Oracle® Central Designer

User Guide

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Oracle Central Designer User Guide, Release 7.0

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Contents

Preface

Documentation accessibility xxi
Related resources xxi
Diversity and Inclusion xxi
Access to Oracle Support xxi
Additional copyright information xxii

1 Customize the workspace

Customize the workspace 1-1
- Reset window layout and show hidden message boxes 1-1
- Show and hide the status bar at the bottom of the screen 1-1
- Choose what appears on startup 1-1
- Change the number of projects that appear in the Recent Projects list 1-1
- View more than one tab in the workspace 1-2

Customize the data in a grid 1-2
- Filter data in a grid 1-2
- Remove a filter in a grid 1-2
- Group data in a grid 1-2
- Remove a grouping in a grid 1-3
- Select the columns that appear in a grid 1-3
- Arrange the columns in a grid 1-3
- Hide a column in a grid 1-3
- Sort data in a grid 1-3

2 Create and configure a study

Set up study parameters 2-1
- Create a study 2-1
- Choose the phase of a study 2-2
- Set the primary layout for a study 2-2
- Select the supported locales for a study 2-2
- Choose the default locale for a study 2-2

Choose the libraries to make available to a study 2-2
Set up study teams 2-3
Add a user to a study team 2-3
Remove a user from a study team 2-4
Save a search in the Users tab 2-4
Configure study administration data 2-4
Import study administration data 2-4
Import Wizard options—CSML or ODM file 2-5
Enter study administration data 2-6
Sponsor settings 2-6
System settings 2-6
Item groups 2-7
Query groups 2-8
Rights groups 2-9
Signature groups 2-10
Export study administration data for use in a user management tool 2-12
Export Wizard options 2-12
(Optional) Create predefined sets of drop-down list options, radio buttons, or checkboxes (codelist subsets) in a study 2-13
Step 1: Create a drop-down list or set of radio buttons or checkboxes (a codelist with codelist items) 2-13
Step 2: Define sets of drop-down list options, radio buttons, or checkboxes (codelist subsets) 2-13
Step 3: Require study designers to select subsets when they are defined for a codelist (Optional) 2-14
Delete a codelist subset 2-14
(Optional) Create review states and stages for use in the InForm Data Viewer 2-14
(Optional) Restrict study design activities 2-16
(Optional) Attach a reference to a study 2-16
Lock the study administration data settings 2-16
(Optional) Remove a reference from a study 2-17
(Optional) Set up your study for coding 2-17
Select dictionary types and verbatim types for a study 2-17

3 Create and configure a library

Create a library 3-1
Set the primary layout for a library 3-1
Select the supported locales for a library 3-2
Choose the default locale for a library 3-2
Set up library teams 3-2
Add a user to a library team 3-2

Remove a user from a library team 3-3
Save a search in the Users tab 3-3
Add a study object or library object to a library 3-4
Categorize a study object 3-4
Create predefined sets of drop-down list options, radio buttons, or checkboxes (codelist subsets) in a library 3-5
Step 1: Create an item to collect data on forms 3-5
Step 2: Create a drop-down list or set of radio buttons or checkboxes (a codelist with codelist items) 3-6
Step 3: Define sets of drop-down list options, radio buttons, or checkboxes 3-6
Step 4: Require an item to use assigned codelists and subsets (Optional) 3-7
Create a study object template 3-7
Create an item type 3-7
Mark an item as mandatory 3-8
Protect a library and all its objects 3-8
Unprotect a library 3-9
Publish an object to make it available to copy into a study 3-9
Publish, republish, or unpublish a library to make its objects available to copy into a study 3-10
Disable a library 3-10

4 Import and export study objects

Import study object into a library or study 4-1
Import study objects 4-1
View completed import jobs 4-3
Importing translated text strings 4-4
Checking for empty strings 4-4
Export a study or library to a file 4-5
Export a study or library 4-5
Export text strings for translation 4-6

5 Use tasks and notes to create collaboration

Create and modify tasks and notes 5-1
Create a task 5-1
Create a collaboration note 5-3
Change the assignees for a standard task 5-5
Edit a task or collaboration note 5-6
Delete a task or collaboration note 5-9
Print a task or collaboration note 5-9
Interact with assigned tasks 5-9
View all tasks assigned to you 5-10

Accept, unaccept, complete, close, or reopen a task 5-10
Complete an assigned task 5-11

6 Design custom events

Step 1: Create a custom event 6-1
Step 2: Add a trigger for a custom event 6-1
Step 3: Add a result for a custom event (the data to export when a custom event is triggered) 6-2
Step 4: Specify run options 6-3
Set the priority for your custom events 6-4
Configure a custom event to run retroactively on existing data 6-4
Make a custom event dependent on another custom event 6-4
Change the endpoint name of more than one custom event 6-5
Mark a custom event change as an in-place revision 6-5
View the differences between two versions of a custom event 6-5
Import custom events 6-6
Import custom events that were created in Oracle InForm Publisher in a release prior to 6.2 6-6
Add a custom event from a library 6-6
Deactivate a custom event 6-7
Example of Oracle InForm to Siebel CTMS integration 6-7
Create a subject with a status of Enrolled 6-7
Initiate an early withdrawal 6-9
Mark a visit as complete and specify the date of visit as the completion date 6-10
Mark the cycle 1 visit as complete and specify the date of visit as the completion date 6-10
Update the date of visit item on the subject completion visit whenever it is changed 6-11

7 Create and test rules

Create rules 7-1
Create an intrinsic rule 7-1
Create a rule without a function 7-6
Create a rule using a function 7-11
Create a workflow rule in a workflow diagram 7-16
Create a global condition 7-17
Test rules 7-18
Check rule syntax 7-18
Write test cases for a rule or global condition 7-18
Write a test case for a rule with an item on a repeating study object 7-20
Run test cases 7-21
Edit rules 7-22

Modify a rule 7-22
Deactivate a rule 7-22
Delete a rule 7-23
Disable or enable one or more rules 7-23
Update the state of a workflow rule 7-23
Disable a workflow rule 7-23

8 Data mappings

Use data mappings, data sets, and data series to associate items 8-1
Create a data mapping 8-1
Create a data set 8-1
Create a data series 8-2
Add an item to a data series by selecting a data series 8-3
Add an item to a data series by selecting a study event or form 8-4
Unmap an item mapping with a data series 8-5
Change the data value associated with a data series 8-5
Rule data mappings 8-6
Modify labels of mapped custom data dimensions 8-6
Delete a custom data dimension 8-6
CDD mappings 8-7
Create a data set to use for CDD mappings 8-7
Map associated forms to a CDD 8-7
Set up a pivot table with CDD data mappings 8-8
Modify CDD date time part data mappings 8-10
CIS data mappings and Clintrial subsets 8-11
Set up data mappings for a Clintrial subset 8-11
Create a custom Clintrial context panel 8-11
Create a Clintrial enrollment panel 8-12
Create a non-patient data (Type 0) panel 8-12
Modify CIS date time part data mappings 8-13

9 Validate and deploy a study

Before you begin: Make sure the workflow is valid 9-1
Follow this four-step process 9-1
Step 1: Validate the study to create the validation baseline 9-2
Validate a study and create a baseline 9-2
View baseline validation errors and warnings 9-2
Make repairs to the study 9-4
Save validation messages to a CSV file 9-5

Make a validation baseline public 9-10
Step 2: Create a deployment instance 9-11
Test the deployment instance 9-12
Step 3: Create a deployment package from a validation baseline 9-12
Create a deployment package: the basics 9-12
Create a full deployment package 9-13
Create an incremental deployment package 9-13
Create an administration data deployment package 9-14
Create a custom events deployment package 9-14
View the deployment packages 9-15
Delete a deployment package 9-15
Step 4: Deploy the study to Oracle InForm 9-15
Initiate automated deployment 9-15
Initiate manual deployment 9-19

10 Perform post-design activities

Lock and protect studies and libraries 10-1
Lock or unlock a data-entry rule 10-1
Lock or unlock a global condition 10-1
Lock or unlock a workflow rule 10-2
Lock a deployment instance 10-2
Protect a study 10-2
Protect and unprotect a library 10-2
Archive and decommission a study 10-3
Archive a study or project 10-3
View errors associated with an archive 10-4
View archived studies and projects 10-4
Delete a study or project 10-4
Download and import an archived study or project 10-4
Delete an archived study or project from the database 10-5
Generate reports 10-5
Generate, save, and print a report 10-6
Data Entry Rule Actions report 10-6
InForm RefName report 10-9
Library Objects Modified in the Study report 10-11
Library Objects Modified in the Library report 10-11
Number of Studies Containing Library Objects report 10-12
Library Objects Modified in Studies report 10-13
Study Baselines Difference report 10-14
Studies Containing Selected Library Object report 10-15

Workflow Rules and Global Conditions Report 10-16
Generate an Annotated Study Book 10-17
Generate an Annotated Study Book 10-17
Print an annotated study book 10-18
Create a PDF file for an annotated study book 10-18
Format dates on the Annotated Study Book for the Japanese locale 10-19
Export the Schedule of Events table to a CSV file 10-19
Translate text 10-20
View locale-specific translations in a layout 10-20
Create, edit, translate, and remove a section note 10-21
Edit and translate a form or section title 10-21
Edit and translate a question for a locale 10-22
Edit and translate a codelist item label override 10-22
Enter and translate the title and short title of the Common Visit 10-22
Translate the short title of a study event 10-23
Translate the short title of a form 10-23
Translate the question text of an item 10-24
Translate a codelist item label 10-24
Create and translate instructions and Help for a study design 10-24

11 Integrate Oracle InForm with Oracle Argus Safety

About the Oracle InForm to Oracle Argus Safety integration 11-1
Overview of designing for integration 11-1
Important study design considerations 11-2
Design Adverse Events, Safety Case, and other forms 11-3
Design the Adverse Event form 11-3
(Optional) Design other forms that may contain data to send to Oracle Argus Safety along with the Adverse Event form 11-4
Create fixed items in the section 11-5
Add a codelist to the fixed item 11-6
Add codelist items to the codelist 11-6
Design a Safety Case form 11-6
Create narrative items 11-8
Create a section (dynamic grid) to collect related data 11-9
Add rules to forms for sending data to Argus Safety 11-12
Write a rule containing the SaveToDb function 11-12
Add required rules to the Adverse Event form 11-13
Send the Reportable or Serious item to Oracle Argus Safety only when the Oracle InForm user marks it as Ready-to-Send 11-14
Send the Reportable or Serious adverse event immediately upon form submission 11-16
Calculate the sequence ID 11-17

Send email to the safety group when an AE is marked as Serious or Significant 11-18
Add rules to the Safety Case form 11-19
(Required) Send a query if no adverse events are on the Safety Case form 11-19
Copy values from an Adverse Event form to a Safety Case form 11-21
Create rules for the narrative 11-23
Add rules for other forms containing adverse event items 11-34
Check for multiple different death dates or patient autopsy completed codes 11-34
Map Oracle InForm data items to Oracle Argus Safety entities 11-35
Download the data mappings from My Oracle Support (MOS) 11-36
Import the data mappings into Oracle Central Designer 11-36
Map Oracle InForm items to entities in Oracle Argus Safety 11-37
Mapping guidelines 11-39
Predefined data sets included in the integration 11-46
(Optional) Create a custom data series 11-88
Select the safety mapping (SafetyLogicalSchema) to deploy 11-89
Set safety event data configuration options in Oracle InForm Publisher 11-89
Configure the Oracle Argus Safety-only attributes 11-89
Supported post-production changes to a dynamic grid 11-91
Supported changes with study version changes 11-92
Supported changes with in-place revision changes 11-93
Changes not supported for study version or in-place revision 11-93

12 FAQs

User interface customization 12-1
Can I arrange user interface elements? 12-1
Study setup 12-1
How is a study's default locale used? 12-2
How do I develop a study across multiple locales? 12-3
How are float values formatted? 12-4
Users Browser searches 12-4
How does the Libraries tab search work? 12-4
What does the Libraries tab search? 12-4
What appears in my Libraries tab search results? 12-5
Is there an easy way to find a study object and add it to the study design? 12-5
Study administration data 12-6
What is study administration data? 12-6
Where can I create study administration data? 12-7
If I enter sponsor information in Oracle Central Designer, does it appear in the Oracle Central Designer Administrator? 12-7
Where does sponsor information appear in Oracle InForm? 12-7

What happens if I import study administration data that refers to study objects that aren't in the study I'm importing to? 12-7
What happens if I import a study administration data object with the same identifier as an existing object in my study? 12-7
What are review states? 12-7
What type of file can I attach to a study as a reference? 12-8
What size file can I attach to a study as a reference? 12-8
Coding setup 12-8
What is a coding map? 12-8
What is a verbatim? 12-8
What is a context item? 12-9
What is a target item? 12-9
What is a query target item? 12-9
Which dictionary types are installed with Central Designer? 12-10
Can I add more than one version of a dictionary type? 12-10
Can I associate multiple verbatim types with a single dictionary type? 12-10
What are the requirements for coding components? 12-10
Library setup 12-10
What is a library? 12-11
What is the System Library? 12-11
What happens if I unpublish an object in the library? 12-11
About publishing, republishing, and unpublishing 12-11
How can I use published study objects in workflows? 12-12
Results of modifying study objects that have been copied to studies and libraries 12-12
What are examples of using libraries effectively? 12-15
Illustration: Example of a production library 12-16
Illustration: Building libraries using study objects from production studies 12-17
Illustration: Building libraries from scratch 12-18
Illustration: Building a study using libraries 12-19
Illustration: Modifying study objects in production libraries 12-20
Illustration: Multiple instances of study objects in production libraries 12-21
What is a template? 12-22
What is a type? 12-23
What is the difference between a template and a type? 12-24
What information can I define for templates and types? 12-24
About searching for a template or type 12-26
What happens when I add a template to a study? 12-26
What is an item type? 12-26
Import and export 12-26
Why would I import or export study data? 12-27
What data format can I import into Oracle Central Designer? 12-27
What conditions must be met before a study object can be imported? 12-28

Considerations for ODM import in Oracle InForm studies 12-28
What modifications can I make to an imported study? 12-31
What CMSL data is not exported or imported? 12-31
What are the requirements for importing ODM metadata? 12-32
How are ODM objects mapped to Oracle Central Designer objects? 12-32
Can I export a single study object? 12-33
Can I export and import text? 12-33
What does a translator do with the exported text strings for translation? 12-33
What is the format of the translation export and import CSV file? 12-35
What are the requirements for the translation file? 12-36
Tasks and notes 12-37
What are tasks and how do I work with them? 12-37
Where do the task types come from? 12-38
How are task statuses used? 12-41
Who does what with tasks? 12-43
What is a collaboration note? 12-43
Custom events 12-44
What are the limitations on triggers? 12-44
Rules 12-44
What types of rules can I create? 12-45
How should I name my rules? 12-45
Can I schedule rules to run in a certain order? 12-46
Can I create a rule with more than one action? 12-46
What happens when I reuse a study object with a data-entry rule? 12-46
What happens when I reuse a study object with a global condition? 12-47
Which object should I add a rule to? 12-47
What happens if I create a rule on a repeating study object? 12-48
Should I use a workflow rule or a global condition? 12-48
What happens if I disable a workflow? 12-49
View all rules for a study object and its children 12-49
Can I cause a subject to fail screening and enrollment? 12-49
Partial SDV 12-50
How is Partial SDV set in Oracle Central Designer? 12-50
How are Partial SDV default values affected by a migration or upgrade? 12-50
How do I automatically include or exclude subjects in Partial SDV using a rule? 12-51
Data mappings 12-52
What is the difference between data mappings, data sets, and data series? 12-52
How are data mappings deployed? 12-53
How long do associations last? 12-54
How are study objects that are part of a data mapping copied? 12-54
What are the custom property settings and design rules for custom context panels? 12-55

Mapping to a data series 12-56
What are my options when mapping an item to a data series? 12-56
Which item data types are compatible with which data series? 12-56
How are units of measurement mapped? 12-57
Why are data dimensions the keys to viewing data? 12-57
How does Oracle Central Designer process data series with unmapped items and without items? 12-58
Mapping to a data set 12-59
What are the standard data dimensions and data set methods? 12-59
Why are data dimensions the keys to viewing data? 12-59
CDD mappings 12-60
What is a Custom-Designed Database (CDD)? 12-60
Example—Creating a CDD mapping 12-60
How data mappings are deployed to CDD tables 12-61
What are the target key types for tables that do not pivot? 12-61
What are the target key type for pivot tables? 12-62
How can I map each drop-out reason to a separate CDD column? 12-63
CIS mappings 12-64
How do I set up CIS data mapping for date time items? 12-64
Clintrial mappings 12-65
How are data mappings generated for specialized Clintrial panels? 12-65
How are data mappings deployed to Clintrial study objects? 12-66
What are Clintrial subsets? 12-67
How does Clintrial use subset keys and subset values in Oracle Central Designer? 12-67
What is the difference between block keys and page keys in CIS data mappings? 12-67
Data mappings vs rules 12-69
Why should I use rules to create data mappings? 12-69
When should I use a data mapping and when should I use a rule? 12-70
How can I map to a specific instance of an item that appears multiple times in a study? 12-70
Example of data mappings for rule creation 12-71
Data mapping examples 12-72
Different ways to set up data mappings 12-72
What are the data mappings to create an SDTM model? 12-72
How do standard versus custom dimensions change the view of the data? 12-73
Validation and deployment 12-74
What's involved in study validation and deployment? 12-74
Validation and deployment definitions 12-74
How do the Oracle Central Designer study components appear in Oracle InForm? 12-75
Validation 12-84
What is a baseline used for? 12-84
What checks are performed during validation? 12-85

What information is not validated? 12-105
Can I delete a validation baseline? 12-105
What happens to the baseline when you upgrade? 12-105
Deployment 12-106
When can I create a deployment package? 12-106
What types of deployment packages can I create? 12-106
What happens when Oracle InForm processes the deployment package? 12-107
When can I delete a deployment package? 12-108
When can I cancel a deployment? 12-109
What are the basics of automated deployment? 12-109
What am I notified about during automated deployment? 12-109
When should I use manual deployment? 12-109
Can I edit or delete a deployment instance? 12-110
How do I deploy an in-place revision? 12-110
Post-design activities 12-110
Decommissioning and archiving FAQs 12-110
What's involved in decommissioning? 12-111
What is the workflow for decommissioning studies and projects? 12-111
What is archiving? 12-111
What information is archived? 12-112
How is deleting a study or project different from archiving? 12-114
What information is deleted when you delete a study or project? 12-114
What are the options for importing an archive? 12-116
What information is imported from an archive? 12-116
Reports and Annotated Study Book FAQs 12-118
What reports can I generate? 12-119
What is an Annotated Study Book? 12-119
What is in the Schedule of Events table in the Annotated Study Book? 12-124
What do the RDE Analytics tables in the Annotated Study Book contain? 12-125
How are layouts handled in an Annotated Study Book versus a deployment package? 12-128
What are the RD Column names in RDE Analytics tables? 12-128
What does the Custom Events table in the Annotated Study Book contain? 12-130
Translating text FAQs 12-131
How can I switch between locales and provide translations? 12-131
Oracle InForm to Oracle Argus Safety integration 12-131
What data does the integration require? 12-132
Why would I make the Safety Case form dynamic? 12-133
When might an Oracle InForm site user include multiple adverse events when sending data to Oracle Argus Safety? 12-133
What is a dynamic grid? 12-134
What are item level mapping and data point mapping in a dynamic grid? 12-134

What is an editable item in a dynamic grid? 12-135
When will an Oracle InForm site user use a Safety Case form? 12-135
How do I include the unit of measurement with items I create in Oracle Central Designer? 12-135
What's in the data sets used to process data transmissions? 12-136
What is the syntax of the _SavetoDB function? 12-137
How does a calculation rule work? 12-137
Are there rules that are not supported for items in the dynamic grid? 12-138
What happens in Oracle InForm when a source form with a dynamic grid is deleted? 12-139
What kind of queries should I include on a dynamic grid item? 12-139
What is data mapping? 12-139
Are there fields that I don't need to map? 12-139
When and how are data mappings validated? 12-140
Which items have data series for transmitting coded or verbatim data? 12-140
What alias names should I use when creating custom data series? 12-140
How do I trigger Oracle InForm Publisher to send adverse event data to Oracle Argus Safety based on an onset date? 12-141
General 12-142
What is a project? 12-142
What happens when I delete a study object? 12-142
What is the difference between an instance and a link? 12-143
What happens when I delete a study or project? 12-146
What happens when I protect a study or library? 12-146
How are study objects sorted in the Project Explorer? 12-146
What are local locks and remote locks? 12-146
What is the primary layout of a study? 12-146

13 What if...

Study administrators 13-1
There are no locales listed on the Languages tab for my study 13-2
I can't add a user to a study team 13-2
I can't archive a study or project 13-2
I was added to a study team, but still don't have the associated rights 13-2
I can't find the dictionary type I want in the Dictionary Types list 13-2
I can't find the verbatim type I want in the Verbatim Types list 13-2
I can't deselect a dictionary type 13-2
I can't add a library object to my study 13-2
I can't search for study objects in a library that I want to search 13-3
There aren't any sponsors listed in the study administration data 13-3
I can't add a form to a signature group 13-3
Library users 13-3

I was added to a library team, but still don't have the associated rights 13-3
I can't archive a library or library project 13-3
I can't edit a library object 13-4
I can't add a library to the Library List for a study 13-4
I can't close a library that I'm not using anymore 13-4
I can't delete an object 13-4
Setting your machine for different locales 13-4
Viewing Japanese characters 13-4
Setting up a keyboard to use different locales 13-5
Additional locale settings 13-5
Dynamic grid 13-6
I want to add one or more source items to a single target item 13-7
Source items and target items have different data configurations 13-7
The source item configuration differs from its parent form configuration 13-7
I'm data mapping with a source item that has a codelist 13-7
Source items have units 13-7
I want to create multiple dynamic grids that have the same source form 13-7
I'm using an item-level mapping for nested items 13-8
I want to map multiple items in a repeating form to a single target item 13-8
The year range differs between the source item and target item or form 13-8
I can't import a project archive 13-8
I export and re-import the same study CSML 13-9
I can't create an item from a user-created type 13-9
I can't mark a project as a template 13-9
Deployment with an in-place revision change fails 13-9
I delete a rule 13-10
I deactivate a rule 13-11
I disable a rule 13-11
I can't disable a rule 13-12
I cut a data-entry rule from a study object, but nothing happened 13-12
A rule test case fails 13-12
Validation produces errors and warnings 13-13
A rule in Oracle InForm is deactivated 13-13
I edit or delete a deployment instance 13-13
There are blank pages in the PDF file created for my annotated study book 13-13

14 Option and property descriptions

Setting up and administering a study 14-1
Home page—Section descriptions 14-2
Status toolbar—Option descriptions 14-2

Coding tab—Option descriptions 14-3
Coding Map dialog boxes—Option descriptions 14-4
Libraries tab—Section descriptions 14-7
Libraries tab—Button descriptions 14-7
References tab—Option descriptions 14-8
Review State editor—Option descriptions 14-8
Review State editor—Option descriptions 14-9
Study General tab—Option descriptions 14-10
Teams tab—Field descriptions 14-10
Deployment Setup tab—Option descriptions 14-11
Study administration data 14-12
Sponsor tab of the Administration editor—Option descriptions 14-13
System settings tab of the Administration editor—Option descriptions 14-13
Item Groups tab of the Administration editor—Option descriptions 14-15
Query Groups tab of the Administration Editor—Option descriptions 14-15
Rights Groups tab of the Administration Editor—Option descriptions 14-15
Signature Groups tab of the Administration editor—Option descriptions 14-15
Study elements and study events 14-16
Study Elements editor—Option descriptions 14-16
Study Events Editor 14-17
Study objects 14-19
Export Translations dialog box—Option descriptions 14-19
Export Wizard options 14-20
History Viewer dialog box—Option descriptions 14-20
Import Wizard options—CSML or ODM file 14-22
Import Wizard options—Oracle InForm resources 14-22
References tab—Option descriptions 14-23
Forms, items, codelists, and codelist items 14-24
Codelists Editor—Option descriptions 14-24
Codelist Items Editor—Option descriptions 14-26
Design tab of the Codelist Editor—Option descriptions 14-27
Design tab of the Form Editor or Section Editor—Option descriptions 14-28
Design tab of the Item Editor—Option descriptions 14-31
Forms and sections editor—Option descriptions 14-38
General tab of the Form Editor or Section Editor—Option descriptions 14-40
Oracle InForm Items Editor—Option descriptions 14-41
Item Properties dialog box—Option descriptions 14-43
Keys dialog box 14-50
Languages tab of the Codelist Item Editor—Option descriptions 14-51
Layouts 14-51
Control Styles dialog box—Option descriptions 14-51

Layout tab options and deployment to the Oracle InForm application 14-54
Study Level Styles and Form Level Styles dialog boxes—Option descriptions 14-58
Study workflow 14-61
Common Visit tab of the Study Design Editor—Option descriptions 14-61
General tab of the Study Event Editor—Option descriptions 14-62
Schedule of Events tab—Option descriptions 14-63
Workflow Diagram tab—Option descriptions 14-63
Workflow Grid tab—Option descriptions 14-64
Import and export 14-64
Import Wizard options—CSML or ODM file 14-65
Import Wizard options—Oracle InForm resources 14-65
Translation file format 14-66
Translation file requirements 14-67
Export Wizard options 14-68
Export Translations dialog box—Option descriptions 14-68
Tasks and notes 14-70
Task Editor dialog box—Option descriptions 14-70
Collaboration Notes Browser—Option descriptions 14-71
Collaboration Note Editor dialog box—Option descriptions 14-72
Task areas—Field descriptions 14-72
Tasks Browser—Option descriptions 14-73
Custom events 14-74
Custom Events editor—Option descriptions 14-74
Rules 14-76
Assign Conditions dialog box—Option descriptions 14-77
Define Test Values for Repeating Instances dialog box—Option descriptions 14-79
Design tab of the Rule Test Cases dialog box—Option descriptions 14-80
Edit Global Conditions dialog box—Option descriptions 14-81
Edit Schedule dialog box—Option descriptions 14-82
Edit Schedule and Rule Action dialog box—Option descriptions 14-83
Edit Workflow Rules dialog box—Option descriptions 14-85
Email Action dialog box—Option descriptions 14-86
Invoke Function dialog box—Option descriptions 14-89
Query Action dialog box—Option descriptions 14-91
New Rule Template dialog box—Option descriptions 14-93
Rule Templates tab—Option descriptions 14-94
Rule Wizard—Option descriptions 14-95
Rules tab—Option descriptions 14-100
Run tab of the Rule Test Cases dialog box—Option descriptions 14-101
Set Review State Action dialog box 14-102
Set Value Action dialog box—Option descriptions 14-103

Workflow Expression Editor dialog box—Option descriptions 14-104
Data mappings 14-105
Custom Dimension Labels - Select Codelist dialog box—Option descriptions 14-106
Data Series Editor—Field descriptions 14-107
Data Series Properties dialog box—Option descriptions 14-107
Data Series Summary tab—Option descriptions 14-108
Data Set Editor—Field descriptions 14-109
Data Set Properties dialog box—Field descriptions 14-110
Date-Time Data Point dialog box—Option descriptions 14-111
Item has units dialog box—Option descriptions 14-111
Mapping Editor—Field descriptions 14-112
Select Custom Dimension dialog box—Option descriptions 14-113
Validation and deployment 14-114
Baselines Browser—Option descriptions 14-114
Create Deployment Package Wizard—Full deployment package 14-117
Create Deployment Package Wizard—Incremental deployment package 14-135
Create Deployment Package Wizard—Administration data deployment package 14-148
Create Deployment Package Wizard—Custom events 14-163
Deployment Editor—Option descriptions 14-171
Pending Approvals tab on the Home Page—Option descriptions 14-172
Deployment History dialog box—Option descriptions 14-174
Deployment Package History dialog box—Option descriptions 14-176
Deployment Request dialog box—Option descriptions 14-179
Deployment Wizard for Oracle InForm deployment 14-180
Jobs Browser—Option descriptions 14-181
Post-design 14-183
In-place revisions 14-184
IPR Configuration dialog box 14-184
In-Place Revision Summary Editor—Option descriptions 14-185
View Differences dialog box—Option descriptions 14-185
IPR History dialog box—Option descriptions 14-187
Annotated Study Book 14-188
Annotated Study Book Options dialog box 14-188
Properties 14-197
CDD data mapping properties 14-198
CIS data mapping properties 14-202
Codelist properties 14-207
Codelist item properties 14-208
Data mapping properties 14-209
Data series standard properties 14-210
Data set properties 14-210

Form and section properties 14-210
Item properties 14-213
Study and library standard properties 14-216
Study design properties 14-216
Study element properties 14-217
Study event properties 14-218
Study project and library project properties 14-219
Properties in the Rule Test Cases dialog box 14-219

Preface

This preface contains the following sections:

- Documentation accessibility
- Related resources
- Diversity and Inclusion
- Access to Oracle Support
- Additional copyright information

Documentation accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc.

Related resources

All documentation and other supporting materials are available on the Oracle Help Center.

Diversity and Inclusion

Oracle is fully committed to diversity and inclusion. Oracle respects and values having a diverse workforce that increases thought leadership and innovation. As part of our initiative to build a more inclusive culture that positively impacts our employees, customers, and partners, we are working to remove insensitive terms from our products and documentation. We are also mindful of the necessity to maintain compatibility with our customers' existing technologies and the need to ensure continuity of service as Oracle's offerings and industry standards evolve. Because of these technical constraints, our effort to remove insensitive terms is ongoing and will take time and external cooperation.

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- Japanese interface of Oracle Health Sciences Customer Support Portal (https://hsgbu-jp.custhelp.com/)

You can also call our 24x7 help desk. For information, visit http://www.oracle.com/us/support/contact/health-sciences-cloud-support/index.html or visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs if you are hearing impaired.

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1

Customize the workspace

In this chapter:

- Customize the workspace
- Customize the data in a grid

Customize the workspace

In this section:

- Reset window layout and show hidden message boxes
- Show and hide the status bar at the bottom of the screen
- Choose what appears on startup
- Change the number of projects that appear in the Recent Projects list
- View more than one tab in the workspace

Reset window layout and show hidden message boxes

1. In the upper-left corner, click **Tools**, then select **Options**.
2. Select the following, and click **OK**.
   - Reset Window Layout
   - Reset Message Boxes

Show and hide the status bar at the bottom of the screen

1. In the upper-left corner, click **Tools**, then select **Options**.
2. Select or deselect **Show Status Bar**, and click **OK**.

Choose what appears on startup

1. In the upper-left corner, click **Tools**, then select **Options**.
2. From the **At Startup** drop-down list, select one of the following, and click **OK**:
   - Show HomePage—The Home Page appears after you log on.
   - Show Workspace—A blank workspace with no project appears after you log on.
   - Load Most Recent Project—The project you opened last appears in the workspace after you log on.

Change the number of projects that appear in the Recent Projects list

1. In the upper-left corner, click **Tools**, then select **Options**.

2. In the number drop-down within the **Display [number] projects in Recent Projects** list option, select the number of projects to appear, and click **OK**.

View more than one tab in the workspace

1. In the Project Explorer, select a study object.
2. Click one of the tabs and drag it within the workspace, without releasing the mouse button.
3. When you see the arrow buttons (), point your mouse to an arrow button. When the application area where the tab will appear is highlighted, release the mouse button.

Customize the data in a grid

In this section:

- Filter data in a grid
- Remove a filter in a grid
- Group data in a grid
- Remove a grouping in a grid
- Select the columns that appear in a grid
- Arrange the columns in a grid
- Hide a column in a grid
- Sort data in a grid

Filter data in a grid

1. In the Project Explorer, select a folder, such as InForm Items.
2. In the grid, right-click a field, then select the **Filter Row** checkbox.
3. Type what you want to filter on in the text box under a filter in the top row.

   You can specify multiple filters.

Remove a filter in a grid

1. In the Project Explorer, select a folder, such as InForm Items, with an applied filter.
2. Right-click any field, then deselect the **Filter Row** checkbox.

Group data in a grid

1. In the Project Explorer, select a folder, such as InForm Items.
2. In the grid, right-click any field, then select **Group**.
3. Drag a column heading into the row above the column headings to group the grid by that heading.

4. Repeat steps 2-3 to group by more than one field.

Remove a grouping in a grid

1. In the Project Explorer, select a folder, such as InForm Items, with a grouping.
2. Above the grid, right-click a field being used to group the items, then deselect the **Group** checkbox.

Select the columns that appear in a grid

1. In the Project Explorer, select a folder, such as InForm Items.
2. In the grid, right-click any column, then select **Columns**.
3. Select the columns that you want to appear in the grid from the **Available Columns** list and use the arrow buttons to move them to the **Displayed Columns** list.
4. Reorder the selected columns using the **Move Up** and **Move Down** buttons.
5. Click **OK**.

Arrange the columns in a grid

1. In the Project Explorer, select a folder, such as InForm Items.
2. In the grid, right-click any column, then select **Columns**.
3. In the Displayed Columns list, select a column and click the **Move Up** and **Move Down** buttons to reposition it.
4. When you are finished arranging the columns, click **OK**.

Hide a column in a grid

1. In the Project Explorer, select a folder, such as InForm Items.
2. In the grid, right-click the field you want to remove, then select **Hide Column**.

Sort data in a grid

1. In the Project Explorer, select a folder, such as InForm Items.
2. In the grid, click the column heading you want to sort on.

   An up-arrow or down-arrow appears to the right of the selected column heading to show whether you have sorted in ascending or descending order.
3. To reverse the sort, select the column heading again.

2

Create and configure a study

In this chapter:

- Set up study parameters
- Set up study teams
- Configure study administration data
- (Optional) Create predefined sets of drop-down list options, radio buttons, or checkboxes (codelist subsets) in a study
- (Optional) Create review states and stages for use in the InForm Data Viewer
- (Optional) Restrict study design activities
- (Optional) Attach a reference to a study
- Lock the study administration data settings
- (Optional) Remove a reference from a study
- (Optional) Set up your study for coding

Set up study parameters

In this section:

- Create a study
- Choose the phase of a study
- Set the primary layout for a study
- Select the supported locales for a study
- Choose the default locale for a study
- Choose the libraries to make available to a study

Create a study

1. In the upper-left corner, click **File**, then select **New Study Project**.
2. Type a name and description of the project and the study, and, optionally, select a template for the study.

   > **Tip:**
   >
   > Templates do not have versions. Therefore, the available templates are the most current.

3. In the Targets section, make sure **InForm** is selected, and click **OK**.

Choose the phase of a study

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. In the Project Explorer, select the study, and make sure the General tab is selected.
3. From the **Phase** drop-down list, select the phase of the study.

Set the primary layout for a study

1. In the library project, in the upper-left corner, click **Tools**, then select **Layout Names Manager**.
2. In the Primary layout name section, select **Main** as the primary layout, or select a layout you created, then click **OK**.

Select the supported locales for a study

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Select the study, then select the Languages tab.
3. In the Languages/Locales list, select the locale or locales for the study.

Choose the default locale for a study

1. In the upper-left corner, click **Tools**, then select **Options**.
2. In the **Default locale** drop-down list, select a locale, then click **OK**.

Choose the libraries to make available to a study

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. In the Project Explorer, select the study.
3. Click the Libraries tab, which appears on the right of the page by default.

> **Tip:**
>
> If you don't see the Libraries tab, at the top left of the page, select **View**, and make sure **Libraries** is selected.

4. Click **Add**.
5. Select one or more libraries with objects that you want to make available to the study, and click **OK**.

Set up study teams

In this section:

- Add a user to a study team
- Remove a user from a study team
- Save a search in the Users tab

Add a user to a study team

Prerequisite: A Oracle Central Designer administrator must add the user to the corresponding study role in the Oracle Central Designer Administrator. For example, to create rules in a study, a user must be assigned to the Rule Creation study role in the Oracle Central Designer Administrator and the Rule Creation study team for the study.

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Select the study, then select the Teams tab.
3. In the [Study name] - Teams section, select the team to which you want to add the user.
4. Click the Users tab, which appears on the right of the page by default.

> **Tip:**
>
> If you don't see the Users tab, at the top left of the page, select **View**, and make sure **Users** is selected.

5. Do one of the following:
   a. Create a new search
      i. Optionally, name the search.
         i. At the top of the tab, select **Actions**, and select **New Search**.
         ii. Type a name for the search, and click **OK**.
      ii. In the **Enter search text** field, enter part or all of the user's name, display name, title, first name, or last name.
      iii. Optionally, to include categories and keywords as parameters, click the down arrows button ( ) next to the Search Filter, and then:
         - Select the Categories tab, and select one or more categories.
         - Select the Keywords tab, and select one or more keywords.
   b. Open a saved search
      i. At the top of the Users tab, select **Actions**, and select **Open Search from Repository**.
      ii. Select a search, and click **Open**.
6. Click **Find**.
7. Select the user that you want to add, and drag the user to the right-hand section.

Remove a user from a study team

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Select the study, then select the Teams tab.
3. In the left section, right-click the user, then select **Remove from Team**.

Save a search in the Users tab

1. In the library project, at the bottom of the Project Explorer, click the **Library Information** ( ) button.
2. Select the library, then select the Teams tab.
3. In the [Study name] - Teams section, select the team.
4. Click the Users tab, which appears on the right of the page by default.

> **Tip:**
>
> If you don't see the Users tab, at the top left of the page, select **View**, and make sure **Users** is selected.

5. At the top of the tab, select **Actions**, and select **Save Search to Repository**.
6. Optionally, type a description for the search, and select an option:
   - Just me—Only you can see and use the search.
   - Everyone—Everyone can see and use the search.
7. Click **Save**.

Configure study administration data

In this section:

- Import study administration data
- Enter study administration data
- Export study administration data for use in a user management tool

Import study administration data

Prerequisite: Create a study.

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. In the Project Explorer, right-click the study, then click **Import Study**.
3. When the Import Study wizard appears, click **Next**.
4. Select whether to import **CSML or ODM file** or **Harvest InForm Resources**.

Your selection determines the options you can specify. For example, If you select CSML import type, you can specify whether to import study objects and administration data, administration data only, or study objects only.

5. Click **Next** to progress through the wizard, and **Finish** to import the study objects and data.

For more information, see:

- Import Wizard options—CSML or ODM file

Import Wizard options—CSML or ODM file

Page	Option	Description
Welcome	-	Introduction page.
Import Type	-	Select the source of the data to import.
-	Import CSML or ODM file	Generate study objects from a file in CSML or ODM format.
-	Harvest InForm Resources	Generate study objects from the components of an Oracle InForm study.
File Location	Path of file to import	Specify the path of the CSML or ODM import file, or click Browse to locate the import file.
Study Administration Import Mode	-	This page appears only for the CSML import type, if the CSML file contains study administration objects.
-	Import study objects and administration data.	Import both study objects and study administration objects.
-	Import administration data only.	Import only study administration objects.
-	Import study objects only.	Import only study objects.
Rule Import Mode	Rule Import Mode	Only the Import as Collaboration Notes option is supported. With this option, each imported rule is converted to a collaboration note in the Oracle Central Designer application. **Note:** This option applies only if the Import Type is ODM; if the Import Type is CSML, the import process creates a Oracle Central Designer rule for each imported rule.
IPR Import Mode	Import IPR data	Select whether to import in-place revision objects. **Note:** This page appears only if the file contains in-place revision objects.
Ready to Import Data to Central Designer	-	View a summary of the import options selected in the wizard.

Enter study administration data

In this section:

- Sponsor settings
- System settings
- Item groups
- Query groups
- Rights groups
- Signature groups

Sponsor settings

In this section:

- Select a study's sponsor
- Remove a study's sponsor

Select a study's sponsor

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Expand the study folder, and select **Administration**.
3. Select the Sponsor tab.
4. In the **Sponsor Name** drop-down list, select a sponsor.
5. Optionally, edit the fields as needed.

Remove a study's sponsor

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. In the Project Explorer, expand the study folder, and select **Administration**.
3. Select the Sponsor tab.
4. In the **Sponsor Name** drop-down list, select a sponsor.
5. Click the **Clear Sponsor** button at the top of the tab.

System settings

In this section:

- Configure system settings
- Restore the default system settings
- Delete system settings

Configure system settings

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Expand the study folder, and select **Administration**.
3. Select the System Settings tab.
4. In the **Settings** drop-down list, select the InForm release you are deploying the study to.
5. In the Value column, select the value for each setting.

Restore the default system settings

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Expand the study folder, and select **Administration**.
3. Select the System Settings tab.
4. In the **Settings** drop-down list, make sure the InForm release you are deploying the study to is selected.
5. Click the **Restore Defaults** button at the top of the tab.

Delete system settings

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Expand the study folder, and select **Administration**.
3. Select the System Settings tab.
4. In the **Settings** drop-down list, make sure the InForm release you are deploying the study to is selected.
5. Click the **Remove Settings** button at the top of the tab.

Item groups

In this section:

- Create an item group and add items to it
- Remove items from an item group

Create an item group and add items to it

> **Tip:**
>
> Group items based on access rights. For example, you can create a group of items to hide from users' view or a group of items to make read-only for a group of users. For more information, see the InForm documentation.

Prerequiste: A form designer must create all of the items for a study before you can group them into item groups.

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Expand the study folder, and select **Administration**.
3. Select the Item Groups tab.
4. In the top-left corner of the tab, click the **Create item group(s)** icon.
5. Enter a group name and description for the new item group.
6. Click **Add**.
7. In the Item Group—Add Itemsdialog box, select the items to include in the group.

   Optionally, you can search for specific items.
8. Click **OK**.

> **Tip:**
>
> To select all of the items in the list, click the checkbox in the column headings.

9. Click **Create**.

   The item group you added appears in the top grid of the Item Groups tab. Its associated items appear in the bottom grid.
10. Next, create a rights group and add item groups to it.

Remove items from an item group

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Expand the study folder, and select **Administration**.
3. Select the Item Groups tab.
4. In the top table, highlight the row for the item group you want to remove an item from by clicking the box on the left.
5. In the bottom table, highlight the row for the item you want to remove by clicking the box on the left, and click **Remove**.
6. To confirm the deletion, click **Yes**.

Query groups

In this section:

- Create a query group

Create a query group

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Expand the study folder, and select **Administration**.
3. Select the Query Groups tab.
4. In the grid, enter a name and description for the query group.

5. Next, after deployment, an Oracle InForm administrator adds users to the query group.

Rights groups

In this section:

- Create a rights group and add item groups to it
- Delete an item group from a rights group

Create a rights group and add item groups to it

Prerequisite: Create an item group and add items to it.

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Expand the study folder, and select **Administration**.
3. Select the Rights Groups tab.
4. In the top-left corner of the tab, click the **Create rights group(s)** icon.
5. Enter a group name and description for the new rights group.
6. Click **Add**.
7. In the Rights Group—Add Item Groups dialog box, select the groups of items to include in the rights group.

   Optionally, you can search for specific items.

   > **Tip:**
   >
   > To select all of the item groups in the list, click the checkbox in the column next to the **Item Group Name** column.

8. For each item group you select, in the Display Override column, select the display setting for the items in the group:
   a. Editable—Items are visible and editable by any user, regardless of the rights assigned to the user.
   b. Hidden—Items are not visible.
   c. ReadOnly—Items are visible but not editable.
9. Click **OK**
10. Click **Create**.

    The rights group you added appears in the top grid of the Rights Groups tab. Its associated item groups appear in the bottom grid.
11. Click **OK**.
12. Next, after the study is deployed, an Oracle InForm administrator adds rights and users to the rights group.

Delete an item group from a rights group

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.

2. Expand the study folder, and select **Administration**.
3. Select the Rights Groups tab.
4. In the top grid, highlight the row for the rights group by clicking the box on the left.
5. In the bottom grid, highlight the row for the item group by clicking the box on the left, and click **Remove**.
6. To confirm the deletion, click **Yes**.

Signature groups

In this section:

- Create a signature group
- Enter translation text for a signature affidavit
- Remove forms from a signature group

Create a signature group

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Expand the study folder, and select **Administration**.
3. Select the Signature Groups tab.
4. In the top-left corner of the tab, click the **Create signature group(s)** icon.
5. In the New Signature Group dialog box, enter a name and description for the signature group and the following information:
   - Invalidation Level—When to invalidate a signature when a hidden item on a form is modified.
     - User—Invalidate the signature if the signer can see the item that changed.
     - Group—Invalidate the signature if at least one signer in the signature group cannot see the item that changed.

     > **Tip:**
     >
     > To prevent signature invalidation when Central Coding updates an item, set the invalidation level to **User**.

   - Reset Form State—Select to indicate whether associating a new signature group with a signed form resets the state of the form to Unsigned in InForm. The original signatures remain valid, but the form requires a signature from a member of the newly associated group.
   - Type—Type of object the users in the group can sign.
     - CRB—Case Report Books.
     - CRF—Forms.
     - CRB, CRF—Case Report Books and forms.

> **Note:**
>
> If a Visit Approval form is created, you have to add it to one of your CRF Signature Groups.

6. Click **Add** and select the checkboxes of the forms you want to add.
7. Click **OK**.
8. Next,Enter translation text for a signature affidavit .

Enter translation text for a signature affidavit

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Expand the study folder, and select **Administration**.
3. Select the Signature Groups tab.
4. Select the signature group you want to enter signature affidavit translation text for.
5. In the Translations grid in the **Language** drop-down list, select the language to use for the signature's meaning and text.
6. In the **Signature Meaning** drop-down list, select the meaning of the signature or enter the meaning.

> **Tip:**
>
> If you are using the English-United States language, you can select from a predefined list, which includes **Approved** and **Reviewed**.

7. In the row for the language you are using, click **View/Edit**.
8. In the Signature Text dialog box, enter the text you want to use for the signature affidavit, and click **OK**.

> **Tip:**
>
> If you are using the English-United States language and want to use the default affidavit text, select the **Use default text (available for English – United States Locale only)** checkbox.

Remove forms from a signature group

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Expand the study folder, and select **Administration**.
3. Select the Signature Groups tab.
4. In the top grid, highlight the signature group from which to remove a form by clicking the box on the left.
5. In the middle grid, highlight the form to remove by clicking the box on the left and click **Remove**.

Export study administration data for use in a user management tool

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Right-click the study, and select **Export Study**.
3. In the Export Data wizard, click **Next**, and on the Export Type page, select **Administration data**.
4. Click **Next** to progress through the wizard, and **Finish** to export the study administration data.

For more information, see:

- Export Wizard options

Export Wizard options

Page	Option	Description
Welcome	-	Introduction page.
Export Type	-	Select the output format and export type.
-	Data Type	**CSML**—Export in Clinical Study Markup Language format. **ODM**—Export in Operational Data Model-compliant format. The Oracle Central Designer application supports the ODM 1.3 standard. **Administration data**—Export only study administration data for the User Management Tool application.
-	Export Type	**Local**—Export to the computer where the Oracle Central Designer application is installed.
Export File Path	Export Directory	Specify the path name and file in which to save the export file, or click Browse to browse for the path name and file in which to save the export file.
Ready to Export Central Designer Data	-	View a summary of the parameters that will be used for the export.

(Optional) Create predefined sets of drop-down list options, radio buttons, or checkboxes (codelist subsets) in a study

In this section:

- Step 1: Create a drop-down list or set of radio buttons or checkboxes (a codelist with codelist items)
- Step 2: Define sets of drop-down list options, radio buttons, or checkboxes (codelist subsets)
- Step 3: Require study designers to select subsets when they are defined for a codelist (Optional)
- Delete a codelist subset

Step 1: Create a drop-down list or set of radio buttons or checkboxes (a codelist with codelist items)

1. At the bottom of the Project Explorer, click the **Items** () button, and expand the InForm Items folder.
2. On the Design tab, in the Codelist Settings section, select one of the following:
   a. Select Single Value—Allow users to select only one option in the list of codelist items.
   b. Select Multiple Values—Allow users to select more than one option in the list of codelist items. If you select this option, you must also enter the minimum and maximum number of checkboxes the user can select.
3. At the top of the page, select the Layout tab.
4. If you haven't already done so, click **Create Layout**.
5. On the right of the page, right-click the codelist that you just created, select **Control Type**, and indicate whether you want to create a set of options in a drop-down list, radio buttons, or checkboxes.

Step 2: Define sets of drop-down list options, radio buttons, or checkboxes (codelist subsets)

1. At the bottom of the Project Explorer, click the **Codelists** () button.
2. In the Project Explorer, expand the **Codelists** folder, and select the codelist you created in Step 1.
3. At the top of the page, select the Subsets tab.
4. Do one of the following:
   - To copy an existing subset, in the top half of the page, select the subset, and click **Replicate**.
   - a. In the top half of the page, click in the last row.
     b. Enter a description for the subset, and press **Enter** or **Tab** to save the changes.

c. Highlight the row.

d. At the bottom right, click **Add**.

e. Select the codelist items to add to the subset, and click **OK**.

f. On the bottom right of the page, use the **Move Up** and **Move Down** buttons to configure the order of the codelist items in the subset.

Step 3: Require study designers to select subsets when they are defined for a codelist (Optional)

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. In the Project Explorer, select the study name.
3. Make sure the General tab is selected.
4. In the Study Restrictions section, select **Require codelist subset selection**.

> **Tip:**
>
> This setting applies to the entire study. Therefore, a study designer who uses a codelist with defined subsets must select a subset.

Delete a codelist subset

1. At the bottom of the Project Explorer, click the **Codelists** ( ) button.
2. Expand the **Codelists** folder, select a codelist, and then select the Subset tab.
3. In the grid at the top, highlight the row for the subset you want to delete by clicking the box on the left.
4. Click **Remove** and confirm the deletion.

> **Tip:**
>
> To locate the item instances that use the codelist with the deleted subset, generate an annotated study book and look at the Codelist Values tables.

(Optional) Create review states and stages for use in the InForm Data Viewer

Show me how to create review states

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Expand the **InForm** folder, right-click **Review States**, and select **New Review State**.
3. Enter a title, RefName, and description, and click **OK**.

> **Tip:**
>
> - If you create a review state to replace a deleted review state, the new review state must have the same RefName and state number as the review state that was deleted.
> - After you deploy the study to InForm, you cannot change the state number or any RefNames in the review state. If you do so, deployment fails.

4. In the Project Explorer, expand the **Review States** folder, and select the review state you created.
5. In the English (United States) tab and, optionally, in the Japanese (Japan) tab, enter the following for the review state:
   - Label—Name for the review state, which appears in hover Help and drop-down lists in InForm.
   - Mnemonic—Abbreviated name for the review state, which appears in column headings in the Data Viewer in InForm.
6. In the Stage 1, Stage 2, and Stage 3 sections, enter the following for each review stage in the review state:
   - Name—RefName of the review stage. Each RefName must be unique within its review state.

     > **Tip:**
     >
     > If you change the RefName property of a stage before deploying, but after developing rules, make sure to update any rules that refer to the stage.

   - Label—Name for the review stage, which appears in hover Help and drop-down lists in InForm.
   - Mnemonic—Abbreviated name for the review stage, which appears in column headings in the Data Viewer in InForm.

   > **Tip:**
   >
   > The Label and Mnemonic fields for the review state and each review stage are required for each InForm product locale (English and Japanese). If a required value is missing in a product locale tab, the value from the other locale (if it is defined) appears in the field in red, and an icon appears in the tab to indicate that translation is required. Study validation also checks for missing translated values. Because both English and Japanese locales are always required for review states, the study definition does not need to have the Japanese locale selected, and you do not need the Japanese language skill to translate the review state fields.

7. Create up to five review states with three stages each.

(Optional) Restrict study design activities

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. In the Project Explorer, select the study name, and make sure the General tab is selected.
3. In the Study Restrictions section, select one or more of the following:
   - Restrict study designers from creating new forms or sections in a study—Study designers can drag and drop library forms and sections into the study, but cannot create new forms or add sections to forms in the study.
   - Restrict study designers from creating new items on forms from libraries—Study designers can drag and drop library forms into the study, but cannot add items to those forms.
   - Restrict study designers from modifying certain properties of items from libraries—Study designers can drag and drop library items into the study, but cannot modify the item Length, RefName, Short Question, Signed Value (integer items only), or Precision (float items only).
   - Restrict study designers from modifying codelists from libraries—Study designers can drag and drop library codelists into the study, but cannot modify the codelist, its codelist items, or its codelist subsets.
   - Require codelist subset selection—When study designers drag and drop codelists with defined subsets into the study, they must select a codelist subset for each item instance they drag and drop the codelist on. The restriction applies to items that exist in the study design, have one or more codelists, and have subsets defined for the codelists.

(Optional) Attach a reference to a study

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Select a study, and select the References tab.
3. In the Title field in the top grid, type a name for the reference.
4. In the bottom-right corner, click **Add File**, and select the file you want to attach to the study.

Lock the study administration data settings

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. To explicitly lock a StudyAdministration object, right-click the **Administration** folder, and select **Lock**.

> **Note:**
>
> When you lock and unlock the StudyAdministration object, the following objects are also locked and unlocked: Sponsor, StudyConfiguration, ItemGroup, RightsGroup, QueryGroup, and SignatureGroup.

(Optional) Remove a reference from a study

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Select a study, and select the References tab.
3. In the Attachments section, select a file, and click **Remove**.

(Optional) Set up your study for coding

In this section:

- Select dictionary types and verbatim types for a study

Select dictionary types and verbatim types for a study

Show me how to set up coding

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. In the Project Explorer, select the **InForm folder**, and make sure the Coding tab is selected.
3. In the **Dictionary Types** list, select the checkbox for the dictionary types to add to the study or library.
4. For each selected dictionary type, in the **Verbatim Types for <Dictionary Name>** list, select the types of verbatims the dictionary uses.

3

Create and configure a library

In this chapter:

- Create a library
- Set the primary layout for a library
- Select the supported locales for a library
- Choose the default locale for a library
- Set up library teams
- Add a study object or library object to a library
- Categorize a study object
- Create predefined sets of drop-down list options, radio buttons, or checkboxes (codelist subsets) in a library
- Create a study object template
- Create an item type
- Mark an item as mandatory
- Protect a library and all its objects
- Unprotect a library
- Publish an object to make it available to copy into a study
- Publish, republish, or unpublish a library to make its objects available to copy into a study
- Disable a library

Create a library

1. At the top of the Oracle Central Designer window, click **File**, then select **New Library Project**.
2. Type names and descriptions of the project and the library.
3. In the Targets section, make sure InForm is selected, and click **OK**.

Set the primary layout for a library

1. In the library project, in the upper-left corner, click **Tools**, then select **Layout Names Manager**.
2. In the Primary layout name section, select **Main** as the primary layout, or select a layout you created, then click **OK**.

Select the supported locales for a library

1. In the library project, at the bottom of the Project Explorer, click the **Library Information** () button.
2. Select the library, and select the Languages tab.
3. In the **Languages/Locales** list, select the locale or locales for the library.

Choose the default locale for a library

1. In the library project, in the upper-left corner, click **Tools**, then select **Options**.
2. In the **Default locale** drop-down list, select a locale, and click **OK**.

Set up library teams

In this section:

- Add a user to a library team
- Remove a user from a library team
- Save a search in the Users tab

Add a user to a library team

Prerequisite: A Oracle Central Designer administrator must add the user to the corresponding library role in the Oracle Central Designer Administrator. For example, to create rules in a library, a user must be assigned to the Rule Creation library role in the Oracle Central Designer Administrator and the Rule Creation library team for the library.

1. In the library project, at the bottom of the Project Explorer, click the **Library Information** () button.
2. Select the library, and select the Teams tab.
3. In the [Study name] - Teams section, select the team to which you want to add the user.
4. Click the Users tab, which appears on the right of the page by default.

> **Tip:**
>
> If you don't see the Users tab, at the top left of the page, select **View**, and make sure **Users** is selected.

5. Do one of the following:
   - Create a new search
     a. Optionally, name the search.
        i. At the top of the tab, select **Actions**, and select **New Search**.

ii. Type a name for the search, and click **OK**.

b. In the Enter search text field, enter part or all of the user's name, display name, title, first name, or last name.

c. Optionally, to include categories and keywords as parameters, click the down arrows button () next to the Search Filter, and then:

– Select the Categories tab, and select one or more categories.

– Select the Keywords tab, and select one or more keywords.

- Open a saved search

a. At the top of the Users tab, select **Actions**, and select **Open Search from Repository**.

b. Select a search, and click **Open**.

6. Click **Find**.
7. Select the user that you want to add, and drag the user to the section at the right.

Remove a user from a library team

1. In the library project, at the bottom of the Project Explorer, click the **Library Information** () button.
2. Select the library, and select the Teams tab.
3. In the left section, right-click the user, and select **Remove from Team**.

Save a search in the Users tab

1. In the library project, at the bottom of the Project Explorer, click the **Library Information** () button.
2. Select the library, then select the Teams tab.
3. In the [Study name] - Teams section, select the team.
4. Click the Users tab, which appears on the right of the page by default.

> **Tip:**
>
> If you don't see the Users tab, at the top left of the page, select **View**, and make sure **Users** is selected.

5. At the top of the tab, select **Actions**, and select **Save Search to Repository**.
6. Optionally, type a description for the search, and select an option:
   - Just me—Only you can see and use the search.
   - Everyone—Everyone can see and use the search.
7. Click **Save**.

Add a study object or library object to a library

1. Open the library project you want to add the study object to.
2. In the library project, at the bottom of the Project Explorer, click the **Library Information** () button.
3. On the left of the page, open the folder where you want to drop the study object.

   For example, if you're searching for a codelist, click **Codelists** ().
4. Search for the study object you want to add to the library.
   a. Click the Libraries tab, which appears on the right of the page by default.

      > **Tip:**
      >
      > If you don't see the Libraries tab, at the top left of the page, select **View**, and make sure **Libraries** is selected.

   b. Enter search text and/or use the tabs to search by category, keyword, library, or study.

      > **Tip:**
      >
      > - If you search by study, to select all available studies, at the top of the filter click **Check All Studies in Repository Results**.
      > - If you search by library, at the top of the filter:
      >   To select all available libraries, select **Check All Libraries in Repository Results**.
      >
      >   To search on the latest versions of each object in the selected libraries, select **Include latest object revisions in Repository**.

   c. Click **Find**.
5. Drag the object from the Libraries tab to the folder in the Project Explorer.
6. Indicate whether you want to add a link to the object or create a copy of the object, then click **OK**.

Categorize a study object

Why should I categorize objects?

You categorize objects with keywords and categories to facilitate searching for the objects in the Libraries Browser.

1. In the library project, at the bottom of the Project Explorer, click the **Library Information** () button.
2. In the Project Explorer, right-click a study object, and select **Categorize**.

3. Do one or more of the following:
   a. Select one or more the categories on the Categories tab, and click **Next**.
   b. On the Keywords tab, select or enter keywords to associate with the object.
4. Click **Apply**.

