/sync operation.

search.usernameAttribute	LDAP attribute used to populate a Signal user's username during an import/sync operation.  Empirica Signal ensures that the username in Empirica Signal matches the username in the directory during an import or refresh operation.
search.firstNameAttribute	LDAP attribute used to populate an Empirica Signal user's first name during an import/sync operation.
search.lastNameAttribute	LDAP attribute used to populate an Empirica Signal user's last name during an import/sync operation.
search.kerberosIdAttribute	LDAP attribute used to identify an Empirica Signal user during Kerberos authentication.
search.syncIdAttribute	LDAP attribute used to identify an Empirica Signal user during a refresh/sync operation.  Typically, this is an attribute that is not subject to change, such as an employee ID.
search.searchQuery	LDAP search query used when the user specifies a search string on the Import LDAP User page.
search.searchQueryNF	LDAP search query used when the user leaves the search string blank on the Import LDAP User page.
search.syncQuery	LDAP sync query used when refreshing users.

## Importing LDAP users

1. Log in to Empirica Signal as a user with the permission, **Administer Users** and **Administer LDAP**.

---

**Note:** Make sure that at least one [user profile](#) exists.

---

2. Click **Settings**  
The Settings page appears.
3. In the **Manage Users** section, click **Edit Users**.  
The Users page appears,
4. Click **Import LDAP Users**. This option is available only if an [LDAP configuration](#) has been set up.
5. From the **User Profile** drop-down list, select the user profile to apply to the LDAP users you import. Available user profiles are those associated with your login group.
6. From the **Domain** drop-down list, select the domain from which you want to import LDAP users. The **Available LDAP Users** list shows users (up to 400) in that domain.
7. In the **Name** field, enter a text string, and click **Find** to filter the list of available LDAP users (optional).
8. To move users from the **Available LDAP Users** list to the **Selected LDAP Users** list, use the arrow buttons. The double-arrow buttons move all users from one list to the other list.
9. Click **Import**.  
Only selected users who do not have a username in the Empirica Signal application are imported. The import operation does not refresh existing Empirica Signal users. See [Refreshing LDAP users](#). A message tells you if an LDAP user that you have selected for import already exists in the application.

## Refreshing LDAP users

1. Log in to Empirica Signal as a user with the permission, **Administer Users** and **Administer LDAP**.
2. Click **Settings**  
The Settings page appears.
3. In the **Manage Users** section, click **Edit Users**.  
The Users page appears,
4. Click **Refresh LDAP Users**. This option is available only if an [LDAP configuration](#) has been set up.

Messages tell you whether or not information for each Empirica Signal user who is set up as an LDAP user is refreshed.

User information in Empirica Signal is refreshed with user information from the LDAP directory if:

The Empirica Signal user is set up as an LDAP user.

There is LDAP information for the user in the LDAP directory, and that information has changed since the last refresh of LDAP users.

Every place that the user name or other information appears in the application, including the User Activity Audit Trail, is updated with the new information from the LDAP directory. Note that it is possible for user names to change as a result of refreshing LDAP users.

- The refresh operation does not add new users from the LDAP server. See [Importing LDAP users](#).
- For users who are set up as LDAP users, do not make changes to user information from within Empirica Signal. If you do so, the changes will be lost when you next refresh LDAP users.

## Using single sign-on

### About single sign-on

Single sign-on is an optional authentication method that allows users to log into the Empirica Signal application and other applications using a single username and password. Using single sign-on, users can log into the environment once and have access to all applications within the environment without re-entering their username and password.

By implementing a single sign-on environment, you simplify your user administration across applications by managing fewer user accounts. You also eliminate the need for users to remember multiple usernames and passwords. You can enable single sign-on for both LDAP users and locally authenticated users.

To enable single sign-on, you must have installed and configured Oracle Access Manager, and installed and configured the Webgate agent on the Empirica Signal application server. Contact Oracle for assistance in installing and configuring these components.

---

**Note:** The Empirica Signal application supports single sign-on using Oracle Access Manager only.

---

For more information on configuring single sign-on, see [Configuring single sign-on](#).



## Configuring single sign-on

Adding Empirica Signal to a single sign-on environment requires several configuration tasks outside of the Signal application before enabling single sign-on for Empirica Signal users. Your application environment determines the configuration responsibilities:

- If Oracle hosts your Empirica Signal installation, contact Oracle to configure single sign-on in your environment. You do not need to perform the tasks in the configuration checklist.
- If you self-host your Empirica Signal installation, you perform the tasks in the configuration checklist. You must also contact Oracle for assistance in performing several configuration tasks. For more information, see the Single Sign-On Configuration Checklist below.

You must have installed and configured Oracle Access Manager before configuring single sign-on. Contact Oracle for assistance.

### Single Sign-On Configuration Checklist

#	Task	Responsibility	Source for Instructions
1	Configure a Webgate agent on the Oracle Access Manager server.	Oracle	Contact Oracle for assistance.
2	Install and configure Webgate on the Empirica Signal application server.	Oracle	Contact Oracle for assistance.
3	Uncomment single sign-on properties in the webvdme.properties file.	Customer	Oracle Health Sciences Empirica Signal Installation Guide.
4	Specify the URL for a custom logout page (optional).	Customer	Oracle Health Sciences Empirica Signal Installation Guide.
5	Change the Empirica Signal application session timeout to be longer than the single sign-on session timeout.	Customer	Oracle Health Sciences Empirica Signal Installation Guide.
6	Configure the Empirica Signal application server for native logins.	Customer	Oracle Health Sciences Empirica Signal Installation Guide.
7	Restart the Empirica Signal service.	Customer	Oracle Health Sciences Empirica Signal Installation Guide.
8	Validate single sign-on by logging in with your single sign-on username and password.	Customer	Oracle Health Sciences Empirica Signal Installation Guide.

9	Create single sign-on users in Oracle Access Manager.	Customer	Oracle Access Manager documentation.
10	Rename existing Empirica Signal usernames to match their associated single sign-on usernames, or create new users as necessary.	Customer	<a href="#">Renaming users</a> <a href="#">Adding or editing a user</a>
11	Select the <b>Enable SSO Login when SSO is configured</b> check box for users and user profiles.	Customer	<a href="#">Adding or editing a user</a> <a href="#">Adding or editing a user profile</a>

## Renaming users

If you are using single sign-on and you rename a user in Signal, you must also rename the user in Oracle Access Manager (OAM). The user names must always be the same. If you migrate to [single sign-on](#) and if any existing Signal usernames do not match the existing single sign-on usernames, you have to rename the Empirica Signal usernames to match.

When you change a username:


- The original username can no longer be used to log into the Empirica Signal application.
- The new username appears throughout the application, including historical activities in the User Activity Audit Trail.
- It is possible to create another user with the same, original username after a rename.
- The application converts usernames to lowercase automatically upon creation and, thus, does not allow duplicate usernames that differ only in case. For example, if you create user jkelley, and then attempt to create user JKelley, an error occurs.

1. Click **Settings**.

The Settings page appears.

2. In the **Manage Users** section, click **Edit Users**.

The [Users page](#) appears.

3. Click the row menu () for the user, and then click **Edit**. You can edit only users in the same login group as you.

The Edit User page appears.

4. Click **Rename User**.

The Rename User page appears.

5. In the **Username** field, type the new username for the user. The name must be unique, and can be up to 100 characters long.

If you are implementing single sign-on, type the single sign-on user name.

6. Click **Save**.

The Edit User page appears with the new username displayed at the top.

If the affected user is currently logged into the application, that user can continue working. Once the user logs out, however, the user must log in using the new username.

## Managing data configurations

### About data configurations

A data configuration identifies and sets up variables from the [source data](#) for use in the Empirica Signal application. The configuration determines the drug variables (such as generic name or trade name) and the event variables (such as PT) that are available for such activities as data mining or querying. It also determines:

- The variables that are available for [subsetting](#) or [stratification](#) for a data mining run.
- Whether and how source data is transformed (for example, extraction of the year portion of a date variable) for use in a data mining runs.
- The hierarchy of terms, such as MedDRA, that is available for browsing terms.
- Whether data is timestamped.
- The case information that is available when users drill down to a list of cases or case details.

You can create data configurations to exert varying degrees of control over user choices. A configuration can tightly control the variables that are available during activities such as creating data mining runs. A configuration can also make more variables available or leave the choice of variables up to the run creator.

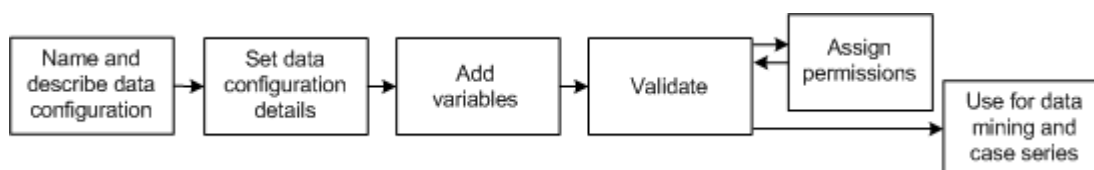
For example, suppose that source data includes both the trade name and generic name for drugs. You can create one data configuration that makes only trade names available, and another data configuration that makes only generic names available. You can also create a single configuration that makes both trade names and generic names available, and then let the run creator determine which one to use.

You work with configurations on the Manage Configurations page. A configuration becomes available for use during activities, such as data mining, only when you have [validated](#) it and granted permissions to it.

You can create a configuration by:

- Importing it.
- Setting it up from scratch.
- Copying and modifying an existing data configuration.

Regardless of how you create the data configuration, you generally perform the following tasks in sequence:



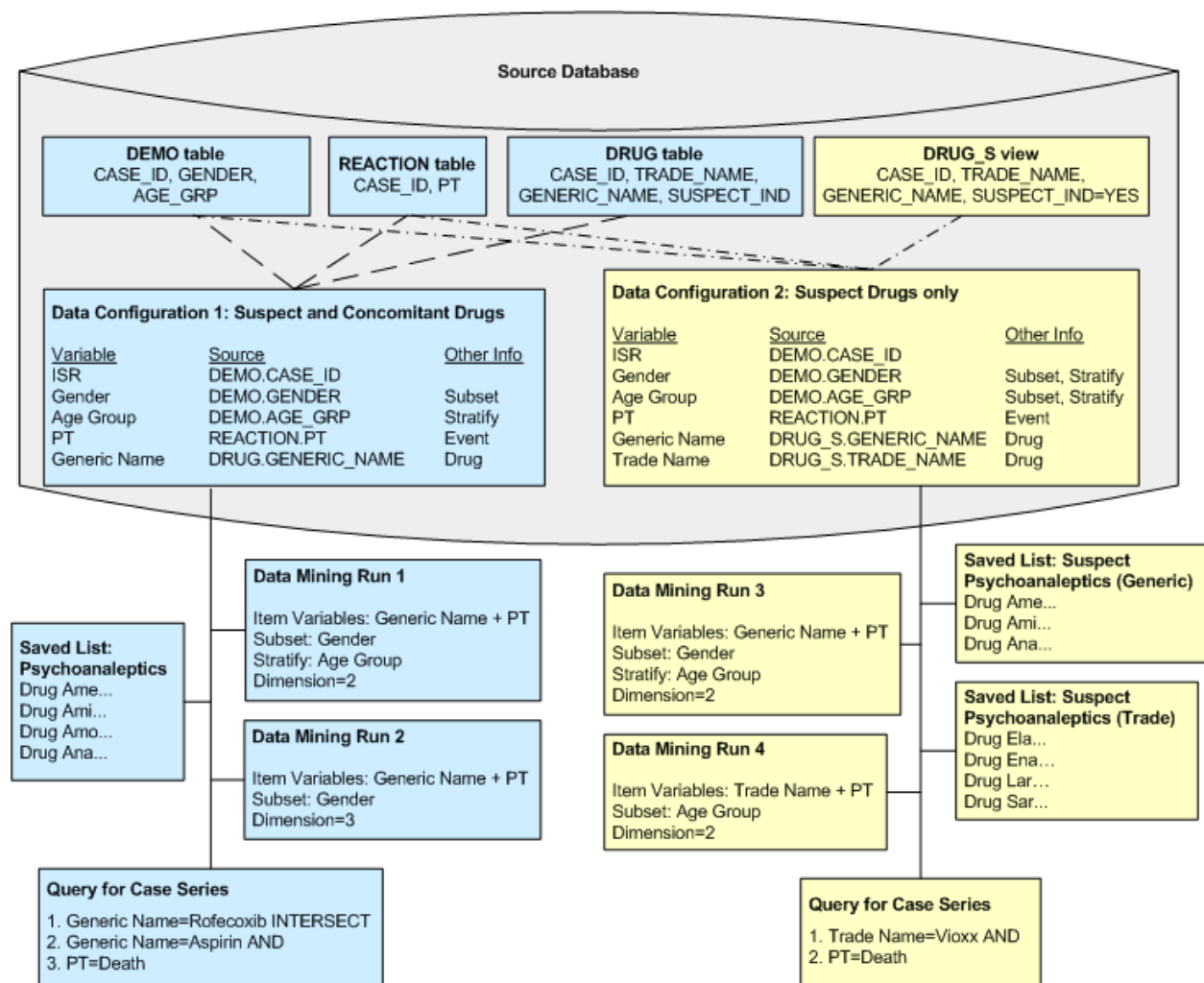
## Data configuration tables

During Empirica Signal installation, a master configuration table for all source databases is created in another Oracle account. The application populates this master configuration table automatically as you add, copy, or import data configurations. When you create a data configuration, an Oracle table, referred to as a data configuration table, is created automatically. This configuration table resides in the same Oracle account as the source data. Multiple data configurations and data configuration tables might exist for an Oracle account.

A supervisor can view the data configuration table for a current run and the master data configuration table for the account from the [Data Sources page](#).

## Example of data configuration

This example shows two data configurations for the same source database. The database includes both tables and views. A view may not include all the data in the table on which it is based. For example, the DRUG table includes all reported drugs for each case, while the DRUG\_S view on that table includes only drugs with a suspect indicator value of YES. The data mining runs and queries that are based on these distinct configurations are different, as both the data selected for each configuration, and the way the data can be used in the application, are different. Providing a variety of configurations can be useful for the comparative analyses conducted by Empirica Signal users.



## Viewing existing data configurations

The Manage Configurations page shows a list of the [data configurations](#) that have been added to any of the source databases. It lists configurations that you created or for which you have the Edit permission. The Is Valid column tells you whether or not a data configuration has been validated.

1. Log in to Empirica Signal as a user with the **Manage Configurations** permission.
2. Click **Settings**.

The Settings page appears.

3. In the **Configure System** section, click **Manage Configurations**.

The Manage Configurations page appears and provides the following information about each data configuration:


Column	Description
Name	Name of the configuration.
Desc	Description of the configuration.
Database Group	Name of the database group to which the configuration is assigned. Results reviewers can use the database group when <a href="#">finding and selecting a data mining run</a> . The application also uses the database group when determining color changes for <a href="#">case ID links</a> that are visited by users.
Owner	Name of the user who created the configuration.
Account	Name of the Oracle account in which the configuration resides.
Table	Name of the Oracle table representing the configuration.
Drilldown Map	Name of the <a href="#">drilldown map table</a> , which specifies the source of case details that display when a user <a href="#">drills down</a> .
Source Desc	Name of the <a href="#">source description table</a> , which provides information about the source data.
Is Valid	Yes, if the configuration has been <a href="#">validated</a> . No, if the configuration requires validation.

## Data configuration options

- To [add a data configuration](#), click **Add Configuration**.
- To [import data configurations](#), click **Import Configurations**.

- To [validate data configurations](#), click **Validate Configurations**.
- To print, download, or [publish](#) multiple data configurations, click **Select Rows**. You can then check the rows for the configurations on which you want to act. You can also click **Select All** to check all rows (or click **Clear All** to uncheck all rows). Then click the action that you want to perform on the selected rows.


### Row menu options

- If you click the row menu () for a data configuration, you can click **Edit** to [view or edit the data configuration](#).
- For information about viewing, printing, or downloading tables or changing the way data displays in the table, see [About tables](#).



## Viewing a data configuration



When you view a data configuration, information about the data configuration as a whole and about variables in the data configuration appears. You can edit the data configuration or the data configuration variables.

1. Click **Settings**.  
The Settings page appears.
2. In the **Configure System** section, click **Manage Configurations**.  
The Manage Configurations page appears.
3. Click the row menu () for the configuration, and then click **Edit**.  
The Modify Configuration page appears, displaying information about the data configuration as a whole and information about configuration variables.

## Data configuration options

- To [add a data configuration variable](#), click **Add New Variable**. For more information, see [Adding a data configuration](#).
- To copy the data configuration, click **Copy this Configuration**. For more information, see [Copying a data configuration](#).
- To delete the data configuration, click **Delete this Configuration**. For more information, see [Deleting a data configuration](#).
- To edit the data configuration, click **Edit** in the right-most column of data configuration information. For more information, see [Editing a data configuration](#).

## Row menu options

- To [edit a data configuration variable](#), click  for the variable, and then click **Edit**. For more information, see [Adding or editing a data configuration variable](#).
- To delete a data configuration variable, click  for the variable, and then click **Delete**. Click **OK** for the message confirming the deletion.

---

**Note:** You cannot delete a data configuration variable if it is referenced by existing data mining runs.

---

For information about viewing, printing, or downloading tables or changing the way data displays in the table, see [About tables](#).

## Data configuration and variables information

The Modify Configuration page provides information about the data configuration and the data configuration variable.

### Data configuration information

The Modify Configuration page provides the following information about the data configuration:

Field	Description
ID	Unique identifier that is assigned automatically to the configuration.
Name	Name of the configuration.
Description	Description supplied for the configuration.
Database Group	Name of the database group to which the configuration is assigned. Results reviewers can use the database group when <a href="#">finding and selecting a data mining run</a> . The application also uses the database group when determining color changes for <a href="#">case ID links</a> that are visited by users.
Owner	Full name associated with the username that created the configuration.
Table	Name of the Oracle table containing the specification of the configuration.
Drill Down Map Table	Name of the <a href="#">drilldown map table</a> , which specifies the source of case details that appear when a user drills down to view case details.
Source Description Table	Name of the <a href="#">source description table</a> , which provides information about the source database.
Timestamped	YES, if the configuration supports <a href="#">timestamped data</a> . NO, if the configuration does not support timestamped data.
Drug Hierarchy Account (or Drug Hierarchy Version Table)	Name of the Oracle account that drug variables with a selection type of <b>Select from Drug Browser</b> in the configuration use for hierarchical values. For timestamped configurations, name of the table that stores one or more valid hierarchy accounts by date.
Event Hierarchy Account (or Event	Name of the Oracle account that event variables with a selection type of <b>Select from Event Browser</b> in the configuration use for

Hierarchy Version Table)	hierarchical values. For <a href="#">timestamped data</a> , name of the table that stores one or more valid hierarchy accounts by date.
Includes Concomitant Drugs	YES, if the configuration includes suspect and concomitant medications. NO, if the configuration includes suspect drugs only. Results reviewers can use this information to <a href="#">find a data mining run</a> .
Hide From Data Mining	YES, if the configuration can be used for case series and reporting only. NO, if the configuration can be used for data mining, case series and reporting.
Valid	YES, if the configuration has been validated successfully. NO, if the configuration has never been validated or failed validation.

**Data configuration variable information**

The Modify Configuration page provides the following information about each variable in the data configuration:

Field	Description
Name	Unique name of the variable as it appears to Empirica Signal users on the Select Configuration page. For example, a column might be named SYMPTOM in the analysis table, and Event in the Empirica Signal application.
Desc	Description of the variable.
Table	Name of the source database table containing the column that corresponds to the variable.
Column	Name of the database table column that corresponds to the variable.
Prefix	A prefix is required only if the variable type is Event, Drug, or Generalized Item. The alphabetical order of prefixes determines the column names for the variables in the <a href="#">complete results table</a> . For example, if the prefix for the drug variable is D and the prefix for the event variable is E, the drug variable is in the ITEM1 column and the event variable is in the ITEM2 column.  <b>Note:</b> Multiple variables with the same prefix cannot be used as item variables in the same data mining run.
Variable Type	For possible variable types, see <a href="#">Adding or editing a configuration variable</a> . If a subtype (Generic, Trade, or Ingredient) is specified for a variable with a variable type of Drug, it appears after Drug in

	parentheses.
Selection Type	For possible selection types, see <a href="#">Adding or editing a configuration variable</a> .
Hierarchy Level	Displays the hierarchy level, if any, specified for event or drug variables with a selection type of Select from Drug (or Event) Hierarchy.
Visibility	DM & Q, if the variable is available for data mining runs and query-based case series. DM, if the variable is available for data mining runs but not for query-based case series.
Hide from Query Wizard	If you do not want the variable to be available during creation of a query, from the <b>Hide from Query Wizard</b> drop-down list, select Yes.
Value Case	For possible value cases, see <a href="#">Adding or editing a configuration variable</a> .
Unique Values Table	Name of the <a href="#">unique values table</a> , if any, associated with the variable.
Hierarchy Table	Name of the hierarchy table, if any, associated with the variable.
Data Transformation	Name of the <a href="#">data transformation</a> , if any, associated with the variable.

## Defining data configurations

### Adding a data configuration

When you add a [data configuration](#), you specify information about the data configuration as a whole and you add data configuration variables. Another alternative is to [copy an existing data configuration](#) and edit it as needed.

The only required attributes of a data configuration are its name, drill-down map, and configuration table name. You might want to create the data configuration with only those attributes, [add variables to the data configuration](#), and then [edit the data configuration](#) to specify additional attributes. Also note that some data configuration attributes, such as permissions to the data configuration, must be specified during editing (not during creation).

1. Click **Settings**.  
The Settings page appears.
2. In the **Configure System** section, click **Manage Configurations**.  
The Manage Configurations page appears.
3. Click **Add Configuration**.  
The Add/Import Configuration page appears.
4. If you have not already done so during your current Empirica Signal session, you must [connect to the Oracle account](#) to contain the configuration.
  - A. From the list of accounts, click the account in which you want to add the new configuration.
  - B. In the **Oracle account** field, leave or enter a different value.
  - C. Click **OK**.

When the system has connected, the Add Configuration page appears.

5. In the **Name** and **Description** fields, enter a unique name and a description for the configuration.

During Empirica Signal activities, users select a configuration to use. The name and description are important and should provide information about the source data. For example, an AERS configuration might be named "2012Q4: AERS+SRS (S + C)", indicating the year and quarter, the fact that SRS data is included, and the fact that both suspect (S) and concomitant (C) drugs are included.

---

**Note:** If a data configuration was deleted by reference only, it is still in the database and you cannot create a new configuration with the same name.

---

6. Next to the **Drilldown Map** field, click **Select/Edit Table** to [specify a drilldown map table](#). Select the table from the **Select Drilldown Table** drop-down list and

click **OK**. If you do not specify a drilldown map table, the configuration will not pass validation.

---

**Note:** If the source data is timestamped, then for each table referenced by the drilldown map table, there must be at least one variable included in the configuration.

---

7. Next to the **Source Description Table** field, click **Select Table** to [select a table](#) that has been set up as a [source description table](#) in the Oracle account to which you are connected. For [timestamped data](#), you should always specify a source description table. If the data is not timestamped, the source description table is optional. In the Select Table dialog box, click a table and click **Save**.
8. To make the configuration unavailable for data mining runs, check **Hide from Data Mining**. The configuration can then be used for other activities, such as querying and reporting, but not for data mining. For example, you should not use for data mining a configuration pointing to source data from which duplicates have not been removed.
9. To identify the configuration as including cases with suspect and concomitant drugs, check **Database includes Concomitant Drugs**. If the configuration includes suspect drugs only, clear this check box.
10. If the source data includes [timestamped data](#), allowing for the recreation of data as of a particular point in time, check **Database is Timestamped**.
11. If you have not checked **Database is Timestamped**, from provide the name of a Drug Hierarchy Account, an Event Hierarchy Account, or both by selecting them from the drop-down lists.

or

If you have checked **Database is Timestamped**, click **Select/Edit Table** to define hierarchy accounts for specified time periods.

If you want to associate drug variables or event variables in the configuration with a dictionary that defines a hierarchy of terms, see [Drug and event hierarchies](#).

12. Select the drug hierarchy value from the **Drug Hierarchy Account** field.  
By default, the value selected is None.
13. Select the event hierarchy value from the **Event Hierarchy Account** field.  
By default, the value selected is None.
14. In the **Configuration Table Name** field, enter the unique name of the table to hold the new configuration in the Oracle account to which you are connected. The table name cannot start with a number, and cannot be edited.
15. Click **Save**.

The configuration is saved and the [Modify Configuration page](#) appears.

Prior to validating the configuration you must add variables. To add configuration variables to the configuration, click **Add New Variable**.

### **Additional configuration activities**

You can perform the following optional activities.

- To [validate the configuration](#), click **Validate Now**.
- To test the configuration, select it for an Empirica Signal activity. You have not yet assigned permissions to the configuration, but you can use it because you are the configuration owner. It is recommended that you test the configuration before assigning permissions to it.
- [Edit the configuration](#) as needed. During editing, you can specify a link to a third-party application (to appear with case details), assign the configuration to a database group, and assign permissions to the configuration. You must assign permissions before other users can access the configuration.
- Validate the configuration again if you made changes to it. Even if the only change was to assign permissions, you must validate the configuration again.

## Connecting to an Oracle account

When you add or import data or topic workflow configurations, the Empirica Signal application must connect to an Oracle account. The first time you connect to an Oracle account during your current session, you must provide the Oracle password. Once you provide the password, you remain connected to that Oracle account until you log out.

1. Click **Settings**.

The Settings page appears.

2. In the **Configure System** section, click **Manage Configurations**.

The Manage Configurations page appears.

3. Click **Add Configuration**.

The Add/Import Configuration page appears.

4. To add a configuration, click the name of an existing Oracle account. For data configurations, click **Choose a Different Account** and provide the name of an Oracle account.

The application adds topic workflow configurations immediately.

Login fields appear.

- A. In the **Oracle password** field, type the password for the Oracle account. The password is case sensitive.

- B. Click **OK**.

When the system has connected, the [Modify Configuration page](#) appears.

or

To import a configuration, click the name of an Oracle account. For data configurations, click **Import Configurations from a Different Account** and provide the name of an Oracle account.

Login fields appear.

- A. In the **Oracle password** field, type the password for the Oracle account. The password is case sensitive.

For topic workflow configurations, if you import from the TOPIC\_WORKFLOW account, you do not need to provide the Oracle password.

- B. To assign the data configurations to a database group, select an existing group or click **Add to new group** and enter a name for the new group. Results reviewers can use this information when [finding and selecting a data mining run](#).

- C. Click **OK**.



## Specifying a drill-down map table

During many activities, such as viewing data mining results, users can click case ID links to [drill down to a list of cases](#) (first-level drilldown) and can then drill down further to [view case details](#) (second-level drilldown). The type of data presented during drilldown is from the source database tables, and is determined by the drilldown map table associated with the data configuration.


Drilldown information comes from the [source data](#). Users do not see values for a variable that includes a [data transformation](#) defined in the configuration, or any values that are missing from the source data.

---

**Note:** Drilling down to view case details is possible only if the appropriate [site option](#) has been set and the user has the appropriate permission.

---

## Selecting a drilldown map table

1. Click **Settings**.  
The Settings page appears.
2. In the **Configure System** section, click **Manage Configurations**.  
The Manage Configurations page appears.
3. Click **Add Configuration**.  
The Add/Import Configuration page appears.  
or
  - A. On the **Manage Configurations** page, click the row menu () for a configuration, and then click **Edit**.  
The Modify Configuration page appears.
  - B. In the right-most column of the configuration, click **Edit**.  
The Edit Configuration Details page appears.
4. Next to the **Drilldown Map** field, click **Select/Edit Table**.  
The Select/Edit Drilldown Table dialog box appears.
5. From the **Select Drilldown table** drop-down list, select a drilldown map table and click **OK**. Available drilldown map tables are those in the Oracle account to which you are connected.

## Creating a drilldown map table

1. In the **Select/Edit Drilldown Table** dialog box, click **Create New Table**.

2. In the **Enter name of new drilldown table** field, type a name for the new table. Table names cannot include:
  - Spaces
  - ?, \, or "

It is recommended that you use a name that distinguishes the table from other drilldown map tables and indicates the table's purpose, such as DRILLDOWN\_MAP.

3. Click **Create Table**.

The new table appears as the selected drilldown table.

The first column of the drilldown map table shows the information type.

4. Edit the drilldown map table as described below.

### Editing a drilldown map table

---

**Note:** The same drilldown map table may be used by more than one data configuration in the Oracle account. Before editing a drilldown map table, make sure you want the changes to apply to all data configurations that refer to the drilldown map table.

---

1. In the **Select/Edit Drilldown Table** dialog box, from the **Select Drilldown table** drop-down list, select the drilldown table.
2. Select the **Type** you want to edit and click **Edit**. (If you want to clear values for the type, click **Clear**.)

Another dialog box appears for you to specify variables for the type.
3. In the **Table** field, click **Select** to open the **Select Table and Column** dialog box and select an available table and column for the drilldown table to reference.

The application populates the Table field and Report ID Column field with your selection. The column should be compatible with the column for case IDs in the source data used in data mining.
4. In the **Section Title** field, type a label for the section of the drilldown map table.

This label appears on the Case Details page as the section heading.
5. In the **Worksheet label** field, type a label for the application to apply to the table worksheet.

This label appears on the worksheet tabs when Case Details are downloaded to Excel.
6. In the **Display Columns** section, select and label each column to include.
  - A. From the first **Column** drop-down list, select a variable.
  - B. In the corresponding **Label** column, type a label (column heading) to apply to the variable in the drilldown table.

In the drilldown information, variables appear in the order in which you specify them.

7. If you want the drilldown information to show only distinct values for the variables, check **Distinct**.
8. Click **Save**.
9. When you have finished specifying all types of information that you need, click **OK**.

The Select/Edit Drilldown Table dialog box appears with the Table, Report ID Field, and Display Columns columns filled in.

### Copying a drilldown map table

1. In the **Select/Edit Drilldown Table** dialog box, from the **Select Drilldown table** drop-down list, select the drilldown table.
2. Click **Copy Table**.
3. In the **Enter name of new drilldown table** field, type a name for the new table. It is recommended that you use a name that distinguishes the table from other drilldown map tables and indicates the table's purpose.
4. Click **Create Table**.
5. Edit the drilldown map table as needed.

### Drilldown information types

The following table lists the types of information that you can include in the drilldown map table and the corresponding label in the drilldown display. The LIST type determines contents of the Cases page (first-level drilldown), and its first variable must represent the case ID. All other types determine contents of the Case Details page (second-level drilldown). Typically, the CASE, DRUG, and EVENT types, at a minimum, are included on the Case Details page. The following table shows each type and the corresponding name of the section on the Case Details page; types are listed in the order in which they appear on the Case Details page.

Type	Description
CASE	Case Information
DRUG	Reported Drugs/Vaccines
EVENT	Reported Events/Symptoms
OUTCOME	Reported Outcomes
SOURCE	Reported Sources
BATCH_LOT	Batches/Lots

DEVICE	Devices
DEVICE_CODE_DEV	Facility Device Codes
DEVICE_CODE_PAT	Facility Patient Codes
DEVICE_MANU_CONCLUDE	Manufacturer Conclusion Codes
DEVICE_MANU_METHOD	Manufacturer Method Codes
DEVICE_MANU_RESULT	Manufacturer Result Codes
DIAGNOSTIC	Diagnostic Procedures Performed
DRUG_HISTORY	Patient Drug History
DRUG_IND	Indications
DRUG_REACT	Drug-Reaction Information
LINKED_CASES	Linked Cases
LITERATURE	Literature References
MEDICAL_CONDITION	Medical Conditions
MEDICAL_HISTORY	Medical History
PATIENT_REGISTRY	Patient Registry Information
PREGNANCY	Pregnancy Information
PREGNANCY_OUTCOME	Pregnancy Outcome
REPORTER	Reporter Information
CAUSE_OF_DEATH	Cause of Death
PARENT	Parent
PARENT_DRUG_HISTORY	Parent Drug History
PARENT_MEDICAL_HISTORY	Parent Medical History
AES_ADDL_HISTORY	Chronological History
AES_ADDL_INFO	Additional Information
AES_CEV_DRUG	Drug-Event Information

AES_CODES_DEV	Device Codes
AES_DEVICE_CODE	Device Problems
AES_DISEASE	Diseases
AES_DOSE	Dosing Regimens
AES_EVAL	Case Evaluation Information
AES_EXPOSED_DEVICE	Devices
AES_LAB	Associated Lab Results
AES_REPORTER	Reporter Information
NARRATIVE	Narrative For example, medical history or laboratory data for the case. See <a href="#">Narrative text</a> for details about setting up narrative text.)

## Selecting an Oracle table or column

If the activity you are performing requires you to specify a table:

1. Click the table name.
2. Click **Save**.

or

If you need to select a table and column:

1. Click a table name.  
The Available Columns list shows columns in that table.
2. Click a column name.
3. Click **Save**.

## Narrative text

If the [source data](#) contains narrative text, you can include the narrative on the [Case Details page](#). There are several ways that narrative text may be set up in the source data.

Assume that there are three categories of narrative text (CAT\_A, CAT\_B, and CAT\_C) and two report IDs (10, 11). The simplest way that narrative text may be stored is for each category of narrative text to have its own column in the source database table, with one row per report ID. This approach is used in the following example:

REPORT_ID	CAT_A	CAT_B	CAT_C
10	This is category A narrative text for case 10.	This is category B narrative text for case 10.	This is category C narrative text for case 10.
11	This is category A narrative text for case 11.	This is category B narrative text for case 11.	This is category C narrative text for case 11.

For the NARRATIVE type in the [drilldown map table](#), you would specify CAT\_A, CAT\_B, and CAT\_C as display columns.

## Concatenation of narrative text

If the narrative text for a column is too long to fit into a single column of data type VARCHAR2, it may be split it up between columns that have the same root name and a two-digit sequence number. In the following example, the narrative text for case ID 10 is stored in three columns:

REPORT_ID	CAT_A01	CAT_A02	CAT_A03	CAT_B	CAT_C
10	This is category A narrative text for case 10.	It is too long to fit into one column of the database table.	So it is split between three columns.	This is category B narrative text for case 10.	This is category C narrative text for case 10.
11	This is category A narrative text for case 11.			This is category B narrative text for case 11.	This is category C narrative text for case 11.