Create predefined sets of drop-down list options, radio buttons, or checkboxes (codelist subsets) in a library

In this section:

- Step 1: Create an item to collect data on forms
- Step 2: Create a drop-down list or set of radio buttons or checkboxes (a codelist with codelist items)
- Step 3: Define sets of drop-down list options, radio buttons, or checkboxes
- Step 4: Require an item to use assigned codelists and subsets (Optional)

Step 1: Create an item to collect data on forms

1. At the bottom of the Project Explorer, click the **Items** () button, and expand the **InForm Items** folder.
2. To the right of the Project Explorer, click the **New** button at the top of the workspace.
3. From the drop-down list, select the type of item to add:
   - Blood pressure—To collect blood pressure information.
   - Compound—To create an item with one or more child items that can be different data types.
   - Date Time—To collect date and time information.
   - Float—To collect numerical values with decimal points, or information for a question with a codelist (a control such as a drop-down list, a set of checkboxes, or a set of radio buttons).
   - Integer—To collect numerical values without decimal points, or information for a question with a codelist (a control such as a drop-down list, a set of checkboxes, or a set of radio buttons).
   - Text—To collect alphanumeric information, or information for a question with a codelist (a control such as a drop-down list, a set of checkboxes, or a set of radio buttons).
   - Yes or No—To collect yes or no answers to questions. A Yes No item contains a predefined codelist with Yes and No options.
4. Enter a Title, RefName, and, optionally, a Description of the item, and click **OK**.
5. Select the new item and, above the grid, click the **Columns** button.

   You may have to scroll to the bottom of the items list to see the new item.
6. Add the columns for the properties you want to configure for the item.

7. In the grid, enter data in the columns, as needed. At the top of the grid, click the **Properties** button, add additional properties for the item, and click **OK**.
8. Click **OK**.

Step 2: Create a drop-down list or set of radio buttons or checkboxes (a codelist with codelist items)

1. At the bottom of the Project Explorer, click the **Items** () button, and expand the **InForm Items** folder.
2. On the Design tab, in the Codelist Settings section, select one of the following:
   - Select Single Value—Allow users to select only one option in the list of codelist items.
   - Select Multiple Values—Allow users to select more than one option in the list of codelist items. If you select this option, you must also enter the minimum and maximum number of checkboxes the user can select.
3. At the top of the page, select the Layout tab.
4. If you haven't already done so, click **Create Layout**.
5. On the right of the page, right-click the codelist that you just created, select **Control Type**, and indicate whether you want to create a set of options in a drop-down list, radio buttons, or checkboxes.

Step 3: Define sets of drop-down list options, radio buttons, or checkboxes

1. At the bottom of the Project Explorer, click the **Codelists** () button.
2. In the Project Explorer, expand the **Codelists** folder, and select the codelist you created in Step 1.
3. At the top of the page, select the Subsets tab.
4. Do one of the following:
   - To copy an existing subset, in the top half of the page, select the subset, and click **Replicate**.
   - To create a new subset:
     a. In the top half of the page, click in the last row.
     b. Enter a description for the subset, and press **Enter** or **Tab** to save the changes.
     c. Highlight the row.
     d. At the bottom right, click **Add**.
     e. Select the codelist items to add to the subset, and click **OK**.
        – On the bottom right of the page, use the **Move Up** and **Move Down** buttons to configure the order of the codelist items in the subset.

Step 4: Require an item to use assigned codelists and subsets (Optional)

1. At the bottom of the Project Explorer, click the **Items** () button, and expand the **InForm Items** folder.
2. In the Project Explorer, select an item that has a codelist with assigned subsets.
3. Click the Properties tab, which appears on the right of the page by default.

> **Tip:**
>
> If you don't see the Properties tab, at the top left of the page, select **View**, and make sure **Properties** is selected.

4. Set the following to False:
   - Change assigned codelist
   - Change assigned subset

> **Tip:**
>
> You only need to configure these settings one time per item. The settings apply to every instance of the item.

Create a study object template

1. In the library project, at the bottom of the Project Explorer, click the **Library Information** () button.
2. At the bottom of the Project Explorer, click the **Items** () button, and expand the **InForm Items** folder.
3. In the Project Explorer, right-click the study object, and select **Set Advanced Options**.
4. Make sure **Mark as Template** is selected, and click **OK**.
5. Save your project.
6. To make the template available for use:
   a. At the bottom of the Project Explorer, click the **Types and Templates** () button and expand the **InForm** folder and the **InForm Items** folder, if necessary.
   b. Right-click the template, and select **Publishing**, then select **Publish**.
   c. Click **OK** to the confirmation message.

Create an item type

1. In the library project, at the bottom of the Project Explorer, click the **Library Information** () button.

2. At the bottom of the Project Explorer, click the **Items** () button, and expand the **InForm Items** folder.
3. In the Project Explorer, right-click the study object, and select **Set Advanced Options**.
4. Select **Mark as Type** and click **OK**.
5. Save your project.
6. To make the item type available for use:
   a. At the bottom of the Project Explorer, click the **Types and Templates** () button and expand the **InForm** folder and the **InForm Items** folder, if necessary.
   b. Right-click the template, and select **Publishing**, then select **Publish**.
7. Click **OK** to the confirmation message.

Mark an item as mandatory

Show me how to mark an item as mandatory
You can mark a top-level item as mandatory for the form or section you're working in so that study designers cannot delete it or its nested items when they use the form or section in their study.

1. At the bottom of the Project Explorer, click the **Forms and Transactions** () button, and expand the **InForm** folder and the **Forms** folder, if necessary.
2. Select the form or section with the item you want to mark as mandatory.
3. At the top of the Design tab, click **Mandatory Items**.
4. Select the item instances you want to make mandatory, and click **OK**.

> **Tip:**
>
> - If the item is used in more than one section on a form, set each instance as mandatory or not mandatory.
> - If the item is used more than one time in a section (as a top-level item and again within a compound item), the mandatory setting only applies to the top-level item instance.

Protect a library and all its objects

1. In the library project, at the bottom of the Project Explorer, click the **Library Information** () button.
2. In the Project Explorer, right-click the library, and select **Protect**.

> **Tip:**
>
> If any study objects in the library are locked, you must unlock them before you protect the library. The error message tells you which objects are locked.

Unprotect a library

1. In the library project, at the bottom of the Project Explorer, click the **Library Information** () button.
2. Right-click the library and select:
   - Unprotect—Unprotect the object only.
   - Unprotect with Children—Unprotect the object and all of its child objects.

Publish an object to make it available to copy into a study

1. In the library project, at the bottom of the Project Explorer, click the **Library Information** () button.
2. At the bottom of the Project Explorer, click the **Items** () button, and expand the **InForm Items** folder.
3. In the Project Explorer, right-click the object, and:
   - To publish—Select **Publishing**, then select **Publish**.
   - To republish a published object that you modified—Select **Publishing**, then select **Republish**.
   - To unpublish a published object—Select **Publishing**, then select **Unpublish**.
4. If prompted, confirm the action you want to take, and click **OK**.

> **Tip:**
>
> - Publish and reuse study objects at the highest-level study object that makes sense. For example, consider publishing and reusing forms rather than individual items, unless you specifically need individual items to be available in a library. A reused form can save you more time than a reused item.
> - Where possible, consider publishing and reusing study events and study elements rather than forms.
> - Consider publishing codelists and codelist items so they can be shared and reused.

Publish, republish, or unpublish a library to make its objects available to copy into a study

1. In the library project, at the top of the Oracle Central Designer window, click **File**, and select **Save Project**.
2. In the library project, at the bottom of the Project Explorer, click the **Library Information** () button.
3. Do one of the following:
   - To publish—In the Project Explorer, right-click a library, and select **Publish Study**, then select **Publish**.
   - To republish—In the Project Explorer, right-click a library, and select **Publish Study**, then select **Republish**.
   - To unpublish—In the Project Explorer, right-click a library, and select **Publish Study**, then select **Unpublish**.
4. If prompted, confirm the action you want to take, and click **OK**.

Disable a library

1. In the library project, at the bottom of the Project Explorer, click the **Library Information** () button.
2. In the Project Explorer, right-click the library, and deselect **Enable Library**.

4

Import and export study objects

In this chapter:

- Import study object into a library or study
- Export a study or library to a file

Import study object into a library or study

In this section:

- Import study objects
- View completed import jobs
- Importing translated text strings
- Checking for empty strings

Import study objects

1. In a study, at the bottom of the Project Explorer, click the **Study Information** ( ) button.

   or

   In a library, at the bottom of the Project Explorer, click the **Library Information** ( ) button.
2. In the Project Explorer, right-click a study or library, and select **Import Study**.
3. Click **Next** to start the Oracle Central Designer Import Wizard.
4. Complete the pages of the Oracle Central Designer Import Wizard. Click **Next** after you finish filling in each page. On the Import Type page, select the source of the data to import.
   - Based on your selections, the Oracle Central Designer Import Wizard prompts you to enter specific information as you progress through the wizard.
   - After you select a file to import and click **Next**, the wizard reviews all the study objects in the file. This process might take several minutes.
5. On the final page of the Oracle Central Designer Import Wizard, click **Finish**. If you are importing a CSML file containing study objects for a system that is not selected as a Deployment System for the study or library, a message appears; choose one of the following options:
   - Continue with the import, and select all the systems in the CSML file as Deployment Systems. If you choose this option, continue to the next step.
   - Cancel the import.

   A message pops up in the lower-right corner when the job starts and completes.

> **Note:**
>
> If you uninstall a deployment system, you cannot import a CSML file that contains study objects for that system.

Table 4-1 Import Wizard options - CSML or ODM file

Page	Option	Description
Welcome	-	Introduction page.
Import Type	-	Select the source of the data to import.
-	Import CSML or ODM file	Generate study objects from a file in CSML or ODM format.
-	Harvest InForm Resources	Generate study objects from the components of an InForm study.
File Location	Path of file to import	Specify the path of the CSML or ODM import file, or click Browse to locate the import file.
Study Administration Import Mode	-	This page appears only for the CSML import type, if the CSML file contains study administration objects.
-	Import study objects and administration data.	Import both study objects and study administration objects.
-	Import administration data only.	Import only study administration objects.
-	Import study objects only.	Import only study objects.
Rule Import Mode	Rule Import Mode	Only the Import as Collaboration Notes option is supported. With this option, each imported rule is converted to a collaboration note in the Oracle Central Designer application. **Note:** This option applies only if the Import Type is ODM; if the Import Type is CSML, the import process creates a Oracle Central Designer rule for each imported rule.
IPR Import Mode	Import IPR data	Select whether to import in-place revision objects. **Note:** This page appears only if the file contains in-place revision objects.
Ready to Import Data to Central Designer	-	View a summary of the import options selected in the wizard.

Table 4-2 Import Wizard options - InForm resources

Page	Option	Description
Welcome	-	Introduction page.
Import Type	-	Select the source of the data to import.
-	Import CSML or ODM file	Generate study objects from a file in CSML or ODM format.
-	Harvest InForm Resources	Generate study objects from the components of an InForm study.
InForm File Location	-	Select the file or trial from which to harvest resources.
-	RSP or XML file	Specify the full path of the RSP or XML file containing MedML definitions of InForm trial components to import, or click Browse to browse to the file.
Rule Import Mode	Rule Import Mode	Only the Import as Collaboration Notes option is supported. With this option, each imported rule is converted to a collaboration note in the Oracle Central Designer application.
Ready to Import Data to Central Designer	-	View a summary of the import options selected in the wizard.

View completed import jobs

1. In a study, at the bottom of the Project Explorer, click the **Study Information** ( ) button.

   or

   In a library, at the bottom of the Project Explorer, click the **Library Information** ( ) button.
2. In the Project Explorer, select a study or library and click the Jobs tab, which appears on the right of the page by default.

   > **Tip:**
   >
   > If you don't see the Jobs tab, at the top left of the page, select **View** and make sure **Job Log** is selected.
3. (Optional) In the Jobs Since list, you can select the period for which you want to view job results. You can also sort the list by the various columns.
4. Click **Refresh**.
5. Select a job and, on the toolbar, click **Show Job Results**, and expand the results for the job by clicking the plus sign to the left of the job name.

Importing translated text strings

To import translated text strings successfully, make sure that the translation file is in the correct format and that all requirements for character formatting are met.

1. In a study, at the bottom of the Project Explorer, click the **Study Information** ( ) button.

   or

   In a library, at the bottom of the Project Explorer, click the **Library Information** ( ) button.
2. In the Project Explorer, right-click a study or library, and select **Translations**, then **Import**.
3. Browse to the location of the CSV file containing the translated strings to import and click **Import**.

   Oracle Central Designer imports each text string to the study object specified in the CSV file. Status messages appear in the **Import log results** field. If an entry cannot be imported (for example, if the import process cannot acquire a lock on the target study object), a message is written to the import log, and the import continues with the next entry. You can re-import the file to process modified or corrected entries.
4. To save the import file messages, click **Save Log Results As**, and select a location.

> **Tip:**
>
> - You can interrupt the import process by clicking **Stop**. No further records are updated, but records that were updated before the stop remain in the study.
> - You can also undo a string import.

Checking for empty strings

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. In the Project Explorer, select a study.
3. In the upper-left corner, click **Actions**, select **Translations**, then **Check for Empty Strings**.
4. In the **Locale** drop-down list, select the locale to check.
5. Click **Run**. The empty strings in the study appear in the Empty strings for study < study name> grid.
6. To navigate to the location of an empty string, click the button at the left of the Owner RefName column, and select **Goto empty string**.

Export a study or library to a file

In this section:

- Export a study or library
- Export text strings for translation

Export a study or library

1. In a study, at the bottom of the Project Explorer, click the **Study Information** ( ) button.

   or

   In a library, at the bottom of the Project Explorer, click the **Library Information** ( ) button.
2. In the Project Explorer, right-click the study or library from which you want to export study objects, and select **Export Study**.
3. Click **Next** to start the Oracle Central Designer Export Wizard.
4. Complete the pages of the Oracle Central Designer Export Wizard. Click **Next** when you finish filling out each page.
5. On the final page of the Oracle Central Designer Export Wizard, click **Finish**.

   An export file is created in the location you specified in the wizard.

> **Note:**
>
> - If errors result when you export to the ODM format, a dialog box containing the errors appears.
> - If an error appears and indicates that an element has incomplete content, you can ignore the error.

Table 4-3 Export Wizard options

Page	Option	Description
Welcome	-	Introduction page.
Export Type	-	Select the output format and export type.

Table 4-3 (Cont.) Export Wizard options

Page	Option	Description
-	Data Type	CSML—Export in Clinical Study Markup Language format. ODM—Export in Operational Data Model-compliant format. The Oracle Central Designer application supports the ODM 1.3 standard. Administration data—Export only study administration data for the User Management Tool application.
-	Export Type	Local—Export to the computer where the Oracle Central Designer application is installed.
Export File Path	Export Directory	Specify the path name and file in which to save the export file, or click Browse to browse for the path name and file in which to save the export file.
Ready to Export Central Designer Data	-	View a summary of the parameters that will be used for the export.

Export text strings for translation

1. In a study, at the bottom of the Project Explorer, click the **Study Information** ( ) button.

   or

   In a library, at the bottom of the Project Explorer, click the **Library Information** ( ) button.
2. In the Project Explorer, right-click a study or library, and select **Translations**, then **Export**.
3. Fill in the fields of the dialog box. For more information, see Export Translations dialog box—Option descriptions.
4. Click **Export**.

   Oracle Central Designer exports all of the text strings that match the selected criteria and saves them in CSV format in the location you specified. Status messages appear in the Export log results field.
5. To save the export log file, click **Save Log Results As** and select a location.

Tip:

- You can interrupt the export process by clicking **Stop**.
- No further records are written to the output file.You can also undo a string import.

5

Use tasks and notes to create collaboration

In this chapter:

- Create and modify tasks and notes
- Interact with assigned tasks

Create and modify tasks and notes

In this section:

- Create a task
- Create a collaboration note
- Change the assignees for a standard task
- Edit a task or collaboration note
- Delete a task or collaboration note
- Print a task or collaboration note

Create a task

> **Note:**
>
> You must save a study object before you can attach a collaboration note or task.

1. In the Project Explorer, select a study object.
2. Click the **Tasks** tab, which appears at the bottom by default, and click **New Task**.

   > **Tip:**
   >
   > If you don't see the Tasks tab, at the top left of the page, select **View**, and make sure **Tasks** is selected.

3. From the **Task Type** drop-down list, select the type of task to create. (Task types are defined in Oracle Central Designer Administrator.)
4. From the **Priority** drop-down list, choose a priority for the task.
5. From the **Due** drop-down list, choose the date that the task is due.
6. On the **Instructions** tab, type the instructions for the task.
7. To edit the appearance of the text, use the buttons on the toolbar.
8. To add an attachment, complete the following steps:

a. Click the **Attachments** button ( ).

b. Click **Add**.

c. Navigate to a file and click **Open**.

d. Click **OK**.

> **Note:**
>
> The maximum size of the attachment is determined by a variety of factors, including information defined in the configuration file, available hard disk space, and available memory. To determine the approximate maximum attachment size, check the maxRequestLength attribute in the machine.config file.

9. Do one of the following:

- If you are creating a Standard task, select the **Assignment** tab and choose the team (or teams) or user (or users) to assign the task to.
- If you are creating a Translation task, select the **Languages** tab and choose the languages to which the task must be translated. (Only the languages configured as supported locales in the Oracle Central Designer Administrator application appear.)

> **Note:**
>
> You must assign every task to at least one individual or team. For translation tasks, the default assignment for the task type is used.

10. Click **OK**.

Option descriptions for Task Editor dialog box

The second tab that appears in the Task Editor dialog box depends on the type of task that is selected. For standard tasks, the dialog box has an Instructions tab, and for translation tasks, the dialog box has an Assignment tab.

Option	Description
Top toolbar	-
Accept, Complete, Close, Reopen, Unaccept	Accept, complete, close, reopen, and unaccept a task.
Top section	-
Study	(READ-ONLY) Study with the study object to which the task is attached.
Object Name	(READ-ONLY) Study object to which the task is attached.
Object Type	(READ-ONLY) Type of study object on which the task was created.
Created	(READ-ONLY) Date and time the task was created.

Option	Description
Requested By	(READ-ONLY) User who created the task.
Status	(READ-ONLY) Status of the task (Open, Accepted, Completed, or Closed).
Task Type	(REQUIRED.) Type of the task. An administrator defines task types in the Oracle Central Designer Administrator application.
Priority	(REQUIRED.) Priority of the task. Options are Critical, High, Medium, and Low.
Due	(REQUIRED.) Deadline for when the task must be completed. **Default value**—Current date and time.
Owner	(READ-ONLY) Person or team to which the task is assigned.
Completed By	(READ-ONLY) User who completed the task.
Completed Date	(READ-ONLY) Date and time the task was completed.
Instructions tab (Appears for standard tasks only)	-
Instructions text field	Text for the task.
Assignment tab (Appears for translation tasks only)	-
[List of roles]	List of roles to which the task can be assigned. If an administrator specified a default role to which the task type is assigned, the role is selected.

> **Note:**
>
> Use the buttons on the toolbar to add an attachment and format the text.

Create a collaboration note

> **Note:**
>
> You must save a study object before you can attach a collaboration note or task.

1. In the Project Explorer, select a study object (study design, study element, study event, form, section, item, codelist, codelist item, mapping, data set, or data series).
2. Right-click the study object, and select **Add Collaboration Note**.
3. From the **Note Type** drop-down list, select a collaboration note type.

> **Note:**
>
> Collaboration note types are defined in the Oracle Central Designer Administrator application.

4. On the **Instructions** tab, type the instructions for the task. To edit the appearance of the text, use the buttons on the toolbar.
5. To add an attachment, complete the following steps:
   a. Click the **Attachments** button ( ).
   b. Click **Add**.
   c. Navigate to a file and click **Open**.
   d. Click **OK**.

> **Note:**
>
> Note: The maximum size of the attachment is determined by a variety of factors, including information defined in the configuration file, available hard disk space, and available memory. To determine the approximate maximum attachment size, check the maxRequestLength attribute in the machine.config file.

6. Click **OK**.

Collaboration Note Editor dialog box - Option descriptions

Option	Description
Fields	-
Study	(READ-ONLY.) Study with the study object to which the collaboration note is attached.
Object Name	(READ-ONLY.) Study object to which the collaboration note is attached.
Object Type	(READ-ONLY.) Type of study object to which you are attaching the collaboration note, such as a form or study event.
Note Type	(REQUIRED.) Type of the collaboration note. An administrator defines collaboration note types in the Oracle Central Designer Administrator application.
Author	(READ-ONLY.) User who created the collaboration note.
Instructions text field	Text for the collaboration note.

> **Note:**
>
> Use the buttons on the toolbar to add an attachment and format the text.

Change the assignees for a standard task

When the status of a task is open, you can change the assignees for a standard task, but you cannot remove all assignees from the task.

> **Note:**
>
> You cannot change the assignees for translation tasks.

1. In the Project Explorer, select a study object (study design, study element, study event, form, section, item, codelist, codelist item, mapping, data set, or data series).
2. On the **Tasks** tab, select a task.

> **Tip:**
>
> If you don't see the Tasks tab, at the top left of the page, select **View**, and make sure **Tasks** is selected.

3. On the toolbar at the top of the **Tasks List**, click **Edit**.
4. Click the **Assignment** tab.
5. Modify the users or teams to which the task is assigned. You must assign the task to at least one person or team.
6. Click **OK**.

Task Editor dialog box - Option descriptions

The second tab that appears in the Task Editor dialog box depends on the type of task that is selected. For standard tasks, the dialog box has an Instructions tab, and for translation tasks, the dialog box has an Assignment tab.

Option	Description
Top toolbar	-
Accept, Complete, Close, Reopen, Unaccept	Accept, complete, close, reopen, and unaccept a task.
Top section	-
Study	(READ-ONLY) Study with the study object to which the task is attached.
Object Name	(READ-ONLY) Study object to which the task is attached.
Object Type	(READ-ONLY) Type of study object on which the task was created.
Created	(READ-ONLY) Date and time the task was created.
Requested By	(READ-ONLY) User who created the task.
Status	(READ-ONLY) Status of the task (Open, Accepted, Completed, or Closed).

Option	Description
Task Type	(REQUIRED.) Type of the task. An administrator defines task types in the Oracle Central Designer Administrator application.
Priority	(REQUIRED.) Priority of the task. Options are Critical, High, Medium, and Low.
Due	(REQUIRED.) Deadline for when the task must be completed. **Default value**—Current date and time.
Owner	(READ-ONLY) Person or team to which the task is assigned.
Completed By	(READ-ONLY) User who completed the task.
Completed Date	(READ-ONLY) Date and time the task was completed.
Instructions tab (Appears for standard tasks only)	-
Instructions text field	Text for the task.
Assignment tab (Appears for translation tasks only)	-
[List of roles]	List of roles to which the task can be assigned. If an administrator specified a default role to which the task type is assigned, the role is selected.

> **Note:**
>
> Use the buttons on the toolbar to add an attachment and format the text.

Edit a task or collaboration note

You can edit the text of collaboration notes and tasks, and you can remove attachments from collaboration notes.

To edit the text of a task:

1. In the Project Explorer, select a study object (study design, study element, study event, form, section, item, codelist, codelist item, mapping, data set, or data series).
2. Click the **Tasks** tab, which appears at the bottom by default, and click **Edit** in the toolbar.

   > **Tip:**
   >
   > If you don't see the Tasks tab, at the top left of the page, select View, and make sure Tasks is selected.

3. Select a task.
4. Edit the task as necessary, and click **OK**.

To edit the text of a collaboration note:

1. In the Project Explorer, select a study object (study design, study element, study event, form, section, item, codelist, codelist item, mapping, data set, or data series).
2. On the **Collaboration Notes** tab, which appears at the bottom by default, and click **Edit**.

> **Note:**
>
> If you don't see the Collaboration Notes tab, at the top left of the page, select **View**, and make sure **Collaboration Notes** is selected.

3. Select a collaboration note.
4. Edit the collaboration note as necessary, and click **OK**.

To remove an attachment from a collaboration note:

1. In the Project Explorer, select a study object (study design, study element, study event, form, section, item, codelist, codelist item, mapping, data set, or data series).
2. On the **Collaboration Notes** tab, which appears at the bottom by default, and click **Edit**.

> **Tip:**
>
> If you don't see the Collaboration Notes tab, at the top left of the page, select **View**, and make sure **Collaboration Notes** is selected.

3. Click the **Attachments** button (a paperclip icon).
4. Select the file you want to remove and click **Remove**.
5. Click **OK**.

Collaboration Note Editor dialog box - Option descriptions

Option	Description
Fields	-
Study	(READ-ONLY.) Study with the study object to which the collaboration note is attached.
Object Name	(READ-ONLY.) Study object to which the collaboration note is attached.
Object Type	(READ-ONLY.) Type of study object to which you are attaching the collaboration note, such as a form or study event.
Note Type	(REQUIRED.) Type of the collaboration note. An administrator defines collaboration note types in the Central Designer Administrator application.
Author	(READ-ONLY.) User who created the collaboration note.
Instructions text field	Text for the collaboration note.

> **Note:**
>
> Use the buttons on the toolbar to add an attachment and format the text.

Task Editor dialog box - Option descriptions

The second tab that appears in the Task Editor dialog box depends on the type of task that is selected. For standard tasks, the dialog box has an Instructions tab, and for translation tasks, the dialog box has an Assignment tab.

Option	Description
Top toolbar	-
Accept, Complete, Close, Reopen, Unaccept	Accept, complete, close, reopen, and unaccept a task.
Top section	-
Study	(READ-ONLY) Study with the study object to which the task is attached.
Object Name	(READ-ONLY) Study object to which the task is attached.
Object Type	(READ-ONLY) Type of study object on which the task was created.
Created	(READ-ONLY) Date and time the task was created.
Requested By	(READ-ONLY) User who created the task.
Status	(READ-ONLY) Status of the task (Open, Accepted, Completed, or Closed).
Task Type	(REQUIRED.) Type of the task. An administrator defines task types in the Central Designer Administrator application.
Priority	(REQUIRED.) Priority of the task. Options are Critical, High, Medium, and Low.
Due	(REQUIRED.) Deadline for when the task must be completed. **Default value**—Current date and time.
Owner	(READ-ONLY) Person or team to which the task is assigned.
Completed By	(READ-ONLY) User who completed the task.
Completed Date	(READ-ONLY) Date and time the task was completed.
Instructions tab (Appears for standard tasks only)	-
Instructions text field	Text for the task.
Assignment tab (Appears for translation tasks only)	-
[List of roles]	List of roles to which the task can be assigned. If an administrator specified a default role to which the task type is assigned, the role is selected.

> **Note:**
>
> Use the buttons on the toolbar to add an attachment and format the text.

Delete a task or collaboration note

Consider deleting tasks that were created in error or that are no longer relevant. Tasks provide an audit trail for assigned activities, so you should not delete tasks if you want to maintain an audit trail of assigned activities.

> **Note:**
>
> Only the creator of a task or a user with the necessary rights can delete a task.

> **Tip:**
>
> If too many tasks appear on the Home Page, use filters to reduce the number shown. For example, view only Open or Accepted tasks.

1. In the Project Explorer, select a study object (study design, study element, study event, form, section, item, codelist, codelist item, mapping, data set, or data series).
2. Do one of the following:
   - For tasks—On the **Tasks** tab, select a task.
   - For collaboration notes—On the **Collaboration Notes** tab, select a collaboration note.
3. Click **Delete**.
4. At the confirmation message, click **Yes**.

Print a task or collaboration note

1. In the Project Explorer, select a study object (study design, study element, study event, form, section, item, codelist, codelist item, mapping, data set, or data series).
2. Do one of the following:
   - For tasks—On the **Tasks** tab, select a task.
   - For collaboration notes—On the **Collaboration Notes** tab, select a collaboration note.
3. Click **Print**.

Interact with assigned tasks

In this section:

- View all tasks assigned to you

- Accept, unaccept, complete, close, or reopen a task
- Complete an assigned task

View all tasks assigned to you

You can view all tasks assigned to you in the Home Page in the My Recent Tasks Since section and the My Tasks section.

On the toolbar, click the **Home Page** button ( ).

The Home Page appears, and the My Recent Tasks Since and My Tasks sections display tasks assigned to you.

Accept, unaccept, complete, close, or reopen a task

1. In the Project Explorer, select a study object (study design, study element, study event, form, section, item, codelist, codelist item, mapping, data set, or data series).
2. Click the **Tasks** tab, which appears at the bottom by default, and select a task.

> **Tip:**
>
> If you don't see the Tasks tab, at the top left of the page, select **View**, and make sure **Tasks** is selected.

3. At the top of the **Tasks** tab, click an action.

Task Editor dialog box - Option descriptions

The second tab that appears in the Task Editor dialog box depends on the type of task that is selected. For standard tasks, the dialog box has an Instructions tab, and for translation tasks, the dialog box has an Assignment tab.

Option	Description
Top toolbar	-
Accept, Complete, Close, Reopen, Unaccept	Accept, complete, close, reopen, and unaccept a task.
Top section	-
Study	(READ-ONLY) Study with the study object to which the task is attached.
Object Name	(READ-ONLY) Study object to which the task is attached.
Object Type	(READ-ONLY) Type of study object on which the task was created.
Created	(READ-ONLY) Date and time the task was created.
Requested By	(READ-ONLY) User who created the task.
Status	(READ-ONLY) Status of the task (Open, Accepted, Completed, or Closed).

Option	Description
Task Type	(REQUIRED.) Type of the task. An administrator defines task types in the Oracle Central Designer Administrator application.
Priority	(REQUIRED.) Priority of the task. Options are Critical, High, Medium, and Low.
Due	(REQUIRED.) Deadline for when the task must be completed. **Default value**—Current date and time.
Owner	(READ-ONLY) Person or team to which the task is assigned.
Completed By	(READ-ONLY) User who completed the task.
Completed Date	(READ-ONLY) Date and time the task was completed.
Instructions tab (Appears for standard tasks only)	-
Instructions text field	Text for the task.
Assignment tab (Appears for translation tasks only)	-
[List of roles]	List of roles to which the task can be assigned. If an administrator specified a default role to which the task type is assigned, the role is selected.

> **Note:**
>
> Use the buttons on the toolbar to add an attachment and format the text.

Complete an assigned task

1. The task appears on your Home Page. Double-click the task to open the specified project and form.
2. Accept the task.
3. Use the instructions in the task to build the form. If you need help from rule designers, translators, or other specialists, create new tasks for the form and assign them to the other teams or users.
4. Complete the form and change the status of the task to **Complete**.

   After reviewing the work and verifying that it is complete, the study architect changes the status of the task to **Closed**.

6
Design custom events

In this chapter:

- Step 1: Create a custom event
- Step 2: Add a trigger for a custom event
- Step 3: Add a result for a custom event (the data to export when a custom event is triggered)
- Step 4: Specify run options
- Import custom events
- Deactivate a custom event
- Example of Oracle InForm to Siebel CTMS integration

Step 1: Create a custom event

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. In the Project Explorer in the **InForm** folder, select **Custom Events** and click **New**.
3. Enter a title, RefName, and optionally, a description for the custom event, and click OK.
4. Enter the following:
   - **Destination name**—Corresponds to the CUSTOMCONTEXTALIAS in InForm Publisher, and appears as the event name in the ODM output that InForm Publisher generates.
   - **Endpoint name**—Corresponds to the endpoint alias, which is a unique identifier for an endpoint where InForm Publisher sends the ODM messages generated for this event. The endpoint is configured in InForm Publisher to point to a URL and send credentials.
5. Next, add a trigger to the custom event.

Step 2: Add a trigger for a custom event

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. In the Project Explorer in the **InForm** folder, open the **Custom Events** folder and select the custom event you want to work with.
3. Select the **Triggers & Results** tab.
4. Click **New Trigger**.
5. Specify whether the trigger is a subject, a common visit, or a study object, and then choose an event.

For example, you can select a subject action like a subject being enrolled or transferred to a new site, or a study object action like a visit being frozen or a form being source verified.

6. Click the **Event type** drop-down list. If additional fields appear below the **Event type** field, make a selection and click OK.
7. On the **Triggers & Results** tab, add triggers, if desired, and in the middle of the page, in the **Logical operator** field, select:
   - AND if you want the result to occur if all of the triggers are satisfied.
   - OR if you want the result to occur if any of the triggers is satisfied.
8. Next, enter the data to export when the custom event is triggered.

> **Tip:**
>
> Oracle Central Designer allows you to create some study object triggers that are not currently supported in Oracle InForm. To save time, avoid creating the following unnecessary triggers:
>
> - Triggers created on special visits such as the Screening visit.
> - Triggers created on Screening or Enrollment special forms.
> - Triggers that are on conditional items and have the following event types:
>   - Query state
>   - Source Verified
>   - Reason Incomplete Value Match
>   - Comment Value Changed
> - Triggers that are on items in repeating sections and have the Source Verified event type.
> - Triggers that are on date time items and have the Value Match event type.

Step 3: Add a result for a custom event (the data to export when a custom event is triggered)

1. On the bottom left of the page, select **Study Information** ().
2. On the left, in the Custom Events folder, select the custom event you want to work with.
3. Select the **Triggers & Results** tab.
4. At the top of the page, click **New Result**.
5. Enter the type of data to export when the custom event is triggered:
   - Subject status
   - Common visit status

- Study object status

6. If you selected **Study object status**, click **Include data** if you want to export additional detailed information about forms.
7. In the **Map to name** field, enter the destination where you want to save the exported data. The Map to name corresponds to the custom event result's alias.
8. In the **Custom Data** field, enter any additional information that you want to send along with the custom event.
9. Click OK.

> **Tip:**
>
> If your custom event uses the Siebel CTMS integration type, and the custom event creates a subject:
>
> - To create a subject with a status of Screen Failed, in the **Map to name** field, you must select ScreenFailureDate and ScreenFailureReason.
> - To create a subject with a status of Early Withdrawal, in the **Map to name** field, you must select WithdrawnDate and WithdrawnReason.
> - To create a subject with a status of Early Termination, in the **Map to name** field, you must select EarlyTerminatedDate and EarlyTerminatedReason.
> - In the Custom Data section **Name** field, select ScreenedStatus, Enrolled Status, or Status.
> - In the Custom Data section **Value** field, enter the value from the Language Independent Code in Siebel CTMS.

> **Tip:**
>
> If your custom event uses the Siebel CTMS integration type, and the custom event sends completion status information:
>
> a. In the **Map to name** field, select CompletedDate.
> b. In the Custom Data section, enter any of the following:
>
> - In the **Name** field, select VisitClinicalItem, and in the **Value** field, enter the clinical item value in the subject visit template in Siebel CTMS.
> - In the **Name** field, select ActivityClinicalItem, and in the **Value** field, enter the clinical item value for the activity in the subject visit template in Siebel CTMS.

Step 4: Specify run options

In this section:

- Set the priority for your custom events
- Configure a custom event to run retroactively on existing data
- Make a custom event dependent on another custom event

- Change the endpoint name of more than one custom event
- Mark a custom event change as an in-place revision
- View the differences between two versions of a custom event

Set the priority for your custom events

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. In the Project Explorer in the **InForm** folder, select **Custom Events**.
3. In the **Priority Group** column for each custom event, enter a number from 1-999 to indicate the order InForm Publisher should run the custom events in. The lowest number is run first.

Configure a custom event to run retroactively on existing data

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. In the Project Explorer in the **InForm** folder, select **Custom Events**.
3. In the **Evaluate On** column for the custom event, select **All data**.

> **Tip:**
>
> Running a custom event against all data could take a long time for large studies, and when the custom event is running, no other custom events can process. Before selecting **All data**, consider whether the time delay is acceptable. For example, you might not want to select **All data** for a large study if the custom event triggers submission of adverse event data to an application like Argus Safety.

> **Tip:**
>
> After you select **All data** and deploy your study, you might want to log back in to Oracle Central Designer and deselect it so that the next time you deploy a study, you don't re-run the custom events for existing data.

Make a custom event dependent on another custom event

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. In the Project Explorer in the **InForm** folder, select **Custom Events**.
3. In the **Prerequisite** column, select a custom event that you want to run before the custom event you're editing.

> **Tip:**
>
> If the custom event you're editing has a trigger on a repeating study object, the prerequisite custom event must have a trigger on the same repeating study object. If the prerequisite custom event has a trigger on a different repeating study object, or on a non-repeating study object, it will not execute in InForm.

Change the endpoint name of more than one custom event

1. At the bottom of the Project Explorer, click the Study Information ( ) button.
2. In the Project Explorer in the **InForm** folder, select **Custom Events**.
3. Select one or more custom events with the same endpoint name.
4. Click **Endpoint**, enter the new endpoint name, and click OK.

Mark a custom event change as an in-place revision

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. In the Project Explorer in the **InForm** folder, select **Custom Events**, then select a custom event.
3. At the top of the **Layout** tab, all the way to the right, click **IPR Configuration**.
4. On the **IPR Configuration** screen, type a description of the change you made to the custom event (optional).
5. Select or add the deployment instance where you want to deploy the in-place revision.
6. Optionally, to compare the new custom event with the same custom event from an existing InForm study version, select the existing study version, and click **View Differences**. For more information, see View the differences between two versions of a custom event.
7. Click **Close**.
8. Next, contact the person who does study validation at your organization to validate and deploy the study.

View the differences between two versions of a custom event

- If you manually deploy your study, you must have a successfully deployed baseline to view the differences between two versions of a form.
- If you perform an in-place revision and manually deploy the study, when you attempt to view the differences between two versions of a form, the differences shown are not correct.

1. At the bottom of the Project Explorer, click the **Forms and Transactions** ( ) button, and expand the **InForm** folder and the **Forms** folder, if necessary.
2. Select a form and select the **Layout** tab.
3. At the top of the **Layout** tab, all the way to the right, click **IPR Configuration**.
4. Select a deployment instance and a study version, and click **View Differences**.

Import custom events

In this section:

- Import custom events that were created in Oracle InForm Publisher in a release prior to 6.2
- Add a custom event from a library

Import custom events that were created in Oracle InForm Publisher in a release prior to 6.2

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. In the Project Explorer in the **InForm** folder, select **Custom Events**.
3. Click **Import**, and select the CSML file that contains the custom event.

> **Tip:**
>
> - The import file is created by a utility that runs during the Oracle InForm 6.2 study migration. It converts existing custom events into CSML for import into Oracle Central Designer.
> - By default, the CSML file is stored on the Oracle InForm application server at `<Installation_Directory>\InForm\Bin\DBOra\<Study_Name>_CustomEvents.csml`.
> Your organization might need to move the file to a location that you can access it from.

> **Note:**
>
> The utility only works for active custom events. Inactive custom events are not available for import.

Add a custom event from a library

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. In the Project Explorer in the **InForm** folder, select **Custom Events**.
3. Select the **Libraries** tab.

> **Tip:**
>
> If you don't see the Libraries tab, at the top left of the page, select **View**, and make sure **Libraries** is selected.

4. Locate the custom event you want, and drag it into the Project Explorer, under **Custom Events**.

> **Tip:**
>
> Make sure that all study objects referenced by the custom event trigger and result exist in the study you're in, in the path defined within the custom event. For example, if a custom event has a trigger on item1, on form1, on studyevent1, make sure that the study or library you're in includes item1 on form1 on studyevent1.

Deactivate a custom event

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. In the Project Explorer in the **InForm** folder, select **Custom Events**.
3. In the **Active** column for the custom event, deselect the checkbox

Example of Oracle InForm to Siebel CTMS integration

In this example, you want to track enrollment counts, early withdrawals, and study completion. You also want visit completion information so that you can pay the sites.

Assumptions about this example:

- You are using a Subject Visit Template (SVT) in Siebel CTMS that uses status tracking visits.
- In the SVT in Siebel CTMS, you defined the maximum number of cycles (4).
- The study has a variable number of dosing visit cycles, depending upon the subject response to the drug.
- Your study design includes a repeating visit with a form that contains an item for entering the cycle number of the visit.

In Oracle Central Designer, you define the following custom events, each with the same destination.

- Create a subject with a status of Enrolled
- Initiate an early withdrawal
- Mark a visit as complete and specify the date of visit as the completion date
- Mark the cycle 1 visit as complete and specify the date of visit as the completion date
- Update the date of visit item on the subject completion visit whenever it is changed

Create a subject with a status of Enrolled

- **Event Name**—SubjectEnrollment
- **Priority**—1
- **Prerequisite**—None

Triggers:

- **Trigger 1**
  - **Trigger type**—Study object trigger type
  - Created on the enrollment form
  - **Event type**—Data Value Changed
- **Trigger 2**
  - **Trigger type**—Study object trigger type
  - Created on the item where users enter the date of enrollment
  - **Event type**—Is Not Empty

Results:

Define a result for every item that you want to send to Siebel CTMS, including:

- **Result 1**
  - **Result type**—Study object status
  - Created on the item where users enter the date of enrollment.
  - **Map to name**—EnrollmentDate
  - **Custom Data section**—A name of EnrolledStatus, with a value of Enrolled
- **Result 2**
  - **Result type**—Study object status
  - Created on the item where users enter the date of enrollment.
  - **Map to name**—EncounterDate
- **Result 3**
  - **Result type**—Study object status
  - Created on the item where users enter the date of enrollment.
  - **Map to name**— ScheduleDate
- **Result 4**
  - **Result type**—Study object status
  - Created on the item where users enter the subject number.
  - **Map to name**—SubjectNumber
  - **Include Data**—Selected

> **Tip:**
>
> Selecting **Include data** ensures that Siebel CTMS is able to process the request without a subject number.

> **Note:**
>
> The value is the language independent code in Siebel CTMS for the status Enrolled.

Initiate an early withdrawal

- **EventName**—EarlyWithdrawal
- **Priority**—2
- **Prerequisite**—None

Triggers:

- **Trigger 1**
  - **Trigger type**—Study object trigger type
  - Created on the item that captures the withdrawal date
  - **Event type**—DataValueChanged
- **Trigger 2**
  - **Trigger type**—Study object trigger type
  - Created on the item that captures the withdrawal date
  - **Event type**—Is Not Empty

Results:

Define a result for every item that you want to send to Siebel CTMS, including:

- **Result 1**
  - **Result type**—Study object status
  - Created on the Subject Number.
  - **Map to name**—SubjectNumber
- **Result 2**
  - **Result type**—Study object status
  - Created on the item that captures the date of enrollment
  - **Map to name**—EnrollmentDate
- **Result 3**
  - **Result type**—Study object status
  - Created on the item that captures the date of enrollment
  - **Map to name**—EncounterDate
- **Result 4**
  - **Result type**—Study object status
  - Created on the item that captures the date of enrollment
  - **Map to name**—ScheduleDate

- **Result 5**
  - **Result type**—Study object status
  - Created on the item that captures the withdrawal date
  - **Map to name**—WithdrawnDate
- **Result 6**
  - **Result type**—Study object status
  - Created on the item that captures the withdrawal reason
  - **Map to name**—WithdrawnReason

Mark a visit as complete and specify the date of visit as the completion date

- **Event Name**—SubjectCompletion
- **Priority**—2
- **Prerequisite**—None

Trigger:

- **Trigger type**—Study object trigger type
- Created on the subject completion visit
- **Event type**—Complete

Result:

- **Result type**—Study object status
- Created on the Date of Visit item for the subject completion visit
- **Map to name**—CompletedDate
- **Custom Data section**—A name of VisitClinicalItem, with a value of the name item where the visit completion date is captured in Siebel SVT

If this visit is a status tracking visit in Siebel CTMS SVT, the subject status is set to StudyComplete.

Mark the cycle 1 visit as complete and specify the date of visit as the completion date

You must define an event for each set of cycles.

- **EventName**—Cycle1VisitComplete
- **Priority**—2
- **Prerequisite**—None

Triggers:

- **Trigger 1**
  - **Trigger type**—Study object trigger type

  - Created on the Cycle visit
  - **Event type**—Complete
- **Trigger 2**
  - **Trigger type**—Study object trigger type
  - Created on the Cycle item
  - **Event type**—Value Match
  - **Operator**— =
  - **Value to compare**—1

Result:

- **Result type**—Study object status
- Created on the Date of Visit item for the subject completion visit
- **Map to name**—CompletedDate
- **Custom Data section**—A name of VisitClinicalItem, with a value of the name item where the visit completion date is captured in Siebel SVT

Update the date of visit item on the subject completion visit whenever it is changed

- **EventName**—CompletionVisitDateChange
- **Priority**—3
- **Prerequisite**—SubjectCompletion event

Triggers:

- **Trigger 1**
  - **Trigger type**—Study object trigger type
  - Created on the item where users enter the date of visit
  - **Event type**—Value Changed
- **Trigger 2**
  - **Trigger type**—Study object trigger type
  - Created on the item where users enter the date of visit
  - **Event type**—Is Not Empty

Results:

- **Result type**—Study object trigger type
- Created on the item where users enter the date of visit
- **Map to name**—CompletedDate
- **Custom Data section**—A name of VisitClinicalItem, with a value of the Date of Visit item for the subject completion visit in Siebel SVT

7

Create and test rules

In this chapter:

- Create rules
- Test rules
- Edit rules

Create rules

In this section:

- Create an intrinsic rule
- Create a rule without a function
- Create a rule using a function
- Create a workflow rule in a workflow diagram
- Create a global condition

Create an intrinsic rule

Prerequisite: Define a rule template. For more information, see the *Rules Reference Guide*.

1. In the Project Explorer, select a form, a form template, an item, an item template, or an item type.
2. Select the **Rules** tab.
3. At the top of the **Rules** tab, click **New Rule**.
4. At the top of the New Rule dialog box, on the **Quick Start** tab, select **Intrinsic Rule**, and select a rule template.
5. Click **Next**.
6. On the **Properties** tab, enter a name and description for the rule, and click **Next**.
7. On the **Preconditions** tab, from the **Evaluate on Event** drop-down list, select one:
   - **Form submission**—Rule executes when an InForm user submits the associated form. To figure out the form that causes the rule to execute, InForm determines rule dependencies by detecting the study objects on which the rule depends.
   - **On demand (batch mode)**—Rule is validated and deployed to InForm with a deactivated status, so the rule does not run in InForm.
8. Click **Next**.
   a. Drag any of the following objects from the tabs on the right to the Expression workspace.
      - Data Mappings tab—Data mapping study object, rule model property, method for a global study object.

- Constants tab—Constants.
- Data tab—Value of a study object, a rule model property, or a method for a repeating study object.

> **Tip:**
>
> To view the rule model properties of all of the study objects, click **Show All**.

For more information, see Rule Wizard—Option descriptions.

b. Add operators and literals, as needed.

   For more information, see *Operators and literals* in the *Rules Reference Guide*.

9. Click **Next**.
10. On the **Actions** tab, in the **If the value is** section, select one of the following options:
    - False—If the rule calculates a False value, the action occurs.
    - True—If the rule calculates a True value, the action occurs.
    - Always—(Default for calculation rules) The action always occurs.
    - Only if no other action executes—The action occurs only if no other action occurs. Select this option only if you define at least two actions.
    - Values to specify:
      - Equals—If the rule calculates a value that is equal to the provided value, the action occurs.
      - Not Equals—If the rule calculates a value that is not equal to the provided value, the action occurs.

      > **Tip:**
      >
      > You can include string values in the Equals and Not Equals fields. Enclose the string in double quotes. For example, "text".

      - Less Than—If the rule calculates a value that is less than the provided value, the action occurs.
      - Greater Than—If the rule calculates a value that is greater than the provided value, the action occurs.
      - Between—If the rule calculates a value that is between the provided values, the action occurs.
      - Inclusive—Select this option to make the number comparisons inclusive. For example, Less Than becomes Less Than or Equal To.
11. In the **Execute these actions** section, choose the action or actions that will occur when the rule executes.
    - Query—Issue a query. A query is a text string that appears on a CRF item in Oracle InForm when a rule on that item fails.

- Email—Send an email message to a distribution list.
- SetValue—Set the value of an item.
- UpdateWorkflow—Recreate the state of a workflow rule.

> **Tip:**
>
> If you are deploying to Oracle InForm 6.1.1 or later, UpdateWorkflow rules are not required.

- SetReviewState—Set the review state of an object.
- SetPartialSDV—Select to automatically move subjects in and out of the SV eligible pool within InForm.

12. Optionally, to specify multiple actions, click **Add Action**.
13. In the Rule Summary section:
    - **Define a query**
      Click the **query** link, and enter the following information for the query:
      - Initial Query State—The state to create the query in.
        * Open—The query is visible on the form and available for response.
        * Candidate—The query is not visible on the form until someone reviews and explicitly opens it.
      - Item—Item to open the query against. You can enter the item's name, drag an item from the Data tab to the field, or enter an expression.

        > **Tip:**
        >
        > You cannot define a query on a fixed item.

      - Locale—Locale of the query message text. Type the query message text in the Message field in the language of this locale.
      - Message—The query text that appears in Oracle InForm. Optionally, you can drag a parameter from the Data, Functions, Constants, or Data Mappings tabs to the message field.

        > **Tip:**
        >
        > * Query text is truncated to 255 characters in Oracle InForm. If the query message has parameters and the message is 255 characters or fewer without the parameters, you receive a warning during validation. If the query message does not have parameters, you receive an error during validation.
        > * To include translated text, type the text in the language of the locale that you selected in the **Locale** drop-down list.

- Message Parameters—Optional parameters that you can create and use in the query message. Type a value or drag information from the Data, Functions, Constants, and Globals tabs.

> **Tip:**
>
> A parameterized string in a query follows the formatting that is specified for the site in InForm. Disallowed and unknown components of a date time value appear as asterisks (*). Leading and following underscores in the value are removed automatically.

Click **OK**.

For more information, see Query Action dialog box—Option descriptions.

- **Specify email information**
  Click the **email** link.

  Enter the following information:

  - Item—Item that triggers the email. You can enter an item RefName or drag an item from the Data tab to the **Item** field.

> **Tip:**
>
> You cannot trigger an email action from a fixed item. Make sure the item you select is not fixed.

  - To—Email addresses to send the email to. Separate the addresses by semicolons.
  - From—Email address to send the email from.

> **Tip:**
>
> If you do not provide an email address, an address is taken from the registry. If the registry does not contain an email address, <*studyname*>@<*default_webserver*> is used.

  - Locale—Locale for the email subject and message. Type the email text in the **Subject** and **Message** fields in the language of this locale.
  - Subject—Email subject.
  - Message—Email message. You can enter a value or drag a parameter from the Data, Functions, Constants, or Data Mappings tabs to the message field.

> **Tip:**
>
> * Do not add an item to the Subject or Message fields if its PHI item property is set to True.
> * To include translated text, type the text in the language of the locale that you selected in the **Locale** drop-down list.

– Message and Subject Parameters—Optional parameters that you can create and use in the Subject field, Message field, and Parameter Value field. You can type a value or drag information from the Data, Functions, Constants, and Globals tabs.

> **Tip:**
>
> A parameterized string in a query follows the formatting that is specified for the site in InForm. Disallowed and unknown components of a date time value appear as asterisks (*). Leading and following underscores in the value are removed automatically.

Click **OK**.

For more information, see Email Action dialog box—Option descriptions

- **Set a value**

> **Tip:**
>
> Set value actions run in InForm in the order you define them in. Make sure to define them in the order that you want them to run.

Click the **[select] = value** link.

Enter the following information:

– Item—Item to set the value for. Enter the item's RefName, or drag an item from the Data tab.

> **Tip:**
>
> You cannot set the value of a fixed item. Make sure the item you select is not fixed.

– Value to set the Item—Value to enter in the item.

  * To use the value that is calculated in the expression, leave the default **value** text.

    - To modify the value that is calculated in the expression, type a value or an expression that will return a value for the item. For example, **value + 2** adds two to the value returned by the expression.

  Click **OK**.

  For more information, see: Set Value Action dialog box—Option descriptions.

- **Set the stage of a review state**
  Click the **SetReviewState** link.

  Enter the following information:

  – Form—RefName of the form to set the review state and stage for. You can enter a value or drag a form from the Data tab.

  – ReviewState—Review state to apply to the form.

  – Review Stage and Review Stage expression–Select the review stage within the selected review state to apply to the form, or create a rule expression that evaluates to a valid review stage. You can enter a value or drag a value from the Data, Functions, Constants, or Data Mappings tabs.

  – Comment—Text that describes the review state change.

  Click **OK**.

  For more information, see: Set Review State Action dialog box.

- Set whether to include or exclude groups of subjects from Partial SDV. For more information, see How do I automatically include or exclude subjects in Partial SDV using a rule?

14. Click **Finish**.

Create a rule without a function

1. In the Project Explorer, select the study design, group of visits (study element), visit (study element), form, section, or item that you want to create the rule on.
2. Select the **Rules** tab.
3. At the top of the **Rules** tab, click **New Rule**.
4. At the top of the New Rule dialog box, on the **Quick Start** tab, select **Constraint Rule**, or **Calculation Rule**.
5. Click **Next**.
6. On the **Properties** tab, enter a name and description for the rule, and click **Next**.
7. On the **Preconditions** tab, from the **Evaluate on Event** drop-down list, select one:
   - **Form submission**—Rule executes when an InForm user submits the associated form. To figure out the form that causes the rule to execute, InForm determines rule dependencies by detecting the study objects on which the rule depends.
   - **On demand (batch mode)**—Rule is validated and deployed to InForm with a deactivated status, so the rule does not run in InForm.
8. Click **Next**.

9. On the **Expression** tab, to create the rule expression:
   a. Drag any of the following objects from the tabs on the right to the Expression workspace.
      - Data Mappings tab—Data mapping study object, rule model property, method for a global study object.
      - Constants tab—Constants.
      - Data tab—Value of a study object, a rule model property, or a method for a repeating study object.

      > **Tip:**
      >
      > To view the rule model properties of all of the study objects, click **Show All**.

      For more information, see Rule Wizard—Option descriptions.
   b. Add operators and literals, as needed.

      For more information, see *Operators and literals* in the *Rules Reference Guide*.
10. Click **Next**.
11. On the **Actions** tab, in the **If the value is** section, select one of the following options:
    - False—If the rule calculates a False value, the action occurs.
    - True—If the rule calculates a True value, the action occurs.
    - Always—(Default for calculation rules) The action always occurs.
    - Only if no other action executes—The action occurs only if no other action occurs. Select this option only if you define at least two actions.
    - Values to specify:
      – Equals—If the rule calculates a value that is equal to the provided value, the action occurs.
      – Not Equals—If the rule calculates a value that is not equal to the provided value, the action occurs.

      > **Tip:**
      >
      > You can include string values in the Equals and Not Equals fields. Enclose the string in double quotes. For example, "text".

      – Less Than—If the rule calculates a value that is less than the provided value, the action occurs.
      – Greater Than—If the rule calculates a value that is greater than the provided value, the action occurs.
      – Between—If the rule calculates a value that is between the provided values, the action occurs.
      – Inclusive—Select this option to make the number comparisons inclusive. For example, Less Than becomes Less Than or Equal To.

12. In the **Execute these actions** section, choose the action or actions that will occur when the rule executes.
    - Query—Issue a query. A query is a text string that appears on a CRF item in Oracle InForm when a rule on that item fails.
    - Email—Send an email message to a distribution list.
    - SetValue—Set the value of an item.
    - UpdateWorkflow—Recreate the state of a workflow rule.

      > **Tip:**
      >
      > If you are deploying to Oracle InForm 6.1.1 or later, UpdateWorkflow rules are not required.

    - SetReviewState—Set the review state of an object.
    - SetPartialSDV—Select to automatically move subjects in and out of the SV eligible pool within InForm.
13. Optionally, to specify multiple actions, click **Add Action**.
14. In the Rule Summary section:
    - **Define a query**
      Click the **query** link, and enter the following information for the query:
      – Initial Query State—The state to create the query in.
        * Open—The query is visible on the form and available for response.
        * Candidate—The query is not visible on the form until someone reviews and explicitly opens it.
      – Item—Item to open the query against. You can enter the item's name, drag an item from the Data tab to the field, or enter an expression.

        > **Tip:**
        >
        > You cannot define a query on a fixed item.

      – Locale—Locale of the query message text. Type the query message text in the Message field in the language of this locale.
      – Message—The query text that appears in Oracle InForm. Optionally, you can drag a parameter from the Data, Functions, Constants, or Data Mappings tabs to the message field.

> **Tip:**
>
> * Query text is truncated to 255 characters in Oracle InForm. If the query message has parameters and the message is 255 characters or fewer without the parameters, you receive a warning during validation. If the query message does not have parameters, you receive an error during validation.
> * To include translated text, type the text in the language of the locale that you selected in the **Locale** drop-down list.

– Message Parameters—Optional parameters that you can create and use in the query message. Type a value or drag information from the Data, Functions, Constants, and Globals tabs.

> **Tip:**
>
> A parameterized string in a query follows the formatting that is specified for the site in InForm. Disallowed and unknown components of a date time value appear as asterisks (*). Leading and following underscores in the value are removed automatically.

Click **OK**.

For more information, see Query Action dialog box—Option descriptions.

- **Specify email information**
  Click the **email** link.

  Enter the following information:

  – Item—Item that triggers the email. You can enter an item RefName or drag an item from the Data tab to the **Item** field.

  > **Tip:**
  >
  > You cannot trigger an email action from a fixed item. Make sure the item you select is not fixed.

  – To—Email addresses to send the email to. Separate the addresses by semicolons.

  – From—Email address to send the email from.

  > **Tip:**
  >
  > If you do not provide an email address, an address is taken from the registry. If the registry does not contain an email address, <*studyname*>@<*default_webserver*> is used.

- Locale—Locale for the email subject and message. Type the email text in the **Subject** and **Message** fields in the language of this locale.
- Subject—Email subject.
- Message—Email message. You can enter a value or drag a parameter from the Data, Functions, Constants, or Data Mappings tabs to the message field.

  > **Tip:**
  >
  > * Do not add an item to the Subject or Message fields if its PHI item property is set to True.
  > * To include translated text, type the text in the language of the locale that you selected in the **Locale** drop-down list.

- Message and Subject Parameters—Optional parameters that you can create and use in the Subject field, Message field, and Parameter Value field. You can type a value or drag information from the Data, Functions, Constants, and Globals tabs.

  > **Tip:**
  >
  > A parameterized string in a query follows the formatting that is specified for the site in InForm. Disallowed and unknown components of a date time value appear as asterisks (*). Leading and following underscores in the value are removed automatically.

Click **OK**.

For more information, see Email Action dialog box—Option descriptions

- **Set a value**

  > **Tip:**
  >
  > Set value actions run in InForm in the order you define them in. Make sure to define them in the order that you want them to run.

Click the **[select] = value** link.

Enter the following information:

- Item—Item to set the value for. Enter the item's RefName, or drag an item from the Data tab.

> **Tip:**
>
> You cannot set the value of a fixed item. Make sure the item you select is not fixed.

  - Value to set the Item—Value to enter in the item.
    - To use the value that is calculated in the expression, leave the default **value** text.
    - To modify the value that is calculated in the expression, type a value or an expression that will return a value for the item. For example, **value + 2** adds two to the value returned by the expression.

  Click **OK**.

  For more information, see: Set Value Action dialog box—Option descriptions.

- **Set the stage of a review state**
  Click the **SetReviewState** link.

  Enter the following information:

  - Form—RefName of the form to set the review state and stage for. You can enter a value or drag a form from the Data tab.
  - ReviewState—Review state to apply to the form.
  - Review Stage and Review Stage expression–Select the review stage within the selected review state to apply to the form, or create a rule expression that evaluates to a valid review stage. You can enter a value or drag a value from the Data, Functions, Constants, or Data Mappings tabs.
  - Comment—Text that describes the review state change.

  Click **OK**.

  For more information, see: Set Review State Action dialog box.

- Set whether to include or exclude groups of subjects from Partial SDV. For more information, see How do I automatically include or exclude subjects in Partial SDV using a rule?

15. Click **Finish**.

Create a rule using a function

1. In the Project Explorer, select the study design, group of visits (study element), visit (study element), form, section, or item that you want to create the rule on.
2. Select the **Rules** tab.
3. At the top of the **Rules** tab, click **New Rule**.
4. At the top of the New Rule dialog box, on the **Quick Start** tab, select **Constraint Rule**, or **Calculation Rule**.
5. Click **Next**.
6. On the **Properties** tab, enter a name and description for the rule, and click **Next**.
7. On the **Preconditions** tab, from the **Evaluate on Event** drop-down list, select one:

- **Form submission**—Rule executes when an InForm user submits the associated form. To figure out the form that causes the rule to execute, InForm determines rule dependencies by detecting the study objects on which the rule depends.
- **On demand (batch mode)**—Rule is validated and deployed to InForm with a deactivated status, so the rule does not run in InForm.

8. Click **Next**.
9. On the **Expression** tab, to create the rule expression:
   a. Drag any of the following objects from the tabs on the right to the Expression workspace.
      - Data Mappings tab—Data mapping study object, rule model property, method for a global study object.
      - Constants tab—Constants.
      - Data tab—Value of a study object, a rule model property, or a method for a repeating study object.

      > **Tip:**
      >
      > To view the rule model properties of all of the study objects, click **Show All**.

      For more information, see Rule Wizard—Option descriptions.
   b. Add operators and literals, as needed.

      For more information, see *Operators and literals* in the *Rules Reference Guide*.
10. Click **Next**.
11. On the **Actions** tab, in the **If the value is** section, select one of the following options:
    - False—If the rule calculates a False value, the action occurs.
    - True—If the rule calculates a True value, the action occurs.
    - Always—(Default for calculation rules) The action always occurs.
    - Only if no other action executes—The action occurs only if no other action occurs. Select this option only if you define at least two actions.
    - Values to specify:
      – Equals—If the rule calculates a value that is equal to the provided value, the action occurs.
      – Not Equals—If the rule calculates a value that is not equal to the provided value, the action occurs.

      > **Tip:**
      >
      > You can include string values in the Equals and Not Equals fields. Enclose the string in double quotes. For example, "text".

- Less Than—If the rule calculates a value that is less than the provided value, the action occurs.
- Greater Than—If the rule calculates a value that is greater than the provided value, the action occurs.
- Between—If the rule calculates a value that is between the provided values, the action occurs.
- Inclusive—Select this option to make the number comparisons inclusive. For example, Less Than becomes Less Than or Equal To.

12. In the **Execute these actions** section, choose the action or actions that will occur when the rule executes.
    - Query—Issue a query. A query is a text string that appears on a CRF item in Oracle InForm when a rule on that item fails.
    - Email—Send an email message to a distribution list.
    - SetValue—Set the value of an item.
    - UpdateWorkflow—Recreate the state of a workflow rule.

      > **Tip:**
      >
      > If you are deploying to Oracle InForm 6.1.1 or later, UpdateWorkflow rules are not required.

    - SetReviewState—Set the review state of an object.
    - SetPartialSDV—Select to automatically move subjects in and out of the SV eligible pool within InForm.
13. Optionally, to specify multiple actions, click **Add Action**.
14. In the Rule Summary section:
    - **Define a query**
      Click the **query** link, and enter the following information for the query:
      - Initial Query State—The state to create the query in.
        * Open—The query is visible on the form and available for response.
        * Candidate—The query is not visible on the form until someone reviews and explicitly opens it.
      - Item—Item to open the query against. You can enter the item's name, drag an item from the Data tab to the field, or enter an expression.

        > **Tip:**
        >
        > You cannot define a query on a fixed item.

      - Locale—Locale of the query message text. Type the query message text in the Message field in the language of this locale.

- Message—The query text that appears in Oracle InForm. Optionally, you can drag a parameter from the Data, Functions, Constants, or Data Mappings tabs to the message field.

  > **Tip:**
  >
  > * Query text is truncated to 255 characters in Oracle InForm. If the query message has parameters and the message is 255 characters or fewer without the parameters, you receive a warning during validation. If the query message does not have parameters, you receive an error during validation.
  > * To include translated text, type the text in the language of the locale that you selected in the **Locale** drop-down list.

- Message Parameters—Optional parameters that you can create and use in the query message. Type a value or drag information from the Data, Functions, Constants, and Globals tabs.

  > **Tip:**
  >
  > A parameterized string in a query follows the formatting that is specified for the site in InForm. Disallowed and unknown components of a date time value appear as asterisks (*). Leading and following underscores in the value are removed automatically.

Click **OK**.

For more information, see Query Action dialog box—Option descriptions.

- **Specify email information**
  Click the **email** link.

  Enter the following information:

  - Item—Item that triggers the email. You can enter an item RefName or drag an item from the Data tab to the **Item** field.

    > **Tip:**
    >
    > You cannot trigger an email action from a fixed item. Make sure the item you select is not fixed.

  - To—Email addresses to send the email to. Separate the addresses by semicolons.
  - From—Email address to send the email from.

> **Tip:**
>
> If you do not provide an email address, an address is taken from the registry. If the registry does not contain an email address, <*studyname*>@<*default_webserver*> is used.

- Locale—Locale for the email subject and message. Type the email text in the **Subject** and **Message** fields in the language of this locale.
- Subject—Email subject.
- Message—Email message. You can enter a value or drag a parameter from the Data, Functions, Constants, or Data Mappings tabs to the message field.

> **Tip:**
>
> * Do not add an item to the Subject or Message fields if its PHI item property is set to True.
> * To include translated text, type the text in the language of the locale that you selected in the **Locale** drop-down list.

- Message and Subject Parameters—Optional parameters that you can create and use in the Subject field, Message field, and Parameter Value field. You can type a value or drag information from the Data, Functions, Constants, and Globals tabs.

> **Tip:**
>
> A parameterized string in a query follows the formatting that is specified for the site in InForm. Disallowed and unknown components of a date time value appear as asterisks (*). Leading and following underscores in the value are removed automatically.

Click **OK**.

For more information, see Email Action dialog box—Option descriptions

- **Set a value**

> **Tip:**
>
> Set value actions run in InForm in the order you define them in. Make sure to define them in the order that you want them to run.

Click the **[select] = value** link.

Enter the following information:

- Item—Item to set the value for. Enter the item's RefName, or drag an item from the Data tab.

  > **Tip:**
  >
  > You cannot set the value of a fixed item. Make sure the item you select is not fixed.

- Value to set the Item—Value to enter in the item.
  - To use the value that is calculated in the expression, leave the default **value** text.
  - To modify the value that is calculated in the expression, type a value or an expression that will return a value for the item. For example, **value + 2** adds two to the value returned by the expression.

Click **OK**.

For more information, see: Set Value Action dialog box—Option descriptions.

- **Set the stage of a review state**
  Click the **SetReviewState** link.

  Enter the following information:
  - Form—RefName of the form to set the review state and stage for. You can enter a value or drag a form from the Data tab.
  - ReviewState—Review state to apply to the form.
  - Review Stage and Review Stage expression–Select the review stage within the selected review state to apply to the form, or create a rule expression that evaluates to a valid review stage. You can enter a value or drag a value from the Data, Functions, Constants, or Data Mappings tabs.
  - Comment—Text that describes the review state change.

  Click **OK**.

  For more information, see: Set Review State Action dialog box.
- Set whether to include or exclude groups of subjects from Partial SDV. For more information, see How do I automatically include or exclude subjects in Partial SDV using a rule?

15. Click **Finish**.

Create a workflow rule in a workflow diagram

You can create a workflow rule for a study element, study event, or form.

> **Note:**
>
> A study object can include only one workflow rule.

1. In the Project Explorer, select a study design (in a study only), study element, or study event.
2. Select the **Workflow Diagram** tab.
3. Right-click a study object, and select **Add Rule**.
4. Enter a name and description for the workflow rule.
5. On the **Expression** tab, create the rule expression:
   a. Drag any of the following objects from the tabs on the right to the Expression workspace.
      - Data Mappings tab—Data mapping study object, rule model property, method for a global study object.
      - Constants tab—Constants.
      - Data tab—Value of a study object, a rule model property, or a method for a repeating study object.

      > **Tip:**
      >
      > To view the rule model properties of all of the study objects, click **Show All**.

      For more information, see Rule Wizard—Option descriptions.
   b. Add operators and literals, as needed.

      For more information, see *Operators and literals* in the *Rules Reference Guide*.
6. Click **OK**.

Create a global condition

> **Tip:**
>
> When you need to apply the same action to multiple study objects, we recommend creating a workflow rule instead of applying a single global condition to multiple study objects. A workflow rule is evaluated only once.

1. In the Project Explorer, select a study design (in a study only), study element, or study event.
2. In the **Workflow Diagram** tab, click **Global Conditions**.
3. To the right of the grid, click **Add**.
4. Enter a name and description for the global condition.
5. Click **OK**.
6. On the **Expression** tab, create the rule expression:
   a. Drag any of the following objects from the tabs on the right to the Expression workspace.

- Data Mappings tab—Data mapping study object, rule model property, method for a global study object.
- Constants tab—Constants.
- Data tab—Value of a study object, a rule model property, or a method for a repeating study object.

> **Tip:**
>
> To view the rule model properties of all of the study objects, click **Show All**.

For more information, see Rule Wizard—Option descriptions.

b. Add operators and literals, as needed.

For more information, see *Operators and literals* in the *Rules Reference Guide*.

7. Click **OK**.

Test rules

In this section:

- Check rule syntax
- Write test cases for a rule or global condition
- Write a test case for a rule with an item on a repeating study object
- Run test cases

Check rule syntax

Check rule syntax to ensure that the code in the rule expression is written correctly.

1. In the Project Explorer, select a form, a form template, an item, an item template, or an item type.
2. Select the **Rules** tab.
3. In the grid, select a rule, and click **Check Syntax**.
4. Select **Show Errors**.
5. At the bottom of the Rules tab, in the Rule Summary section, resolve any reported errors.

Write test cases for a rule or global condition

1. In the Project Explorer, select a study design (in a study only), study element, study event, form, section, or item.
2. Select the Rules tab.
3. Optionally, to see the rules' child rules click **Show Child Rules**.

4. Select a rule, and click **Rule Tests**.
5. In the list of rules on the left of the Rule Test Cases dialog box, select a rule.
6. In the toolbar, click **Create**.
7. Provide test values for the items that are used in the rule:
   - Item with a single-select codelist—From the drop-down list, select a codelist item to test. The code and label appear in the drop-down list. To view the RefName, select the Test Properties tab, and then point to the item in the grid.
   - Item with a multi-select codelist—Click the box at the end of the field, and select one or more codelist items to test.
   - Item without a codelist—Type the value to test. For an integer, float, or text item, you must follow the item's requirements, which appear in the Test Properties tab when you point to an item.
   - Date time item—Provide values for the parts of the date time item that are allowed.
     - To test for an empty date—Select Empty date, or select Empty for a date time component.
     - To test for an unknown value—Select Unknown for a date time component. Unknown is available only if an unknown value is allowed for the date time part and if the date time part is not required.
   - Item on a repeating section, form, or study event—Click the box at the end of the field, and provide values in the dialog box that appears.

   Note:

   To provide an empty value for an item with a codelist, select the <empty> option. For items without a codelist, do not enter a value in the field. The field changes to <empty>.

   Note:

   To enter test cases without using a mouse, use the **Tab** key to advance to cells. Use the **spacebar** to open dialog boxes from within cells, such as the date picker dialog box.
8. In the **Expected Result** field, do one of the following:

   Note:

   For data-entry rules, one Expected Result field appears for each of the rule actions.

   - For data-entry rules: Select the expected result or type the expected value, based upon the values that you provided in the test case. For example:
     - Rule issues a query—Select QUERY or NOQUERY.
     - Rule sends an email message—Select Sent or Not Sent.

  - Rule sets a value—Calculate and type the expected value. For example, for a BMI rule, use the Height and Weight values in the test case to calculate the value.
- For workflow rules: Select the study object that you expect to appear next in the workflow, based upon the test case.
- For global conditions: Select **True** or **False**, depending on how you expect the expression to evaluate based on the test case.

9. At the bottom of the dialog box, click **Save Tests**.
10. Write additional test cases as necessary. Optionally, use Copy and Paste on the toolbar to create test cases.

> **Note:**
>
> To run test cases for a rule that references third-party code (for example, ODP.NET), the referenced third-party components must be installed on the client computer.

Write a test case for a rule with an item on a repeating study object

When you write a test case and one of the items in a rule is on a repeating study object, you can provide test values for each instance of the item. For more information about writing test cases, see Write test cases for a rule or global condition.

1. In the Project Explorer, select a study design (in a study only), study element, study event, form, section, or item.
2. Select the Rules tab.
3. Optionally, to see the rules' child rules click **Show Child Rules**.
4. Select a rule, and click **Rule Tests**.
5. In the list of rules on the left of the Rule Test Cases dialog box, select a rule.
6. In the cell that contains <repeating>, click the box at the end of the cell.
7. To create a test instance for an additional instance of the repeating study object:
   a. Select the study object.
   b. Click either **Add Repeating Instance** or **Copy Repeating Instance**.

      For example, if a rule refers to an item on a repeating form, you can specify an item path for each instance of the repeating form on which the item exists.
8. To mark an instance of the repeating study object as current or deleted, right-click the study object path, and select either **Mark as Current** or **Mark as Deleted**.

   > **Note:**
   >
   > The first repeating instance is marked as current after you create a test case.

9. Provide test values for the items that are used in the rule:

> **Note:**
>
> You can select any study object in the tree to provide values. Values of child study objects also appear in the grid for their parents. If the rule contains multiple items that are children of repeating study objects, they are listed in the Repeating Items section; select an item to provide its test values in the grid.

- Item with a single-select codelist—From the drop-down list, select a codelist item to test. The code and label appear in the drop-down list. To view the RefName, select the Test Properties tab, and then point to the item in the grid.
- Item with a multi-select codelist—Click the box at the end of the field, and select one or more codelist items to test.
- Item without a codelist—Type the value to test. For an integer, float, or text item, you must follow the item's requirements, which appear in the Test Properties tab when you point to an item.
- Date time item—Provide values for the parts of the date time item that are allowed.
  - To test for an empty date, select **Empty date**, or select **Empty** for a date time component.
  - To test for an unknown value, select **Unknown** for a date time component. Unknown is available only if an unknown value is allowed for the date time part and if the date time part is not required.

10. Click **OK**.
11. At the bottom of the dialog box, click **Save Tests**.

Run test cases

When you run test cases, the syntax of the selected rules is checked.

> **Note:**
>
> To skip a written test case, select the test case, open the Test Properties tab on the Run tab, and set the IgnoreTest property to **True**.

1. n the Project Explorer, select a study design (in a study only), study element, study event, form, section, or item.
2. Select the Rules tab.
3. Optionally, to see the rules' child rules click **Show Child Rules**.
4. Select a rule, and click **Rule Tests**.
5. Select the **Run** tab.
6. In the list of rules on the left of the Rule Test Cases dialog box, select the test cases to run.

> **Tip:**
>
> To select all test cases for a rule, select the rule. To select all rules and test cases, right-click the tree and select **Check All**.

7. Click **Execute Tests**.

> **Note:**
>
> To run test cases for a rule that references third-party code (for example, ODP.NET), the referenced third-party components must be installed on the client computer.

8. If the syntax check succeeds but the rule compilation fails do the following:
   a. Attempt to resolve the errors.
   b. Validate the study, and attempt to resolve the errors using the error messages generated by the validation.
   c. Make sure that any review states you have defined for the study are complete.

Edit rules

In this section:

- Modify a rule
- Deactivate a rule
- Delete a rule
- Disable or enable one or more rules
- Update the state of a workflow rule
- Disable a workflow rule

Modify a rule

1. In the Project Explorer, select the object you created the rule on, and select the **Rules** tab.
2. In the grid, select a rule, and click **Edit**.
3. Modify the rule as necessary, and click **Finish**.

Deactivate a rule

1. In the Project Explorer, select a study design (in a study only), study element, study event, form, section, or item.
2. Select the **Rules** tab.
3. In the grid, select a rule, and click **Edit**.
4. Select the **Preconditions** tab, and in the **Evaluate on Event** drop-down list, select **On Demand (Batch Mode)**.

5. Click **Finish**.

Delete a rule

1. In the Project Explorer, select a study design (in a study only), study element, study event, form, section, or item.
2. Select the **Rules** tab.
3. In the grid, select a rule, and click **Delete**.

Disable or enable one or more rules

1. In the Project Explorer, select a study design (in a study only), study element, study event, form, section, or item.
2. Select the **Rules** tab.
3. Select one or more rules, and at the top of the workspace, click **Disable** or **Enable**.

Update the state of a workflow rule

To instruct Oracle InForm to re-evaluate the workflow for a subject after workflow rules and global conditions run:

- If you are deploying a study to an Oracle InForm release prior to 6.1.1, you can create a rule with the Update Workflow action.

  For example, if you change the parameters on a workflow rule that assigns subjects to treatment arms at the beginning of a study, you can use the UpdateWorkflow action to retrigger all the rules after that point in the workflow and determine which forms and visits should appear.

  To implement this functionality, you can add a checkbox to a form at the beginning of the study, and then create a rule with the UpdateWorkflow action that fires when a user selects the checkbox.
- If you are deploying a study to Oracle InForm release 6.1.1 or later, Oracle InForm re-evaluates the workflow without user interaction.

  When you validate a study that contains a rule with the UpdateWorkflow action, a warning appears and indicates that the rule is not required for studies that are deployed to Oracle InForm release 6.1.1 or later.

Disable a workflow rule

To disable a workflow rule, you disable the workflow the rule is associated with.

1. At the bottom of the Project Explorer, click the **Visit Schedule** () button.
2. Select a study design, study element, or study event.
3. Select the **Workflow Diagram** tab, and click **Disable Workflow**.

8
Data mappings

In this section:

- Use data mappings, data sets, and data series to associate items

Use data mappings, data sets, and data series to associate items

In this section:

- Create a data mapping
- Create a data set
- Create a data series
- Rule data mappings
- CDD mappings
- CIS data mappings and Clintrial subsets

Create a data mapping

You can create a data mapping when you design your study to define what your data will look like. You can create data mappings in both studies and libraries.

1. At the bottom of the Project Explorer, click the **Data Mappings** () button.
2. In the Project Explorer right-click a mapping folder and select the option shown:
   a. For Rule Mappings, select **New Rule Mapping**. Mappings definitions are not generated or validated.
   b. For CDD Mappings in the InForm Mappings folder, select **New CDD Mapping**. Mappings are generated and validated for a Customer-Defined Database.
   c. For CIS Mappings in the InForm Mappings folder, select **New CIS Mapping**. Mappings are generated and validated for synchronizing between the InForm application and the Clintrial application.
3. Enter the **Title**, **RefName**, and **Description**.

You can now create a data set in the data mapping.

Create a data set

The only place to create a data set is in a data mapping.The task must contain a procedure. Use the <steps> element for a multi-step procedure. Use the <steps-informal> element for a single-step procedure.

1. At the bottom of the Project Explorer, click the **Data Mappings** () button.
2. Expand a data mapping folder, right-click a data mapping, and select **New Data Set**.
3. Fill in the fields. **Title** and **RefName** are required.
4. To specify standard data dimensions, select one or more from the Standard Data Dimensions section.
5. To specify custom data dimensions for the data set:
   a. In the Custom Data Dimensions section, type a name and description and choose a data type for each custom data dimension.
   b. In the Codelist Lookup column, click the ellipsis button.
   c. On the Custom Dimension Labels window, from the **Description** drop-down list, select a an item.
   d. Highlight a code and click **OK**.

   Or:

   a. In the Custom Data Dimensions section, type a name and description, choose a data type, and click the ellipsis button in the Codelist Lookup column.
   b. On the Custom Dimension Labels window, click **New**.
   c. For the Object Name, type the **Title**, **RefName**, and **Description**, and click **OK**.
   d. In the grid, type the **Code** and **Label** pairs. To require users to select only the codelist labels that are in the codelist, select **Use only listed labels**. If you do not select it, a user-defined codelist label can be used.

> **Note:**
>
> If you select **Use only listed labels**, the codelist must have at least one codelist item

6. Click **OK**.
7. If the data set is in a CDD or CIS data mapping, in the **Properties Browser**, set the values of the appropriate CDD or CIS custom properties.

You can now create a data series in the data set.

Create a data series

A data series is a grouping of items with the same clinical meaning, such as items that measure weight. You can add items to a data series. These items can appear on multiple forms and study events. The only place to create a data series is in a data set.

> **Tip:**
>
> In CDD and CIS data mappings, the order in which you add data series to a data set determines the order of items in the CDD or Clintrial target table.

> **Tip:**
>
> You cannot change the order after a data series is added to a data set except by modifying the Item Order property in the Clintrial Design module after the data mappings are synchronized to the Clintrial application.

1. At the bottom of the Project Explorer, click the **Data Mappings** ( ) button.
2. Expand a data mapping folder, right-click a data mapping, and select **New Data Series**.
3. Fill in the fields. **Title** and **RefName** are required. **Description** and **Alias** are optional.

   If specified, the alias is used as the column name in the customer-defined database (CDD) or as the Clintrial item name in CIS mappings. If not, the RefName is used as the column header. Because RefNames must be unique throughout a study, you must create an alias if the RefName is used by a study object. Data series aliases must be unique within a data set.
4. From the **Type** drop-down list, select the data type for the series.

   The data types of an item and data series must be compatible for you to add the item to the data series.
5. Click **OK**.
6. If the data series is in a CDD or CIS data mapping, in the **Properties Browser**, set the values of the appropriate CDD or CIS custom properties.

You now can add one or more items to the data series.
For more information, see:

- Add an item to a data series by selecting a data series
- Add an item to a data series by selecting a study event or form
- Unmap an item mapping with a data series
- Change the data value associated with a data series

Add an item to a data series by selecting a data series

1. At the bottom of the Project Explorer, click the **Data Mappings** ( ) button.
2. In the Project Explorer, select one of the following:
   - Rule Mappings
   - InForm Mappings > CDD
   - InForm Mappings > CIS
3. Select a data series to display the items in the grid.
4. Select the **Add To** tab.
5. Do one of the following:
   - In the **Filter** field, type a keyword.
   - Click **Advanced Filtering**.
     - Specify the properties on which to apply the filter.

  - Specify the display format for the filtered results.

- Click **Refresh Results** ().

The item is added to the data series.

6. If you selected a data series that has custom dimensions, select the custom data dimension to use, and from the **Labels** drop-down list, choose a codelist label for the custom data dimension. Optionally, depending on how the custom data dimensions were set up, you might be able to provide a user-defined label in the **Labels** field. Click OK.

> **Note:**
>
> If you type a label or modify an existing label, a new codelist item is created for the codelist.

7. Optionally, add more items to the data series.

Add an item to a data series by selecting a study event or form

At the study event level, you indicate whether the item is mapped to the data series only when it appears on a specific study event or form.

1. In the Project Explorer, select the form or study event containing the item to be added to a data series.
2. Select the **Data Series Summary** tab.

   If a form is selected, its items appear in the grid.

   If a study event is selected, its forms appear in the grid.
3. Optionally, to change your view of the grid, use the filters at the top of the grid.
4. In the item's row in the grid, click the cell in the column for the data series to which you want to add the item.

> **Note:**
>
> If the item cannot be added to the data series—for example, if the data types for the item and data series are not compatible—**None compatible** appears in the cell.

5. Click the drop-down arrow at the right end of the cell, and select one of the following options from the list:
   - **None**—The item is not added to the data series.
   - **Always**—The item is always mapped to the data series, on every form, in every study, and in the library.
   - **Form**—The item is mapped to the data series only when the item appears on a specific section (or form, if the form has no sections). You can select this option for multiple sections or forms.

- **Study Event**—(Available only when a study event is selected.) The item is mapped to the data series only when it appears on any form in a specific study event. You can select this option for multiple study events.
- **Study Event & Form**—(Available only when a study event is selected.) The item is mapped to the data series only when it appears on a specific form in a specific study event.

6. If you selected a data series that has custom dimensions, select a value for each custom dimension, or, if providing a user-defined value is allowed, type a value for each custom dimension.

   If the item is an integer or float, you can map the normalized value, entered value, or entered unit to the data series.

   > **Note:**
   >
   > You can create one data series for each type of value, so you can map the item to three data series (one for each representation of the unit).

7. For an integer or float item with a selected unit, select the item representation to map to the data series. You have the following options:
   - Normalized value
   - Entered value
   - Entered unit
8. Optionally, add the item to more data series, or add other items to data series.

Unmap an item mapping with a data series

When you unmap an item in a study, the item is no longer part of the data series for the study, but it is still part of the data series in the library in which it is saved.

1. At the bottom of the Project Explorer, click the **Data Mappings** () button.
2. In the Project Explorer, select a data series.
3. Right-click the item, and select **Unmap the Data Series**.

> **Note:**
>
> You can restore an unmapped item if you want the item to be part of the data series for a study.

The mapping between the item and data series is removed, and the value in the **State** column changes to Unmapped for the item.

Change the data value associated with a data series

When you add an integer or float item with a selected unit to a data series, you choose if you want to map the normalized value, entered value, or normalized units to the data series. You can change the data value that is mapped at any time.

1. At the bottom of the Project Explorer, click the **Data Mappings** () button.
2. In the Project Explorer, select a data series.
3. In the grid, right-click an integer or float item, and select **Modify data point value collected**.
4. In the Item has Units window, select the value to associate with the data series, and click **OK**.

Rule data mappings

In this section:

- Modify labels of mapped custom data dimensions
- Delete a custom data dimension

Modify labels of mapped custom data dimensions

When you add an item to a data series in a data set with a custom data dimension, you are prompted to select a value for the custom data dimension and the data mapping. You can change the value at any time.

1. At the bottom of the Project Explorer, click the **Data Mappings** () button.
2. In the Project Explorer, select a data series.
3. In the grid, right-click an item and select **Modify labels**.
4. From the **Labels** drop-down list, choose a codelist label for the custom data dimension. Optionally, depending on how the custom data dimensions were set up, you might be able to provide a user-defined label in the **Labels** field.

> **Note:**
>
> If you type a label or modify an existing label, a new codelist item is created for the codelist.

5. Click **OK**.

Delete a custom data dimension

1. At the bottom of the Project Explorer, click the **Data Mappings** () button.
2. In the Project Explorer, select a data mapping.
3. In the grid, right-click a data set and select **Properties**.
4. In the **Custom Data Dimensions** section, right-click a custom data dimension, and select **Delete Row**.

CDD mappings

In this section

- Create a data set to use for CDD mappings
- Map associated forms to a CDD
- Set up a pivot table with CDD data mappings
- Modify CDD date time part data mappings

Create a data set to use for CDD mappings

When you create a deployment package, you choose the data mappings to include in the package, and the selected data mappings are deployed as CDDs in Oracle InForm. Data mappings created for CDD data mappings are deployed to Oracle InForm but must be enabled in Oracle InForm.

Map associated forms to a CDD

The target table for an association has a fixed format consisting of ID and index columns to identify visit instance, form instance, and patient for the data in the two associated forms. Instead of specifying data sets and data series for the data in each form, you specify the association.

1. Create two repeating forms and associate them. For more information, see the User Guide for Form Designers.
2. Create a data set.

> **Note:**
>
> Do not create any data series in the data set. You can create mappings for associations only in a data set that has no data series.

3. At the bottom of the Project Explorer, click the **Forms and Transactions** ( ) button.
4. In the **Properties** tab, select the associated forms as the value of the **Associated Forms** property, and press Enter.

> **Tip:**
>
> If you don't see the **Properties** tab, at the top left of the page, select **View**, and make sure **Properties** is selected.

> **Note:**
>
> If you change the association between two forms, you must manually update the data mapping by changing the value of the Associated Forms CDD custom property of the data set.

Set up a pivot table with CDD data mappings

The target key type specifies the composition of the primary key columns of the target table. Each time a component of the primary key changes from the previous primary key submitted, InForm inserts a new row in the target table.

1. Create a data set for the target table.
2. In the **Properties Browser**, select a **Target Key Type** value that begins with Pivot, and press Enter.
3. Create a data series for each column in the target table.
4. In the **Properties Browser**, select True as the value of the **Pivot Column** property for the data series to use as the pivot column, and press Enter.
5. For each text data series, in the **Properties Browser**, specify the maximum length of the target column as the value of the **Target Column Max Length** property, and press Enter.

CDD mapping properties

Study object	Option	Description
Item	Data Label	User-defined string to use for searching on data in the column. Maximum length is 30 characters. This label is included in the CDD data mapping control path definition in the InForm database. For CDD data mappings, it also appears in target CDD data mapping tables that have any of the following key types: Patient to Control, Pivot Patient, Pivot Visit, Pivot Form, and Pivot Section.
Data set	Associated Forms	Names of pairs of forms for which associations have been created. Selecting a pair of associated forms results in the generation of CDD data mappings for that association.

Study object	Option	Description
-	Target Key Type	For the following key types, the target key type specifies the composition of the primary key columns of the target table. Each time a component of the primary key changes from the previous primary key submitted, the InForm application inserts a new row in the target table. Primary keys consist of the following DBUIDs and indexes: • **Patient Only**—PatientID, FormIndex, ItemsetIndex. • **Patient Visit (default)**—PatientID, VisitID, FormIndex, ItemsetIndex, and VisitIndex. • **Patient to Form**—PatientID, VisitID, FormIndex, ItemsetIndex, VisitIndex, and FormID. • **Patient to Section**—PatientID, VisitID, FormIndex, ItemsetIndex, VisitIndex, FormID, and SectionID. • **Patient to Itemset**—PatientID, VisitID, FormIndex, ItemsetIndex, VisitIndex, FormID, SectionID, and ItemsetID. • **Patient to Item**—PatientID, VisitID, FormIndex, ItemsetIndex, VisitIndex, FormID, SectionID, ItemsetID, and ItemID. • **Patient to Control**—PatientID, VisitID, FormIndex, ItemsetIndex, VisitIndex, FormID, SectionID, ItemsetID, ItemID and five ControlIDs. A target table with this key type also contains a data label that can be used for data selection. For the following key types, the primary key columns are PatientID, VisitID, ItemsetIndex, VisitIndex, FormID, SectionID, ItemsetID, ItemID and five ControlIDs. The key type selection determines the composition of

Study object	Option	Description
		a pivot set. Within a pivot set, data points mapped to non-pivot columns are repeated in each row. Target tables with these key types also contain a data label that can be used for data selection. Pivot set keys consist of the following DBUIDs and indexes: • **Pivot Patient**—PatientID and VisitIndex • **Pivot Visit**—PatientID, VisitID, and VisitIndex • **Pivot Form**—PatientID, VisitID, FormID, and VisitIndex • **Pivot Section**—PatientID, VisitID, FormID, SectionID, and VisitIndex
Data series	Pivot Column	Identifies the column to use as the pivot column, if the key type is Pivot Form, Pivot Patient, Pivot Section, or Pivot Visit. **Note**: Only one column can be the pivot column, and it must be the first column in the table.
-	Target Column Max Length	Maximum length of a column, in the range 1-255. This property is applicable for columns with a type of STRING.

Modify CDD date time part data mappings

You can configure CDD data mappings for date time items so either the entire date appears in a single database column in the CDD or each date time part appears in a separate database column in the CDD. The generated data mappings include the SPLITDATE attribute of the TARGETCOLUMNTYPE tag.

1. At the bottom of the Project Explorer, click the **Data Mappings** () button.
2. In the Project Explorer, select a data series.
3. In the grid, right-click and item and select **Modify data point date part.**
4. Select one of the following:
   - **All in one column**—Changes the data mapping from multiple columns to one column.
   - **Split columns**—Changes the data mapping from one column to a column for each date time part.
5. Click OK.

CIS data mappings and Clintrial subsets

In this section:

- Set up data mappings for a Clintrial subset
- Create a custom Clintrial context panel
- Create a Clintrial enrollment panel
- Create a non-patient data (Type 0) panel
- Modify CIS date time part data mappings

Set up data mappings for a Clintrial subset

1. Create a data set for the grouping panel that contains the subset, and:
   - In the **Custom Data Dimensions** section of the **Data Set Properties** dialog box, add a custom data dimension for the subset key item.
     The name of the custom data dimension becomes the name of the subset key item in the data mappings and in the Clintrial panel. This name must not be the same as the RefName or alias of any data series in the data set.
   - In the **Custom Dimension Labels - Select Codelist** dialog box, select or create a codelist that has a codelist item label for each value that the subset key item can have.
2. Create a data series for each item in the subset.
3. Add the items that participate in the subset to the appropriate data series.
4. In the **Select Custom Dimension** dialog box for each item:
   a. Select the custom data dimension you created for the subset key item.
   b. In the **Labels** column, select the label that corresponds to the subset key item value with which the item will be stored in Clintrial.
   c. Click OK.

Create a custom Clintrial context panel

1. Create a data set for the context panel.
2. Create a data series for each context item.
3. On the **Properties** tab, set the values of custom properties for the data set and each data series, and press Enter.

   > **Tip:**
   >
   > If you don't see the **Properties** tab, at the top left of the page, select **View**, and make sure **Properties** is selected.

4. Optionally, map items to the data series.

> **Note:**
>
> The validation process checks the design of a custom context panel for compliance with Clintrial design rules. However, the Oracle Central Designer user interface does not enforce similar checking. Therefore, make sure that your definition of a custom Clintrial context panel does not violate Clintrial design considerations.

Create a Clintrial enrollment panel

1. Create a data set for the enrollment panel.

   > **Note:**
   >
   > Master-detail relationships are not supported in enrollment panels. If the **Detail Key Item**, **Detail Panel**, **Master Item**, or **Master Panel** CIS custom properties have values in the data set for an enrollment panel, validation fails.

2. On the **Properties** tab, set the value of the **Panel Type** CIS custom property to Enrollment, and press Enter.

   > **Tip:**
   >
   > If you don't see the **Properties** tab, at the top left of the page, select **View**, and make sure **Properties** is selected.

3. Create a data series for each screening or enrollment item to include in the panel. (Clintrial does not have a separate panel for screening and enrollment data.)
4. Add items to the data series.

Create a non-patient data (Type 0) panel

1. Create a data set for the non-patient data panel.

   > **Note:**
   >
   > Master-detail relationships are not supported in non-patient data panels. If the **Detail Key Item**, **Detail Panel**, **Master Item**, or **Master Panel** CIS custom properties have values in the data set for a non-patient data panel, validation fails.

2. On the **Properties** tab, set the value of the **Panel Type** CIS custom property to Non-Patient Data, and press Enter.

> **Tip:**
>
> If you don't see the **Properties** tab, at the top left of the page, select **View**, and make sure **Properties** is selected.

3. Create a data series for each item to include in the panel.

> **Note:**
>
> Do not map items to any of the data series in the panel.

Modify CIS date time part data mappings

You can set up CIS data mappings for date time items so that either all data appears in a single database column in the Clintrial database or so each date time part appears in a separate database column in the Clintrial database.

To split data mappings for a date time item into date part components, you define a separate data series and mapping for each date part. The data mappings that the Oracle Central Designer application generates include the DATEPART attribute of the CTITEM tag.

1. In the Project Explorer, select a data series.
2. Right-click an item, and select **Modify data point date part**.
3. To change the data mapping from multiple columns to one column, select All in one column.

   Or:

   To change the data mapping from one column to a column for each date time part:

   a. Select **Split Columns**.

   b. In the **CIS Date Part** list, select the date time part to map.
4. Click OK.

9

Validate and deploy a study

In this chapter:

- Before you begin: Make sure the workflow is valid
- Follow this four-step process

Before you begin: Make sure the workflow is valid

Before you start the validation and deployment process, validate the workflow to make sure that it is valid and that all of the study objects that it references still exist in the study.

If you receive an error during validation about an invalid workflow, perform these steps:

1. At the bottom of the Project Explorer, click the **Visit Schedule** () button.
2. Select a study design, study element, or study event.
3. Select the **Workflow Diagram** tab.
4. Right-click the workspace, and select **Refresh Workflow**.
    - Oracle Central Designer corrects the issues with the workflow. For example, if a workflow arrow is not pointing to anything, it is removed. You receive a message that tells you about any visible changes that have been made.
    - If no issues are detected, Oracle Central Designer does not change the workflow.

Follow this four-step process

The process of validating and deploying a study consists of the following steps:

1. Validate the study, creating a validation baseline.
2. Create a deployment instance.
3. Create a deployment package from a validation baseline.
4. Deploy the study to Oracle InForm.

There are two methods for deploying to the Oracle InForm application:
Automated deployment—A study design is moved directly from the Oracle Central Designer application to the Oracle InForm environment. For more information, see Initiate automated deployment.

Manual deployment—You must deliver and install a deployment package to the InForm environment. For more information, see Initiate manual deployment.

For more information, see:

- Step 1: Validate the study to create the validation baseline
- Step 2: Create a deployment instance
- Step 3: Create a deployment package from a validation baseline

- Step 4: Deploy the study to Oracle InForm

Step 1: Validate the study to create the validation baseline

In this section:

- Validate a study and create a baseline
- View baseline validation errors and warnings
- Make repairs to the study
- Save validation messages to a CSV file
- Make a validation baseline public

Validate a study and create a baseline

Show me how to validate a study and create a baseline

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Right-click the study folder, click **Validate**, and then **Study**.
3. In the message box that indicates the validation has started, click **OK**.
4. After the job finishes, check the status on the **Baselines** tab, located by default at the bottom of the Oracle Central Designer window.

   > **Tip:**
   >
   > If you don't see the Baselines tab, at the top left of the page, select View, and make sure Baselines is selected.

   A validation baseline can have the following statuses:

   - **Invalid**—One or more errors. The validation baseline cannot be used in a deployment package.
   - **Invalid with warnings**—One or more warnings. A user must indicate that the warnings can be ignored before using the validation baseline in a deployment package.
   - **Pending**—Validation is in process.
   - **Valid**—No errors. The validation baseline can be used in a deployment package.
   - **Valid with warnings**—One or more warnings. A user has indicated that the warnings can be ignored, and the validation baseline can be used in a deployment package.
5. Make needed repairs to the study.

View baseline validation errors and warnings

You can deploy a study that has received validation warnings, but you must acknowledge the warnings to indicate that you understand them and choose to ignore them to proceed with building the deployment package.

1. Open the **Baselines** tab.

> **Tip:**
>
> If you don't see the **Baselines** tab, at the top left of the page, select **View**, and make sure **Baselines** is selected.

2. Click **Refresh**.
3. Select the baseline validation to view.
4. Click **Show Validation**.
5. Expand the node that appears to the left of the row.

> **Tip:**
>
> To view the rest of a truncated message, hover over the text.

For more information, see:

- Resolve validation errors and warnings
- Ignore validation warnings

Resolve validation errors and warnings

You can build a deployment package only if validation produces no errors and no warnings, or if you resolve, acknowledge, or choose to ignore all warnings. A warning indicates that the study is valid, but the behavior of the study in Oracle InForm might not be expected or desired.

1. Open the **Baselines** tab.

> **Tip:**
>
> If you don't see the **Baselines** tab, at the top left of the page, select **View**, and make sure **Baselines** is selected.

2. Review the **Description** for each message for which the **Validation Type** is *Error* or *Warning*.
3. Double-click the error or warning.

   The error or warning may occur in multiple locations. If so, correct them one at a time.
4. Update the study definition as necessary to correct each error or warning, and save your changes.

Ignore validation warnings

You can build a deployment package only if validation produces no errors and no warnings, or if you resolve, acknowledge, or choose to ignore all warnings. A warning indicates that the study is valid, but the behavior of the study in Oracle InForm might not be expected or desired.

You ignore all warnings as a group. You cannot select specific warnings to ignore.

1. Open the **Baselines** tab.

> **Tip:**
>
> If you don't see the **Baselines** tab, at the top left of the page, select **View**, and make sure **Baselines** is selected.

2. Select a baseline with the status, Invalid with Warnings.
3. Examine the warning messages.
4. If you decide to ignore the warnings, click **Ignore Warnings**.

   The status of the validation baseline changes to *Valid with Warnings*.

Make repairs to the study

1. On the **Baselines** tab, view the messages for the validation baseline.

> **Tip:**
>
> If you don't see the **Baselines** tab, at the top left of the page, select **View**, and make sure **Baselines** is selected.

2. Review the **Description** for each message for which the **Validation Type** is *Internal Error*.

> **Note:**
>
> To view the complete text of a message that is truncated because of column size, hold the cursor over the portion of text that is visible. Alternately, select a row, and then right-click it and select **Properties**.

3. Right-click the error or warning.
4. Select **Repair Study**.
5. To start the repair, click **OK**.

> **Note:**
>
> You cannot undo this action.

6. If all the issues are resolved or Oracle Central Designer doesn't find any issues, click **OK**.

   If the study repair tool cannot resolve all issues, save a copy of the event log and contact Oracle Support.

> **Tip:**
>
> You can run study repair any time you want from the **Tools** menu.

Save validation messages to a CSV file

From the Baselines Browser or the Jobs Browser, you can save the processing messages for all validation baselines to a comma-separated value (CSV) file that can be opened in a Microsoft Excel spreadsheet.

This file contains all of the columns that the Baselines Browser or the Jobs Browser can display. This information differs between the Baselines Browser and the Jobs Browser. Additionally:

- A file saved from the Baselines Browser contains messages only from validation jobs.
- A file saved from the Jobs Browser contains messages from all types of jobs that appear in the Jobs Browser. These messages can include information from validation, deployment, and import jobs.

To save validation baseline messages from the Baselines tab:

1. Open the **Baselines Browser**.

> **Note:**
>
> If the Baselines Browser is not visible, select **View** > **Baselines**.

2. Click **Save As**, or right-click the browser, and select **Save As**.
   The Save As dialog box appears.
3. Browse to the location in which to save the file.
4. Specify a file name, and click **Save**.

To save validation baseline messages from the Job Log:

1. In the row of browser tabs, select the **Jobs Browser**.
   The Jobs Browser appears.
2. Select the **Jobs** tab.

> **Tip:**
>
> If you don't see the Jobs tab, at the top left of the page, select **View**, and make sure **Jobs** is selected.

3. Click **Save As**, or right-click the browser, and select **Save As**.
   The Save As dialog box appears.
4. Browse to the location in which to save the file.
5. Specify a file name, and click **Save**.

Baselines Browser - Option descriptions

Option	Description
Buttons	-

Option	Description
Edit	Edit the name and description of the selected baseline.
Delete	Delete the selected baseline. You can only delete a baseline that does not have a deployment package associated with it.
Ignore Warnings	View warning messages and either update the study to correct them or indicate that you will ignore the warnings.
Make Public	Mark a baseline as public so that other users can view and work with it.
Show Validation/Hide Validation	• **Show Validation**—Change from a grid to a tree structure that you can expand to view the validation messages generated during baseline creation. • **Hide Validation**—Change from a tree structure back to a grid that lists only baselines without validation messages.
Refresh	Refresh the display of baselines from the Oracle Central Designer database. Job results for baselines that are expanded are also refreshed from the database.
Save As	Save the contents of the Baselines Browser to a comma-separated value (CSV) file that can be opened in a Microsoft Excel spreadsheet.
Fields	**Note:** Not all fields appear in the default view. Optionally, you can add the other fields to the browser view, and you can rearrange the order of fields. For more information, see Showing and hiding a field.
Baseline ID	Unique identifier of the baseline.
Date Created	Date and time that the baseline was created.
Deployed	Yes or No, indicating whether the baseline has been processed for deployment.
Description	Description of the baseline, updated if you edit the baseline.
Job ID	Unique identifier of the job in which the baseline was created.
Name	Name of the baseline. By default, the name consists of the string **Validation baseline**, along with the date and time it was created.

Option	Description
Public	Yes or No, indicating whether the validation baseline has been made public.
Revision	Revision number of the baseline. The revision consists of three numbers: "Major.Minor.Revision," such as 1.0.2. • **Major and minor number**—The version number of the study design study object. If the study design does not have a version number, the first two numbers are 0.0, such as 0.0.4. • **Revision number**—The number of revisions made to the study since the most recent version label (either major or minor) was created.
Status	Status of the baseline: • **Valid**—No warnings and no errors. A baseline with this status can be processed for deployment. • **Valid with Warnings**—One or more warnings exist, but a user has updated them with the Ignore Warnings menu command. A baseline with this status can be processed for deployment. • **Pending**—Validation is in process. • **Invalid with Warnings**—One or more warnings exist and have not been updated with the Ignore Warnings menu command. A baseline with this status cannot be processed for deployment. • **Invalid**—One or more errors exist. A baseline with this status cannot be processed for deployment.
Study ID	Unique identifier of the study for which the baseline is generated.
Sub-columns	The following columns are in the grid that appears when you click Show Job Results and expand the results for a job.
Code	Unique identifier for the validation error or warning. You can provide the code when submitting issues to Oracle Support.
Description	Description of the baseline message.
Date Created	Date and time the validation message was created.
Issue Name	Type of issue for which the job result is reporting. This field contains a value only if the job result is a validation error on a rule. Options include Rule Name and sometimes Function Name.
Job Id	Unique identifier of the job in which the baseline was created.
Job Result Id	Unique identifier of the baseline message.
Object RefName	RefName of the study object that is reported in the validation message. This field contains a value only if the job result is a validation error on a rule.

Option	Description
Object Title	Title of the study object that is reported in the validation message. This field contains a value only if the job result is a validation error on a rule.
Path	Path of the study object that is reported in the validation message. This field contains a value only if the job result is a validation error on a rule.
Validation Type	Type of message: • **Information**—Description of the processing step being performed during validation. • **Warning**—Irregularity that should be investigated. Further processing (for example, creation of a deployment package) can be performed if you explicitly choose to ignore warnings. • **Error**—Fatal problem. No further processing (for example, creation of a deployment package) can be performed until all errors are corrected.
Warning Ignored	Indicates if you have chosen to ignore a warning.

Job Log Browser - Option descriptions

> **Note:**
>
> Not all fields appear in the default view. Optionally, you can add the other fields and rearrange the browser view.

Option	Description
Buttons	-
Hide Job Results/ Show Job Results	• **Show Job Results**—Change from a grid to a tree structure that you can expand to view the job results for each job. • **Hide Job Results**—Change from a tree structure back to a grid that lists only jobs without job results.
Refresh	Refresh the display of jobs from the Oracle Central Designer database. When you refresh, the job results for expanded jobs are also refreshed.
Save As	Save the contents of the Jobs Browser to a comma-separated value (CSV) file that can be opened in a Microsoft Excel spreadsheet.
Jobs Since	Drop-down list specifying how far back the display of job results goes.
Columns	-
Finish Time	Date and time at which the job ended.
Job State	Run status of the job, either Started or Finished.
Job Id	Unique identifier of the job that generated the listing.

Option	Description
Job Result	Indicates whether the job scheduler ran successfully for the specified job. This field is **not** an indication of the status of the job. • Succeeded • Failed
Name	Name of the job: • **For deployment package jobs**—Name of the deployment package. • **For library import jobs**—[Import to], plus the name of the target library. • **For validation jobs**—[Validation baseline], plus the date and time of job submission.
Start Time	Date and time when the job started.
Status	Overall status of the job results for the selected job. • **Information**—Job results contain only informational messages. This status also appears if the job has started but no job results have been reported yet. • **Warning**—Job results contain at least one warning (but no errors). • **Error**—Job results contain at least one error.
Status Icon	Icon that corresponds to the status of the job.
Study Id	Unique identifier of the study for which the job was run.
Type	Type of job, either Import, Validation, or BuildDeploymentPackage.
Sub-columns	The following columns are in the grid that appears when you click Show Job Results and expand the results for a job.
Code	Unique identifier for the validation error or warning. You can provide the code when submitting issues to Oracle Support.
Date Created	Date and time the message was generated.
Description	Text of the message.
Issue Name	Type of issue for which the job result is reporting. This field contains a value only if the job result is a validation error on a rule. Options include Rule Name and sometimes Function Name.
Job Id	Unique identifier of the job that generated the listing.
Job Result Id	Unique identifier of the job result.
Object RefName	RefName of the study object that is reported in the job result. This field contains a value only if the job result is a validation error on a rule.
Object Title	Title of the study object that is reported in the job result. This field contains a value only if the job result is a validation error on a rule.

Option	Description
Path	Path of the study object that is reported in the job result. This field contains a value only if the job result is a validation error on a rule.
Target	Target application for which you validate the study and to which you deploy the study.
Type	Type of message: • **Information**—Description of the processing step being performed in the job. • **Warning**—Irregularity that should be investigated. Further processing (for example, creation of a deployment package) can be performed if you explicitly choose to ignore warnings. • **Error**—Fatal problem. No further processing (for example, creation of a deployment package) can be performed until all errors are corrected.
Type Icon	Icon that corresponds to the type of message.
Warning Ignored	True or False, indicating whether you have chosen to ignore the warning message for the purpose of performing additional processing.

Make a validation baseline public

When you create a validation baseline, it is considered temporary. Only you can view and work with it. Subsequent validation jobs that you run overwrite it. To enable other users to view and work with a validation baseline, you must make it public.

> **Note:**
>
> If you don't explicitly make the validation baseline public, creating a deployment package automatically makes it public.

1. Open the **Baselines** tab.

   > **Tip:**
   >
   > If you don't see the **Baselines** tab, at the top left of the page, select **View**, and make sure **Baselines** is selected.

2. Select a baseline and click **Make Public**.
3. In the **Name** field, type the name of the baseline.
4. In the **Description** field, type a description for the baseline.
5. Click **OK**.

Step 2: Create a deployment instance

Create a deployment instance to define the Oracle InForm servers to which to deploy the study. You do this by creating a deployment instance study object for each server.

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Select a study.
3. Select the **Deployment Setup** tab.
4. On the toolbar at the top of the Deployment Setup tab, click Create Deployment Instance ( ).
5. In the **Name** field, type the RefName of the deployment instance.

   The name that you choose is used when you deploy the study manually.
6. In the **Type** drop-down list, select the type of deployment instance:
   - **DEV—**Development
   - **LIVE—**Production
   - **QA—**Quality assurance
   - **TRN—**Training
   - **UAT—**User acceptance testing
7. In the **Trial URL** field, type the URL used to log on to the machine on which to deploy the Oracle InForm study.
8. In the **Status URL** field, type the URL used to query for the deployment status of the study.

   > **Note:**
   >
   > You can add one deployment instance for each server type.
9. To require approval for the deployment instance, select the **Approvals Required** check box.
10. In the **Description** field, type a description of the deployment instance.
11. Click **OK**.

> **Note:**
>
> To reference a deployment instance in a deployment request, the deployment instance must not have any unsaved changes.

Go to:

- Test the deployment instance

Test the deployment instance

To test the deployment instance URL:

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Select a study.
3. Select the **Deployment Setup** tab.
4. Select the URL.
5. On the toolbar at the top of the **Deployment Setup** tab, click the **Test URL** button.

> **Note:**
>
> When using Federation credentials, it is recommended to also validate the compatibility of your Federation Identity Provider (IdP) by attempting a non-LIVE autodeployment, since a non-compatible IdP may cause the deployment to fail. If this is the case, please log in using your Oracle Health IAMS credentials instead.
>
> For more information on Federation credentials, see the *Oracle InForm User Guide for Site Users*.

Step 3: Create a deployment package from a validation baseline

In this section:

- Create a deployment package: the basics
- Create a full deployment package
- Create an incremental deployment package
- Create an administration data deployment package
- Create a custom events deployment package
- View the deployment packages
- Delete a deployment package

Create a deployment package: the basics

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Right-click a study, and select **Create Deployment Package**.
3. To start the **Create Deployment Package Wizard**, click **Next**.
4. On the **Select a Deployment Package Type** page, specify the type of deployment package to create (full, incremental, administration data, or custom events).

   Based on this choice, the Create Deployment Package Wizard prompts for different information as you progress through the wizard.
5. On the final page of the **Create Deployment Package Wizard**, click **Finish**.

A deployment package job starts, and a slide-up message appears to indicate when the job starts and completes.

6. When the job completes, check the status in the Jobs Browser.

> **Tip:**
>
> Develop naming conventions for validation baselines and deployment packages. For example, name validation baselines that are created while testing the study design differently from validation baselines that are actually deployed.

Create a full deployment package

A full deployment package contains everything needed to deploy a complete study, including study administration data.

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Right-click a study, and select **Create Deployment Package**.
3. To start the **Create Deployment Package Wizard**, click **Next**.
4. On the **Select a Deployment Package Type** page, select **Full package** and click **Next**.
5. Select the baseline from the drop-down list and click **Next**.

   If you select an unpublished validation baseline, it becomes public during creation of the deployment package.
6. Select one or more locales and click **Next**.
7. Select the layout to deploy and click **Next**.

   The locale selected determines the language in which forms appear.
8. Enter a name and description for the deployment package.
9. To use the default email drop box, select **Use default**. Otherwise, enter an email address for the drop box.
10. To apply the newly deployed study version to all sites, select **Yes**.
11. Click **Next**.
12. Review the options and click **Finish**.

Create an incremental deployment package

You can create an incremental deployment package for a previously created deployment package when changes have been made to the study. The incremental deployment package contains everything needed to deploy a complete study, plus additions and changes to the study reflected in Alternate forms in Oracle InForm. Alternate forms are not created for repeating forms, or forms with a dynamic grid.

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Right-click a study, and select **Create Deployment Package**.
3. To start the **Create Deployment Package Wizard**, click **Next**.

4. On the Select a **Deployment Package Type** page, select **Incremental package** and click **Next**.
5. From the drop-down list, select the previously created deployment package for which this is an incremental package and click **Next**.
6. From the drop-down list, select the validation baseline to use and click **Next**.

   The date and time of the baseline must be later than the validation baseline used to create the deployment package selected on the previous page.
7. Enter a name for the deployment package and an optional description.
8. To use the default email drop box, select **Use default**. Otherwise, enter an email address for the drop box.
9. To apply the newly deployed study version to all sites, select **Yes**.
10. Click **Next**.
11. Review the options and click **Finish**.

Create an administration data deployment package

The administrative data deployment package contains only administration study data.

1. At the bottom of the Project Explorer, click the Study Information ( ) button.
2. Right-click a study, and select **Create Deployment Package**.
3. To start the **Create Deployment Package Wizard**, click **Next**.
4. On the Select a **Deployment Package Type** page, select **Administrative package** and click **Next**.
5. Select the baseline from the drop-down list and click **Next**.

   If you select an unpublished validation baseline, it becomes public during creation of the deployment package.
6. Enter a name and description for the deployment package.
7. Review the options and click **Finish**.

Create a custom events deployment package

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Right-click a study, and select **Create Deployment Package**.
3. To start the **Create Deployment Package Wizard**, click **Next**.
4. On the Select a **Deployment Package Type** page, select **Custom events** and click **Next**.
5. Select a baseline that has Custom Event IPR changes and click **Next**.
6. Select one or more locales and click **Next**.
7. Enter a name and description for the deployment package.
8. To use the default email drop box, select **Use default**. Otherwise, enter an email address for the drop box.
9. To apply the newly deployed study version to all sites, select **Yes**.

10. Click **Next**.
11. Review the options and click **Finish**.

View the deployment packages

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. In the Project Explorer, double-click the **Deployment** folder.

Delete a deployment package

Only deployment packages that have **not** been associated with a successful deployment to LIVE/UAT should be deleted.
Deleting packages associated with successful deployment to LIVE/UAT is prevented in the user interface when the deployment was an autodeployment.

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.

   (Optional) Enter the result of the step here.
2. Select the **Deployment** folder.
3. Right-click the row containing the deployment package you want to delete, and click **Delete**.

   > **Note:**
   >
   > If you have used manual deployment for this study previously, use caution when deleting deployment packages. Deleting packages that have been manually deployed to LIVE/UAT could result in issues when validating or deploying in-place revisions.

   For more information, see What checks are performed during validation > Validation for in-place revisions and Can I delete a validation baseline?
4. Confirm the deletion.
5. Click **OK**.

Step 4: Deploy the study to Oracle InForm

In this section:

- Initiate automated deployment
- Initiate manual deployment

Initiate automated deployment

Automated deployment is the process through which a study design is moved directly from the Oracle Central Designer application to the Oracle InForm environment.

> **Note:**
>
> Automated deployment is supported only in release 6.1 and later of the Oracle InForm application.

The deployment request is the basis of the automated deployment process. Automated deployment involves four steps:

1. The Oracle Central Designer application transfers the deployment package to the Oracle InForm server and installs the package according to the schedule configured in the deployment request. Set up the Oracle InForm environment.
2. Create a deployment instance to define the Oracle InForm servers to which to deploy the study.
3. Create a deployment request for a deployment package.
4. If the deployment requires it, obtain approval.

Oracle Central Designer transfers the deployment package to the Oracle InForm server and installs the package according to the schedule configured in the deployment request.
For more information, see:

- Set up the Oracle InForm environment
- Create a deployment request
- Obtain deployment approval, if required
- Cancel a deployment
- Viewing the history of deployments associated with your user account
- View the history of a deployment package
- Viewing and exporting the deployment log

Set up the Oracle InForm environment

You must create the Oracle InForm server and study before you use the automated deployment feature. For more information, see the *Oracle InForm Study and Reporting Setup Guide*.

Before you can perform automated deployments to Oracle InForm, you also must meet the following prerequisites:

- In Oracle Central Designer Administrator, roles must exist with the Create deployment request and Approve deployment request rights, and users must be assigned to these roles. For more information, see the *Administrator Guide*.
- Users assigned to roles with the Create deployment request and Approve deployment requests rights must be on the study team. For more information, see Set up study teams.
- The deployment instance to which the deployment will be performed must be set up. For more information, see Create a deployment instance.
- In Oracle Central Designer Administrator, configure the default deployment options for each type of deployment instance.