For the NARRATIVE type in the drilldown map table, you would specify CAT\_A, CAT\_B, and CAT\_C as display columns. Empirica Signal would concatenate values in the CAT\_A01, CAT\_A02, and CAT\_A03 columns because their root name is the same (CAT\_A). Values are concatenated in the order of the columns' two-digit sequence numbers.

## Narrative text spanning multiple rows

In the source data, there may be a column that stores the category and another column that stores the narrative text. If there are multiple rows per report ID, you must use the option "NARRATIVE spans multiple rows" in the drilldown map table for the NARRATIVE type. This approach is used in the following example:

<b>REPORT_ID</b>	<b>NARRATIVE_CATEGORY</b>	<b>NARRATIVE_TEXT</b>
10	CAT_A	This is category A narrative text for case 10.
10	CAT_B	This is category B narrative text for case 10.
10	CAT_C	This is category C narrative text for case 10.
11	CAT_A	This is category A narrative text for case 11.
11	CAT_B	This is category B narrative text for case 11.
11	CAT_C	This is category C narrative text for case 11.

For narrative data stored this way, the Oracle data type of the column storing the narrative text is typically CLOB (character large object), so there is no restriction on narrative length. For the NARRATIVE type in the drilldown map table, you would specify NARRATIVE\_CATEGORY and NARRATIVE\_TEXT as display columns and you would check **NARRATIVE spans multiple rows**.



## Source description table

A source description table (or view) describes the [source data](#) that is used in the Empirica Signal application. Information from this table appears when users do the following:

- View case details.
- View a results table on the Data Mining Results page.
- Display notes when viewing source tables from the [Data Sources page](#).

Additionally, this table defines information needed for timestamped data. You must specify a source description table for a [data configuration](#) that supports timestamped data.

A source description table is created and populated outside of the Empirica Signal application using standard Oracle tools or any application that enables working with Oracle tables. The table must be in the Oracle account containing the source database tables. A data configuration in the Empirica Signal application then refers to the table. An existing data configuration can be edited to add a source description table to it.

### Content of the source description table

For the table name, it is recommended that the name distinguishes the table from other source description tables and indicates the table's purpose. A source description table must include one row with the following columns. All columns must be included, even if they are not used.

Column	Data Type	Description
ID	NUMBER(1)	Unique identifier of the row. (There will be only one row.)
DESCRIPTION	VARCHAR2(30)	Description of the source data.
LOADDATE	DATE	Date and time when the source data was loaded.
SOURCE	VARCHAR2(30)	Source of the safety data.
DRUGDICTIONARY	VARCHAR2(30)	Reserved for future use.
DRUGDICTIONARYVER	VARCHAR2(30)	Reserved for future use.
EVENTDICTIONARY	VARCHAR2(30)	Reserved for future use.
EVENTDICTIONARYVER	VARCHAR2(30)	Reserved for future use.
ASOFDATE	DATE	Supports use of timestamped data.
EARLIEST_ASOFDATE	DATE	Supports use of timestamped data

For example, suppose the DESCRIPTION is TEST\_AERS\_2007, the LOADDATE is 02-Jan-2008, and the SOURCE is NTIS. The description of the source database appears in the application as:

Source Data: TEST\_AERS\_2007 from NTIS on 02-Jan-2008

You can view the source description table on the [Data Sources page](#).

## Timestamped data

To support [timestamped data](#), the application must know the range of dates that are valid for users to enter when prompted for an As Of date. The following two columns of the source description table define the range:

- **ASOFDATE**—Latest date for which there is consistent source data.
- **EARLIEST\_ASOFDATE**—Earliest date for which there is consistent source data.

The values of these columns are determined during the data preparation process.

On Empirica Signal pages where users specify an As Of date, the default date that appears is the ASOFDATE from the source description table. Users can change the displayed date to another date that is earlier than or equal to the ASOFDATE and later than or equal to the EARLIEST\_ASOFDATE.

## Drug and event hierarchies

In the Empirica Signal application, hierarchies indicate the way in which terms, typically adverse event terms or drug terms, are organized in the source data. For example, FOI FDA AERS data uses the MedDRA medical terminology, which is a hierarchical classification system for event terms. Other databases use COSTART terminology for event terms, or the WHO Anatomical Therapeutic Chemical (ATC) classification system for drug terms.

Hierarchical terms are stored in a separate Oracle account, referred to as a hierarchy account, which you can associate with variables in the data configuration. For example, suppose that the source data contains PT, HLT, HLG, and SOC values, which were determined by MedDRA. In the data configuration, you associate the PT, HLT, HLG, and SOC variables with the appropriate level of the MedDRA hierarchy of terms in the hierarchy account.

For a data configuration that supports timestamped data, you must specify the [hierarchy versions](#) that correspond to various time periods of the source data. For example, several different versions of MedDRA might have been used over time.

If hierarchy information is set up:

- Users can select drug or event terms [from the hierarchy](#) during certain activities. (They must also set a [user preference](#) to enable hierarchies.)
- A run creator can check **Include drug/event hierarchies' primary paths in run results** to add hierarchy levels to the data mining results generated by the run. Terms in these columns represent the primary path in the hierarchy and are assigned by the application using information in the hierarchy account. They might be different than the hierarchy terms, if any, that are in the source data.
- A sector map can be displayed for data mining results.

---

**Note:** An alternate way to set up hierarchy information is to use [hierarchy tables](#), which are supported for historical reasons.

---


## Specifying hierarchy versions for timestamped data

For a data configuration that supports [timestamped data](#), you must specify hierarchy versions for various time periods of the [source data](#). The source data contains start and end dates for each row of data.

For example, the data includes the following:

Case ID	Start	Stop
100	01-01-2004	06-01-2004
200	06-01-2004	01-01-2005
300	01-01-2005	

Suppose MedDRA Version 6.1 was used for coding source data until June 1, 2004, then MedDRA Version 7.0 was used. On January 1, 2005, MedDRA Version 7.1 was used. You need to tell the Empirica Signal application which data uses each version of MedDRA. The instructions below explain how to specify the MedDRA versions.

1. Click **Settings**.  
The Settings page appears.
2. In the **Configure System** section, click **Manage Configurations**.  
The Manage Configurations page appears.
3. Click the row menu () for the configuration, and then click **Edit**.  
The Modify Configuration page appears.
4. In the top section, select the configuration and then click the **Edit** link in the far right column.  
The [Edit Configuration Details page](#) appears.
5. Next to the **Event Hierarchy Version Table** field, click **Select/Edit Table**.  
The Event Hierarchy Accounts for Configuration dialog box appears.
6. If you are using a single hierarchy account for the configuration, enter the account name in the first row (labeled ALL DATES) in the Hierarchy Account column. For example:

	Date	Hierarchy Account
<b>ALL DATES</b>	<input type="text"/>	MEDDRA61
	<input type="text"/>	<input type="text"/>
	<input type="text"/>	<input type="text"/>
		<input type="text"/>

7. If you are using more than one version, in the **Date** column in the first row enter the earliest cutoff date in mm/dd/yyyy format. In the **Hierarchy Account** column, enter the appropriate MedDRA account name.
8. In the next row, enter a date and a different hierarchy account.
9. Repeat this process as needed.
10. For the last time period, enter only an account. For example:

Define Effective Dates for the Event Hierarchy Accounts

	Date	Hierarchy Account
<b>DATE &lt;=</b>	<input type="text" value="06/01/2004"/>	MEDDRA61
<b>06/01/2004 &lt; DATE &lt;=</b>	<input type="text" value="01/01/2005"/>	MEDDRA70
<b>01/01/2005 &lt; DATE</b>	<input type="text"/>	MEDDRA71
	<input type="text"/>	<input type="text"/>
		<input type="text"/>

Add additional empty rows upon saving

11. If you need to add more dates and hierarchy accounts than can currently fit on this page, check **Add additional empty rows upon saving**.
12. Click **Save**.  
If you checked **Add additional empty rows upon saving**, additional rows appear.
13. When you are finished specifying accounts, clear the **Add additional empty rows upon saving** checkbox and click **Save**.

## Unique values table

A unique values table (UVT) contains all unique values that exist in the [source data](#) for a specific configuration variable. When displaying all values for a variable, the Empirica Signal application references the unique values table for that variable. (The exception to this is on the Select Criteria page for results of a data mining run, where users select from a list of values in the data mining results.)

When you define [data configuration variables](#), if a variable's selection type is Distinct Value List, Select from Drug Hierarchy, or Select from Event Hierarchy, you can also specify a unique values table. If you do not specify a UVT for a variable, the application creates the corresponding UVT automatically when you [validate the data configuration](#). If the source data is updated, as in a timestamped data configuration, you must also update the unique values tables or delete them for the individual variables so that they will be re-created (and updated) automatically during validation.

A unique values table name starts with UVT by default. The table must have an ITEM\_VALUE column, which contains one row for each unique value. The column type of the ITEM\_VALUE column must match the column type of the corresponding column in the source database table.

If text values for a variable are [mapped](#), the unique values table contains source data values, not the mapped values.


---

**Note:** In a timestamped database there are no start dates and end dates associated with the unique values table so all unique values that ever existed are in the unique values tables.

---

A supersuser can view the unique values tables on the [Data Sources page](#).

## Adding or editing a data configuration variable

When creating or editing a data configuration, you can add or modify configuration variables as described below. You can also delete data configuration variables by clicking the row menu () for the variable on the Modify Configuration page and then clicking **Delete**.


If you edit or delete data configuration variables after the data configuration has been used to create a data mining run or a query-based case series, you might not be able to view results for that run or that case series properly. For example, if you use a variable as an item variable in a data mining run, then change its variable type so that it is no longer an item variable, Empirica Signal will not be able to display the run results properly.

1. Click **Settings**.


The Settings page appears.

2. In the **Configure System** section, click **Manage Configurations**.

The Manage Configurations page appears.

3. Click the row menu () for the data configuration, then click **Edit**.

The [Modify Configuration page](#) appears.

4. Click the **Add New Variable** link , or click  for a configuration variable, and then click **Edit**.

The Edit Variable page appears.

5. In the **Name** field, enter the name of the variable.

Variable names display throughout the application, including when users select criteria for viewing data mining results, defining queries, or creating report definitions. For example, a column might be named SYMPTOM in the Oracle table, but renamed to appear as Event in the application.

6. In the **Description** field, type a description of the variable.

7. Next to the **Table** field, click **Select Table/Column**.

The Select Table and Column dialog box appears.

A data configuration can refer to one or more tables in a database, and one or more columns in each table. For example, you might create a data configuration that gets data from a demographics table, a drugs table, and an events table. However, if you already created an Oracle view that combines data from those three tables, you can refer to that view instead of to the three tables.

- A. From the **Available Columns** list, [select the column](#) and click **Save**. You can select any table in the Oracle account to which you are connected, and any column in that table.

The Edit Variable page appears with the column you selected displayed in the Column field.

8. In the **Prefix** field, enter a prefix.

A prefix is required only if the variable type is Event, Drug, or Generalized Item. The alphabetical order of prefixes determines the column names for the variables in the [complete results table](#). For example, if the prefix for the drug variable is D and the prefix for the event variable is E, the drug variable is in the ITEM1 column and the event variable is in the ITEM2 column.

---

**Note:** Multiple variables with the same prefix cannot be used as item variables in the same data mining run.

---

9. From the **Variable Type** drop-down list, select a variable type.

To determine which variable type is appropriate, you might want to know the Oracle data type of the column. To view the Oracle data type, click **Select Table/Column** next to the Table field. In the Available Columns list, the data type appears in parentheses after the column name.

The variable type can be one of the following:

Variable Type	Meaning
Other	Identifies a variable that is not available as an item variable in data mining runs. If you want the variable to be available for subsetting or stratification of data mining runs, check <b>Use as Subset Variable</b> or <b>Use as Stratification Variable</b> . The column must have an Oracle data type of CHAR, VARCHAR2, NUMBER, FLOAT, INTEGER, DECIMAL, or SMALLINT.
Age	Identifies the patient age. The column must have an Oracle data type of CHAR, VARCHAR2, NUMBER, INTEGER, or SMALLINT.  The selection type for this type of variable must be either Distinct Value List or Continuous.
Drug	Identifies the drug or vaccine. All variables of this type are available as item variables in data mining runs. The column must have an Oracle data type of CHAR or VARCHAR2.  A prefix must be specified for this type of variable, and its selection type must be either Distinct Value List or Select from Drug Hierarchy.
Event	Identifies the event or symptom. All variables of this type are available as item variables in data mining runs. The column must have an Oracle data type of CHAR or VARCHAR2.  A prefix must be specified for this type of variable, and its selection type must be either Distinct Value List or Select from Event Hierarchy.
External Report ID	For use when you want to include a link to an external (third-party) application from case details. (To do so, you specify an external application URL on the <a href="#">Edit Configuration Details page</a> .) To use this feature, there must be a mapping of Empirica Signal case IDs to the



IDs used by the external application. A suggested way to provide the mapping is to include in the demographics table an additional column, such as EXTERNAL\_ID, to contain the external ID associated with each case ID in the demographics table. In the data configuration, you must include a variable for that column and assign to it the variable type External Report ID. There can be only one variable of the type External Report ID in the data configuration.

If the case IDs used by the external application are the same as the Empirica Signal case IDs, an external report ID is not needed to link to the external application.

Gender	<p>Identifies the patient gender. The column must have an Oracle data type of CHAR or VARCHAR2.</p> <p>The selection type for this type of variable must be either Distinct Value List or Free Text.</p>
Generalized Item	<p>Identifies variables other than drug or event that are available as item variables in data mining runs. For example, if the Gender variable's type is Generalized Item, users can perform data mining for combinations for Drug, Event, and Gender values. The column must have an Oracle data type of CHAR or VARCHAR2.</p> <p>A prefix must be specified for this type of variable, and its selection type must be Distinct value List.</p>
Report ID	<p>Identifies the case ID (report ID or ISR). The column must have an Oracle data type of CHAR or VARCHAR2. You must include a Report ID variable for each source database table referenced by a configuration variable. As a result, the configuration might have several Report ID variables.</p> <p>The selection type for a Report ID variable must be Distinct Value List, and the variable cannot be identified as a subset variable or stratification variable.</p>
	<p><b>Note:</b> In the Query Wizard, this type of variable allows entry of a string of report IDs separated by commas.</p>
Valid Start Date, Valid End Date	<p>Applies only if the data configuration supports <a href="#">timestamped data</a> (that is, <b>Database is Timestamped</b> is checked for the data configuration). Identifies the column in the source data that contains a start date or end date for each record.</p> <p>You must include a Valid Start Date variable and a Valid End Date variable for each source database table referenced by a configuration variable. As a result, a data configuration might have several start and end date variables.</p> <p>The selection type for this type of variable must be Continuous.</p>

**Note:** If the variable type is Drug, you must also specify a variable subtype of Generic, Ingredient, or Trade. Each subtype can be used for only one data

configuration variable. The subtype makes the variable's values available for selection on the Drugs tab as a generic name, an ingredient, or a trade name.

10. If you want the variable to be available for [subsetting](#) data mining runs, check **Use as subset variable**. Typically, the Variable Type of a subset variable is Other. You can define multiple variables in a data configuration as subset variables, though only one subset variable can be selected for a given data mining run.
11. If you want the variable to be available for [stratification](#) of a data mining run, check **Use as stratification variable**. Typically, the variable type of a stratification variable is Other. Although you can define a variable with a variable type of Drug, Event, or Generalized Item as a stratification variable, you cannot use the same variable as both an item variable and a stratification variable in the same run.

---

**Note:** Stratification variables that are not associated with [data transformations](#) are available as [additional covariates](#) in logistic regression runs.

---

12. From the **Selection Type** drop-down list, choose a selection type, which determines how users specify values for the variable when performing activities such as creating a query.

Selection Type	Meaning
Distinct Value List	Users choose values from a list. Variables with a variable type of Generalized Item, or of Other (with <b>Use as subset variable</b> or <b>Use as stratification variable</b> checked), must use this selection type. For variables with this selection type, you can identify a unique values table to supply the list of values. If you do not define a unique values table, the application creates one automatically when you <a href="#">validate the data configuration</a> .
Select from Drug Hierarchy, Select from Event Hierarchy	Use one of these selection types only if a drug or event hierarchy account is specified at the level of the configuration as a whole and you want users to be able to browse for and select terms from the hierarchy. (Users can also select values from a list.) If you do not specify this selection type, users need to select hierarchy terms from an alphabetized list instead of the hierarchy. See <a href="#">Drug and event hierarchies</a> .  Note: If there is a <a href="#">hierarchy table</a> specified for the individual variable, select the variable type Distinct Value List for the variable.
Continuous	Users specify a range of values by entering From and To values.
Free Text	Users type in a text string for which matches will be found.

13. In the **Hierarchy Level** field, select the hierarchy level.  
  
If the selection type of the variable is **Select from Drug Hierarchy** or **Select from Event Hierarchy**, and a drug or event hierarchy account is specified at the level of the data configuration, you must select a hierarchy level to tell the application which level of the hierarchy is represented by the variable.

---

**Note:** This field has no effect if there is a hierarchy table specified for the individual variable.

---

14. If you do not want the variable to be available during creation of a query, from the **Hide from Query Wizard** drop-down list, select **Yes**.
- 

**Note:** Regardless of this setting, a variable that uses a data transformation that maps values, defines cutpoints, or converts dates is not selectable in the [Query Wizard](#).

---

15. In the **Value Case** field for variables whose Oracle data type is CHAR or VARCHAR2, indicate the capitalization style that is used in the source data. The application automatically converts terms that users enter in the **Drug and Event Term** selection fields on the [Select Criteria page](#) to the capitalization style before a match is attempted, as follows:
- **Exact Match**—Entered values are not converted, and must match the case of the source data exactly.
  - **All Upper**—Values are in all upper case in the source data. Entered values are converted to all upper case.
  - **All Lower**—Values are in all lower case in the source data. Entered values are converted to all lower case.
  - **Upper First Letter Each Word**—The first letter of each word is capitalized in the source data. Entered values are converted so that the first letter of each word is in upper case and the rest are in lower case. For example, the entered value, Renal failure, becomes Renal Failure.
  - **Upper First Letter Each Term**—Values are in mixed case in the source data. Entered values are converted so that the first letter of each term is in upper case and the rest of the term is lower case. For example, the entered value, Drug Hypersensitivity, becomes Drug hypersensitivity.
16. In the **Unique Values Table** field, identify an Oracle table or view that contains the list of all possible values for the variable. You can specify an existing [unique values table](#) (from the Oracle account in which the configuration resides) by typing in its name.
- A. To select from a list of tables, click **Select Table**.
  - B. From the **Select Table** dialog box, select the table and click **Save**.

If you leave this field blank, the application creates a unique values table during configuration [validation](#).

---

**Note:** In a timestamped database, no start and end dates are associated with the unique values table, so all unique values that ever existed are in the tables.

---

17. To specify a hierarchy table for the variable, in the **Hierarchy Table** field, type the table name, or click **Select Table** to choose from all tables in the Oracle account to which you are connected. To supply a table name, click **Create New Table**.

The recommended way to set up event or drug hierarchies is to associate an Oracle account of hierarchy information with the configuration (on the Edit Configuration Details page). The ability to associate an individual variable with a hierarchy table still exists to provide backward compatibility with data configurations created in previous releases. For more information, see [Event and drug hierarchies](#).

18. In the **Data Transformation** field, specify a data transformation to transform source data into other values available for selection when data mining runs are created:
  - If you do not want to transform source data for the variable, click **None** (the default).
  - To [map text values](#), click **Text mapping**. This option applies only to variables that are based on a CHAR or VARCHAR value in the source database.
  - To [define variable cutpoints](#), click **User-defined cutpoints**. This option applies only to variables that are based on a NUMBER or DATE value in the source database.
  - To [exclude synthetic values](#), such as the names of Standardized MedDRA Queries (SMQs), click **Synthetic values**. This option applies only to variables that are based on a CHAR or VARCHAR value in the source database.
  - To [convert date values](#), select **Date function** and enter the function in the field. To select a function from a list, click **Select Function**. This option applies only to variables that are based on a DATE value in the source database.

19. Click **Save**.

If a warning message appears, as when there are leading or trailing white spaces in the source data for the variable, you can fix the problem or click **Ignore Warnings**, and then **Continue**.

20. Next, [validate the data configuration](#). For more information, see [Validating data configurations](#).

## Validating data configurations

Only data configurations that have passed a validation process are available for use during Empirica Signal activities. You must validate or re-validate a data configuration in the following situations:

- When it has been newly created.
- When it has been modified in any way, including changes to permissions.
- When it has been newly imported.

The validation process might generate warnings and errors. If warnings (but no errors) are generated, you can ignore them so that the data configuration passes validation. If errors are generated, you must correct them before the data configuration passes validation.


You can either validate a single data configuration, after modifying it, or validate multiple data configurations at the same time. For example, if you import multiple configurations, you might want to validate them all at once.

1. Click **Settings**.

The Settings page appears.

2. In the **Configure System** section, click **Manage Configurations**.

The Manage Configurations page appears.

3. To validate a single data configuration that you have just modified, click the row menu () for a configuration, and then click **Edit**.

The [Modify Configuration page](#) appears.

- A. Click **Validate Now**.

- If you select **Validate Now**, the application validates the data configuration. If valid, click **Continue**.

or

To validate multiple data configurations at the same time, on the [Manage Configurations page](#), click **Validate Configurations**. For example, if you [import](#) multiple data configurations, you can validate them all at once. When you validate multiple data configurations, the validation process is a background job that continues to run even if you exit the application.

The Configuration Validation page appears, showing the data configuration name, description, and validation status of each data configuration.

- A. Check the data configurations that you want to validate. (You can also check **Check All** or **Check None**.)

- B. Click **Validate**.

While the validation process runs, validation results are displayed.

4. When validation is complete, click **Continue**.
5. If necessary, [edit the configuration](#) and revalidate it.

## Validation process

During validation, the application does the following:

- **Shows errors and warnings, if any**—If there are errors, you cannot save the data configuration. Warning messages are prefaced by Warning. To ignore warning messages, check **Ignore Warnings**.
- **Runs the Oracle ANALYZE command for tables, if necessary, for tables that contain actual case data**—This command generates statistics on the underlying data. Oracle uses the statistics to optimize the performance of SQL commands, which the application uses for such tasks as displaying results. The ANALYZE command is run automatically during Empirica Signal installation. If views (rather than tables) are referenced, the ANALYZE command is run on the underlying table(s).
- **Creates a [unique values table](#) for any variable of the selection type Distinct Value List, Select from Drug Hierarchy, or Select from Event Hierarchy, but does not have an associated unique values table**—Although you cannot save a new data configuration in this state, it is possible for imported data configurations to be in this state.
- **Creates Oracle column indexes for columns referenced by any variable, if they do not already exist**—If a variable references a column in a view, no index is added.

## Situations that generate error or warning messages

Situations that generate an error message or warning message include the following:

- There are no variables defined for the configuration.
- There is not a variable of the type **Report ID** for each source database table referenced by the data configuration.
- The configuration has more than one variable of the type **External Report ID**.
- There are leading or trailing white spaces in the source data for a variable. Manually entered values that do not also include the leading or trailing spaces do not match the source data. For example, when entering data values in the Query Wizard or specifying drugs or events as selection criteria for run results.
- **Database is timestamped** is checked for the data configuration, but each source database table referenced by the data configuration does not have a variable of the type **Valid Start Date** and a variable of the type **Valid End Date**. Note that the source database table must contain columns (of the Oracle data type **DATE**) representing start and end dates for the data configuration to reference them.
- There is no drilldown map table defined for the data configuration.
- The drilldown map table does not include a row for the LIST, CASE, DRUG, or EVENT sections.

- The data configuration includes a variable of the selection type **Select from Event Hierarchy** or **Select from Drug Hierarchy**, but no event or drug hierarchy account is specified for the configuration.
- The data configuration includes a variable of the selection type **Select from Event Hierarchy** or **Select from Drug Hierarchy**, but the variable type is not **Event** or **Drug**, or no hierarchy level is set for the variable.
- **Database is timestamped** is checked for the data configuration, but there is not at least one variable for each source database table referenced by the drilldown map table.

## Publishing multiple data configurations

After you [validate a data configuration](#), you add permissions to login groups and users and publish the selected data configuration to the groups and users.

1. Click **Settings**.  
The Settings page appears.
2. In the **Configure System** section, click **Manage Configurations**.  
The Manage Configurations page appears.
3. Click **Select Rows**.  
The Manage Configurations page appears.
4. Select a row and click **Publish**.  
The Publish Configurations page appears.
5. To grant permissions for the configuration to your [login group](#), in the **Group Permissions** section next to the **Login Group**, click **No Access**, **Read**, or **Edit**.

or

To grant permissions to individual users in your login group, in the **Individual Permissions** section next to the **user**, click **No Access**, **Read**, or **Edit**.

A user's permissions for a configuration are determined by settings for both the individual user and the user's login group. For example, if the individual user has Read access, but that user's login group has Edit access, the user has Edit access.

Users with Read permission for a configuration can select the configuration for tasks such as creating a run or case series. Users with Edit permission can edit , copy, and delete the configuration, as well as use for tasks such as creating a run or case series.

6. Click **Save**.



## Importing data configurations

When you import [data configurations](#) from an Oracle account, you register them for use with the Empirica Signal application. When you import, all of the data configurations in the specified Oracle account are imported or re-imported.

If a data configuration has been deleted permanently, it cannot be re-imported. If it has had references to it removed, however, but has not been deleted permanently, it can be re-imported.

A data configuration cannot be imported or re-imported if there is another data configuration with the same name in another Oracle account.

In most cases, data configurations are created within the Empirica Signal application. If created outside of the application, a data configuration must have the same table structure as if it was defined within the application.

1. Click **Settings**.  
The Settings page appears.
2. In the **Configure System** section, click **Manage Configurations**.  
The Manage Configurations page appears.
3. Click **Import Configurations**.  
The Add/Import Configuration page appears.
4. The accounts from which you can re-import are listed as links for you to click, or you can select a different account by clicking **Import Configurations from a Different Account**.  
The data configurations in the account are imported.
5. [Edit the data configurations](#) that you imported, as necessary. In some cases, changes to the Oracle tables that are referenced by the configuration (such as the [drilldown map table](#)) might be required. Existing data configurations that are re-imported retain their permissions, so you do not need to re-assign the permissions unless you want to change them.
6. [Validate the data configurations](#) that you imported. When a configuration is imported or re-imported, it must be revalidated before it can be used to create new runs, queries, case series, or saved lists. Existing runs, queries, case series, and saved lists based on a re-imported configuration might not work correctly until the configuration is revalidated.
7. If you have modified a data configuration, test it by selecting it for tasks in the application. You have not yet assigned permissions to the data configuration, but you can use it because you are the data configuration owner.
8. Validate the data configuration again, if you made changes to it. Even if the only change was to assign permissions, you must validate the data configuration again.

## Editing a data configuration


When editing a data configuration, you can modify the data configuration as a whole, or add, modify, or delete variables in the data configuration. Certain information about data configurations can be specified only during editing and not when creating the data configuration. This information includes fields related to third-party links from case details, database groups, and permissions.

1. Click **Settings**.

The Settings page appears.

2. In the **Configure System** section, click **Manage Configurations**.

The Manage Configurations page appears.

3. Click the row menu () for the configuration, and then click **Edit**.

The Modify Configuration page appears, displaying information about the data configuration as a whole at the top and information about configuration variables below.

4. To modify the data configuration as a whole, next to the data configuration name in the top portion of the page, click **Edit**.

The Edit Configuration Details page appears.

5. Modify fields as necessary. For descriptions of fields, except those related to third-party links, database group, and permissions, see [Adding a data configuration](#).

---

**Note:** If you modify the name of an existing data configuration, all references to that name by existing runs, case series, and saved lists are updated automatically.

---

6. Optionally, select the drug hierarchy value from the **Drug Hierarchy Account** field.

By default, the value selected is None. See [drug and event hierarchies](#) for more information.

7. Optionally, select the event hierarchy value from the **Event Hierarchy Account** field.

By default, the value selected is None.

8. You can specify a link to appear on the Case Details page. For example, you can provide a link to a third-party application page providing further information about the case.

- A. In the **Third Party Link Text** field, enter the name of the link to appear on the Case Details page. If you do not specify a name, the link name is External Link.

- B. In the **Third Party Link URL** field, enter the URL for the third-party application page. You can use the following substitution variables:

- **\$REPORT\_ID\$**—Will be replaced by the value of the variable specified as the Report ID Col for the LIST section of the drilldown map table for the configuration.
- **\$EXTERNAL\_REPORT\_ID\$**—Will be replaced by the value of the external report ID for the case. If you use this substitution variable, the configuration must include a variable of the type, External Report ID.

For example: [https://lincoln/caseinfo.asp?caseid=\\$REPORT\\_ID\\$](https://lincoln/caseinfo.asp?caseid=$REPORT_ID$)

9. To assign the configuration to a **Database Group**, you can select an existing group from the drop-down list, or select **Add to new group** and enter a name for the new group. Results reviewers can use this information when [finding and selecting a data mining run](#). The application also uses the database group when determining color changes for [case ID links](#) that are visited by users.

10. Assign group permissions.

- A. To grant permissions to your [login group](#), in the **Group Permissions**, Login Group section, next to the **Login Group**, click **Read** or **Edit**.
- B. To grant permissions to individual users in your login group, in the **Individual Permissions**, User section, next to the **username**, click **Read** or **Edit**.

Users with Read permission for a configuration can select the data configuration for tasks such as creating a run or case series. Users with Edit permission can edit, copy, and delete the data configuration, as well as use it for tasks such as creating a run or case series.

A user's permissions for a data configuration are determined by settings for both the individual user and the user's login group. For example, if the individual user has Read access but that user's login group has Edit access, the user has Edit access.


11. Click **Save**.

The data configuration is saved and the Modify Configuration page appears.


12. Optionally, [add or edit data configuration variables](#). For more information, see [Adding or editing a data configuration variable](#).
13. [Validate the data configuration](#). Even if the only change was to assign permissions, you must validate the data configuration again.
14. Certain attributes of a data configuration or its variables require you to log out of the application and log back in before they take effect. For this reason, Oracle suggests that you always log out and back in if you want to see the effect of your changes.

## Copying a data configuration

You can create a data configuration by copying an existing data configuration and editing the copy as necessary.

1. Click **Settings**.  
The Settings page appears.
2. In the **Configure System** section, click **Manage Configurations**.  
The Manage Configurations page appears.
3. Click the row menu () for the configuration, and then click **Edit**.  
The Modify Configuration page appears
4. Click **Copy this Configuration**.  
The Add Configuration page appears.
5. In the **Name** field, supply a unique name for the new data configuration. (The default name is Copy of, followed by the name of the original data configuration).
6. In the **Description** field, modify the supplied description as needed to describe the new data configuration.
7. In the **Configuration Table Name** field, enter the unique name of the table to hold the new data configuration in the Oracle account to which you are connected.
8. Click **Save**.  
The data configuration is saved and the Modify Configuration page appears.
9. [Edit the data configuration](#), as necessary. During editing, you can specify a link to a third-party application, assign the data configuration to a database group, and assign permissions to the configuration. (These attributes are not copied with the data configuration.)
10. [You must assign permissions](#) before other users can access the data configuration. Before assigning permissions, you might want to validate the data configuration and test it by using it for activities such as data mining.
11. [Validate the data configuration](#).

## Deleting a data configuration

1. Click **Settings**.  
The Settings page appears.
2. In the **Configure System** section, click **Manage Configurations**.  
The Manage Configurations page appears.
3. Click the row menu () for the configuration, and then click **Edit**.  
The Modify Configuration page appears
4. Click **Delete this Configuration**.  
The Delete Configuration page appears.
5. If you are not a superuser, you cannot delete the data configuration if any objects are associated with it. If you are a superuser, you have two options:
  - To remove the data configuration from the application, but leave it in the database so that it can later be re-imported, click **Remove Reference Only**.
  - To delete the data configuration completely, including deleting it from the database, click **Delete Permanently**.
6. If any objects reference this configuration, you can transfer queries, report definitions, and saved lists to a [compatible data configuration](#). From the **What would you like to do with objects that reference this configuration?** drop-down list, select a configuration.  
  
Any queries, report definitions, and saved lists that are not compatible with the data configuration that you select are deleted.  
  
or  
  
To delete all queries, report definitions, and saved lists instead of transferring them, at the bottom of the list, select **Delete All Referenced Objects**.  
  
All case series, data mining runs, and report outputs based on this configuration are permanently deleted.  
  
Before continuing, you might wish to:
  - Add the query portion of query-based case series to the Query Library (from the Case Series tab).
  - Make sure that the configuration is not referenced by any [drug profile configurations](#) or [signal configurations](#), because such references are removed.
  - Attach run results, case lists or case details, and report outputs to a topic.

7. Click **Delete**.

---

**Note:** When you delete a data configuration that is associated with an [alias](#), the target status of the alias becomes Broken.

---

## Transforming data

### About data transformations

A data transformation is a means of mapping text values to new values, converting date values, or organizing numeric or date values into groups. The source data remains unchanged, and the transformed values are available for selection when you create data mining runs.

You specify data transformations for individual variables within a [data configuration](#). The results of the transformation do not affect the actual source data.

For example, suppose that the source data contains a date variable RCVD\_DATE. You want to allow run creators to select half-years as subset categories. You can use a data transformation to convert the date values for the RCVD\_DATE variable to new half-year values, such as 2003H1 and 2003H2. A data mining run creator can then use the half-year variable for subsetting, and select different half-year values as subset categories. The source safety data continues to store only date values, but the run results refer to the half-year values instead of the full-date values.

### Transformation options

To transform data in a data configuration, you can do the following:

- [Map text values](#).
- [Define variable cutpoints](#).
- [Convert date values](#).

When you define data transformations, it is preferable to include a new data configuration variable for the transformed data. For example, if the RCVD\_DATE variable exists, and you want to transform its data, keep the RCVD\_DATE variable as is in the data configuration and add a new variable, such as RCVD\_HALFYR, to store the transformed data.

An additional transformation option allows you to upload a list of [synthetic values](#) that are in the source data. For example, you could upload the names of Standardized MedDRA Queries (SMQs) to be ignored by [MGPS](#) when estimating the shrinkage parameters for EBGm scores. Note that custom terms are ignored automatically for the estimation of shrinkage parameters.

---

**Note:** The raw RR scores for combinations involving custom terms and the excluded synthetic values are shrunk by the Bayesian formula, but they do not participate in the determination of the formula itself.

---

For any one data configuration variable, you can only specify one data transformation type. However, you can add variables that reference the same column in the source database. You can also specify a different transformation for each of those variables. For example, suppose that the source database has a RCVD\_DATE column. You could create a RCVD\_HALFYR variable to convert date values and a RCVD\_RANGE variable that groups received dates according to date cutpoints.

## Transformation results

When you define data transformations that map text values, define variable cutpoints, or convert date values, note that:

- Variables that transform data are not available for creating [queries](#) or defining [reports](#).
- Variables that map text values are available for creating [saved lists](#). The mapped values, however, do not match the source data. As a result, the saved list does not pass validation. You can save and use the saved list, even though it does not pass validation.
- Transformed variables are not available as the drug variable, event variable, or as additional covariates in [a logistic regression run](#).
- If included in the drilldown map table, a variable that transforms data shows the source data, rather than the transformed data, when users [drill down to a list of cases](#) or to [view case details](#).
- If you define a data transformation for a variable in a data configuration, for which there are existing runs that use the variable, users cannot drill down correctly in the run results until the runs are re-executed.

---

**Note:** These restrictions do not apply to a synthetic values transformation.

---



## Mapping text values

Mapping text values from the [source data](#) to specified text values or to a different hierarchy of terms involves a [data transformation](#). For example, you can use mapping to do the following:

- Combine multiple adverse events from the source data into a single combined event.
- Specify that PTs from the source data should use a non-primary path for hierarchy values assigned by the application.
- Recode drug names from the source data.

The mapped values can be selected for use in an MGPS data mining run.

---

**Note:** See [Defining custom terms](#) for another way of mapping values to a term that you specify for a data mining run. See [Comparing custom terms and mapped text values](#) for information on the differences between these features.

---

To map text values, you use a text editor to create a file that contains the mappings and then you upload the file to a mapped variable in the configuration. To view the current mappings for a variable, edit the configuration, and for the mapped variable click **View Current Mapping**.

---

**Note:** If you modify a mapping file, your changes are not applied automatically to the mapped variable. You must edit the configuration and upload the modified mapping file for the mapped variable.

---

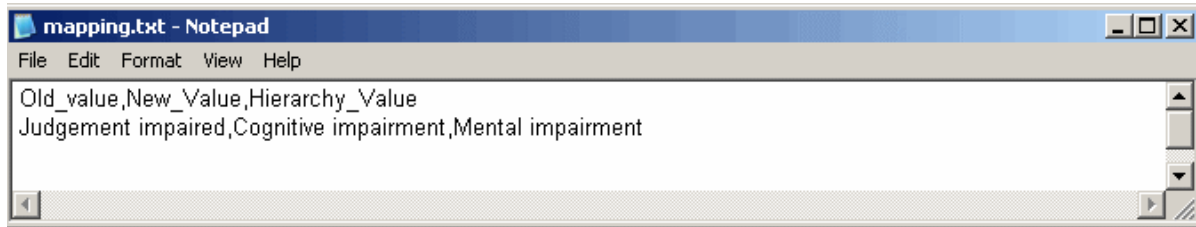
## Text mapping process

1. Determine how you want to map values. This example maps several PTs to the term, Cognitive impairment, and specifies that the term Cognitive impairment will use hierarchy values for the PT, Mental impairment.
2. In Microsoft Notepad, or another text editor, create a mapping file and type the following column headings on the first line of the document:



3. On the second line, type in the first old value (as it appears in the data, including capitalization), a comma, and then the new value. The new value does not need to exist in the source data. You must specify both an old value and new value. If you do not specify both values, values might be omitted from run results.
4. Type in the value that uses the hierarchy that you want to use for the new value. The hierarchy value is used only if the mapped variable is set up with a hierarchy. An exact match (including capitalization) of the hierarchy value must exist in the hierarchy, although it does not need to exist in the source data. If the mapped variable is set up to use a hierarchy, you must specify a hierarchy value.

5. You must separate each term with a comma. Do not include extra spaces or any extra carriage returns.




---

**Note:** If a term includes a comma, enclose the term in double quotation marks (for example, "Gastric ulcer, perforated"). If a term includes a double quotation mark, enter a backslash before the double quotation mark (for example, "Gastric ulcer, \"perforated\"). When you view the current mapping on the Edit Variable page, the double quotation marks and/or backslashes do not appear.

---

6. Repeat this process for each value that you want to map. This example maps several PTs to the same new value and hierarchy value. This is not a requirement for the mapping file. In the same mapping file, you can map different PTs to different new values and hierarchy values.




---

**Note:** You can perform only one level of mapping. In the above example, if you also map Cognitive impairment to Cognitive decline, none of the old values are mapped to Cognitive decline.

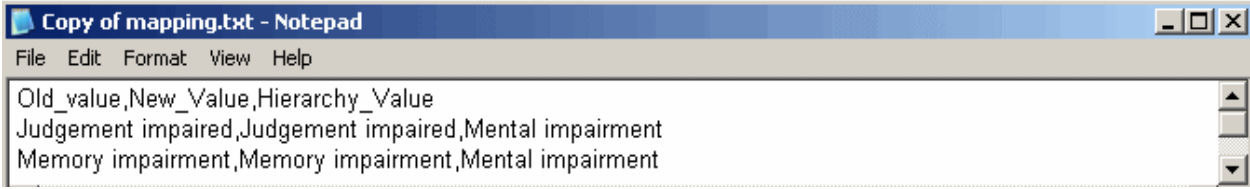
---

In the last line of the above example, the old value is mapped to a new value but continues to use the hierarchy of the old value. If the new value already exists in the source data, the hierarchy value applies to the existing value, as well. In this example, if Cognitive impairment is in the source data, the hierarchy for Mental impairment is used for it.

7. Make sure that there are no extra carriage returns or spaces in the file. The mapping does not work properly if there are extra carriage returns or spaces.
8. Save the file with the extension .csv.

### Changing only the hierarchy

If you want to change only the hierarchy used for the old value, enter the same old and new value, and then the hierarchy value:




### Generating results for mapped values

When creating a data mining run, choose the new variable. (Because you did not modify the original variable that variable is also still available for selection.) Results are generated for combinations including the new value, as in the following example:

Generic_Name	PT	HLT	HLGT	SOC	N	EBGM	EB05	EB95	PRR
Insulin	Cognitive impairment	Mental impairment (excl dementia and memory loss)	Mental impairment disorders	Nerv	<a href="#">487</a>	1.55	1.44	1.67	

**Note:** There might be more results for Insulin and the pre-mapped terms than for Insulin and the new mapping term because cases that include multiple pre-mapped terms are counted only once for the new mapping term.

## Adding a mapped variable to the configuration

1. Click **Settings**.  
The Settings page appears.
2. In the **Configure System** section, click **Manage Configurations**.  
The Manage Configurations page appears.
3. Click the row menu () for the data configuration, then click **Edit**.  
The [Modify Configuration page](#) appears.
4. Click the **Add New Variable** link.  
The Edit Variable page appears.
5. In the **Name** field, enter the name of the variable.  
Variable names display throughout the application, including when users select criteria for viewing data mining results, defining queries, or creating report definitions. For example, a column might be named SYMPTOM in the Oracle table, but renamed to appear as Event in the application.
6. In the **Description** field, type a description of the variable.
7. Next to the **Table** field, click **Select Table/Column**.  
The Select Table and Column dialog box appears.
8. As the **Column** of source data, select the drug or event variable containing values that you want to map. The source column must be a text value.
9. In the **Prefix** field, enter a prefix.
10. From the **Variable Type** drop-down list, select **Event** or **Drug**.
11. Do *not* check **Use as subset variable** or **Use as stratification** variable.
12. Optionally, set up the mapped variable to use a hierarchy.
13. Set **Hide From Query Wizard** to **Yes**. (Even if this setting is set to **No**, the mapped variable is not available in the Query Wizard.)
14. In the **Data Transformation** section, click **Text mapping** and then click **Upload Table**.
15. From the **Upload Text Map CSV File** dialog box, next to the **File to Upload** field, click **Browse**.  
The application displays the Choose File to Upload dialog box, providing access to your documents.

16. Select the mapping file and click **Open**. The mapping file must be in the format described in [Mapping text values](#).
17. Click **Upload**.  
The Edit Variable page appears.
18. To make sure the mappings are correct, click **View Current Mapping**.
19. Click **Save**.
20. [Validate](#) the configuration.

---

**Note:** If you map a variable in a configuration for which there are existing runs that use the variable, users cannot [drill down](#) correctly in the run results until the runs are re-executed.

---

## Comparing custom terms and mapped text values

The Empirica Signal application offers two options for grouping values, such as a list of drugs or a list of events, together for use in a data mining run without affecting source data. These features are:

- **Custom Terms**—see [Defining custom terms](#).
- **Mapped Text Values**—see [Mapping text values](#).

While these options are similar, each has different advantages and limitations. The differences between these features are, as follows:


Options	Custom Terms	Mapped Text Values
MGPS runs can include:	X	X
Logistic regression runs can include:	X	
Set up using query logic:	X	
Set up once, then reusable: (Manage Configurations permission)		X
Set up for each run: (Create Data Mining Run permission)	X	
Can be set up for variables configured to use a hierarchy table:		X
Can be set up for variables configured to use a hierarchy account:	X	X

When a custom term is added to a data mining run, that custom term cannot include a variable with mapped text values. Oracle recommends that when mapping text values, instead of applying this data transformation directly to a configuration variable, set up a new configuration variable based on the same table and column specifically to incorporate the mapping. When two different variables are offered in this way, the values of the original variable remain available for inclusion in a custom term. See [About data transformations](#).

## Defining variable cutpoints

Categorization based on cutpoints is a type of [data transformation](#). If the source data for the [data configuration](#) does not contain a variable that categorizes values in a way that is needed for stratification or subsetting during a data mining run, you can create categories by defining cutpoints for the variable. You can define categories for only a continuous variable; that is, numeric or date variables.

For example, the source data contains Age, but not Age Group. The data miner wants to subset data by the following groups: 18 or younger, 19-65, and over 65. You can define a variable based on Age, and then categorize those age values into groups by specifying cutpoint values that indicate the range of each category.

1. Click **Settings**.  
The Settings page appears.
2. In the **Configure System** section, click **Manage Configurations**.  
The Manage Configurations page appears.
3. Click the row menu () for the data configuration, then click **Edit**.  
The [Modify Configuration page](#) appears.
4. To add a variable to represent the cutpoints, click the **Add New Variable** link. For more information, see [Adding or editing a data configuration variable](#).  
The Edit Variable page appears.
5. In the **Name** field, enter the name of the variable.  
Variable names display throughout the application, including when users select criteria for viewing data mining results, defining queries, or creating report definitions. For example, a column might be named SYMPTOM in the Oracle table, but renamed to appear as Event in the application.
6. In the **Description** field, type a description of the variable.
7. Next to the **Table** field, click **Select Table/Column**.  
The Select Table and Column dialog box appears.
8. As the **Column** of source data, select the variable containing values that you want to map. The source column must contain numeric or date values.
9. Set **Hide From Query Wizard** to **Yes**. (Even if this setting is set to **No**, the mapped variable is not available in the Query Wizard.)
10. In the **Data Transformation** section, click **User-defined cutpoints**, and then click **View/Edit**.  
The Cutpoints for Variable dialog box appears.

11. To assist you in determining which categories to define, you can [view column statistics](#) about the distribution of values for the field in the entire source database.
12. In the first row, which starts with **VALUE <=**, in the **Value** column, enter the last value in the first category.
13. In the **Label** column, enter a label for the first category. For a date value, use the format, mm/dd/yyyy. For example, 12/14/2006.
14. In the next row, enter the last, or highest, value and a label for the second category. (You must enter the cutpoint values in ascending order.)
15. Continue defining categories until you are ready to define the last category.
16. For the last category, enter only a label. There is no need to enter a value. For example:

Define Cutpoints for Variable 'Age (yrs)'

	Value	Label
	<b>VALUE &lt;=</b> 18	18 or younger
18	<b>&lt; VALUE &lt;=</b> 65	19 through 65
65	<b>&lt; VALUE</b>	Over 65

[View Column Statistics](#)

Add additional cutpoints upon saving

Minimum Value:

Maximum Value:

17. If you need to add more categories than you can currently fit on this page, check **Add additional cutpoints upon saving**. When you click **Save**, you can add more categories.



18. Optionally, enter values into the **Minimum Value** field and the **Maximum Value** field.

The minimum and maximum apply to the source values, not the transformed values. This option is useful if you want to exclude extreme values from inclusion in a data mining run. The excluded values are considered missing. They are assigned the value that the user sets for the [user preference](#), **Replace Missing Values with**.

When specifying a minimum and maximum value for a date value, use the format mm/dd/yyyy, for example, 12/14/2007.

19. Click **Save**.


If you checked **Add additional cutpoints upon saving**, another row is added.

20. When you are finished specifying categories, clear **Add additional cutpoints upon saving**, and click **Save**.

The cutpoints for the variable are created. If you define cutpoints for a variable in a configuration for which there are existing runs that use the variable, users cannot [drill down](#) correctly in the run results until the runs are re-executed.

## Converting date values

A date conversion is a [data transformation](#). For a variable that is based on a date value in the source data, you can convert the date value to a year, a half year, or a quarter year.

1. Click **Settings**.  
The Settings page appears.
2. In the **Configure System** section, click **Manage Configurations**.  
The Manage Configurations page appears.
3. Click the row menu () for the data configuration, then click **Edit**.  
The [Modify Configuration page](#) appears.
4. To add a variable to represent the converted data values, click the **Add New Variable** link. For more information, see [Adding or editing a data configuration variable](#).  
The Edit Variable page appears.
5. In the **Name** field, enter the name of the variable.  
Variable names display throughout the application, including when users select criteria for viewing data mining results, defining queries, or creating report definitions. For example, a column might be named SYMPTOM in the Oracle table, but renamed to appear as Event in the application.
6. In the **Description** field, type a description of the variable.
7. Next to the **Table** field, click **Select Table/Column**.  
The Select Table and Column dialog box appears.
8. As the **Column** of source data, select the variable containing values that you want to convert. The source column must contain date values.
9. Set **Hide From Query Wizard** to **Yes**. (Even if this setting is set to **No**, the mapped variable is not available in the Query Wizard.)
10. In the **Data Transformation** section, click Date function, and then click **Select Function**.  
The Function Specification for Variable dialog box appears.
11. Select one of the following functions:
  - **QUARTER**—Convert the date to a quarter year formatted as the four-digit year followed by the quarter (for example, 2006Q1, 2006Q2, 2006Q3, and 2006Q4).
  - **YEAR**—Convert the date to a four-digit year.

- **HALF**—Convert the date to a half-year formatted as the four-digit year followed by the half year (for example, 2006H1 and 2006H2).

12. Enter a minimum or maximum value (optional). The minimum and maximum apply to the source values, not the transformed values.

This option is useful if you want to exclude extreme values from inclusion in a run. The excluded values are considered missing. The application assigns the value that the user sets for the [user preference](#), **Replace Missing Values with**.

When specifying a minimum and maximum value, use the format mm/dd/yyyy, for example, 12/14/2006.

13. Click **Save**.

The date values for the variable are converted.

---

**Note:** If you convert a date variable in a configuration for which there are existing runs that use the variable, users cannot [drill down](#) correctly in the run results until the runs are re-executed.

---

## Viewing column statistics

When you are [adding a column](#) for a numeric variable to a report definition on the Edit Data Source dialog box, or [defining cutpoints](#) for a numeric or date variable in a data configuration on the Cutpoints for Variable dialog box, you can click **View Column Statistics** to view information about the distribution of values for the variable in the source data.

The Column Value Statistics dialog box appears.

The following information is provided for numeric and date variables:

- **A histogram**—A graph of grouped (binned) data showing frequency distribution. The x-axis represents values from the source data and the y-axis represents counts of cases. A shaded rectangular block in the graph represents each bin. A bin is a range of x-axis values. The top of each block indicates the count of cases for the bin.
- **Minimum**—Minimum value.
- **Maximum**—Maximum value.
- **Distinct Values**—Number of distinct values.
- **Total Values**—Total number of values.

The following additional information is provided for date variables:

- **Average**—Average value.
- **Standard Deviation**—Standard deviation of values.
- **Variance**—Variance of values.

When you point to a block in the histogram, the following information appears:

- The range of x-axis values for the bin.
- The cumulative count of cases with that range of values.
- The cumulative percentage of cases with that range of values.

To close the Column Value Statistics dialog box, click **Close**.

## Excluding synthetic values

When estimating shrinkage parameters for EBGM scores generated by a data mining run, [MGPS](#) does not consider custom terms. If source data includes other synthetic values, such as standardized MedDRA queries, you must exclude those values for the appropriate [data configuration variable](#). Once synthetic values have been excluded, MGPS does not consider them when estimating shrinkage parameters for EBGM scores.

---

**Note:** AERS data releases provided to you by Oracle are already configured to exclude SMQs as synthetic values.

---

1. In Microsoft Notepad, or another text editor, create a file containing the synthetic values.
  - The file must have only one column of up to 200 characters.
  - The first row in the file must be the header, Value.
2. Make sure that there are no extra carriage returns or spaces in the file.
3. Save the file with the extension, .csv.
4. On the **Edit Variable** page, choose the appropriate variable type, **Number**.
5. In the **Data Transformation** section, click **Synthetic values**.
6. Click **Upload Table**.

The Upload Synthetic Items File dialog box appears.
7. Click **Browse**.

The Choose File to Upload dialog box appears.
8. Select the file of synthetic values and click **Open**.
9. Click **Upload**.

The Edit Variable page appears.
10. To make sure the values are correct, in the **Data Transformation** section, select **Synthetic values** and click **View Current Values**.

The Current Synthetic Item Values list for <variable> dialog box appears, showing the uploaded values.
11. Click **Close**.
12. Click **Save**.
13. [Validate](#) the data configuration.

---

**Note:** When you have excluded synthetic values, users creating a data mining run do not need to take any additional steps to exclude them.

---

## Managing aliases

### About aliases

An alias is a named reference to a data mining run, report output, or data configuration. Currently, aliases can be used in setting up a [drug profile configuration](#) and in [run definition files](#) (managed by Oracle).

A drug profile configuration can reference aliases for data mining runs or report outputs. When a user navigates to the Drugs tab, any aliases referenced by the drug profile configuration are resolved. When source data is updated and new runs and report outputs are created, you can modify the aliases to point to different runs and report outputs, rather than modifying the drug profile configuration.

## Viewing existing aliases

If you have permission to view the target of an [alias](#), the alias is listed on the Manage Aliases page.

1. Log into the Empirica Signal application as a user with the Manage Aliases permission.
2. Click **Settings**.  
The Settings page appears.
3. In the **Configure System** section, click **Manage Aliases**.  
The Manage Aliases page appears.
4. From the **Target Type** drop-down list, select the target type for which you want to view aliases, or -- to include all types (optional).

The Manage Aliases page appears and provides the following information about each alias:

Column	Description
Name	Name of the alias. The name must be unique among other aliases for the same target type.
Target Type	One of the following values: <ul style="list-style-type: none"> <li>• <b>Configuration</b>—The target is a data configuration.</li> <li>• <b>Data Mining Run</b>—The target is a completed data mining run (MGPS or logistic regression).</li> <li>• <b>Report Output</b>—The target is a report output.</li> </ul>
Target	Name and/or identifier of the specific data configuration, data mining run, or report output with which the alias is associated. <b>Note:</b> If you change the name of a data mining run, report output, or data configuration that is the target of an existing alias, this field is updated automatically for that alias.
Target Status	One of the following values: <ul style="list-style-type: none"> <li>• <b>Valid</b>—The alias target exists and, in the case of a data configuration, is valid.</li> <li>• <b>Broken</b>—The alias target has been deleted. In the case of a data configuration, the target status also becomes Broken if the data configuration becomes invalid.</li> </ul>
Created By	Name of the user who created the alias.
Created	Date and time when the alias was created.




Modified By Name of the user who last modified the alias.

---


Modified Date and time when the alias was last modified.

---

### Manage Alias page options

- To add an alias, click **Add Alias**. For more information, see [Adding or editing an alias](#).
- To edit an alias that you created, click the row menu () for an alias, and then click **Edit**.

### Row menu options

If you click the row menu () for an alias, you can do the following:

- To view an alias, click **View**.
- To edit an alias that you created, click **Edit**.
- To delete an alias that you created, click **Delete**. If you delete an alias that is referenced by a drug profile configuration, that reference is removed from the drug profile configuration.

---

**Note:** If you have the Administer Users permission, you can edit or delete aliases created by other users in your login group.

---

## Adding or editing an alias

1. Click **Settings**.

The Settings page appears.

2. In the **Configure System** section, click **Manage Aliases**.


The Manage Aliases page appears.

3. From the **Target Type** drop-down list, select the target type for which you want to view aliases, or -- to include all types (optional).

4. To add a new alias, click **Add Alias**.

The Add Alias page appears.

or

To edit an alias, click the row menu () for the alias, and then click **Edit**. You can edit only aliases that you have created, except that if you have the Administer Users permission, you can edit aliases created by any user in your login group.

The Edit Alias page appears.

5. In the **Alias Name** field, enter an alias name.

6. From the **Target Type** drop-down list, select the target type. For more information, see [Viewing existing aliases](#).

7. From the **Target** drop-down list, select the target. For more information, see [Viewing existing aliases](#).

8. Click **OK**.

## Managing drug profile configurations

### About drug profile configurations

A drug profile configuration is the specification of which data mining runs and which report outputs are the source of charts that users can add to a drug profile layout (on the Drugs tab). To access the Drugs tab, a user must set a drug profile configuration as a [user preference](#).

For example, a drug profile configuration specifies that for generic drugs, the MGPS 2D run is 2007Q4: Generic (S + C). In a drug profile, users who have that configuration set as a user preference can add charts for a generic drug based on the results of the 2007Q4: Generic (S + C) run.

---

**Note:** Drug profile configurations are separate from drug profile layouts. Drug profile layouts, which are saved collections of charts as well as their placement and display options, can be used with various drug profile configurations. For example, if you are using the layout, Generic + trade comparators, and you change your user preference to a different drug profile configuration, the Generic + trade comparators layout is still available.

---

Only report outputs from an [all cases summary report](#) can be used in a drug profile configuration. This is a special type of interactive report that must meet certain criteria.

In the drug profile configuration, you can specify data mining runs and report outputs for generic names, trade names, and ingredients. To specify a run or report output, you can select either the run name or an [alias](#) that has been set up for the run or report output.

You might want to create multiple drug profile configurations for different purposes. For example, you can set up one drug profile configuration for AERS data and another drug profile configuration for proprietary data. For information on setting up the drug profiles feature, see [Setting up drug profiles](#).

## Setting up drug profiles

To implement the features of the Drugs tab for your organization, an administrator must complete some configurable steps.

### Required permissions

To set up the Drug Profiles feature, an administrator must have the following permissions:

- View Data Mining Results
- Create Data Mining Run
- View Drug Profiles
- Create Drug Profile Layouts
- Create Report Definitions
- Administer Users
- Administer Drug Profiles
- Manage Aliases

### Setting up the Drug Profiles feature

Follow the steps below to set up the Drug Profiles feature. These steps include an example of a single initial drug profile layout that presents source data and data mining results from the frequently used standard AERS+SRS (S) data configuration.

#### Create an all cases summary report

For a drug profile layout to include distribution tables or graphs of source data, you create an [all cases summary report](#) for the Generic drug subtype.

1. Click the **Reports** tab.
2. On the **Report Definitions** page, click **Interactive Reports**.
3. On the **Interactive Reports** page, click **Create Definition**.  
The Create Definition page appears.
4. Create an all cases summary report. See [Creating or editing an interactive report definition](#).
  - A. From the **Configuration** drop-down list, select the configuration.
  - B. In the **Name** and **Description** fields, type a name for the report and a description.
  - C. To add the report definition to an existing project, select it from the **Add to existing project** drop-down list.

or

To add it to a new project, specify the project name in the **Add to a new project named** field.

- D. From the **Type** drop-down list, select **Summary of all Cases**.

This report type contains a single row variable for a drug subtype (such as Generic) and includes columns that show the distribution of cases by such variables as Gender, Age Group, and Report Received Year. You then run the report on the current AERS+SRS (S) configuration. (The report collects data across the entire configuration and can take some time to run.)

5. When the report output for the all cases summary report is complete, add an alias for the report output. (This step also is optional, but recommended.)

### Create an alias

To streamline the process of keeping drug profile layouts that include data mining run results current over time, add an [alias](#) for each of those data mining runs.

1. Click **Settings**.
2. On the Settings page in the **Configure System** section, click **Manage Aliases**.
3. On the **Manage Aliases** page, click **Add Alias**. For information on adding an alias, see [Adding and editing an Alias](#).
4. Add a **Latest <run type> alias** for each of these runs, such as Latest Generic (S), and associate each alias with the most recent run of that type.

This step is optional, but recommended. For example, each quarterly AERS data release includes a standard set of MGPS data mining runs that are based on the current AERS+SRS (S) configuration. When each subsequent AERS data release is received, you update the aliases to reference the newest available run, which has the effect of keeping all of the drug profile configurations that use those aliases up to date without requiring individual edits to every drug profile configuration.

### Add a drug profile configuration

For each drug subtype (Generic, Trade, or Ingredient), you specify a report output (to supply source data) and data mining runs of different types (to supply run results). Oracle recommends that you supply the aliases you set up for the report output and data mining runs, rather than the actual names. See [Adding or editing a drug profile configuration](#).

1. Click **Settings**.
2. On the Settings page in the **Configure System** section, click **Manage Drug Profile Configurations**.
3. On the **Manage Drug Profile Configurations** page, click **Add Drug Profile Configuration**.

The Add Drug Profile Configuration page appears.

---

**Note:** The report output for the all cases summary report you created is available for selection in the Generic section, but not in the Trade or Ingredient sections of

the page. Later, you can create and run an all cases summary report for each drug subtype, set up aliases, and edit the drug profile configuration to reference them.

---

4. If your organization uses the Signal Management feature, include a reference to the [signal configuration](#) to enable drilldown from values in the DRUG column on the Drug Overviews page to the drug profile on the Drugs tab. See [Viewing drug overviews](#).
5. Publish the drug profile configuration. See [Publishing objects](#).

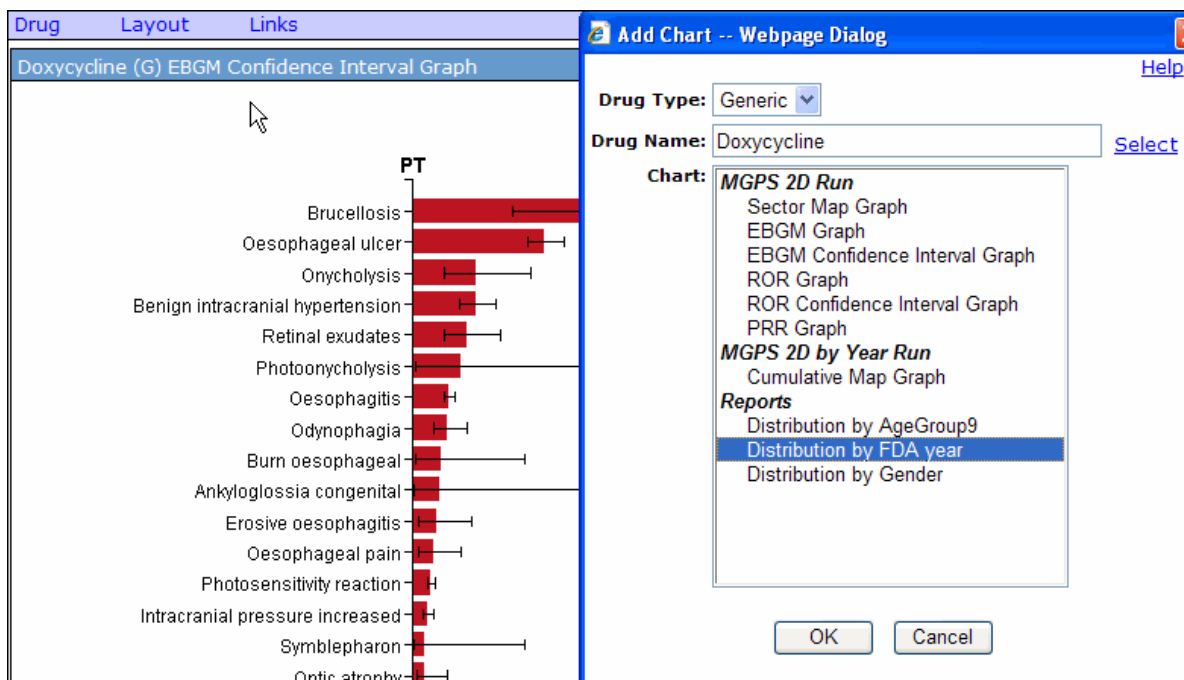
### **Set your user preference**

1. Set your user preference, **Drug Profile Configuration**, to the drug profile configuration you created as an alias. See [Setting user preferences](#).
2. Log out of the Empirica Signal application, then log back in.  
The Drugs tab should now be available to you.

### **Create a drug profile layout**

Create a drug profile layout. For more information, see [Viewing a drug profile](#).

1. Click the **Drugs** tab.
2. On the **Drug Profile** page, click **Layout**.
3. From the **Layout** menu, select **Create**.
4. Select at least one chart to include in the layout; for example, a graph of data from one of the data mining runs you defined for the drug profile configuration, or a graph or table of source data from the report output. For more information, see [Adding a chart to a drug profile layout](#).
5. Add more charts and arrange them as desired.



6. Publish the drug profile layout. See [Publishing objects](#).
7. Set your user preference, **Drug Profile Layout**, to the drug profile layout you created

### Grant users View Drug Profiles permission

1. For each of the users who will use drug profiles, [edit the user account](#) to grant the **View Drug Profiles** permission.
2. Optionally, grant the **Create Drug Profile Layouts** permission, as well. See [Adding or editing a user](#) and [User permissions](#).

---

**Note:** Of the users who will use drug profiles, any who were logged in when you granted the drug profiles permission(s) must log out of the application and log back in.

---

3. The users who will use drug profiles can now set their [user preferences](#), **Drug Profile Configuration** and **Drug Profile Layout**, to the objects you created (alias and drug profile layout). After the users log out and log back in, the Drugs tab is visible and the drug profile layout provided by default.

### Refine the drug profile configuration and layout

You can now repeat steps of this process as needed to refine the drug profile configuration and drug profile layout. For example, you might create and run an additional all cases summary report for each of the other drug subtypes, Trade and Ingredient, add an aliases for them, edit the drug profile configuration to include them, and modify or add other drug profile layouts.

### Refreshing data for a drug profile

When a data update is available, such as when new AERS+SRS (S) data is released each quarter, you refresh the data used by the drug profiles:

1. Rerun each all cases summary report referenced by the drug profiles configuration on the new AERS+SRS (S) data configuration and save the output.
2. Rerun each data mining run referenced by the drug profiles configuration. (The standard AERS+SRS (S) data mining runs may already have been rerun at release installation.)
3. Update all aliases, for both report outputs and data mining runs, that are in use by the drug profiles configuration. If you chose not to use aliases, update each drug profiles configuration to supply the new report output and data mining run names.

---

**Note:** Run definition files and Report definition files can update existing aliases automatically.

---



## Viewing existing drug profile configurations

The Manage Drug Profile Configurations page lists [drug profile configurations](#) that you created or that are published to you. If you have the Administer Users permission, the page also lists unpublished configurations created by any users in your login group.


1. Log into the Empirica Signal application as a user with the permission, Administer Drug Profiles.
2. Click **Settings**.  
The Settings page appears.
3. From the **Configure System** section, click **Manage Drug Profile Configurations**.  
The Manage Drug Profile Configurations page appears and provides the following information about each drug profile configuration:

Column	Description
ID	Automatically assigned unique identifier of the configuration.
Name	Name of the configuration.
Description	Description of the configuration.
Created By	Name of the user who created the configuration.
Created	Date and time when the configuration was created.
Modified	Date and time when the configuration was last modified.
Modified By	Name of the user who last modified the configuration.

### Drug profile configuration options

- To [add a drug profile configuration](#), click **Add Drug Profile Configuration**.


### Row menu options

If you click  for a drug profile configuration that you created, you can also do the following:

- To [view a drug profile configuration](#), click **View**.
- To [edit a drug profile configuration](#), click **Edit**.
- To [rename a drug profile configuration](#), click **Rename**. If any users have the configuration set as a user preference, that setting is changed automatically to the new name.

- To [publish a drug profile configuration](#), click **Publish**. (If you have the Administer Users permission, you can publish configurations created by any users in your login group.)
- To delete a drug profile configuration, click **Delete**.
- For information about viewing, printing, or downloading tables or changing the way data displays in the table, see [About tables](#).

## Viewing a drug profile configuration


1. Click **Settings**.  
The Settings page appears.
2. From the **Configure System** section, click **Manage Drug Profile Configurations**.  
The Manage Drug Profile Configurations page appears
3. Click the row menu () for a configuration, and then click **View**.  
The Drug Profile Configuration Description dialog box appears and provides the following information. Many of these fields are specified separately based on Drug Subtype (Generic Name, Ingredient Name, Trade Name) as defined in the data configuration variables:

Field	Description
Drug Profile Configuration Name	Name of the drug profile configuration.
ID	Automatically assigned identifier of the drug profile configuration.
Description	Description of the drug profile configuration.
Signal Configuration	Name and ID of the <a href="#">signal configuration</a> (if any) associated with the drug profile configuration. When the drug profile configuration and the specified signal configuration are both in use by a user and that user has a drug layout set as a user preference, then drug names on the Drug Overviews page (on the Signals tab) are links that go to the Drugs tab.  <b>Note:</b> Regardless of the drug type on the Drug Overviews page, the drug is considered by the Drugs tab to be a generic name. Thus, only the generic name settings in the drug profile configuration are used.
Report Output ID	Name and ID of (or <a href="#">alias</a> for) an <a href="#">all cases summary report</a> , which is a specific type of interactive report.
MGPS 2D ID	Name and ID of (or alias for) a completed two-dimensional MGPS data mining run for which charts can be added on the Drugs tab. This can also be a run that uses cumulative subsetting. In this case, only the subset that is the accumulation of all the other subsets is used.
MGPS 2D by Year ID	Name and ID of (or alias for) a completed two-dimensional MGPS data mining run that uses cumulative subsetting by year, for which charts can be added on the Drugs tab.

MGPS 3D ID	Name and ID of (or alias for) a completed three-dimensional MGPS data mining run for which charts can be added on the Drugs tab. Subsetted three-dimensional runs are not available to select.
LR 2D ID	Name and ID of (or alias for) a completed logistic regression data mining run for which charts can be added on the Drugs tab. The set of drugs included in logistic regression results is typically smaller than the set of drugs in MGPS results. On the Drugs tab, graphs for logistic regression results are available only if the selected drug was included in the model or added explicitly during creation of the run.