Create a deployment request

Create a deployment request for a deployment package to define where the study is deployed, what the deployment options and schedule are, and who should be notified of the deployment.

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Double-click the **Deployment** folder.
3. Select the deployment package to deploy by clicking it.
4. On the toolbar at the top of the **Deployment Setup** tab, click **Deployment**, and select **Request**.
5. From the **Name** drop-down list, select the target deployment instance.
6. Set the deployment schedule. You can perform the deployment immediately or at a specific time.

> **Note:**
>
> A LIVE deployment, configured to deploy immediately, is delayed five minutes.

7. From the **Deployment option** drop-down list, select whether to deploy to a new trial or modify an existing trial.
8. From the **Reason for deployment** drop-down list, select one or more reasons for the deployment request.
9. Optionally, enter additional information about the deployment.

> **Note:**
>
> This information is not included in the email notifications.

10. In the **Email distribution list** table, select the users to receive email notifications about the deployment.

> **Tip:**
>
> If approvals are required for the deployment instance, you must select at least one user with the right to approve deployments.

11. Optionally, to set the deployment start delay option, select the **Advanced** tab.

    For more information, see Deployment Request dialog box—Option descriptions.
12. Click **OK**.
13. If your study requires deployment request approval, click **Request Approval**.

    You must wait for approval before continuing with the deployment request.
14. Click **Deploy**.
15. Review the deployment information, then click **Deploy**.

> **Note:**
>
> Make sure the schedule of deployments to the LIVE deployment instance does not interfere with the operation of the production environment.

16. If the deployment request does not require an approval, the Oracle InForm Login dialog box appears.
17. Type your Oracle InForm user name and password, and click **Login**.

Obtain deployment approval, if required

1. On the toolbar, click the **Home Page** button ().
2. Select the **Pending Approvals** tab.
3. In the grid, select a deployment request.
4. On the toolbar, click **Approve/Reject**. This locks the request.
5. Do one of the following:
   - To approve the request, select **Approve**, sign the approval affidavit by providing your password, and click **Approve**. You will be asked to log into Oracle InForm.
   - To reject the request, select **Reject**, select a reason for rejecting, optionally, type additional information in the corresponding text box, and click **Reject**.

   Oracle Central Designer immediately transfers the deployment package to the Oracle InForm server and installs it according to the schedule specified in the deployment request.

Cancel a deployment

1. At the bottom of the Project Explorer, click the **Study Information** () button.
2. In the Project Explorer, double-click the **Deployment** folder, then click one of the deployment packages shown in the grid.
3. From the toolbar at the top of the list, click **Deployment** and select **History**.

> **Note:**
>
> The History choice is available only if the deployment package has been deployed.

4. Select a deployment and do one of the following:
   - To cancel a deployment with the status of Scheduled or Submitted, click **Cancel Deployment**.
   - To cancel a deployment request that has not been approved or rejected yet, click **Cancel Deployment Request**.
5. Enter a reason for the cancellation and, optionally, additional information, and click **OK**.

6. If presented with the Oracle InForm Login, type your Oracle InForm user name and password, click **Login**., and confirm the login.

Viewing the history of deployments associated with your user account

You can view detailed information about the deployment requests:

- You created.
- Awaiting your approval.
- Approved or rejected by you.

> **Note:**
>
> If you have the **View deployments across studies** right, you see a complete record of automated deployments from all studies.

In the upper-left corner, click **Tools**, then **Deployment History**.

View the history of a deployment package

You can view a complete history of all the deployment requests created for a deployment package, and any approvals, rejections, or cancellations associated with the deployment requests.

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. In the Project Explorer, click the **Deployment** folder.
3. Select a deployment package from the grid.
4. On the toolbar above the grid, select **Deployment**, then **History**.

Viewing and exporting the deployment log

To follow the progress of a deployment after the deployment package has been transferred to the Oracle InForm server, view the deployment log. The following information is available for each entry:

- Deployment Step—Description of step reached in the deployment process.
- Timestamp—Time when the step was reached and the entry was added to the log.

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. In the Project Explorer, click the **Deployment** folder.
3. Select a deployment package from the grid.
4. On the toolbar above the grid, select **Deployment**, then **History**.
5. Select a deployment and click **View Log** on the toolbar.
6. To export the complete deployment log to a CSV file, click **Export**.

Initiate manual deployment

Manual deployment involves these steps:

…..Create a deployment instance

- Save a deployment package
- Install the deployment package
- Execute the deployment package

Save a deployment package

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. In the Project Explorer, select the **Deployment** folder.
3. From the grid, select the deployment package to deliver.
4. On the toolbar above the grid, click **Save as**.
5. If you are deploying to Oracle InForm release 6.1 or later:
   a. In the **Deployment options** section, in the **Deployment Start Delay** field, specify a time in milliseconds to delay deployment.
   b. Select a deployment instance to which to deploy the study. The Type and URL fields are populated with the deployment type and deployment URL for the selected deployment instance. Oracle Central Designer does the following:
      - Determines whether Oracle InForm needs to update the study workflow.
      - Identifies rules that were deleted or disabled since the most recent successful deployment so that the rules in Oracle InForm can match what is in Oracle Central Designer.
6. Click **Save**, and specify the location in which to save the deployment package ZIP file.

Install the deployment package

There are two ways to install the deployment package:

1. Use the Deployment Wizard.
2. Use the command-line options.

For more information, see:

- Install the study and update the rules
- Use the Deployment Wizard
- Use the command-line options

Install the study and update the rules

Install the study

1. If you are deploying to an Oracle InForm release prior to 6.1, you must use the PKGInst.exe file from the Oracle Central Designer software distribution to process the deployment package and install the study to the Oracle InForm application.
   a. Copy the PKGInst.exe file in the InstallSupport folder on the software distribution.

b. Paste the file to the Oracle InForm server, and run the deployment from that location.

2. Save a deployment package to the file system.
3. Save the package in a location from which it can be retrieved (for example, a folder on a shared network).
4. Install the deployment package on the computer where Oracle InForm is running. You must have the following administrative privileges on the Oracle InForm computer:
   - Permission to install and register COM objects.
   - Permission to write to the \bin and \Trials folders in the Oracle InForm directory structure.
5. Install the deployment package:
   - Using the Deployment Wizard.
     or
   - Using command-line options.

Update the study rules

If you migrated to Oracle Central Designer release 2.1.2 or later and this is the first time you are deploying to Oracle InForm release 6.1.1 or later, you must do one of the following to update the workflow rules for the study.

- Run the pfadmin updateworkflow command. For more information, see the *Oracle InForm Installation Guide* or the *Oracle InForm Study and Reporting Setup Guide*.
- n the Oracle InForm application, run rules in batch mode. For more information, see the *Oracle InForm User Guide for Administrators*.

Use the Deployment Wizard

1. Log on to the computer where the Oracle InForm server software is installed.
2. Open a command prompt and run the following command to open the Deployment Wizard:

   PKGInst.exe [/df *File***]**

   where **File** is the full path to the deployment package ZIP file.
3. Click **Next** to complete the pages of the Deployment Wizard.
4. Click **Finish**.

Use the command-line options

Using this feature, you can execute a deployment package by running a script that contains command-line deployment options or a reference to a configuration file of deployment options.

1. Log on to the computer where the Oracle InForm server software is installed.
2. Open a Microsoft Windows command window.
3. Do one of the following:
   - In the directory where the deployment package is saved, run the `PKGInst.exe` executable, along with the desired deployment options.
   - Execute a script that contains the desired deployment options.

- Execute a script that refers to an XML configuration file containing the desired deployment options.

Deployment command-line options

The usage for the deployment command-line feature is as follows:

```
/help |
/testconversion | /testc |
/silent [/ConfigFilefilename] |
[[/LogFileNamefilename][/UnpackDirectorydirectoryname][/
ForceBASEInstall (TRUE | FALSE)][/CheckInFormVersion (TRUE | FALSE)][/
DontExitIfUnsuccessful (TRUE | FALSE)][/ServerServerName][/
TrialTrialName][/UserUserName ][/Password UserPassword]
[/Strict (TRUE | FALSE)][/TrialCreateModeValue (DB [/Connect
DatabaseConnectString]| DSN [/TRIDSNDSNString])]]
```

For example, the following statement installs the ASM916S deployment package, without prompting for user input, to a study called ASM916 on an Oracle InForm server called INF916:

```
ASM916S.exe /silent /LogFileName ASM916S.log /ForceBASEInstall TRUE /
Server INF916 /Trial ASM916 /User ASM916uid /Password ASM916pid /
Strict TRUE /TrialCreateModeValue DB /Connect APPSRV_dev1
```

Option	Description
/help	Display a dialog box summarizing the command-line usage and options.
/CsmlToMedml or /cm [filename]	Convert the study to MedML.

Note:

Optionally, you can specify a file name. If you do not specify a file name, an XML file is saved in the directory that holds the deployment package.

Option	Description
/Csml [filename]	Extract the CSML from the deployment package. **Note:** Optionally, you can specify a file name. If you do not specify a file name, a CSML file is saved in the directory that holds the deployment package.
/RuleAssembly or /rule [directoryname]	Extract the rule assembly and all function DLL files. **Note:** Optionally, you can specify a directory in which to store the files. If you do not specify a directory, a rule directory is created in the directory that holds the deployment package, and all extracted files are saved in the directory.

Option	Description
/DesignerUnit or /unit [directoryname]	Export the units file. **Note:** Optionally, you can specify a directory in which to store the file. If you do not specify a directory, the file is saved in the directory that holds the deployment package.
/Version or /ver	Obtain the release number of the Oracle Central Designer application from which the deployment package was created.
/testconversion or /testc	Test whether the deployment package can create MedML from CSML, without installing the MedML files in an Oracle InForm study. The MedML files generated by the deployment process are saved to a temporary system directory or to a directory that you specify using the /UnpackDirectory option.
/silent	Run in silent mode (without prompting for user input), using the options specified either on the command line or in the configuration file named in the /ConfigFile option. In silent mode the Deployment Wizard appears, enabling you to follow the progress of the deployment, but does not prompt you for deployment options.
/ConfigFile *filename*	Use the specified configuration file to obtain deployment options.
/LogFileName *filename*	Create a log file in the specified location. By default, a log file called StudyInstaller.log is created in the Oracle InForm installation folder.
/UnpackDirectory *directoryname*	Unzip the deployment package in the specified local directory. Deployment files include: • Deployment package EXE file. • Deployment DLLs. • MedML.xml file containing the MedML generated by the deployment process if the deployment is unsuccessful. If you do not specify this option, the files are unzipped to a temporary system directory. The StudyInstaller.log file includes the location of the deployment files.

Option	Description
/ForceBASEInstall (TRUE | FALSE)	• **TRUE**—Clear the study database, if the study exists, and install the Base study. • **FALSE**—(Default) Do not force the Base study to be installed.
/CheckInFormVersion (TRUE | FALSE)	• **TRUE**—(Default) Check the Oracle InForm version to make sure that it is compatible with the current version of the Oracle Central Designer application. If the software versions are not compatible, deployment does not continue. • **FALSE**—Do not check the Oracle InForm version to make sure that it is compatible with the current version of the Oracle Central Designer application. You might select this option if you are running deployment with the /testconversion option, which does not install the study MedML.
/DontExitIfUnsuccessful (TRUE | FALSE)	• **TRUE**—Keep the Deployment Wizard open if the deployment is unsuccessful. • **FALSE**—(Default) Close the Deployment Wizard if the deployment is unsuccessful.
	The following values are required if you run deployment in silent mode; otherwise, they are optional. If you specify any of the following command-line options and do not run in silent mode, the corresponding fields in the Deployment Wizard are populated with the values you specify.
/Server *ServerName*	Name of the Oracle InForm application server.
/Trial *TrialName*	Name of the Oracle InForm study.
/User *UserName*	Oracle user name for the study database.
/Password *UserPassword*	Oracle password for the study database.
/Strict (TRUE | FALSE)	• **TRUE**—Only complete MedML definitions of study components can be loaded into the study; an incomplete definition causes the installation to fail. • **FALSE**—Incomplete study component definitions are permitted.
/TrialCreateModeValue (DB | DSN)	• **DB**—The deployment process creates an ODBC connection for the study to the specified database instance. When you specify this option, include the connection string to the database instance in the /Connect option. • **DSN**—The study uses an existing ODBC connection. When you specify this option, include the name of the study DSN in the /TRIDSN option.
/Connect *DatabaseConnectString*	Connection string for the Oracle instance.
/TRIDSN *DSNString*	ODBC System DSN for the Oracle InForm study.

Option	Description
/ServerAutoStartup	The Oracle InForm server starts automatically when the InForm Service starts. If you do not include the /ServerAutoStartup option, the Oracle InForm server must be started manually.
/TrialAutoStartup	The Oracle InForm study starts automatically when the InForm Service starts. If you do not include the /TrialAutoStartup option, the Oracle InForm study must be started manually.
/CacheInitWaitTime	Time to wait (in milliseconds) for the Oracle InForm caches to initialize.

Deployment ConfigFile options

As an alternative to entering deployment options at the command line or in a script, you can include the options for executing a deployment package in a configuration file referenced by the /ConfigFile command-line option. The configuration file is in XML format.

Option	Description
<DeploymentData>	xmlns:xsd="http://www.w3.org/2001/XMLSchema" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="http://www.phaseforward.com/DeploymentData/2006-04-25"
<HostName />	Reserved for future use.
<HostUserName />	
<HostUserPassword />	
<HostSharedDirectory />	
<HostSharedDirectoryLocalPath />	
<TargetType/>	INFORM
<ServerName/>	Name of the Oracle InForm application server.
<TrialName/>	Name of the Oracle InForm study.
<UserName/>	Oracle user name for the study database.
<UserPassword/>	Oracle password for the study database.
<StrictMode/>	• **TRUE**—Only complete MedML definitions of study components can be loaded into the study; an incomplete definition causes the installation to fail. • **FALSE**—Incomplete study component definitions are permitted.
<TrialMode/>	• **DB**—The deployment process creates an ODBC connection for the study to the specified database instance. When you specify this option, include the connection string to the database instance in the <DatabaseConnectString/> option. • **DSN**—The study uses an existing ODBC connection. When you specify this option, include the name of the trial DSN in the <TRIDSN /> option.

Option	Description
<TRIDSN />	ODBC System DSN for the Oracle InForm study.
<DatabaseConnectString/>	Connection string for the Oracle instance.
<TrialStartupMode/>	• **Automatic**—The Oracle InForm study starts automatically when the Oracle InForm Service starts. • **Manual**—The Oracle InForm study must be started manually.
<ServerStartupMode/>	• **Automatic**—The Oracle InForm server starts automatically when the Oracle InForm Service starts. • **Manual**—The Oracle InForm server must be started manually.
<ForceBASEInstall/>	• **TRUE**—Clear the study database, if the study exists, and install the Base study. • **FALSE**—(Default) Do not force the Base study to be installed.
<CheckInFormVersion/>	• **TRUE**—(Default) Check the Oracle InForm version to make sure that it is compatible with the current version of the Oracle Central Designer application. If the software versions are not compatible, deployment does not continue. • **FALSE**—Do not check the Oracle InForm version to make sure that it is compatible with the current version of the Oracle Central Designer application. You might select this option if you are running deployment with the /testconversion option, which does not install the study MedML.
<ProtocolName />	Reserved for future use.
<ProtocolUserName />	
<ProtocolUserPassword />	
<DBAdminUser />	
<DBAdminUserPassword />	
<DataSpace />	
<TableSpace />	
<UNCHelpDirectory />	
<VirtualHelpDirectory />	
<WebPath />	
<SSL/>	

Execute the deployment package

In this section:

- Deployment command-line options
- Deployment ConfigFile options
- Sample deployment configuration file

Deployment command-line options

The usage for the deployment command-line feature is as follows:

/help |

/testconversion | **/testc** |

/silent [**/ConfigFile** *filename*] |

[[**/LogFileName** *filename*][**/UnpackDirectory** *directoryname*][**/ForceBASEInstall** (**TRUE** | **FALSE**)][**/CheckInFormVersion** (**TRUE** | **FALSE**)][**/DontExitIfUnsuccessful** (**TRUE** | **FALSE**)][**/Server** *ServerName*][**/Trial** *TrialName*][**/responsefile** *File*]

[/Strict (TRUE | FALSE)][/TrialCreateModeValue (DB [/Connect DatabaseConnectString]| DSN [/TRIDSN DSNString])]]

For example, the following statement installs the ASM916S deployment package located in the C:\ directory, without prompting for user input, to a study called ASM916 on an Oracle InForm server called INF916:

```
Oracle.Designer.DeploymentInstaller /DeploymentFile C:\ASM916S.zip/
silent /LogFileName ASM916S.log /ForceBASEInstall TRUE /Server INF916 /
Trial ASM916 /User ASM916uid /Password ASM916pid /Strict TRUE /
TrialCreateModeValue DB /Connect APPSRV_dev1
```

Option	Description
/help	Display a dialog box summarizing the command-line usage and options.
/CsmlToMedml or /medml [filename]	Convert the study to MedML.

Note:

Optionally, you can specify a file name. If you do not specify a file name, an XML file is saved in the directory that holds the deployment package.

Option	Description
/FullCsml [filename]	Extract the CSML from the deployment package. **Note:** Optionally, you can specify a file name. If you do not specify a file name, a CSML file is saved in the directory that holds the deployment package.
/InFormCsml	Extract the CSML that was deployed to Oracle InForm.
/RuleAssembly or /rule [directoryname]	Extract the rule assembly and all function DLL files. **Note:** Optionally, you can specify a directory in which to store the files. If you do not specify a directory, a rule directory is created in the directory that holds the deployment package, and all extracted files are saved in the directory.

Option	Description
/DesignerUnit or /unit [directoryname]	Export the units file. **Note:** Optionally, you can specify a directory in which to store the file. If you do not specify a directory, the file is saved in the directory that holds the deployment package.
/CustomProperties or /CP	Extract the custom properties.
/Target targetid [foldername]	Extract the CSML to the specified folder.
/TargetList	Target applications for the deployment package.
/Version or /ver	Obtain the release number of the Oracle Central Designer application from which the deployment package was created.
/silent	Run in silent mode (without prompting for user input), using the options specified either on the command line or in the configuration file named in the /ConfigFile option.
/ConfigFile *filename*	Use the specified configuration file to obtain deployment options.
/LogFileName *filename*	Create a log file in the specified location. By default, a log file called StudyInstaller.log is created in the Oracle InForm installation folder.
/UnpackDirectory *directoryname*	Unzip the deployment package in the specified local directory. Deployment files include: • Deployment package. • Deployment DLLs. • MedML.xml file containing the MedML generated by the deployment process if the deployment is unsuccessful. If you do not specify this option, the files are unzipped to a temporary system directory. The StudyInstaller.log file includes the location of the deployment files.
/ForceBASEInstall (TRUE | FALSE)	• **TRUE**—Clear the study database, if the study exists, and install the Base study. • **FALSE**—(Default) Do not force the Base study to be installed.

Option	Description
/CheckInFormVersion (TRUE | FALSE)	• **TRUE**—(Default) Check the Oracle InForm version to make sure that it is compatible with the current version of the Central Designer application. If the software versions are not compatible, deployment does not continue. • **FALSE**—Do not check the Oracle InForm version to make sure that it is compatible with the current version of the Central Designer application. You might select this option if you are running deployment with the /testconversion option, which does not install the study MedML.
/DontExitIfUnsuccessful (TRUE | FALSE)	• **TRUE**—Keep the Deployment Wizard open if the deployment is unsuccessful. • **FALSE**—(Default) Close the Deployment Wizard if the deployment is unsuccessful.
-	The following values are required if you run deployment in silent mode; otherwise, they are optional. If you specify any of the following command-line options and do not run in silent mode, the corresponding fields in the Deployment Wizard are populated with the values you specify.
/Server *ServerName*	Name of the Oracle InForm application server.
/Trial *TrialName*	Name of the Oracle InForm study.
/responsefile *File*	Name of the TXT file that contains the Oracle user name and password for the Oracle InForm study database.
/Strict (TRUE | FALSE)	• **TRUE**—Only complete MedML definitions of study components can be loaded into the study; an incomplete definition causes the installation to fail. • **FALSE**—Incomplete study component definitions are permitted.
/TrialCreateModeValue (DB | DSN)	• **DB**—The deployment process creates an ODBC connection for the study to the specified database instance. When you specify this option, include the connection string to the database instance in the /Connect option. • **DSN**—The study uses an existing ODBC connection. When you specify this option, include the name of the study DSN in the /TRIDSN option.
/Connect *DatabaseConnectString*	Connection string for the Oracle instance.
/TRIDSN *DSNString*	ODBC System DSN for the Oracle InForm study.
/ServerAutoStartup	The Oracle InForm server starts automatically when the Oracle InForm Service starts. If you do not include the /ServerAutoStartup option, the Oracle InForm server must be started manually.

Option	Description
/TrialAutoStartup	The Oracle InForm study starts automatically when the Oracle InForm Service starts. If you do not include the /TrialAutoStartup option, the Oracle InForm study must be started manually.
/DeploymentStartDelay	Time to wait (in milliseconds) for the Oracle InForm caches to initialize before deploying.
/IPRServer *ServerName*	Name of the deployment instance that points to the Oracle InForm study to which to apply the in-place revisions. You specify the deployment instance name when you create the deployment instance.

Deployment ConfigFile options

As an alternative to entering deployment options at the command line or in a script, you can include the options for executing a deployment package in a configuration file referenced by the /ConfigFile command-line option. The configuration file is in XML format.

Option	Description
<DeploymentData>	xmlns:xsd="http://www.w3.org/2001/XMLSchema" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="http://www.phaseforward.com/DeploymentData/2006-04-25"
<HostName />	Reserved for future use.
<HostUserName />	
<HostUserPassword />	
<HostSharedDirectory />	
<HostSharedDirectoryLocalPath />	
<TargetType/>	INFORM
<ServerName/>	Name of the InForm application server.
<TrialName/>	Name of the InForm study.
<UserName/>	Oracle user name for the study database.
<UserPassword/>	Oracle password for the study database.
<StrictMode/>	• **TRUE**—Only complete MedML definitions of study components can be loaded into the study; an incomplete definition causes the installation to fail. • **FALSE**—Incomplete study component definitions are permitted.
<TrialMode/>	• **DB**—The deployment process creates an ODBC connection for the study to the specified database instance. When you specify this option, include the connection string to the database instance in the <DatabaseConnectString/> option. • **DSN**—The study uses an existing ODBC connection. When you specify this option, include the name of the trial DSN in the <TRIDSN /> option.

Option	Description
<TRIDSN />	ODBC System DSN for the Oracle InForm study.
<DatabaseConnectString/>	Connection string for the Oracle instance.
<TrialStartupMode/>	• **Automatic**—The Oracle InForm study starts automatically when the Oracle InForm Service starts. • **Manual**—The Oracle InForm study must be started manually.
<ServerStartupMode/>	• **Automatic**—The Oracle InForm server starts automatically when the Oracle InForm Service starts. • **Manual**—The Oracle InForm server must be started manually.
<ForceBASEInstall/>	• **TRUE**—Clear the study database, if the study exists, and install the Base study. • **FALSE**—(Default) Do not force the Base study to be installed.
<CheckInFormVersion/>	• **TRUE**—(Default) Check the Oracle InForm version to make sure that it is compatible with the current version of the Oracle Central Designer application. If the software versions are not compatible, deployment does not continue. • **FALSE**—Do not check the Oracle InForm version to make sure that it is compatible with the current version of the Oracle Central Designer application. You might select this option if you are running deployment with the /testconversion option, which does not install the study MedML.
<ProtocolName />	Reserved for future use.
<ProtocolUserName />	
<ProtocolUserPassword />	
<DBAdminUser />	
<DBAdminUserPassword />	
<DataSpace />	
<TableSpace />	
<UNCHelpDirectory />	
<VirtualHelpDirectory />	
<WebPath />	
<SSL/>	

Sample deployment configuration file

```
<DeploymentData xmlns:xsd="http://www.w3.org/2001/XMLSchema"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="http://
www.phaseforward.com/DeploymentData/2006-04-25">

<HostName />
```

```
<HostUserName />

<HostUserPassword />

<HostSharedDirectory />

<HostSharedDirectoryLocalPath />

<TargetType>INFORM</TargetType>

<ServerName>INF916</ServerName>

<TrialName>ASM916</TrialName>

<UserName>ASM916uid</UserName>

<UserPassword>ASM916pid</UserPassword>

<StrictMode>false</StrictMode>

<TrialMode>DB</TrialMode>

<TRIDSN />

<DatabaseConnectString>APPSRV_dev1</DatabaseConnectString>

<TrialStartupMode>Manual</TrialStartupMode>

<ServerStartupMode>Manual</ServerStartupMode>

<ForceBASEInstall>false</ForceBASEInstall>

<CheckInFormVersion>true</CheckInFormVersion>

<ProtocolName />

<ProtocolUserName />

<ProtocolUserPassword />

<DBAdminUser />

<DBAdminUserPassword />

<DataSpace />

<TableSpace />

<UNCHelpDirectory />

<VirtualHelpDirectory />

<WebPath />

<SSL>false</SSL>
```

```
</DeploymentData>
```

10

Perform post-design activities

In this chapter:

- Lock and protect studies and libraries
- Archive and decommission a study
- Generate reports
- Generate an Annotated Study Book
- Translate text

Lock and protect studies and libraries

In this section:

- Lock or unlock a data-entry rule
- Lock or unlock a global condition
- Lock or unlock a workflow rule
- Lock a deployment instance
- Protect a study
- Protect and unprotect a library

Lock or unlock a data-entry rule

A lock is automatically applied when you begin editing a rule and is released when you save the rule. If you want to work on a rule for an extended period of time, you can explicitly lock it to prevent others from working on it.

1. In the Project Explorer, select the study object on which the data-entry rule has been created.
2. Select the **Rules** tab.
3. To explicitly lock a data-entry rule, right-click the data-entry rule, then select **Lock**.
4. To unlock a data-entry rule that you explicitly locked, right-click the data-entry rule, and select **Unlock**.

Lock or unlock a global condition

1. In the Project Explorer, select a study design, study element, or study event.
2. Select the **Workflow Diagram** tab.
3. At the top of the Workflow Diagram tab, click **Global Conditions**.
4. To explicitly lock a global condition, right-click a global condition, then select **Lock**.

5. To unlock a global condition that you explicitly locked, right-click a global condition, then select **Unlock**.

Lock or unlock a workflow rule

To explicitly lock a workflow rule:

1. In the Project Explorer, select a study design, study element, or study event.
2. Select the **Workflow Diagram** tab.
3. Right-click a workflow rule, and select **Lock Rule**.

> **Note:**
>
> Workflow rules appear as diamond-shaped objects in the workflow.

To unlock a workflow rule that you explicitly locked:

1. In the Project Explorer, select a study design, study element, or study event.
2. Select the **Workflow Diagram** tab.
3. Right-click a workflow rule, and select **Unlock Rule**.

Lock a deployment instance

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Select the study.
3. Select the **Deployment Setup** tab.
4. To explicitly lock a deployment instance, right-click a deployment instance, select **Lock and Protect**, then **Lock**.
5. To unlock a deployment instance that you explicitly locked, right-click a deployment instance, select **Lock and Protect**, then click **Lock**.

Protect a study

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Right-click the study, then select **Protect**.

Protect and unprotect a library

To protect a library:

1. At the bottom of the Project Explorer, click the **Library Information** ( ) button.
2. Right-click the library and select **Protect**.
   The icons to the left of the library and all of the study objects within the library change to reflect a protected status.

> **Note:**
>
> You cannot delete study objects that are the direct children of a protected study object. After you protect a study object, you cannot select Undo, but you can select Unprotect.

To unprotect a library:

1. At the bottom of the Project Explorer, click the **Library Information** ( ) button.
2. Right-click the library and select **Unprotect**.
   The icon to the left of the library changes to reflect an unprotected status.

> **Note:**
>
> Unprotecting a library or a study object in a library does not affect study objects that you copied from the library into a study.

Archive and decommission a study

In this section:

- Archive a study or project
- View errors associated with an archive
- View archived studies and projects
- Delete a study or project
- Download and import an archived study or project
- Delete an archived study or project from the database

Archive a study or project

1. At the top of the Oracle Central Designer window, click the **Save** ( ) button.
2. In a study, at the bottom of the Project Explorer, click the **Study Information** ( ) button.

   or

   In a library, at the bottom of the Project Explorer, click the **Library Information** ( ) button.
3. Right-click the study project or library project, and select **Archive**, then **Create Archive**.
4. If you selected a study, specify whether you want to archive the study or the entire study project.

View errors associated with an archive

If errors occur during the creation of an archive, you can view the errors on the project's Jobs tab.

> **Tip:**
>
> If you don't see the Jobs tab, at the top left of the page, select **View**, and make sure **Jobs** is selected.

If a project or study fails to import, you can view the errors in a study project that is created to show error messages.

1. In the upper-left corner, click **File**, then **Open**.
2. Select the **Import Archive Project Placeholder**, and click **Open**.
3. Open the Jobs tab, where you can view the errors associated with the archive.

View archived studies and projects

1. Open a study, study project, or library project.
2. In the Project Explorer, right-click a study, study project, or library project, and select **Archive**, then **View Archives**.

Delete a study or project

1. (Optional but highly recommended) Perform a full database backup.
2. (Optional) Archive the study or project.
3. In the Project Explorer, right-click a study, study project, library, or library project, and select **Delete**.
4. Click **Yes**, and click **Yes** again.

Download and import an archived study or project

You can import an archive into the database in which it was created or into another database. You cannot import an archived study, study project, or library project if it still exists in the target database—first you must delete the existing study, study project, or library project.

Before you can import an archived study or project, you must download it from the database. Optionally, you can delete the file from the database after downloading it.

To download an archived study or project:

1. (Optional) Perform a full database backup.
2. In the Project Explorer, right-click a study, study project, or library project, and select **Archive**, then **View Archives**.
3. Select an archive, and click **Download**.

4. Click **Yes** to delete the archive permanently from the database, or click **No** to leave the archive in the database.
5. Navigate to a location for saving the archive, modify the file name as necessary, and click **Save**.
6. Click **Close**.

To import an archived study or project:

1. Download the archive file from the database.
2. To import a study, open a study project. To import a study project or library project, close the project in which you are working.
3. Do one of the following:
   - Right-click a study or study project, and select **Archive**, then **Import Archive**.
   - Right-click the library project, and select **Archive**, then **Import Archive**.
4. When the Import from Archive wizard appears, click **Next**.
5. On the File Location page, click **Browse**, and navigate to and select the file to import.
6. On the Archive Contents page, click **Next**.
7. Click **Finish**.
   If you imported a study, the project is reloaded. If you imported a project, you can open it by selecting **File**, then **Open**.

Delete an archived study or project from the database

Archives are stored on the database server until you delete them. Optionally, you can delete an archive when you download it. For more information, see Download and import an archived study or project.

> **Note:**
>
> You cannot undo the deletion of an archived study or project from the database.

1. In the Project Explorer, right-click a study, study project, or library project, and select **Archive**, then **View Archives**.
2. Select one or more archives
3. Click **Delete**.
4. Click **Yes**.

Generate reports

In this section:

- Generate, save, and print a report
- Data Entry Rule Actions report
- InForm RefName report

- Library Objects Modified in the Study report
- Library Objects Modified in the Library report
- Number of Studies Containing Library Objects report
- Library Objects Modified in Studies report
- Study Baselines Difference report
- Studies Containing Selected Library Object report
- Workflow Rules and Global Conditions Report

Generate, save, and print a report

Show me how to generate a report

1. In the Project Explorer, select a study object (study design, study element, study event, form, section, item, codelist, codelist item, mapping, data set, or data series).
2. Select **Actions**, then **Reports**.
3. From the **Reports** drop-down list, select a report, then click **Run Report**.

> **Tip:**
>
> If no reports are available for the study object, the message, There are no reports for the selected object, appears in the drop-down list.

4. To save the report:
   a. At the top of the Reports dialog box, click **Save As**.
   b. Navigate to the location in which to save the report.
   c. In the **File name** field, type the name of the report, and click **Save**.

      The report is saved as a CSV file.
5. To print the report, at the top of the dialog box, click **Print**.

> **Note:**
>
> When you generate a report for a study that contains an invalid workflow, an error occurs, and the report cannot be run.

Data Entry Rule Actions report

The Data Entry Rule Actions report runs at the study level. The report lists each data-entry rule action/locale combination in a study. Each row in the report corresponds to a supported locale for a unique rule action. For example, if a data-entry rule has two actions and two supported locales, the report would display four rows for that rule. This report does not include data for workflow rules or global conditions. The selected study must have at least one defined locale for this report to run.

The report displays each rule only once, regardless of the number of times that the study object on which it exists is used in a study. For example, a rule that is defined on an item that appears on more than one form appears once in the report.

> **Note:**
>
> This report contains InForm-specific study objects and is not available for studies that do not have InForm selected as one of the Deployment Systems or contain only non-InForm study objects. When you generate a report for a study that contains an invalid workflow, an error occurs, and the report cannot be run.

Running this report should not be considered a substitute for validation. Errors (or lack thereof) encountered while generating this report are not necessarily a reflection of study validity.

> **Note:**
>
> This report runs against data in the database. Oracle recommends that you save the study before running the report.

Field	Description
Action Expression	For SetValue expressions: The expression that you create in the SetValue Action box. For Update Workflow actions: UpdateWorkflow().
Action Type	Type of action, such as Query or SetValue, that occurs upon evaluation of the rule expression.
Email Sender Email Recipient Email Subject Email Body	(Applicable for Email actions only.) The following information about the email that is sent upon evaluation of the rule expression: • Sender's email address • Recipient's email address • Subject • Body text
Error Message(s)	Description of the error(s) encountered while gathering data for the data-entry rule action/locale combination represented in this row.
Error status icon	Indicates whether an error was encountered while gathering data for the data-entry rule action/locale combination represented in this row. • A red circle with an X indicates that an error occurred. • A green circle with a checkmark indicates that no error occurred.

Field	Description
Locale	Locale in which translated text appears for the action. Translated text appears in the following fields: • Email Subject (if applicable) • Email Body (if applicable) • Query Text (if applicable) • Target Form Mnemonic • Target Item Question
Query Status	(Applicable for Query actions only.)
Query Text	Status and text of the query that is created upon evaluation of the rule expression.
Rule Description	Description for the data-entry rule.
Rule Last Update User	Name of the user who most recently updated the data-entry rule.
Rule Match	Selection in the Rule Wizard > Actions > If the value is section. For example, Always.
Rule Name	Name of the data-entry rule.
Rule Revision	Revision number of the data-entry rule.
Rule Status	Status of the data-entry rule; either Enabled or Disabled.
Rule Switch	Expression for the data-entry rule.
Rule Timestamp	Date and time when the data-entry rule was most recently updated.
Rule Trigger	Event that causes the rule to run; either FormSubmission or OnDemand.
Rule Type	Type of rule; either Intrinsic (for a rule created based on a rule template) or Expression (for a calculation or constraint rule).
Study Object RefName Study Object Title Study Object Type	The following information about the study object on which the data-entry rule exists: • RefName. • Title. • Type.
Target Form Mnemonic Target Form RefName	Short title and RefName of the form on which the item that is the target of the rule action exists.

Note:

If the item is used on multiple forms in the study, the mnemonics and RefNames for the forms are listed and separated by semicolons.

Field	Description
Target Item Number Target Item Question Target Item RefName Target Item Title	Number, question, RefName, and title of the item that is the target of the rule action. For example: • For Query actions, the item on which the query appears. • For Email actions, the item to which the email action is attached. You select this item in the Email Action dialog box, in the Item field. • For SetValue actions, the item for which a value is set. This information does not apply to UpdateWorkflow actions. **Note:** If the item is used on multiple forms in the study, the item numbers for the forms are listed and separated by semicolons. **Note:** When an item appears on only one form and is in a repeating section, therefore ending in zero, such as **2.10**, the number in the Target Item Number column is enclosed in single brackets, such as **'2.10'**.

InForm RefName report

The InForm RefName report runs at the study level. The report lists the full InForm RefName paths of all items (InForm controls) for a study. The selected study must have at least one defined locale for this report to run.

The InForm RefName report includes:

- One item per row.
- Items in the study design.
- Items that hold data. For example, the RefName for a compound item without child controls does not appear in the report.

- Up to five levels of nested items.

> **Note:**
>
> This report contains InForm-specific study objects and is not available for studies that do not have InForm selected as one of the Deployment Systems or contain only non-InForm study objects. When you generate a report for a study that contains an invalid workflow, an error occurs, and the report cannot be run.

The report does not process items on non-clinical forms, such as Regulatory Document and Visit Report forms.

> **Note:**
>
> This report runs against data in the database. Oracle recommends that you save the study before running the report.

Field	Description
Control 1 RefName	RefName of the item.
Control 2-5 RefName	RefNames of the items that are conditional on the item or that are children of the compound item. For a codelist item that contains multiple conditional items, a control is created to contain the conditional items. The control name includes the RefName of the codelist item, which is: • Prefixed with GC_. • Appended with the numerical position of the codelist item in the codelist. For example, if the Medication item has three codelist items with two items that are conditional on the third codelist item, the following control is created to contain the items that are conditional on the third codelist item: GC_Medication3
Error Message(s)	The error that occurred while the report processed the data for the item.
Error status icon	Indicates whether an error occurred while the report processed the data for the item. • A red circle with an X indicates that an error occurred. • A green circle with a checkmark indicates that no error occurred.
Form RefName	RefName of the form on which the item exists.
Item RefName	RefName of the item.

Field	Description
Itemset RefName	RefName of the repeating section on which the item exists. If the item is not on a repeating section, this field is blank.
Section RefName	RefName of the section in which the item exists. If a section is not defined, the Form RefName for the item appears in this field.
Visit RefName	RefName of the study event in which the item exists. If the form on which the item study object is located is a common form, CommonCRF appears in this field.

Library Objects Modified in the Study report

Level at which the report runs

The report runs at the study level.

Description

The report lists study objects (when they exist) that were copied from a library to the study and then modified and saved in the study. For a copied study object to appear in the report, it must be saved before it was modified. Similarly, if you copy the study object, modify it without saving it, and then save it, the study object does not appear in the report.

Purpose

If all study objects in the library have been fully tested, use the report to identify study objects that might require further testing as part of the test plan.

Additionally, you can use the report to monitor whether designers are adhering to library standards for a particular study.

Fields

Field	Description
Study Object Title	Title of the study object in the study.
Study Object RefName	RefName of the study object in the study.
Library Object Title	Title of the study object in the library.
Library Object RefName	RefName of the study object in the library.

Library Objects Modified in the Library report

Level at which the report runs

The report runs at the study level.

Description

The report lists study objects (when they exist) that were copied from a library to the study and then modified and saved in the library.

Purpose

Use the report to identify the study objects that were modified in the library after being copied to a study, so you can determine if an update to the study object in the study is required, as well.

Fields

Field	Description
Study Object Title	Title of the study object in the study.
Study Object RefName	RefName of the study object in the study.
Library Object Title	Title of the study object in the library.
Library Object RefName	RefName of the study object in the library.

> **Note:**
>
> It is possible for a study object to appear in the report if it has not been modified and saved in the study. For example, if a study object is linked in multiple libraries, copied to a study, and subsequently modified and saved in one of the libraries, the study object appears in the report.

Number of Studies Containing Library Objects report

Level at which the report runs

The report runs at the library level.

Description

The report lists:

- Study objects (when they exist) that were created in the library and copied into a study.
- The number of studies to which each study object was copied.

> **Note:**
>
> Study objects that are marked as templates or types do not appear in the report.

Purpose

Use the report to determine the number of studies to which a study object has been copied from the library.

Fields

Field	Description
Library Object Title	Title of the study object in the library.
Library Object RefName	RefName of the study object in the library.
Number of Studies	Number of studies in which the study object is used.

> **Note:**
>
> A study object copied into a single library two or more times is counted only once.

Library Objects Modified in Studies report

Level at which the report runs

The report runs at the library level.

Description

The report lists:

- Study objects (when they exist) that were created in the library and copied into a study.
- The study to which each study object was copied.

> **Note:**
>
> Study objects that are marked as templates or types do not appear in the report.

Purpose

Use the report to identify how frequently a study object was modified after it was copied from a library to a study. Many updates to a study object might indicate that the study object needs to be updated in the library.

Fields

Field	Description
Library Object Title	Title of the study object in the library.
Library Object RefName	RefName of the study object in the library.
Study Copied To	Name of the study to which the study object was copied. A study object has a row for each study to which it is copied.

Study Baselines Difference report

Level at which the report runs

The report runs at the study level.

Description

The report lists:

- Names of the project, study, and both baselines selected.
- Versions of the study for which each baseline was created.
- Date the report was generated and the name of the person who generated the report.

You can export the report to a comma-separated value (CSV) file type.

> **Note:**
>
> - At this time, the Study Baselines Difference report does not report differences for study administration data, notes, or tasks.
> - The Study Baselines Difference report only reports on study objects that exist in a baseline. As a result, because baselines only include study objects in the study design, the Study Baselines Difference report does not report on study objects that are not in a study design.

Purpose

Use the report to compare the study objects in valid baselines. For each study object that changed, the report displays either detailed or grouped information.

- **Detailed information**—Lists the study objects that changed between the two baselines, and displays the following information for each changed study object:
  - RefName of the study object.
  - Name of the study object property.
  - Previous and current value of the property.
  - Whether the study object was added, deleted, or modified in the more recent baseline.
- **Grouped information**—Lists the study objects that changed between the two baselines and groups similar changes into a single difference for the study object. Displays whether the study object was added, deleted, or modified, but does not display details about the modification

Running the report decreases the amount of time it takes to determine the differences between two valid public study baselines.

- **Objects with detailed information**
  - Codelists

  - Codelist items
  - Codelist subsets
  - Constants
  - Custom events (the custom event study object and its properties)
  - Data mappings
  - Data series
  - Data sets (including custom dimensions)
  - Elements
  - Events
  - Forms
  - Items (compound, date, time, float, integer, and text)
  - Mapped items (items mapped to a data series)
  - Rules (global condition, data entry, and workflow)
  - Rule templates
  - Sections
  - Study design
  - Study-level styles
- **Objects with grouped information**
  - Custom event triggers
  - Custom event results
  - Form layouts
  - Functions
  - Help
  - Rules (complex changes to a rule and actions changed for a rule)
  - Workflows
  - Workflow layouts

Studies Containing Selected Library Object report

Level at which the report runs

The report runs in a library only for study elements, study events, forms, sections, items, codelists, codelist items, mappings, data sets, and data series.

Description

The report lists the studies to which the study object has been copied from a library.

> **Note:**
>
> Study objects that are marked as templates or types do not appear in the report.

Purpose

Use the report to identify the number of studies to which a study object has been copied. The usage of a study object might influence a decision to maintain a study object or remove it from the library.

Additionally, when you are considering changing a study object and propagating the change to the studies in which the study object is used, the report can help you determine the impact of the change.

Fields

Field	Description
Study Title	Title of the study to which the selected study object was copied.

Workflow Rules and Global Conditions Report

The Workflow Rules and Global Conditions Report runs at the study level and outputs all active and inactive rules from the study design as a CSV file.

Fields	Description
Status	Icon that indicates the status of the report: • **Green check mark** ()—Indicates the report ran successfully. • **Red X** ()—Indicates an error occurred when the report was run. A description of the error appears in the Error Message(s) column.
Error Message(s)	Description of the error(s) encountered while gathering data for rule action information.
Rule Name	Name of the workflow rule or global condition.
Rule Status	Status of the workflow rule or global condition; either Enabled or Disabled.
Rule Type	Type of rule; either WorkflowRule or GlobalCondition.
Rule Description	Description for the workflow rule or global condition.
Rule Switch	Expression for the workflow rule or global condition.
Rule Match	Shows the information about which value selection in InForm will produce the result. For example, if Gender = female, a dynamic pregnancy form would open and this field shows that “female” is the match that will produce the result.
Dynamic Type	Visit, form, or form and visit.
Target Visit RefName	RefName of the visit in which the item that is the target of the rule action exists.

Fields	Description
Target Form RefName	RefName of the form on which the item that is the target of the rule action exists. **Note:** If the item is used on multiple forms in the study, the forms are listed and separated by semicolons.
Workflow Owner	Where the workflow rule or global condition resides in the study design.
Workflow Owner Type	Object type of the workflow owner object.

Generate an Annotated Study Book

In this section:

- Generate an Annotated Study Book
- Print an annotated study book
- Create a PDF file for an annotated study book
- Format dates on the Annotated Study Book for the Japanese locale
- Export the Schedule of Events table to a CSV file

Generate an Annotated Study Book

Note:

In the Annotated Study Book and Form Preview window, if a row contains many components, the browser that displays the page might wrap text to fit all components onto the page. Consequently, for Asian languages, a wrapped text label might appear to have vertical orientation, with a single character on each line, because the browser wraps text on a word boundary, and a single character can represent a word. To compensate, you can make the question portion of the row smaller so the labels in the control section are wide enough not to wrap.

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. Select the study.
3. In the upper-left corner, click **File**, then **Annotated Study Book Options**.
4. Select display and cover page options.

5. Click **OK**.
6. In the upper-left corner, select **File**, then **View Annotated Study Book**.
7. If the deployment properties of the study include more than one locale or layout format, or the Annotated Study Book includes an In-place Revisions Summary table and the study contains in-place revision objects with IPR configurations for one or more deployment instances, the View Annotated Study Book dialog box appears.
8. In the **Layout** and **Language** fields, select the name of the layout and a locale.

> **Note:**
>
> The language setting that you specify when generating an Annotated Study Book and the locale setting that you specify when generating a deployment package for InForm are independent and can produce different results.

9. In the **Deployment instance** field, select the deployment instance for which to display the IPR Summary table.
10. Click **OK**.

    When you generate an Annotated Study Book with a Schedule of Events table, and the study contains an invalid workflow, an error message appears in a dialog box and in the Schedule of Events table, and forms are listed in the Annotated Study Book in alphabetical order regardless of the selected order. When this occurs, the option to save the Schedule of Events table as a CSV file is disabled.

For more information, see Annotated Study Book Options dialog box.

Print an annotated study book

1. Generate an annotated study book.
2. In the Annotated Study Book window, click **Print**.
3. Specify printer options.
4. Click **Print**.

Create a PDF file for an annotated study book

> **Note:**
>
> To generate a PDF file for an annotated study book, you need a PDF print driver such as Adobe Acrobat PDF Distiller or PDFcamp from verypdf.com, Inc.

1. Generate an annotated study book.
2. In the Annotated Study Book window, click **Print**.
3. Select a print queue that is backed by a PDF print driver.
4. Optionally, to set preferences for PDF generation, select **Preferences**.

5. Specify preferences for PDF generation, then click **OK**.
6. Specify a file location, then click **OK**.

Format dates on the Annotated Study Book for the Japanese locale

For studies developed in the Japanese locale, the long date format is used to format the dates (Generated Date and Sponsor Date) that appear on the cover page of the Annotated Study Book.

Optionally, you can customize the long date format in the following way:

1. On your PC, open the **Control Panel** and select **Region and Language Options**.
2. Click **Region and Language**.
3. In the **Format** drop-down list, select Japanese (Japan).
4. In the lower-right corner, click **Additional Settings**.
5. On the **Date** tab, in the **Long date** drop-down list, select a formatting option.
6. Select the **Time** tab and select a **Time format**.
7. Click **OK**, then click **OK** again to close the Control Panel.
8. Generate the Annotated Study Book for the Japanese locale.

   The dates on the cover page match the configuration that you specified in the Control Panel.

Export the Schedule of Events table to a CSV file

1. Generate an Annotated Study Book.
2. In the lower-left corner of the dialog box, click **Save Time & Events as**.

> **Note:**
>
> This option appears only when **Schedule of Events Table** is selected in the Annotated Study Book Options dialog box.

3. Type a file name, and click **Save**.

> **Tip:**
>
> The CSV file is different from the Schedule of Events table in the Annotated Study Book in the following ways:
>
> - The titles of forms might contain HTML tags, such as and .
> - The row for the study event appears in three rows instead of one.

Translate text

In this section:

- View locale-specific translations in a layout
- Create, edit, translate, and remove a section note
- Edit and translate a form or section title
- Edit and translate a question for a locale
- Edit and translate a codelist item label override
- Enter and translate the title and short title of the Common Visit
- Translate the short title of a study event
- Translate the short title of a form
- Translate the question text of an item
- Translate a codelist item label
- Create and translate instructions and Help for a study design

View locale-specific translations in a layout

Every layout supports all locales. You do not need to create a unique layout for every form and locale in the study. Use the Locales drop-down list on the toolbar in the Layout tab to switch between locales and provide translations.

> **Note:**
>
> Layouts that you created in release 1.2 display text in the locale for which the layout was created.

When you select a locale other than the default locale for a study, the locale name appears above the work area, and all captions and questions appear in the language for the locale. If the values are not translated for the locale, the text for the primary locale appears in red.

1. At the bottom of the Project Explorer, click the **Forms and Transactions** ( ) button.
2. Select a form or item, and select the **Layout** tab.
3. On the toolbar, select **Layout**, and then select the locale to view.

   The locale appears, along with all locale-specific text strings.

> **Note:**
>
> Text that you modify is saved for the selected locale only. For example, you can modify captions, notes, and section titles, and the values are saved for the locale.

Create, edit, translate, and remove a section note

You can add section notes to the layouts for forms only.

> **Note:**
>
> For a form with multiple layouts, if you add or edit a section note or caption for a locale, the text is visible in all of the layouts. For example, if a study supports English and French, and you have two layouts, Layout1 and Layout2, both layouts support both English and French. If you edit a note or caption in Layout1 for the French locale, the note or caption is always visible in Layout2 for the French locale.

To create a note:

1. At the bottom of the Project Explorer, click the **Forms and Transactions** () button.
2. Select a form, and select the **Layout** tab.
3. Right-click a form or section header, and make sure that **Section Note** is selected. An editable note field appears below the header.

To edit or translate a note:

1. At the bottom of the Project Explorer, click the **Forms and Transactions** (**Forms and Transactions** () button.
2. Select a form, and select the **Layout** tab.
3. From the **Locale** menu on the toolbar, select a locale for which you want to edit or translate text.
4. Right-click the note, and select **Edit Note**.
5. Type the note, and press **Enter**.

To remove a note:

1. At the bottom of the Project Explorer, click the **Forms and Transactions** () button.
2. Select a form, and select the **Layout** tab.
3. Right-click a form or section header, and make sure that **Section Note** is not selected.

Edit and translate a form or section title

1. At the bottom of the Project Explorer, click the **Forms and Transactions** () button.
2. Select a form, and select the **Layout** tab.

3. At the top of the Layout tab, click **Locale**, and select the locale to edit or translate.
4. Right-click a section header, and select **Edit Title**.
5. Type the new section or form title, and press **Enter**.

Edit and translate a question for a locale

1. At the bottom of the Project Explorer, click the **Forms and Transactions** () button.
2. In the Project Explorer, select a form or item, and select the **Layout** tab.
3. At the top of the Layout tab, select the **Locale**, then select a locale for which you want to edit or translate text.
4. Right-click a question, then select **Edit Question**.
5. Type the question text, then press **Enter**.

Edit and translate a codelist item label override

You can override the label for a codelist item in a layout.

1. At the bottom of the Project Explorer, click the **Forms and Transactions** () button.
2. In the Project Explorer, select a form or item, and select the **Layout** tab.
3. Right-click the control for codelist items, and select **Edit Label Override**.
4. From the **Codelist item** drop-down list, select a codelist item.
5. In the **Label override** field, type the new label for the codelist item.
6. Click **OK**.

> **Note:**
>
> When you override a codelist item label for a codelist that is shared across multiple objects and uses the Study Completion Status Items property, sometimes InForm displays the codelist item label incorrectly. Instead of overriding the codelist item label, you can create a separate codelist with codelist items containing the labels that you need.

Enter and translate the title and short title of the Common Visit

In the Common Visit tab, which is part of the editor for the study design, you can enter, edit, and translate the title and short title for a study's common visit. A common visit is created during deployment when a study contains common forms.

Specifying a title and short title is optional. For studies with common forms, if you translate a title or short title for one language, you must translate values for all languages.

1. At the bottom of the Project Explorer, click the **Visit Schedule** () button.

2. Select the study design.
3. Select the **Common Visit** tab.
4. Enter title and short title values in the fields at the top.
5. Optionally, in the **Languages** column of the Languages section, select the drop-down arrow at the end of the cell, and select a language for translation.

> **Note:**
>
> For studies with common forms, if you translate a title or short title for one language, you must translate values for all languages.

6. Type a translated title and short title.
7. Press **Enter**, or click the next row.
8. Type translations for all languages in the study.

Translate the short title of a study event

You can translate the short title of a study event into the languages and locales with which you have been associated in your skills profile. An administrator sets up this profile in the Oracle Central Designer Administrator application. The short title of a study event is deployed as the visit mnemonic in the InForm application.

1. At the bottom of the Project Explorer, click the **Elements and Events** () button.
2. Select a study event.
3. Select the **General** tab.
4. In the **Language** column of the Short Title Languages section, click the arrow that appears when you move the cursor over the far-right side of the cell in the first available row, and select the language for translating the short title.
5. In the **Short Title** column, type the translated text.
6. Press **Enter**, or click the next row.

Translate the short title of a form

You can translate the short title of a form into the languages and locales with which you have been associated in your skills profile. An administrator user sets up this profile in the Oracle Central Designer Administrator application. The short title of a form is deployed as the form mnemonic in the InForm application.

1. At the bottom of the Project Explorer, click the **Forms and Transactions** () button.
2. Select a form.
3. In the **Language** column of the Short Title Languages section, click the arrow that appears when you move the cursor over the far-right side of the cell in the first available row, and select the language into which to translate the short title.
4. In the **Short Title** column, type the translated text for the short title.
5. Press **Enter**, or click the next row.

Translate the question text of an item

1. At the bottom of the Project Explorer, click the **Items** () button, and expand the **InForm Items** folder.
2. Select an item.
3. On the Design tab, in the **Language** column of the Languages section, click the arrow that appears when you move the cursor over the far-right side of the cell in the first available row, and select the language into which you want to translate the question text.
4. In the **Question** column, type the translated text for the item question.
5. In the **Short Question** column, type the translated text for the short version of the item question.
6. Press **Enter**, or click the next row.

Translate a codelist item label

You can translate the text of a codelist item label into the languages and locales with which you have been associated in your skills profile. An administrator sets up this profile in the Oracle Central Designer Administrator application.

1. At the bottom of the Project Explorer, click the **Items** () button, and expand the **InForm Items** folder.
2. Select a codelist item.
3. On the Design tab, in the **Language** column, click the arrow that appears when you move the cursor over the far-right side of the cell in the first available row, and select the locale for which to translate the codelist item label.
4. In the **Label** column, type the translated text for the codelist item label.
5. Press **Enter**, or click the next row.

Create and translate instructions and Help for a study design

You can create study documents that are specific to a target application or locale for study designs, study elements, study events, forms, sections, and items.

You can provide instructions and Help information if the study or library supports one or more locales, and if you have been given skills to work in the locales (in the Oracle Central Designer Administrator application).

To create and delete instructions and Help:

1. In the Project Explorer, select a study object (study design, study element, study event, form, section, item, codelist, or codelist item).
2. Select the **Instructions & Help** tab.
3. To select a locale for the study documents, select the tab for the locale. The tabs are located along the bottom of the workspace.
4. To create or edit study documents:

a. Type in the text area.

b. Optionally, use the toolbar to format the appearance of the text. You can use HTML formatting characters.

5. To delete study documents:

a. At the top of the **Instructions & Help** tab, click the **Delete** button.

b. Choose one of the following options:

- Delete the study documents for only the selected locale.
- Delete the study documents for all locales.

To translate instructions and Help:

1. In the Project Explorer, select a study object (study design, study element, study event, form, section, item, codelist, or codelist item).
2. Select the **Instructions & Help** tab.
3. To select a locale for the study documents, select the tab for the locale. The tabs are located along the bottom of the workspace.
4. Optionally, copy and paste study documents from a locale for which the information is already written.
5. Select the locale to which you want to translate.
6. Translate the study documents.
7. Optionally, use the functions at the top of the **Instructions & Help** tab to format the appearance of the text.

11

Integrate Oracle InForm with Oracle Argus Safety

In this chapter:

- About the Oracle InForm to Oracle Argus Safety integration
- Design Adverse Events, Safety Case, and other forms
- Add rules to forms for sending data to Argus Safety
- Map Oracle InForm data items to Oracle Argus Safety entities
- Set safety event data configuration options in Oracle InForm Publisher
- Supported post-production changes to a dynamic grid

About the Oracle InForm to Oracle Argus Safety integration

Oracle Argus Safety is a pharmacovigilance platform that allows sponsors to procure clinically significant adverse event (AE) or serious adverse event (SAE) information on drug subjects. The Oracle InForm to Oracle Argus Safety integration automates the reporting of these events, enabling sponsors to reliably acquire relevant information for their studies.

Using the Oracle Central Designer data mapping feature, you define the data that is sent to Oracle Argus Safety as well as which changes trigger a follow up.

The Oracle InForm Publisher component monitors your Oracle InForm study database and sends adverse event information and other information such as medical history, concomitant medications, and labs to Oracle Argus Safety based on either the time frames you configure in Oracle InForm Publisher or the data entered into Oracle InForm.

For more information, see:

- Overview of designing for integration
- Important study design considerations

Overview of designing for integration

AEs and SAEs are documented in Oracle InForm along with information about the event, such as medications taken and current status of the AE.

You can collect and transmit AE and SAE data using two types of forms:

- Adverse Event forms
- Safety Case forms

> **Note:**
>
> Oracle recommends that you set up and configure the Argus Safety integration for your study before you deploy your study to Oracle InForm.

When designing a study that uses the Oracle InForm to Oracle Argus Safety integration, you must do the following work in Oracle Central Designer:

1. Design forms such as Adverse Event forms, other related forms, and (optionally) the Safety Case form.
2. If desired, add items to the Safety Case forms using a dynamic grid. Using a dynamic grid allows Oracle InForm site users to manually select records that must be part of a safety case, based on their clinical judgment rather than simply relying on automated submissions.
3. Add rules to the Adverse Event and Safety Case forms that trigger and direct the transmission of safety event data from Oracle InForm to Oracle Argus Safety.
4. Map the Oracle InForm safety event data items to corresponding items in Oracle Argus Safety. Oracle InForm and Oracle Argus Safety use the data mapping feature of Oracle Central Designer to configure how safety event data items on Oracle InForm forms correspond to safety event entities in Oracle Argus Safety.
5. Configure Oracle Argus Safety-only attributes to set up how Oracle InForm Publisher moves the adverse event data from Oracle InForm to Oracle Argus Safety.