4. When you are done viewing the drug profile configuration, click **OK**.

## Adding or editing a drug profile configuration

1. Click **Settings**.  
The Settings page appears.
  2. From the **Configure System** section, click **Manage Drug Profile Configurations**.  
The Manage Drug Profile Configurations page appears
  3. To add a new configuration, click **Add Drug Profile Configuration**.  
The Add Drug Profile Configuration page appears.  
  
or  
  
To edit a configuration, click the row menu () for the configuration, and then click **Edit**.  
  
The Edit Drug Profile Configuration page appears.
  4. If your organization uses [signal management](#) from the **Signal Management Configuration** drop-down list, select a [signal configuration](#).  
  
When the drug profile configuration and the specified signal configuration are both in use by a user and that user has a drug layout set as a user preference, then drug names on the Drug Overviews page (on the Signals tab) are links that go to the Drugs tab.
- 
- Note:** Regardless of the drug type on the Drug Overviews page, the drug is considered by the Drugs tab to be a generic name. Thus, only the generic name settings in the drug profile configuration are used.
- 
5. For each section on the page, you can specify report outputs and runs that you created or that are published to you. (If you have the Administer Users permission, you can also specify unpublished report outputs and runs created by any users in your login group.) For any report outputs and runs that you can specify, you can also specify any existing aliases for them.
  6. Click **Next**.  
The Save Drug Profile Configuration page appears.
  7. Enter or edit the name and description of the drug profile configuration.
  8. To [save the drug profile configuration](#), click **OK**.  
  
The Manage Drug Profile Configurations page appears. If you created a drug profile configuration it appears as the bottom row.

## Referencing data mining runs and aliases

The data mining runs that you reference in a drug profile configuration must have an item variable with the [subtype](#) Generic, Trade, or Ingredient (depending on the section of the [drug profile configuration](#)) in the data configuration.

Lists of available report outputs and data mining runs also include aliases for those objects. If the drug profile configuration refers to an alias, the alias is resolved each time a user goes to the Drugs tab. This is useful if updates of data and new data mining runs are expected, and you want charts for those new runs to be available on the Drugs tab.

For example, the drug profile configuration refers to an alias named, Latest 2D Generic. The alias can be updated to point to new data mining runs, but the drug profile configuration does not need to be updated and users do not need to set their user preference to a new drug profile configuration.

---

**Note:** Users of the Drugs tab can view charts for all report outputs and data mining runs that are referenced by their current drug profile configuration, regardless of whether or not they can view the report outputs or runs elsewhere in the application

---

When defining a drug profile configuration, consider which data configurations the data mining runs and report outputs that you reference are based on.

### Available drugs list

Another consideration is that when users select drugs when adding a chart (on the Drugs tab), the list of available drugs can differ depending on the type of chart. For example, suppose that the 2D run results, but not the 3D run results, include custom terms. When selecting drugs for an EBGm graph, but not for a nested confidence interval graph, users are able to select custom terms (the nested interval graph applies only to results for the 3D run). For consistency of available drugs that can be selected for various chart types, the drug profile configuration should reference similarly constructed data mining runs.

Users can also select drugs from the Drug menu. In constructing the list of available drugs that can be selected from the Drug menu, the application uses the following objects, in order of precedence:

- MGPS 2D Run
- MGPS 2D by Year Run
- Report Output
- MGPS 3D Run
- LR 2D Run

## Saving a drug profile configuration

When you have [added or edited a drug profile configuration](#) and clicked **Next**, the Save Drug Profile Configuration page appears.

1. In the **Name** field, enter a name for the drug profile configuration.

---


**Note:** If you are editing an existing drug profile configuration and you change its name, the existing configuration is renamed.

---

2. Optionally, in the **Description** field, enter a description of the drug profile configuration.
3. Click **OK**.

Oracle recommends that you test the drug profile configuration before publishing it. To do so, you can set your [user preference](#), Drug Profile Configuration, to the new drug profile configuration and go to the Drugs tab.

## Renaming a drug profile configuration

1. Click **Settings**.  
The Settings page appears.
2. From the **Configure System** section, click **Manage Drug Profile Configurations**.  
The Manage Drug Profile Configurations page
3. Click the row menu () for a drug profile configuration, and then click **Rename**.
4. In the **Name** field, enter a new name for the drug profile configuration.
5. Optionally, in the **Description** field, modify the description of the drug profile configuration.
6. Click **OK**.

---

**Note:** If any users have the drug profile configuration set as a [user preference](#), that setting is changed automatically to the new name.

---



## Defining the Links menu

The Drugs tab includes a Links menu that provides access to specified URLs. By default, the menu includes links to FDA label information and NIH label information for the drug associated with the current chart window. You can change the default links or add other links.

1. In the Signal/WEB-INF/classes subdirectory of the server location to which the Empirica Signal application was installed, open the `webvdme.properties` file.
2. Find lines starting with `URLLINK` . Lines for the default links are:
 

```
URLLINK.1.LINK_NAME=FDA Label Information
URLLINK.1.LINK_URL=http://www.accessdata.fda.gov/scripts/cder/drugsatfda/
index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm
=\$DRUG\$
URLLINK.2.LINK_NAME=NIH Label Information
URLLINK.2.LINK_URL=http://dailymed.nlm.nih.gov/dailymed/search.cfm?startswith
=\$DRUG\$
```
3. Modify or add links.
  - For each link on the Links menu, there must be a pair of lines, one defining the name of the menu option and one specifying the URL.
  - In the URL, use the following string if you need to substitute in the drug name associated with the current chart window: `\$DRUG\$`
  - The number after `URLLINK` determines the order of options in the Links menu. For example, to add a link to the two default links, you add two lines starting with `URLLINK.3`. You can renumber links, but the numbers must be consecutive, starting with 1, and you cannot skip numbers.

## Managing topic workflow configurations

### Topic workflow configurations

A topic workflow configuration defines how the [topics](#) feature works in the application, including the fields that store topic information and the workflow states that you can assign to track progress. You can set up topic workflow configurations and the topic feature to accommodate your organization's processes. Users with the Manage Topic Workflow Configurations permission can work with topic workflow configurations.

The following checklist is for designing a new topic workflow configuration. Customize the following tasks at any time, in any order:

- User settings
- Topic fields
- Topic field values
- Workflow states for topic states and action states
- Topic field accessibility and action field accessibility by states
- Attachment field accessibility by types
- Email notification rules
- Topic templates

These definitions affect the appearance and behavior of the user interface for using topics.

A Sample Topic Workflow Configuration is provided with the application. The sample configuration can be used as a starting point when you design a configuration by copying and editing it. You can also review the [definitions in the Sample Topic Workflow Configuration](#) and base your design on them. The Sample Topic Workflow Configuration itself should not be edited.

---

**Note:** Changes to a topic workflow configuration that is already in use are not recommended.

---

In addition, you can prepare topic features by defining the access permissions to the Empirica Signal users. For more information, see [Setting up the topics feature](#).

## Setting up the topics feature

The Topics features is configured by an administrator who performs several tasks. A sequential outline of those tasks is based on the [sample topic workflow configuration](#) delivered with the application.

To perform the steps in this outline, an administrator must have been assigned the Manage Topic Workflow Configurations and Administer Users permissions. To add the work team fields, it is also necessary to have Superuser permission.

1. Make a copy of the Sample Topic Workflow Configuration supplied with Empirica Signal as the basis for a new topic workflow configuration. For more information, see [Copying a topic workflow configuration](#).

---

**Note:** The Sample Topic Workflow Configuration should not be edited.

---

2. Edit the new [topic workflow configuration](#).  
  
Your design can be based on the Sample Topic Workflow Configuration. For more information, see [Definitions in the sample topic workflow configuration](#).
3. Publish the new topic workflow configuration to your login group. For more information, see [Publishing objects](#).
4. Edit your login group to select the new topic workflow configuration as its Topic Workflow Configuration setting. For more information, see [Editing a login group](#).
5. Create one or more work teams for your login group. A work team can contain all of the users in a given login group, or a specified subset of those users. For more information, see [Adding/editing a work team](#).
6. If you created work teams, [assign work team permissions](#) to each work team member.
7. If your topic workflow configuration includes any fields with a context of work team, a Superuser must set the **Topic workflow configuration for work team custom fields** site option.
8. For each of the users in the login group (or work team), including yourself, edit the user account to grant the View Topics permission. For more information, see [Adding/editing a user](#) and [User permissions](#).
9. Log out of the application, and log in again. The Topics tab is now available to you.

Users who were already logged in when you granted the View Topics permission must log out of the application and log in again.

If the topic workflow configuration defines application data results as an allowed attachment type, the **Save to Topic** link also appears above tables, graphs, report output, and other Empirica Signal objects.

## Manage Topic Workflow Configurations page

On the Manage Topic Workflow Configurations page, you can list the topic workflow configurations you created or have been published to your login group.

### General activities

The following links appear at the top of the page and affect the entire page:

- [Add Workflow Configuration](#)
- [Import Workflow Configuration Account](#)
- [Import Workflow Configuration File](#)
- [Back](#)
- [Columns](#)
- [Print](#)
- [Download](#)

### Row-specific activities

The following menu options are available from the row menu, located in the leftmost column of the table, and affect an individual row in the table:

- [Edit](#)
- [Copy](#)
- [Delete](#)
- [Publish](#)
- [Export](#)
- [Create PDF](#)
- [Manage Fields](#)
- [Manage Topic States](#)
- [Manage Action States](#)
- [Manage Topic Templates](#)
- [Manage Email Notification Rules](#)

### Field descriptions—Manage Topic Workflow Configurations page

In this section, you can view the information for each topic workflow configuration.

Field	Description
ID	Identifier that is assigned when the configuration is added or imported. Each topic workflow configuration ID is unique and is not re-used if the

configuration is deleted.

---

Name	Name of the topic workflow configuration.
Description	Description of the topic workflow configuration.
Account Name	Name of the Oracle database account that contains topic workflow configuration data.
Owner	Name of the user who created the topic workflow configuration.

---

## Adding topic workflow configurations

### Copying a topic workflow configuration

The application provides a sample configuration named *Sample Topic Workflow Configuration*. This configuration can be copied and used to create a customized configuration.


Users need the Manage Topic Workflow Configurations permission to copy an existing configuration and modify it.

---

**Note:** When you copy a topic workflow configuration, the latest versions of templates are also copied. However, any existing topics that are based on the configuration are *not* copied.

---

To copy a topic workflow configuration, follow these steps:

1. Click **Settings**, and click **Manage Topic Workflow Configurations**.  
The Manage Topic Workflow Configurations page appears.
2. Click the row menu () , and click **Copy**.  
The Copy Workflow Configuration page appears.
3. Type a unique name for the topic workflow configuration.
4. Optionally, modify the description of the topic workflow configuration.
5. Click **Save**.  
The new topic workflow configuration is added to the same Oracle account as the original.
6. To test the topic workflow configuration before assigning it to a [login group](#) or completing topics feature setup:
  - A. Set the [user preference](#) *Topic Workflow Configuration* to the new configuration (only users with the Manage Topic Workflow Configurations permission can set this preference).
  - B. Log out and log back in.
  - C. Click the [Topics tab](#) to add and edit topics that use the new configuration.

## Definitions in the sample topic workflow configuration

A sample topic workflow configuration is provided with the Empirica Signal application. To design a new topic workflow configuration, you can copy the sample and edit it. Use the information below as a guide when designing a new topic workflow configuration.

### Basic configuration options

When you [edit a topic workflow configuration](#) you set these configuration options:

Option	Definition
Name	Sample Topic Workflow Configuration
Description	Sample Topic Workflow Configuration
Allow topic to be visible to	( ) One and only one work team (o) Zero, one or more work teams
Allow topic to be linked to	(o) Topics in any state ( ) Topics in final state
Allow addition of comments to	x  Topics  x  Attachments  x  Actions
Allow sources of attachments	x  External URL  x  Application Data  x  External Document  x  Note
Allow topic state closure only when all actions are completed	(cleared)
Allow action state closure only when attachments or comments are provided for action	(cleared)

### Field definitions: topics

When you view existing fields, the Context column indicates whether a given field applies to topics, attachments, actions, or possibly to several of these contexts.

The sample topic workflow configuration defines the following fields for topics:

<b>Column Name</b>	<b>Display Name</b>	<b>Format</b>	<b>Filter Field</b>
TOPIC_NAME	Topic name	String	No
TOPIC_DESCRIPTION	Topic description	String	No
CURRENT_STATE_ID	Current state	Integer	Yes
STATE_CHANGE_REASON	Reason for change	String	No
ASSIGNED_TO_USER_ID	Assigned to user	Integer	Yes
SEARCH_KEYWORDS	Keywords	String	Yes
RESOLUTION	Resolution	String	No
RESOLUTION_DATE	Resolution date	Date	No

(This table presents a subset of the different attributes that can be set when you add or edit a field.)

### **Field definitions: actions**

The sample topic workflow configuration includes the following fields for actions:

<b>Column Name</b>	<b>Display Name</b>	<b>Format</b>	<b>Filter Field</b>
ACTION_NAME	Action name	String	No
ACTION_DESCRIPTION	Action description	String	No
ACTION_STATE_ID	Action state	Integer	No
ASSIGNED_TO_USER_ID	Assigned to user	Integer	No
PLANNED_COMPL_DATE	Planned completion date	Date	No
ACTUAL_COMPL_DATE	Actual completion date	Date	No

### **Field definitions: attachments**

The sample topic workflow configuration includes the following fields for attachments:

<b>Column Name</b>	<b>Display Name</b>	<b>Format</b>	<b>Filter Field</b>
NAME	Attachment name	String	No



DESCRIPTION	Attachment description	String	No
URL_ADDRESS	URL address	String	No
FILE_NAME	File name	String	No

### Topic states

The sample topic workflow configuration defines the following workflow states for topics:

Name	Description	Initial State	Final State	Next Possible States
Init	Initial state	Yes	No	Assigned, Closed, Escalated
Assigned	Actively being reviewed	No	No	Closed, Escalated
Escalated	Warrants further attention	No	No	Assigned, Closed
Closed	No further action needed or expected	No	Yes	Assigned

### Topic field accessibility

The sample topic workflow configuration defines the [level of user access](#) to topic fields for a topic in each workflow state as follows:

Topic Field Column Name	Init	Assigned	Escalated	Closed
TOPIC_NAME	Required	Required	Required	Required
TOPIC_DESCRIPTION	Editable	Editable	Editable	Editable
CURRENT_STATE_ID	Editable	Editable	Editable	Editable
STATE_CHANGE_REASON	-- (Hidden)	Required	Required	Required
ASSIGNED_TO_USER_ID	Editable	Required	Required	Required
SEARCH_KEYWORDS	Editable	Editable	Editable	Editable
RESOLUTION	-- (Hidden)	-- (Hidden)	-- (Hidden)	Required
RESOLUTION_DATE	-- (Hidden)	-- (Hidden)	-- (Hidden)	Required

## Action states

The sample topic workflow configuration defines the following workflow states for actions:

<b>Name</b>	<b>Description</b>	<b>Initial State</b>	<b>Final State</b>	<b>Next Possible Action States</b>
Init	Initial state	Yes	No	Closed
Closed	Action completed	No	Yes	

## Action field accessibility

The sample topic workflow configuration defines the [level of user access](#) to action fields for an action in each workflow state as follows:

<b>Action Field Column Name</b>	<b>Init</b>	<b>Closed</b>
ACTION_NAME	Required	Required
ACTION_DESCRIPTION	Editable	Editable
ACTION_STATE_ID	Editable	Editable
ASSIGNED_TO_USER_ID	Editable	Editable
PLANNED_COMPL_DATE	Editable	Editable
ACTUAL_COMPL_DATE	Editable	Editable

## Attachment field accessibility

The sample topic workflow configuration defines the [accessibility of attachment fields](#) for each type of attachment as follows:

<b>Field Name</b>	<b>External URL</b>	<b>Empirica Signal Result</b>	<b>External Document</b>	<b>Note</b>
NAME	Required	Required	Required	Required
DESCRIPTION	Editable	Editable	Editable	Editable
URL_ADDRESS	Required	-- (Hidden)	-- (Hidden)	-- (Hidden)
FILE_NAME	-- (Hidden)	-- (Hidden)	Required	-- (Hidden)

## Adding a topic workflow configuration

Typically, organizations use only one topic workflow configuration. You can add a blank topic workflow configuration that includes a minimal design for topic workflow. You can define the fields, workflow states, user access levels, e-mail notification rules, and templates.

Alternatively, Empirica Signal provides a *Sample Topic Workflow Configuration* which you can use as a starting point for a new topic workflow configuration.

1. Click **Settings**, and click **Manage Topic Workflow Configurations**.

The Manage Topic Workflow Configurations page appears.

2. On the [Manage Topic Workflow Configurations page](#), click **Add Workflow Configuration**.

The Add Configuration page appears.

3. Enter a name and a description for the topic workflow configuration.

**Note:**

- If a topic workflow configuration was deleted by reference only, it is retained in the database and you cannot create a new configuration with the same name.
- The description for the topic workflow configuration should be up to 1000 characters.

4. Click **Save**.

The topic workflow configuration is added to the list on the [Manage Topic Workflow Configurations page](#).

5. It is recommended to test a topic workflow configuration before you assign it to a [login group](#). To test, do the following:

- A. Set your [user preference](#) for Topic Workflow Configuration to the new configuration.

---

**Note:** Only users with the Manage Topic Workflow Configurations permission can set this preference.

---

- B. Log out and log back in.
- C. Click the [Topics tab](#) to add and edit topics that use the new configuration.
- D. When you are finished, assign the topic workflow configuration to the login group.

## Importing a workflow configuration account

---

**Note:** This option is used when installing or upgrading the Empirica Signal application. Typically, you do not need to perform this process during regular system use.

---

When you import topic workflow configurations from an Oracle account, the application does the following:

- Adds any new topic workflow configurations found in the Oracle account.
- Re-imports any topic workflow configurations found in the Oracle account that have been deleted from the application by having references removed. Any topics (and comments associated with them) that existed at the time of the deletion are also restored.

---

**Note:** If a topic workflow configuration has been deleted permanently, it cannot be re-imported.

---

A confirmation dialog box displays after topic workflow configurations are imported successfully. The import does not affect your current or existing topic workflow configurations.

1. Click **Settings**.  
The Settings page appears.
2. From the **Configure System** section, click **Manage Topic Workflow Configurations**.  
The [Manage Topic Workflow Configurations page](#) appears.
3. Click Import Workflow Configuration Account.  
A confirmation dialog box appears.
4. Click **OK**.  
The application imports the topic workflow configuration account.
5. Oracle recommends that you test an imported topic workflow configuration before assigning it to a [login group](#).
  - A. Set your **Topic Workflow Configuration** [user preference](#) to the new configuration (only users with the **Manage Topic Workflow Configurations** permission can set this preference).
  - B. Log out and log back in.
  - C. To add and edit topics that use the new configuration, click the **Topics** tab.


## Editing a topic workflow configuration

On the Edit Workflow Configuration page, the topic workflow configuration options determine how users can work with topics that are created using the topic workflow configuration.

---

**Note:** Editing a topic workflow configuration that is already in use is not recommended.

---

1. Click Settings, and click Manage Topic Workflow Configurations.  
The Manage Topic Workflow Configurations page appears.
2. Click the row menu () , and click **Edit**.  
The Edit Workflow Configuration page appears.
3. Update the values in the Name and Description fields as needed.
4. Edit the [options](#) to customize the topic workflow configuration.
5. Click **Save**.
6. Log out and log in again to see the changes in the application.

### Field descriptions—Edit Workflow Configuration page

Field	Description
Allow topic to be visible to	<p>Defines the level of cross-team interaction enabled for topics. You can choose one of the following:</p> <ul style="list-style-type: none"> <li>• <b>One and only one work team</b>—Topics can be reviewed by, and assigned to, the members of a single specified work team. For configurations that select this option, it may be useful to give one or more administrative users the View Topics across Work Teams <a href="#">user permission</a>.</li> <li>• <b>Zero, one or more work teams</b>—Topics can be reviewed by, and assigned to, the members of all work teams selected in the Visible to work teams field of a specific topic. Topics visible to zero work teams are accessible only to the user who created them.</li> </ul> <hr/> <p><b>Note:</b> For a user to view or act on topics that have been made visible to a work team, appropriate <a href="#">work team permissions</a> must be assigned to that user.</p>
Allow topic to be linked to	<p>Defines how the topic linking feature functions. You can choose one of the following:</p> <ul style="list-style-type: none"> <li>• <b>Topics in any state</b>—Users can add a reference link from one topic to another topic regardless of workflow state.</li> <li>• <b>Topics in final state</b>—Users can add a reference link from one topic</li> </ul>

to another topic that is in a final state.

---

**Note:** For a user to link two topics, both topics must be visible to the user's work team with the Edit Topics or Edit Topic Actions [work team permission](#).

---

Allow addition of comments to

Select one or more of these check boxes to enable the comment feature, which allows users to add free-text comments. You can enable the comment feature for:

- Topics—Comments can be added and appear in the [Topic Comments section of the Topic page](#).
- Attachments—Comments can be added for attachments to a topic in the [Topic Attachments section of the Topic page](#) and for attachments to an action in the [Action Attachments section of the Topic Action page](#).
- Actions—Comments can be added and appear in the [Action Comments section of the Topic Action page](#).

Comments cannot be edited or deleted after entry.

---

**Note:** To add comments, users need the Edit Topics/Actions work team permission. To add attachments, users need the Add/Edit/Delete Attachments in Open Topics/Actions or Edit Attachments in Closed Topics/Actions work team permission.

---

Allow sources of attachments

Select one or more of these check boxes to enable the attachment feature, which allows users to add supporting information to a topic or action. You can clear a check box to prevent attachments in that format from being added.

- Application Data—A **Save to Topic** link is added to pages throughout Empirica Signal to allow the currently displayed object to be saved as an attachment to a topic or action. A [site option](#) can be set to limit the number of rows in table displays that can be saved with topics.
- External URL—Attachments in the form of a URL can be added.
- External document—Files, including documents, spreadsheets, and images, can be added to the topic. A [site option](#) can be set to limit the size of files saved with topics.
- Note—Users can enter text to provide an overall description of several other attachments that are added

Attachments of the selected types can be added to a topic or to individual actions, and can be edited or deleted. Attachments to a topic appear in the [Topic Attachments section of the Topic page](#) and attachments to an action appear in the [Action Attachments section of the Topic Action page](#).

---

**Note:** To add attachments, users must have the Add/Edit/Delete Attachments in Open Topics/Actions or the Edit Attachments in Closed Topics/Actions [work team permission](#).

---

Allow topic state

If checked, an edit check assures that users can assign a final workflow state to a topic only when all of that topic's actions are in a final state.

---

closure only when all actions are completed If cleared, users can assign a final state to a topic regardless of the workflow state of that topic's actions.

---


Warn on action state closure if no attachments or comments are provided for action If checked, users who assign a final workflow state to an action that does not have any associated comments or attachments receives a warning message.  
If cleared, users can assign a final state to an action at any time without a warning.

---

## Deleting a topic workflow configuration

1. Click **Settings**, and click **Manage Topic Workflow Configurations**.

The Manage Topic Workflow Configurations page appears.

2. Click the row menu () , and click Delete.

The Delete Workflow Configuration page appears.

3. If you are a Superuser, two options appear:

- Remove Reference only—Deletes the configuration by reference.

The configuration and any existing topics, including all comments and the associated attachments are no longer accessible from the application. However, all of the data remains in the database and can be [re-imported](#) if necessary.

- Delete permanently—Deletes the configuration from the database, along with all topics, including all comments and attachments associated with them.

A message informs you that for 21 CFR Part 11 compliance, you must print each topic for the topic workflow configuration and export tables from the Oracle account. Before you print the topics, verify that the [topic workflow configuration options](#) allow addition of comments to topics, actions, and attachments are all checked. This assures all comments are included, even if these settings were changed in the topic workflow configuration over time.

The following tables store data for topics and topic workflow configurations. The `_x` suffix represents the unique identifier in the `TM_CONFIG_LOCAL` table for a topic workflow configuration.

<b>Topic tables</b>	<b>Topic workflow configuration tables</b>
TM_TOPIC_x	TM_CONFIG_LOCAL
TM_TOPIC_COMMENT_x	TM_STATE_x
TM_ATTACHMENT_x	TM_STATE_TOPICATTRIBUTE_x
TM_ATTACHMENT_CONTENT_x	TM_STATE_TRANSITIONS_x
TM_ATTACHMENT_COMMENT_x	TM_TOPIC_FIELD_x
TM_TOPICWORKTEAM_x	TM_TOPIC_CODEVALUES_x
TM_TOPICLINKS_x	TM_EMAIL_NOTIFN_RULES_x



TM_TOPIC_ACTION_x	TM_ATTACH_ATTR_x
TM_ACTION_COMMENT_x	TM_ATTACH_TYPE_x
TM_ACTION_ATTACHMENT_x	TM_ACTIONSTATE_x
TA_ATTACH_CONTENT_x	TM_ACTIONSTATE_ATTR_x
TA_ATTACH_COMMENT_x	TM_ACTIONSTATETRANS_x
	NY_REASON_CATEGORY
	NY_RULES_x
	NY_MESSAGE_x
	NY_DESTINATION_x
	NY_STATE_RULE_MAP_x
	NY_ACTION_RULE_MAP_x
	NY_FIELD_MODIFY_MAP_x
	NY_CATEGORY_MAP_x
	NY_REMIND_x
	NY_HISTORY_x
	NY_ACTION_REMIND_MAP_x

## Create PDF

### Create PDF for topic workflow configuration


On the Manage Topic Workflow Configurations page, you can document a topic workflow configuration using the **Create PDF** link in the row menu. To create a PDF, you must have the Manage Topic Workflow Configurations permission.

The PDF document contains tables that describe the components of a Topic Workflow Configuration and includes the following data:

- Topic workflow configuration name, ID, description, account name, owner, and published status
- Workflow Configuration Options
- Site Options for Workflow Configurations
- Fields
  - Topic Fields
  - Action Fields
  - Work Team Fields
  - Defined values
  - Defined Values for Linked Fields
- Topic States
- Topic Field Accessibility by State
- Action States
- Action Field Accessibility by State
- Attachment Field Accessibility by Type
- Topic Templates
- Topic Template Actions
- Email Notification Rules


The PDF output appears in a landscape orientation and has the creation date and time in the document footer. For any table, if the number of columns exceeds the page width, then the table wraps appropriately. If any of the sections describe components of the topic workflow configuration that are not being used, then **None** appears beneath the respective section heading.

## Creating a PDF for a topic workflow configuration

1. Click **Settings**.  
The Settings page appears.
2. In the Configure System section, click Manage Topic Workflow Configurations.  
The Manage Topic Workflow Configurations page appears.
3. Select the row menu (  ) for a configuration, and select **Create PDF**.  
A File Download dialog box appears, and prompts you to either open or save the PDF.
4. Click **Save**.  
The Save As dialog box appears.
5. Type the file name and click **Save**.  
The application saves the PDF on your local computer.  
For information on the sections of the PDF file, see [Create PDF for topic workflow configuration](#).

## Export topic workflow configurations

### Export topic workflow configuration

On the Manage Topic Workflow Configurations page, you can export a topic workflow configuration using the **Export** link from the row menu (). The exported topic workflow configuration can be imported into another application instance with the same topic schema version (as seen on the About page). This can be useful when developing the topic workflow configuration in a test environment and then loading it into a production environment.

You must have the Manage Topic Workflow Configurations permission to export the topic workflow configuration.

When you click **Export**, the selected topic workflow configuration is exported into a `.dat` file in XML format, which you can save on your local computer. By default, the file name is `<Topic Workflow Configuration name>.dat`.

The exported `.dat` file contains the following data:

- Topic schema version
- Export format version
- Exported timestamp
- Exported user information
- Topic workflow configuration metadata (such as, Name, Description, and ID)
- Fields

Fields that include work team contexts are not exported.

- Up to 5000 defined values for fields

A warning message appears if more than 5000 values have been defined for a field. If you proceed, the first 5000 values are exported based on their display order.

- Topic states and state information
- Topic field accessibility by state
- Action states and action state information
- Action field accessibility by state
- Attachment field accessibility by type
- Email notification rules

Recipient values that are exported can include Assigned User, Previous Assigned User and Work Team Members. Individual usernames are not included in the export.


The Topic Field Modified or Action Field Modified notification reasons that reference fields that include work team contexts are not exported. These fields can exist in the Message Subject and Message Text, however, because they will not be exported, they will not be populated when the email is sent on the imported side.

- Topic templates

If a topic template contains populated topic or action fields, and these fields have a work team context, then the topic template is not exported.

The history of the topic template is not exported.

## Exporting a topic workflow configuration

1. Click **Settings**.  
The Settings page appears.
2. In the Configure System section, click Manage Topic Workflow Configurations.  
The Manage Topic Workflow Configurations page appears.
3. Click the row menu () for a configuration, and click **Export**.  
A File Download dialog box appears.
4. Click **Save**.  
The Save As dialog box appears.
5. Enter the file name and click **Save**.  
The application saves the .dat file on your local computer.  
For information on the sections of the .dat file, see [Export topic workflow configuration](#).

## Import topic workflow configurations

### Import topic workflow configuration

On the Manage Topic Workflow Configuration page, you can import a previously exported topic workflow configuration using the **Import Workflow Configuration File** link.

To import the topic workflow configuration, you must have the Manage Topic Workflow Configurations permission. During the import, you can name and describe the topic workflow configuration.

The imported .dat file contains the following data:

- Topic schema version
- Export format version
- Exported timestamp
- Exported user information
- Topic workflow configuration metadata (Name, Description, and ID)
- Fields
- Up to 5000 defined values for fields
- Topic states and state information
- Topic field accessibility by state
- Action states and action state information
- Action field accessibility by state
- Attachment field accessibility by type
- Email notification rules
- Topic templates

---

**Note:** Fields with a work team context are not included in the export and import of Topic Workflow Configurations. Also, the Topic Field Modified and Action Field Modified email notification rules that reference fields with a work team context are not included. If these exist in the original Topic Workflow Configuration, they must be added to the imported Topic Workflow Configuration using Manage Fields and Manage Email Notification Rules.

---

## Importing a topic workflow configuration file

1. Click **Settings**.  
The Settings page appears.
2. In the Configure System section, click Manage Topic Workflow Configurations.  
The Manage Topic Workflow Configurations page appears.
3. Click Import Workflow Configuration File.  
The Import Workflow Configuration File page appears.
4. Click **Browse** to locate and select the .dat file on the local computer.
5. Click **Upload**.
6. In the **Name** field, type a name for the file.
7. Optionally, in the **Description** field, type a description.
8. Click **Save**.  
The new Topic Workflow Configuration appears in the Manage Topic Workflow Configurations table.



## Managing fields

### Fields

In a [topic workflow configuration](#), you can define fields to store information for topics, actions, and attachments. Every topic workflow configuration includes a set of standard fields, and custom fields to store information related to topics that your organization finds useful.

To define whether or not a field appears for topics or actions in a given workflow state or for attachments of a certain type, you also specify the [topic field accessibility by state](#), [action field accessibility by state](#), and [attachment field accessibility by type](#).

## Manage Fields page

On the Manage Fields page, you can view all defined fields, including fields that apply only to certain states in the topic or action workflow, or to certain types of attachments. You can add, modify, and delete these fields.

### General activities

The following links appear at the top of the page and affect the entire page:

- [Add Field](#)
- [Modify Display Order](#)
- Manage Accessibility
  - [Topic Fields by State](#)
  - [Action Fields by State](#)
  - Attachment Fields by Type
- Back
- [Columns](#)
- [Print](#)
- [Download](#)

### Row-specific activities

The following menu options are available from the row menu, located in the left most column of the table, and affect an individual row in the table:

- [Edit](#)
- [Define Values](#)
- [Delete](#)

### Field descriptions—Manage Fields page

Field	Description
Name	Oracle database column name for the field.
Format	One of the following values: <ul style="list-style-type: none"> <li>• <b>String</b>—Alphanumeric text value for the field.</li> <li>• <b>Integer</b>—Positive integer value for the field.</li> <li>• <b>Date</b>—Date in mm/dd/yyyy format in the field.</li> </ul>
Filter	<ul style="list-style-type: none"> <li>• <b>Yes</b> if the field acts as a display filter, appearing above tables of topic-related data as a drop-down list populated by all stored values. See <a href="#">Identifying a field as a filter field</a>.</li> </ul>

- Select **No** for fields that are not used to filter displayed data.


Custom/Standard	<p>One of the following values:</p> <ul style="list-style-type: none"> <li>• <b>Standard</b>—A field included in all topic workflow configurations.</li> <li>• <b>Custom</b>—A field added to the topic workflow configuration by your organization.</li> </ul>
Display Name	Name of the field as it appears in the user interface.
Order	<p>Position of the field within the workflow. The number indicates the place in the workflow of the field.</p> <p>The context determines where the Empirica Signal application uses the order:</p> <ul style="list-style-type: none"> <li>• <b>For a topic</b>—In the Add Topic or Topic General Information section of the Topic.</li> <li>• <b>For an action</b>—In the Add Topic Action or Action General Information section of the Topic Action page.</li> <li>• <b>For an attachment</b>—On the Add Attachment page.</li> </ul> <p>You can <a href="#">modify the order</a> of both standard and custom fields.</p> <p><b>Note:</b></p> <ul style="list-style-type: none"> <li>• The order applies to all fields with a given context</li> <li>• You can assign a single order value for the field.</li> </ul>
Context	<p>One or more of the following values:</p> <ul style="list-style-type: none"> <li>• Topic</li> <li>• Action</li> <li>• Attachments</li> <li>• Work teams</li> </ul>
Field Type	<p>One of the following field type options:</p> <ul style="list-style-type: none"> <li>• <b>Single Value</b>—A single value field type. This is the default field type.</li> <li>• <b>Append-only</b>— A multiple values field type in which a previously selected value cannot be removed. See <a href="#">Adding a multi-selection list field</a>.</li> <li>• <b>Multiple Values</b>—A multiple values field type that supports adding and removing values.</li> <li>• <b>Append-only and constrained</b>—An append-only field whose values are restricted based on work team. See <a href="#">Constraining field values by work team</a>.</li> <li>• <b>Linked</b>—The subsidiary field in a linked pair. See <a href="#">Adding linked fields</a>.</li> </ul>
Field Values	<p>Defined values for the field:</p> <ul style="list-style-type: none"> <li>• A field with defined values appears with a list selection control</li> </ul>

in the user interface. See [Adding a drop-down list field](#) or [Adding a multi-selection list field](#).

- A field without defined values appears as a value-entry field.
-

## Adding a field

You can add a custom field to a topic workflow configuration. Adding a field adds a column to an Oracle database table, so you must specify the data type (for example, string, integer, or date). For string fields, specify the maximum length. You can also make selections that affect how users interact with the field in the user interface, including the field label displayed, how users select values for the field and whether the field applies to topics, actions, or attachments, or any combination of these contexts.

1. Click **Settings**, and click **Manage Topic Workflow Configurations**.  
The Manage Topic Workflow Configurations page appears.
2. Click the row menu () , and click **Manage Fields**.  
The Manage Fields page appears.
3. To add a field, click **Add Field**.  
The Add Field page appears.
4. In the **Column name** field, type the field name to appear in the Oracle database.  
The name must begin with a letter. It must be up to 30 characters in length, and consist of uppercase letters, numbers, and the special characters \$, \_, and # only.
5. In the **Display name** field, type the field name to appear in the user interface.  
The display name appears as the label for the field and as a column header.
6. From the **Format** drop-down list, select the format for field values:
  - String (also specify the maximum field length)
  - Integer
  - Date
7. In the **Length** field, specify the length of the field as an integer.
8. Optionally, specify a type for the field. Types affect the way the field appears in the user interface:
  - Single Value, Append-only, Multiple Values
  - Linked and the parent field to link the field to
  - Constrained
9. Select a context for the field. The field can appear as and store values for topics, actions, attachments, or work teams, or any combination of these contexts.
10. To limit the values that can be selected for a field based on the work team membership of the current user; select the **Work teams** check box in addition to one of the other contexts. See [Constraining field values by work team](#).

---

**Note:** A superuser must set the Topic workflow configuration for work team custom fields site option to this configuration and the configuration must be published. If your organization uses more than one topic workflow configuration, you must define custom fields with the work team context identically in each topic workflow configuration

---

11. Select the **Display as filter** field check box to display the field and its values above tables in the user interface. See [Identifying a field as a filter field](#).
12. Click **Save**.

Fields appear in the user interface as value-entry fields unless you explicitly define a valid set of values for them. For example, description fields are typically value-entry fields that allow users the flexibility to enter any value.

You can [define valid values](#) for custom fields that have a format of string or integer, and for certain standard fields. Fields with defined values appear in the user interface as drop-down lists or, if you define a field as Append-only, a multi-selection list. See [Adding a drop-down list field](#) and [Adding a multi-selection list field](#).

## Editing a field

1. Click **Settings**, and click **Manage Topic Workflow Configurations**.

The Manage Topic Workflow Configurations page appears.

2. Click the row menu () , and click **Manage Fields**.

The Manage Fields page appears.

3. From the action row menu, click **Edit**.


The Edit Field page appears.

4. Optionally, modify the following fields:

<b>Field</b>	<b>Description</b>
Display name	The label that appears when adding or editing a topic or action.
Length	The length of String field can be increased. For a string format field, the Length field becomes editable. If you provide a new length that is less than or equal to an existing value, the page displays an error message.
Type	The following changes to Type can be made: <ul style="list-style-type: none"> <li>• Append Only to Multiple Values</li> <li>• Multiple Values to Append Only</li> <li>• Single Value to Multiple Values</li> <li>• Single Value to Append Only</li> </ul>
Display as filter field	Add or remove the field as a Quick filter.

5. Click **Save**.

## Viewing a field

1. Click **Settings**, and click **Manage Topic Workflow Configurations**.  
The Manage Topic Workflow Configurations page appears.
2. Click the row menu () , and click **Manage Fields**.  
The Manage Fields page appears displaying the fields.



## Deleting a field

1. Click **Settings**, and click **Manage Topic Workflow Configurations**.

The Manage Topic Workflow Configurations page appears.

2. Click the row menu () , and click **Manage Fields**.

The Manage Fields page appears.

3. From the action row menu, click **Delete**.

---

**Note:** This option is available for custom fields only.

---

4. Click **OK**.

The Manage Fields page refreshes with the updated table information.

- If you are not a superuser, you can delete a field only if no values are present for that field in any existing topics or work teams. To prevent a field from appearing for the topics feature, you can assign an access level of -- (Hidden) to the field for all topic states, all action states, or all attachment types.
- If you are a superuser, you can delete a field for which a value is present in an existing topic. A warning message informs you that for 21 CFR Part 11 compliance, you must print each topic for the topic workflow configuration, and export tables from the Oracle account for the topic workflow configuration. For a complete list of topic and topic workflow configuration tables, see [Deleting a Topic Workflow Configuration](#).

---

**Note:** If the field is referenced in any Topic Field Modified or Action Field Modified email notification rules, you must edit the notification rule before the field is deleted. A dialog box appears with a list of the relevant notification rules.

---

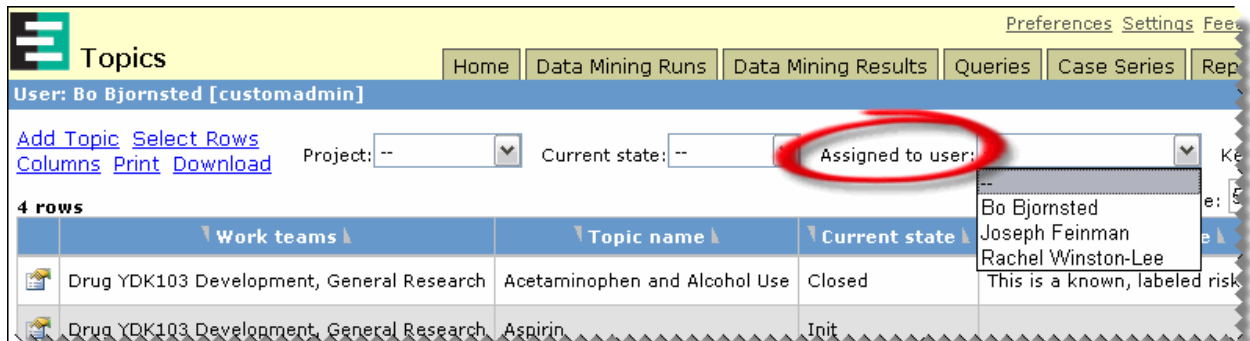
Or, if you attempt to delete the field, which is referenced in existing topic templates, the application prompts you to first remove the field value from the topic templates and then delete the field.

---

## Identifying a field as a filter field

Any field in a topic workflow configuration can be identified as a filter field. A filter field appears above tables of topic-related data, such as the table of topics on the Topics page, and includes a drop-down list containing all of the values that have been entered for this field. Using filter fields, users can limit the number of rows that appear in a table to only those that match the value selected for this field.

For example, you might define the Assigned to user field as a filter field so that users can choose to view only topics assigned to themselves.



Note that:

- Only fields that store a limited number of values (no more than 50 but, typically, less) should be identified as filter fields, as longer lists can become difficult for users to navigate effectively.
- The first 30 characters of each field value are shown in the drop-down list. Longer values are shortened to 30 characters.
- All of the filter fields appear in a single line above a table. Only four or five filter fields appear before horizontal scrolling is required.
- If an attachment field is identified as a filter field, it appears above tables of topic attachments and above tables of action attachments.

1. Click **Settings**.

The Settings page appears.

2. In the Configure System section, click Manage Topic Workflow Configurations.

The Manage Topic Workflow Configurations page appears.

3. Click the row menu (📄) for a field, and click **Manage Fields**.

The Manage Fields page appears.

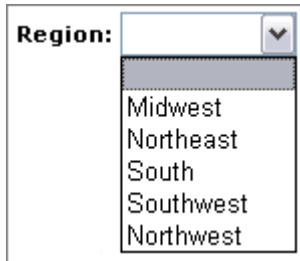
4. [Add](#) or [edit](#) the field, as necessary.

The Add Field or Edit Field page appears. For more information, see Adding a field or Editing a field.

5. Check Display as filter field.
6. Click **Save**.

## Adding a drop-down list field

When you add a field to a topic workflow configuration, it appears by default in the user interface as a value-entry field and accepts any alphanumeric value a user enters. An alternative is to provide a limited set of possible entries for a field so that a drop-down list appears in the user interface. For example:



Users can select a single value from a drop-down list, and can change the selected value for the field at any time (if permitted for a given workflow state by the topic or action field access level). Drop-down lists structure data entry by limiting the number of possible entries. They also assure that the values stored for a field are consistent.

---

**Note:** An alternative is to add a field that appears with a multi-selection list control in the user interface. There are two field types that support this: Append-only and Multiple Values. If the field is Append Only, users can select one or more values, but cannot remove any previously selected and saved value. If the field is Multiple Values, users can select one or more values, and can remove previously saved values. See [Adding a multi-selection list field](#).

---

1. Click **Settings**.  
The Settings page appears.
2. In the Configure System section, click Manage Topic Workflow Configurations.  
The Manage Topic Workflow Configurations page appears.
3. Click the row menu (📄) for a field, and click **Manage Fields**  
The Manage Fields page appears.
4. Click **Add Field**.  
The Add Field page appears.
5. In the **Column name** field, enter a column name.
6. In the **Display name** field, enter a name to appear in the user interface.
7. From the **Format** drop-down list, select the format of the field: String, Integer, or Date.
8. If you specified a **String** format, in the **Length** field, enter the maximum field length.


9. In the **Type** section, select Single Value.
10. In the **Context** section, select the field context. The field can be used to collect information for a topic, action, attachment, or work team.
11. Optionally, specify the field to be used for filtering by checking **Display as filter** field. See [Identifying a field as a filter field](#).
12. Click **Save**.

The Manage Fields page appears.

---

**Note:** You can design a pair of drop-down list fields that are linked. Selections available for the second field in the pair are dependent on the selection for the first in the pair. See [Adding linked fields](#).

---

13. Click  for the field you added, and then click **Define Values**.  
The [Define Valid Field Values page](#) appears.
14. Click **Add Value**.
15. The [Add Value page](#) appears.
16. In the **Value** field, enter a value for users to select.
17. Click **Save**.
18. Repeat steps 14 - 17 to add all possible values for the field. Alternatively, you can store all field values in a .csv (comma-separated value) file and then upload it. See [Uploading a table of valid values](#).
19. [Modify the display order](#) of the valid values as needed. Click **Modify Display Order**.

The Modify Display Order dialog box appears.

- A. From the **Values for Dropdown** list, select a value.
- B. To change the order of the value in the list, use the up-arrow and down-arrow buttons.
- C. Click **OK**.
- D. Click **Back**.

The Manage Fields page appears. The values you defined appear in the Field Values column.

By default, the new field appears as a drop-down list for a topic or action that is in any workflow state, for any type of document-style attachment, or for a work team. The field is editable; that is, users can select a value from the list or select " " (blank).

or

You can make this field required (the blank value is not offered, and users must select one of the defined values before saving).

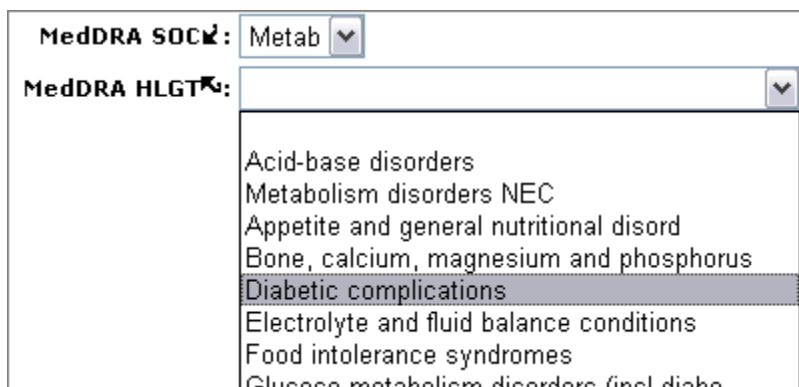
## Adding linked fields

In cases where user interaction with a pair of fields is improved by requiring a selection for one field before presenting the values that are valid for another, you can include a linked pair of [drop-down lists](#) in your topic workflow configuration.

In the following example, the user interface presents linked fields for selecting a MedDRA SOC and MedDRA HLGT:




Users must select a value for the parent field, MedDRA SOC, first. The list of values for the subsidiary field, MedDRA HLGT, is then populated with values that are valid given that initial selection.




Note that:

- You must define valid values for both of the fields in a linked pair. Both fields appear as drop-down lists in the user interface.
- Both of the fields in a linked pair must be custom fields that you add to the topic workflow configuration.
- You must define two different fields as the linked pair. A field cannot be selected as its own Link to parent field.

### Add the first, parent, field

1. Click **Settings**.  
The Settings page appears.
2. In the Configure System section, click Manage Topic Workflow Configurations.  
The Manage Topic Workflow Configurations page appears.
3. Select the row menu (  ) for a field, and select **Manage Fields**  
The Manage Fields page appears.

4. Click **Add Field**.  
The Add Field page appears.
5. In the **Column Name** field, enter a column name.
6. In the **Display name** field, type a name to display in the user interface.
7. From the **Format** drop-down list, select either string or integer as the format.
8. For a string field, in the **Length** field, specify a maximum field length.
9. In the **Type** section, do not check any options.
10. In the **Context** section, select the field context. The field can be used to collect information for a topic, action, attachment, or work team.
11. To use the field as a filter, check **Display as filter** field. See [Identifying a field as a filter field](#).
12. Click **Save**.
13. Click **Back**.  
The Manage Fields page appears.
14. Click  for the parent field, and then click **Define Values**.  
The [Define Valid Field Values page](#) appears.
15. Click **Add Value**.  
The [Add Value page](#) appears.
16. In the **Value** field, enter a value for users to select.
17. Click **Save**.
18. Repeat steps 14 - 16 to add all possible values for the field. Alternatively, you can store all field values in a .csv (comma-separated value) file and then upload it. See [Uploading a table of valid values](#).
19. [Modify the display order](#) of the valid values as needed. For more information, see [Modifying the display order for the values](#).

### **Add the second, subsidiary, field**

On the **Add Field** page, enter a second field.


1. In the **Column Name** field, enter a column name.
2. In the **Display name** field, type a name to display in the user interface.
3. From the **Format** drop-down list, select either string or integer as the format.
4. For a string field, in the **Length** field, specify a maximum field length.



5. In the **Type** section, check **Linked** and, from the **Link to parent field** drop-down list, select the field you added as the parent field.
6. In the **Context** section, select the same field context(s) as for the parent field.
7. Optionally, specify the field to be used for filtering by checking **Display as filter** field. See [Identifying a field as a filter field](#).
8. Click **Save**.

The Manage Fields page appears.

## Define the parent-child values

1. On the Manage Fields page, click  for the subsidiary field, and then click **Define Values**.

The [Define Valid Field Values page](#) appears.

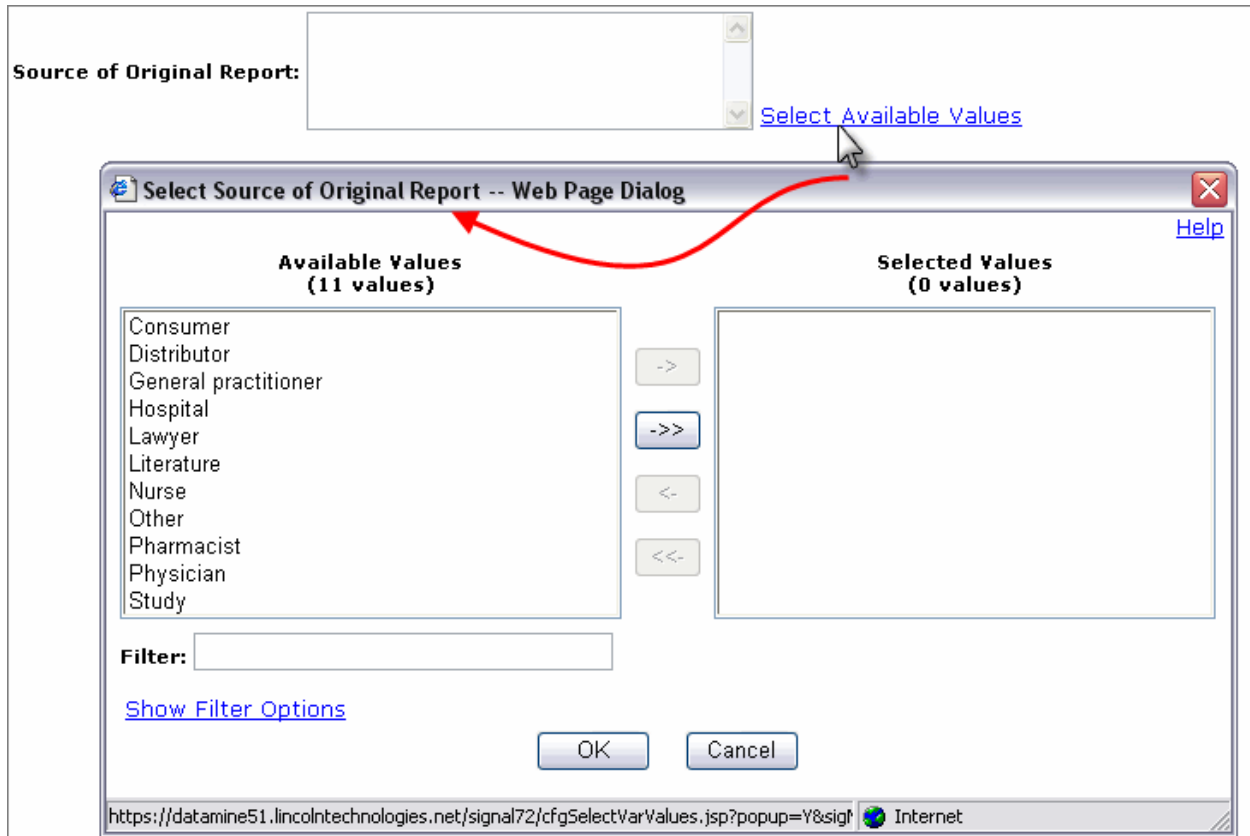
2. Click **Add Value**.
3. On the [Add Value page](#), supply the values for users to select. For each value that you add, from the **Link to parent value** drop-down list, identify the value for the parent field that must be selected for this value to be available. Click **Save**.
4. Repeat step 3 to add all possible values for the field. Alternatively, you can store all field values in a .csv (comma-separated value) file and then upload it. See [Uploading a table of valid values](#).
5. [Modify the display order](#) of the valid values, as needed. For more information, see [Modifying the display order for the values](#).

By default, both new fields will be editable for a topic or action in any workflow state, or for any type of document-style attachment: users can select a value or select " " (blank).

6. Alternatively, you can make one or both of these fields required (the blank value is not offered, and users must select one of the defined values before saving). Generally, you should apply the same access level to both of the fields in the linked pair. See [Managing topic field accessibility by state](#), [Managing action field accessibility by state](#), or [Managing attachment field accessibility by type](#).

## Adding a multi-selection list field



When you add a field to a topic workflow configuration, it appears by default in the user interface as a single value-entry field and accepts any alphanumeric value that a user enters. Alternatives to single value-entry include Append-Only and Multiple Values. Both of these multi-selection list fields provide a limited set of possible values and both appear in the user interface with a link to a multi-selection list.



Like a [drop-down list field](#), a multi-selection list field limits the number of possible entries that users can make and enforces consistency. Append-only fields also assure that any value selected at one point in time cannot be deleted or replaced. Users cannot later edit this type of field to remove or replace a value. Multiple Values fields do allow users to edit the field and remove or replace values.

**Note:** You can further reduce the possibility of user error when entering field values by setting up a multi-selection field and then specifying the work team or teams that can select each of its valid values. See [Constraining field values by work team](#).

1. Click **Settings**.  
The Settings page appears.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.  
The Manage Topic Workflow Configurations page appears.

3. Click the row menu () for a field, and click **Manage Fields**  
The Manage Fields page appears.
4. Click **Add Field**.  
The Add Field page appears.
5. In the **Column Name** field, enter a column name.
6. In the **Display name** field, type a name to display in the user interface.
7. From the **Format** drop-down list, select either string or integer as the format.
8. For a string field, in the **Length** field, specify a maximum field length.
9. In the **Type** section, check **Append-only** or **Multiple Values**.
10. In the **Context** section, select the field context. The field can be used to collect information for a topic, action, attachment, or work team.
11. To use the field as a filter, check **Display as filter** field. See [Identifying a field as a filter field](#).
12. Click **Save**.  
The Manage Fields page appears. The added field is at the bottom of the table.
13. Click  for the field you added, and then click **Define Values**.  
The [Define Valid Field Values page](#) appears.
14. Click **Add Value**.
15. On the [Add Value page](#), supply a value for users to select.
16. Click **Save**.
17. Repeat this step to add all possible values for the field. Alternatively, you can store all field values in a .csv (comma-separated value) file and then upload it. See [Uploading a table of valid values](#).
18. Click **Back**.  
The Manage Fields page appears.  
By default, the new field appears with a **Select Available Values** link next to it for a topic or action that is in any workflow state, for any type of document-style attachment, or for a work team. The field is editable: that is, users can select values for it or leave it blank.

or

You can make this field required (users must select at least one value before saving). See [Managing topic field accessibility by state](#), [Managing action field accessibility by state](#), or [Managing attachment field accessibility by type](#).

## Constraining field values by work team

When you add a field to a topic workflow configuration, it appears by default in the user interface as a value-entry field and accepts any alphanumeric value that a user enters. A more structured alternative is to [add a multi-selection list field](#), which allows users to select one or more values but not to remove any previously saved value(s). You can further limit the values that users can select for a multi-selection field by specifying the values that the members of a work team are able to select; that is, to constrain the field's valid values based on work team. This feature can reduce the possibility of user error when entering data and prevent the loss of information collected over time.


---

**Note:** If your organization uses more than one topic workflow configuration, any custom fields for the work team context must be defined identically in each topic workflow configuration.

**Note:** One of the following steps requires a Superuser to set a site option setting. Other steps require the Manage Topic Workflow Configurations user permission and the Manage Administer permission.

---


### Add the field to a topic workflow configuration

1. Click **Settings**.  
The Settings page appears.
2. In the Configure System section, click Manage Topic Workflow Configurations.  
The Manage Topic Workflow Configurations page appears.
3. Click the row menu () for a field, and click **Manage Fields**  
The Manage Fields page appears.
4. Click **Add Field**.  
The Add Field page appears.
5. In the **Column Name** field, enter a column name.
6. In the **Display name** field, type a name to display in the user interface.
7. From the **Format** drop-down list, select either string or integer as the format.
8. For a string field, in the **Length** field, specify a maximum field length.
9. In the **Type** section, check **Append-only** or **Multiple Values**.
10. In the **Type** section, check **Constrained values based on work team**.
11. In the **Context** section, select the field context. You must check at least one of these options. The field can be used to collect information for a topic, action, attachment, or work team.

12. In the **Context** section, check **Work Team**.
13. To use the field as a filter, check **Display as filter** field. See [Identifying a field as a filter field](#).
14. Click **Save**.

The Manage Fields page appears. The added field is at the bottom of the table.

## Define the values

1. On the Manage Fields page, click  for the field, and then click **Define Values**.  
The [Define Valid Field Values page](#) appears.
2. Click **Add Value**.
3. On the [Add Value page](#) supply a value for users to select.
4. Click **Save**.
5. Repeat steps 2 - 4 to add all possible values for the field. Alternatively, you can store all field values in a .csv (comma-separated value) file and then upload it. See [Uploading a table of valid values](#).
6. Click **Back**.

By default, the new field will be editable for a topic or action that is in any workflow state or for every type of document-style attachment. You can make this field required (users must select at least one value before saving), hidden, or visible in certain states or for certain attachment types. See [Managing topic field accessibility by state](#), [Managing action field accessibility by state](#), or [Managing attachment field accessibility by type](#).


## Set site options

A superuser performs the following:

1. Click **Settings**.  
The Settings page appears.
2. In the **Administer System** section, click **Set Site Options**.  
The Site Options page appears.
3. From the **Topic workflow configuration for work team custom fields** drop-down list, select the topic workflow configuration that has the constrained value field.

Custom work team fields appear when you add and edit work teams only after your topic workflow configuration has been published and this site option has been set.

4. Click **Save**.

5. Click **Settings**.  
The Settings page appears.
6. In the **Manage Users** section, click **Edit Work Teams**.  
The Edit Work Teams page appears.
7. Click  for a work team, and then click **Edit**.  
The [Edit Work Team page](#) appears. Your new field appears as a multi-selection list field.
8. To specify values for members of this work team to select for this field in the user interface, next to the multi-selection list field, click **Select Available Values**.
9. To define the values to present to each set of users, repeat this step for each work team.
10. Log out, then log back in.
11. To test your new field, click the **Topics** tab and then add or edit a topic, action, or attachment. The values available for selection in this field reflect your membership in one or more work teams.

## Display order for fields and field values

You can set the display order of the standard and custom fields in addition to the display order of field values.

Standard fields appear in the following order:

1. Topic fields
2. Action fields
3. Attachment fields

The custom fields appear after the standard fields in the order you added them. You can modify the default sequence on the:




- For a topic—On the [Add Topic page](#) or Topic General Information section of the Topic page.
- For an action—On the [Add Topic Action page](#) or Action General Information section of the Topic Action page.
- For a document-style attachment—On the [Add Attachment page](#).
- For a work team—On the [Edit Work Team page](#).

---

**Notes:** A field can only have one display order, even if it appears in more than one context. You can prevent a field from appearing when the topic or action is in a given state by assigning a field access level of **hidden** to the field for that state. This also applies to attachments of different types.

---

## Modifying the display order for a field

1. Click **Settings**, and click **Manage Topic Workflow Configurations**.  
The Manage Topic Workflow Configurations page appears.
2. Click the row menu () , and click **Manage Fields**.  
The Manage Fields page appears.
3. To order a field, click **Modify Display Order**.  
The Modify Display Order dialog box appears.
4. The dialog box lists every field in the currently assigned display order. For each field, the identifying information appears as **Display name [COLUMN\_NAME] (ID=#)**.
5. Click a field to select it.
6. Use the  and  keys to move the field up or down in the list.
7. When sequencing is complete, click **OK**.  
A new order number is assigned to the field.



## Managing field values

### Viewing valid values for a field

To present a list of values for a field in the user interface, instead of a value-entry field, you supply one or more valid values for that field. You can define values for:

- Standard fields with a format of string.
- Custom fields with a format of string.
- Custom fields with a format of integer.

You must define values for custom fields that have one of these types:

- Linked

---

**Note:** You must define values for both the controlling parent field and its subsidiary field. Typically, all values for the parent field are defined before the values for the subsidiary field are defined.

---

- Append-only
- Constrained and Append-only
- Multiple Values
- Constrained and Multiple Values


You can also specify the order in which the values appear in the list. If the field is not required, users can select " " (blank) to leave the field empty.

1. Click **Settings**.


The Settings page appears.

2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.

The Manage Topic Workflow Configurations page appears.

3. Click the row menu () for a field, and click **Manage Fields**.

The Manage Fields page appears

4. Click  for a field, and then click **Define Values**.

The Define Valid Field Values page appears and provides the following information:

Column	Description
Value	Value that is available for selection in the topic field.
Link to Parent	Value that must be selected for the parent field for this value to be available. Applies to the subsidiary field in a linked pair only.


Order            Number indicating the display order for the value.

---

### Define Field Values options

- To [add a value](#), click **Add Value**.
- To [order values](#), click **Modify Display Order**.
- To [upload a table of values](#), click **Upload Table**. You must prepare a comma-separated value (.csv) file to use this option.




### Row menu options

If you click  for a value, you can do the following:

- To [edit a value](#), click **Edit**.
- To delete a value, click **Delete**. Click **OK** to complete the deletion.

If you delete or change a value that is already in use in a topic, the original value remains in any topics that have used that value; however, the value is no longer available for selection in that, or any other, topic.

## Adding and editing valid values for a field

1. Click **Settings**.  
The Settings page appears.
2. In the Configure System section, click Manage Topic Workflow Configurations.  
The Manage Topic Workflow Configurations page appears.
3. Click the row menu () for a field, and click **Manage Fields**  
The Manage Fields page appears
4. Click  for a field, and then click **Define Values**.  
The [Define Valid Field Values page](#) appears.
5. To add a value, click **Add Value**.  
The Add Value page appears.  
or  
To edit a value, click  for the value, and then click **Edit**.  
The Edit Value page appears.
6. In the **Value** field, enter a value.  
If the field you are adding is the subsidiary field in a linked pair, select the value that this value is subsidiary to in the Link to parent value field.  
For example, if a MedDRA SOC field and a MedDRA HLGT field are linked, users will select an SOC value and then a list of relevant HLGT values is made available for selection.
7. Click **Save**.
8. Repeat this process as needed to define all valid values for the field. Alternatively, you can save all values in a .csv file and [upload the table of values](#).

## Uploading a table of valid values

### Create the table of values

1. Determine the valid values for the field.
2. Prepare a Microsoft Notepad file with a single column and with a column heading in the first row. Enter a single value of up to 100 characters in each subsequent row.

---

**Note:** For a field that is the subsidiary field in a [linked pair](#), the table that you upload should contain two columns. The first column should contain the values for that field, and the second column should contain the values that are valid for the controlling, parent field.

---

For example:

#### Typical format:

	A
1	Source
2	Physician
3	Pharmacist
4	Lawyer
5	Consumer
6	Study
7	Literature
8	Distributor
9	Other
10	Nurse
11	Hospital
12	Specialist physician

#### Format for subsidiary linked fields only:


	A	B
1	HLGT	SOC
2	Neoplastic and ectopic endocrinopathies	Endo
3	Parathyroid gland disorders	Endo
4	Thyroid gland disorders	Endo
5	Acid-base disorders	Metab
6	Metabolism disorders NEC	Metab
7	Appetite and general nutritional disord	Metab
8	Bone, calcium, magnesium and phosphorus	Metab
9	Diabetic complications	Metab
10	Electrolyte and fluid balance conditions	Metab
11	Food intolerance syndromes	Metab

3. Save the file with the .csv (comma-separated value) file extension.

### Upload the table of valid values

1. Click **Settings**.  
The Settings page appears.
2. In the Configure System section, click Manage Topic Workflow Configurations.  
The Manage Topic Workflow Configurations page appears.
3. Click the row menu (☰) for a field, and click **Manage Fields**

The Manage Fields page appears

4. Click  for a field, and then click **Define Values**.

The [Define Valid Field Values page](#) appears.

5. Click **Upload Table**.

The Upload Values dialog box appears.

6. In the **File to upload** field, enter the full path and file name of the .csv file, or click Browse to locate the file on your computer.

7. Click **Upload**.




The application adds all values in the file after the first row as valid values.

8. If necessary, you can [edit the values](#) or [change the display order](#) for the values.

## Modifying the display order for field values

You can specify the order in which valid field values appears in the drop-down list for that field.

To order valid values for a field, follow these steps:

1. Click **Settings**, and click **Manage Topic Workflow Configurations**.  
The Manage Topic Workflow Configurations page appears.
2. Click the row menu () , and click **Manage Fields**.  
The Manage Fields page appears.
3. From the action row menu, click **Define Values**.  
The Define Valid Field Values page appears for the field.
4. Click **Modify Display Order**.  
The Modify Display Order dialog box appears.
5. Use the  and  keys to move values up and down in the list.
6. Click **OK**.

## Managing field access

### Managing topic field accessibility by state

Once you have defined topic states and fields, you define the level of access that users have to each field when a topic is in each of the workflow states. You specify whether each field is required, editable (but not required), visible (but not editable), or hidden in each state. If you make a field required for a state, a topic cannot be saved in that state until the user provides a value for the field.

The access levels that you define are enforced when:

- A user edits a topic that is currently in that state.
- A user assigns that state to the topic. For example, suppose that the RESOLUTION field is editable in the Reviewed state and required in the Closed state. While the topic state is Reviewed, users can leave the RESOLUTION field empty. However, the user who changes the topic's state to Closed is required to provide a resolution.
- In addition, when a topic is created during the process of [saving an attachment to a topic](#) from another page in the application (if enabled as an attachment type for the topic workflow configuration), the TOPIC\_NAME is required but no other requirements for the Initial state are enforced until the first time that topic is edited.


Access levels apply only when a topic is edited. When a topic is viewed, all non-hidden fields are display-only.

1. Click **Settings**.

The Settings page appears.

2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.

The [Manage Topic Workflow Configurations page](#) appears.

3. Click the row menu () for a configuration, and then click **Manage Fields**.

The Manage Fields page appears.

4. Click **Manage Accessibility**.

5. From the menu, select **Topic Fields by State**.

The Manage Topic Field Accessibility by State page appears and presents a table with a column for each topic state and a row for each topic field.

For reference, you can review the field access levels for topic workflow states [defined in the Sample Topic Workflow Configuration](#).

6. From the drop-down lists in the access level cells, select an access level for each field when a topic is in that state. The access levels are:

<b>Access Level</b>	<b>Description</b>
---------------------	--------------------

--	<p>Hidden. Does not appear on the Topic page.</p> <p>For example, you assign this access level to the RESOLUTION and RESOLUTION_DATE fields for topics that are in any state other than Closed.</p>
Visible	<p>Appears on the Topic page as an informational message. Values cannot be entered or modified.</p> <hr/> <p><b>Note:</b> This access level should only be assigned to fields that store informational, rather than process-related, data for the topic. For example, this access level is not recommended for the CURRENT_STATE_ID field in any state, since a topic's current state should always be editable (or required).</p>
Editable	<p>Appears on the Topic page and entries are allowed.</p> <p>For example, you assign this access level to the TOPIC_DESCRIPTION field for topics that are in any state.</p>
Required	<p>Appears on the Topic page and an entry must be made. If you leave this field blank, topic information cannot be saved.</p> <p>For example, you assign this access level to the STATE_CHANGE_REASON field when topics are in any state other than Initial to assure that a meaningful log of the changes made to a topic is kept.</p>

7. Click **Save**.



## Managing action field accessibility by state

Once you have defined action states and fields, you define the level of access that users have to each field when an action is in each of those states. You specify whether each field is required, editable (but not required), visible (but not editable), or hidden in each state. If you make a field required for a state, an action cannot be saved in that state until the user provides a value for the field.

The access levels that you define are enforced when:

- A user edits an action that is in that state.
- A user assigns that state to the action.


Access levels apply only when an action is edited. When an action is viewed, all non-hidden fields are display-only.

1. Click **Settings**.

The Settings page appears.

2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.

The [Manage Topic Workflow Configurations page](#) appears.