Important study design considerations

Because a successful Oracle InForm to Oracle Argus Safety integration depends on your Oracle Central Designer study design, we suggest considering the following issues before adding items to the Adverse Event and Safety Case forms in Oracle Central Designer.

Include one or more Adverse Events per Oracle Argus Safety case as needed

Each Oracle Argus Safety case includes one study subject only, but it can also be made up of one or more adverse events per individual case.

Decide what information is relevant to send to Oracle Argus Safety

Consider what other relevant information should go to Oracle Argus Safety, such as medical history, concomitant medications, or lab results, and how this data should be selected (automatically via time frames or manually using a dynamic grid).

Decide whether the information should be sent automatically or via clinical judgment

Using a Safety Case form and a dynamic grid, allows you to give Oracle InForm site users the option of selecting the specific adverse events and other information they want to send to Oracle Argus Safety, as opposed to only sending relevant data automatically based on time frames.

Fine tune your rules

When creating the rules that define the behavior of your Oracle Argus Safety integration, ask yourself relevant questions, such as: Should only serious adverse events go to Oracle Argus Safety? Are there multiple death or autopsy dates in your study design? Do you need to create rules to copy data from one place to another?

Consider what items need to be mapped to which data series

In addition to items in your forms that need to be mapped to the specific types of data series that are being sent, items should be mapped to the appropriate data series in one of the following Oracle Argus Safety data sets available in Oracle Central Designer:

- **Safety_Config**—This data set identifies items and forms used by Oracle InForm Publisher for safety processing.
- **Safety_Significant**—This data set identifies items that are monitored for changes after the initial transmission to Oracle Argus Safety and is used to determine whether updated transmissions are needed. As a designer, you determine the items mapped to the data series in the Safety_Significant data set. These items should be significant for safety and will trigger a follow-up for safety integration when changed.

Design Adverse Events, Safety Case, and other forms

In this section:

- Design the Adverse Event form
- (Optional) Design other forms that may contain data to send to Oracle Argus Safety along with the Adverse Event form
- Design a Safety Case form

Design the Adverse Event form

An Adverse Event form is a form designed to collect adverse event data. Oracle InForm sends the collected data to Oracle Argus Safety.

When designing an Adverse Event form, consider that:

- You can map only one item in a repeating section on the AE form to the Subject_AdverseEvent narrative. The text in this item will appear at the beginning of the narrative for each AE selected in the dynamic grid in the order the AE is selected.
- When you design control captions that will be used in a dynamic grid (for example, for an item question or codelist label), make sure that they are fully labeled so that the data makes sense in the dynamic grid.
- If an in-place revision includes a form or section used as a source form for a dynamic grid section, you must apply the same in-place revision to the dynamic grid section.

> **Note:**
>
> Each Oracle Argus Safety case includes one study subject only, but it can also be made up of one or multiple adverse events per single case. For more information, see When can an Oracle InForm site user include multiple adverse events when sending data to Argus?

To design an Adverse Event form in Oracle Central Designer:

1. At the bottom of the Project Explorer, click the **Visit Schedule** () button.
2. Right-click the study event to which you want to add the Adverse Event form to, select **New**, and select **Form**.
3. Enter a **Title**, **RefName**, and **Description**, and click **OK**.
4. In the Project Explorer, select the new form, and make sure the **Design** tab is selected.
5. In the upper-right above the grid, select the **Repeating** check box.
6. In the grid, add adverse event items. You must include a date/time item to capture the onset date of the adverse event.
7. Define the trigger questions used to activate rules.

   The following questions are used to trigger rules to initiate the transmission of the adverse event data:

   - **Serious** (the item will be reported). The question might be: Was this a Serious Adverse Event?
   - **Reportable** (the item is not serious but should still be reported). The question might be: Should this event be reported?

   For each of these items, follow these guidelines:

   - For **Type**, select **Yes No Item**. This type includes a built-in codelist that allows the user to select Yes or No.
   - Enter **Title**, **RefName**, **Question**, and **Short Question**. For example: *Reportable*, *Report*, *Is this a non-serious event, but still should be reported?*, and *Report?*
   - Select the **Item Req** check box.

(Optional) Design other forms that may contain data to send to Oracle Argus Safety along with the Adverse Event form

Once you have created the Adverse Event form, you have the option to create other forms to send historical or clinical data to Oracle Argus Safety as part of a case (for example, medical history, concomitant medications, lab test results).

When designing other forms that may contain data to send to Oracle Argus Safety along with the Adverse Event form, consider that:

- When you design control captions that will be used in a dynamic grid (for example, for an item question or codelist label), make sure that they are fully labeled so that the data makes sense in the dynamic grid.

- If an in-place revision includes a form or section used as a source form for a dynamic grid section, you must apply the same in-place revision to the dynamic grid section.

To design other forms:

1. At the bottom of the Project Explorer, click the **Visit Schedule** () button.
2. Right-click the study event to which you want to add the form to, select **New**, and select **Form**.
3. Enter a **Title**, **RefName**, and **Description**, and click OK.
4. In the Project Explorer, select the new form, and make sure the **Design** tab is selected.
5. If you want this to be a repeating form, in the upper-right above the grid, check the **Repeating** check box.
6. If you want this to be a flat form with a repeating section:
   a. Uncheck or keep unchecked the **Repeating** check box.
   b. Expand the visit with the related form you want to add the section to, right-click the form, and select **New Section**.
   c. Enter a **Title**, **RefName**, and **Description**, and click **OK**.
   d. Make sure the **Design** tab is selected.
   e. In the upper-right above the grid, select the **Repeating** check box.
7. If you want this a flat form with a fixed, repeating section so you can send data the user doesn't enter:
   a. Uncheck or keep unchecked the **Repeating** check box.
   b. Expand the visit with the related form you want to add the section to, right-click the form, and select **New Section**.
   c. Enter a **Title**, **RefName**, and **Description**, and click **OK**.
   d. Make sure the **Design** tab is selected.
   e. In the upper-right above the grid, select the **Fixed** and **Repeating** check boxes.
   f. Create fixed items in the section. (See link below.)
   g. For each item that you want to define as a fixed item, add a codelist to the fixed item and codelist items to the codelist. (See link below.)
8. In the grid, add items.

For more information, see:

- Create fixed items in the section
- Add a codelist to the fixed item
- Add codelist items to the codelist

Create fixed items in the section

1. In the Project Explorer, select a form or section, and select the **Design** tab.
2. On the toolbar, click **Columns**, and display the columns that you need in the grid, including **Codelist** and **Item Properties**.

3. In the grid, create items on the form or section by typing values in each field. Press **Tab** to advance to the next field and, when you have reached the end of a row, to the next item.

   Your changes are saved after you move the cursor away from the row.

4. To modify the properties of an item:

   a. In the **Item Properties** field, click **Edit**, or, on the toolbar, select **Item Properties**.

   b. Define the properties of the item. The fields that appear in the dialog box depend upon the type of item that you select. These properties are also available on the **Design** tab for an item.

Add a codelist to the fixed item

1. On the bottom left of the page, select **Forms and Transactions** ().

   > **Tip:**
   >
   > If your study uses codelist subsets, you can select a different subset for each item instance that uses the subset's parent codelist. Therefore, we recommend navigating to the item and codelist by first opening the form the item is used on.

2. On the left, in the **Forms** folder, select the form or section that contains the item, and select the **Design** tab.
3. In the grid, select an integer, text, or float item.
4. Do one of the following:
   - If the codelist already exists, select it from the drop-down list in the **Codelist** field.
   - Create a codelist on the item.
5. If codelist subsets are configured for the codelist, and you're required to select one, select the subset that you want to use.

Add codelist items to the codelist

1. In the Project Explorer, select the **Codelists** Explorer bar.
2. In the **Codelists** folder, select a codelist.
3. In the rows and columns of the grid, type information about each codelist item to include in the codelist.
4. After you complete each row, and after the final row, press **Enter**, or tab to the next row.

Design a Safety Case form

A Safety Case form allows Oracle InForm site users to group multiple adverse events that relate to a single Oracle Argus Safety case and report them together.

When designing a Safety Case form, consider that:

- If you map multiple items on the Safety Case form to the Case level narrative, the text entered in those items will appear in the narrative sent to Oracle Argus Safety in the order in which the items appear on the form. For more information, see Create narrative items.
- If a site user enters multiple AEs on the Safety Case form, the onset date will be the onset date of the earliest AE marked as Serious. Or, if all non-serious AEs were selected, it will be the earliest onset date of any AE.

> **Note:**
>
> You don't need a Safety Case form if each Oracle Argus Safety case will only include one AE and all details are sent based on time frames or if you have configured Oracle InForm Publisher to send adverse events automatically.

To design a Safety Case form:

1. At the bottom of the Project Explorer, click the **Visit Schedule** () button.
2. Right-click the study event to which you want to add the Safety Case form to, select **New**, and select **Form**.

   Study events are designated by the Study Event icon ().
3. Enter a **Title**, **RefName**, and **Description**, and click **OK**.

   > **Tip:**
   >
   > Form RefNames are used as the column header in Reporting Data Extracts, and are also used by rule writers to identify the correct study object to use in a rule.
4. In the Project Explorer, select the new form, and make sure the **Design** tab is selected.
5. In the upper-right above the grid, select the **Repeating** check box.
6. Create a **non-repeating section** and add items that relate to the Oracle Argus Safety case as a whole. You might include an item that triggers the case to be sent to Oracle Argus Safety when the user submits the form by adding a question such as "Is this item ready to be sent to Argus?"
7. Create narrative items. (See link below.)
8. Create dynamic grids for any data to send to Oracle Argus Safety such as adverse events, concomitant medications, or medical history. These items are necessary for the site user to decide whether to send the Safety Case form to Argus. To select what data gets sent to Argus, see Map Oracle InForm items to entities in Oracle Argus Safety. (See link below.)

> **Note:**
>
> If you have used the dynamic grid feature, you must include the following characteristics when configuring Oracle InForm Publisher:
>
> - **AE IsSerious Control**—Shows where the **IsSerious** check box resides on the form.
>
> **AE IsReportable Control**—Shows where the **IsReportable** check box resides on the form.

9. Next, add rules to the form to specify whether to transmit safety event data immediately or at a configured interval.

For more information, see:

- Create narrative items
- Create a section (dynamic grid) to collect related data

Create narrative items

Narrative items in the Safety Case form allow Oracle InForm site users to include additional information to provide context on Adverse Events sent to Oracle Argus Safety.

When designing a Safety Case form, decide whether the complete and cumulative narrative must be sent to Oracle Argus Safety with each transmission or whether only the changes since the last submission must be sent.

You can create multiple narrative items for a single Safety Case form.

1. At the bottom of the Project Explorer, click the **Items** () button, and expand the **InForm Items** folder.
2. To the right of the Project Explorer, click the **New** button at the top of the workspace.
3. From the drop-down list, select **Text**.
4. Enter a **Title**, **RefName**, and, optionally, a **Description** of the item, and click **OK**.
5. In the **Form Editor**, go to the **Display Override** column and select the default display behavior of the item when a layout is generated:
   - **ReadOnly**—The item is visible but not editable.
   - **Editable**—The item is visible and editable by any user, regardless of the rights assigned to the user.
   - **Hidden**—The item is not visible.
   - **None**—The item is visible to all users, and visible and editable by any user who has the rights to view and/or edit the item.
6. In **Study Administration**, select the **System Settings** tab.
7. Go to **NarrativeUpdatesOnly** and set the value to either:
   - – **No**(default)—The complete narrative must be sent with each transmission to Oracle Argus Safety (cumulative).

– **Yes**—Only narrative data that is new since the last transmission to Oracle Argus Safety will be sent (incremental).

> **Note:**
>
> To select **Yes**, you need at least one **ReadOnly** narrative item, one **Editable** narrative item, and one **Hidden** narrative item so that all narrative updates are properly stored in the Safety Case form. Oracle recommends to add two or three narrative items of each type, since text fields in Oracle InForm are limited to 2,000 characters, while the narrative field in Argus can store up to 10,000 characters.
>
> To select **No**, you need to have **Editable** and **ReadOnly** fields for the narrative item. By doing this, sites cannot remove any previously entered narrative information.

Create a section (dynamic grid) to collect related data

A dynamic grid on a form is a type of repeating section that allows users of the Oracle InForm-Oracle Argus Safety integration to manually select records that must be part of a safety case, based on their clinical judgment.

To create a dynamic grid:

1. At the bottom of the Project Explorer, click the **Visit Schedule** () button.
2. Expand the visit with the form you want to add the section to, right-click the form, and select **New Section**.
3. Enter a **Title**, **RefName**, and **Description**, and click **OK**.

> **Note:**
>
> Oracle recommends adding the sections in the order you want them to appear on the form. However, you can change the order in which the items appear in the dynamic grid within Oracle InForm by selecting the item and clicking **Move Up** or **Move Down**.

4. Make sure the **Design** tab is selected and mark the section as **Dynamic Grid** in the check box.
5. In the **Create Target Items from Source for "(dynamic grid title)" Section** dialog box, enter the following information:
   - In **Search for Source Item**, at the top of the dialog box, select the visit, form, and (optionally) section that contain the items you want to make available to the Oracle InForm site user's collection of related data and click **Add**.

> **Note:**
>
> The source item you select must be **Editable** or **ReadOnly**, and repeating on one level (repeating form with a flat section or a flat form with a repeating section).

- In **Item to be Added to "(dynamic grid title)" Section**, at the bottom of the dialog box, select either **Item level** or **Data point** as the type of mapping you want for each item. For more information, see What are item level mapping and data point mapping in a dynamic grid?

> **Note:**
>
> The default mapping level for every item is **Item level**. To convert any item to a **Data point** item, click its check box in the **Convert to New Item** column.

6. Optionally, use the **Move Up** and **Move Down** buttons to configure the order of the items in the dynamic grid section.
7. Click **OK**.
8. (Optional) If multiple source items must be available in the dynamic grid (for example an Adverse Event form and a pregnancy form), you can add additional sources to the same dynamic grid. For more information, see Add or remove multiple sources in a dynamic grid.
9. (Optional) To create an item directly in the dynamic grid, select a type of item from the list in the **Type** column, and then enter a **Title**, **RefName**, **Question** and **Short Question**. Items added directly in the dynamic grid are editable items, but you can opt to map them to a source. For more information, see Add or remove multiple sources in a dynamic grid.
10. In the Project Explorer, select the form with the dynamic grid section, and select the **Layout** tab.
11. Accommodate the layout setting for the dynamic grid to match the largest of the items you plan to use as sources. For example, if you have multiple text sources with different character limits, always use the one that allows the most characters as the basis for your dynamic grid.

> **Note:**
>
> The amount of data copied onto the Safety Case form differs based on the type of source form. For example, for adverse events, copy over only the information the site needs to confirm that they selected the correct AE. All other information does not need to be copied for AEs. For AEs, the data can be split between forms to go to Oracle Argus Safety if you are using Oracle InForm Publisher 2.1.1 or higher.

For more information, see:

- Add or remove multiple sources in a dynamic grid

Add or remove multiple sources in a dynamic grid

You can add one or more sources to, as well as remove previously added sources from, a dynamic grid section. For more information on all the considerations you must have when adding one or multiple sources to a dynamic grid, see the Dynamic grid section under What if...

Add and map sources to a dynamic grid section

1. At the top of the **Design** tab, click **Dynamic Grid** and select **Configure mapping** or click the **Edit Dynamic Grid** icon ().
2. In the Sources section at the top of the **Configure Dynamic Grid Mappings for "(dynamic grid title)" Section** dialog box, click **Add Source** to add a new source.
3. In the **Add Sources** dialog box, select the visit, form, and (optionally) section that contain the items you want to make available to the Oracle InForm site user's collection of related data and click **Add** to add the source and close the dialog box, or click **Add / Next** to continue adding sources.
4. In the **Item Mappings** section at the bottom of the **Configure Dynamic Grid Mappings for "(dynamic grid title)" Section** dialog box, select the item you want to map to a new source and click **Add Mapping**.
5. In the **Add Mapping Object to "(item title)" Item** dialog box, select the source and item you want to add and click **Add** to map the source to the target item and close the dialog box, or click **Add / Next** to continue adding sources to that target item. The **Item Mappings** section of the dialog box will update with the sources mapped to each item.

> **Tip:**
>
> To select individual nested items in a source instead of parent items only, click on **Show nested items**.

Remove sources from a dynamic grid

When removing sources from a dynamic grid, consider that:

- If you remove a source after data has already been entered in Oracle InForm, the dynamic grid dialog box displays the latest mapping. This means that a user will not be able to add or remove records that are from a removed source via the dialog box.
- In order to remove old mappings, if needed, delete and undelete the source record. This will leave it struck out on the dynamic grid section.

To remove a source from a dynamic grid:

1. At the top of the Design tab, click Dynamic Grid and select Configure mapping or click the Edit Dynamic Grid icon ().
2. In the **Sources** section at the top of the **Configure Dynamic Grid Mappings for "(dynamic grid title)" Section** dialog box, click **Remove Source** to remove a source from the list.

3. Click **OK**.

Add rules to forms for sending data to Argus Safety

In this section:

- Write a rule containing the SaveToDb function
- Add required rules to the Adverse Event form
- Add rules to the Safety Case form
- Add rules for other forms containing adverse event items

Write a rule containing the SaveToDb function

The rules you write must contain the SaveToDb function, which evaluates the state of specific controls on the form to determine whether or not to load the InForm Publisher queue with data from the form.

1. At the bottom of the Project Explorer, click the **Forms and Transactions** () button, and expand the **InForm** folder and the **Forms** folder, if necessary.
2. In the Project Explorer, select the AE or Safety Case form.
3. Select the **Rules** tab.
4. At the top of the **Rules** tab, click **New Rule**.
5. At the top of the New Rule dialog box, on the **Quick Start** tab, select **Calculation Rule**. For more information, see How does a calculation rule work?

   This specifies that the rule should always be evaluated when the form is submitted.
6. Click **Next**.
7. On the **Properties** tab, enter a name and description for the rule, and click **Next**.
8. On the **Preconditions** tab, from the **Evaluate on Event** drop-down list, select **Form Submission**.
9. Click **Next**.
10. On the **Expression** tab, build the _SaveToDB rule. The expression to create is:
    `_SaveToDB(<Message>,<Trialname>);`
    a. To the right of the Expression workspace, select the **Functions** tab and expand **RuleEventFunctions**.
    b. Drag **_SaveToDb(string, string)** to the Expression workspace.
    c. On the **Invoke Function** dialog box, enter values for the **message** and **trialName** parameters to define whether or not the data should be sent to the Oracle InForm Publisher queue and the name of the trial.
       - **Message (string)**—Parameter that triggers Oracle InForm Publisher to send the data to Oracle Argus Safety. The text of the message parameter is fixed.
         IsReadyToSend— If the site never completes the item, it will be sent to Argus within after a time interval configured in Oracle InForm Publisher.

IsReportableOrSerious—Marks the safety event as serious and sends it to Argus Safety after a time interval configured in Oracle InForm Publisher.

- **Trialname (string)**—Name of the study, populated by the GetTrialName() predefined function.

For example: *Functions._SaveToDb(IsReadyToSend,Cardio)*

d. Click **OK**.

11. Click **Next**.
12. On the **Actions** tab, in the **If the value is** section, select a value that describes when the action should occur. Include a specific value, specify that the value must be **False** or **True**, or select **Always**, the default value for calculation rules, to state that the action always occur.
13. In the **Execute these actions** section, choose **SetValue** to set the value as specified.
14. Click **Finish**.

The rule appears in the Rule Summary.

Add required rules to the Adverse Event form

Once the Adverse Events forms are complete, add required rules to them so that safety data can be sent from Oracle InForm to Oracle Argus Safety.

1. Add one of these rules to the Adverse Event form:
   - A rule that says a safety event, marked as Reportable or Serious, is sent to Oracle Argus Safety only when the Oracle InForm site user explicitly marks the item as Ready to Send.

     > **Note:**
     >
     > If you have both Adverse Event form(s) and a Safety Case form, the rule goes on the Safety Case form.

   - A rule that says a safety event, marked as Reportable or Serious, is sent immediately upon form submission.

   The item must evaluate to Yes or No (True or False). You can create the items with Yes and No codelists for each of the controls. You create the rules on the form, but the rules reference specific items on the form.
2. (Optional; required only if you are using a Safety Case form and allowing the site user to select only one adverse event) Add a rule that checks whether the sequence number in the AEID field on the Adverse Event form is empty and then populates it with an incremental number to create the sequence ID.
3. (Recommended if you are using a Safety Case form) To alert the Safety group or study team that there is a serious or significant adverse event, before the Oracle InForm site user creates the Safety Case form, add a rule that sends email to the Safety group when an adverse event is Serious or Significant.

> **Note:**
>
> For all other item-level rules (for example, a check on onset date), you should reference the form and section as well as the item in the rule. For example, if you reference the full path on the onset date item on the Adverse Event form in a query rule, the query only fires on the Adverse Event form. If only the shared item is referenced, the query opens on both the Adverse Event form and Safety Case form.

For more information, see:

- Send the Reportable or Serious item to Oracle Argus Safety only when the Oracle InForm user marks it as Ready-to-Send
- Send the Reportable or Serious adverse event immediately upon form submission
- Calculate the sequence ID
- Send email to the safety group when an AE is marked as Serious or Significant

Send the Reportable or Serious item to Oracle Argus Safety only when the Oracle InForm user marks it as Ready-to-Send

> **Note:**
>
> If you have both Adverse Event form(s) and a Safety Case form, the rule goes on the Safety Case form.

Item	Description
When to use	This rule is typically used when you want to indicate explicitly that the safety event information is ready to be sent to Oracle Argus Safety. You might use this rule when: • The Oracle InForm user wants to make sure that any related labs or concomitant medications have been entered before transmitting the AE to Oracle Argus Safety. • A review process is in place. This rule can be used for a combined AE/ Safety Case form or for a separate Safety Case form.

Item	Description
Purpose	Ensures that a safety event, marked as Reportable or Serious, is sent to Oracle Argus Safety only when explicitly marked as Ready-to-Send. **Note:** The case will be sent automatically after 24 hours of initial form submission.
Triggering controls	Y or N codelists for the following: • Item marking the safety event ready to send (the ready-to-send item). • Item marking the safety event reportable (the reportable item). • Item marking the safety event serious (the serious item).
Action when rule is triggered	Reportable or Serious item value is Y, and Ready-to-Send item value is Y: • Message—IsReadyToSend • Result—The safety event data is sent to Argus Safety immediately. Reportable or Serious item value is Y, but Ready-to-Send item value is N: • Message—IsReportableOrSerious • Result—The safety event data is sent to Oracle Argus Safety after an interval that is configured in Oracle InForm Publisher. Ready-to-Send item value is Y, but neither the Reportable nor the Serious item value is Y: • Message—IsCancelled • Result—The _SaveToDB function does one of the following: – Cancels a pending submission. – Sends a nullification submission to Oracle Argus Safety if the safety event was submitted previously. – Does nothing if the safety event was not marked Reportable or Serious previously.

Item	Description
Rule expression	`(!this.AEInfoSct.IsSerious.Empty && this.AEInfoSct.IsSerious.Value != 'N')|| (! this.AEInfoSct.IsReportable.Empty && this.AEInfoSct.IsReportable.Value != 'N')? (! this.AEInfoSct.IsReadyToSubmit.Empty && this.AEInfoSct.IsReadyToSubmit.Value != 'N') ? _SaveToDb("SafetyConstants.IsReadyToSend", GetTrialName()) : _SaveToDb("SafetyConstants.IsReportableOrSerious", GetTrialName()): _SaveToDb("SafetyConstants.IsCancelled", GetTrialName()`

Send the Reportable or Serious adverse event immediately upon form submission

Item	Description
When to use	Use this rule when you want the safety event data to be sent immediately after form submission, and you don't need the Oracle InForm user to indicate that the data is ready to send.
Purpose	Sends a safety event immediately to Oracle Argus Safety if the safety event is marked Reportable or Serious.
Triggering controls	Y or N codelists for the following: • Item marking the safety event reportable (the Reportable item). • Item marking the safety event serious (the Serious item).

Item	Description
Action when rule is triggered	Reportable or Serious item value is Y: • Message—IsReadyToSend • Result—The safety event data is sent to Oracle Argus Safety immediately. Neither the Reportable nor the Serious item value is Y: • Message— IsCancelled • Result—The _SaveToDB function does one of the following: – Cancels a pending submission. – Sends a nullification submission to Oracle Argus Safety if the safety event was submitted previously. – Does nothing if the safety event was not marked Reportable or Serious previously.
Rule expression	`(!this.AEInfoSct.IsSerious.Empty && this.AEInfoSct.IsSerious.Value != 'N')|| (! this.AEInfoSct.IsReportable.Empty && this.AEInfoSct.IsReportable.Value != 'N')? _ SaveToDb("SafetyConstants.IsReadyToSend", GetTrialName()): _ SaveToDb("SafetyConstants.IsCancelled", GetTrialName())`

Calculate the sequence ID

This rule is required only if you are using a Safety Case form and allowing the site user to select only one adverse event.

This rule checks whether the sequence number in the Adverse Events form is empty and then populates it with an incremental number, starting at 1 and incrementing by 1 each time. Because the rule checks across multiple visits, it must be written at the visit level.

Item	Description
When to use	If you are only allowing the site to add one AE to each Safety Case form, this rule adds a read-only sequence ID, which is calculated by a rule.
Purpose	The site user will be able to add this ID to an item on the Safety Case form. The actual sequence ID generated by Oracle InForm cannot have rules written on it. This rule allows the study designer to base rules on the Safety Case form on this sequence ID.
Triggering controls	Upon form submission by the site user.

Item	Description
Action when rule is triggered	When the site user submits the form, the rule will populate the sequence ID item.

Rule expression	On the form, use a read-only field with a rule that calculates the sequence ID. In this example, the rule is calculating the AEID on the AE form.
	For example:
	`evaluate on Form Submission`
	
	`value = /Calculate SAE Sequence ID from the current index*/ this.eSAE.Current().sctSAE001_01.SAEAESEQ.Empty`
	
	`when value is true set this.eSAE.Current().sctSAE001_01.SAEAESEQ.Value = this.eSAE.CurrentIndex + 1`

Send email to the safety group when an AE is marked as Serious or Significant

Serious adverse events need to be reported to the FDA within a certain window of time from when the sponsor is made aware of them. The sponsor awareness date is calculated from the date the adverse event is marked as Serious.

If there is a separate Safety Case form, that triggers the creation of a case in Oracle Argus Safety.

If the site forgets to add a Safety Case form, the email can be used to alert the safety group that a Safety Case form is needed.

Item	Description
When to use	If you are using a separate AE and Safety Case form, you can optionally add a rule to send an email to your safety group or study team when the AE is marked Serious or Significant.
Purpose	Alert the safety group or study team that there is an SAE in the system before the site user creates the safety case form that triggers the SAE to be sent to Oracle Argus Safety.
Triggering controls	Y or N codelists for the following: • Item marking the safety event as Serious (the serious item). • Item marking the safety event as Significant (the significant item).
Action when rule is triggered	Sends an email to the safety group or study team. You can customize the content of the email based on study team needs.

Item	Description

Rule expression	In the example below, the user has added AE event, subject number, site number, and the AE sequence number.
	
	`evaluate on Form Submission`
	
	`value = !`
	`this.AE001.Current().IsDeleted &&`
	`!`
	`this.AE001.Current().sctAE001_01.A`
	`ESER.Empty &&`
	`this.AE001.Current().sctAE001_01.A`
	`ESER.Value ==`
	`this.AE001.Current().sctAE001_01.A`
	`ESER.clNY_1.cliNY_4`
	
	`when value is true`
	`send email on`

Add rules to the Safety Case form

Once the Safety Case forms are complete, add required rules to them so that safety data can be sent from Oracle InForm to Oracle Argus Safety.

1. (Required) If no adverse events are on the form, issue a query to alert the Oracle InForm site user to add an adverse event to the form or delete the entire form if the case is not needed anymore.
2. (Required, if you added a sequence ID field on the Adverse Event form and the Safety Case form has an item for the site user to enter the sequence ID), copy value from Adverse Event form to a Safety Case form.

   If you reference exactly where the shared item is, the query will only be generated on the referenced form. Otherwise, a query is sent for both the Adverse Event and Safety Case forms, but will be read only for the Safety Case form and the Oracle InForm user will not be able to change the value.

For more information, see:

- (Required) Send a query if no adverse events are on the Safety Case form
- Copy values from an Adverse Event form to a Safety Case form
- Create rules for the narrative

(Required) Send a query if no adverse events are on the Safety Case form

Use this rule in case the Oracle InForm site user completes a Safety Case form and then removes all related adverse events from the dynamic grid. The Adverse Event forms themselves may still exist but are irrelevant. Because there are no adverse events on the Safety Case form, no adverse events would be a part of the Oracle Argus Safety case. An Oracle Argus Safety case needs at least one adverse event to be a valid case.

- This rule should be written on an item in a flat section on the Safety Case form. In this example, it is the narrative field.
- It is preferable to have this rule attached to an item in a flat section that is at the top of the CRF, if one exists. Safety Case forms can be quite long and, if the query is at the bottom of the form, the site user could miss the fact that there is a query open.
- The query should instruct the site user to either: 1) add an AE/SAE (if the case is still valid) or 2) delete the Safety Case form itself (if the case should be nullified).

Item	Description
When to use	If you are using a Safety Case form with an add entry section to add adverse events.
Purpose	If you clear the sequence ID of the only itemset or if you delete the only itemset, nothing will be sent to Oracle Argus Safety to update the case. An error message is generated in Oracle InForm Publisher, but not displayed to the site user. Clearing the AE sequence number field in a Safety Case form, when an AE form is associated with the Safety Case form, should trigger a nullification message in Oracle Argus Safety, not an error message from Oracle InForm Publisher. This rule should be set up to open a query to the site user when there are no adverse events present in the itemset on the Safety Case form.
Triggering controls	All sequence ID fields in the itemset are blank.
Action when rule is triggered	Opens a query.

Rule expression	The rule below generates a query if a form is submitted without an entry in the fields that trigger transmission of safety data.
	
	`evaluate on Form Submission`
	
	`value = ! this.eSAE.Current().sctSAE001_03NAR.SAENARR_1.Empty && this.eSAE.sctSAE001_02AE.SAEAESPID.Values.Length < 1`
	
	`when value is true issue query on this.eSAE.Current().sctSAE001_03NAR.SAENARR_1: Missing eSAE info. Please review and update if needed.`

Copy values from an Adverse Event form to a Safety Case form

Item	Description
When to use	You have one item on the Safety Case form that requires the Oracle InForm site user to enter a sequence ID.
Purpose	Use this rule to copy information from the Adverse Event form that would allow the site to confirm that they have chosen the correct adverse event on the Safety Case form.
Triggering controls	Form submission.
Action when rule is triggered	Data is copied from the source form (Adverse Event) to the Safety Case form.

Item	Description
Rule expression	The rule below is an example of a rule that could be written on the Safety Case form to copy data over from the AE form. In this case, the rule is copying the onset date field from the AE form: `evaluate on Form Submission` `value = /Calculation rule to map value in AESDTH to SAEAESDTH when identifiers in AE and SAE forms are not empty and identifiers in source and destination forms match. Clear the mapped field if source is cleared*/` `!` `this.eSAE.Current().sctSAE001_02AE.Current().SAEAESPID.Empty &&` `this.AE001.sctAE001_01.AESPID.Values.Length > 0` `&&_IsValueInArray(this.eSAE.Current().sctSAE001_02AE.Current().SAEAESPID.Value,this.AE001.sctAE001_01.AESPID.Values) &&` `this.AE001.sctAE001_01.cmpAESER.AESDTH.Values.Length > 0 &&` `this.AE001.sctAE001_01.cmpAESER.AESDTH.AllObjects[(this.eSAE.Current().sctSAE001_02AE.Current().SAEAESPID.Value)-1] != null ?` `1 : 99` `when value == 1` `set this.eSAE.Current().sctSAE001_02AE.Current().SAEAESDTH.Value = this.AE001.sctAE001_01.cmpAESER.AESDTH.AllObjects[(this.eSAE.Current().sctSAE001_02AE.Current().SAEAESPID.Value)- 1]!=null? Convert.ToString(this.AE001.sctAE001_01.cmpAESER.AESDTH.AllObjects[(this.eSAE.Current().sctSAE001_02AE.Current().SAEAESPID.Value)- 1]): " "` `when value == 99` `set this.eSAE.Current().sctSAE001_02AE.Current().SAEAESDTH.Empty = true`

Create rules for the narrative

In the **NarrativeUpdatesOnly** system setting, define how the Safety Case form will group new narrative items when sending them to Oracle Argus Safety.

NarrativeUpdatesOnly = No

Item	Description
When to use	If you are selecting **No** for **NarrativeUpdatesOnly** to send the cumulative narrative for each transmission to Oracle Argus Safety.
Purpose	To add submitted text from the editable text field into a ReadOnly field cumulatively and clear the editable text field.
Triggering controls	Form submission.
Action when rule is triggered	Copies narrative text entered by site to ReadOnly fields.

Item	Description

Rule expression	The rule below is an example of a rule that could be written on the Safety Case form. In this case, there are three editable narrative fields named:
	• **D_NARRATIVE1_001**
	• **D_NARRATIVE1A_001**
	• **D_NARRATIVE1B_001**
	Depending on the length of the entered string and space left in each mapped field, these narrative fields are to be mapped to the following five ReadOnly fields:
	• **D_NARRATIVE2_001**
	• **D_NARRATIVE3_001**
	• **D_NARRATIVE4_001**
	• **D_NARRATIVE5_001**
	• **D_NARRATIVE8_001**
	When the length of the entered text (combined) exceeds the combined max length of the 5 mapped fields, the mapped text in the first text box will be overwritten by the remaining text. Once the text is mapped over to the target fields, the editable field clears out.
	You have the ability to update the editable narrative fields until the **Send to Safety** check box is checked.
	
	`evaluate on Form Submission`
	`value =`
	`(!`
	`this.D_ESAE001.Current().D_ESAE22001.`
	`D_NARRATIVE1_001.Empty ||`
	`!`
	`this.D_ESAE001.Current().D_ESAE22001.`
	`D_NARRATIVE1A_001.Empty ||`
	`!`
	`this.D_ESAE001.Current().D_ESAE22001.`
	`D_NARRATIVE1B_001.Empty) &&`
	`!`
	`this.D_ESAE001.Current().D_ESAE23001.`
	`D_SAESUBMIT_001.Empty ?`
	`(`
	`this.D_ESAE001.Current().D_ESAE22001.`
	`D_NARRATIVE2_001.GetValue("") +`
	`this.D_ESAE001.Current().D_ESAE22001.`
	`D_NARRATIVE3_001.GetValue("") +`
	`this.D_ESAE001.Current().D_ESAE22001.`
	`D_NARRATIVE4_001.GetValue("") +`
	`this.D_ESAE001.Current().D_ESAE22001.`
	`D_NARRATIVE5_001.GetValue("") +`
	`this.D_ESAE001.Current().D_ESAE22001.`
	`D_NARRATIVE8_001.GetValue("") +`
	`Environment.NewLine +`
	`Environment.NewLine +`
	`"##" +`

Item	Description
	Functions.GetSiteTime().ToString("ddM MMyyyyHHmm") + "##" + this.D_ESAE001.Current().D_ESAE22001. D_NARRATIVE1_001.GetValue("") + this.D_ESAE001.Current().D_ESAE22001. D_NARRATIVE1A_001.GetValue("") + this.D_ESAE001.Current().D_ESAE22001. D_NARRATIVE1B_001.GetValue("")).Lengt h > 10000 ? (this.D_ESAE001.Current().D_ESAE22001 .D_NARRATIVE2_001.GetValue("") +this.D_ESAE001.Current().D_ESAE22001 .D_NARRATIVE3_001.GetValue("") +this.D_ESAE001.Current().D_ESAE22001 .D_NARRATIVE4_001.GetValue("") +this.D_ESAE001.Current().D_ESAE22001 .D_NARRATIVE5_001.GetValue("") +this.D_ESAE001.Current().D_ESAE22001 .D_NARRATIVE8_001.GetValue("") +Environment.NewLine +Environment.NewLine +"##" +Functions.GetSiteTime().ToString("dd MMMyyyyHHmm") +"##" +this.D_ESAE001.Current().D_ESAE22001 .D_NARRATIVE1_001.GetValue("") + this.D_ESAE001.Current().D_ESAE22001. D_NARRATIVE1A_001.GetValue("") + this.D_ESAE001.Current().D_ESAE22001. D_NARRATIVE1B_001.GetValue("")).Subst ring((this.D_ESAE001.Current().D_ESAE 22001.D_NARRATIVE2_001.GetValue("") +this.D_ESAE001.Current().D_ESAE22001 .D_NARRATIVE3_001.GetValue("") +this.D_ESAE001.Current().D_ESAE22001 .D_NARRATIVE4_001.GetValue("") +this.D_ESAE001.Current().D_ESAE22001 .D_NARRATIVE5_001.GetValue("") +this.D_ESAE001.Current().D_ESAE22001 .D_NARRATIVE8_001.GetValue("") +Environment.NewLine +Environment.NewLine +"##" +Functions.GetSiteTime().ToString("dd MMMyyyyHHmm") +"##" +this.D_ESAE001.Current().D_ESAE22001 .D_NARRATIVE1_001.GetValue("") + this.D_ESAE001.Current().D_ESAE22001. D_NARRATIVE1A_001.GetValue("") + this.D_ESAE001.Current().D_ESAE22001. D_NARRATIVE1B_001.GetValue("")).Lengt

Item	Description
	h - 10000,10000) : (this.D_ESAE001.Current().D_ESAE22001. D_NARRATIVE2_001.GetValue("") + this.D_ESAE001.Current().D_ESAE22001. D_NARRATIVE3_001.GetValue("") + this.D_ESAE001.Current().D_ESAE22001. D_NARRATIVE4_001.GetValue("") + this.D_ESAE001.Current().D_ESAE22001. D_NARRATIVE5_001.GetValue("") + this.D_ESAE001.Current().D_ESAE22001. D_NARRATIVE8_001.GetValue("") + Environment.NewLine + Environment.NewLine + "##" + Functions.GetSiteTime().ToString("ddM MMyyyyHHmm") + "##" + this.D_ESAE001.Current().D_ESAE22001. D_NARRATIVE1_001.GetValue("") + this.D_ESAE001.Current().D_ESAE22001. D_NARRATIVE1A_001.GetValue("") + this.D_ESAE001.Current().D_ESAE22001. D_NARRATIVE1B_001.GetValue("")) :"99" when value != "99" set this.D_ESAE001.Current().D_ESAE22001. D_NARRATIVE5_001.Value = value.Length >= 6000 ? value.Length >= 8000 ? value.Substring(6000,2000): value.Substring(6000,value.Length-600 0) : " " when value != "99" set this.D_ESAE001.Current().D_ESAE22001. D_NARRATIVE4_001. Value = value.Length >= 4000 ? value.Length >= 6000 ? value.Substring(4000,2000): value.Substring(4000,value.Length-400 0) : " " when value != "99" set this.D_ESAE001.Current().D_ESAE22001. D_NARRATIVE3_001.

Item	Description
	Value = value.Length >= 2000 ? value.Length >= 4000 ? value.Substring(2000,2000): value.Substring(2000,value.Length-200 0) : " " when value != "99" set this.D_ESAE001.Current().D_ESAE22001. D_NARRATIVE2_001.Value = value.Length >= 2000 ? value.Substring(0,2000): value.Substring(0,value.Length) when value != "99" set this.D_ESAE001.Current().D_ESAE22001. xNARRATIVE1N.Value = this.D_ESAE001.Current().D_ESAE22001. D_NARRATIVE1_001.Value when value != "99" set this.D_ESAE001.Current().D_ESAE22001. xNARRATIVE1AN.Value = this.D_ESAE001.Current().D_ESAE22001. D_NARRATIVE1A_001.Value when value != "99" set this.D_ESAE001.Current().D_ESAE22001. xNARRATIVE1BN.Value = this.D_ESAE001.Current().D_ESAE22001. D_NARRATIVE1B_001.Value when value != "99" set this.D_ESAE001.Current().D_ESAE22001. D_NARRATIVE1_001.Value = " " when value != "99" set this.D_ESAE001.Current().D_ESAE22001. D_NARRATIVE1A_001.Value = " " when value != "99" set this.D_ESAE001.Current().D_ESAE22001. D_NARRATIVE1B_001.Value = " " when value != "99" set this.D_ESAE001.Current().D_ESAE22001. D_NARRATIVE8_001.Value = value.Length >= 8000 ? value.Length >= 10000 ? value.Substring(8000,2000):

Item	Description
	`value.Substring(8000,value.Length-8000)` `: " "`

NarrativeUpdatesOnly = Yes

Item	Description
When to use	If you are selecting **Yes** for **NarrativeUpdatesOnly** to send the incremental narrative for each submission to Oracle Argus Safety.
Purpose	To add submitted text from the editable text field into a ReadOnly field cumulatively, overwrite its corresponding Hidden field, and clear the editable text field.
Triggering controls	Form submission.
Action when rule is triggered	Copies narrative text entered by site to Hidden and ReadOnly fields.

Item	Description

Rule expression	The rule below is an example of a rule that could be written on the Safety Case form. In this case, there are three editable narrative fields named:
	• **D_NARRATIVE1_001**
	• **D_NARRATIVE1A_001**
	• **D_NARRATIVE1B_001**
	Depending on the length of the entered string and space left in each mapped field, these narrative fields are to be mapped to the following five ReadOnly fields:
	• **D_NARRATIVE2_001**
	• **D_NARRATIVE3_001**
	• **D_NARRATIVE4_001**
	• **D_NARRATIVE5_001**
	• **D_NARRATIVE8_001**
	When the length of the entered text (combined) exceeds the combined max length of the 5 mapped fields, the mapped text in the first text box will be overwritten by the remaining text. Once the text is mapped over to the target fields, the editable field clears out.
	Also in this example, all narrative editable text fields are mapped to the same number of Hidden fields on a 1 to 1 basis.
	You have the ability to update the editable narrative fields until the **Send to Safety** check box is checked.
	
	`evaluate on Form Submission`
	`value =`
	`(!`
	`this.D_ESAE001.Current().D_ESAE220`
	`01.D_NARRATIVE1_001.Empty ||`
	`!`
	`this.D_ESAE001.Current().D_ESAE220`
	`01.D_NARRATIVE1A_001.Empty ||`
	`!`
	`this.D_ESAE001.Current().D_ESAE220`
	`01.D_NARRATIVE1B_001.Empty) &&`
	`!`
	`this.D_ESAE001.Current().D_ESAE230`
	`01.D_SAESUBMIT_001.Empty ?`
	`(`
	`this.D_ESAE001.Current().D_ESAE220`
	`01.D_NARRATIVE2_001.GetValue("") +`
	`this.D_ESAE001.Current().D_ESAE220`
	`01.D_NARRATIVE3_001.GetValue("") +`
	`this.D_ESAE001.Current().D_ESAE220`
	`01.D_NARRATIVE4_001.GetValue("") +`
	`this.D_ESAE001.Current().D_ESAE220`
	`01.D_NARRATIVE5_001.GetValue("") +`
	`this.D_ESAE001.Current().D_ESAE220`

Item	Description
	01.D_NARRATIVE8_001.GetValue("") + Environment.NewLine + Environment.NewLine + "##" + Functions.GetSiteTime().ToString(" ddMMMyyyyHHmm") + "##" + this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE1_001.GetValue("") + this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE1A_001.GetValue("") + this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE1B_001.GetValue("")) .Length > 10000 ? (this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE2_001.GetValue("") + this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE3_001.GetValue("") + this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE4_001.GetValue("") + this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE5_001.GetValue("") + this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE8_001.GetValue("") + Environment.NewLine + Environment.NewLine + "##" + Functions.GetSiteTime().ToString(" ddMMMyyyyHHmm") + "##" + this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE1_001.GetValue("") + this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE1A_001.GetValue("") + this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE1B_001.GetValue("")) .Substring((this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE2_001.GetValue("") + this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE3_001.GetValue("") + this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE4_001.GetValue("") + this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE5_001.GetValue("") + this.D_ESAE001.Current().D_ESAE220

Item	Description
	01.D_NARRATIVE8_001.GetValue("") + Environment.NewLine + Environment.NewLine + "##" + Functions.GetSiteTime().ToString(" ddMMMyyyyHHmm") + "##" + this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE1_001.GetValue("") + this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE1A_001.GetValue("") + this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE1B_001.GetValue("")) .Length - 10000,10000) : (this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE2_001.GetValue("") + this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE3_001.GetValue("") + this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE4_001.GetValue("") + this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE5_001.GetValue("") + this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE8_001.GetValue("") + Environment.NewLine + Environment.NewLine + "##" + Functions.GetSiteTime().ToString(" ddMMMyyyyHHmm") + "##" + this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE1_001.GetValue("") + this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE1A_001.GetValue("") + this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE1B_001.GetValue("")) :"99" when value != "99" set this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE5_001.Value = value.Length >= 6000 ? value.Length >= 8000 ? value.Substring(6000,2000): value.Substring(6000,value.Length- 6000)

Item	Description
	: " " when value != "99" set this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE4_001.Value = value.Length >= 4000 ? value.Length >= 6000 ? value.Substring(4000,2000): value.Substring(4000,value.Length- 4000) : " " when value != "99" set this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE3_001.Value = value.Length >= 2000 ? value.Length >= 4000 ? value.Substring(2000,2000): value.Substring(2000,value.Length- 2000) : " " when value != "99" set this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE2_001.Value = value.Length >= 2000 ? value.Substring(0,2000): value.Substring(0,value.Length) when value != "99" set this.D_ESAE001.Current().D_ESAE220 01.xNARRATIVE1N.Value = this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE1_001.Value when value != "99" set this.D_ESAE001.Current().D_ESAE220 01.xNARRATIVE1AN.Value = this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE1A_001.Value when value != "99" set this.D_ESAE001.Current().D_ESAE220 01.xNARRATIVE1BN.Value = this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE1B_001.Value when value != "99" set this.D_ESAE001.Current().D_ESAE220 01.D_NARRATIVE1_001.Value = " "

Item	Description

	when value != "99"
	    set
	this.D_ESAE001.Current().D_ESAE220
	01.D_NARRATIVE1A_001.Value = " "
	when value != "99"
	    set
	this.D_ESAE001.Current().D_ESAE220
	01.D_NARRATIVE1B_001.Value = " "
	when value != "99"
	    set
	this.D_ESAE001.Current().D_ESAE220
	01.D_NARRATIVE8_001.Value =
	value.Length >= 8000 ?
	value.Length >= 10000 ?
	value.Substring(8000,2000):
	value.Substring(8000,value.Length-
	8000)
	: " "
	
	xRuleNarrative1Ato1D
	evaluate on Form Submission
	value = !
	this.D_NARRATIVE1A_001.Empty ?
	2 : 101
	when value == 2
	    set
	this.D_NARRATIVE1D_001.Value =
	this.D_NARRATIVE1A_001.Valuewhen
	value == 2
	    set
	this.D_NARRATIVE1A_001.Empty =
	true
	when value == 101
	    set
	this.D_NARRATIVE1D_001.Value = " "
	
	xRuleNarative1to1C
	evaluate on Form Submission
	value = !
	this.D_NARRATIVE1_001.Empty ? 1 :
	100
	when value == 1
	    set
	this.D_NARRATIVE1C_001.Value =
	this.D_NARRATIVE1_001.Valuewhen
	value == 1
	    set
	this.D_NARRATIVE1_001.Empty = true
	when value == 100
	    set

Item	Description
	this.D_NARRATIVE1C_001.Value = " " **xRuleNarrative1Bto1E** evaluate on Form Submission value = ! this.D_NARRATIVE1B_001.Empty ? 3 : 102 when value == 3 set this.D_NARRATIVE1E_001.Value = this.D_NARRATIVE1B_001.Valuewhen value == 3 set this.D_NARRATIVE1B_001.Empty = true when value == 102 set this.D_NARRATIVE1E_001.Value = " "

Add rules for other forms containing adverse event items

If there are two places where date of death or autopsy could be reported, check to make sure they are the same and, if not, create a query.
For more information, see:

- Check for multiple different death dates or patient autopsy completed codes

Check for multiple different death dates or patient autopsy completed codes

If multiple death dates are entered into Oracle InForm for one subject, it is possible that the wrong death date could be sent to Oracle Argus Safety. If collected multiple times, make sure death dates for the subject are the same across fields to avoid errors, since only one of these fields will be mapped to the data series and, thus, sent to Oracle Argus Safety. This applies to autopsy date as well.

Item	Description
When to use	If your study includes the death or autopsy date in multiple places, check to make sure that the dates match.
Purpose	This rule checks for the entry of multiple different death dates or patient autopsy completed codes. If a user mistakenly enters different death dates or patient autopsy completed codes on multiple instances, incorrect data might be transmitted to Oracle Argus Safety.
Triggering controls	Date of death and/or patient autopsy completed codes, depending on what you are looking for.

Item	Description
Action when rule is triggered	This is a Constraint rule that issues a query.
Rule expression	The example below checks for the entry of multiple different death dates AND patient autopsy completed codes. `evaluate on Form Submission value = /Fire a query if Date of Death on eSAE form (flat section) doesn't match Date of Death captured in DISP (Disposition Follow-up) OR DISPLTFU (Disposition Long Term Follow-up) visits*/ ! this.evtVISLOGS.eSAE.Current().sctSAE001_01.cmpDeath.SAEAEDTHDTC.Empty && (! this.evtDISP.DS006_3.sctDS006_3_01.DSSTDAT_5.Empty || ! this.evtDISPLTFU.DS006_4.sctDS006_4_01.DSSTDAT_5.Empty) && (Functions._GetDateDifference(this.evtDISP.DS006_3.sctDS006_3_01.DSSTDAT_5.Value,this.evtVISLOGS.eSAE.Current().sctSAE001_01.cmpDeath.SAEAEDTHDTC.Value,Constants.DateTimeParts.Days)!= 0) || (Functions._GetDateDifference(this.evtDISPLTFU.DS006_4.sctDS006_4_01.DSSTDAT_5.Value,this.evtVISLOGS.eSAE.Current().sctSAE001_01.cmpDeath.SAEAEDTHDTC.Value,Constants.DateTimeParts.Days)!= 0) ? true : false when value is true issue query on this.evtVISLOGS.eSAE.Current().sctSAE001_01.cmpDeath.SAEAEDTHDTC: Sample Query`

Map Oracle InForm data items to Oracle Argus Safety entities

In this section:

- Download the data mappings from My Oracle Support (MOS)
- Import the data mappings into Oracle Central Designer

- Map Oracle InForm items to entities in Oracle Argus Safety
- (Optional) Create a custom data series
- Select the safety mapping (SafetyLogicalSchema) to deploy

Download the data mappings from My Oracle Support (MOS)

The Oracle InForm to Oracle Argus Safety integration enables you to send clinical safety events entered in Oracle InForm directly to Oracle Argus Safety. The necessary Oracle Central Designer data mappings may be downloaded from My Oracle Support.

1. Go to the Oracle Help Center page for your release.
2. Click on **Release Notes**.
3. Sign in to My Oracle Support if you are not signed in already.
4. Scroll down to the **Download data mappings for Oracle InForm to Oracle Argus Safety integration** section.
5. Right click the **SafetyLogicalSchemaLibrary.csml** file and download it by saving the link to your PC.

Import the data mappings into Oracle Central Designer

Follow these steps to import the Oracle Argus Safety data mappings, data series, and data sets into your Oracle InForm study using Oracle Central Designer.

Prerequisite: the Job Scheduler must be running.

1. At the bottom of the Project Explorer, click the **Study Information** ( ) button.
2. In the Project Explorer, right-click the study you want to add the data mappings to and select **Import Study**.
3. Click **Next** to start the Oracle Central Designer Import Wizard.
4. On the **Import Type** page, select **Import CSML or ODM file** and click **Next**.
5. Browse to where you downloaded the SafetyLogicalSchemaLibrary.csml file containing the data mappings, select it, and click **Open**.
6. Click **Next**.
7. Complete the remaining pages of the **Oracle Central Designer Import Wizard**. Click **Next** after you finish filling in each page.
8. On the final page of the **Oracle Central Designer Import Wizard**, click **Finish**.

   If you are importing a CSML file containing study objects for a system that is not selected as a Deployment System for the study or library, a message appears. Continue with the import, and select all the systems in the CSML file as Deployment Systems. If you choose this option, continue to the next step.

   A message pops up in the lower-right corner when the job starts and completes.

9. At the bottom of the Project Explorer, click the **Data Mappings** ( ) button.
10. To verify that the safety data mappings have been imported and installed, in the **Project Explorer** open the **InForm Mappings** folder, then open the **CDD** folder.

11. Expand the **SafetyLogicalSchema** data mappings to see that the predefined data series and data sets are there.

Import Wizard options - CSML or ODM file

Page	Option	Description
Welcome	-	Introduction page.
Import Type	-	Select the source of the data to import.
-	Import CSML or ODM file	Generate study objects from a file in CSML or ODM format.
-	Harvest Oracle InForm Resources	Generate study objects from the components of an Oracle InForm study.
File Location	Path of file to import	Specify the path of the CSML or ODM import file, or click Browse to locate the import file.
Study Administration Import Mode	-	This page appears only for the CSML import type, if the CSML file contains study administration objects.
-	Import study objects and administration data.	Import both study objects and study administration objects.
-	Import administration data only.	Import only study administration objects.
-	Import study objects only.	Import only study objects.
Rule Import Mode	Rule Import Mode	Only the Import as Collaboration Notes option is supported. With this option, each imported rule is converted to a collaboration note in the Oracle Central Designer application. **Note:** This option applies only if the Import Type is ODM; if the Import Type is CSML, the import process creates a Oracle Central Designer rule for each imported rule.
IPR Import Mode	Import IPR data	Select whether to import in-place revision objects. **Note:** This page appears only if the file contains in-place revision objects.
Ready to Import Data to Central Designer	-	View a summary of the import options selected in the wizard.

Map Oracle InForm items to entities in Oracle Argus Safety

Oracle InForm and Oracle Argus Safety use the data mapping feature of Oracle Central Designer to configure how safety event data items on Oracle InForm forms correspond to safety event entities in Oracle Argus Safety.

> **Note:**
>
> Items within the dynamic grid should be mapped to their respective source forms and not the dynamic grid.

The tables in this section show the content of the safety data sets and data series supplied with Oracle Central Designer.

- To view the definitions of the data series in a data set, select the **Data Set** tab.
- To view study objects by title in Oracle Central Designer, in the menu bar above the Project Explorer, select **Options**, then **Display Names**, then **Titles**.

> **Note:**
>
> When you add an item to a data series by selecting a study event or form, you can determine when the item is mapped to the study event or form.

1. At the bottom of the Project Explorer, click the **Forms and Transactions** () button, and expand the **Oracle InForm** folder and the **Forms** folder, if necessary.
2. In the Project Explorer, select the form or study event containing the item to be added to a data series.
3. Select the **Data Series Summary** tab.
4. At the top of the **Data Series Summary** tab, from the **Mapping** drop-down list select **SafetyLogicalSchema**. The data sets and their data series appear in the workspace as columns.
5. At the top of the **Data Series Summary** tab, pull down the **Data Set** list and select **Safety_Config**.
6. Starting with the Adverse Event form, add all items and forms to be sent to Oracle Argus Safety to the Safety_Config data set by clicking the drop-down at the right end of the data series cell and selecting **Form** to map the item only when it appears in this section on the form.
7. At the top of the **Data Series Summary** tab, pull down the **Data Set** list and select **Safety_Significant**.
8. Create mappings on the Adverse Event form for those items you want Oracle InForm Publisher to monitor for changes and send a follow-up transmission when changes occur.
9. Perform the same steps for the Safety Case form and any other forms with adverse event items on them.

> **Note:**
>
> If the item cannot be added to the data series—for example, if the data types for the item and data series are not compatible—None compatible appears in the cell.

> **Tip:**
>
> The association remains with the item whenever it is used. This means you can create a data mapping between an item and a data series once and never have to recreate it in other studies.

For more information, see:

- Mapping guidelines
- Predefined data sets included in the integration

Mapping guidelines

In this section:

- Include items that you map once in the Safety_Config data series
- Include items you want to monitor for changes to the Safety_Significant data series
- Map the data series to a specific instance of an item
- Map a form to multiple dynamic grids
- Map repeating data sets to items that can occur multiple times in a message
- Map items that include the unit in the item definition
- Map items coded in Oracle InForm
- Map items coded in Oracle Argus Safety
- Map to the MedDRA version
- Map narrative items

Include items that you map once in the Safety_Config data series

Add all items and forms to be sent to Oracle Argus Safety to the Safety_Config data set. This tells Oracle InForm Publisher where the items are located.

After you add an item to a data series in a data mapping, you can specify the circumstances for which the item is mapped to the data series. For example, an item that appears on several forms in a study can be added to a data series, but you might want to analyze data collected for the item only when it appears on a specific form. In that situation, you can map the item to the data series for the specific form.

Data Series Title	Description
Any AE Form Control	Control used to identify the Adverse Event form. Map this data series to any item on the Adverse Event form. Required.

Data Series Title	Description
Any SE Form Control	Control used to identify the Safety Case form in a study design with separate Adverse Event and Safety Case forms. Map this data series to any item on the Safety Case form. Required in a design with separate Adverse Event and Safety Case forms.
SE Current Status Control	Item used to store the accepted or rejected status of the most recent safety transmission file. Typically this item is on the Adverse Event or Safety Case form.
SE Related AE Sequence Number Control	Map the item on the Safety Case form that collects the sequence ID of the Adverse Event form. If this is mapped to an item in a repeating itemset, then time frames will not be used for related adverse events. Unnecessary when using dynamic grids.
AE Start Date Control	Onset date of the adverse event. This data series is used to identify by date range the related safety event data that appears on other forms.
SafetyCaseAEDynamicGrid	Control used to identify the dynamic grid where the adverse events that will be part of the safety case will be selected. **Note:** You don't need this data series if you are using InclusionTargets. For more information, see Map a form to multiple dynamic grids.

Include items you want to monitor for changes to the Safety_Significant data series

The **Safety_Significant** data set is an empty data set in which you create the data series and mappings for items that are monitored for changes after initial transmission to determine whether follow-up for safety integration is needed. For example, if an AE item containing data about a reaction recurrence is mapped to a data series in the Safety_Significant data set, a follow-up for safety integration is triggered when a user changes the data in the reaction recurrence item.