3. Click the row menu () for a configuration, and then click **Manage Fields**.

The Manage Fields page appears.

4. Click Manage Accessibility.

5. From the menu, select **Action Fields by State**.

The Manage Action Field Accessibility by State page appears and presents a table with a column for each action state and a row for each action field.

For reference, you can review the field access levels for action workflow states [defined in the Sample Topic Workflow Configuration](#).

6. From the drop-down lists in the action state cells, select an access level for each field when an action is in that state. The access levels are:

Access Level	Description
--	Hidden. Does not appear on the Topic Action page. For example, you assign this access level to the ACTUAL_COMPL_DATE field for actions that are in the Initial state.
Visible	Appears on the Topic Action page as an informational message. Values cannot be entered or modified.

---

**Note:** This access level should only be assigned to fields that store informational, rather than process-related, data for the action. For example, this access level is not recommended for the ACTION\_STATE\_ID field in any state, since an action's current state should always be editable (or required).

---

Editable	Appears on the Topic Action page and entries are allowed. Typically, this access level is used for most action fields in most states.
Required	Appears on the Topic Action page and an entry must be made. If you leave the field blank, the action cannot be saved. For example, you assign this access level to the ACTUAL_COMPL_DATE field when actions are in the Closed state.

---

7. Click **Save**.

## Managing attachment field accessibility by type

Once you have [edited a topic workflow configuration's options](#) to select the types of attachments that can be added to a topic (or action), and defined fields for attachments, you specify the level of access that users have to each field based on the type of attachment. You specify whether each field is hidden, visible, editable, or required for an external document such as a URL, file, or note, or for an Empirica Signal object. If you make a field required for an attachment type, that attachment cannot be added or edited until the user provides a value for the field.

---

**Note:** Specifications made for Empirica Signal objects apply only when the attachment is edited. When an Empirica Signal object is [saved as an attachment to a topic](#), the Name field is required, the Description field is optional, and all other fields are hidden.


---

1. Click **Settings**.

The Settings page appears.

2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.

The [Manage Topic Workflow Configurations page](#) appears.

3. Click the row menu () for a configuration, and then click **Manage Fields**.

The Manage Fields page appears.

4. Click Manage Accessibility.

5. From the menu, select **Attachment Fields by Type**.

The Manage Attachment Field Accessibility by Type page appears and presents a table with a column for attachment type and a row for each attachment field.

For reference, you can review the field access levels for attachment fields [defined in the Sample Topic Workflow Configuration](#).

6. From the drop-down lists in the attachment type cells, select an access level for each field when an attachment is of that type. The access levels are:

Access Level	Description
--	Hidden. Does not appear when users add or edit an attachment. For example, you assign this access level to the URL_ADDRESS field for every type of attachment, except for URL, and to the FILE_NAME field for every type of attachment, except for external documents.
Visible	Appears when users add or edit an attachment as an informational message. Values cannot be entered or modified.

Editable	Appears when users add or edit an attachment and entries are allowed. For example, you assign this access level to the DESCRIPTION field for all attachment types.
Required	Appears when users add or edit an attachment and an entry must be made. If the field is left blank, the attachment cannot be saved. For example, you might assign this access level to the URL_ADDRESS field for the URL attachment type, and to the FILE_NAME field for the external document attachment type.

7. Click **Save**.

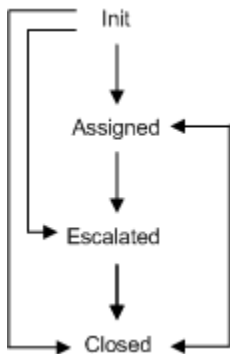
## Managing workflow states

### Topic states

To create a structured workflow for processing topics, each [topic workflow configuration](#) defines the workflow states that can be assigned to a topic. For each workflow state, the next possible state or states that can be assigned are also defined.

For example, the sample topic workflow configuration includes workflow states of Init (Initial), Assigned, Escalated, and Closed for topics. When a topic is in the Init state, it can move to any of the other three states. When it is in the Assigned state, the next possible states are Escalated or Closed.

The illustration shows the workflow supported by these states.



---

**Note:** Each topic workflow configuration also defines a separate set of workflow states that can be assigned to the actions for a topic. See [Action states](#) for more information.

---

## Manage Topic States page

On the Manage Topic State page, you can add, modify, and delete the topic states.

### General activities

The following links appear at the top of the page and affect the entire page:

- [Add State](#)
- [Back](#)
- [Columns](#)
- [Print](#)
- [Download](#)

### Row-specific activities

The following menu options are available from the row menu, located in the left most column of the table, and affect an individual row in the table:

- [Edit](#)
- [Delete](#)

### Field descriptions—Manage Topic State page

In this section, you can view the information for each topic workflow state.

Field	Description
Name	Name of the topic workflow state.
Description	Description of the topic workflow state.
Initial State	<p>Select <b>Yes</b> for a workflow state assigned automatically to a new topic when it is added.</p> <p>Select <b>No</b> for a state to indicate the topic is in progress or closed.</p> <p><b>Note:</b> When you add a topic workflow state, the <b>Init</b> topic workflow state is supplied with the value set to <b>Yes</b>. You cannot add or change this setting for any other topic workflow state.</p>
Final State	<p>Select <b>Yes</b> for a workflow state to indicate no further information is expected to be gathered for a topic.</p> <p>Select <b>No</b> for a state to indicate the topic is new (initial state) or in progress.</p> <p>Topics in a final state can be reopened if the next defined possible state is not in the Final State and, if the topic is visible to work teams and the user has the Reopen Topics/Actions <a href="#">work team permission</a>.</p>

---


**Note:** You can set a topic workflow configuration option to require that all actions be in a final state before the topic itself can be move to a final state. See [Editing Workflow Configuration Options](#).

---

Next Possible States	States a user can assign to a topic that is in this state. Determines the transitions that are possible from one state to another.
----------------------	------------------------------------------------------------------------------------------------------------------------------------

---

## Adding a topic state

1. Click **Settings**, and click **Manage Topic Workflow Configurations**.  
The Manage Topic Workflow Configurations page appears.
2. Click the row menu () , and click **Manage Topic States**.  
The Manage Topic States page appears.
3. To add a topic workflow state, click **Add State**.  
The Add State page appears.
4. Type the Name of the topic workflow state.
5. Type the Description of the topic workflow state.
6. In the **Possible next states** field, select the states that users can assign to a topic that is in this state. To [select a state](#), do the following:
  - A. Click **Select States**.  
The Select States dialog box appears.
  - B. Select the states to which the topic can transition.
7. To indicate that a state closes a topic when it is assigned, select the **This is a final state** check box.  
  
To work with a topic that is in a final state and visible to any work teams, a user must have the Reopen Topic [work team permission](#), and a non-final state, such as, Reopened, must be defined as a possible next state. The user can then reopen the topic and change its current state to a non-final state before editing it further.

---

**Note:** The topic workflow configuration may also require that all of a topic's actions be in a final state before the topic itself can be assigned a final state. See [Editing Workflow Configuration Options](#).


---
8. Click **OK**.  
  
After you define the workflow states for topics and define the fields that store topic information, you should review the [level of access](#) assigned to each field and state. When you add a new state, by default every topic field is editable when the topic is in that state. You can modify the level of access for each field to hidden, visible, editable, or required for the new state.



## Editing a topic state

1. Click **Settings**, and click **Manage Topic Workflow Configurations**.

The Manage Topic Workflow Configurations page appears.

2. Click the row menu () , and click **Manage Topic States**.

The Manage Topic States page appears.

3. From the action row menu, click **Edit**.

The Edit State page appears.

4. Modify the **Name** of the topic workflow state.

If you modify a state name, any topics currently in that state are updated automatically.

---

**Note:** You can rename the state named **Init**. However, it is always considered to be the initial state for a topic and is assigned automatically to every new topic created.

---

5. Modify the **Description** of the topic workflow state.

6. In the **Possible next states** field, specify the states that users can assign to a topic that is in this state.

---

**Note:** If state transitions are changed and these transitions are referenced in Topic State Changed email notification rules, you need to first edit the notification rule. A list of the effected email notification rules is displayed.

---

7. To [select a state](#), do the following:

- A. Click **Select States**.

The Select States dialog box appears.

- B. Select the available states to which the topic can transition.

8. To indicate that a state closes a topic when it is assigned, select the **This is a final state** check box. To work with a topic that is in a final state and visible to all work teams, a user must have the Reopen Topic [work team permission](#), and a state other than Final, must be defined as a possible next state. This allows the user to reopen the topic and change its current state to that non-final state before editing it further.


---

**Note:** The topic workflow configuration may also require that all of a topic's actions be in a final state before the topic itself can be assigned a final state. See [Editing Workflow Configuration Options](#).


---

9. Click **OK**.

## Viewing a topic state

1. Click **Settings**, and click **Manage Topic Workflow Configurations**.  
The Manage Topic Workflow Configurations page appears.
2. Click the row menu () , and click **Manage Topic States**.  
The Manage Topic States page appears having the topic state [information](#).

## Deleting a topic state

1. Click **Settings**, and click **Manage Topic Workflow Configurations**.  
The Manage Topic Workflow Configurations page appears.
2. Click the row menu () , and click **Manage Topic States**.  
The Manage Topic States page appears.
3. From the action row menu, click **Delete**.  
A dialog box appears for confirmation. You cannot delete the Init (Initial) state, and you cannot delete a state that is currently assigned to any topics. To determine which topics are in a given state, click the Topics tab and then sort the table using the Current state column.
4. Click **OK**.
5. The Manage Topic State page refreshes with the updated table information.

---

**Note:** When you delete a topic state, it is removed automatically as one of the next possible states for any other states. You may need to adjust the e-mail notification rules and the assignment of next possible states for the remaining states.

---

## Action states

To create a structured workflow for completing actions, each [topic workflow configuration](#) defines the workflow states that can be assigned to an action. For each workflow state, the next possible state or states that can be assigned are also defined. For example, you can set up a topic workflow configuration so that an action passes through the workflow states Initial, Assigned, and Closed.

Once you have defined action states and the fields that store action information, you define the [level of access](#) that users have to each field when an action is in each of the states. You specify whether each field is visible, editable, or required when the action is in each state.

---

**Note:** Each topic workflow configuration also defines a separate set of workflow states that can be assigned to a topic as a whole. See [Topic states](#) for more information.

---

## Manage Action States page

On the Manage Action State page, you can add, modify, and delete the action states.

### General activities

The following links appear at the top of the page and affect the entire page:

- [Add Action State](#)
- [Back](#)
- [Columns](#)
- [Print](#)
- [Download](#)

### Row-specific activities

The following menu options are available from the row menu, located in the left most column of the table, and affect an individual row in the table:

- [Edit](#)
- [Delete](#)

### Field descriptions—Manage Action State page


In this section, you can view the information for each action state.

Field	Description
Name	Name of the action state.
Description	Description of the action state.
Initial State	Select <b>Yes</b> for the workflow state assigned automatically to a new action when it is added. Select <b>No</b> for a state to indicate the action is in progress or closed.
Final State	Select <b>Yes</b> for a workflow state to indicate no further information is expected to be gathered for an action. Select <b>No</b> for a state to indicate an action is new (initial state) or in progress.  <b>Note:</b> You can set a topic workflow configuration option to require an action to have an associated comment or attachment before a final state can be assigned to it. See Editing Workflow Configuration Options for more information.
Next Possible	States that a user can assign to an action that is in this state. Determines the transitions that are possible from one state to another.

## States

---

## Adding an action state

1. Click **Settings**, and click **Manage Topic Workflow Configurations**.  
The Manage Topic Workflow Configurations page appears.
2. Click the row menu () , and click **Manage Action States**.  
The Manage Action States page appears.
3. To add an action state, click **Add Action State**.  
The Add Action State page appears.
4. Enter the Name of the state.
5. Enter the Description of the state.
6. In the Possible next states field, specify the states that users are able to assign to an action in this state.
7. To select a state, click **Select Action States**.
8. To indicate this state closes an action when assigned, select the **This is a final State** check box.

---

**Note:** The topic workflow configuration may also require all of a topic's actions be in a final state before the topic itself can be assigned a final state. See [Editing Workflow Configuration Options](#).


---

9. Click **OK**.

## Editing an action state

1. Click **Settings**, and click **Manage Topic Workflow Configurations**.

The Manage Topic Workflow Configurations page appears.

2. Click the row menu () , and click **Manage Action States**.

The Manage Action States page appears.

3. From the action row menu, click **Edit**.

The Edit Action State page appears.

4. Modify the **Name** of the action state.

If you modify a state name, any actions currently in that state are updated automatically.

---

**Note:** You can rename the state named **Init**. However, it is always considered to be the initial state for an action and is automatically assigned to every new action created.

---

5. Modify the **Description** of the action state.

6. In the **Possible next states** field, specify the states that users can assign to an action that is in this state.

---

**Note:** If state transitions are changed and these transitions are referenced in Action State Changed email notification rules, you need to first edit the notification rule. A list of the effected email notification rules is displayed.

---

7. To select a state, click **Select Action States**.

8. To indicate that this state will close an action when it is assigned, select the **This is a final state** check box.

---


**Note:** The topic workflow configuration may also require all of a topic's actions be in a final state before the topic itself can be assigned a final state. See Editing Workflow Configuration Options

---

9. Click **OK**.




## Viewing an action state

1. Click **Settings**, and click **Manage Topic Workflow Configurations**.  
The Manage Topic Workflow Configurations page appears.
2. Click the row menu () , and click **Manage Action States**.  
The Manage Action States page appears having the action state information.

## Deleting an action state

1. Click **Settings**, and click **Manage Topic Workflow Configurations**.

The Manage Topic Workflow Configurations page appears.

2. Click the row menu () , and click **Manage Action States**.

The Manage Action States page appears.

3. From the action row menu, click **Delete**.

A dialog box appears for confirmation. You cannot delete the **Init** (Initial) state, and you cannot delete a state that is currently assigned to any action.

4. Click **OK**.

The Manage Action States page refreshes with the updated table information.

---

**Note:** When you delete a state, it is removed automatically as one of the possible next states for any other action states. You may need to adjust the email notification rules and the assignment of next possible states for the remaining action states.

---

## Managing email notification rules

### Manage Email Notification Rules page

On the Manage Email Notification Rules page, you can add, modify, and delete email notification rules.

#### General activities

The following links appear at the top of the page and affect the entire page:

- [Add Email Notification Rule](#)
- [Back](#)
- [Columns](#)
- [Print](#)
- [Download](#)

The **Notification Reason** filter appears at the top of the page and affects the email notification rules table.

#### Row-specific activities

The following menu options are available from the row menu, located in the leftmost column of the table, and affect an individual row in the table:

- [Edit](#)
- [Delete](#)

#### Field descriptions—Manage Email Notification Rules page

Field	Description
ID	Email notification rule identifier.
Rule Name	Email notification rule name.
Notification Reason	<p>The following activities initiate an automated email:</p> <ul style="list-style-type: none"> <li>• Topic Added—A new topic is created.</li> <li>• Topic Deleted—A topic is deleted.</li> <li>• Topic Modified—A topic is modified.</li> <li>• Topic Field Modified—A topic field is modified.</li> <li>• Topic State Changed—The workflow state of a topic changes.</li> <li>• Topic Assignment Changed—A topic assignment changes.</li> <li>• Action Added—An action is added to a topic.</li> <li>• Action Deleted—An action is deleted.</li> </ul>

- Action Modified—An action is modified.
- Action Field Modified—An action field is modified.
- Action State Changed—The workflow state of an action changes.
- Action Assignment Changed—An action assignment changes.
- Email Reminder—Daily, at a time specified in Site Options.

Multiple rules can be defined for each email notification reason.

---

Message Subject	Email subject line.
-----------------	---------------------

---


Message Text	Email text.
--------------	-------------

---

Send To	<p>Message recipients:</p> <ul style="list-style-type: none"> <li>• <b>Work Team Members</b>—All members of the work team, or teams that can view the topic.</li> <li>• <b>Assigned User</b>—User who is currently assigned to the topic or action</li> <li>• <b>Previous Assigned User</b>—User who was previously assigned to the topic.</li> <li>• <b>Individual users</b>—Enabled users in login group, regardless of topic visibility. Users must have an email address associated with their username.</li> </ul>
---------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

---

## Adding an email notification rule

1. Click **Settings**, and click **Manage Topic Workflow Configurations**.  
The Manage Topic Workflow Configurations page appears.
2. Click the row menu () , and click **Manage Email Notification Rules**.  
The Manage Email Notification Rules page appears.
3. To create a rule, click **Add Email Notification Rule**.  
The Add Email Notification Rule page appears.
4. Type the rule name in the **Notification rule name** text field.
5. From the **Notification reason** drop-down list, select the type of activity that triggers the notification. For more information, see [Field descriptions—Manage Email Notification Rules page](#).
6. From the **Send to** list, select the recipient names. For more information, see [Field descriptions—Manage Email Notification Rules page](#).
7. Type a subject for email messages generated for the selected reason.  
You can include field variables in this subject. When the message is generated, the current values replace the field variables of the referenced fields.  

---

**Note:** You must provide a message subject in order to save the email notification rule.


---
8. Type the message text.  
You can include field variables in this text. When the message is generated, the current values replace the field variables of the referenced fields.
9. To insert a field variable, click [Show Fields](#).  
Before including fields in the message subject or message text, ensure that the resulting emails will not contain sensitive or confidential information.  

---

**Note:** When you select a field variable, it is inserted at the position of the cursor.

---
10. Click **OK**.

## Editing an email notification rule


1. Click **Settings**, and click **Manage Topic Workflow Configurations**.  
The Manage Topic Workflow Configurations page appears.
2. Click the row menu () , and click **Manage Email Notification Rules**.  
The Manage Email Notification Rules page appears.
3. Select the row menu, and select **Edit**.  
The Edit Email Notification Rule page appears.
4. Modify the fields.
5. For more information, see [Field descriptions—Manage Email Notification Rules page](#).

---

**Note:** The **Notification reason** field is disabled during the edit mode and cannot be modified.

---

## Deleting an email notification rule

1. Click **Settings**, and click **Manage Topic Workflow Configurations**.  
The Manage Topic Workflow Configurations page appears.
2. Click the row menu () , and click **Manage Email Notification Rules**.  
The Manage Email Notification Rules page appears.
3. Select the row menu, and select **Delete**.  
A message box appears to confirm the deletion.
4. Click **OK**.

## Inserting a field variable into email notification

---

**Note:** Before including fields in the message subject or message text, ensure that the resulting emails will not contain sensitive or confidential information.

---

To provide contextual information in an email message, you can include field variables that will be replaced by current values when the message is generated. For example, an email notification rule that includes field variables in the message text appears as follows:

The state for the <<topic.TOPIC\_NAME>> topic has been changed to <<topic.CURRENT\_STATE\_ID>>. The following reason for this change was provided: <<**topic.STATE\_CHANGE\_REASON**>>.

When an email message is generated based on this rule, the body of the actual message might read:

The state for the Acetaminophen and Alcohol Use topic has been changed to Closed. The following reason for this change was provided: **This is a known, labeled risk.**

---

**Note:** Action e-mails trigger when you click **Save** on the Topic Action page. Any topic field included in an Action email message reflects the last saved General Information value.

---

1. On the [Edit Email Notification Rule page](#), click **Show Fields**.

For a topic-related email notification reason, a page lists all topic fields. For an action-related reason, the page lists all topic fields and all action fields.

2. Highlight a field to insert a variable for it into the message text.
3. Click **OK**.

The field variable is inserted at the location of the cursor.



## About topic templates

### Manage Topic Templates page

Topic templates can serve as the starting point for creating new topics. If you have the Manage Topic Workflow Configurations permission, you can add and manage topic templates for a particular topic workflow configuration that is published to your login group.

#### General activities

The following links and filters appear at the top of the page and affect the entire page.

- [Add Topic Template](#)
- [Back](#)
- [Columns](#)
- [Print](#)
- [Download](#)

#### Row-specific activities

The following menu options are available from the row menu, and affect an individual row in the table:

- [View](#)
- [Edit](#)
- [Copy](#)
- [Delete](#)

### Field descriptions—Manage Topic Templates page


Field	Description
ID	Identifier that was assigned automatically when the topic template was created. Each topic template ID is unique and is not re-used if the template is deleted.
Name	Name of the topic template.
Work Teams	Work teams whose member can use the topic template.
Description	Description of the topic template.
Created By	Name of the user who created the topic template.
Created	Date and time when the topic template was created.

Modified By	Name of the user who last modified the topic template.
Modified	Date and time when the topic template was last modified.
Date	Date specified as offsets. Date offsets specified in the topic template are inherited by topics as actual dates, offset from the time of topic creation.

## Adding a topic template

Adding a topic template is similar to adding a topic, however, the values entered are inherited by topics created from the template.

To add a topic template, follow these steps:

1. Click **Settings**.  
The Settings page appears.
2. From the **Configure System** section, click **Manage Topic Workflow Configurations**.  
The Manage Topic Workflow Configurations page appears.
3. Select the row menu () for a topic workflow configure, and click **Manage Topic Templates**.  
The Manage Topic Templates page appears.
4. Click the **Add Topic Template** link.

The Add Topic Template page appears, and displays all fields in the Topic Template General Information section that are available in the Initial state, except for the following:

- Topic state
- Assigned to user
- Keywords
- Reason for Change
- Project

The Comments, Attachments, and Links are not available in topic templates. Actions are available after you save a topic template.

5. To allow users to access the topic template, from the **Visible to work team** list, select the work teams to which the users belong. By default, all work teams appear in this list even if the topic workflow configuration is configured for only one work team. When creating a new topic, only members of the selected work teams will have access to this topic template.

---

**Note:** To select multiple work teams, hold down the **Ctrl** key and click each work team. Deselect a work team by holding down the **Ctrl** key and clicking the work team. You can click **Browse** to select from a descriptive list of work teams.

---

6. In the **Name** and **Description** fields, type a template name and a description for the topic template.
7. For the other fields on the page, specify values for any other Topic fields to include in the template. You can also add actions to the template.

Date fields are specified as offsets. Date offsets specified in the topic template are inherited by topics as actual dates, offset from the time of topic creation.

8. Click **Save**.

The new topic template appears in the Manage Topic Template table.


or

If you want to add actions to the newly created topic template from the Add Topic Template page, click **Save & Edit**.

The Topic Template Actions and History of Topic Template sections appear, and you can perform further editing.

## Selecting a work team for topic template

To allow users to use the topic template when creating a new topic, the template must be made visible to a work team in which the users belong.

1. Click **Settings**, and click **Manage Topic Workflow Configurations**.  
The Manage Topic Workflow Configurations page appears.
2. Click the row menu () , and click **Manage Topic Templates**.  
The Manage Topic Templates page appears.
3. Click **Add Topic Template**.  
The Add Topic Template page appears with a set of fields for topic template-related information. The specific fields that appear depend on your topic workflow configuration.
4. Next to the **Visible to work team** field, click **Browse**.  
The Browse Work Teams dialog box appears and provides information about each work team in your login group in a table that include these columns:

Column	Description
ID	Unique identifier of a topic template.
Name	The name of the work team.
Description	Descriptive text about the work team.
Login Group	The name of the login group. Each work team is a subset of a login group.
All Users	Yes, if all users in the login group are members of the work team. No, if users have been individually added to the work team.
Users	The full name and Empirica Signal username of each member of the work team. Blank, if all users in the login group are members of the work team.
Created By	Name of the user who created the work team.
Created	Date and time when the work team was created.
Modified By	Name of the user who last modified the work team.
Modified	Date and time when the work team was last modified.

5. Select the row for the work team that you want.
6. Click **OK**.

The Add Topic Template page appears with the selected work team in the **Visible to work team** drop-down list.



For information about viewing, printing, or downloading tables or changing the way data displays in the table, see [About tables](#).

## Topic Template page

On the Topic Template page, you can view and edit topic template information, including their actions and history.

To expand the sections on this page, click **Show All**, or click  for a single section. To hide section details, click  for the section or click **Hide All**.

### Sections

Section	Description	Available actions
Topic Template General Information	<p>Displays the current field values that describe a topic template:</p> <ul style="list-style-type: none"> <li>Includes all standard and custom fields accessible in the initial state, except the following: <ul style="list-style-type: none"> <li>Topic State</li> <li>Topic Assigned to User</li> <li>Project</li> <li>Keywords</li> </ul> </li> <li>Each field accepts text, numeric, or provides a list of pre-defined values that you can select. A field that accepts text may also offer a <b>Select Available Values</b> link so you can select one or more values from a list.</li> <li>A date field appears as offsets expressed in days. When the template is used, the date field in the topic is computed based on topic creation date plus topic template offset.</li> <li>Arrow icons may appear after the names of a pair of fields to show that they are a linked pair. For example, if fields for Country () and State () appear, the arrows indicate that you must select a value for the Country field first and then select a value for the State field. You cannot select a State value first: the values available for State depend on the Country you select.</li> <li>The Visible to work team field displays a comma separated list of work teams whose members will be able to use the topic template. When the page is in the edit mode, it appears as a list.</li> <li>To save changes to the Topic Template General Information section, click <b>Save</b>. Saved changes are shown as entries in the History of Topic Template General Information section.</li> </ul>	None

---

**Note:** The **Save** button affects only the Topic Template General Information section of the topic template. You do not need to click Save after you work with Actions.

---

Topic Template Actions	<p>Displays a list of each specific activity identified for the topic template. Actions may reflect research activities, such as, literature searches, scheduled meetings, or any other activity you wish to track for the topic template. When in the edit mode, you can click <a href="#">Add Topic Template Action</a> to add an action, or click row menu for an action to view, edit, or delete.</p> <p>A Date fields appear as offsets expressed in days. When the template is used, the date field in the topic action is computed based on topic creation date plus offset.</p>	<a href="#">View</a> <a href="#">Edit</a> Delete
History of Topic Template General Information	<p>Displays information on changes that have taken place for the topic template. A new row is added to the table each time you click Save in the Topic Template General Information section.</p>	None

### Field descriptions—Topic Template General Information


Depending on your organization’s workflow configuration, the following fields appear in this section.

Field	Description
Visible to work team	The work team or teams whose members can view or act on the topic template. You can click Browse to select a work team from a descriptive list.
Name	Name of the topic template.
Description	Description of the topic template.



## Viewing a topic template

To view a topic template, follow these steps:


1. Click **Settings**, and click **Manage Topic Workflow Configurations**.  
The Manage Topic Workflow Configurations page appears.
2. Click the row menu () , and click **Manage Topic Templates**.  
The Manage Topic Templates page appears.
3. Click the row menu, and click **View**.  
The Topic Template page appears.

## Editing a topic template

When you edit a topic template, you can perform all the actions of viewing a topic template.

1. Click **Settings**, and click **Manage Topic Workflow Configurations**.

The Manage Topic Workflow Configurations page appears.

2. Click the row menu () , and click **Manage Topic Templates**.

The Manage Topic Templates page appears.

3. Click the row menu, and click **Edit**.

The Topic Template page appears.

4. In the Topic General Information section, specify values.

5. Click **Save**.

6. In the Topic Template Actions section, do any of the following:

- A. Click **Add Topic Template Action** to add an action.

- B. Click the row menu, and click **View**.

The Topic Template Action page appears.

- C. Click the row menu, and click **Edit**.


The Topic Template Action page appears.

- D. Click the row menu, and click **Delete**.

A confirmation dialog box appears.


## Copying a topic template

On the Manage Topic Templates page, if you have the Manage Topic Workflow permission, you can copy an existing topic template using the **Copy** link in the row menu. Template topic actions are included in the copy.

1. Click **Settings**.  
The Settings page appears.
2. From the **Configure System** section, click **Manage Topic Workflow Configurations**.  
The Manage Topic Workflow Configurations page appears.
3. Click the row menu () for a topic workflow configure, and then click **Manage Topic Templates**.  
The Manage Topic Templates page appears.
4. Click the row menu for a topic template, and then click **Copy**.  
The Copy Topic Template page appears.
5. In the **Name** field, leave the default name or type a different template name.
6. In the **Description** field, type a description of the topic template.
7. Click **Save**.  
The Manage Topic Templates page appears. The copy appears in the table.

## Deleting a topic template

On the Manage Topic Template page, you can delete a topic template using the **Delete** link in the row menu. When a topic template is deleted, any topics created previously with that template are not affected.



1. Click **Settings**.  
The Settings page appears.
2. From the **Configure System** section, click **Manage Topic Workflow Configurations**.  
The Manage Topic Workflow Configurations page appears.
3. Click the row menu () for a topic workflow configure, and then click **Manage Topic Templates**.  
The Manage Topic Templates page appears.
4. Click the row menu for a topic template, and then click **Delete**.  
A confirmation dialog box appears.
5. Confirm the deletion by clicking **OK**.  
The topic template table refreshes with the updated information.

**About topic template action****Topic Template Action page**

On the Topic Template Action page, you can view and edit template action information. The page allows you to view the history of the topic template actions. In edit mode, you can also perform activities based on your permissions and topic workflow configuration.

To expand the sections on this page, click **Show All**, or click  for a single section. To hide section details, click  for the section or click **Hide All**.

**Sections**

Section	Description	Available actions
Template Action General Information	<p>Displays the current values in the standard or custom fields that describe the template action:</p> <ul style="list-style-type: none"> <li>The fields can be display-only, editable, or required. If a field is required, an asterisk (*) appears next to it and the action cannot be saved until you provide a value for the field.</li> <li>Each field accepts text, numeric, and date values, or provides a list of pre-defined values that you can select. If a value is not required in the field, you can select <b>(a blank value)</b> to indicate no value for the field. A field that accepts text may also offer a <b>Select Available Values</b> link so you can select one or more values from a list.</li> <li>Arrow icons may appear after the names of a pair of fields to show that they are a linked pair. For example, if fields for Country () and State () appear, the arrows indicate that you must select a value for the Country field first and then select a value for the State field. You cannot select a State value first: the values available for State depend on the Country you select.</li> <li>To save changes in the Template Action General Information section, click <b>Save</b>.</li> </ul>	None
<hr/> <p><b>Note:</b> The <b>Save</b> button affects only the Template Action General Information section of the topic template. You do not need to click <b>Save</b> after you work with other sections of this page.</p> <hr/>		

History of Template Action General Information	Displays information on changes that have taken place for the template action. A new row is added to the table each time you click <b>Save</b> in the Template Action General Information section.	None
---------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------

---

### Field descriptions—Template Action General Information


Depending on your organization’s workflow configuration, the following field appears in this section.

Field	Description
Action name	Name of the action.
Action description	Description of the action.
Planned completion date	Planned date for the completion of the action.
Actual completion date	Date the action was completed.

If another user edits the same topic template action at the same time, the first one to save the action will have their changes saved. The second user gets an error indicating the action has been changed since the edit session began. The General Information section of the page becomes visible, allowing the user to print or take a screen shot, so that the information can be re-entered.


## Adding a topic template action

To add a topic template action, follow these steps:

1. Click Settings, and click Manage Topic Workflow Configurations.  
The Manage Topic Workflow Configurations page appears.
2. Click the row menu () , and click **Manage Topic Templates**.  
The Manage Topic Templates page appears.
3. Click the row menu, and click **Edit**.  
The Topic Template page appears.
4. In the Topic Template Actions section, click **Add Topic Template Action**.  
The Add Topic Template Action dialog box appears.
5. Type action name and description for the topic template action.  
Date fields are specified as offsets. Date offsets specified in the topic template are inherited by topics as actual dates, offset from the time of topic creation.
6. Enter values for any other fields to be included in the template action.  
Date fields are specified as offsets. Date offsets specified in the topic template are inherited by topics as actual dates, offset from the time of topic creation.
7. Click **Save**.  
The new topic template action appears in the Topic Template Actions table of the Topic Template page.

## Viewing a topic template action


To view a topic template action, follow these steps:

1. Click Settings, and click Manage Topic Workflow Configurations.  
The Manage Topic Workflow Configurations page appears.
2. Click the row menu () , and click **Manage Topic Templates**.  
The Manage Topic Templates page appears.
3. Click the row menu, and select **View**.  
The Topic Template page appears.
4. In the Topic Template Actions section, select the row menu, and select **View**.  
The Topic Template Action page appears.



## Editing a topic template action

When you edit a topic template action, you can perform activities of viewing a topic template action.

1. Click Settings, and click Manage Topic Workflow Configurations.  
The Manage Topic Workflow Configurations page appears.
2. Click the row menu () , and click **Manage Topic Templates**.  
The Manage Topic Templates page appears.
3. Click the row menu, and click **Edit**.  
The Topic Template page appears.
4. In the Topic Template Action section, do any of the following:
  - A. Click [Add Topic Template Action](#) to add an action.
  - B. Click the row menu, and click **View**.  
The Topic Template Action page appears in a view mode.
  - C. Click the row menu, and click **Edit**.  
The Topic template Action page appears in an edit mode.
  - D. Click the row menu, and click **Delete**.  
A confirmation dialog box appears.

## **Managing signal configurations**

### **About signal configurations**

The Signals tab is available only when there is a signal configuration assigned to the user's [login group](#). The signal configuration defines the behavior and content of the Signals tab, including which data mining runs are the source of information.

Most aspects of a signal configuration are defined by Oracle to meet your organization's needs. There are, however, aspects of a signal configuration that you might want to modify.

You can edit the column headers and tooltip on the Drug-Event Combinations page; add and edit signal comment types; define and manage review periods; and edit the column headers and tooltip on the Drug Overviews page.

## Manage Signal Configuration page


On the Manage Signal Configuration page, you can modify, delete, and publish the signal configurations. Users must have Administer Signal Management permission or be a superuser to access this page.

### General activities

The following links appear at the top of the page and affect the entire page:

- [Columns](#)
- [Print](#)
- [Download](#)
- [Back](#)

### Row-specific activities

The following menu options are available from the row menu () , located in the left most column of the table, and affect an individual row in the table:

- [Edit](#)
- [Publish](#)

### Field descriptions—Manage Signal Configurations page

In this section, you can view the list of signal configurations. For each signal configuration, the application displays the following information:

Field	Description
Name	Signal configuration name. When more than one signal configuration is published to a user, this name appears above the drug-event combination table on the Signals tab.
Description	Description of the signal configuration.
Topic Workflow Configuration	Name of the topic workflow configuration that is integrated with the signal management configuration. When this integration exists, users can associate topics with drug-event combinations using the <a href="#">Document Review</a> dialog box, and topics are stored in this topic workflow configuration.  <b>Note:</b> If drug-event combinations have associated topics, you cannot change the associated topic workflow configuration until you remove the associated topics. The <a href="#">Signal History</a> maintains a log of all changes.
Topic Product Field	Topic field in which drug names from drug-event combinations associated with topics are stored. You can also use the Topic filter when

browsing for existing topics from the [Document Review](#) dialog box.