> **Note:**
>
> The data series in the Safety_Significant data set must have the same aliases as the corresponding data series in the message body data sets. Therefore, copy and pasting data series from the message body data sets into the Safety_Significant data set is recommended.

Map the data series to a specific instance of an item

Most data sets are associated with elements in the safety event transmission that occur only once. You map the data series in these data sets to a specific instance of an item:

- In a non-repeating section (that is, not an Oracle InForm itemset).
- On a non-repeating form.
- In a non-repeating visit.
- On the instance of the AE form that is being submitted. Although the AE form is most often repeating, only the data in the current instance of the AE form being submitted is transmitted.

If the item is on a form that occurs in multiple visits, you must map the data series to a specific instance of the study event and form.

> **Note:**
>
> You can map multiple items to the same data series, and you can map similar items from different forms to the same data series in a repeating data set. For example, you can map items from a Lab Local and a Lab Central form to the same data series in the Subject_LabTest data set. When you do this, the safety event transmission treats the items as coming from different instances, so the transmission message contains a different element for each form. To do this, make a copy of the entire dataset or add them into the current one. Then map one dataset to the LabLocal form and the other to the LabCentral form.

Map a form to multiple dynamic grids

You might have an Adverse Event form that points to two or more dynamic grids; for example, the Safety Case Adverse Event dynamic grid and a Medical History dynamic grid. To instruct Oracle InForm Publisher on what exact instances to pull from:

1. For each dataset associated with each dynamic grid, select the dataset you need to map to two or more dynamic grids.
2. Under that dataset, add a data series with the alias *InclusionTargets*.
3. Right-click on the InclusionTargets data series and select **Properties**.
4. In the **Data Series Properties** dialog box, create an identifier in the **RefName** field with the prefix *InclusionTargets_*. For example, *InclusionTargets_MedHx*. Click **OK**.
5. Map each dynamic grid you wish to select instances from to the InclusionTarget data series.

> **Note:**
>
> When mapping a target, Oracle Central Designer and Oracle InForm will include all instances of a column if it exists in multiple dynamic grids. To narrow the selection to the specific dynamic grids that you need when using InclusionTargets, make each dynamic grid unique by adding a column exclusive to that dynamic grid which will be the item mapped to the InclusionTargets data series.

For more information, on creating a dynamic grid, see Create a section (dynamic grid) to collect related data.

Map repeating data sets to items that can occur multiple times in a message

The data series in repeating data sets are mapped to items that can occur multiple times in a safety event transmission message. You can map these data series to items in repeating sections, forms, and visits. Each data series in a repeating data set must be mapped to the same repeating section, form, and visit. When a form containing repeating data is submitted, the safety event transmission message includes the mapped data from all applicable instances of the form.

> **Note:**
>
> If you have configured Oracle InForm Publisher to select related data based on dates, the configuration may affect the number of instances that are sent in a safety event transmission message. For example, multiple AEs might be sent with the submitted AE if their dates are within the configured range for related data.

Only the following data sets are repeatable:

- Subject_AdverseEvent
- Subject_ConMed
- Subject_LabTest
- Subject_MedicalHistory
- Subject_PastDrugHistory
- Subject_SuspectDrug

Map the data series in the following data sets to the same form as the Subject_SuspectDrug data set:

- Subject_SuspectDrug_ReactionRecurrence
- Subject_SuspectDrug_ReactionRelatedness
- Subject_Death

Map the data series in the following data sets to the same form as the Subject_Death data set:

- Subject_CauseOfDeath

- Subject_Autopsy

If an item occurs in multiple forms or visits, you can map a data series to the item in a specific form or in a specific form and visit by on the Data Series Summary tab of the form or study event.

You can map multiple items to the same data series, and you can map similar items from different forms to the same data series in a repeating data set. For example, you can map items from a Lab Local and a Lab Central form to the same data series in the Subject_LabTest data set. When you do this, the safety event transmission treats the items as coming from different instances, so the transmission message contains a different element for each form.

> **Note:**
>
> The mappings need to be in the same order for each element. For example, if you map Lab Name and Test Date to LabLocal and LabCentral, both Name and Date need to appear in the forms in the same order.

Map items that include the unit in the item definition

1. At the bottom of the Project Explorer, click the **Forms and Transactions** ( ) button, and expand the **InForm** folder and the **Forms** folder, if necessary.
2. Select a study event.
3. Above the grid, click the **Data Series Summary** tab.
4. In the **Items** column, select the item to map.
5. In the **Units** dialog box, select **Entered Value**, and click **OK**.

   The item is mapped to the data series.

> **Tip:**
>
> - You do not need to create a separate mapping for the units.
> - When Oracle InForm Publisher generates the data transmission message, it populates the element for the corresponding unit data series with the unit.
> - Automatic mapping of units is supported only for data series that have a corresponding unit data series. It is not supported for custom data series. To map an item with included units to a custom data series, you must also create a custom data series for the units and map the two data series to the item value and units separately.
> - If you map an item that is designed with units included, and you map its corresponding unit data series to another item, the unit value of the item designed with units overrides the manual data series mapping for the unit.

Map items coded in Oracle InForm

If the Oracle InForm study is integrated with an external coding application, such as Oracle Central Coding, you can map the items so that the encoded data is transmitted to Oracle Argus Safety.

1. Map the following data series to the corresponding AE description items, as identified in Which items have data series for transmiting coded or verbatim data?:
   - AE_VerbatimTerm
   - AE_LowLevelTerm
   - AE_PreferredTerm
   - AE_LLTMedDRAVersion
   - AE_PTMedDRAVersion

   > **Tip:**
   >
   > To make sure that the data sent to Argus Safety application is encoded in Oracle InForm, map the data series listed above in the Safety_Significant data set as well as in the Subject_AdverseEvent data set.

   When Oracle Argus Safety receives an AE description, if all of the items mapped to these data series have data, it does not attempt to code the verbatim. However, if Oracle Argus Safety receives the verbatim before the item is encoded in Oracle InForm, it attempts to encode the item and places the encoded values in the appropriate Oracle Argus Safety fields. When the external coding application returns encoded values to Oracle InForm, the updated values on the form trigger a follow-up to Oracle Argus Safety. An Oracle Argus Safety user can accept the follow-up. The Oracle InForm codes replace the Oracle Argus Safety codes.
2. Map the appropriate data series to the item containing the encoded MedDRA lower-level term. For example, map the ConMed_Indication data series to the lower-level term for the concomitant medication indication.

   > **Tip:**
   >
   > You can transmit either the verbatim or the encoded version, but not both. To transmit both, map the verbatim item and let Oracle Argus Safety encode it. See Map items coded in Oracle Argus Safety.
3. Map the data series for the MedDRA version to the item containing the version of the MedDRA dictionary used to encode the item.

   > **Tip:**
   >
   > You can transmit either the verbatim or the encoded version, but not both. To transmit both, map the verbatim item and let Oracle Argus Safety encode it. See Map items coded in Oracle Argus Safety.

Map items coded in Oracle Argus Safety

If you want the items to be encoded by the coding module of Oracle Argus Safety or to be encoded manually by Oracle Argus Safety users, you can map the items so that the verbatim data is transmitted to Argus Safety for coding.

1. Map the AE_VerbatimTerm data series to the item in which the Oracle InForm user enters the AE description.
2. Do not map the following data series:
   - AE_LowLevelTerm
   - AE_PreferredTerm
   - AE_MedDRAVersion
3. Map the appropriate data series to the item containing the verbatim entered by the Oracle InForm user. For example, map the MedicalHistory_Name data series to the item in which the user entered a medical history event.
4. Do not map the MedDRA version data series.

When Oracle Argus Safety receives the data and creates a case, it attempts to encode the verbatims. If it cannot encode them, a warning appears when the Pending E2B file is accepted, and a user can encode the items manually through the Oracle Argus Safety user interface.

Map to the MedDRA version

Each data series for an item that can be coded has a corresponding data series, called <dsname>MedDRAVersion. <dsname> is the name of the data series to which the MedDRA version applies.

1. (Coding data) If the transmitted data is encoded in Oracle InForm or in a coding application that is integrated with the InForm, map the <dsname>MedDRAVersion data series to an item that holds the version of the MedDRA dictionary used to encode the transmitted data.

   When you map the <dsname>MedDRAVersion data series, you signal Oracle Argus Safety that the corresponding data is encoded, and the coding module in Oracle Argus Safety does not encode the data.
2. (Verbatim data) If you want the coding to take place in Oracle Argus Safety, do not map the <dsname>MedDRAVersion data series.

   Leaving the <dsname>MedDRAVersion data series unmapped signals Oracle Argus Safety that the corresponding data is verbatim and should be encoded in Oracle Argus Safety.

Map narrative items

- Compound items are not supported as a narrative field.
- Only one text item is supported as a narrative in an itemset in a Safety form.
- Set **NarrativeUpdatesOnly** to **Yes** to sendnew narrative items as chronological follow-ups (incremental) to previous narrative submissions. When set to **No**, each new narrative item will be sent with all previous narrative item submissions chronologically attached (cumulative) in the same submission.

> **Note:**
>
> Multiple items can be mapped to the narrative at the case level. The contents of all mapped items will be concatenated together in the order the items appear on the form. Items on the AE form that need to be part of the narrative must be mapped at the Subject_AdverseEvent level. Only one item from each repeating section can be mapped at the Subject_Adverse Event level. These items will appear before any of the items mapped at this level in the narrative sent to Oracle Argus Safety.

Predefined data sets included in the integration

In this section:

- Safety_Case data set
- Subject data set
- Subject_AdverseEvent data set
- Subject_Autopsy data set
- Subject_CauseOfDeath data set
- Subject_ConMed data set
- Subject_Death data set
- Subject_Lab Test data set
- Subject_MedicalHistory data set
- Subject_PastDrugHistory data set
- Subject_SuspectDrug data set
- Subject_SuspectDrug_ReactionRecurrence data set
- Subject_SuspectDrug_ReactionRelatedness data set
- Reporter data set

Safety_Case data set

Data Series Title	Description	Location in Oracle Argus Safety
SeriousIndicator	Whether the case is serious.	Case Form / Analysis / Case Serious
OccurenceCountryCode	Where the adverse event occurred.	Case Form/ General / General Information / Country of Incidence
SeriousnessDeathIndicator	Whether the case resulted in death.	Case Form / Analysis / Case Serious / Notes
SeriousnessLifeThreatening Indicator	Whether the case is life threatening.	Case Form / Analysis / Case Serious / Notes

Data Series Title	Description	Location in Oracle Argus Safety
SeriousnessHospitalization Indicator	Whether the case requires inpatient hospitalization or prolonging of existing hospitalization.	Case Form / Analysis / Case Serious / Notes
SeriousnessDisablingIndicator	Whether the case results in persistent or significant disability or incapacity.	Case Form / Analysis / Case Serious / Notes
SeriousnessCongenital AnomalyIndicator	Whether the case results in a congenital anomaly or birth defect.	Case Form / Analysis / Case Serious / Notes
SeriousnessOtherIndicator	Whether the case contains a medically important condition.	Case Form / Analysis / Case Serious / Notes

Data Series Title	Description	Location in Oracle Argus Safety
Narrative	An overall case narrative to send to the Oracle Argus Safety application. This data set can be mapped to multiple items on the SAE case form. The contents of all mapped items will be concatenated together in the order the items appear on the form. Items on the AE form that need to be part of the narrative must be mapped at the Subject_AdverseEvent level. These items will appear before any of the items mapped at this level in the narrative sent to Argus Safety.	Case Form / Analysis / Case Analysis / Narrative

Note: Compound items are not supported

Data Series Title	Description	Location in Oracle Argus Safety
	dasanarrativefield.	

Subject data set

Data Series Title	Description	Location in Oracle Argus Safety
NameInitials	Patient initials.	Case Form / Patient / Patient Information / Initials
BirthDateTime	Patient date of birth.	Case Form / Patient / Patient Information / Date of Birth
OnsetAge	Age at the time of onset of the reaction.	Case Form / Patient / Patient Information / Age
OnsetAgeUnit	Unit for the age at time of onset of the reaction (for example, years, months).	Case Form / Patient / Patient Information / Age Units
GestationPeriod	Gestation period when the adverse event was observed in the fetus.	Case Form / Patient / Patient Information / Pregnancy Details / Weeks at Onset If a valid value is entered, the Pregnant field is selected as well.
GestationPeriodUnit	Unit for the gestation period (weeks, months, trimester).	Case Form/ Patient / Patient Pregnancy Details / Weeks at Onset If a value is entered, the Pregnant field is selected.
AgeGroupCode	Patient age group (for example, adolescent, adult).	Case Form / Patient / Patient Age Group
Weight	Patient weight.	Case Form / Patient / Weight

Data Series Title	Description	Location in Oracle Argus Safety
WeightUnit	Unit for the patient weight (for lb, kg).	Case Form / Patient / Patient Weight Oracle Argus Safety requires kg. If you collect weight in pounds, set the study design to perform the conversion to kg.
Height	Patient height.	Case Form / Patient / Patient Height
HeightUnit	Unit for the patient height (for in, cm).	Case Form / Patient / Patient Height Oracle Argus Safety requires cm. If you collect height in inches, set the study design to perform the conversion to cm.
SexCode	Patient gender	Case Form / Patient / Patient Gender
LastMenstrualDateTime	Date of the last menstrual period the adverse event occurred.	Case Form / Patient / Patient Date of LMP
MedicalHistory	Text item used to summarize the history and concurrent conditions of patient.	Case Form / Patient / Notes
InvestigationResult	Results of tests and procedures to the investigation of the patient. Map this data series when structured information is not available.	Case Form / Patient / Relevant Test
RaceCode	Patient race.	Case Form / Patient / Patient Ethnicity
BreastFeedingIndicator	Indicates whether the patient breast feeds an infant.	Case Form / Patient / Patient Details / Breastfeeding
OccupationCode	Occupation of the patient.	Case Form / Patient / Patient Details / Occupation
PregnancyDueDateTime	Due date for the pregnancy.	Case Form / Patient / Pregnancy Due Date
ProspectiveIndicator	Whether the sponsor was aware of the pregnancy before the birth.	Case Form / Patient / Pregnancy Prospective
RetrospectiveIndicator	Whether the sponsor became aware of the pregnancy after the birth.	Case Form / Patient / Pregnancy Retrospective
FetusCount	Number of fetuses in the pregnancy.	Case Form / Patient / Pregnancy Fetus Count

Subject_AdverseEvent data set

Data Series Title	Description	Location in Oracle Argus Safety
AE_VerbatimTerm	Symptom or description of the adverse event as entered by the Oracle InForm user. Required.	Case Form / Events / Event Information / Description as Reported
AE_LowLevelTerm	MedDRA lower-level term (LLT) for the adverse event or reaction.	Case Form / Events / Event Encoding / Lower Level Term

> **Note:**
>
> Do not map this data series if the item will be encoded in Oracle Argus Safety.

Data Series Title	Description	Location in Oracle Argus Safety
AE_PreferredTerm	MedDRA preferred term (PT) for the adverse event or reaction.	Case Form / Events / Event Encoding / Preferred Term

Note:

Do not map this data series if the item will be encoded in Oracle Argus Safety.

Data Series Title	Description	Location in Oracle Argus Safety
AE_LLTMedDRAVersion	Version of MedDRA that was used to code the verbatim term to the lower-level term. **Note:** Do not map this data series if the item will be encoded in Oracle Argus Safety.	For items to be encoded in Oracle Argus Safety, MedDRA version is required by the format used for transmitting data but does not appear in Oracle Argus Safety.

Data Series Title	Description	Location in Oracle Argus Safety
AE_PTMedDRAVersion	Version of MedDRA that was used to code the verbatim term to the preferred term. **Note:** Do not map this data series if the item will be encoded in Oracle Argus Safety.	For items to be encoded in Oracle Argus Safety, MedDRA version is required by the format used for transmitting data but does not appear in Oracle Argus Safety.
AE_TermHighlightedCode	Term highlighted by the reporter (for example, highlighted as serious, highlighted as not serious, serious and not highlighted, not serious, and not highlighted).	Case Form / Events / Event Information / Term Highlighted by Reporter
AE_StartDateTime	Onset or start date of the adverse event.	Case Form / Events / Event Information / Onset Date/Time
AE_EndDateTime	End date of the adverse event.	Case Form / Events / Event Information / Stop Date/Time
AE_FirstDoseToOnset Duration	Duration between the first dose of the study drug and the onset date of the adverse event if exact tart and end dates are not known or the duration is less than one day.	Case Form / Events/ Event Information / Onset Latency
AE_FirstDoseToOnsetDuration Unit	Unit for the first dose to onset duration (Minutes, Hours).	Case Form / Events/ Event Information / Onset Latency

Data Series Title	Description	Location in Oracle Argus Safety
AE_LastDoseToOnset Duration	Duration between the last dose of the study drug and the onset date of the adverse event if exact start and end dates are not known or the duration is less than one day.	Case Form / Events/ Event Information / Onset From Last Dose
AE_LastDoseToOnsetDuration Unit	Unit for the last dose to onset duration (Minutes, Hours).	Case Form / Events/ Event Information / Onset From Last Dose
AE_OutcomeCode	Outcome of the adverse event at the last observation (for example, Recovered, Fatal).	Case Form / Events/ Event Information / Outcome of Event
AE_SeverityCode	Severity of the adverse event (for example, Severe, Moderate, Mild).	Case Form / Events/ Event Information / Event Intensity
AE_HospitalizationStart DateTime	Date that the patient was admitted to the hospital as a result of the adverse event.	Case Form / Event / *<event name>* / Seriousness Criteria / Hospitalization / Details / Start Date
AE_HosptializationEnd DateTime	Date that the patient was discharged from the hospital after having been admitted as a result of the adverse event.	Case Form / Event / <event name> / Seriousness Criteria / Hospitalization / Details / End Date
AE_InterventionRequired Indicator	Indicates whether the adverse event required intervention.	Case Form / Event / *<event name>* / Seriousness Criteria / Intervention Required
AE_Duration	Duration of the adverse event if exact start and end dates are not known or if the duration is less than one day.	Case Form / Events / Event Information / Duration
AE_DurationUnit	Unit for the duration of the adverse event.	Case Form / Events / Event Information / Duration
AE_SeriousnessDeathIndicator	Whether the adverse event resulted in death.	Case Form / Event / *<event name>* / Seriousness Criteria / Death
AE_SeriousnessLifeThreatening Indicator	Whether the adverse event was life threatening.	Case Form / Event / *<event name>* / Seriousness Criteria / Life Threatening
AE_SeriousnessHospitalization Indicator	Whether the adverse event resulted in hospitalization or prolonged existing hospitalization.	Case Form / Event / *<event name>* / Seriousness Criteria / Hospitalization
AE_SeriousnessDisabling Indicator	Whether the adverse event resulted in persistent or significant disability or incapacity.	Case Form / Event / <event name> / Seriousness Criteria / Disability
AE_SeriousnessCongenital AnomalyIndicator	Whether the adverse event resulted in a congenital anomaly or birth defect.	Case Form / Event / *<event name>* / Seriousness Criteria / Congenital Anomaly
AE_SeriousnessOtherIndicator	Whether the adverse event was a medically important condition.	Case Form / Event / *<event name>* / Seriousness Criteria / Other

Data Series Title	Description	Location in Oracle Argus Safety
AE_SeriousnessOtherComment	The medically important condition indicated by the Other Indicator item.	Case Form / Event / *<event name>* / Seriousness Criteria / <Other Comment Text>
AE_MedicallySignificant Indicator	Whether the adverse event was medically significant.	Case Form / Event / *<event name>* / Seriousness Criteria / Medically Significant
AE_SubjectDroppedFromStudy Indicator	Whether the subject dropped out of the study because of the adverse event.	Case Form / Event / *<event name>* / Diagnosis / Dropped From Study Due to Event
AE_RelatedToStudyConduct Code	Whether the adverse event was related to a study procedure.	Case Form / Event / *<event name>* / Diagnosis / Related to Study Conduct
AE_ReceivedTreatmentCode	Whether the patient received treatment for the adverse event (Yes, No, Unknown).	Case Form / Event / *<event name>* / Diagnosis / Treatment Received
AE_SubjectHasPriorHistory Code	Whether the patient had experienced the adverse event in the past (Yes, No, Unknown).	Case Form / Event / *<event name>* / Diagnosis / Patient Has Prior History
AE_LackOfEfficacyIndicator	Whether the adverse event indicates a lack of efficacy of the study drug.	Case Form / Event / <event name> / Diagnosis / Lack of Efficacy
AE_DiseaseProgression Indicator	Whether the adverse event caused the disease to progress.	Case Form / Event / <event name> / Diagnosis / Progression of Disease
AE_AdverseDrugWithdrawal ReactionIndicator	Whether the adverse event was caused by withdrawal of the drug.	Case Form / Event / *<event name>* / Diagnosis / Adverse Drug Withdrawal Reaction
AE_InfectionIndicator	Whether the adverse event resulted in an infection.	Case Form / Event / <event name> / Diagnosis / Infection

Data Series Title	Description	Location in Oracle Argus Safety
AE_CaseNarrative	An item from an AE form that needs to appear in the narrative for the case in Oracle Argus Safety. If multiple AEs are selected using the dynamic grid functionality, the item mapped will appear for each AE selected in the order it was selected in the dynamic grid. This information will appear in the case narrative in Oracle Argus Safety before the items on the SAE form mapped at the Safety_Case level. **Note:** Compound items are not supported as a narrative field. **Note:** Only one text item is supported as	Case Form / Analysis / Case Analysis / Narrative

Data Series Title	Description	Location in Oracle Argus Safety
	a narrative in an itemset in a Safety form.	

Subject_Autopsy data set

Data Series Title	Description	Location in Oracle Argus Safety
AutopsyCauseOfDeath	Cause of death as determined by autopsy. This can be a repeating itemset. Map to the user-entered verbatim or to the encoded MedDRA lower-level term.	Case Form / Patient / Death / Autopsy Results / Preferred Term Case Form / Events / Seriousness Criteria / Death / Details / Autopsy Results / Preferred Term

Data Series Title	Description	Location in Oracle Argus Safety
AutopsyCauseOfDeath MedDRAVersion	Version of MedDRA used to code the autopsy cause of death if the autopsy cause of death is mapped to a lower-level term.	For items to be encoded in Oracle Argus Safety, MedDRA version is required by the format used for transmitting data but does not appear in Oracle Argus Safety.

Note: If AutopsyCauseOfDeathis mapped to the user-

Data Series Title	Description	Location in Oracle Argus Safety
	entered cause, do not map this field.	

Subject_CauseOfDeath data set

Data Series Title	Description	Location in Oracle Argus Safety
CauseOfDeath	Reported cause of death. This can be a repeating itemset. Map to the user-entered verbatim or to the encoded MedDRA lower-level term.	Case Form / Patient / Death / Cause of Death / Preferred Term Case Form / Events / Seriousness Criteria / Death / Details / Cause of Death / Preferred Term

Data Series Title	Description	Location in Oracle Argus Safety
CauseOfDeath MedDRAVersion	Version of MedDRA used to code the cause of death if mapped to a lower-level term. **Note:** If CauseOfDeath is mapped to other user-entered ca	For items to be encoded in Oracle Argus Safety, MedDRA version is required by the format used for transmitting data but does not appear in Oracle Argus Safety.

Data Series Title	Description	Location in Oracle Argus Safety
	use, do not map this field.	

Subject_ConMed data set

Data Series Title	Description	Location in Oracle Argus Safety
ConMed_SeparateDoseCount	Number of separate dosages.	Case Form / Products / Dosage Regimens / Frequency
ConMed_DosageIntervalUnit Count	Number of units in the dosage interval.	Case Form / Products / Dosage Regimens / Frequency
ConMed_DosageIntervalUnit	Units in which the dosage interval is defined (for example days, months).	Case Form / Products / Dosage Regimens / Frequency
ConMed_DosageFrequency	Frequency that the dosage was given to the patient (for example, 2 times per day).	Case Form / Products / Dosage Regimens / Frequency
ConMed_Dosage	Number of units in the dosage (for example, 20).	Case Form / Products / Dosage Regimens / Dose Units
ConMed_DosageUnit	Units in which the dosage is defined (for example, mg).	Case Form / Products / Dosage Regimens / Daily Dosage Units
ConMed_CumulativeDosage	The total dose administered before the first sign, symptom, or reaction occurred.	Case Form / Products / Total Dose to Primary Event
ConMed_CumulativeDosage Unit	Units in the cumulative dosage (for example, mg).	Case Form / Products / Total Dose to Primary Event

Data Series Title	Description	Location in Oracle Argus Safety
ConMed_DosageDescription	Description of the dosage. Use this item if it is not possible to provide structured dosage information.	Case Form / Products / Dosage Regimens / Dose Description
ConMed_DosageFormCode	Pharmaceutical form of the dosage (for example, tablets, capsules, syrup).	Case Form / Products / Product Information / Formulation
ConMed_AdministrationRouteCode	Route of administration of the drug (for example, intravenous, oral).	Case Form / Products / Dosage Regimens / Patient Route of Administration
ConMed_StartDateTime	Start date of the dosing regimen.	Case Form / Products / Dosage Regimens / Start Date/Time
ConMed_EndDateTime	End date of the dosing regimen.	Case Form / Products / Dosage Regimens / Stop Date/Time
ConMed_RecurReAdministration Code	Whether the adverse event recurred when the drug was readministered (Yes, No, Unknown).	Case Form / Products / Product Details / Rechallenge Results
ConMed_ActionTakenCode	Action taken by the doctor or patient with the drug in response to the adverse event.	Case Form / Products / Product Details / Action Taken
ConMed_AdditionalInformation	Additional information about the concomitant medication.	Case Form / Products / Notes
ConMed_MedicinalProductName	Proprietary medicinal name of the concomitant medication.	Case Form / Products / Product Information / Product Name
ConMed_Indication	Reason that the concomitant medication was prescribed. Map to the user-entered verbatim or to the encoded MedDRA lower-level term.	Case Form / Products / Product Indication / Coded Indication

Data Series Title	Description	Location in Oracle Argus Safety
ConMed_IndicationMedDRA Version	Version of MedDRA used to code the indication if the indication is mapped to a lower-level term. **Note:** If Indication is mapped to text entered by the use	For items to be encoded in Oracle Argus Safety, MedDRA version is required by the format used for transmitting data but does not appear in the Oracle Argus Safety.

Data Series Title	Description	Location in Oracle Argus Safety
	r, d o n o t m a p t h i s f i e l d .	
ConMed_ParentAdministration RouteCode	If the patient is a fetus, the route by which the drug was administered to the parent.	Case Form / Products / Dosage Regimens / Parent Route of Administration
ConMed_FirstDoseToOnset Duration	If the exact start and end dates are not known or the interval is less than one day, the time between the first administration of the drug and the onset of the adverse advent.	Case Form / Products / Time Interval Between First Dose / Primary Event
ConMed_FirstDoseToOnset DurationUnit	Unit for first dose to onset duration (for example, minutes, hours).	Case Form / Products / Time Interval Between First Dose / Primary Event
ConMed_LastDoseToOnset Duration	If the exact start and end dates are not known or the interval is less than one day, the time between the last administration of the drug and the onset of the adverse advent.	Case Form / Products / Time Interval Between Last Dose / Primary Event
ConMed_LastDoseToOnset DurationUnit	Unit for last dose to onset duration (for example, minutes, hours).	Case Form / Products / Time Interval Between Last Dose / Primary Event
ConMed_TreatmentDuration	Duration of the dosing regimen if exact start and dates are not known.	Case Form / Products / Dosage Regimens / Duration of Regimen
ConMed_TreatmentDuration Unit	Unit for the treatment duration (for example, days, months).	Case Form / Products / Dosage Regimens / Duration of Administration
ConMed_OngoingIndicator	Whether the patient is still taking the concomitant medication.	Case Form / Products / Product Detail / Ongoing

For more information, see:

- Map dosage frequency items in the Subject_ConMed data set

Map dosage frequency items in the Subject_ConMed data set

The Subject_ConMed data set includes the following data series for mapping dosage frequency.

- Dosage quantity data series:
  - **ConMed_Dosage**—Number of units in the dosage (for example, 20).
  - **ConMed_DosageUnit**—Units in which the dosage is defined (for example, mg).
  - **ConMed_SeparateDoseCount**—Number of separate dosages.
- Timing interval of dosage administration data series:
  - **ConMed_DosageIntervalUnitCount**—Number of units in the dosage interval.
  - **ConMed_DosageIntervalUnit**—Units in which the dosage interval is defined (for example days, months).
- Complete dosage information selected from a codelist data series:
  - **ConMed_DosageFrequency**—Frequency that the dosage was given to the patient (for example, 2 times per day).

The way you map to these data series depends on how you collect dosage frequency in the study.

- **Single item with a codelist**—If users select all components of the dosage frequency as codelist items (for example, 2 times per day, 3 times per day, twice per week), map the dosage frequency item to the ConMed_DosageFrequency data series.
- **Single text item**— If users enter all components of the dosage frequency as text (for example, if they enter 3mg, once every 2 days):
  - Create hidden items to capture each component of the dosage frequency definition and populate those items with a rule.
  - Map the hidden items representing the components of the dosage frequency definition to the appropriate data series. In the above example, the values that would be transmitted are:
    - ConMed_Dosage—3
    - ConMed_DosageUnit—mg
    - ConMed_SeparateDoseCount—1 (that is, one time every two days)
    - ConMed_DosageIntervalUnitCount—2
    - ConMed_DosageIntervalUnit—days

    If the user enters 3mg, twice daily, the values transmitted are:
    - ConMed_Dosage—3
    - ConMed_DosageUnit—mg
    - ConMed_SeparateDoseCount—2
    - ConMed_DosageIntervalUnitCount—1

    * ConMed_DosageIntervalUnit—days

- **Multiple items**—If users enter the dosage frequency in multiple items, map each item to the data series for the appropriate component of the dosage frequency definition.

> **Note:**
>
> Map dosage frequency items either to the dosage quantity and dosage interval data series or to the DosageFrequency data series, but not to all six data series. Mapping all six data series raises a warning.

Subject_Death data set

Data Series Title	Description	Location in Oracle Argus Safety
DeathDateTime	Date of patient death.	Case Form / Patient / Death / Date of Death
PatientAutopsyCompleted Code	Whether an autopsy was performed (Yes, No, Unknown).	Case Form / Patient / Death / Autopsy Done / Autopsy Results Available

Subject_Lab Test data set

Data Series Title	Description	Location in Argus Safety
Test_DateTime	Date and time of the lab test or procedure.	Case Form / Patient / Lab Data / Lab Data / Date

Data Series Title	Description	Location in Argus Safety
Test_Name	Name of the lab test or procedure performed to diagnose or confirm the adverse event or to investigate a non-drug cause.	Case Form / Patient / Lab Data / Lab Data / Test

Note:

If the mapped item is a codelist item, the label for the codelist will be sent instead of the value. If the item is not a codelist item, the val

Data Series Title	Description	Location in Argus Safety
	ue stor ed for the ite m will be sen t.	
Test_Result	Result of the lab test or procedure.	Case Form / Patient / Lab Data / Lab Data / Results
Test_UOMCode	Unit of measure for the result of the lab test or procedure.	Case Form / Patient / Lab Data / Lab Data / Units
Test_NormalLowRange	Normal low range for the lab test or procedure.	Case Form / Patient / Lab Data / Lab Data / Norm Low
Test_NormalHighRange	Normal high range for the lab test or procedure.	Case Form / Patient / Lab Data / Lab Data / Norm High
Test_AdditionalInformation AvailabilityIndicator	Whether additional information is available for the lab test or procedure.	Case Form / Patient / Lab Data / Lab Data / Notes

Subject_MedicalHistory data set

Data Series Title	Description	Location in Oracle Argus Safety
MedicalHistory_Name	Condition, disease, or surgical procedure in the patient's medical history. Map to the user-entered verbatim or to the encoded MedDRA lower-level term.	Case Form / Patient / Other Relevant History / Description

Data Series Title	Description	Location in Oracle Argus Safety
MedicalHistory_MedDRA Version	Version of MedDRA used to code the medical history name if the medical history name is mapped to a lower-level term. **Note:** If MedicalHistory_Name is mapped to a text field entered by the user, do not map this field.	For items to be encoded in Oracle Argus Safety, MedDRA version is required by the format used for transmitting data but does not appear in the Oracle Argus Safety.
MedicalHistory_StartDateTime	Start date of the condition, disease, or surgical procedure.	Case Form / Patient / Other Relevant History / Start Date
MedicalHistory_Continuing Indicator	Whether the patient still has the condition or disease (Yes, No, Unknown).	Case Form / Patient / Other Relevant History / Ongoing
MedicalHistory_EndDateTime	End date of the condition, disease, or surgical procedure.	Case Form / Patient / Other Relevant History / Stop Date
MedicalHistory_Comment	Description of the relevant medical history for the patient. Used when more structured information, such as dates and terms, is unknown.	Case Form / Patient / Other Relevant History / Note

Subject_PastDrugHistory data set

Data Series Title	Description	Location in Oracle Argus Safety
PastDrugHistory_DrugName	Name of a drug previously taken but not used concomitantly and not potentially involved in the adverse event.	Case Form / Patient / Other Relevant History / Description
PastDrugHistory_StartDate Time	Date when the previously taken drug was started.	Case Form / Patient / Other Relevant History / Start Date
PastDrugHistory_EndDate Time	Date when the last dose of the previously taken drug was given.	Case Form / Patient / Other Relevant History / Stop Date
PastDrugHistory_Drug Indication	Reason for taking the previously taken drug. Map to the user-entered verbatim or to the encoded MedDRA lower-level term.	Case Form / Patient / Other Relevant History / Indication
PastDrugHistory_Indication MedDRAVersion	Version of MedDRA used to code the indication if the indication is mapped to a lower-level term.	For items to be encoded in Oracle Argus Safety, MedDRA version is required by the format used for transmitting data but does not appear in Oracle Argus Safety.
PastDrugHistory_Drug Reaction	Adverse event experienced when taking the previously taken drug. Map to the user-entered verbatim or to the encoded MedDRA lower-level term).	Case Form / Patient / Other Relevant History / Reaction

Data Series Title	Description	Location in Oracle Argus Safety
PastDrugHistory_Reaction MedDRAVersion	Version of MedDRA used to code the indication if the indication is mapped to a lower-level term. **Note:** If reaction is mapped to a text field entered by the user, do not map this field.	For items to be encoded in Oracle Argus Safety, MedDRA version is required by the format used for transmitting data but does not appear in Oracle Argus Safety.

Subject_SuspectDrug data set

Note:

How you map dosage frequency data depends on your study design.

Data Series Title	Description	Location in Oracle Argus Safety
SuspectDrug_SeparateDose Count	Number of separate dosages.	Case Form / Products / Dosage Regimens / Frequency
SuspectDrug_DosageInterval UnitCount	Number of units in the dosage interval.	Case Form / Products / Dosage Regimens / Frequency

Data Series Title	Description	Location in Oracle Argus Safety
SuspectDrug_DosageInterval Unit	Units in which the dosage interval is defined (for example days, months).	Case Form / Products / Dosage Regimens / Frequency
SuspectDrug_Dosage Frequency	Frequency that the dosage was given to the patient (for example, 2 times per day).	Case Form / Products / Dosage Regimens / Frequency
SuspectDrug_Dosage	Number of units in the dosage (for example, 20).	Case Form / Products / Dosage Regimens / Dose Units
SuspectDrug_DosageUnit	Units in which the dosage is defined (for example, mg).	Case Form / Products / Dosage Regimens / Daily Dosage Units
SuspectDrug_Cumulative Dosage	The total dose administered before the first sign, symptom, or reaction occurred.	Case Form / Products / Total Dose to Primary Event
SuspectDrug_Cumulative DosageUnit	Units in the cumulative dosage (for example, mg).	Case Form / Products / Total Dose to Primary Event
SuspectDrug_Dosage Description	Description of the dosage. Use this item if it is not possible to provide structured dosage information.	Case Form / Products / Dosage Regimens / Dose Description
SuspectDrug_DosageForm Code	Pharmaceutical form of the dosage (for example, tablets, capsules, syrup).	Case Form / Products / Product Information / Formulation
SuspectDrug_Administration RouteCode	Route of administration of the drug (for example, intravenous, oral).	Case Form / Products / Dosage Regimens / Patient Route of Administration
SuspectDrug_Gestation PeriodAtExposure	Gestation period at time of exposure to the drug.	Case Form / Patient / Patient Information / Pregnancy / Weeks at Exposure or Trimester of Exposure
SuspectDrug_StartDateTime	Start date of the dosing regimen.	Case Form / Products / Dosage Regimens / Start Date/Time
SuspectDrug_FirstDoseTo OnsetDuration	If the exact start and end dates are not known or the interval is less than one day, the time between the first administration of the drug and the onset of the adverse event.	Case Form / Products / Time Interval Between First Dose/ Primary Event
SuspectDrug_FirstDosageTo OnsetDurationUnit	Unit for first dose to onset duration (for example, minutes, hours).	Case Form / Products / Time Interval Between First Dose/ Primary Event
SuspectDrug_EndDateTime	End date of the dosing regimen.	Case Form / Products / Dosage Regimens / Stop Date/Time
SuspectDrug_Recur ReAdministrationCode	Indicates whether the adverse event recurred when the drug was readministered (Yes, No, Unknown).	Case Form / Products / Product Details / Rechallenge Results

Data Series Title	Description	Location in Oracle Argus Safety
SuspectDrug_ActionTaken Code	Action taken by the doctor or patient with the drug in response to the adverse event.	Case Form / Products / Product Details / Action Taken
SuspectDrug_Additional Information	Additional information about the drug.	Case Form / Products / Notes
SuspectDrug_Medicinal ProductName	Proprietary name of the medicinal product name. If SuspectDrug_ MedicinalProduct Name is not mapped, the Sponsor Drug Name is transmitted.	Case Form / Products / Product Information / Product Name
SuspectDrug_Indication	Reason that the drug was prescribed. Map to the user-entered verbatim or to the encoded MedDRA lower-level term.	Case Form / Products / Product Indication / Coded Indication

Data Series Title	Description	Location in Oracle Argus Safety
SuspectDrug_Indication MedDRAVersion	Version of MedDRA used to code the indication if the indication is mapped to a lower-level term. **Note:** If Indication is mapped to text entered by the use	For items to be encoded in Oracle Argus Safety, MedDRA version is required by the format used for transmitting data but does not appear in Oracle Argus Safety.

Data Series Title	Description	Location in Oracle Argus Safety
	r, d o n o t m a p t h i s fi e l d .	
SuspectDrug_BatchNumber	Batch or lot number of the drug.	Case Form / Products / Dosage Regimens / Batch / Lot #
SuspectDrug_Parent AdministrationRouteCode	If the patient is a fetus, the route by which the drug was administered to the parent.	Case Form / Products / Dosage Regimens / Parent Route of Administration
SuspectDrug_Treatment Duration	Duration of the dosing regimen if exact start and dates are not known.	Case Form / Products / Dosage Regimens / Duration of Regimen
SuspectDrug_Treatment DurationUnit	Unit for the treatment duration (for example, days, months).	Case Form / Products / Duration of Administration
SuspectDrug_Overdose Indicator	Whether the patient took more than the prescribed amount of the drug before experiencing the adverse event.	Case Form / Products / Product Detail / Overdoes
SuspectDrug_AbuseIndicator	Whether the patient abused the drug (for example, took pain medication without pain).	Case Form / Products / Product Detail / Abuse
SuspectDrug_Tampering Indicator	Whether the product appeared to be tampered with before it was taken.	Case Form / Products / Product Detail / Tampering
SuspectDrug_TakenPreviously AndToleratedCode	Whether the patient had taken the drug previously and had tolerated it (Yes, No, Unknown).	Case Form / Products / Product Detail / Taken Previously And Tolerated
SuspectDrug_InteractingIndic ator	Whether it is believed that the interaction of this non-study co-suspect drug with the study drug(s) caused the adverse event.	Case Form / Products / Product Detail / Interacting
SuspectDrug_Ongoing Indicator	Whether the patient is still taking the drug.	Case Form / Products / Product Detail / Ongoing

For more information, see:

- Map dosage frequency items in the Subject_SuspectDrug data set

Map dosage frequency items in the Subject_SuspectDrug data set

The Subject_SuspectDrug data set includes the following data series for mapping dosage frequency.

- Dosage quantity data series:
  - **SuspectDrug_Dosage**—Number of units in the dosage (for example, 20).
  - **SuspectDrug_DosageUnit**—Units in which the dosage is defined (for example, mg).
  - **SuspectDrug_SeparateDoseCount**—Number of separate dosages.
- Timing interval of dosage administration data series:
  - **SuspectDrug_DosageIntervalUnitCount**—Number of units in the dosage interval.
  - **SuspectDrug_DosageIntervalUnit**—Units in which the dosage interval is defined (for example days, months).
- Complete dosage information selected from a codelist data series:
  - **SuspectDrug_DosageFrequency**—Frequency that the dosage was given to the patient (for example, 2 times per day).

The way you map to these data series depends on how you collect dosage frequency in the study.

- **Single item with a codelist**—If users select all components of the dosage frequency as codelist items (for example, 2 times per day, 3 times per day, twice per week), map the dosage frequency item to the SuspectDrug_DosageFrequency data series.
- **Single text item**— If users enter all components of the dosage frequency as text (for example, if they enter 3mg, once every 2 days):
  - Create hidden items to capture each component of the dosage frequency definition and populate those items with a rule.
  - Map the hidden items representing the components of the dosage frequency definition to the appropriate data series. In the above example, the values that would be transmitted are:
    - SuspectDrug_Dosage—3
    - SuspectDrug_DosageUnit—mg
    - SuspectDrug_SeparateDoseCount—1 (that is, one time every two days)
    - SuspectDrug_DosageIntervalUnitCount—2
    - SuspectDrug_DosageIntervalUnit—days

    If the user enters 3mg, twice daily, the values transmitted are:
    - SuspectDrug_Dosage—3
    - SuspectDrug_DosageUnit—mg
    - SuspectDrug_SeparateDoseCount—2
    - SuspectDrug_DosageIntervalUnitCount—1
    - SuspectDrug_DosageIntervalUnit—days

- **Multiple items**—If users enter the dosage frequency in multiple items, map each item to the data series for the appropriate component of the dosage frequency definition.

> **Note:**
>
> Map dosage frequency items either to the dosage quantity and dosage interval data series or to the DosageFrequency data series, but not to all six data series. Mapping all six data series raises a warning.

Subject_SuspectDrug_ReactionRecurrence data set

Data Series Title	Description	Location in Oracle Argus Safety
SuspectDrug_RecurredAE	MedDRA lower-level term (LLT) for the reaction that recurred when the drug was readministered.	Case Form / Events / Associated with Rechallenge? / Product

Subject_SuspectDrug_ReactionRelatedness data set

> **Note:**
>
> If you want to send causality information from Oracle InForm to Oracle Argus Safety, you must map the **SuspectDrug_AssessmentResult** and **SuspectDrug_ReactionID** to items on the AE form. If this is a multiple drug study, you must also map the **SuspectDrug_DrugName** to items on the AE form.
>
> All fields mapped in the **Subject_SuspectDrug_ReactionRelatedness** data set must be on the AE form. However, they do not all need to belong to the same itemset.

Data Series Title	Description	Location in Argus Safety
SuspectDrug_AssessmentSource	Source of assessment (for example, investigator).	Case Form / Events / Assessments / Causality / As Reported, As Determined

Note:

The value of the item mapped to the SuspectDrug_AssessmentSource data series for an adverse event that has been coded determines whether the

Data Series Title	Description	Location in Argus Safety
		reaction relatedness data for the adverse event specified in the SuspectDrug_ReactionID and SuspectDrug_MedicinalProductName data series appears as Determined Ca

Data Series Title	Description	Location in Argus Safety
		usality or Reported Causality in Argus Safety. • PHARMACEUTICALCOMPANY_AsDetermined • Anyothe

Data Series Title	Description	Location in Argus Safety
	rvalue—AsReported	
SuspectDrug_AssessmentMethod	Method of assessment (for example, global introspection).	Case Form / Events / Assessments / Causality / As Reported, As Determined
SuspectDrug_AssessmentResult	Result of assessment (for example, related, possibly related).	Case Form / Events / Assessments / Causality / As Reported, As Determined
SuspectDrug_ReactionID	MedDRA lower-level term (LLT) for the reaction that was assessed for relatedness to the drug.	Case Form / Events / Assessments / Causality / As Reported, As Determined

Data Series Title	Description	Location in Argus Safety
SuspectDrug_Name	If the study contains multiple investigational products, you need to create an itemset for entering causality for the AE. It is best to use a codelist for the product name. Map this to the item in the itemset that collects the product name the site user is entering the causality (AssessmentResult) for. **Note:** If this item has a codelist attached, Oracle InForm Publisher always sends the code stored in the database for items with a cod	Case Form / Events / Assessments / Causality / As Reported, As Determined

Data Series Title	Description	Location in Argus Safety

elist and not the label shown on the screen.

Note:

In order for the relatedness to come over correctly, the study designer should use the same codelist on all forms

Data Series Title	Description	Location in Argus Safety
		where the study drug name is entered. If the study designer chooses to have the end user enter free text for the Drug Name, the causality they intend may not be what is sen

Data Series Title	Description	Location in Argus Safety
		t ove r to Ora cle Arg us Saf ety.

Reporter data set

Case Form / Reporter Information / Occupation

Data Series Title	Description	Location in Argus Safety
QualificationCode	Qualification of the reporter of the case, for example, physician, pharmacist.	Case Form / General / Reporter Information / Reporter Type

Note:

If this field is not collected in the Oracle InForm study or is not mapped, Oracle InForm Publisher sends the value Physician to Oracle Argus Safety.

Data Series Title	Description	Location in Argus Safety
JobTitle	Occupation of the reporter of the case.	Case Form / Reporter Information / Occupation

(Optional) Create a custom data series

In addition to the predefined data series in the SafetyLogicalSchema data mapping, you can add custom data series to the following data sets:

- Safety_Case
- Subject
- Subject_AdverseEvent

Custom data series support transmitting data collected in Oracle InForm to custom fields in Oracle Argus Safety.

1. At the bottom of the Project Explorer, click the **Forms and Transactions** ( ) button, and expand the **InForm** folder and the **Forms** folder, if necessary.
2. Expand a data mapping folder, right-click a data mapping, and select **New Data Series**.
3. Fill in the fields. **Title** and **RefName** are required. **Description** and **Alias** are optional.

   If specified, the alias is used as the Clintrial item name in CIS mappings. If not, the RefName is used as the column header. Because RefNames must be unique throughout a study, you must create an alias if the RefName is used by a study object. Data series aliases must be unique within a data set. For more information, see What alias names should i use when creating custom data series?
4. From the **Type** drop-down list, select the data type for the series.

   The data types of an item and data series must be compatible for you to add the item to the data series.
5. Click **OK**.

> **Tip:**
>
> - The RefName and Title are user-defined. We recommend that you use a naming convention that is similar to the names of other data series in the data set.
> - The index numbers must be unique within each data set. For example, in the Subject data set, you can create Cust_General_Str_1 and Cust_General_Num_2, but you cannot create Cust_General_Str_1 and Cust_General_Num_1.
> - The alias must match the user-defined field to be populated in Argus Safety. Use the naming convention in What alias names should i use when creating custom data series?. For example, to populate custom string field 1 on the General tab of Argus Safety, map a custom data series in the Safety_Case data set using the alias Cust_General_Str_1.

Select the safety mapping (SafetyLogicalSchema) to deploy

When you deploy the study, you must select the mapping you need to deploy with the study.

In the Create Deployment Package Wizard, select the **Customer Defined Database (CDD) Mappings** dialog box, select **SafetyLogicalSchema** for the CDD mapping.

Set safety event data configuration options in Oracle InForm Publisher

In this section:

- Configure the Oracle Argus Safety-only attributes

Configure the Oracle Argus Safety-only attributes

Set up how Oracle InForm Publisher moves the adverse event data from Oracle InForm to Oracle Argus Safety. Perform these tasks after your work in Oracle Central Designer is complete, but before deploying your study to Oracle InForm.

> **Note:**
>
> Oracle InForm Publisher is installed as part of the Oracle InForm installation. For more information, see the *Oracle InForm Installation Guide* and the *Configuration Guide* for Oracle InForm Publisher.

1. Identify the Oracle Argus Safety-related attributes that apply to the study.

> **Tip:**
>
> - To configure time frames to trigger Oracle InForm Publisher to send safety data automatically, specify the number of days before and after the onset date of the adverse event (AE Range Starting Offset (days) and AE Range Ending Offset (days)) that Oracle InForm Publisher should use to include all Adverse Event forms started during the range or to include other forms associated with an adverse event.
> - If you are allowing the Oracle InForm site user to choose which AEs are relevant for sending to Oracle Argus Safety, instead of using time frames, you need to set AE Range Staring Offset and AE Range Ending Offset values to -1.
> - If the Oracle InForm site user can select relevant concomitant medications, set ConMed Range Starting Offset and Ending Offset to -1.
> - If the Oracle InForm site user can select relevant labs, set Lab Range Starting Offset and Ending offset to -1.

2. When you submit a ticket to Oracle Services to set up the integration with Oracle Argus Safety, communicate which attributes to include and their values.

Oracle creates the subscriber and populate its settings, and then adds the trial to the subscriber.

Field	Description
Argus Safety Only	-
AE Range Starting Offset (days)	Number of days before the onset date of an adverse event that the Oracle InForm Publisher application should consider when determining which Adverse Event (AE) forms (in addition to the AE form on which the adverse event was reported) are associated with the adverse event. If an instance of a related AE form has a start date within the range specified in the AeRangeStartingOffset and AeRangeEndingOffset settings, the safety event data from the related form is transmitted to the Oracle Argus Safety application. The default value is 14. • To include all AE forms that were started before the AE onset date, enter -1. • To include no AE forms that were started before the AE onset date, enter 0.
AE Range Ending Offset (days)	Number of days after the onset date of an adverse event that the Oracle InForm Publisher should consider when determining which Adverse Event (AE) forms are associated with the adverse event. If an instance of a related AE form has a start date within the range specified in the AeRangeStartingOffset and AeRangeEndingOffset settings, the safety event data from the related form is transmitted to the Oracle Argus Safety application. The default value is 14. • To include all AE forms that were started after the AE onset date, enter -1. • To include no AE forms that were started after the AE onset date, enter 0.
Lab Range Starting Offset (days)	Number of days before the onset date of an adverse event that the Oracle InForm Publisher application should consider when determining which Lab forms are associated with the adverse event. If an instance of a related Lab form has a start date within the range specified in the LabRangeStartingOffset and LabRangeEndingOffset settings, the safety event data from the related form is transmitted to the Oracle Argus Safety application. The default value is 14. • To include all Lab forms that were started before the AE onset date, enter -1. • To include no Lab forms that were started before the AE onset date, enter 0.

Field	Description
Lab Range Ending Offset (days)	Number of days after the onset date of an adverse event that the Oracle InForm Publisher application should consider when determining which Lab forms are associated with the adverse event. If an instance of a related Lab form has a start date within the range specified in the LabRangeStartingOffset and LabRangeEndingOffset settings, the safety event data from the related form is transmitted to the Oracle Argus Safety application. The default value is 14. • To include all Lab forms that were started after the AE onset date, enter -1. • To include no Lab forms that were started after the AE onset date, enter 0.
ConMed Range Starting Offset (days)	Number of days before the onset date of an adverse event that the Oracle InForm Publisher application should consider when determining which Concomitant Medication (ConMed) forms are associated with the adverse event. If an instance of a related ConMed form has a start date within the range specified in the ConMedRangeStartingOffset and ConMedRangeEndingOffset settings, the safety event data from the related form is transmitted to the Oracle Argus Safety application. The default value is 14. • To include all ConMed forms that were started before the AE onset date, enter -1. • To include no ConMed forms that were started before the AE onset date, enter 0.
ConMed Range Ending Offset (days)	Number of days after the onset date of an adverse event that the Oracle InForm Publisher application should consider when determining which Concomitant Medication (ConMed) forms are associated with the adverse event. If an instance of a related ConMed form has a start date within the range specified in the ConMedRangeStartingOffset and ConMedRangeEndingOffset settings, the safety event data from the related form is transmitted to the Oracle Argus Safety application. The default value is 14. • To include all ConMed forms that were started after the AE onset date, enter -1. • To include no ConMed forms that were started after the AE onset date, enter 0.

Supported post-production changes to a dynamic grid

If you need, you can make some changes to dynamic grid sections after deploying your study.

In this section:

- Supported changes with study version changes
- Supported changes with in-place revision changes
- Changes not supported for study version or in-place revision

Supported changes with study version changes

The following study version changes are supported for dynamic grids after deploying your study:

- Adding a new dynamic grid.
- Adding a target item to an existing dynamic grid.
- Adding a new editable item to an existing dynamic grid.
- Adding a new source to an existing dynamic grid.
- Removing a source item previously mapped to an existing dynamic grid.
- Removing a target item from an existing dynamic grid.
- Removing an editable item from a dynamic grid.
- Removing a source from an existing multi-source dynamic grid.
- Removing a dynamic grid section.

> **Note:**
>
> Removing a dynamic grid section is not supported for Oracle InForm to Oracle Argus Safety integration because removing the safety logical schema mappings is not study-version specific.

- Changing the source item properties (such as label, question or control) on an item previously mapped to an existing dynamic grid.
- Changing the target item properties (such as label, question or control) on an item previously mapped to an existing dynamic grid.
- Changing the editable item properties (such as label, question or control) on an item previously mapped to an existing dynamic grid.

> **Note:**
>
> Although you can do in-place revisions and study version changes to add sources to dynamic grid, the Oracle InForm to Oracle Argus Safety integration does not support changing it from single-source to multi-source. The reason for this is that the Oracle InForm to Oracle Argus Safety integration requires safety mappings, which are not version specific.

Supported changes with in-place revision changes

The following in-place revision changes are supported for dynamic grids after deploying your study:

- Adding mapped items to target on an existing dynamic grid.
- Adding an item to a source and map it to an existing dynamic grid.
- Adding a new editable item to an existing dynamic grid.
- Adding a new source to an existing dynamic grid.
- Removing mapped items from a target on an existing dynamic grid.
- Removing a source from an existing multi-source dynamic grid.

> **Note:**
>
> In-place revisions to remove a source will not result in data loss in the Inform user interface, and data sync will still occur until any existing links between the source are the target are broken.

- Changing the source item properties (such as label, question, or control) on an item previously mapped to an existing dynamic grid.
- Change the target item properties (such as label, question, or control) on an item previously mapped to an existing dynamic grid that is not shared with the source.
- Change editable item properties (such as label, question, or control) on an item previously mapped to an existing dynamic grid.

> **Note:**
>
> Although you can do in-place revisions to add sources to dynamic grid, the Oracle InForm to Oracle Argus Safety integration does not support changing it from single-source to multi-source. The reason for this is that the Oracle InForm to Oracle Argus Safety integration requires safety mappings, which are not version specific.

Changes not supported for study version or in-place revision

The following changes are not supported after deploying your study, either with study version change or in-place revision:

- Changing a section from dynamic grid (single or multi-source) to another type of section.
- Changing a section to a dynamic grid section (single or multi-source).
- Changing the type of item mapping (item level or data point mapping).
- Incremental deployment for changes on source or target forms.

12
FAQs

In this chapter:

- User interface customization
- Study setup
- Library setup
- Import and export
- Tasks and notes
- Custom events
- Rules
- Partial SDV
- Data mappings
- Validation and deployment
- Post-design activities
- Oracle InForm to Oracle Argus Safety integration
- General

User interface customization

In this section:

- Can I arrange user interface elements?

Can I arrange user interface elements?

To arrange the following user interface elements, drag and drop them within the Oracle Central Designer application window:

- Fields in most grids.
- Tabs in editors.
- Browsers that are grouped.

Study setup

In this section:

- How is a study's default locale used?
- How do I develop a study across multiple locales?
- How are float values formatted?

- Users Browser searches
- How does the Libraries tab search work?
- What does the Libraries tab search?
- What appears in my Libraries tab search results?
- Is there an easy way to find a study object and add it to the study design?
- Study administration data
- Coding setup

How is a study's default locale used?

The default locale for a study is used to store study metadata that can be localized.

- After modifying the default locale, you do not need to restart the Oracle Central Designer application.
- If you do not set the default locale, the regional setting is used. The regional setting is set in the Control Panel > Regional and Language Options > Regional Options tab > Standards and formats section. If you modify the regional setting, you must close and reopen the Oracle Central Designer application to use the new locale.
- You select from the same list of locales that are available when you specify a regional setting.

Display properties that the default locale affects
The default locale affects the display properties of the following:

- Some fields, such as the Default Question for a form, display the text for the default locale.
- The title bar in the workspace displays the default locale. For example: Form : Demographics -- en-US
- Float numbers are formatted according to the numeric standards for the default locale.

Typing translated data
You can enter translated data in the following ways:

- You can enter translated data without specifying the locale, and the data is saved as data for the default locale. For example, you can enter the Default Question of an item in the Item Editor > Design tab > Default Question field.
- You can enter translated data explicitly for a locale, and the data is saved as data for the specified locale. For example, you can enter the Default Question of an item in the Item Editor > Design tab > Languages section > Question field.

Making sure that the language in which you develop a study is the default locale for which study metadata is saved
To design a study for any locale, you must make sure that:

- In the Oracle Central Designer Administrator application, the locale is selected.
- In the Oracle Central Designer application, the locale is selected for the study.

- The user profiles in the Oracle Central Designer Administrator application list the locale as a skill.

How do I develop a study across multiple locales?

You specify the default locale for a study in Oracle Central Designer. Localizable study metadata is saved according to the default locale.

Language in which to type text values

You can enter item questions, labels, and text strings in any language, regardless of the default locale for the study. However, in some places, such as a form's Design tab, you can enter labels and question text without specifying a locale. In these cases, the default locale determines the language or locale that is assigned to the entered text. If the default locale is not included in the list of supported locales for the study, the entered text is saved for the locale but is not deployed. Only the supported locales for the study are deployed.

Typing text values using an explicit locale

If you work on a study with a locale that is different from the default locale, you can enter a study object's properties with an explicit locale. See the following table for places where the default locale is used and where you can specify an explicit locale.

Study object	Property	Specify a value in the default locale here	Specify a value in an explicit locale here
Study event	Title	Study Event Editor > General tab	Study Event Editor > General tab
-	Short Title	Study Event Editor > General tab	Study Event Editor > General tab
Form	Short Title	Study Forms Editor	Form Editor > General tab
-	Form Title	Not available.	Form Editor > Layout tab
Item	Question	• Form Editor > Design tab • Study Items Editor	Item Editor > Design tab
-	Short Question	• Form Editor > Design tab • Study Items Editor	Item Editor > Design tab
-	Caption	Not available.	Form Editor > Layout tab
Codelist item	Label	• Item Editor > Design tab • Codelist Editor > Design tab • Study Codelist Items Editor	Codelist Item Editor > Languages tab

Rule component	Specify a value in the default locale here	Specify a value in an explicit locale here
Query text	Not available.	Query Action dialog box.
Subject or Message	Not available.	Email Action dialog box.