---

Modified By	Role or name of the user who modified the configuration.
Modified	Date and time when the configuration was modified.
Is Valid	<This attribute is no longer used.>
Created	Date and time when the configuration was created.
Created By	Role or name of the user who created the configuration.
ID	Identifier assigned automatically to the configuration when the configuration was created. Each configuration ID is unique and is not re-used if the configuration is deleted.


---

## Editing a signal configuration

You can edit signal configurations if you have the Administer Signal Management permission.

1. Click **Settings**.  
The Settings page appears.
2. In the **Configure System** section, click **Manage Signal Configurations**.  
The Manage Signal Configurations page appears.
3. Click the row menu () for the signal configuration, and then click **Edit**.  
The Edit Signal Configuration page appears.
4. Edit the fields shown by entering values or selecting from drop-down lists. For more information, see the [field](#) descriptions below.
5. Click **Save**.


### Field descriptions—Edit Signal Configuration page

Field	Description
Name	Signal configuration name. When more than one signal configuration is published to a user, this name appears on the Signals tab, above the drug-event combination table.
Description	Description of the signal configuration.
Default signal view	Name of the signal view that is used when you select the Signals tab, then select Drug-Event Combinations, and select -- from the Drug drop-down list. The application also uses the default signal view as the default view for drugs that do not have a default view selected.  <b>Note:</b> To specify a default view for a drug, on the Drug Overviews page, click  for a drug, and then click <b>Edit</b> .
Topic workflow configuration	Name of the topic workflow configuration that is integrated with the signal management configuration. When this integration exists, users can associate topics with drug-event combinations using the <a href="#">Document Review</a> dialog box, and topics are stored in this topic workflow configuration.  <b>Note:</b> If drug-event combinations have associated topics, you cannot change the associated topic workflow configuration until you remove the associated topics. The <a href="#">Signal History</a> maintains a log of all changes.

Topic Product Field	Topic field in which drug names from drug-event combinations associated with topics are stored. You can also use the Topic Product Field filter when browsing for existing topics from the <a href="#">Document Review</a> dialog box.
<a href="#">Edit drug-event combinations column table</a>	Click to edit the column headers and tooltips on the Drug-Event Combinations page.
<a href="#">Edit comment type table</a>	Click to delete a comment type or edit comment text, abbreviations, and options.
<a href="#">Edit review period table</a>	Click to delete a review period or edit the name of a drug review period.
Edit drug overview column table	Click to edit the column description and tooltip on the Drug Overviews page.
Disable default view	Select to disable the default view on the Drug-Event Combinations page.
Disable review period	Select to disable review periods on the Drug-Event Combinations page.
Disable private comment	Select to disable private comments on the Drug-Event Combinations page.

## Editing the columns on the Drug-Event Combinations page

Signal summary columns appear on the Drug-Event Combinations page. When signal management is set up for your organization, you can edit the column headers and tooltips for the Drug-Event Combinations page.


1. Click **Settings**.  
The Settings page appears.
2. In the **Configure System** section, click **Manage Signal Configurations**.  
The Manage Signal Configurations page appears.
3. Click the row menu () for the signal configuration, and then click **Edit**.  
The Edit Signal Configuration page appears.
4. Click Edit drug-event combinations column table.  
The Edit Drug-Event Combinations Column Table dialog box appears.
5. Click **Edit** for a column.  
The Edit Drug-Event Combinations Column dialog box appears.
6. Edit the [fields](#). For more information, see the field descriptions below.
7. Click **Save**.
8. Click **Close**.

### Field descriptions—Edit Drug-Event Combinations Column dialog box

Field	Description
Column name	Name of the column on the Drug-Event Combinations page. The name can appear in the tooltip when you hover the cursor on the column header if [%COLCODE] is included in the column description.
Column description	Description of a column on the Drug-Event Combinations page. The description appears as a tooltip when you hover the cursor on the column label.
Column label	Text to appear as the column header on the Drug-Event Combinations page.

## Adding a signal comment type

User with Administer Signal Management permission can add a new comment type.

1. Click **Settings**.  
The Settings page appears.
2. In the **Configure System** section, click **Manage Signal Configurations**.  
The Manage Signal Configurations page appears.
3. Click the row menu () for the signal configuration, and then click **Edit**.  
The Edit Signal Configuration page appears.
4. Click Edit comment type table.  
The Edit Comment Type Table dialog box appears.
5. Click **Add Comment type**.  
The Add/Edit Comment Type dialog box appears.
6. Fill in the [fields](#) according to the following table.
7. Click **Save**.
8. Click **Close**.

### Field descriptions—Add/Edit Comment Type dialog box


Field	Description
Comment text	Description of the comment type. When users perform Document Review, this value appears in the <b>Comment</b> drop-down list.
Abbreviated comment text	Shortened version of the comment type. When users select this comment in Document Review, this value appears in the Comment column on the Drug-Event Combinations page.
Is suppress reason?	If you select <b>Yes</b> , the comment is available in the Document Review dialog box as a reason for suppressing a drug-event combination.  If this field is not set to <b>Yes</b> for any comments, then the <b>Suppress drug-event combination</b> checkbox does not appear on the Document Review dialog box.
Is review reason?	If you select <b>Yes</b> , the comment is available to select in the <b>Comment</b> field in the Document Review dialog box.  If private comments are enabled, the comment is available to be added as a private comment.



Requires detailed comment	If you select <b>Yes</b> , users must enter an additional free-text comment in the Document Review dialog box when selecting this comment.
Requires associated topic	If you select <b>Yes</b> , users must associate a topic with the drug-event combination in the Document Review dialog box when selecting this comment.
Review after delta threshold	Enter the number of new cases after which a signal that has been suppressed (on the Document Review dialog box) becomes unsuppressed.

## Editing a signal comment type

The application provides signal comment types when signal management is set up for your organization. Signal comment types are pre-defined comments that are available to users in the Document Review dialog box. Additionally, you can [add](#), [change sort order](#), and [delete](#) the comment types.


1. Click **Settings**.  
The Settings page appears.
2. In the **Configure System** section, click **Manage Signal Configurations**.  
The Manage Signal Configurations page appears.
3. Click the row menu () for the signal configuration, and then click **Edit**.  
The [Edit Signal Configuration page](#) appears.
4. Click Edit comment type table.  
The Edit Comment Type Table dialog box appears.
5. For a comment, click **Edit**.  
The Add/Edit Comment Type dialog box appears.
6. Modify the [fields](#) as desired, according to the following table.
7. Click **Save**.
8. Click **Close**.

### Field descriptions—Edit Comment Type Table dialog box

Field	Description
Comment text	Description of the comment type (Read Only). When users perform Document Review, this value appears in the <b>Comment</b> drop-down list.
Abbreviated comment text	Shortened version of the comment type (Read Only). When users select this comment in Document Review, this value appears in the Comment column on the Drug-Event Combinations page.
Is suppress reason?	If you select <b>Yes</b> , the comment is available in the Document Review dialog box as a reason for suppressing a drug-event combination.  If this field is not set to <b>Yes</b> for any comments, then the <b>Suppress drug-event combination</b> checkbox does not appear on the Document Review dialog box.
Is review	If you select <b>Yes</b> , the comment is available to select in the <b>Comment</b> field

reason?	in the Document Review dialog box. If private comments are enabled, the comment is available to be added as a private comment.
Requires detailed comment	If you select <b>Yes</b> , users must enter an additional free-text comment in the Document Review dialog box when selecting this comment.
Requires associated topic	If you select <b>Yes</b> , users must associate a topic with the drug-event combination in the Document Review dialog box when selecting this comment.
Review after delta threshold	Enter the number of new cases after which a signal that has been suppressed (on the Document Review dialog box) becomes unsuppressed.


## Deleting a signal comment type

1. Click **Settings**.  
The Settings page appears.
2. In the **Configure System** section, click **Manage Signal Configurations**.  
The Manage Signal Configurations page appears.
3. Click the row menu () for the signal configuration, and then click **Edit**.  
The [Edit Signal Configuration page](#) appears.
4. Click Edit comment type table.  
The Edit Comment Type Table dialog box appears.
5. For a comment, click **Delete**.  


If you delete a comment that has been referenced, the comment will still be visible when [viewing the signal history](#). However, the comment will not be in the list of available comments on which to filter the drug-event combinations page nor on the Drug Comments page.

An alternative to deleting a comment is to set **Is Suppress Reason?** and **Is Review Reason?** to **No**. This prevents the comment from being selected any longer, but the comment can be used in filtering and tallying comments.
6. Click **Close**.


## Changing the sort order of a signal comment type

1. Click **Settings**.  
The Settings page appears.
2. In the **Configure System** section, click **Manage Signal Configurations**.  
The Manage Signal Configurations page appears.
3. Click the row menu () for the signal configuration, and then click **Edit**.  
The [Edit Signal Configuration page](#) appears.
4. Click Edit comment type table.  
The Edit Comment Type Table dialog box appears.
5. Click Change Sort Order.  
The Comment Sort Order dialog box appears.
6. To change the order of the comments types, click a comment type and use the up arrow and down arrow to move it up or down within the list.
7. Click **OK**.


## Adding a review period

1. Click **Settings**.  
The Settings page appears.
2. In the **Configure System** section, click **Manage Signal Configurations**.  
The Manage Signal Configurations page appears.
3. Click the row menu () for the signal configuration, and then click **Edit**.  
The Edit Signal Configuration page appears.
4. Click Edit review period table.  
The Edit Review Period Table dialog box appears.
5. Click Add New Review Period.  
The Add/Edit Review Period dialog box appears.
6. In the **Review Period** field, type a name for the new review period.
7. Click **Save**.  
The Edit Review Period Table dialog box appears. The application has added the new review period to the table.
8. Click **Close**.

## Editing a review period


1. Click **Settings**.  
The Settings page appears.
2. In the **Configure System** section, click **Manage Signal Configurations**.  
The Manage Signal Configurations page appears.
3. Click the row menu () for the signal configuration, and then click **Edit**.  
The Edit Signal Configuration page appears.
4. Click Edit review period table.  
The Edit Review Period Table dialog box appears.
5. Click **Edit** for a review period.  
The Add/Edit Review Period dialog box appears.
6. In the **Review Period** field, modify the name of the review period.
7. Click **Save**.  
The Edit Review Period Table dialog box appears. The application has changed the name of the review period.
8. Click **Close**.

## Deleting a review period

1. Click **Settings**.  
The Settings page appears.
2. In the **Configure System** section, click **Manage Signal Configurations**.  
The Manage Signal Configurations page appears.
3. Click the row menu () for the signal configuration, and then click **Edit**.  
The Edit Signal Configuration page appears.
4. Click Edit review period table.  
The Edit Review Period Table dialog box appears.
5. Click **Edit** for a review period.  
The Add/Edit Review Period dialog box appears.
6. For a selected review period, click **Delete**.  
The Add/Edit Review Period dialog box appears. The review period has been deleted.
7. Click **Close**.




## Changing the sort order of a review period

1. Click **Settings**.  
The Settings page appears.
2. In the **Configure System** section, click **Manage Signal Configurations**.  
The Manage Signal Configurations page appears.
3. Click the row menu () for the signal configuration, and then click **Edit**.  
The [Edit Signal Configuration page](#) appears.
4. Click Edit review period table.  
The Edit Review Period Table dialog box appears.
5. Click Change Sort Order.  
The Comment Sort Order dialog box appears.
6. To change the order of the review periods, click a review period and use the up arrow and down arrow to move it up or down within the list.
7. Click **OK**.

## Configuring the columns that appear on the Drug Overviews page

On the Edit Signal Configuration page, you can edit the appearance of the columns on the Drug Overviews page.


1. Click **Settings**.  
The Settings page appears.
2. In the **Configure System** section, click **Manage Signal Configurations**.  
The Manage Signal Configurations page appears.
3. Click the row menu () for the signal configuration, and then click **Edit**.  
The Edit Signal Configuration page appears.
4. Click Edit drug overview column table.  
The Edit Drug Overview Column Table dialog box appears.
5. For a drug overview column, click **Edit**.
6. Fill in the [fields](#). For more information, see the field descriptions below.
7. Click **Save**.

### Field descriptions—Edit Drug Overview Column dialog box

Field	Description
Column name	Name of the column on the Drug Overviews page.
Column label	Text to appear as the column heading on the Drug Overviews page.
Column tooltip	Description of a column on the Drug Overviews page. The description appears as a tooltip when you hover the cursor on the column label on Drug Overviews page.

## Editing the view that corresponds to a column on the Drug Overviews page

On the Edit Signal Configuration page, you can edit the view that corresponds to a drug overview column.

1. Click **Settings**.  
The Settings page appears.
2. In the **Configure System** section, click **Manage Signal Configurations**.  
The Manage Signal Configurations page appears.
3. Click the row menu () for the signal configuration, and then click **Edit**.  
The [Edit Signal Configuration page](#) appears.
4. Click Edit drug overview column table.  
The Edit Drug Overview Column Table dialog box appears.
5. To the right of a drug overview column, click **Edit**.  
The Edit Drug Overview Column dialog box appears.
6. Edit the fields as desired. For more information, see [Configuring the columns that appear on the Drug Overview page](#).  
  
You can review the views and corresponding review periods defined for the column if the signal configuration has the review period feature set up and the column you are editing has a Column Kind of **LINK: DEC**.
7. Click **Save**.


## Mapping reviewers to users

On the Signals tab, reviewers can be assigned to drugs and drug-event combinations. In releases prior to Empirica Signal 7.0, signal reviewers were added explicitly and were separate from usernames. Beginning with the 7.0 release, usernames were used instead and, as a result, the existing signal reviewers were mapped to usernames. This mapping was performed during the upgrade to the 7.0 release. However, it is possible that the mapping was not performed completely during the upgrade and must be completed. In this case, if you have the Administer Signal Management permission, you can map the remaining reviewers to usernames as needed.

---

**Note:** If some, but not all, reviewers have been mapped to usernames, lists of reviewers on the Signals tab differentiate the reviewers with the suffix (user) or (reviewer) after the name. Once all reviewers have been mapped to usernames, the suffix no longer appears.

---

1. Click **Settings**.  
The Settings page appears.
2. In the **Configure System** section, click **Manage Reviewer-User Mapping**.  
The Manage Reviewer-User Mapping page appears and lists reviewers from the prior release.
3. To list only reviewers who have not yet been mapped to usernames, select **Display Unmapped Reviewers**.
4. Click the row menu () for the reviewer who you want to map to a username, and then click **Edit Reviewer User Mapping**.
5. From the User list, select a username. The username becomes the display name of the user.
6. Click **Save**.

## Maintaining data mining runs


### Managing data mining run storage

The Empirica Signal tools for managing data mining run storage are intended for the use of an Oracle Database Administrator who is responsible for the Empirica Signal database.

To archive a run, you export the run data and set the archived flag to **Yes**. To de-archive a run, you import the run data and clear the Archived flag.

1. Click **Settings**.  
The Settings page appears.
2. In the **Administer System** section, click **Manage Run Storage**.  
The Manage Run Storage page appears.

### Row menu options

If you click the row menu () for a run, you can do the following:

- To [export the run data](#), click **Export Run Data**.
- To [import the run data](#), click **Import Run Data**.
- To mark a run as archived, click **Set Archived Flag** and click **OK**. The value in the Archived column changes to Yes.
- To clear the Archived flag, click **Clear Archived Flag**.
- To move the run to a different tablespace, click **Create Move Script**.

On the Data Mining Runs page, you can include an Archived column showing the setting of the Archive flag. If the Archived flag for a run is set to **Yes**, the run description on the Data Mining Runs page starts with **Archived**. If the Archived flag is **Yes** for a run, you cannot view run results.


## Exporting data mining run data

1. Click **Settings**.

The Settings page appears.

2. In the **Administer System** section, click **Manage Run Storage**.

The Manage Run Storage page appears.

3. Click the row menu () for the run, and then click **Export Run Data**.

The Export Run Data page appears.

4. Follow instructions on the Export Run Data page, as shown in the following example:

```
--
-- To successfully archive run data, you may need DBA privileges for your database.
--

-- Step 1: Export the Run Data
-- Export the oracle data for the following tables: WEBVDME70.OutputData_379, WEBVDME70.DRUG_INDEX_379, WEBVDME70.EVENT_INDEX_379
-- This can be done using an Oracle EXPORT command similar to the one below:

EXP WEBVDME70/<password>@<tns_name> log=run_379.log file=run_379_out.dmp tables=(OutputData_379, DRUG_INDEX_379, EVENT_INDEX_379)

-- Step 2: Mark the Run as "Archived"
-- Mark the Run as Archived from the Manage Run Storage page

-- Step 3: Truncate the data in the following tables: WEBVDME70.OutputData_379, WEBVDME70.DRUG_INDEX_379, WEBVDME70.EVENT_INDEX_379
-- NOTE: Do NOT use the DROP TABLE command. The empty tables need to exist for the application to work properly
-- The truncation can be done using the oracle TRUNCATE or DELETE FROM commands:

TRUNCATE TABLE WEBVDME70.OutputData_379;
TRUNCATE TABLE WEBVDME70.DRUG_INDEX_379;
TRUNCATE TABLE WEBVDME70.EVENT_INDEX_379;

DELETE FROM WEBVDME70.OutputData_379;
DELETE FROM WEBVDME70.DRUG_INDEX_379;
DELETE FROM WEBVDME70.EVENT_INDEX_379;
```

5. Click **Close**.


## Importing data mining run data

1. Click **Settings**.

The Settings page appears.

2. In the **Administer System** section, click **Manage Run Storage**.

The Manage Run Storage page appears.

3. Click the row menu () for the run, and then click **Import Run Data**.

The Import Run Data page appears.

4. Follow instructions on the Import Run Data page, as shown in the following example:

```
--
-- To successfully de-archive run data, you may need DBA privileges for your database.
--
-- Step 1: Make sure the following tables current contain 0 rows:
-- WEBVDMESMTTEST.OutputData_337, WEBVDMESMTTEST.DRUG_INDEX_337, WEBVDMESMTTEST.EVENT_INDEX_337
-- Step 2: Import the Run Data into empty run tables
-- Import the oracle data for the following tables: WEBVDMESMTTEST.OutputData_337, WEBVDMESMTTEST.DRUG_INDEX_337, WEBVDMESMTTEST.EVENT_INDEX_337
-- This can be done using an Oracle IMPORT command similar to the one below:
--
IMP WEBVDMESMTTEST/<password>@<tns_name> ignore=y log=run_337_in.log file=run_337.dmp tables=(OutputData_337, DRUG_INDEX_337, EVENT_INDEX_337)
--
-- Step 3: Verify Row Counts for tables
-- Compare the row counts listed in the export and import logs.
--
-- Step 4: Clear the "Archived" flag for the Run
-- Clear the Archived flag for the Run from the Manage Run Storage page
```

5. Click **Close**.

## Marking the data mining run as archived


On the [Data Mining Runs page](#), you can include an Archived column showing the setting of the Archive flag. You set the Archived flag on the

1. Click **Settings**.

The Settings page appears.

2. In the **Administer System** section, click **Manage Run Storage**.


The Manage Run Storage page appears.

3. To set the Archive flag to **Yes**, click the row menu () for the run, and then click **Set Archived Flag**.

- A. Confirm that you want to mark the run as Archived by clicking **OK**.

The value in the Archived column changes to Yes. You can now import this run data.

or

To clear the Archive flag, click  for a run with the Archived value of Yes, and then click **Clear Archived Flag**.

- B. Confirm that you want to clear the Archived flag by clicking **OK**.

The value in the Archived column changes to No. You can now export this run data.

---


**Note:** If the Archived flag for a run is set to Yes, the run description on the Data Mining Runs page starts with Archived. If the Archived flag is Yes for a run, you cannot view run results (except that you can view the complete results table on the [Data sources page](#)).

---




## Moving a data mining run

The application provides a SQL script that you can run to transfer the tables and indexes for a data mining run to a different tablespace. For example, you might want to move a frequently used run to its own tablespace to improve performance, or move a run to a different tablespace to facilitate archiving of the run at the tablespace level.

1. Click **Settings**.  
The Settings page appears.
2. In the **Administer System** section, click **Manage Run Storage**.  
The [Manage Run Storage page](#) appears.
3. Click the row menu () for the run, and then click **Create Move Script**.  
The Move Run Script page appears and displays a SQL script.
4. Copy the SQL script and paste it into an ASCII text editor, such as Notepad.
5. Edit the script to define the destination tablespace for the run.
6. Save the script in a text file and execute it using Oracle tools.

## Changing user default data mining runs

1. Click **Settings**.  
The Settings page appears.
2. In the **Administer System** section, click Change User Default Runs.  
The Manage Signal Configurations page appears.
3. Select the row menu () for the signal configuration, and then click **Edit**.  
The Change Default Run page appears.
4. From the **Change the Default Run for users with a current Default Run of** drop-down list, select the default run to replace for all users. Click **Browse** to [find and select a run](#).
5. From the **to the following run** drop-down list, select the name of the run to replace the existing default run.
6. Click **Replace Default Run**.  
[User preferences](#) are updated to reflect the new default run. The next time the user logs in, the new default run is used.
7. Click **Continue**.


---

**Note:** This option affects only current settings of user preferences.

---

## Creating a run definition file

A run definition file is an input file that can be used to execute MGPS and logistic regression data mining runs externally. The runs and results then appear in the Empirica Signal application. Only the execution of the runs occurs outside of the application. For more information about executing data mining runs externally, contact Oracle.

1. Click the **Data Mining Runs** tab.  
The Data Mining Runs page appears.
2. Click the row menu () for the run, and then click **Create Definition File**.  
The Input file appears.  
Contact Oracle for more information.

## Managing the server

### Viewing currently logged in users

The Current Users page provides the information about users in your login group who are currently logged into the Empirica Signal application.

1. Click **Settings**.

The Setting page appears.

2. In the **Monitor System** section, click View Currently Logged In Users.

The Current Users page appears and displays the following information about the currently logged in users:

<b>Column</b>	<b>Description</b>
User Name	Full name followed by the username in brackets.
Login Date	Date and time when the user logged in. The date and time format is set by the site administrator.
Session ID	Automatically assigned identifier for the user's Empirica Signal session.
IP	IP address of the computer from which the user connected to the application.

## About auditing

The Empirica Signal Auditing feature tracks user activity that occurs in the application. Auditing captures detailed information about user actions, such as data run creation, that provides you with an easily accessible, historical account of user activity occurring in the following signal categories:

- Authentication
- Errors
- Administration
- Login Groups
- Users
- Aliases
- Case Series, Queries
- Configurations
- Data Mining Runs
- Reports
- Saved Lists
- View Results
- Drug Profiles
- Signals
- Signal Administration
- Signal Reviewer
- Topics
- Topic Administration

---

**Note:** Auditing occurs automatically. You do not need to install or enable the auditing feature.

---

An administrator can access audited user activity by viewing the User Activity Audit Trail and use the information to:


- Trace actions by one or more users over time.
- Monitor configuration modifications.
- Monitor permission or authentication issues.
- Monitor administration changes.
- Troubleshoot errors.
- Identify suspicious activity or security incidents.
- Identify any violations in policies and procedures.

Using the User Activity Audit Trail, you can better enforce your company's security policy and assist users with errors or issues.

The application maintains audited user activity indefinitely. You cannot modify or delete user activity through Empirica Signal.

## Viewing the user activity audit trail

Administrators use the User Activity Audit Trail to view actions performed by users in their login group. You can filter this activity by username, activity, date, or any combination. The User Activity Audit Trail also includes activities of deleted users.

1. Click **Settings**.  
The Settings page appears.
2. From the **Monitor System** section, click **View User Activity Audit Trail**.  
The User Activity Audit Trail page appears.
3. From the **User** drop-down list, select a user, or to view activities for all users, select --.  
  
Deleted users are denoted in the drop-down list with the (deleted) status appended to their usernames.
4. In the **Start Date** and **End Date** fields, specify a time period for which to include user activities, or before or after a specific date. Enter dates in the format MM/DD/YYYY, or click the **Calendar** icon  to select dates.  
  
To include all activity for all users and activities, leave these fields blank.
5. Select the activities that you want to include in the report.  
  
To include or exclude specific activities, select or clear activity check boxes (such as Login Failed) .  
  
To include or exclude all activities listed for the category, select or clear category check boxes (such as Authentication).  
  
To include all activities, click **Check All**.  
  
To clear all check boxes, click **Clear All**.

---

**Note:** To include Publish, Rename, and Copy activities, select the appropriate Edit activity.

---

6. Click **View User Activity**.  
The User Activity Audit Trail appears and provides the following information:

Column	Description
ID	Unique activity identifier.
Username	Username of the user who performed the activity.

---

**Note:** The report denotes deleted users by appending (deleted) to

---

	the username.
Session	Unique identifier for the user's Empirica Signal session.
IP Address	IP address of the computer used to connect to the application. In cases, where the connected user is a system user the IP address displays ::1 (local).
Activity Name	Category and name of the activity.
Activity Date	Date and time when the user activity occurred. The date and time format is determined by a <a href="#">site option</a> , and by your time zone preference.
Additional Information	Details about the activity that was performed. This might include the name and unique identifier of an object where the identifier is in parentheses, such as CaseSeries=My Case Series(533). For system errors, an error ID appears. The Signal server log file contains the same error identifier and more details about the error.

For information about viewing, printing, or downloading tables or changing the way data displays in the User Activity Audit Trail, see [About tables](#).



## Viewing the server status

Within the Empirica Signal application, two types of computer processing occur:

- Foreground or interactive processing, such as the specification of runs.
- Background or batch processing, such as the execution of runs.

If you are running on a single-processor server, that processor must perform both types of processing. If you are running on a multi-processor server, you can control how the available processors are used to perform foreground or background processing.

On the Server Status page, you to set the maximum number of processors to use for background processing; that is, the number of concurrent runs that can be performed. For a dedicated server, Oracle recommends that you set the maximum to one less than the number of processors that are on the server. For a shared server, Oracle recommends a smaller number of maximum processors.

For example, if there are three processors on a dedicated Empirica Signal server, and you set the maximum number of processors to 2, then two runs can run at the same time.

1. Click **Settings**.  
The Settings page appears.
2. In the **Monitor System** section, click **View Server Status**.  
The Server Status page appears.
3. In the **Maximum Processors** field, type the maximum number of processors for the server listed.
4. Click **Save**.  
A message tells you that your update was successful.
5. Click **Continue**.

## Viewing free disk space

The option to view free disk space is intended for users who are familiar with Oracle storage mechanisms.

1. Click **Settings**.  
The Settings page appears.
2. In the **Monitor System** section, click **View Free Space**.  
The View Free Space page appears.
3. From the **Tablespace** drop-down list, select an Oracle tablespace.  
Information about remaining space for each file in the selected tablespace appears.

## Setting site options

A site option is a setting that customizes an aspect of the Empirica Signal application. Setting site options requires the superuser permission.

---

**Note:** The site options in the Password Restrictions section are not applicable to single sign-on passwords. You can set password restrictions for single sign-on users in Oracle Access Manager.

---

1. Click **Settings**.
2. From the Administrator System section, select **Set Site Options**.  
The Site Options page appears.
3. Edit the fields as necessary.  
For more information about each field, see [Field descriptions—Site Options page](#).
4. Click **Save**.
5. Optionally, you can do one of the following:
  - To review your changes, select **Review Changes**.
  - To continue to work on the application, select **Continue**.

### Field descriptions—Site Options page

Field	Description
Password Expiration	<p>Enter the number of days until user passwords expire. This optional setting affects passwords for all users. The expiration period is counted from when the user was created or when the password was last changed. The default value is 90 days.</p> <p><b>Note:</b> Individual users can be configured so their password never expires. Also, when a user's password has expired, the user can create a new password.</p>
Expiration Warning	<p>Enter the number of days prior to password expiration that a warning message begins to display when users log in. This optional setting affects passwords for all users. The default value is 15 days.</p> <p>The expiration warning period is counted from when the user is created or when the user's password is last changed.</p>
Minimum Length	<p>Enter the minimum length of new passwords. Passwords can be up to 64 characters long. Existing passwords are not affected by this value. The default value is 8.</p>

<p>Number of Attempts Allowed</p>	<p>Select the number of times users can attempt to log in with an incorrect or missing password before the account is locked. The default value is 3. When this limit is reached, an email message is sent to all Superusers and to all user names with the Administer Users permission in the same login group as the locked account.</p>
<p><b>Note:</b> When a user account is locked, the <b>Account locked</b> check box is checked automatically for the user. To unlock the user account, <a href="#">edit the user</a> and clear the check box.</p>	
<p>Number of Passwords Retained</p>	<p>Indicate the number of unique passwords that are retained in the history of the user. Passwords retained in a user's history cannot be re-used.</p> <p>For example, suppose that you set this field to 100. Each time the user changes the password, the old password is retained (up to 100) and when a new password is selected, it cannot match any of those in the history. If you want to allow password re-use, set this value to 0. If you want to prevent password re-use, set this value to a high number such as 1000. The default value is 8.</p>
<p>Alphabetic          Numeric          Non-alphanumeric          Lower case          Upper case</p>	<p>Enter a number in each field to define how many of each character must be present when new passwords are set. The default value for each character is one.</p>
<p>SMTP Server</p>	<p>Enter the name of the SMTP server to use for email notification of run completion, feedback email, and error email. This field must be filled in correctly for these email functions to work.</p>
<p>Feedback Email</p>	<p>Enter the email addresses for <a href="#">feedback</a> that is sent by Empirica Signal application users. You can enter one address or multiple addresses separated by commas.</p>
<p>Error Email</p>	<p>Enter the email address for notification of system errors. You can enter one address or multiple addresses separated by commas.</p> <p><b>Note:</b> System errors are also recorded in the User Activity Audit Trail.</p>
<p>Date Format,          Time Format</p>	<p>Select the date format and time format to use for server date/times that are displayed in Empirica Signal application.</p> <p><b>Note:</b> UTC is Coordinated Universal Time (abbreviated as UTC).</p>

Auto-Start Local Listener	If <b>Yes</b> , the listener process starts automatically when a batch run is submitted. This option needs to be set to <b>Yes</b> unless the listener process does not run on the Web server.
Log Level	Select the type of information to be included in the <code>weberror.log</code> file on the Empirica Signal server.
Max Memory Per Report	Enter the maximum amount (MB) of memory that a single report is allowed to use when executing. It is recommended you consult with Oracle support before changing this value. The max value is usually 768 MB.  <b>Note:</b> To decrease the amount of memory used by reports, set the Generate drill-down Information option to <b>No</b> while editing report attributes.
Max number of rows per table allowed in topic attachments	Maximum number (n) of rows of tabular data that can be saved as an attachment to a topic.  Only the first rows of the displayed tabular data are saved as the attachment. A message informs you that not all rows are being saved
Max number of bytes per file allowed in topic attachments	Maximum size (MB) of files that can be added as an attachment to a topic. If you try to add a larger file as an attachment, an error message appears.
Time to send topic email reminder notifications	Hour of day when Email Reminders for Email Notification Rules are sent.
Max cache size for LR index tables and data files	Maximum size (MB) of Oracle index tables or files saved during execution of a logistic regression run.
Allow Case Comment/Review/Exclusion	Select to include the Reviewer Input section on the Case Details page, or clear to prevent the Reviewer Input section from appearing. This only affects the Case Details page that you access on the Case Series tab.
Show "Drugs" tab	Select to show the Drugs tab to users with appropriate permissions.
Show "Data Mining Runs" tab	Select to show the Data Mining Runs tab to users with appropriate permissions.
Show "Queries" tab	Select to show the Queries tab.
Show "Case Series" tab	Select to show the Case Series tab.
Show "Reports" tab	Select to show the Reports tab.
Show "Data Mining Results"	Select to show the Data Mining Results tab to users with

tab	appropriate <a href="#">permissions</a> .
Show "Signals" tab	Select to show the Signals tab to users with appropriate permissions.
Allow Free Text Signal Comments	Select to allow users to enter free text comments when, on the Signals tab, they filter a drug-event combination or add a comment when reviewing a signal summary. Regardless of the setting of this option, users can select from a list of predefined comments.
Allow Automatic Assignment of Reviewers to Drugs	Select to allow users with appropriate permissions to assign reviewers to drugs automatically.
Enable Interactive Reports	Select to show the Interactive Reports link on the Reports tab.
Enable Query Wizard	Select to enable use of the Query Wizard to define queries.
Allow Case Count on Query Preview Page	Select to show the <b>Show case count by default on preview page</b> check box on the Set User Preferences page.
Enable Second Level drill-down on Cases Page	Select to allow users to drill down to <a href="#">view case details</a> for a particular case when they are viewing a list of cases. This option does not apply to the Case Series tab or to a <b>case ID</b> hyperlink in a report; you can always drill down to case details from these locations.
Enable Download Case Details	Select to allow users to <a href="#">download</a> case details.
Enable LDAP	Select to enable the creating, updating, and authentication of users via an LDAP directory.
Enable OBI EE Reporting	Select to allow users to generate OBIEE reports.
Add message to Notes for Results (Table and Graphs)	Enter text to display below tables or graphs of data mining results. For example, the message might read "These data do not, by themselves, demonstrate causal associations; they may serve as an impetus for further investigation."
Notes for Signal Management Interactions Graph	Enter text to display at the bottom of the <a href="#">Interactions page</a> for a drug-event combination on the Signals tab.
Drug-event combination comment length	Maximum length of detailed comments for drug-event combinations on the Signals tab.
Topic workflow configuration for work team	For organizations using the <a href="#">topics</a> feature, indicates the topic workflow configuration that implements custom fields for

custom fields

work teams. The selected configuration also must be published to the login group for the fields to be visible when a work team is added or edited for that login group. See [Adding or editing a work team](#) and [Constraining field values by work team](#).

## Sending a message to all users

If you have the Administer Users permission, you can send an email message to all Empirica Signal users who:

- Have an email address associated with their username.
- Are in your login group.
- Have an active user account (that is, the Account disabled check box is cleared on the [Add/Edit User](#) page).

For example, you might want to send a message announcing an upgrade or scheduling server maintenance.

1. Click **Settings**.

The Settings page appears.

2. In the **Administer System** section, click Send Message to All Users.

The Send to All Users page appears.

3. In the **Subject** field, enter the subject of your message.

4. In the **Comments** field, enter the text of your message.

5. Click **Send**.

The application sends the message to users, regardless of whether or not they are currently logged in, and displays a confirmation for each message sent.