How are float values formatted?

The formatting of a float value depends on the default numeric settings for the default locale. For example, if the default locale is French (France), and you type a value of **123.45**, the number appears as **123,45** after you navigate to a different part of the application and return.

If you change the numeric settings for the default locale—for example, if you change the decimal point character for the French locale from a comma to a period—the default settings are still used. In this example, a comma is still used as the decimal point character.

Users Browser searches

When you search for a user in the Users tab, text, keywords, categories, and libraries are connected with the AND operator. Criteria within each parameter are connected with the OR operator. For example:

- Text that you type
  AND
- Keyword1 OR Keyword2
  AND
- Category1 OR Category2

How does the Libraries tab search work?

When you search for an object in the Libraries tab, text, keywords, categories, and libraries or studies are connected with the AND operator. Criteria within each parameter are connected with the OR operator. For example:

- Text that you type
  AND
- Keyword1 OR Keyword2
  AND
- Category1 OR Category2
  AND
- Library1 OR Library2
  OR
- Study1 OR Study2

What does the Libraries tab search?

Titles, RefNames, and descriptions of:

- Study elements and study events.
- Forms and items.
- Codelists and codelist items.
- Mappings.

Titles and RefNames of:

- Templates and types.

RefNames of:

- Functions.
- Constants.

Additionally:

- **In a study project**
  - In selected libraries, only published study objects are searched.
  - In libraries you do not select, no study objects are searched.
  - Studies are not searched.
- **In a library project**
  - In selected libraries, only published study objects are searched, unless you select **Include latest object revisions in Repository**.
    If you select **Include latest object revisions in Repository**:
    * The *latest revisions* of study objects in libraries are searched.
    * *All* study objects in all studies are searched.

    If you leave the checkbox unselected, studies are not searched.
  - In libraries you do not select, only the latest revisions of study objects are searched.

What appears in my Libraries tab search results?

- **In a study project**
  - Results include only published study objects, which appear below the Objects Foundcontainer.
- **In a library project**
  Library objects are grouped according to whether they are the published versions or the latest revisions.
  - Below the Objects Foundcontainer, published library objects are organized by library and then object type, such as form or item.
  - If you select **Include latest object revisions in Repository**, the Repository container appears below all library containers and holds the latest revisions of library objects, organized by study or library and then object type, such as form or item.
    * If the published version of a library object is different from the latest revision, the object appears in two places—in the container for the library that holds it (for the published version), and below the Repository container (for the latest revision).
    * If the latest revision is the same as the published version, the object appears as a published object, in the top section, organized by library.

Objects appear as follows:

Title (RefName): Description

Is there an easy way to find a study object and add it to the study design?

Yes. You can use the Add To browser, which appears as a tab in the top right corner of the user interface by default, to search for and add study objects that are available, based on the

study object you select in the Project Explorer. For example, if you select an item in the Project Explorer, codelists that are available to be added to that item appear in the Add To browser.

Study administration data

In this section:

- What is study administration data?
- Where can I create study administration data?
- If I enter sponsor information in Oracle Central Designer, does it appear in the Oracle Central Designer Administrator?
- Where does sponsor information appear in Oracle InForm?
- What happens if I import study administration data that refers to study objects that aren't in the study I'm importing to?
- What happens if I import a study administration data object with the same identifier as an existing object in my study?
- What are review states?
- What type of file can I attach to a study as a reference?
- What size file can I attach to a study as a reference?

What is study administration data?

For a study that you deploy to Oracle InForm, you can include the following study administration data. For some of the data, you create the objects in Oracle Central Designer, and populate them in Oracle InForm.

- **Sponsor information**—Details about the study sponsor.
- **System settings**—Oracle InForm-specific system settings.
- **Item group**—A group of items that you want to assign the same display override access settings (Hidden, Editable, or Read-only). You create item groups, and add them to rights groups. In Oracle InForm or your organization's user management tool, you add users to the rights groups, and those users have the specified access to the items in the item groups.
- **Rights group**—A container for a set of rights that you create in Oracle Central Designer, and assign users and rights to in Oracle InForm or your organization's user management tool. In Oracle Central Designer, you also add item groups to the rights groups to set the display override access settings for the items.
- **Query group**—A container for a set of users who can act on queries created by other members of the group in Oracle InForm. You create query groups in Oracle Central Designer, and then add users to them in Oracle InForm or your organization's user management tool.
- **Signature group**—A group of forms that require signature, and the signature type that is required for the forms. You create the signature group in Oracle Central Designer, and add users to the group in Oracle InForm or your organization's user management tool. The users that you add are granted the right to sign the forms in the group.

You can choose to deploy these settings with your study design, or in their own deployment package.

Where can I create study administration data?

- The Oracle Central Designer Administrator—An application administrator can create sponsor information in the Oracle Central Designer Administrator, and all of the sponsor's details then become available in Oracle Central Designer.
- Oracle Central Designer—You can create study information in Oracle Central Designer, and only the sponsor name becomes available in the Oracle Central Designer Administrator.

If I enter sponsor information in Oracle Central Designer, does it appear in the Oracle Central Designer Administrator?

Only the sponsor name, but not its details, appears in the Oracle Central Designer Administrator when you create a sponsor in Oracle Central Designer.

Where does sponsor information appear in Oracle InForm?

Sponsor information does not appear in Oracle InForm. It is for documentation and reporting purposes only.

What happens if I import study administration data that refers to study objects that aren't in the study I'm importing to?

References to study objects that don't exist in the study you're importing the study administration data to are removed from the study administration data objects during the import.

What happens if I import a study administration data object with the same identifier as an existing object in my study?

The existing study administration data object is not deleted. Instead, a new study object is created and its version is incremented.

What are review states?

In Oracle Central Designer, you can create as many as five review states for a study, each with three review stages. In Oracle InForm the review states are available as form-level states in the Data Viewer. If defined, the custom review states can provide users with greater flexibility in tracking the data review progress.

For example, you can create two custom review states, labeled Medical Review and Data Management Review, each with three stages of Needs Review, Pending, and Reviewed. A custom review state is in one of its three stages at any time. The first stage is the default stage for a defined custom review state.

Additionally, you can write rules that read and set the review stage of a form.

What type of file can I attach to a study as a reference?

You can attach:

- A shortcut to a file
- A physical copy of a file
- A shortcut to a URL

What size file can I attach to a study as a reference?

The maximum size of the attachment is determined by a variety of factors, including information defined in the configuration file, available hard disk space, and available memory. To determine the approximate maximum attachment size, check the maxRequestLength attribute in the machine.config file.

Coding setup

In this section:

- What is a coding map?
- What is a verbatim?
- What is a context item?
- What is a target item?
- What is a query target item?
- Which dictionary types are installed with Central Designer?
- Can I add more than one version of a dictionary type?
- Can I associate multiple verbatim types with a single dictionary type?
- What are the requirements for coding components?

What is a coding map?

A coding map is a study object that contains the necessary information to code an item. By creating a coding map in Oracle Central Designer, you can populate the values of any additional read-only fields with codes and terms that are selected in Oracle Central Coding.

What is a verbatim?

A verbatim is the original, free-form, reported text that describes the adverse event, disease, drug, or other item to be coded in Oracle Central Coding. You can map each verbatim to only one coding dictionary. For example, to code to both Japanese and English dictionaries for the same item on the form, you must create two verbatims on the form.

A verbatim can be one of the following:

- Top-level item.
- Child of a top-level compound item.

- Child of a nested compound item.

What is a context item?

A context item is an item that provides additional coding information, such as the indication and route of administration for drugs, that can be displayed with an item coded using the WHO-DD dictionary.

A context item can be one of the following:

- Top-level item.
- Child of a top-level compound item.
- Child of a nested compound item.
- Conditional on another item.

What is a target item?

A target item is an item that holds a term, code, or additional information after a verbatim is coded. It is a target for one and only one verbatim per dictionary type. Target items can hold dictionary level information or additional information that is defined by a dictionary.

A target item must be one of the following:

- Top-level item.
- Child of a top-level compound item.

A target item cannot be:

- A child of a nested compound item.
- Conditional on another item.

What is a query target item?

A query target item is an item that you designate as the item to create queries on. It can be the verbatim, or another item. Any query created by an application such as Oracle Central Coding or Oracle DMW is created on the query target item. You can designate an item as a query target for only one verbatim.

If you select a query target item for a coding map, you can only deploy the study to a version of the InForm application that supports coding query targets. For more information, see the Oracle InForm documentation.

A query target item must be:

- A top-level item.
- Visible and available for editing in Oracle InForm. Items designated as query targets must not have the Display Override property set to ReadOnly or Hidden in Oracle Central Designer.

A query target item cannot be:

- Conditional on another item.
- The child of a top-level compound item, but can be the top-level compound item itself.

Which dictionary types are installed with Central Designer?

The following dictionary types are installed with Oracle Central Designer:

- **MedDRA**—Medical Dictionary for Drug Regulatory Activities
- **MedDRAJ**—Japanese version of the MedDRA dictionary
- **WHO-DD**—World Health Organization Drug Dictionary
- **JDrug**—Japanese drug dictionary

An administrator can also import additional standard or custom dictionaries.

Can I add more than one version of a dictionary type?

Yes. A version consists of dictionary metadata and dictionary data. In most cases, versions are different only in data, but new versions can also contain new metadata.

Can I associate multiple verbatim types with a single dictionary type?

Yes, you can.

What are the requirements for coding components?

- A verbatim (the item to code) and its target and context items must be on the same form.
- If a form has a repeating section, all items referenced in the coding map must all be either in the repeating section or outside the repeating section.
- All verbatims, context items, and target items must be text items. Query target items do not need to be text items.
- You can map each verbatim to only one coding dictionary. For example, to code to both Japanese and English dictionaries for the same item on the form, you must create two verbatims on the form.
- You can designate an item as a query target for only one verbatim.
- If you select a query target item for a coding map, you can only deploy the study to a version of the InForm application that supports coding query targets. For more information, see the InForm documentation.

Library setup

In this section:

- What is a library?
- What is the System Library?
- What happens if I unpublish an object in the library?
- About publishing, republishing, and unpublishing
- How can I use published study objects in workflows?
- Results of modifying study objects that have been copied to studies and libraries

- What are examples of using libraries effectively?
- What is a template?
- What is a type?
- What is the difference between a template and a type?
- What information can I define for templates and types?
- About searching for a template or type
- What happens when I add a template to a study?
- What is an item type?

What is a library?

A library is a container used to store related study objects and templates to be published for reuse in studies or other libraries. Oracle Central Designer libraries store study objects for reuse and help enforce standards.

A librarian creates libraries within library projects, populates the library, and publishes the library for use in studies.

What is the System Library?

The System library is installed when you install Oracle Central Designer. It contains default items, codelists, templates, and other items that appear as choices and default values in Oracle Central Designer.

Oracle recommends that you do not modify information in the System library. Instead, copy item types from the System library to another library, and modify information in the new library.

When you create an item, you can choose to base it on any of the types in the libraries in the Library list, so make sure you add the new library to the list. Optionally, if you do not want the item types in the System library to appear as options, you can remove the System library from the Library list.

To view the Library list:

1. From the menu bar at the top of the Oracle Central Designer window, click **File**, then **Open**.
2. From the **Project Types** drop-down list, select **Libraries**.

What happens if I unpublish an object in the library?

If you copied the object into a study, unpublishing in the library makes it unavailable for future copying unless you republish it.

About publishing, republishing, and unpublishing

You must publish study objects that were created in a library to allow users to search for them in the Libraries Browser. You can publish, republish, and unpublish study objects only in a library. You must save a study object before you publish or republish it.

In a library, you can publish any of the following.

What to publish	Notes
A single study object	When you publish a study object, you publish its most recent version or revision.
A study object and its child study objects.	• When you publish a form and its children, sections on the form are also published. • Publishing child study objects is not supported for mappings. • If you modify a study object or one of its children, you can use the Republish option to publish the study object and its children again. • If you copy a study object with child study objects from the Libraries tab to a study or library, the child study objects are also copied, regardless of whether or not they are published.
All study objects	NA

Tip:

To prevent users from finding study objects using the Libraries tab, unpublish the study objects.

How can I use published study objects in workflows?

You can develop study workflows in either a study or a library, and you can use study objects found in a Libraries tab search to define a workflow in a study in the following ways:

- **Add a published study object to a workflow**—You can drag a published study object from the Libraries tab to a workflow tab in a study (for example, you can drag a published study event to the Workflow Diagram tab in the Study Editor or Study Element Editor). When you do this, the study object from the Libraries tab is added to the workflow in the study.
- **Replace a published study object in a workflow**—You can drag a published study object from the Libraries tab onto a study object in a study (for example, you can drag a published form from the Libraries tab and drop it onto a form object in the Workflow Diagram tab in the Study Event Editor of a study). When you do this, the study object from the Libraries tab replaces the definition of the study object. This method enables you to create an outline of a study workflow without defining the properties of the study objects and then to replace the placeholder study objects with fully defined, published study objects.

Results of modifying study objects that have been copied to studies and libraries

The following table describes the results of modifying a study object after you drag the study object from the Libraries tab to a study or library.

> **Note:**
>
> In the following sections, the library or study that contains the study object is the *source location*. The library or study to which you are adding a study object is the *target location*.

After you add a study object from a library to a library using the Libraries tab:

Action	Result	Example
If you modify the study object or one of its children in the source location and drag the modified study object objects to the target location:	You are prompted to choose one of the following: • Update the study object in the target location. If you choose this option, the study object and any modified children are updated, but unchanged study objects are not updated. • Create a link to the updated study object and its children in the target location. If you choose this option, a new RefName is created for the study object in the target location.	After you add a form from LibraryA to LibraryB using the Libraries tab, if you modify the form or one of its items in LibraryA and drag the modified form or item to LibraryB, you are prompted to choose one of the options described above.
If you modify the study object in the target location and then drag the study object to the source location:	You are prompted to choose one of the following: • Update the study object in the source location. • Create a link to the modified study object.	After you add a form from LibraryA to LibraryB using the Libraries tab, if you modify the form in LibraryB and then drag the form to LibraryA, you are prompted to choose one of the options described above.

After you add a study object from a library to a study or from a study to a library using the Libraries tab:

Action	Result	Example
If you create a new study object in the target location and drag a child of the original study object to the new study object:	The two child study objects in the target location are automatically linked	After you add FormA from a library to a study using the Libraries Browser, if you create FormB in the study and drag ItemA (a child of FormA) to FormB using the Libraries tab, ItemA on FormA and ItemA on FormB are automatically linked in the study.

Action	Result	Example
If you modify the original study object in the source location and then drag it to the same parent in the target location:	You are prompted with the following two options: • Update the study object and its children in the target location. The study object and any modified children are updated to the study object that you previously added. Unchanged study objects are not updated. • Cancel adding the original study object and its children to the target location.	After you add FormA from a library to EventA in a study using the Libraries tab, if you modify FormA in the library and then drag it again to EventA in the study, you are prompted to choose one of the options described above.
If you modify the original study object in the source location and then drag it to a different parent (that does not already contain the study object) in the target location:	You are prompted with the following two options: • Update the study object and its children in the target location. The study object and any modified children are linked to the study object in the target location, and the study object in the target location is updated. • Cancel adding the original study object and its children to the target location.	After you add FormA from a library to EventA in a study using the Libraries tab, if you modify FormA in the library and then drag it to EventB (which does not yet contain FormA), you are prompted with the options described above.
If you modify one or more children of the study object in the source location and then drag the study object to the target location:	You are prompted with the following two options: • Update the children in the target location. The child study objects that were modified are updated in the target location. • Cancel adding the original study object and its children to the target location.	After you add FormA from a library to a study using the Libraries tab, if you modify one or more items on FormA in the library and then copy FormA to the study again, you are prompted with the options described above.
If you drag the study object that you already added to the same parent in the target location:	You receive a message indicating that the study object cannot be added to the same parent more than once if the study object has not been updated.	After you add FormA from a library to a study using the Libraries tab, if you have not modified FormA and try to add FormA to the study again using the Libraries tab, a message appears, indicating that the study object cannot be added to the parent more than once if the study object has not been updated.

Note:

If you create a study object in the source location, add it to a target location, and then drag the study object back to the source location without modifying the study object in the target location, you are asked if you want to update the study object.

For example, if you create a study object in LocationA (either a study or library), copy it to LocationB (either a study or library), and then drag the study object from LocationB back to LocationA without modifying it in LocationB, you are asked if you want to overwrite the study object in LocationA or cancel. If you updated the study object in LocationA and you choose to overwrite, you lose the changes when the study object from LocationB is added to LocationA.

If you add a study object to a study from a library, copy and paste the study object within the study, and then add the study object from the library to the study again, none of the copies is updated.

The RefNames of study objects are never updated when a study object is updated.

You cannot use the Libraries tab to create multiple copies of a study object within a target location. Use the Copy option to create multiple copies of a study object within a study or library.

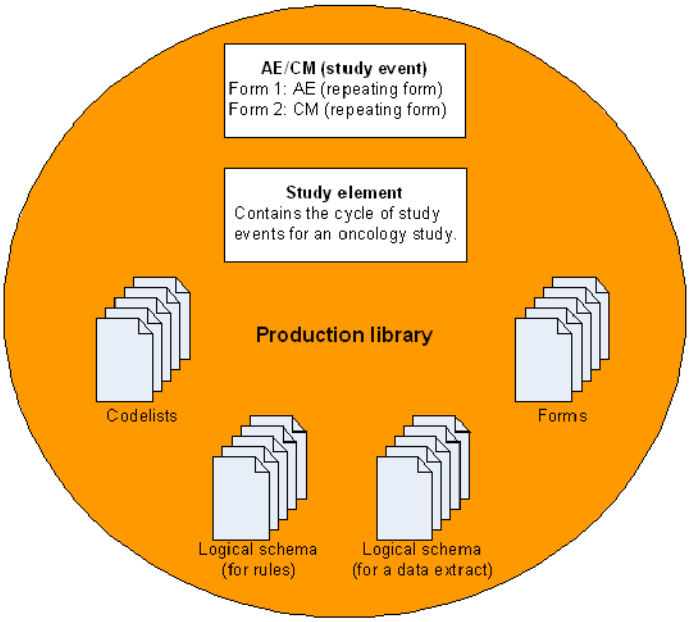
To determine whether a study object is a link or a copy of another study object, check the Identifier field in the Properties tab. If the identifiers are identical, the study objects are links; otherwise, they are copies.

What are examples of using libraries effectively?

- Illustration: Example of a production library
- Illustration: Building libraries using study objects from production studies
- Illustration: Building libraries from scratch
- Illustration: Building a study using libraries
- Illustration: Modifying study objects in production libraries
- Illustration: Multiple instances of study objects in production libraries

Illustration: Example of a production library

Figure 12-1 Example of a production library

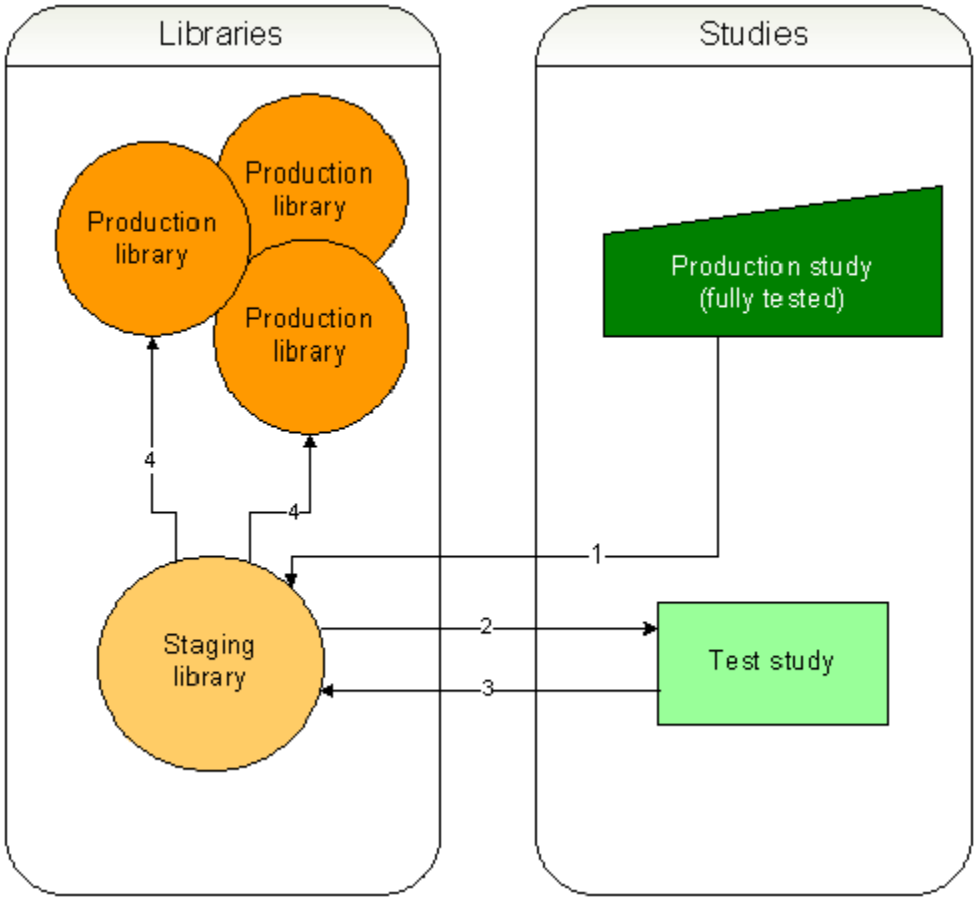


The illustration provides examples of content that you can include in a production library, including:

- Study elements.
- Study events.
- Forms (in or not in study events).
- Codelists.
- Mappings.

Illustration: Building libraries using study objects from production studies

Figure 12-2 Illustration: Building libraries using study objects from production studies



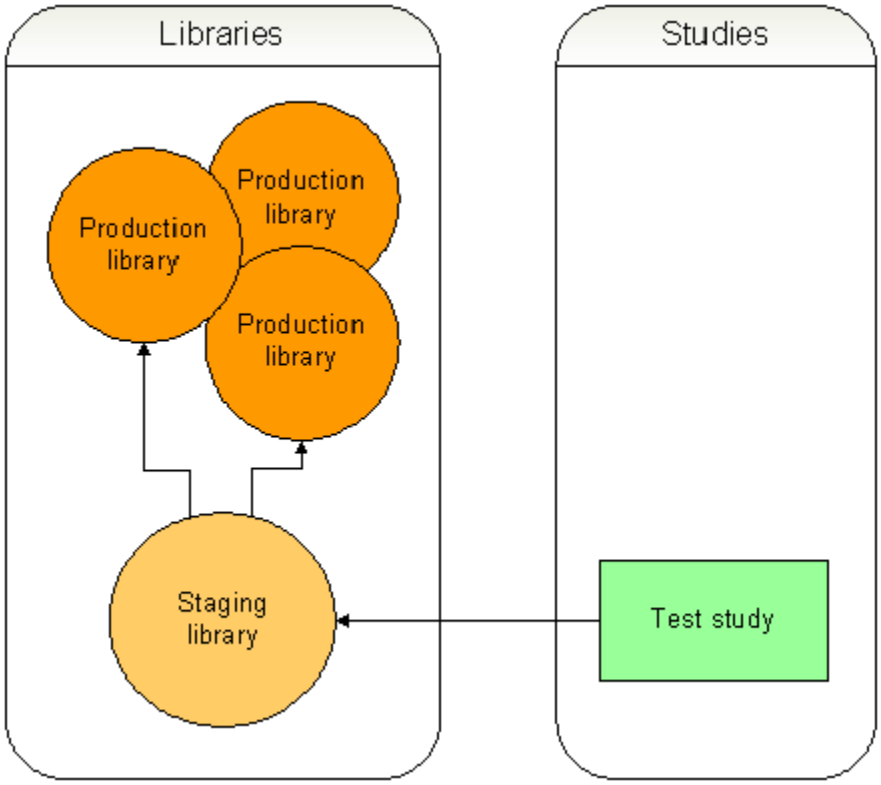
The illustration shows how you can add study objects from a production study to a production library. The production study has been validated in the Oracle Central Designer application and fully tested in the target application.

The numbers indicate the order in which study objects move among studies and libraries.

Oracle recommends implementing a process that requires study objects to be approved before they can be added to a production library. This task might be performed by a standards group.

Illustration: Building libraries from scratch

Figure 12-3 Building libraries from scratch

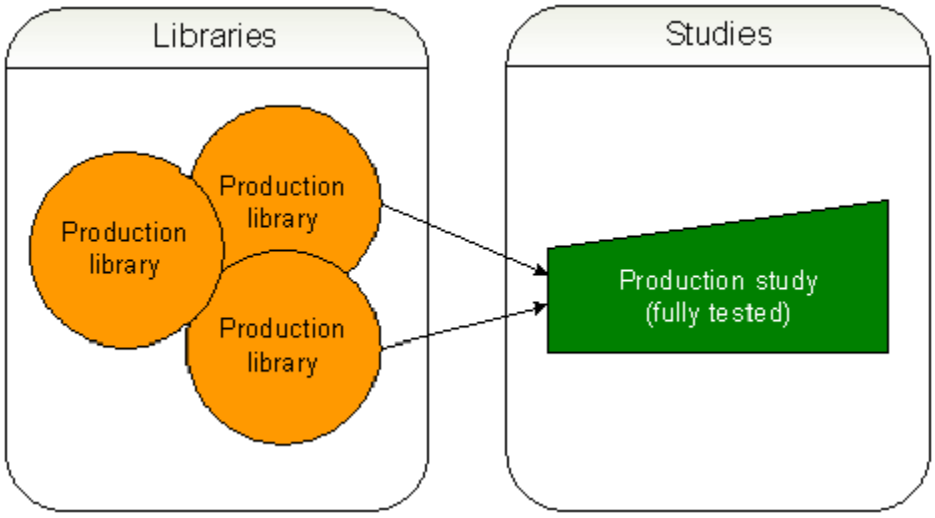


The illustration shows how you can create study objects in a test study and then add them to a production library.

Oracle recommends implementing a process that requires study objects to be approved before they can be added to a production library. This task might be performed by a standards group.

Illustration: Building a study using libraries

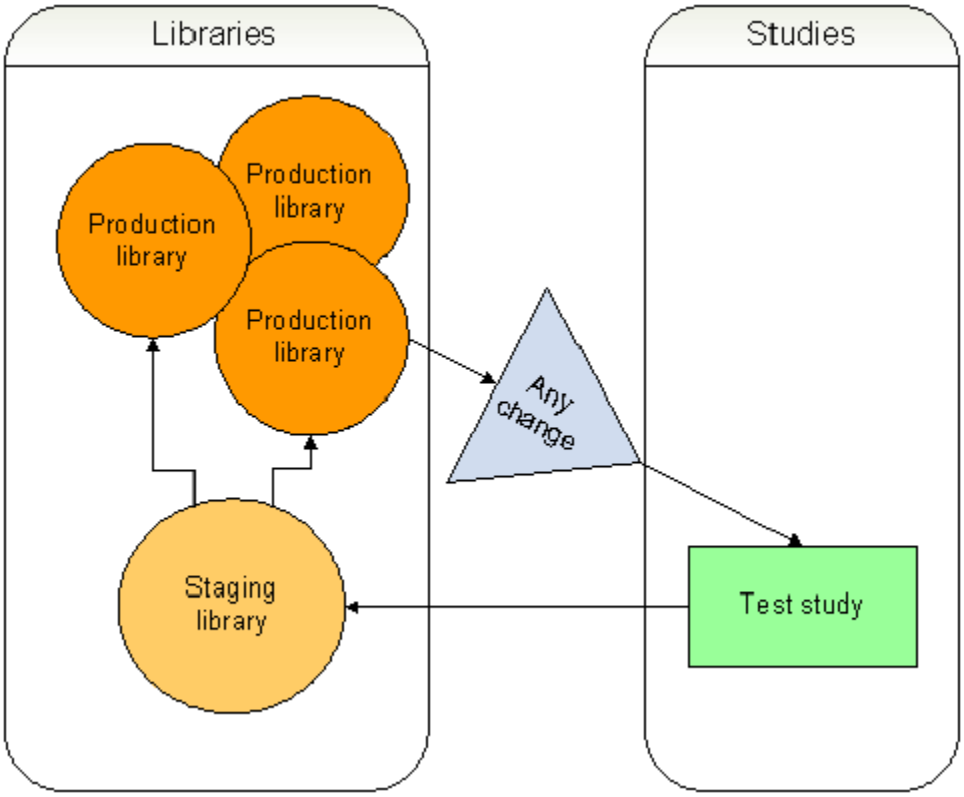
Figure 12-4 Building a study using libraries



The illustration shows how you can add study objects from a production library directly to a production study. The production study has been validated in the Oracle Central Designer application and fully tested in the target application.

Illustration: Modifying study objects in production libraries

Figure 12-5 Modifying study objects in production libraries



The illustration shows how you can modify study objects that are in a production library.

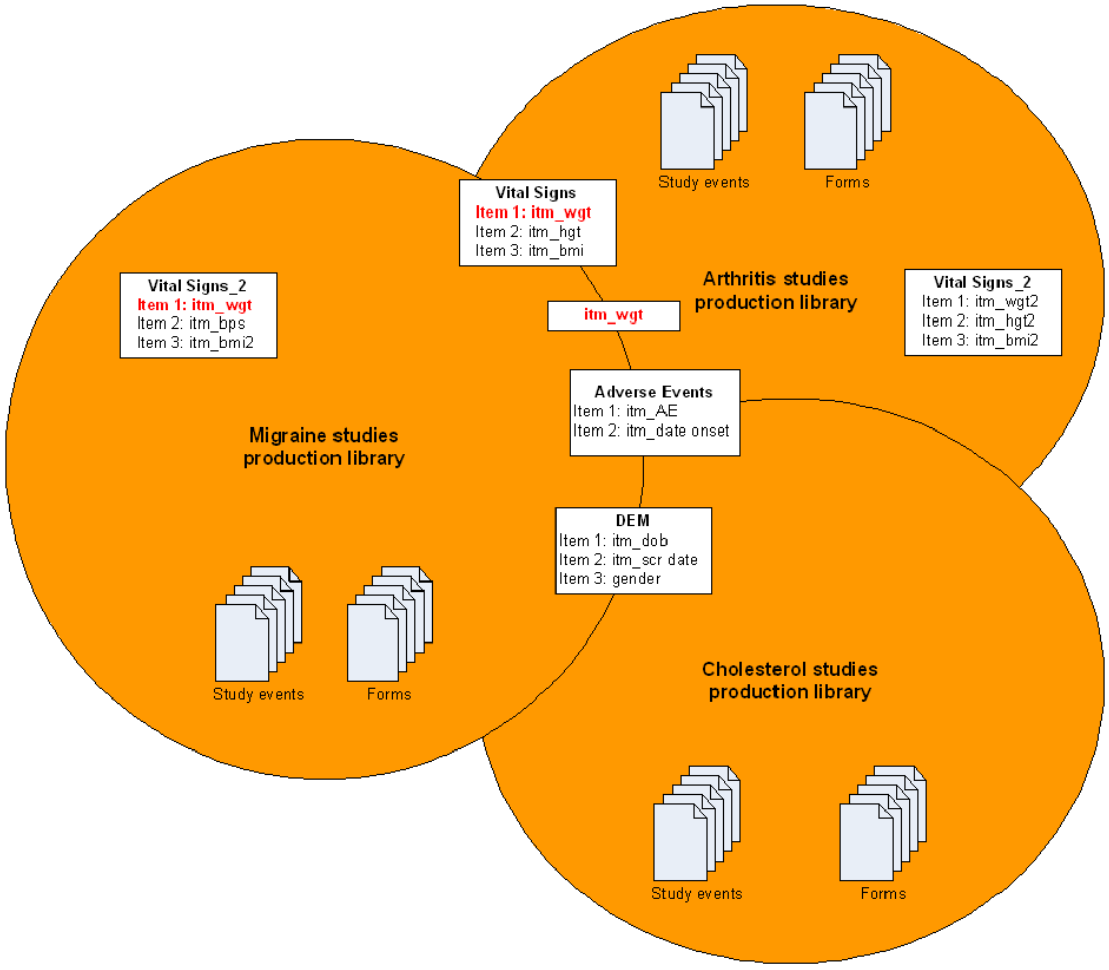
Oracle recommends updating the version number of the study object in the staging library to track changes.

The processes determined by your company determine whether trivial changes, such as a typo correction, need to be retested in the target application.

Oracle recommends implementing a process that requires study objects to be approved before they can be added to a production library, even if they have only been modified and have already been in a production library. This task might be performed by a standards group.

Illustration: Multiple instances of study objects in production libraries

Figure 12-6 Multiple instances of study objects in production libraries



Study objects, including forms and items, can appear multiple times in a single library and can also appear in other libraries. For example, in the illustration:

- The following forms were copied with the **Copy > Link** option:
  - **Vital Signs**—Appears in both the Arthritis and Migraine libraries.
  - **DEM**—Appears in both the Migraine and Cholesterol libraries.
  - **Adverse Events**—Appears in all three libraries
- An item may be in a library in multiple places. For example, the itm_wgt is:
  - In the Migraine library as part of the Vital Signs_2 form.
  - In both the Migraine and Arthritis libraries as part of the Vital Signs form.
  - In both the Migraine and Arthritis libraries as a standalone item.

What is a template?

Characteristic	Description
Definition	A template is study object that is either partially or fully defined and that can be used to create other study objects.
Available for	You can create templates for the following study objects: • Study projects • Studies • Study elements • Study events • Forms • Items • Codelists • Mappings
Purpose of study templates	Study templates can decrease the time and effort required to build a study. Think about how to set up study templates to minimize work that users might need to perform. For example, you might create templates for different therapeutic areas, compounds, devices, and biologic areas.
After creating	After you create and publish a template, users can create study objects from the template. You do not need to publish study project templates and study templates to make them available. When you create a study object, you can (but are not required to) create it from a template.
History links	A study object created from a template inherits the characteristics of the template but has no history link to the template. Therefore, changing the template does not affect the study object, and the reverse is also true.
Versions	Templates do not have versions; therefore: • For study project templates and study templates, the last **saved** version of a template is used when you create a study project or study from the template. • For other study object templates, the last **published** version of a template is used when you create a study object from a template.

Characteristic	Description
Where to view templates	Study project and study templates are viewable when you create a study project or study. You can view all other templates in the library project in which they are created in the following places in the Project Explorer: • Under the **Templates** container. For example, within the Templates container, the Forms container has all form templates. • Under the containers for each study object.
Rule templates	You can also create rule templates.

> **Note:**
>
> You can protect templates and types. However, if you create a new study object from a protected template or type, the newly created study object is not protected.

What is a type?

A type is a study object that is either partially or fully defined and can be used to create other study objects. Types are like templates except that types appear as options in the Actions menu and in the Project Explorer menu when you create a new study object. Types are used only for items. Some commonly used types, including Float, Text, and Integer, are included in the System library.

Marking an item as a type automatically marks it as a template, as well.

Types have the following requirements:

- You can create types for items only.
- You can create types in libraries only.
- An item marked as a type is automatically marked as a template (and you cannot remove the template categorization).

After you create an item type and publish it, other users can create items from the type.

When you create an item, you must select a type on which to base it, and you choose from types that are in:

- The System library. These types are installed with Oracle Central Designer.
- Libraries that appear in the Library List for the study.

If a type with the same name appears in both the System library and another library, the type from the non-System library is used for creating the item.

An item created from a type inherits the characteristics of the type on which it was based, but the item has no history link to the type. Therefore, a change to the type does not affect the item, and the reverse is also true. Additionally, types do not have versions, so the last published version of a type is always used.

Types appear in the following places in the Project Explorer:

- In a library, types appear under the Types container. For example, the Items container contains all item types in the library.
- In studies and libraries, item types appear under the container for items.

> **Note:**
>
> You can protect templates and types. However, if you create a new study object from a template or type, the newly created study object is not protected.

What is the difference between a template and a type?

Characteristic	Templates	Types
Purpose	To provide predefined information about a study object. You are not required to base new study objects on templates.	To provide predefined information about an item. When you create an item, you must choose a type on which to base it.
You can create templates and types for the following study objects	Study projects, studies, study elements, study events, forms, items, codelists, and mappings.	Items only
How to create study objects from a template or type	**Creating a study project or study:** You are allowed but not required to choose a template. **Creating all other study objects:** To create a study object based on a template, find the template in the Libraries tab and then copy it to your study.	Creating an item: You must choose an item type.

What information can I define for templates and types?

The following table contains examples of the kinds of information that you can define for templates and type. All study objects created from a template or type inherit the characteristics of the template or type.

> **Note:**
>
> You can create a study object, such as a study or study event, copy study objects to it from a library, and then mark the study object as a template. If you use the template to create a study object, the study objects that were copied from the library do not retain history information from the study objects in the library.

Study object	Information you can define
Templates	-
Study project	• The references required for creating studies in the project, such as protocols or goals. • Any studies or study objects that are contained in the project.
Study	• Study deployment requirements, including languages and form layouts. • Study language requirements. • A defined Library List containing the libraries from which study objects and templates will be taken to build the study. • The references required for building a study, such as a protocol or study goals. • The users (assigned to study teams) who will be working on the study. • The instructions and Help information for the study. • The functions and constants that will be used in the study. • Workflow components, including commonly used forms, special forms, and any other commonly used study objects. • Mappings, including items and mappings to items, forms, and study events. • Mappings, including items and mappings to items, forms, and study events.
Study element	• The study objects contained in the study element and their workflow. • Instructions and Help for the study element.
Study event	• The study objects contained in the study event and their workflow. • Instructions and Help for the study event.
Form	• A designed layout. • The study objects contained in the form. • Instructions and Help for the form.
Item	• Design information, including a question, title, units, and length. • A codelist including codes and labels. • Data entry rules, such as a range check. • A designed layout. • Instructions and Help for the item.
Codelist	• The codes and labels contained in the codelist.
Mapping	• A name, RefName, and description of the mapping. • The data sets, data series, and items contained by the mapping.
Types	-

Study object	Information you can define
Item	• Design information, including a question, title, units, and length. • A codelist including codes and labels. • Data entry rules, such as a range check. • A designed layout. • Instructions and Help for the item.

About searching for a template or type

A primitive type is a type of item that is installed with Oracle Central Designer. Primitive item types include:

- Integer Variable
- Text Variable
- Float Variable
- Compound Variable
- Date Time Variable

What happens when I add a template to a study?

The children of templates are treated like regular study objects unless they are also marked as templates. For example, if you add a codelist template from a library to two different items in another library, the codelist items are links as long as they are not marked as templates.

You can add study objects to a study template using the **Libraries** tab. If you copy a study object from a library to a study template and then create a study from the study template, the study objects in the study are linked to the original study objects in the library.

What is an item type?

An item type is a user-created item, or a System Library type of item. Item types include:

- Integer Item
- Text Item
- Float Item
- Compound Item
- Date Time Item

Import and export

In this section:

- Why would I import or export study data?

- What data format can I import into Oracle Central Designer?
- What conditions must be met before a study object can be imported?
- Considerations for ODM import in Oracle InForm studies
- What modifications can I make to an imported study?
- What CMSL data is not exported or imported?
- What are the requirements for importing ODM metadata?
- How are ODM objects mapped to Oracle Central Designer objects?
- Can I export a single study object?
- Can I export and import text?
- What does a translator do with the exported text strings for translation?
- What is the format of the translation export and import CSV file?
- What are the requirements for the translation file?

Why would I import or export study data?

Importing and exporting are useful for:

- Working with customer support to analyze problems in a study.
- Moving a study from one server to another.
- Importing study objects into a library or study. For example, if a study contains many study objects that you expect to reuse, you can use the import feature to create the study objects quickly in a library or study. After a study has been imported, you can revise, add, or delete study objects as needed.
- Exporting a study or library to a file, for archiving or for importing back into Oracle Central Designer or to an ODM-compliant system.

What data format can I import into Oracle Central Designer?

You can import a file in CSML or ODM format.

- Clinical Study Markup Language (CSML) is an XML-based markup language developed by Oracle for representing and exchanging clinical data definitions created in Oracle Central Designer.
- Operational Data Model (ODM) is an XML-based standard developed by the Clinical Data Interchange Standards Consortium (CDISC) for representing and exchanging clinical data.
  For example, you can use the CSML option to import an exported Oracle Central Designer study into another study.

> **Note:**
>
> You cannot import a CSML file into a library if the file contains a study design. A CSML file contains a study design if you exported the CSML from a study. To add study objects that are in a CSML file to a library, import the CSML file into a study, use the Libraries tab to search for the study objects, and then drag them to the library.

What conditions must be met before a study object can be imported?

Pre-import checking verifies that the following conditions are met before ODM is transformed to CSML for import into Oracle Central Designer.

- All requirements are met. For more information, see Considerations for ODM import in InForm studies.
- The input file is a well-formed XML file and is fully compliant with the ODM 1.3 schema.

> **Note:**
>
> Error and warning messages appear as Job Results on the Central Designer Job tab.

> **Note:**
>
> You cannot import a CSML file into a library if the file contains a study design. A CSML file contains a study design if you exported the CSML from a study. To add study objects that are in a CSML file to a library, import the CSML file into a study, use the Libraries tab to search for the study objects, and then drag them to the library.

Considerations for ODM import in Oracle InForm studies

You can reuse ODM-formatted study design metadata that is exported from a third-party application. Consider the following if you are importing metadata in ODM format into Oracle Central Designer to use in the creation of Oracle InForm studies or libraries.

- **Common visits**—The ODM specification allows multiple common StudyEventDefs, while Oracle Central Designer allows only one common visit. All common StudyEventDefs in an ODM import file are consolidated into a single common visit after import. The forms defined for the common visits in the ODM import file appear in the single common visit in Oracle Central Designer.

  The CommonVisit definition for the common visit that appears in Oracle Central Designer contains a LongTitle and ShortTitle, which are populated by the Description and Name defined in the first common StudyEventDef in the ODM import file.
- **Units**—The MeasurementUnit in the ODM import file is matched with entries in the Oracle Central Designer database based on unit symbols, but not unit names. If a unit in the ODM import file is not recognized as a unit in the Oracle Central Designer database, a warning message appears and the unit is not imported.
- **Metadata**—Oracle Central Designer does not recognize some ODM metadata (for example, the attribute SDSVarName). Any element or attribute in the ODM import file that is not recognized by Oracle Central Designer is ignored, and is not imported. You cannot recover this metadata after import.

- **Rules**—RangeCheck is the ODM simple range-checking attribute. Because the Oracle Central Designer application uses rules for range checking, ODM RangeChecks are imported as collaboration notes so that you can create the appropriate RangeCheck rules after importing.
- **Import file type**—Snapshot ODM represents a complete picture of a study at a point in time. Transactional ODM represents the life of the study over time. Oracle Central Designer supports standard ODM with a file type of Snapshot.
  Oracle Central Designer does not support ODM file chaining. The ODM specification allows files to be chained together through the FileOID and PriorFileOID attributes. File chaining is primarily used in Transactional ODM, but can also be used in Snapshot ODM to break up study metadata into multiple files that are chained together. Transactional ODM uses file chaining to create a final end state of a study upon import completion. Because Oracle Central Designer does not support file chaining, if you import Transactional ODM, an error occurs.

  > **Note:**
  >
  > You cannot import Oracle InForm metadata that you extracted from Oracle InForm Adapter with a Transactional file type. You must specify Snapshot as the file type parameter when you export data from Oracle InForm Adapter. For more information see the Oracle InForm Adapter *User Guide*.

- **Workflow**—Because the OrderNumber attribute is optional for StudyEventDefs in an ODM import file, the order in which the StudyEventDefs appear in the ODM is the order in which they appear in the Oracle Central Designer workflow.
  - A study event with an OrderNumber attribute is assigned a sequence number, unless its predecessor in the workflow has a type of Scheduled.
  - A study event with no OrderNumber attribute is placed at the end of the workflow, in the order in which it is read from the ODM import file.

  > **Note:**
  >
  > Any study event, with or without an OrderNumber attribute, is assigned a sequence number of zero if its predecessor in the workflow has a type of Scheduled.

- **Localization**—Oracle Central Designer imports localized data specified in an ODM import file. The translated data appears in Oracle Central Designer in the language to which it was localized. For more information, see the ODM specification for the TranslatedText element on the CDISC web site.
  The following localized study objects can be imported:
  - Forms.
  - Sections.
  - Items (Question, Text, and Description).
  - The decoded value for codelist items.
  - Symbols for measurement units.

- **Granularity**—Granularity is an optional ODM file attribute. If present, it must be set to All or Metadata. If Granularity is set to Metadata, the document cannot contain AdminData , ClinicalData, or ReferenceData sections.
- **Naming uniqueness**—Oracle Central Designer enforces naming uniqueness with Universal Unique Identifiers (UUIDs). A UUID is a Global Unique Identifier (GUID) that is created using the Object Identifier (OID) for a study object. If the OID is not a valid GUID or is already used by another object, the import process generates a GUID using Microsoft's GUID generation algorithm.
  For example, during the import, to create a StudyEventOID, Oracle Central Designer:

  1. Truncates the OID to the maximum allowed length.
  2. Removes disallowed characters.

  In addition, within an ODM import file, ODM allows the reuse of RefNames if the RefName is for a different type of study object. However, Oracle Central Designer requires unique RefNames for all study objects in a study, and for all study objects in an import file. To enforce the uniqueness of RefNames in the import file, Oracle Central Designer adds prefixes to the imported study object RefNames according to the study object type.

  If an ODM import file contains study objects with the same RefName, Oracle Central Designer uses the following logic:

  – For study objects of the same type, Oracle Central Designer creates a new object with a different ID but the same RefName, and adds a prefix to the RefName.
  – For study objects not of the same type, Oracle Central Designer imports the study object and displays a warning that duplicate RefNames exist.

> **Note:**
>
> If you import multiple ODM files, and duplicate RefNames exist between the files, Oracle Central Designer allows you to import the study objects. You must resolve RefName conflicts after import to validate the study.

Oracle Central Designer applies the following prefixes for study objects with duplicate RefNames within an ODM import file.

CSML object type	Prefix
StudyDesign	SD_
StudyEvent	SE_
DataView (from the FormDef definition in the ODM import file)	DF_
DataView (from the ItemGroupDef definition in the ODM import file)	DI_
IntegerVariable, FloatVariable, DateTimeVariable, or TextVariable	VR_
CodeList	CL_
CodeListItem	CI_

What modifications can I make to an imported study?

After you import a study from an external source, you should review the imported study object definitions to identify the additions and changes they require. For example:

- If you import a file in CSML format, Oracle Central Designer rules are created. If any rule refers to a user-defined function that does not exist in the target study, import the user-defined function to the study. If a required constant does not exist in the study or in a library that the study uses, add the constant or add the appropriate library to the Library List.
- If you import from a source other than CSML, imported rules are not converted to Oracle Central Designer rules; instead, they appear as collaboration notes. You must create a rule for each rule in the import file that you want to use in the library or study.
- To use imported study objects as valid deployable Oracle Central Designer study objects, you should review the imported study objects to add additional information that is not contained in the ODM format. For example, you must:
  - Create form layouts for imported forms.
  - Translate study object labels and text strings as needed for multi-lingual studies.
  - Create a range check rule for each imported ODM RangeCheck that you want to use in the library or study. For more information, see the *Rules Reference Guide*.
  - Resolve RefName conflicts for all study objects you want to deploy to a target application.
  - Connect any scheduled imported events or elements in the proper order with arrows, and provide hours between the visits.
- If studies or study objects were marked as templates, you must re-mark the study objects as templates.

> **Note:**
>
> If you harvest Oracle InForm resources and publish them in a library, both forms and sections appear in the forms group when you search for study objects. However, in the Project Explorer, forms and sections have different icons. Using naming conventions that clearly distinguish forms from sections is recommended.

What CMSL data is not exported or imported?

> **Note:**
>
> Exporting and importing do not preserve notes, categorization, or ancestry.

When study CSML is exported and then imported into a new study, baselines are not included. Use caution exporting/importing CSML if there is a chance you may do any in-place revisions on the study. In order to validate an in-place revision, which compares the current

potential baseline and previous baselines, baselines that have been deployed to LIVE/UAT must exist.

When functions are declared in the study CSML, functions are imported except under the following circumstances:

- When you import CSML in a study, and a function in the CSML already exists in a library that is in the Library List for the study. The function is already available for use. You do not receive an error or warning.
- When the function assembly does not exist in the database. You receive a warning.

What are the requirements for importing ODM metadata?

The Oracle Central Designer import feature supports a subset of the ODM standard, using only the metadata that fits into the Oracle Central Designer CSML schema.

You can import metadata in ODM format into Oracle Central Designer as long as the metadata:

- Complies with version 1.3 of the ODM standard.
- Contains only standard ODM objects with no extensions.
- Has a file type of Snapshot and contains only one study, one metadata version, and one protocol.
- Includes measurement units that are present in the Oracle Central Designer Units definition in the database.

> **Note:**
>
> If the metadata contains units that are not present in the Oracle Central Designer database, a warning occurs, and the units are not imported.

How are ODM objects mapped to Oracle Central Designer objects?

The following table describes how ODM elements are mapped to Oracle Central Designer study objects during import.

ODM element	Oracle Central Designer study object
Study	Study design
StudyEventDef	Study event
FormDef	Form
ItemGroupDef	Section
ItemDef (datatype=INTEGER)	Integer item
ItemDef (datatype=FLOAT)	Float item
ItemDef (datatype=DATE, TIME, DATETIME)	Date time item
ItemDef (datatype=TEXT, STRING)	Text item
CodeList	CodeList
CodeListItem	CodeListItem

Can I export a single study object?

No. When you export a study or library, you export the entire study or library. You cannot selectively export certain study objects.

Can I export and import text?

You can export all text strings for a target application and locale into a CSV file, translate them locally, and then re-import the translated strings.

This option is useful for outsourcing translations. After exporting the text strings for a selected target application and locale to a CSV file, you can send the file to a third-party translation vendor to translate the strings. When the translated strings are returned, you import them back into the Oracle Central Designer database. You perform the export and import separately for each locale to be translated.

You can export and import text strings at any time during the development of a study, including updates after a study has gone live. For example, to generate a test file to validate the process with a translation vendor, you can export the text strings for a partially developed study. When the study is completely developed, you can export the strings again, have the vendor translate the remaining strings, and import the completed translation file.

> **Note:**
>
> The text string export and import feature works only with the current format of layouts. If your study contains layouts that were created in release 1.2 or earlier of Oracle Central Designer, you must convert the layouts to the current format before exporting or importing text strings.

What does a translator do with the exported text strings for translation?

After the text strings for a study or library are exported, a translator adds translated strings to the exported file and saves the file.

> **Note:**
>
> If you use Microsoft Excel spreadsheet software as the CSV file editor, you must import the exported file as Unicode UTF-8; you cannot simply open the file and edit it. Additionally, you must export the edited file as Unicode UTF-8 CSV; you cannot save it and preserve the correct formatting. You might want to develop a Microsoft Excel macro specification or other tool that performs this processing. For guidance, see the Microsoft Excel documentation.

Translation file format

The translation export and import CSV file consists of a header and translation records in the following formats.

Header

The header contains the following values: RefName,OwnerType,SrType, Id,Revision,<*ReferenceLocaleValue*>,< *LocaleToTranslate*>.

- <*ReferenceLocaleValue*>—Locale of the strings from which to translate, as specified in the Locale to translate from field of the Export Translations dialog box. Example: en-US.
- <*LocaleToTranslate* >—Locale to which text strings are being translated, as specified in the Locale to translate field of the Export Translations dialog box. Example: fr-FR.

Example of file header

```
RefName,OwnerType,SrType,Id,Revision,en-US,fr-FR
```

Records

Each translation record contains the following fields: <RefName>,<OwnerType>,<SrType, <Id>,<Revision>,<*ReferenceLocaleValue*>,< *LocaleToTranslate*>, as described in the following table.

Field	Description
RefName	RefName of the study object that owns the string.
OwnerType	Internal type of the study object that owns the string resource.
SrType	Internal type of the field that references the string resource.
Id	GUID of the string resource in CSML.
Revision	Revision number of the study object for which the text string is defined.
ReferenceLocaleValue	Text string in the locale to translate.
LocaleToTranslate	Translated text string. This value is empty when you export the file. The translator fills in the value before you import the file.

Note:

The LocaleToTranslate is the only value that may be changed in each record.

Examples of file records

```
Layout_5fxx,LayoutPlan,ItemCaption,d067b170-8885-11e1-
b0c4-0800200c9a66,12, "DOV Form","Forme pour la date de visite"
```

```
Itm_DOB,DateTime,Question,26beca46-663e-4841-ab8b-03ff6b7a78f9,5,"Date of
Birth","Date de naissance"
```

Translation file requirements

- Do not change any values in the translation file except the strings in the LocaleToTranslate position (last field in each record).
- The header record must be present.
- Each record must conform to the following standards:
  - All records must have the same number of fields.
  - RefName and Id fields must not be empty.
  - RefName length must be less than or equal to 63 characters.
  - Revision and OwnerType lengths must be less than or equal to 255 characters.
  - ReferenceLocaleValue and LocaleToTranslate lengths must be less than or equal to 32000 characters.
- Double quotation marks (") are required for any field that contains a line break, double quote, or comma and are optional for any other field.
- If a field contains a double quotation mark character [for example, Dizzy ("Groggy")], you must include another double quotation mark as an escape character, as follows: "Dizzy (""Groggy"")".
- Lines must end with a Windows-style (CRLF) line terminator.

What is the format of the translation export and import CSV file?

The translation export and import CSV file consists of a header and translation records in the following formats.

Header

The header contains the following values: RefName,OwnerType,SrType, Id,Revision,<*ReferenceLocaleValue*>,< *LocaleToTranslate*>.

- <*ReferenceLocaleValue*>—Locale of the strings from which to translate, as specified in the Locale to translate from field of the Export Translations dialog box. Example: en-US.
- <*LocaleToTranslate* >—Locale to which text strings are being translated, as specified in the Locale to translate field of the Export Translations dialog box. Example: fr-FR.

Example of file header

```
RefName,OwnerType,SrType,Id,Revision,en-US,fr-FR
```

Records

Each translation record contains the following fields: <RefName>,<OwnerType>,<SrType, <Id>,<Revision>,<*ReferenceLocaleValue*>,< *LocaleToTranslate*>, as described in the following table.

Field	Description
RefName	RefName of the study object that owns the string.
OwnerType	Internal type of the study object that owns the string resource.
SrType	Internal type of the field that references the string resource.

Field	Description
Id	GUID of the string resource in CSML.
Revision	Revision number of the study object for which the text string is defined.
ReferenceLocaleValue	Text string in the locale to translate.
LocaleToTranslate	Translated text string. This value is empty when you export the file. The translator fills in the value before you import the file.

> **Note:**
>
> The LocaleToTranslate is the only value that may be changed in each record.

Examples of file records

```
Layout_5fxx,LayoutPlan,ItemCaption,d067b170-8885-11e1-
b0c4-0800200c9a66,12, "DOV Form","Forme pour la date de visite"

Itm_DOB,DateTime,Question,26beca46-663e-4841-ab8b-03ff6b7a78f9,5,"Date of
Birth","Date de naissance"
```

What are the requirements for the translation file?

- Do not change any values in the translation file except the strings in the LocaleToTranslate position (last field in each record).
- The header record must be present.
- Each record must conform to the following standards:
  - All records must have the same number of fields.
  - RefName and Id fields must not be empty.
  - RefName length must be less than or equal to 63 characters.
  - Revision and OwnerType lengths must be less than or equal to 255 characters.
  - ReferenceLocaleValue and LocaleToTranslate lengths must be less than or equal to 32000 characters.
- Double quotation marks (") are required for any field that contains a line break, double quote, or comma and are optional for any other field.
- If a field contains a double quotation mark character [for example, Dizzy ("Groggy")], you must include another double quotation mark as an escape character, as follows: "Dizzy (""Groggy"")".
- Lines must end with a Windows-style (CRLF) line terminator.

Tasks and notes

In this section:

- What are tasks and how do I work with them?
- Where do the task types come from?
- How are task statuses used?
- Who does what with tasks?
- What is a collaboration note?
- Task Editor dialog box—Option descriptions
- Collaboration Notes Browser—Option descriptions
- Collaboration Note Editor dialog box—Option descriptions
- Task areas—Field descriptions
- Tasks Browser—Option descriptions

What are tasks and how do I work with them?

About tasks

A task is a request that you attach to a study object (a study, study element, study event, form, or item). A task is similar to a collaboration note except that you assign a task to an individual or to a whole study team. In a task, you can include detailed information and specify a due date and priority. You can format the text of a task and attach a file to it.

Example of using tasks

For example, a study workflow designer builds the framework for a study and includes information about the rules that will be required. A study architect can create rules to use as placeholders, without defining their expressions, and then create tasks for rule creation and assign them to the rule development team.

Level at which to create tasks

You can create a task on the study object, such as the form to be designed, or the parent study object, if the study object has not been created.

If the study object does not exist, consider creating a placeholder study object and then creating the task on the study object. For example, when the task assignee double-clicks the task in the Home Page, the Project Explorer opens, and the user is brought directly to the study object.

In general, create one task for each activity to be completed so that completed and remaining work can be assessed accurately.

Copying study objects with tasks

Tasks are not copied when a study object is copied from a library or published in a library.

Task types

When you create a task, you must choose a type on which to base it.

Where do the task types come from?

Administrators create task types in the Oracle Central Designer Administrator application. Task types are used to identify the type of the task and the way the task is used. Task types can be classified as Standard or Translation. Administrators select a default team to which tasks of each type are assigned. Selecting a default team is optional for standard tasks.

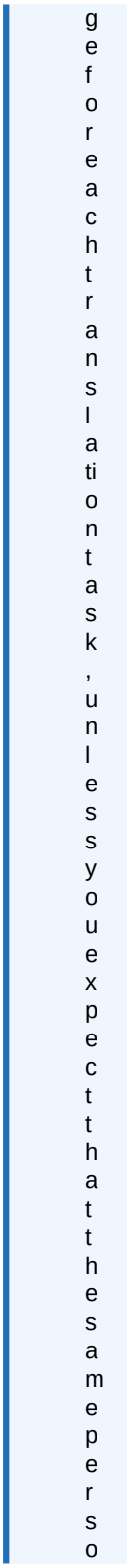
When you create a task, you choose a task type on which to base the task.