In the email message:

- The date and time of the message is the date and time at which you clicked **Send**.
- The **From** line shows the email address associated with your username. If there is no email address associated with your username, the **From** line shows the email address associated with the **Feedback Email** field on the [Set Site Options](#) page.
- The **Subject** line shows the text you entered in the subject line.

6. Click **Continue**.



## Manually restarting the listener process

The Empirica Signal listener process is responsible for identifying background work and assigning it to processes for execution. The listener process starts when the application starts up, and updates an associated heartbeat date and time value every 2-30 seconds while the application is running.

Occasionally, the listener process terminates unexpectedly (either because it encounters an error or is stopped by a system operator).

When a run is submitted, the application checks the heartbeat value to determine if the listener process is still running. If the listener process is not running, the application restarts it automatically, if the Auto-Start Local Listener site option is set to Yes. You can also restart the listener process manually from within the application at any time.

1. Click **Settings**.  
The Settings page appears.
2. In the **Administer System** section, click **Restart Listener**.  
The Starting Listener page appears.  
A message states that the listener was started.

---

**Note:** You can restart the listener process only if the listener is running as part of the Empirica Signal website. If the listener is running outside of the Empirica Signal website, clicking **Restart Listener** has no effect.

---



## Appendices

### A: MGPS independence model

#### MGPS independence model

Prior to Version 5.0 of WebVDME (which was the previous name of the Empirica Signal application), signal scores for 3D data mining results were computed using the MGPS independence model described here. Starting in WebVDME 5.0, the primary way of computing signal scores for 3D results changed to the MGPS interaction model. For compatibility with older data mining runs, the application continues to compute scores using the independence model as well.

The MGPS interaction model computes values of INTSS, described in [MGPS computations](#). The independence model computes values of EBGMDIF\_IND. The names of columns related to the independence model end in \_IND.

The difference between the independence model and the interaction model affects only 3D results. Thus, the values of EBGMDIF and EBGMDIF\_IND, which are for 2D results, are the same.

#### 2D results

For a 2D result, it is assumed that the probability of finding items  $i$  and  $j$  in the same report is the same as the probability of finding  $i$  times the probability of finding  $j$ :

$$P(i,j) = P(i) \times P(j)$$

For a two-dimensional run that is not stratified, expected counts are computed as follows:

$$E(i,j) = N_{\text{total}} \times P(i,j) = N_{\text{total}} \times P(i) \times P(j)$$

For a two-dimensional run that is stratified, computations are as follows:

$$E(i,j) = \sum E_c(i,j) = \sum N_{\text{total},c} \times P_c(i,j) = \sum N_{\text{total},c} \times P_c(i) \times P_c(j)$$

where the summations occur over the  $C$  strata.

The signal score is the EBGMDIF\_IND value, which is a more stable estimate than RR; the so-called shrinkage estimate. The EBGMDIF value is computed as the geometric mean of the posterior distribution of the true Relative Ratio.

#### 3D results

For a 3D result, it is assumed that the probability of finding items  $i$ ,  $j$ , and  $k$  in the same report is the same as the probability of finding  $i$  times the probability of finding  $j$  times the probability of finding  $k$ :

$$P(i,j,k) = P(i) \times P(j) \times P(k)$$

For a three-dimensional unstratified run, the expected count is computed as follows:

$$E(i,j,k) = N_{\text{total}} \times P(i,j,k) = N_{\text{total}} \times P(i) \times P(j) \times P(k)$$

In the stratified independence model, it is assumed the above equations hold for each stratum. So, if there are C strata:

$$P_c(i,j,k) = P_c(i) \times P_c(j) \times P_c(k)$$

for a given stratum c.

For a three-dimensional stratified analysis, the expected count is computed as follows:

$$E(i,j,k) = \sum E_c(i,j,k) = \sum N_{\text{total},c} \times P_c(i,j,k) = \sum N_{\text{total},c} \times P_c(i) \times P_c(j) \times P_c(k)$$

where the summations occur over the C strata.

The signal score for a 3D combination is the EBGMDIF\_IND value, computed as follows:

$$\text{EBGMDIF\_IND} = \text{EBGM\_IND} - \text{E2D\_IND} / \text{E\_IND}$$

where E2D\_IND is the expected count based on the all-2-factor log linear model.

## B: Hierarchy tables

### Using hierarchy tables

[Data configurations](#) defined in older versions of the Empirica Signal application might have used hierarchy tables instead of an event hierarchy account to set up hierarchies for events. The following information is for reference only. See [Drug and event hierarchies](#) for information about the newer method of setting up hierarchies for drugs or events.

When you use hierarchy tables, users must select from a list of event or drug values, instead of using the hierarchy browser. The Select Criteria page and results table use general labels for the hierarchical levels: Level 0, Level 1, and Level 2. If both a hierarchy account and a hierarchy table are specified by the configuration, the hierarchy table takes precedence.

A hierarchy table specifies a hierarchy of terms (such as drugs and events) available for selecting criteria for data mining results before viewing them. A hierarchy table has no effect on the generation of statistical results for a run.

For each configuration variable for which you want to use a hierarchy, there must be a hierarchy table. If there is a hierarchy table specified for one or more variables in a configuration, then a run creator has the option to use the hierarchy or not.

You can create a hierarchy table outside of the Empirica Signal application using tools that provide access to the Oracle database. The table must be in the Oracle account containing the source database tables. You refer to the table from a configuration variable within the Empirica Signal application. You can also edit an existing configuration variable to add a hierarchy table to it.

---

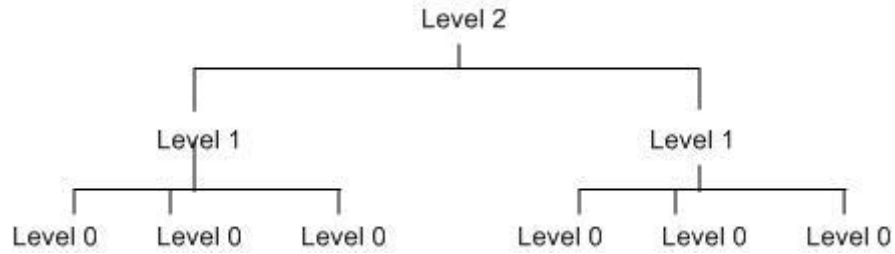
**Note:** You can also create a hierarchy table while you are editing a configuration variable. In this situation, an empty hierarchy table is created and you must populate it outside of the application.

---

For the table name, Oracle recommends that you use a name that identifies the table as a hierarchy; for example, DRUG\_HIER or EVENT\_HIER. A hierarchy table must include the following columns:

- **ITEM\_VALUE**—Drug or event name. This is Level 0 of the hierarchy. There must be one value for each unique drug or event name.
- **H1\_VALUE**—Middle-level term of the drug or event hierarchy. This is Level 1 of the hierarchy.
- **H2\_VALUE**—Top-level term of the drug or event hierarchy. This is Level 2 of the hierarchy. If you are creating a two-level hierarchy, this column can be empty.

There can be zero levels, one level, or two levels in a hierarchy, as in the following example:



Each Level 0 term can have only one Level 1 term associated with it. Each Level 1 term can have only one Level 2 term associated with it.

---

**Note:** If a drug is not included in the hierarchy table, it is not available when the results reviewer filters results according to a Level 1 or Level 2 term. For example, all drugs except DrugA are in the hierarchy table and have a Level 2 value of OTC or RX. If the reviewer filters according to the Level 2 terms OTC and RX, DrugA is not in the displayed results. (However, DrugA is still available as a Level 0 term even if it is not in the hierarchy table.) When source data is updated and includes new drugs or events, this situation may occur unless the hierarchy table is updated as well.

---

You can view hierarchy tables on the [Data sources page](#).

## Glossary

### A

**action:** An activity that contributes to a topic, such as performing research, completing project management milestones, or collecting supporting documentation.

**aggregate bar graph:** Type of bar graph that uses horizontal bars to show numeric values of column variables in a report for each value of the row variable in the report.

**aggregation method:** Way in which values for an analysis variable are displayed in a report, e.g., actual value, count of unique values, percentage, mean, etc.

**analysis variable:** In a report, column variables for which values are displayed for each combination of row variables, e.g., adverse event counts (analysis variable) for each row (Gender).

### B

**background:** In a statistical calculation, the background or background ratio is the number used to form a disproportionality ratio with respect to the drug of interest. In epidemiology, the background (or "comparator") rate would be disease or event incidence in the general population, which we cannot measure in Empirica Signal. In its place, Empirica Signal uses the "rest of the data base", i.e., reports not including the drug of interest, as the background. A restriction on the database, as in subset analysis, can cause different background ratios to be considered.

**background processing:** Allows specific case series and report creation and editing processes to run non-interactively and uninterrupted, allowing you to navigate away from the page and perform other tasks simultaneously.

**bar graph:** Graph type, available for data mining results, that shows strength of association between a drug and event by plotting their statistical scores as the length of a horizontal bar.

**Bayesian statistics:** A theory of inference in which information from observed data is combined with prior knowledge by probabilistic rules to produce a posterior probability distribution for the unknown quantities under study. In MGPS, the observed values of N/E are combined with knowledge about the overall distribution of true relative reporting ratios to produce improved posterior estimates of each relative reporting ratio.

**box plot:** Graph type, available for report data, that summarizes mean, upper and lower quartiles, and minimum and maximum values. Also known as a box and whisker plot.

**breakdown variable:** Report variable used to break down the values of another variable by values or groups of values; for example, adverse event counts might be broken down by sex.

**built-in report:** Report definition that is predefined by Oracle and delivered with Empirica Signal for all customers.

### C

**case series:** List of the case identifiers of cases of interest that have been selected and saved.

**chart:** In a drug profile, a graph based on data mining run results or a graphical or tabular report based on source data and showing distribution of cases by variables such as gender.

**confidence interval:** The likely range of the true value, approximated from the data in a sample. The larger the number of reports, the narrower the confidence interval. Defines the range in which the true value for an entire population is likely to fall. Data mining runs produce 5% and 95% confidence limits (such as EB05 and EB95): there is a 90% probability that the values bounded by these limits contain the true value.

**confidence interval graph:** Graph type, available for data mining results, that shows 5% and 95% confidence limits superimposed on a bar graph.

**confidence limit:** The values that define the upper and lower boundaries of the confidence interval for the true value. Data mining runs produce 5% and 95% confidence limits (such as EB05 and EB95).

**cumulative map graph:** Graph type, available for data mining results, that compares strength of associations between drugs and events across multiple cumulative subsets.

**cumulative subset:** Type of subset that groups source data for data mining into separate, overlapping backgrounds where all but the first subset contains data from previous subsets; used typically to study the strength of variable associations over time.

**custom term:** Pseudo-value specified (for a particular data mining run) for inclusion in cases that meet specified criteria. When data mining is performed, Empirica Signal acts as if the custom term is present for those cases and generates statistics for the custom term.

## D

**data configuration:** Object that defines which and how variables from source data are available for use in Empirica Signal.

**data configuration variable:** Mapping of a database table column to a variable that can be used in Empirica Signal.

**data mining results:** The statistical values calculated by the algorithm applied to data by a data mining run.

**data mining run:** The process of extracting data from a source database, applying statistical algorithms to the data, and generating statistical results.

**data transformation:** Means of mapping text values to a new value, converting date values, or organizing numeric or date values into groups.

**database group:** Means of categorizing configurations for use in finding related configurations and controlling the behavior of color changes of visited case ID links.

**database restriction:** Means of limiting which cases in source data will be included in a data mining run by specifying a query.



**detail bar graph:** Type of bar graph that uses horizontal bars to show subject counts for one or two variables in a report.

**dimension:** Number of ways in which variables are combined in a data mining run.

**discrete map graph:** Graph type, available for data mining results, that compares strength of associations between drugs and events across multiple discrete (non-overlapping) subsets.

**discrete subset:** Type of subset that partitions source data for data mining into separate backgrounds and is used typically to study the strength of variable associations based on such factors as age or gender.

**drilldown:** The process of uncovering more detailed information about the cases that are included in data mining run results, in a case series, or in a report.

**drilldown map table:** Table that is associated with a configuration and determines which types of case information will appear when you drill down to a list of cases or case details.

**drug profile:** Presentation of statistical and other information about one or more drugs.

**drug profile configuration:** A drug profile configuration is the specification of which data mining runs and which report outputs are the source of charts that can be added to a drug profile.

**drug profile layout:** Saved collection of result charts and report charts, as well as their placement and display options.

## E

**EBGM:** Empirical Bayesian Geometric Mean. A more stable estimate than RR; the so-called shrinkage estimate, computed as the geometric mean of the posterior distribution of the true Relative Ratio.

## H

**hierarchy graph:** Graph type available for 3-dimensional results to highlight situations in which there are interaction effects beyond what would be predicted from the largest of the previously computed 2-factor associations.

## I

**interactive report:** Report that is either based on cases found by a query for which users can provide values when the report is run; includes all cases for a specified data configuration and is used by the drug profile feature; or is created by Oracle as a customer-specific report.

**INTSS:** Interaction Signal Score. Way of measuring the strength of a combination of more than 2 dimensions beyond what would be expected from the largest of the previously computed component 2-factor associations.

## L

**LDAP user:** User for which authentication is performed by LDAP (Lightweight Directory Access Protocol) , which is an internet protocol used to look up information stored in a directory on a server.

**login group:** A group of users with similar needs for accessing configurations, projects, data mining runs, case series, reports, and saved lists.

**logistic regression run:** Data mining run that computes LROR, LR05, and LR95, representing the Logistic Regression Odds Ratio and the 90% confidence interval from 5% to 95%.

**LROR:** Logistic Regression Odds Ratio. Computed as the exponential of the logistic regression coefficient connecting the specified response and predictor term.

## M

**MGPS:** A statistical algorithm that can be applied to data to generate scores by a data mining run. MGPS, or Multi-Item Gamma Poisson Shrinker, is a way of finding unexpectedly frequent combinations in a database.

**MGPS run:** Data mining run that computes EBGM, EB05, and EB95, representing the Empirical Bayes Geometric Mean and the 90% confidence interval from 5% to 95%.

**minimum count:** Number of times, specified when a data mining run is created, that a combination of items must occur in order for it to be included in MGPS computations.

## N

**native login:** When single sign-on is enabled, logging in to Empirica Signal from outside the single sign-on environment, such as through a remote desktop connection.

**nested confidence interval graph:** Graph type showing sets of confidence intervals that is available for 3-dimensional results to highlight situations in which there are interaction effects beyond what would be predicted from the largest of the previously computed 2-factor associations.

## O

**overlap graph:** Graph type available for 3-dimensional results to highlight situations in which there are interaction effects beyond what would be predicted from the largest of the previously computed 2-factor associations.

## P

**pattern:** Specification by the results reviewer of the type of items, such as drug-drug-event or event-drug-drug, to appear in the results.

**permission:** User's right to perform a particular task, as assigned by the user administrator.

**PRR:** Proportional Reporting Ratio, an optional computation available for two-dimensional data mining results.

## Q

**query:** Specification of criteria based on variables and values in the source data.

**Query Wizard:** Series of Empirica Signal pages that guide you through the process of retrieving case IDs that meet specified conditions and creating a subject list containing those case IDs.

**query-based case series:** Case series that was created by finding reports IDs that meet the conditions of a specified query of source data.

## R

**report definition:** Specification of which columns and rows from the source data will appear in the report; a report definition is run to produce a report.

**report output:** Saved, static results of running a report definition.

**ROR:** Reporting Odds Ratio. Computed as:  $ROR = (PRR\_A * PRR\_D) / (PRR\_B * PRR\_C)$ . With stratification, ROR is computed as a weighted average of the ROR within each stratum.

**RR:** Relative Ratio. (Same as N/E) Observed number of cases with the combination divided by the expected number of cases with the combination.

## S

**saved list:** Group of up to 1,000 terms that can be used as criteria for viewing data mining results.

**scatter plot:** Graph type, available for report data, that plots data points on horizontal and vertical axes and shows the relationship between two or more continuous variables.

**score:** A statistical value computed by the algorithm applied to data by a data mining run.

**sector map:** Graph type that is available for data mining results and in signal management to show data for a particular drug across all SOC, with SOCs and PTs represented as tiles whose color, size, and ranking represent statistical information.

**signal:** A report or reports of an event with an unknown causal relationship to treatment that is recognized as worthy of further exploration and continued surveillance.

**signal configuration:** Configuration defines the behavior and content of the Signals tab, including which data mining runs are the source of information.

**signal view:** Saved specification of columns, sort order, and SQL WHERE clause for the Drug-Event Combinations page on the Signals tab.

**site option:** One of many system-wide options that the site administrator can set to control such elements as password restrictions, date and time formats, licensing, etc., for Empirica Signal.

**source data:** The safety data that is stored in an Oracle database and accessed by Empirica Signal.

**source description table:** Table that provides a source data description that may appear (depending on the configuration) below certain displays of data. Also used in setting up timestamped data.

**stratification:** Statistical adjustment of baseline frequencies of drug-event combinations to adjust for confounding by covariates such as gender or receipt year.

**subsetting:** Option for data mining run to divide source data into separate backgrounds, one for each value of the subset variable; discrete (partitioned) or cumulative (overlapping) subsets can be used.

## T

**timestamped data:** Data that can be reconstructed for different periods of time so that users can view data "as of" a particular date and time.

**timestamping:** Technique for representing multiple versions of the same source data within one physical database.

**topic:** Means of organizing and tracking issues identified through various methods. Reference materials, including run results, graphs, and reports from Empirica Signal or external documents related to the subject can be stored with the topic.

**topic workflow configuration:** Definition of how the topic feature will work, including standard and custom fields that appear in topics, as well as workflow states.

## U

**unique values table:** Contains all unique values that exist in the source data for a specific configuration variable.

**user activity audit trail:** Report on user activities for selected usernames, activities, and dates.

**user preference:** Setting that customizes an aspect of the system for only your username.

**user profile:** Set of attributes (login group and quota), user roles, permissions, and default user preferences that can be applied to users.

**user role:** Set of permissions that may be needed by a particular type of user (such as results reviewer or report designer).

## W

**work team:** Subset of users in a login group that would collaborate on a topic. There can be multiple work teams within the same login group, and the same user can be in just one or multiple work teams. Topics that are made visible to a work team can be viewed by, or assigned to, any of its members.

**workflow state:** Progress indicators for a topic or action such as Initial, Assigned, Escalated, and Closed.

## Index

2

2D results ..... 224

3

3D results ..... 226

A

Acrobat Reader ..... 3, 546, 548

action attachments.... 510, 515, 516, 518,  
520, 521, 522, 528

action comments.....506, 528

action fields 710, 724, 726, 728, 731, 734,  
738, 739, 741, 742, 744, 747

action states..... 523, 528, 529, 713, 747

actions 491, 520, 523, 528, 529, 546, 747,  
784, 785

advanced options .....202, 205

advanced parameters ..... 156

age group breakdown ..... 440

aggregate bar graphs . 412, 414, 416, 417

aliases ..... 673, 674, 676, 678

all cases summary reports... 81, 371, 386,  
387, 394, 396, 678

analysis variables 328, 341, 344, 348, 394

archived..... 809

archiving runs..... 123, 806, 807, 808

arranging columns.....65

As Of date ..... 60, 80, 635

attachment fields 710, 713, 724, 726, 728,  
731, 734, 738, 739, 741, 742, 744, 749

attachments ..... 510, 514, 520, 522, 546

auditing .....814, 816

automatic assignment of reviewers.... 473,  
475, 476

Available Values list..... 41

B

background processing .....321, 323, 324,  
325, 336, 396, 407

    Cancelling a job..... 325

    Viewing job status ..... 324

bar graphs .113, 114, 119, 222, 231, 233,  
240, 245, 414, 417, 421, 441

Base SAS .....3

box plots..... 412, 414, 422, 424

breakdown details (in reports) ... 353, 356,  
357, 360, 361, 367

breakdown variables.. 119, 328, 341, 344,  
353, 357, 361, 367, 394, 397, 426, 428

browser settings .....3

built-in reports..... 3, 327, 379

C

case details ..... 71, 72, 75, 233, 237, 242,  
256, 259, 304, 369, 627

Case ID..... 375

case ID links.....34, 75, 76, 304

case series 58, 72, 73, 74, 220, 242, 247,  
271, 292, 295, 297, 299, 302, 309,  
310, 311, 313, 314, 316, 317, 318,  
319, 320, 321, 336, 340, 341, 353,  
522, 620, 655

Case Series page ..... 299

cases ..... 72, 302, 304, 318

charts.. 98, 105, 107, 110, 113, 114, 115,  
117, 119, 371

color palette .....109, 229, 414

column statistics .....344, 366, 670

columns65, 215, 344, 347, 348, 375, 409, 414, 459, 620, 633, 792, 803, 804

comments..304, 438, 448, 456, 477, 480, 483, 506, 514, 793, 795, 798

comments for drug-event combinations .....477, 480, 482

confidence interval graphs..114, 222, 235, 237, 452

content details (in reports) ..... 348

converting date values.....641, 657, 668

counts ..... 348

covariates ..... 160, 172, 192, 215

cumulative map graph 117, 222, 245, 247

custom terms 43, 86, 131, 132, 134, 135, 138, 141, 144, 146, 156, 160, 172, 173, 175, 181, 186, 195, 202, 269, 271, 273, 274, 276, 328, 399, 562, 657, 659, 664, 671, 687

cutpoints.....229, 665

**D**

data configuration variables. 79, 365, 620, 623, 641, 668

data configurations.... 7, 77, 81, 181, 299, 311, 551, 556, 614, 616, 617, 619, 620, 623, 626, 647, 650, 651, 652, 654, 655

data mining results.... 197, 198, 200, 202, 205, 209, 215, 219, 222, 678

data mining runs 7, 17, 58, 121, 123, 125, 127, 141, 179, 180, 181, 185, 186, 190, 192, 193, 195, 200, 806, 807, 808, 809, 810, 811, 812

data source (in reports) ..... 347

data source tables..... 551, 556, 558, 560

database group..... 28, 76, 200, 617, 619, 620, 623, 626, 652

database restrictions 7, 81, 127, 129, 134, 135, 137, 181, 186, 195, 200, 269, 271, 273, 274, 276, 288, 399, 400

date-time format..... 820

detail bar graphs..... 412, 414, 418, 421

dimensions.138, 141, 156, 179, 200, 202, 205, 209, 252

discrete map graph .....222, 240, 242

disk space ..... 819

downloading ..... 68

drilldown map table72, 75, 304, 551, 553, 617, 619, 623, 627, 647

drilling down.. 71, 72, 73, 74, 75, 76, 319, 320, 369, 620, 627

drug names ..... 208

drug notes .....471, 472

drug overviews .....466, 469

Drug Overviews page.....803, 804

drug profile configurations... 93, 101, 466, 677, 678, 683, 685, 687, 689, 690

drug profile layouts .....7, 93, 94, 96, 100, 101, 104, 105, 107, 108, 394, 466, 678

drug profiles ..... 7, 93, 94, 95, 101, 678

drug reviewers.....469, 475, 476

drug subtypes..... 394, 619, 641, 678, 687

drug-event combinations....432, 440, 441, 442, 452, 477, 480, 482

Drug-Event Combinations page..... 432

drugs.....95

Drugs tab ..... 7, 94, 687

- E**
- EBGM ..... 1, 10, 121, 138, 209, 827
  - email .....491, 820, 825
  - email messages ..... 39, 767, 769
  - email notification rule .....764, 767
  - Empirica Signal ..... 7, 37
  - event combination statistics ..... 452
  - Excel .....3
  - excluded cases .....302, 304
  - exiting .....40
  - exporting run data .....806, 807
  - eXtensible Markup Language ..... 374
  - External Report ID ..... 641
- F**
- FAQs ..... 17
  - FDA .....99
  - feedback .....39, 820
  - feedback email ..... 820
  - field values..... 734
  - filtering drug-event combinations 438, 439
  - filters..... 41, 299, 341, 438, 439, 560
- G**
- generic name mapping..... 156
  - generic names .....208, 687
  - graphs7, 93, 98, 105, 109, 110, 113, 114, 202, 222, 224, 226, 227, 229, 231, 233, 237, 240, 242, 245, 247, 250, 252, 254, 256, 258, 261, 264, 327, 366, 409, 412, 414, 415, 416, 417, 418, 421, 422, 424, 426, 442, 452, 455, 484, 486, 514, 670, 687, 820
  - gray-scale graphs.....229, 414
  - grouped values .....341, 353, 361
- H**
- help.....38
  - hierarchies 7, 43, 86, 156, 186, 637, 638, 641, 647, 659, 829
  - Hierarchy Browser. 43, 86, 135, 173, 202, 276, 288, 400
  - hierarchy graphs ..... 222, 226, 254, 256
  - hierarchy version table ..... 638
- I**
- importing data configurations ..... 651
  - importing run data .....806, 808
  - independence model.. 138, 209, 226, 258, 827
  - index tables..... 556
  - interaction scores.....138, 198, 215
  - interactions ..... 442
  - interactive report definition .368, 387, 396
  - interactive reports... 7, 81, 271, 367, 370, 375, 386, 387, 394, 396, 397, 677, 678
  - INTSS..... 138, 209, 252, 442
  - INTSS value ..... 115, 254
  - item variables.....91, 146, 152, 202, 641
  - items of the same type ..... 156, 205
- J**
- job details .....190, 192
  - job queue..... 336
  - job status.....323, 324
- L**
- layouts ....65, 93, 96, 100, 101, 104, 105, 107, 108, 491, 677
  - LDAP .....603, 609

LDAP configuration ..... 603

LDAP users..... 571, 575, 608, 609

Library.....134, 273, 399

license key ..... 820

linked fields..... 728

Links menu..... 691

listener process..... 826

log files..... 170

log level ..... 820

logging in..... 26, 574, 610

logical operators ..... 278

login groups 28, 134, 197, 273, 399, 503, 562, 566, 567, 575, 578, 580, 581, 589, 590, 592, 594, 601, 613, 693, 787, 820

logistic regression 10, 101, 127, 160, 162, 170, 172, 173, 175, 186, 215, 224

logistic regression run 127, 160, 173, 181, 192, 200, 202, 209, 215

lr.log file ..... 170, 192

**M**

map graphs 117, 224, 233, 237, 240, 242, 245, 247

mapped variable ..... 662

mapping text values ... 641, 657, 659, 664

messages..... 39, 609, 767, 825

MGPS .. 10, 101, 137, 138, 186, 209, 222, 224, 231, 240, 254, 261, 664, 827

MGPS computations..... 138, 181

MGPS run..... 127, 146, 200, 202, 209

Microsoft Excel.....3

Microsoft Internet Explorer .....3

minimum count.....28, 156

missing values .....28, 202

**N**

narrative text ..... 75, 627, 633

nested confidence interval graphs ..... 115, 222, 226, 250, 252, 442

NIH .....99

**O**

operator priority..... 278

Oracle Access Manager ..... 610

Oracle account.... 620, 623, 626, 701, 702

overlap graphs..... 222, 226, 258, 259

**P**

palette choices..... 229

passwords..... 26, 27, 573, 575, 820

patterns (in data mining results) ..... 205

PDF file ..... 3, 259, 455, 708, 709

permissions . 90, 134, 197, 273, 399, 562, 567, 569, 570, 578, 579, 580, 587, 595, 596, 602, 652, 693, 820

popup windows .....3

precision ..... 219

preferences ..... 28

prefix..... 209, 215, 620, 641, 647

prerequisites .....3

previewing a report ..... 373

projects ..... 61

PRR ..... 10, 141, 156, 209, 306, 309

PRR computations .....141, 181, 309

PTs.....267, 488

publishing ..... 58



**Q**

queries 7, 58, 74, 81, 134, 135, 269, 273,  
274, 276, 278, 286, 287, 288, 289,  
291, 292, 293, 311, 314, 319, 341,  
353, 371, 397, 399, 400

Queries page ..... 271

Query Library ..... 129, 269, 295, 655

query logic ..... 276, 278, 292, 664

Query Wizard..... 129, 269, 274, 314, 321,  
397, 641, 820

query-based reports ... 367, 386, 387, 397

quota.....127, 575

**R**

remapping text values 641, 657, 659, 664

renaming users.....581, 613

report attributes..... 368

report definitions... 58, 68, 321, 327, 329,  
333, 341, 344, 347, 352, 353, 356,  
357, 361, 367, 368, 369, 371, 373,  
374, 375, 377, 378, 379, 387, 394,  
396, 404, 407, 662

Report Definitions page333, 340, 341, 379

report descriptors..... 371

report graphs .....412, 414

Report ID .....289, 641

report outputs ...7, 58, 59, 101, 327, 379,  
394, 404, 407, 408, 409, 411, 513,  
514, 522

report structure ..... 328

reports.7, 59, 68, 81, 101, 110, 119, 209,  
247, 289, 321, 327, 328, 329, 332,  
352, 357, 360, 369, 370, 371, 373,  
374, 375, 379, 386, 397, 404, 409,  
411, 412, 513, 534

results criteria ..... 91, 202, 205, 208

results graphs..... 227

results tables..... 198, 209, 215, 219, 220

review .....304, 456, 458

review period..... 459, 462, 469, 799, 800,  
801, 802

reviewers .... 28, 447, 469, 473, 475, 476,  
620, 805, 820

roles.....569, 579, 583, 585, 586, 587

ROR ..... 10, 156, 209

ROR computations..... 144

Rows per Page ..... 62, 375, 409

run definition file.....673, 812

run details.....186, 190

run options.....179, 181

run parameters.....156, 181, 195

run results .190, 197, 198, 202, 205, 209,  
215, 222

run storage ..... 806, 807, 808, 810

**S**

SAS.....3

saved lists.. 81, 83, 84, 86, 88, 89, 90, 91

scatter plots ..... 412, 414, 426, 428

sector maps110, 202, 222, 224, 261, 264,  
267, 268, 484, 486, 488, 489

Selected Values list ..... 41

selecting values from a list ..... 41

selection types..... 641

server status ..... 818

set operators ..... 278

settings..... 34

signal comment type ..... 793

signal comments .452, 793, 795, 797, 798

signal configurations.. 431, 469, 592, 787, 788, 790

signal detection methods ..... 10

signal history ..... 455, 456

signal management ..... 431

signal sets ..... 431

signal views 459, 461, 462, 463, 464, 469, 788, 790

Signals tab ..... 431

similar drug-event combinations ..... 449

single sign-on .. 26, 27, 40, 567, 573, 575, 581, 610, 613

    Adding and Editing Users ..... 575

    Changing Your Password ..... 27

    Configuring ..... 611

    Exiting ..... 40

    Logging in ..... 26

    Renaming Users ..... 581, 613

single sign-on username ..... 574

site options ..... 7, 820

sort order ..... 65, 153, 375, 409, 798, 802

source data ... 7, 60, 75, 77, 86, 121, 202, 295, 327, 551, 553, 556, 635, 638, 640, 647, 678

source description table ..... 551, 556, 623, 635

source details ..... 521

special characters ..... 51, 86, 202

SQL WHERE clause 28, 65, 202, 215, 341, 368, 370, 439, 459, 462, 476, 477, 558, 560

statistics 7, 114, 117, 138, 141, 144, 162, 202, 209, 215, 268, 327, 452, 455, 489

stratification 141, 144, 146, 147, 209, 553

stratification variables... 81, 147, 200, 641

subset labels ..... 155

subset variables ... 81, 146, 149, 152, 153, 155, 200, 209, 641

subsetting ..... 149

suggestions ..... 39

superuser ..... 562, 575

synthetic values . 138, 141, 144, 641, 657, 671

**T**

tables ..... 62, 65, 67, 68, 553, 627, 632

tablespace ..... 810

tabs ..... 36

template ..... 770, 778, 779, 781

template action ..... 786

third-party link ..... 641, 652

time zone ..... 28

timestamped data . 60, 80, 299, 620, 635, 638, 640

topic actions ..... 506, 520, 521, 522, 523, 528, 529, 531, 534, 542, 544, 726, 747

topic attachments 59, 506, 510, 513, 515, 516, 518, 520, 521, 522, 546, 548, 749, 820

topic comments ..... 496, 506, 548

topic email notification rules 764, 767, 769

topic field values 726, 728, 731, 734, 739, 741, 742, 744

topic fields . 708, 713, 724, 726, 728, 731, 734, 738, 739, 741, 742, 744, 745, 769, 772

topic links ..... 505

- topic reports .....534, 542, 544
- topic states .496, 509, 534, 542, 713, 745
- topic template ... 456, 713, 770, 772, 778, 780, 784, 785
- Topic Template page ..... 776
- topic workflow configurations.....491, 496, 501, 520, 528, 592, 626, 693, 694, 696, 697, 701, 702, 703, 706, 708, 710, 712, 713, 714, 724, 726, 728, 731, 734, 738, 739, 741, 742, 744, 745, 764, 767, 769, 770, 781, 820
- topics .....7, 59, 198, 252, 415, 428, 445, 458, 491, 493, 499, 500, 501, 503, 505, 506, 509, 513, 515, 516, 518, 520, 523, 529, 534, 542, 544, 546, 548, 575, 595, 596, 602, 693, 710, 714, 728, 742, 745, 767, 776, 779, 781
- Topics feature..... 693
- Topics page ..... 493
- trade names ..... 208
- transferring cases .....74, 81, 299, 319
- transforming data ..... 366, 657, 659, 664, 665, 668, 670, 671
- U**
- unique values tables.. 190, 551, 556, 620, 640, 647
- URLs.....99, 510
- User Activity Audit Trail.....575, 609, 814, 816
- user administration ..... 561, 610
- user passwords..... 27, 573, 575, 820
- user permissions . 561, 562, 570, 580, 587
- user preferences ...28, 561, 567, 575, 578
- user profiles561, 566, 567, 569, 570, 575, 578
- user roles...561, 562, 569, 575, 578, 579, 580, 583, 585, 586, 587, 588
- usernames ..... 574, 575, 581, 613
- users ... 28, 561, 562, 571, 575, 578, 579, 580, 581, 582, 594, 608, 610, 613, 813, 816
- V**
- valid values .....741, 742, 744
- validation .....617, 620, 623
- variable cutpoints.....641, 657, 665
- variable subtype ..... 641
- variable types ..... 81, 641, 662
- variables ....146, 149, 152, 172, 173, 200, 209, 668
- variables (in reports) ..... 328
- W**
- WinZip..... 3, 68
- work team fields 726, 728, 731, 734, 738, 739, 741, 742, 744
- work teams 503, 561, 562, 590, 592, 595, 596, 599, 601, 602, 734, 772
- workflow configuration account ..... 702
- workflow configuration options..... 703
- X**
- XML (in reports).....368, 374
- Z**
- ZIP file.....3
- zooming in .....264, 267, 488