You can create multiple task types for each task classification. Task classifications are predefined and you cannot modify them.

Task classification	Description	Example
Standard	Used for all non-translation tasks assigned to an individual or team. When you create a standard task, you can override the default assignment.	• Task name: Create form • Default teams: Study designers, Form designers

Task classification	Description	Example
Translation	Used for tasks that request translation of a study object into one or more languages. When you create a translation task, you choose the language into which the study object must be translated.	• Task name: Translate form • Default team: Translation team

Note: Oracle recommends selecting only one langua

Task classification	Description	Example
		

Task classification	Description	Example
		nwilltranslateintoallofthesselectedlanguages.

How are task statuses used?

Task assigned to you appear on your Home Page. All tasks appear on the Tasks tab.

> **Note:**
>
> If a task is overdue, the status displayed in the status field is Overdue—[Current status], such as Overdue—Accepted.

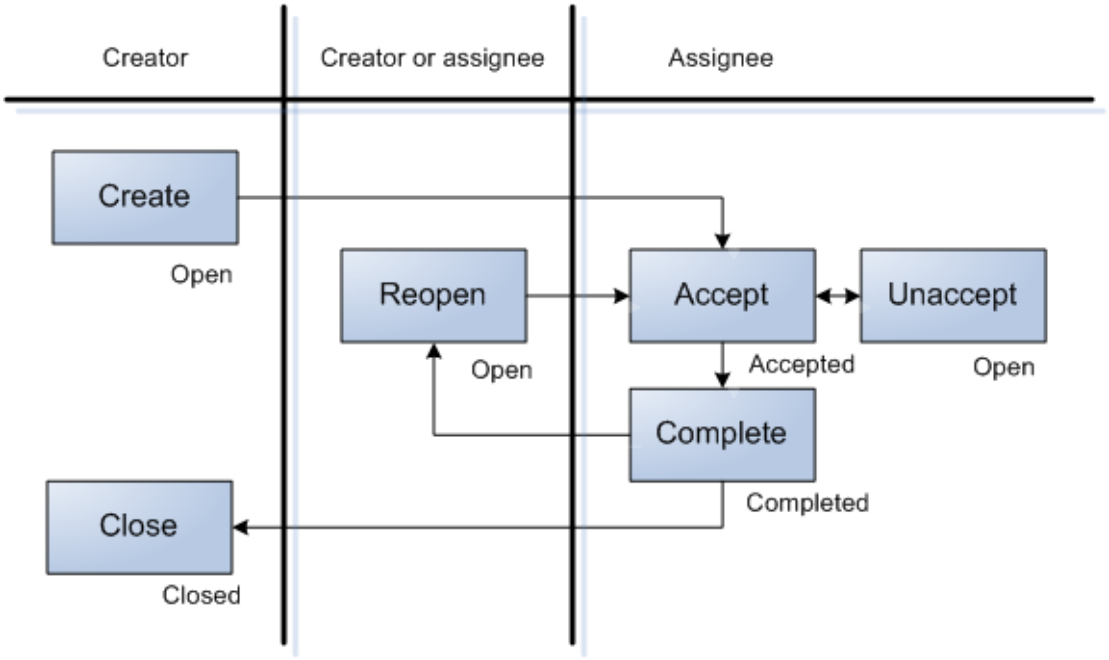
Procedure	Task status	Description
Creating a task	Open	When you create a task, you assign it to one or more individuals or teams.
Accepting a task	Accepted	When you accept a task, you take responsibility for completing the task. Only one person can accept a task, and you can only accept tasks that are assigned to you. After you accept a task, you can: • Mark it as Complete after you finish all required work. • Unaccept it if you will no longer work on the task.
Unaccepting a task	Open	You can unaccept a task that you have accepted but will no longer work on. An unaccepted task is assigned to the team to whom it was originally assigned. If no default team was selected, you are prompted to assign the task to a team or individual.
Completing a task	Completed	You can mark as Complete only those tasks that you have accepted. A completed task is assigned to the task creator. The task creator can do the following to a completed task: • Close it if work is complete. • Reopen it if work is not complete.
Closing a task	Closed	You can close completed tasks that you created. You close a task after you verify that all work has been completed. A closed task is assigned to the task creator.

Procedure	Task status	Description
Reopening a task	Open	Two people can reopen a task, the person who created it and the person who completed it. A reopened task is assigned to the individual or team to whom it was assigned by default. If no default team was selected, you are prompted to assign the task to a team or individual.

Who does what with tasks?

In the following illustration, activities appear in boxes with task statuses below them.

Figure 12-7 Tasks workflow



What is a collaboration note?

A collaboration note is a note that you attach to any study object, such as a project, study, study element, study event, form, or item. A collaboration note is like an electronic sticky note in which you include annotations, comments, messages, and file attachments. View the collaboration notes that are attached to a study object and, optionally, to its children, on the Collaboration Notes tab.

When you create a collaboration note, you must choose a type on which to base it. Collaboration note types are used to identify the type and purpose of a collaboration note.

You can filter the view of collaboration notes in the Collaboration Notes Browser according to type.

For example, an administrator might create a collaboration note type called Information to provide important information about study objects in a study and a Usage note type to tell where a study object can be used.

Custom events

In this section:

- What are the limitations on triggers?
- Custom Events editor—Option descriptions

What are the limitations on triggers?

Compund item - When a data change item trigger is set within a compound item, the trigger occurs when any items within the compound item gets edited.

Visit state triggers - These triggers (Frozen, Locked, Complete, and SV Complete) occur only when all expected forms in the visit have been started. Visit state should match the state in the InForm application.

Float data type - When a codelist value is float type and it includes decimal point with zero (.0), decimal point with zero (.0) cannot be included in the CODELISTVALUE column in the PFEX_ITEMTRIGGER table. Use an integer in this instance. For example, for 12.0, use 12.

Repeating instance output - Displays only the instance that triggered the output.

Rules

In this section:

- What types of rules can I create?
- How should I name my rules?
- Can I schedule rules to run in a certain order?
- Can I create a rule with more than one action?
- What happens when I reuse a study object with a data-entry rule?
- What happens when I reuse a study object with a global condition?
- Which object should I add a rule to?
- What happens if I create a rule on a repeating study object?
- Should I use a workflow rule or a global condition?
- What happens if I disable a workflow?
- View all rules for a study object and its children
- Can I cause a subject to fail screening and enrollment?
- Assign Conditions dialog box—Option descriptions

- Define Test Values for Repeating Instances dialog box—Option descriptions
- Design tab of the Rule Test Cases dialog box—Option descriptions
- Edit Global Conditions dialog box—Option descriptions
- Edit Schedule dialog box—Option descriptions
- Edit Schedule and Rule Action dialog box—Option descriptions
- Edit Workflow Rules dialog box—Option descriptions
- Email Action dialog box—Option descriptions
- Invoke Function dialog box—Option descriptions
- Query Action dialog box—Option descriptions
- New Rule Template dialog box—Option descriptions
- Rule Templates tab—Option descriptions
- Rule Wizard—Option descriptions
- Rules tab—Option descriptions
- Run tab of the Rule Test Cases dialog box—Option descriptions
- Set Review State Action dialog box
- Set Value Action dialog box—Option descriptions
- Workflow Expression Editor dialog box—Option descriptions

What types of rules can I create?

You can create the following types of rules:

- **Data-entry rule**—Checks whether data is valid or sets the value of an item based on a calculation. Different actions occur as a result of the evaluation of the rule expression. For example, an email can be sent or a query can be created.
  You can create a data-entry rule for a study design, a group of visits (a study element), a visit (a study event), a form, or an item.

  Types of data-entry rules include:

  - **Intrinsic**—An intrinsic rule is a constraint rule or calculation rule based on a predefined rule template. Rule templates can be created for constraint rules and calculation rules. If no rule templates have been defined for the selected study object, then you cannot create an intrinsic rule for the study object.
  - **Constraint**—Checks whether data is valid.
  - **Calculation**—Sets the value of an item based on a calculation.
- **Workflow rule**—Tests data values to determine the group of visits (study element), visit (study event), or form to which a subject progresses next.
  You can create a workflow rule for a group of visits (a study element), a visit (a study event), or a form.
- **Global condition**—When applied to a study object, a global condition determines whether the study object will appear for a particular subject.

How should I name my rules?

You are not required to use a naming convention for rules, but conventions can help you distinguish one type of rule from another and avoid duplicate RefNames. If you want to adopt a naming convention, consider prefixing rules with the following:

- wr - workflow rule
- gc - global conditions
- rul - data-entry rules (for example, rulDMConsDtCompare)

Can I schedule rules to run in a certain order?

You cannot set the order in which data-entry rules are run.

Can I create a rule with more than one action?

No. To write a rule that sets a value and sends an email, program the edit check in two separate rules, one to perform the calculation and another to contain the email action. For example, consider the scenario where a rule should send an Initial email when a Serious Adverse Event has occurred and should also send a Follow-up email when subsequent changes are made to the Adverse Event form after the initial email has been sent.

In this scenario, you should create two rules:

- Rule 1: Calculate the value of a hidden item that stores the date the Initial email versus Follow-up email needs to be sent.
- Rule 2: Create an explicit trigger dependency on this hidden item, and specify an action to send email based on its value (Initial or Follow-Up).

You can create a rule with multiple actions, with some exceptions.

For a rule, you can create:

- Multiple calculation actions using the Set Value Action dialog box.
- Multiple query actions, as long as the queries are on the same item.
- A combination of the previous two.

You cannot create multiple query actions if the queries are on different items.

> **Note:**
>
> Multiple query actions appear as additional lines in the Rules report.

What happens when I reuse a study object with a data-entry rule?

The rule is also reused, because rules are part of study objects.

- When a rule is part of a study object template or type, the rule is automatically part of all study objects created from the template or type.
- When a rule is part of a study object and the study object is copied into another project, the rule is copied with the study object.

- For valid data-entry rules, if you modify the RefName of a study object referenced by the rule, the data-entry rule is automatically updated with the change.

> **Tip:**
>
> If you modify the RefName of a study object from within the rule expression, the study object is not updated in rules that reference the study object.

What happens when I reuse a study object with a global condition?

Global conditions appear to be attached to study objects but are actually part of a workflow. They are copied with study objects in the following way:

- If a study event contains a form with a global condition, the global condition is actually part of the study event. When you use the Libraries tab to copy the study event from a study to a library, the global condition is copied. The global condition is not copied if you copy only the form.
- If you use the **Libraries** tab to copy the study event from a study to a library, publish only the form, and copy only the form into a study, the global condition is not copied into the study because the global condition is part of the workflow at the study event level.
- When a global condition is on a study element or study event that is created directly under the study design in the Project Explorer, the global condition cannot be copied from a study to a library. The global condition is actually on the study design, and you cannot copy a study design from a study to a library.

Which object should I add a rule to?

A rule that is part of a study object can refer only to:

- The study object and its children.
- Properties and values of the study object and its children.

Tips

- The child items of a compound item are in the scope of the compound item.
- If a study object falls outside the scope of a rule, you can:
  - Create the rule on a study object that is higher in the hierarchy and that has the necessary study object in its scope.
  - Move the necessary study object within the scope of the study object on which you create the rule.
  - Add the study object to a data series. Study objects that are part of mappings can be included in any rule in a study.
- To allow for reuse, create data-entry rules on the lowest-level study object that is reasonable based on scope requirements. For example, if an item requires a range check, create the range check on the item, not on the form that contains the item.
- Do not create all rules on the study design. Although all study objects in the study are in scope, you cannot reuse the rules because you cannot reuse study designs.

- If one or more study objects are outside the scope of a study object, we recommend creating the rule on a higher-level study object that has all required study objects in its scope.
  If you choose this option, the data-entry rule might be less likely to be reused because it is created on a study object that might not be reused in many other studies, but you are no longer limited by the scope of a particular study object.
- As early as possible, plan the study object on which every rule will be created. For example, if a study event contains two forms, and you have a rule that requires data from both forms, the scope of the rule will allow you to create the rule on the study event or a higher study object.
- A workflow rule is part of the workflow it is created in. If you want to use the logic of a workflow rule in multiple workflows, you must create it in each workflow separately.

What happens if I create a rule on a repeating study object?

When you create a rule on a repeating study object, and data is entered or updated in Oracle InForm:

- The rule executes only on the instance of the itemset, repeating form, or repeating visit where the data changes. It does not execute on all instances of the study object.
- The rule action (such as issuing a query) occurs only on the instance of the itemset, repeating form, or repeating visit where the data changes, not on all instances.
- If the rule has a dependency on another study object, and data is entered or changed on the other study object, InForm executes the rule against all instances of the itemset, repeating form, or repeating visit.

Should I use a workflow rule or a global condition?

When to use workflow rules

- To determine the branch of a study workflow that a subject should follow.
  For example, you can use a workflow rule to determine whether a subject completes a study with the standard termination visit or continues on to a set of extended visits.
- To apply the same action to multiple study objects.

When to use global conditions

- To make a single study workflow object dynamic.
  For example, you can use a global condition to generate a pregnancy test form for female subjects.
- To apply a single action to a single study object.
  Because you can apply only one global condition per study object, you must create an expression that evaluates all relevant data points in one global condition. Therefore, you cannot apply the global condition to multiple study objects if the other study objects require other actions.

What happens if I disable a workflow?

You cannot disable an individual workflow rule or global condition. However, if you disable a workflow, all workflow rules and global conditions associated with the workflow are disabled.

> **Tip:**
>
> This functionality only applies to the current workflow, and does not apply to child workflows. For example, if you disable a workflow at the study design level, the child workflows at the event or form level are not disabled.

When you deploy a study with a disabled workflow, the forms associated with that workflow appear in InForm in the order specified by their sequence numbers in the Workflow Diagram.

If you deploy to an Oracle InForm release prior to release 6.1.1:

- Disabled rules are not validated in Oracle Central Designer.
- Disabled rules are excluded from the deployment package.
- A validation warning appears and indicates that the study contains disabled rules.

If you deploy a study to Oracle InForm release 6.1.1 or later:

- Disabled rules are deployed to Oracle InForm as read-only.
- A validation warning appears and indicates that the study contains disabled rules.

View all rules for a study object and its children

1. In the Project Explorer, select a study design (in a study only), study element, study event, form, section, or item.
2. Select the **Rules** tab, and select **Show Child Rules**.

Can I cause a subject to fail screening and enrollment?

You can design a rule that causes a subject to fail Screening and Enrollment in InForm. To do so:

- Create a rule on the Screening and Enrollment form or any of its child study objects (such as an item on the form).
- Add a query action to the rule.

When a subject fails Screening and Enrollment, an Oracle InForm user with the appropriate rights can override the failure if the study is configured to permit screening and enrollment overrides.

Partial SDV

In this section:

- How is Partial SDV set in Oracle Central Designer?
- How are Partial SDV default values affected by a migration or upgrade?
- How do I automatically include or exclude subjects in Partial SDV using a rule?

How is Partial SDV set in Oracle Central Designer?

The default values for SVFirstNSubjects and SVautoSelectRate represent 100% SDV.

- **SVFirstNSubject** = 0
- **SVAutoSelectRate** = 100
- **SVDefaultInclude** = Include

> **Note:**
>
> Set to **Include** if you are not using rules to determine which subjects should or should not be in SV eligible pool.

When you deploy, the Site values in Oracle InForm will not necessarily be changed as a result of the deployment. The site values are only updated if they all match the current default values.

- If all Site Values match the Default Values, the Site Values will be changed to the new Default Values that were included in the deployment from Oracle Central Designer.
  For example, if you have a new study, and never modified the Site Values (and therefore they still exist as SVFirstNSubject = 0 and SVAutoSelectRate = 100), they will be populated with the new Default Values from Oracle Central Designer.
- If any of the Site Values do not match the Default Values, the Site Values will remain as is.
  For example, if you have an ongoing study, and changed the Site Values to be SVFirstNSubject = 5 and SVAutoSelectRate = 50, they will remain this way regardless of the new Default Values that are coming from Oracle Central Designer.

How are Partial SDV default values affected by a migration or upgrade?

Oracle Central Designer is designed so that the behavior defined for Partial SDV does not change when you migrate or upgrade from a version of Oracle Central Designer prior to version 6.3. In Oracle Central Designer 6.3.x, you now have the ability to update Partial SDV settings for Oracle InForm sites globally within Oracle Central Designer.

- In versions of Oracle InForm prior to version 6.3, there was only one value stored for each of the following settings for a site, and they could only be edited in the Oracle InForm user interface on a site-by-site basis. These are now known as Site Values.
  - **SVFirstNSubject**
  - **SVAutoSelectRate**
- When you migrate to Oracle InForm 6.3.x, two new values plus a new parameter are added to the database for these settings. These new settings are collectively known as the Default Values.
  - **SVFirstNSubject** = 0
  - **SVAutoSelectRate** = 100
  - **SVDefaultInclude** = Include
    Because this setting is new in Oracle InForm 6.3.x, the **Site Value** is automatically populated with **Include**, which matches the actual behavior prior to Oracle InForm 6.3. As a result, the behavior will not change.

How do I automatically include or exclude subjects in Partial SDV using a rule?

There are two features that together define whether to include or exclude subjects in Partial SDV based on characteristics captured on CRFs.

- The **SVDefaultInclude** system setting (on the System settings tab of the Administration editor) defines whether to include or exclude all subjects from the SDV pool by default before a rule is triggered. Make sure that this setting is set to **Include** (default) or **Exclude** depending on the default behavior you want.
- The **SetPartialSDV** rule action in the **Edit Rule** dialog box on the **Actions** tab defines how to automatically move subjects in and out of the SV eligible pool within InForm based on a rule and the default behavior defined by the **SVDefaultInclude** setting.

To include a subject in the SV eligible pool when the SVDefaultInclude system setting is set to Exclude:

1. Open the Edit Rule dialog box, and click the **Actions** tab.
2. In the Execute these actions section, select the **SetPartialSDV** action.p
   This is the default setting. In the Rule Summary section, the value appears as **SetPartialSDV (true).** This text is a link.

   When the rule is satisfied and the rule action SetPartialSDV is true, the subject will be included in the SV eligible pool.

To exclude a subject from the SV eligible pool when the SVDefaultInclude system setting is set to Include:

1. Open the Edit Rule dialog box, and click the **Actions** tab.
2. In the Rule Summary section, click the **SetPartialSDV (true)** link. The Set PartialSDV Action dialog box appears.
3. Select **Exclude**, and click **OK**. The link in the Rule Summary section is updated to **SetPartialSDV (false)**.

When the rule is satisfied and the rule action SetPartialSDV is false, the subject will be excluded from the SV eligible pool.

> **Note:**
>
> If a data entry error is made and a subject is incorrectly marked as failing screening, that subject will be excluded from the SV pool. If the form is updated to correct the mistake, the rule is not automatically re-triggered. To add the subject back into the SV pool you must add a second rule action where SetPartial SV is true.

Data mappings

In this section:

- What is the difference between data mappings, data sets, and data series?
- How are data mappings deployed?
- How long do associations last?
- How are study objects that are part of a data mapping copied?
- What are the custom property settings and design rules for custom context panels?
- Mapping to a data series
- Mapping to a data set
- CDD mappings
- CIS mappings
- Clintrial mappings
- Data mappings vs rules
- Data mapping examples

What is the difference between data mappings, data sets, and data series?

You use data mappings, data sets, and data series to group items into abstract associations. The associations that you create are independent of the way that you collect data values in forms.

- **Data mappings**—A data grouping that provides an alternate data view of a study. For example, you can group data sets to form an SDTM (Study Data Tabulation Model) data mapping.
  - Data mappings are not affected when you move items between forms.
  - You can create a data mapping before you design your study or as part of the study design process.
  - You can create one or more mappings in a study or library, but they are not required for any project.

In a data mapping, items are added to a data series. The association remains with the item whenever it is used. You can compare the parts of a data mapping to database concepts with which you are already familiar.

Compare a mapping to	Compare a data set to	Compare a data series to
A database schema	A database table	A column in a table
A Microsoft Excel workbook	A worksheet	A column in the worksheet

- **Data sets**—A grouping of one or more related data series. For example, the Temperature data series and Weight data series might comprise a Vital Signs data set.
  When you create a data set, you can specify standard and custom dimensions.
- **Data series**—A grouping of one or more items with the same clinical meaning, such as one or more items that measure weight.
  When you create a data series, you choose a data type for it.

Example—Data mapping

Data set: Vital signs initial	Data set: Vital signs final
Data series: Temperature	Data series: Temperature
Data series: Weight	Data series: Weight
Data series: Pulse rate	Data series: Pulse rate
Data series: Blood pressure	Data series: Blood pressure

How are data mappings deployed?

Data mappings created for Customer-Defined Databases (CDDs) or for TDE data mappings are deployed to the Oracle InForm application but must be enabled in the Oracle InForm application.

Similarly, CIS data mappings must also be enabled. To enable your data mappings in the InForm application, you must create a synchronization connection in the CIS application.

CIS and CDD data mappings

You can create a data mapping when you design your study to define what your data will look like. When you create a deployment package, you choose the data mappings to include in the package, and the selected data mappings are deployed as CDDs in the InForm application.

You can also use mapping definitions to create CIS mappings. CIS mappings are used to transfer data from an InForm study to a Clintrial protocol using the CIS application.

SDTM data mappings

You cannot create complete SDTM data mappings with a data mapping in the Oracle Central Designer application; however, the ability to create SDTM data mappings is available as an Oracle Services offering.

Rules and data mappings

You can write a rule that references a data mapping, but you cannot use rules to manipulate data mappings.

Rule creation

Data mappings can also be used for rule creation.

How long do associations last?

After you add an item to a data series in a data mapping, the association between the item and data mapping persists wherever the item and data mappings are used.

This means you can create a data mapping between an item and a data series once and never have to recreate it in other studies.

Even when a mapped item and data mapping are not used together in a study, the association still exists. If you use the data mapping in another study and later add the item to the study, the item's mapping is restored. Similarly, the data mapping is restored if a study contains an item and the data mapping is later added to the library.

How are study objects that are part of a data mapping copied?

You can copy study objects from a library to a study or another library as well as from a study to another study. You also can copy study objects in the Project Explorer.

When you copy a data mapping, data set, or data series within a study or library, the new study object contains item mappings.

Copied study object	Copied within a study or library	Copied from one study or library to another
Data mapping, data set, or data series	Mappings to items that are part of the data series are retained in the new study object.	Item mappings are not copied to the new study object.
Item, Form, or study event that is mapped to a data series	The new study object is mapped to the data series. If you break the link between the original and the new study object, the new study object is still mapped to the data series.	The study object is copied, but data mappings are not copied. **Note:** If you drag and drop a study object that is mapped to a data series, and the study object already exists in the library, the database contains a data point for the study object, and the drop operation reuses that data point as is. The application warns you that the drag and drop operation is not supported. If you continue, any data mappings in the dropped study object that are different from the data mappings that are associated with the study object that already exists in the library are removed.

> **Note:**
>
> When a data series is copied within a study or library, the items that are part of a data series are not copied, but data series mappings to items are copied. For example, if an item is added to a data series, and the item is mapped to be part of the data series only when the item appears in a specific form, the mapping of the item to the data series for the form is copied. Similarly, if you copy a data set or mapping definition containing a data series, the mappings are also copied. If you use the new data series in another study, the mappings are retained. If you later add the item and form that are mapped to the data series to the study containing the data series, the mapping appears in the Data Series Summary tab.

What are the custom property settings and design rules for custom context panels?

The table below describes the custom property settings and design rules for custom context panels.

Design consideration	Custom property settings	Design rules
Data set	Panel Type—Context panel.	A data mapping can have only one data set for which the Panel Type value is Context panel.
Data series for:	-	-
• Subject key item	• Context Type—Subject-related context item. • Is Key—True.	• A context panel can have only one subject key item. • If the data type of the data series is Text, the value of the DB Format Length custom property cannot be greater than 80.
• Block key item	• Context Type—Visit-related context item. • Is Key—True.	A context panel can have only one block key item.
• Page key item	• Context Type—Page-related context item. • Is Key—True.	A context panel can have only one page key item.
Data series for the following key items for repeating visits and forms:	-	-
• Block repeat key (visit index) item	• Context Type—Visit-related context item. • Is Key—True. • Repeated—True.	A context panel can have only one block repeat key item.
• Page repeat key (form index) item	• Context Type—Page-related context item. • Is Key—True. • Repeated—True.	A context panel can have only one page repeat key item.

Mapping to a data series

In this section:

- What are my options when mapping an item to a data series?
- Which item data types are compatible with which data series?
- How are units of measurement mapped?
- Why are data dimensions the keys to viewing data?
- How does Oracle Central Designer process data series with unmapped items and without items?

What are my options when mapping an item to a data series?

You have the following options for mapping an item to a data series:

- The item is always mapped to the data series, on every form, in every study, and in the library.
- (Available only when a study event is selected.) The item is mapped to the data series only when it appears on any form in a specific study event. You can select this option for multiple study events.
- The item is mapped to the data series only when the item appears on a specific section (or form, if the form has no sections). You can select this option for multiple sections or forms.
- Available only when a study event is selected.) The item is mapped to the data series only when it appears on a specific form in a specific study event.
- The item is not added to the data series. For example, an item can be mapped to one data series in a study but not another.

Which item data types are compatible with which data series?

When you create a data series, you select a data type for it. When you add items to data series, their types must be compatible.

The following table indicates the item types that you can add to each data series type.

Item type	Text	Integer	Float	Date time
Text item	Yes	No	No	No
Integer item	Yes	Yes	Yes	No
Float item	Yes	No	Yes	No
Date time item	Yes. You are asked if you want to choose part of the date or the whole date.	Yes. You are asked to choose the part of the date.	No	Yes

Tips:

- You can add any item to a data series with a text type, but if the data mapping is for a CDD, the value that is provided for an item (in InForm) is saved in the

customer-defined database (CDD) as the data type of the data series. Therefore, if you add a float item to a text data series, the float item is saved as a text item in the CDD.

- In a rule data mapping, Oracle recommends creating data series with a type that matches the type of the item or items that will be added to the data series.

How are units of measurement mapped?

When an integer or float item that has data collected in multiple units is added to a data series in a mapping, the Item has units dialog box appears, prompting you to choose the data value to map to the data series.

You have the following options:

Option	Description
Normalized Value	Map the normalized value of the item with the data series. Normalization is the process of converting data to a required format. The normalized units appear in parentheses.
Entered Value	Map the entered value of the item with the data series. The entered value can be the same as or different from the normalized value.
Entered Unit	Map the unit in which a value is entered.

For example, a Weight item appears on three forms. Two forms collect the weight value in kilograms, and one form collects the weight value in pounds. The Weight items are normalized to kilograms.

Values collected or mapped	Source	Values in data series
Values collected for the Weight items	Form 1	75 kg
	Form 2	155 lb
	Form 3	62 kg
Normalized values mapped to a data series	Form 1	75
	Form 2	70.45
	Form 3	62
Entered values mapped to a data series	Form 1	75
	Form 2	155
	Form 3	62
Entered units mapped to a data series	Form 1	kg
	Form 2	lb
	Form 3	kg

Why are data dimensions the keys to viewing data?

When you create a data set, you specify standard data dimensions, which indicate the additional information that will be saved when study data is collected.

> **Note:**
>
> Clintrial users might find it helpful to compare specifying data dimensions to choosing a panel type. Data dimensions are similar to panel keys.

Standard data dimension	Information saved
Study	RefName of the study.
Subject	Subject ID.
Section	RefName of the section.
Section Index	Instance of a repeating section.
Event	RefName of the study event.
Event Index	Instance of a repeating study event.
Form	RefName of the form.
Form Index	Instance of a repeating form.
Item	RefName of the item.

You can also specify custom data dimensions. Like standard data dimensions, custom data dimensions specify additional information that is saved when study data is collected. You can provide names and values for custom data dimensions by selecting or creating a codelist, and you can allow a user-defined value. When you add an item to a data series contained by the data set, you are prompted to select a custom dimension label. You can choose a label from the list of codelist items, or, if providing a user-defined value is allowed, you can type a label name.

> **Note:**
>
> In CIS data mapping definitions, custom dimensions are used to identify a subset key item for pages with multiple sections that contain the same panel items. The value of the subset key item determines the section in which data appears.

How does Oracle Central Designer process data series with unmapped items and without items?

A data series can have mapped items, unmapped items, or no items.

When generating CIS data mappings, the Oracle Central Designer application processes data series with unmapped items and data series with no items as follows:

- **Unmapped items**—The Oracle Central Designer application generates the panel mappings for the data set where the data series is created. The item mappings for the panel have no control path specifications.
- **No items**—The Oracle Central Designer application does not generate mappings for the data series. If none of the data series for a data set have any items, the Oracle Central Designer application does not generate a panel mapping for the data set. However, note the following exceptions:
  - **Enrollment panel**—The Oracle Central Designer application always generates mappings for the Clintrial enrollment panel. If a data set for a

custom enrollment panel does not exist, the enrollment panel mappings are made up of:

* The items in the combined screening and enrollment forms in the study design, if they exist.
* The items in the combined default screening and enrollment forms generated by the Oracle Central Designer application, if the forms are not defined in the study design.

– **Non-patient data panel**—If a data set has a Panel Type property value of Non-Patient Data, the data series have no items by definition. The Oracle Central Designer application generates mappings for a non-patient data panel and does not generate item mappings.

– **Derived item**—If a data series in the data set has a Derived property value of True, the Oracle Central Designer application generates an item mapping with no control path.

Mapping to a data set

In this section:

- What are the standard data dimensions and data set methods?
- Why are data dimensions the keys to viewing data?

What are the standard data dimensions and data set methods?

When you create a data set, you can select standard data dimensions that enable the data set methods you need in the Data Mappings tab.

Each data set method enables you to reference a particular subset of the instances of an item in a study. For example, the StudyEvent(StudyEvents) data set method returns a data set subset with data from only the specified study event. To enable the StudyEvent(StudyEvents) data set method, you select the Event standard data dimension when creating the data set.

You can use this approach if you design your data mappings before the complete specifications for your rules are known. With this approach, you can add an item to a data series without considering all of the forms and study events in which it is used. In your rule expression, you can use data set methods to select specific instances of the item.

> **Note:**
>
> This approach is less efficient than adding an item to a data series with a data mapping type that narrows the selection of instances of the item. When possible, select for specific instances of an item when adding it to a data series.

Why are data dimensions the keys to viewing data?

When you create a data set, you specify standard data dimensions, which indicate the additional information that will be saved when study data is collected.

Data dimensions are the keys to the data. The way the keys are defined determines how you can view the data that is collected.

For example, a Vital signs data set contains several data series, including Weight. After data is collected, the Weight data series provides the weight values that were recorded in the study. The data series does not include context information, such as identifying information for the subject and the study event in which weight was recorded. To provide this information, you can specify standard data dimensions for a data set.

CDD mappings

In this section:

- What is a Custom-Designed Database (CDD)?
- Example—Creating a CDD mapping
- How data mappings are deployed to CDD tables
- What are the target key types for tables that do not pivot?
- What are the target key type for pivot tables?
- How can I map each drop-out reason to a separate CDD column?

What is a Custom-Designed Database (CDD)?

A data series is a grouping of one or more items with the same clinical meaning, such as one or more items that measure weight.

You can add items to a data series, and the items that you add can appear on multiple forms and study events. A data series provides you with a grouping of all study data collected for the item or items.

> **Note:**
>
> The only place to create a data series is in a data set. the only place to create a data set is in a data mapping. To view this data in an organized way, you must map the data series to a Customer-Defined database (CDD) to view the data in an organized way.

When you create a data series, you are prompted to provide a title, RefName, and alias for the data series.

- Because RefNames must be unique throughout a study, you must create an alias if the RefName is used by a study object. Data series aliases must be unique within a data set.
- If an alias is present, it is used as the column name in the customer-defined database (CDD) or as the Clintrial item name in CIS mappings.
- If an alias is not present, the RefName is used as the column header.

Example—Creating a CDD mapping

The following data mapping could be used to create a customer-defined database (CDD) in the InForm application.

Data mapping	Data set	Data series	Items	Standard data dimensions
Study name	Vital Signs	BP	Blood pressure	Subject Study Event
-	-	Temp	Temperature	-
-	-	PulseRate	Pulse Rate	-
-	Demographics	Gender	Gender	Subject Study
-	-	DOB	Date of Birth	-
-	-	Race	Race	-

How data mappings are deployed to CDD tables

When you create a deployment package and choose one or more data mappings to create CDD data mappings:

- Each data set becomes a target table, and each data series becomes a column in the table.
- The key columns of the target tables are defined by the value of the Target Key Type CDD custom property on the data set.
- Additional attributes of the target tables and columns are defined by the values of CDD custom properties on the item, data set, and data series.
- When you map an item with a unit into a text data series, you must choose whether to map the entered value, normalized value, or entered unit. However, all items are mapped as the entered value regardless of what is specified when the item is mapped. InForm CDD supports the mapping of the different parts, but there is no option in InForm to choose the column names or which parts to include, so the CDD data mapping from data mapping definitions ignores this setting.
- All values in a multi-select codelist are mapped to a single column. It is not possible to define a data series mapping in such a way that each possible value of a multi-select codelist appears in a different CDD table column.
- When you define a data set, you can specify one or more standard data dimensions and custom data dimensions. Standard and custom data dimensions are not used in CDD data mappings.
- You can define CDD data mappings for associations by associating two forms and selecting those forms as the value of the Associated Forms property on a data set.

What are the target key types for tables that do not pivot?

These target key types enable you to define CDD tables in which data is grouped by a portion of the control path of the data point in the InForm application.

For example, to capture all of the data for a single patient in one row, you might define a target table with the Patient Only target key type. To capture the data for each form in a single row, with a new row for each patient and visit, you might define a target table with the Patient to Form target key type.

The primary key of the target table determines how data is inserted into CDD target tables. When you create a CDD target table definition, the primary key of the table is a set of database IDs (DBUIDs) and indexes that correspond to the components of a data point's control path or a subset of the control path. When the InForm application loads data into a CDD table, it creates a new row each time the value of the primary key changes.

In tables that do not pivot, each target key type specifies the components of the primary key of the target table. For example, the primary key of a table with a target key type of Patient to Form consists of columns containing the PatientID, VisitID, ItemsetIndex, VisitIndex, and FormID.

Target key type	Primary key components	Data grouping in target table
Patient Only	PatientID, FormIndex, ItemsetIndex.	All data for a patient in one row.
Patient Visit	PatientID, VisitID, FormIndex, ItemsetIndex, and VisitIndex.	All data for a visit in one row, with a new row for each patient or visit.
Patient to Form	PatientID, VisitID, FormIndex, ItemsetIndex, VisitIndex, and FormID.	All data for a form in one row, with a new row for each patient, visit, or form.
Patient to Section	PatientID, VisitID, FormIndex, ItemsetIndex, VisitIndex, FormID, and SectionID.	All data for a section in one row, with a new row for each patient, visit, form, or section.
Patient to Itemset	PatientID, VisitID, FormIndex, ItemsetIndex, VisitIndex, FormID, SectionID, and ItemsetID.	All data for an itemset instance in one row, with a new row for each patient, visit, form, section, or itemset row.
Patient to Item	PatientID, VisitID, FormIndex, ItemsetIndex, VisitIndex, FormID, SectionID, ItemsetID, and ItemID.	All data for an item in one row, with a new row for each patient, visit, form, section, itemset, or item.
Patient to Control	PatientID, VisitID, FormIndex, ItemsetIndex, VisitIndex, FormID, SectionID, ItemsetID, ItemID and five ControlIDs. **Note:** A target table with the Patient to Control key type also contains a data label that can be used for data selection. The data label is specified in the Data Label custom property of the item.	Each control on a separate row.

What are the target key type for pivot tables?

Target key types for pivot tables enable you to define CDD tables in which you can map multiple data points to the same CDD table column or associate a particular data point with each row in the table.

In pivot tables, insertion of data is organized around a set of rows called a pivot set. The data points that make up a pivot set share the same values in specified parts of their control paths. The target key type of a pivot table determines where each pivot set breaks by defining which parts of the control path are the same within a pivot set.

For example, in a table with a target key type of Pivot Section, a pivot set is made up of all data points in which the patient, visit, form, and section components of the control path match.

One of the columns in a pivot table is identified as the pivot column. Each time the InForm application loads one pivot set of data into a pivot table, it creates a new row for each data point mapped to the pivot column, and it duplicates data points mapped to nonpivot columns in each of those rows.

In pivot tables, the target key type determines the composition of a pivot set. Within a pivot set, data points mapped to the columns that are not in the pivot set are repeated in each row. You might choose one of these target key types to be able to select all data values that have some related data value in common, for example, to select all lab values for a specific test that were collected on the same date.

The primary key columns are PatientID, VisitID, ItemsetIndex, VisitIndex, FormID, SectionID, ItemsetID, ItemID, and five ControlIDs. Pivot target tables also contain a data label that can be used for data selection. The data label is specified in the Data Label custom property of the item.

Target key type	Pivot set components
Pivot Patient	PatientID and VisitIndex.
Pivot Visit	PatientID, VisitID, and VisitIndex.
Pivot Form	PatientID, VisitID, FormID, and VisitIndex
Pivot Section	PatientID, VisitID, FormID, SectionID, and VisitIndex

How can I map each drop-out reason to a separate CDD column?

If you are implementing a Customer-defined Database (CDD), and, for example, want to map each drop-out reason to a separate CDD column, we recommend that you consider using one of the following designs:

- **Create a compound item**—Create a compound item in which the No response to the study completion status question has multiple-selection child items for each drop-out reason. The compound item and its child items do not have a value for the Special Fields custom property.
- **Create a hidden Yes No item**—Create a hidden item with a codelist that has Yes and No codelist items.
  Custom properties:
  - **Item**—Special Fields property value is **Completion status (Study Completion)**.
  - **Yes codelist item**—Study Completion Status Items value is **Complete Study (Study Completion)**.
  - **No codelist item**—Study Completion Status Items value is **Incomplete Study (Study Completion)**.
- **Create a hidden item**—Create a hidden item with a codelist in which each codelist item corresponds to a child item in No response of the visible compound item.
  Custom property:
  - **Item**—Special Fields property value is **Drop out reason (Study Completion)**.
- **Create calculation rules**—Create calculation rules that map:

  - The Yes response in the compound item to the Yes codelist item in the hidden Yes No item.
  - The No response in the compound item to the No codelist item in the hidden Yes No item.
  - The selected child item in the No response of the compound item to the corresponding codelist item in the hidden Reason for noncompletion item.

> **Note:**
>
> Because the compound item allows multiple selections, and the hidden item requires a single selection, the rule must contain logic that prioritizes the noncompletion reason to select in the hidden item if multiple reasons are selected in the compound item.

- **Create a CDD mapping**—In a CDD mapping, map each child item in the compound item to a different data series. Each data series maps to a separate CDD column.

CIS mappings

In this section:

- How do I set up CIS data mapping for date time items?

How do I set up CIS data mapping for date time items?

Clintrial database result	Data series and data mapping setup
Entire date appears in a DATE database column. The DATE data type corresponds to the Oracle DATE database format.	1. In the **Item Editor** for the date time item, select the **Required** and **Allowed** checkboxes for each date part. 2. Map the date time item to a data series with a type of Date Time.
Entire date appears in a DATETIME database column. The DATETIME data type corresponds to the Oracle DATE database format.	1. In the **Item Editor** for the date time item, select the **Required** and **Allowed** checkboxes for each date and time part. 2. Map the date time item to a data series with a type of Date Time.
Entire date appears in a TEXT database column. The TEXT data type corresponds to the Oracle VARCHAR(n) format.	1. Map the date time item to a data series with a type of Text. 2. In the **Date-Time Data Point** dialog box, select **All in one column**, and click OK.

Clintrial database result	Data series and data mapping setup
Each date time part appears in a separate TEXT database column. The TEXT data type corresponds to the Oracle VARCHAR(n) format.	1. Map the date time item to a data series with a type of Text. 2. In the **Date-Time Data Point** dialog box, select **Split columns**. 3. In the **CIS Date Part** list, select the date time part to map, and click OK. 4. Repeat these steps for each date time part. Place each date time part in a different data series.
Each date time part appears in a separate FIXED database column. The FIXED data type corresponds to the Oracle NUMBER(n) database format.	1. Map the date time item to a data series with a type of Integer. 2. In the **Date-Time Data Point** dialog box, select **Split columns**. 3. In the **CIS Date Part** list, select the date time part to map, and click OK. 4. Repeat these steps for each date time part. Place each date time part in a different data series.

Clintrial mappings

In this section:

- How are data mappings generated for specialized Clintrial panels?
- How are data mappings deployed to Clintrial study objects?
- What are Clintrial subsets?
- How does Clintrial use subset keys and subset values in Oracle Central Designer?
- What is the difference between block keys and page keys in CIS data mappings?

How are data mappings generated for specialized Clintrial panels?

Panel Type value	How panel is used	What is included in CIS data mappings
Context	Contains context items, which are included in every record in a clinical data table. The context items form the primary key of the clinical data record.	• **If selected**—Custom context panel made up of the items that are mapped to the data series in the data set. • **If not selected (default)**—Default context panel created during deployment. **Note:** A data mapping can have only one data set with a Context panel type.

Panel Type value	How panel is used	What is included in CIS data mappings
Enrollment	Contains screening and enrollment data for each study subject. The Clintrial application does not use separate records for screening and enrollment data.	• **If selected**—Custom enrollment panel made up of the items that are mapped to the data series in the data set. The data mappings for the custom enrollment panel exist only in the data mapping where the data set is defined. • **If not selected (default)**—Enrollment panel made up of: – The items in the combined screening and enrollment forms in the study design, if they exist. – The items in the combined default screening and enrollment forms generated by the Oracle Central Designer application, if the forms are not defined in the study design. – The data mappings for either version of the default enrollment panel are included in the mappings for all data mappings for a study.
Non-Patient Data	Contains data that is not related to a particular subject or visit, such as standard coding thesauruses, view codelists, or laboratory normal ranges.	If selected, the Oracle Central Designer application generates data mappings for a non-patient data panel that has a column for each data series in the data set. **Note:** The data series in a non-patient data set must not have any items mapped to them.

How are data mappings deployed to Clintrial study objects?

When you create a deployment package and choose one or more data mappings to use to create CIS data mappings:

- Each data set becomes a panel, and each data series becomes an item in the panel.
- A custom data dimension on a data set is mapped to the Subset Item in the Clintrial application. Only one custom data dimension is supported for each data set.
- The Panel Type is defined by the value of the Panel Type CIS custom property on the data set.

- Other panel and panel item attributes are defined by the values of CIS custom properties on the study event, form, data set, and data series.
- Only normalized values mapped to the Clintrial application.

What are Clintrial subsets?

In the Clintrial application, subsets provide a way to group similar items together in a page section.

A subset page section can occur multiple times on a study page in a Type 0, Type 2, or Type 4 panel, with each different value of a subset key item representing distinct rows (subsets) of data. Each occurrence of a subset page section constitutes a separate observation.

You might want to set up data mappings for a subset if both of the following are true:

- Your InForm study collects identical data items on multiple forms (for example, lab test results for different body systems).
- You want to store the data in a single panel in the Clintrial application.

For example, in the Medika-Clinical sample study in the Clintrial application, the LABLNG page template has subset page sections for blood chemistry (LABCHEM), hematology (LABHEM), and urinalysis (LABURN). Each of these sections is made up of the same panel items, including the subset key item TEST_TYPE. The value of TEST_TYPE distinguishes the type of lab test represented by each subset of lab data.

How does Clintrial use subset keys and subset values in Oracle Central Designer?

When subsets are used in the Clintrial application, one item in a panel is designated as the subset key item. The value of the subset key item determines the record in which to store a set of subset data.

In the CIS data mappings generated by the Oracle Central Designer application:

- The panel (CTPanel) data mapping identifies the subset key item. The Oracle Central Designer application obtains the name of the subset key item from the name of a custom dimension defined on a data set. An unmapped item with the name of the custom dimension is added to the data mappings for the panel and becomes a column in the panel when synchronized to the Clintrial application.
- The item (CTItem) data mappings hold the subset value (the value of the subset key item). The Oracle Central Designer application obtains the subset value from the custom dimension label that you associate with an item when you map it to a data series within the data set.

What is the difference between block keys and page keys in CIS data mappings?

Block keys are identifiers for Clintrial blocks, which correspond to Oracle Central Designer study events and InForm visits. Page keys are identifiers for Clintrial pages, which correspond to Oracle Central Designer and Oracle InForm forms.

All data that is synchronized to Clintrial must have a block key and a page key associated with it. The context panel in a Clintrial study contains items that hold the values of the block key and page key. These items are called the block key item and the page key item.

In Oracle Central Designer, the data series in the data set that is marked as the context panel (the value of the Panel Type custom property is Context Panel) identify the block key item and the page key item.

For more information, see:

- How are block key values assigned?
- How are page key values assigned?

How are block key values assigned?

Any of the following definitions can be used as the value of the block key item:

- By default, the RefName of the study event.
- If the RefName of the study event contains a double underscore (for example, Week2__21), the value that follows the double underscore.
- The Block Key Value custom property for the study event. If a value is specified for the Block Key Value custom property, that value overrides the block key value formed from all or a part of the RefName.

For common visits, the value of the Shared Form Block Key custom property on the study design becomes the value of the block key in data mappings for the internal visit definition (the CommonCRF visit) that the InForm application requires for common forms.

The resulting block key value must conform to the specifications of the data series for the block key item in the context panel:

- The data type must convert to a compatible data type.
- The length must be within the length specified in the DB Format Length CIS custom property.
- If the data type of the data series is float, the precision must be within the precision specified in the DB Format Float Precision CIS custom property.

For example, validation fails if:

- The block key value is First but the block key item has a type of Integer.
- The block key value is 99 but the page key item has a Length of 1.

How are page key values assigned?

Any of the following definitions can be used as the value of the page key item:

- By default, the RefName of the study form.
- If the RefName of the study form contains a double underscore (for example, Hema__21), the value that follows the double underscore.
- The Page Key Value custom property for the study form. If a value is specified for the Page Key Value custom property, that value overrides the page key value formed from all or a part of the RefName.

The resulting page key value must conform to the specifications of the data series for the page key item in the context panel:

- The data type must convert to a compatible data type.
- The length must be within the length specified in the DB Format Length CIS custom property.
- If the data type of the data series is float, the precision must be within the precision specified in the DB Format Float Precision CIS custom property.

For example, validation fails if:

- The page key value is First but the page key item has a type of Integer.
- The page key value is 99 but the page key item has a Length of 1.

Data mappings vs rules

In this section:

- Why should I use rules to create data mappings?
- When should I use a data mapping and when should I use a rule?
- How can I map to a specific instance of an item that appears multiple times in a study?
- Example of data mappings for rule creation

Why should I use rules to create data mappings?

Because data mappings behave like global variables, you can create data mappings to classify and query data more easily in rules. Any rule in a study can refer to any item that is part of a data mapping in the study.

Using data mappings for rules also simplifies the process of looking at arrays of data, such as data that is collected over time. When a single item is used in multiple forms, you can use the array of data collected for the item in rules. For example, you can check that dates of visits are sequential or calculate aggregate values for the data.

Useful structure for rule creation

The first data mapping that you create for the purpose of rule creation should contain subject information, as you are most likely to need this information to be available for all rules. Over time, you will probably add and subtract information in the data mapping. The following data sets provide a useful structure:

- **A data set for single-item data series.**
  In this data set, include items for which the data does not change in the study, including enrollment-type items, demographics items, and any other items that are static for a subject. Examples of items that you might include in the data set include Initials and Date of Birth.

  When a data series contains an item on a single form, and the item is not part of a repeating form or a repeating section, the data series is treated as an alias for the item itself and can be accessed as if it were a single global variable.
- **A data set for ongoing, per-visit information.**
  In this data set, include items with values that change for the subject from study event to study event. This type of information is an array of data. For example, you might include items that appear on a Vital Signs form or a Physical Exam Results form, or items that are related to adverse events or concomitant medications.

Mappings and data extraction

Mappings can also be used for data extraction.

When should I use a data mapping and when should I use a rule?

If you need to create a rule on a study object, such as a form, but an item that the rule must reference is not in the scope of the study object, you have the following options:

- Add the item to a data series, so you can use the item in any rule in the study.
- Move the rule to a higher-level study object that includes all study objects that are needed for the rule in its scope.

There is no set guideline for which approach is better. The Oracle Central Designer application does not require you to use data mappings for rule creation, and you must weigh the benefits and limitations of using data mappings when making this decision.

- **Benefits and limitations of using a data mapping.**
  You can create the rule on a lower-level study object, thus improving the likelihood that the rule will be reused.

  However, you must include the data mapping in every study that uses the study object on which the rule is created.
- **Benefits and limitations of moving a rule to a higher-level study object.**
  You can create the rule on the study object with all study objects in its scope without adding another item to the data mapping.

  However, if the rule is created at a higher-level study object, the likelihood that it will be reused might be low. For example, some organizations might be more likely to reuse an item or form rather than an entire study event.
- **Oracle recommendation.**
  Oracle recommends that you create a data mapping and use it for rule creation if you use:
  - Every instance of a study object in one or more rules. Add the study object to a data mapping.
    For example, you should create a data mapping if you have a repeating Adverse Event form and a rule must reference the event description or event ID from every single instance of the form.
  - An item frequently in a study. Add the item to a data mapping.
  - An item and a rule in many studies. Consider adding the item to a data mapping.

How can I map to a specific instance of an item that appears multiple times in a study?

If an item that you will use in a rule appears multiple times in a study, you can use either of the following approaches to setting up a data mapping so that you can reference specific instances of the item:

- When you add an item to a data series in the Data Series Summary tab of the Form or Study Event editor, specify the instances of the item that you want to be mapped to the data series.
- When you create a data set, select standard data dimensions that enable the data set methods you need in the Data Mappings tab.

Example of data mappings for rule creation

The following sample data mappings can be used for rule creation.

Data mapping	Data set	Data series	Items	Sample rule expressions
Rules (Single data point in data mapping)	BMI	Weight	• Weight item always part of the data series. • Weight item appears on only one form.	BMI.Weight.Value / Math.Pow(BMI.Height.Value, 2)
-	-	Height	• Height item always part of the data series. • Height item appears on only one form.	-
Rules (Multiple data points in data mapping)	BMI	Weight	• Weight item always part of the data series. • Weight item appears on multiple forms, so you must specify which value to use in the rule expression.	BMI.StudyEvent(StudyEvents.Visit1).Weight.Values[0] / Math.Pow(BMI.Height.Value, 2) BMI.StudyEvent(StudyEvents.FinalVisit).Weight.Values[0] / Math.Pow(BMI.Height.Value, 2)
-	-	Height	• Height item always part of the data series. • Height item appears on only one form.	-

Note:

- Math.Pow computes the power of a value. You can also define functions for calculating a squared value.
- As with any calculation rule, in data mapping rules you should check for empty values and for division by zero.

Data mapping examples

In this section:

- Different ways to set up data mappings
- What are the data mappings to create an SDTM model?
- How do standard versus custom dimensions change the view of the data?

Different ways to set up data mappings

Consider a study in which a weight value is collected for every subject. To group all weight information, you have several options:

- If a single weight item appears on multiple forms, you can add a weight item to a weight data series.
- If multiple weight items appear in the study, you can:
  - Add all weight items to a weight data series.
  - Add one or several weight items to multiple weight data series.

If you create three data series (one for each value type), you can map a different value type to each data series.

> **Tip:**
>
> To see the mappings at a glance, use naming conventions to indicate the data series used for the different value types. For example, for the weight data series, create the following data series: Weight_Normalized, Weight_Entered, and Weight_Units.

What are the data mappings to create an SDTM model?

Mapping	Data set	Data series	Items
SDTM	VS_OBS	tempEnteredValue tempNormalizedValue tempEnteredUnit	The temp item is always part of all three data series.
-	-	weightEnteredValue weightNormalizedValue weightEnteredUnit	The weight item is always part of all three data series.
-	-	systolicValueEnteredValue systolicValueNormalizedValue systolicValueEnteredUnit	The systolicValue item is always part of all three data series.
-	DM	BRTHDT	Date of birth
-	-	SEX	Sex

Mapping	Data set	Data series	Items
-	-	ETHNIC	Ethnicity

How do standard versus custom dimensions change the view of the data?

To understand how you might use custom data dimensions, consider the following example, which illustrates how you can use standard and custom data dimensions to look at your data in different ways.

Item	Options
Left eye cloudiness	Clear Moderately cloudy Very cloudy
Left eye color	Brown Blue Green
Right eye cloudiness	Clear Moderately cloudy Very cloudy
Right eye color	Brown Blue Green

Subject	Left cloud	Left color	Right cloud	Right color
A	Moderately cloudy	Blue	Clear	Blue
B	Very cloudy	Brown	Very cloudy	Brown
C	Clear	Green	Clear	Blue

Alternately, you might want to pivot your data on a piece of information, such as Eye.

In the following example, Subject is selected as a standard data dimension. In addition, a custom data dimension of Eye has been created with the values of Left and Right. When you add items that collect data for the left eye to the data series, you select the Left value for the custom dimension. When you add items that collect data for the right eye to the data series, you select the Right value for the custom dimension.

Subject	Eye	Cloudiness	Color
A	Left	Very cloudy	Blue
A	Right	Clear	Blue
B	Left	Very cloudy	Brown
B	Right	Very cloudy	Brown
C	Left	Clear	Green
C	Right	Clear	Blue

Validation and deployment

In this section:

- What's involved in study validation and deployment?
- Validation and deployment definitions
- How do the Oracle Central Designer study components appear in Oracle InForm?
- Validation
- Deployment

What's involved in study validation and deployment?

Study validation and deployment is a two-step process:

1. Prepare a study to move from the design environment to a test or production environment.
2. Move the study to the test or production environment.

For validation to succeed, a study must contain the following study objects at a minimum:

- One study event.
- One form for each study event.
- One item for each form.
- A label for each codelist item.

> **Tip:**
>
> - You can validate and deploy a study but not a library.
> - You must validate a study before you can create a deployment package. The process of validation checks for conditions that would make it impossible to deploy the study. When you validate a study, the Oracle Central Designer application creates a validation baseline.
>
> Validate as often as needed to make sure that the design will be deployable. When deciding how frequently to validate, consider that validation requires you to save the study.

Validation and deployment definitions

Study validation and deployment use the following terms.

Term	Definition
Approval	Consent to deploy a study directly to the Oracle InForm application, given by a user with the appropriate rights.

Term	Definition
Baseline	A snapshot of all components in a study. Validation creates a baseline.
Baselines Browser	A browser in which you view the results of validation and make temporary baselines public so that other users can work with them.
Deployment	The process of sending a study to a target application. To collect data, a study must be deployed into a target application as a complete deployment package. There are two types of deployment: • **Automated**—A study design is moved directly from the Oracle Central Designer application to the Oracle InForm environment. • **Manual**—You must deliver and install a deployment package to the Oracle InForm environment.
Deployment instance	The environment to which you deploy a study.
Deployment request	A request to deploy a study directly to the Oracle InForm application. • If your study is configured so that deployment requests require approval, the user who makes the request must have the appropriate rights to deploy the study to the Oracle InForm application. • If your study is configured so that deployment requests do not require approval, the user who makes the request does not need to have the appropriate rights to deploy the study to the Oracle InForm application.
Jobs Browser	A browser in which you view the results of asynchronous jobs, such as validation or import.
Pending Approvals tab	A tab on the Home page in which you view, approve, or reject deployment requests that are waiting your approval, and review approval records.
Study validation	The process of checking the status of a study to indicate if the study is ready for deployment. The study validation process determines whether all essential components exist and are consistent.
Target application	The application (for example, the Oracle InForm application) on which a completed deployment package runs.

How do the Oracle Central Designer study components appear in Oracle InForm?

When you deploy a study created in the Oracle Central Designer application to the Oracle InForm application, the Oracle Central Designer study components and workflow are

translated to Oracle InForm study components. The conversion to Oracle InForm study components is based on both the data definition of each study component and the layout specified for each form or item in the Oracle Central Designer application.

Oracle Central Designer study component	Corresponding Oracle InForm study component	Notes
Codelist	Radio, checkbox, or pulldown control	The following codelist specifications determine how codelist items deploy to the Oracle InForm application: • **Single selection**—Deploys as a radio or pulldown control. • **Multiple selection**—Deploys as a checkbox control. • The Layout section of the Oracle Central Designer Options dialog box (available from the Tools > Options menu) specifies the following defaults: – Automatic formatting of codelist-based controls based on the number of codelist items. – Default control sizes. • The layout specification in the Oracle Central Designer application determines whether a radio control is displayed vertically or horizontally. You can also use the layout specification to indicate whether a codelist is single selection, single selection with user, or multiple selection, and whether codelist items in a single-selection codelist deploy as a radio control or a pulldown control.
Codelist item	Simple control	-
Collaboration note	No corresponding component	This type of study object is not deployed to the Oracle InForm application.
Data series	• Table column in CDD mapping definition. • Panel item in CIS mapping definition.	-

Oracle Central Designer study component	Corresponding Oracle InForm study component	Notes
Data set	• Table in CDD mapping definition. • Panel in CIS mapping definition.	The data dimensions of a data set form the key for each row of a CDD table. Data values defined as custom dimensions form pivot columns around which the data in the table is organized.
Description	No corresponding component	Study object descriptions are visible only in a Oracle Central Designer annotated study book.
Form	Form	• In the Oracle Central Designer application, a form note is specified in the layout definition. • The Short Title specified in the Oracle Central Designer application deploys as the form mnemonic in the Oracle InForm application. • The form RefName is used in Reporting and Analysis and in CDD table columns for which no data series alias exists.
-	Alternate form	• In the Oracle InForm application, an alternate form is used to collect new or changed information for those subjects who have started the original version of the form. • A form containing new or changed items in a subsequent, incremental deployment deploys as an alternate form for those subjects who have started the original version of the form. • Alternate forms are not created when you install an incremental deployment package that contains additions to repeating forms or itemsets.

Oracle Central Designer study component	Corresponding Oracle InForm study component	Notes
-	Associated forms	Two forms defined as repeating and linked with the AssociatedForm property in the Oracle Central Designer application deploy as associated forms in the Oracle InForm application.
-	Common form	A form defined as a common form deploys as a common form.
-	Date of Visit form	If you do not include a special Date of Visit item in the study, a default Date of Visit form is deployed to the Oracle InForm application.
-	Dynamic form	A form for which the precondition is the outcome of a workflow rule or global condition deploys as a dynamic form in the Oracle InForm application.
-	Enrollment form	If you do not include a special Enrollment form in the study, a default Enrollment form is deployed to the Oracle InForm application.
-	Regulatory report forms and visit report forms	You can create regulatory report and visit report forms in the NonClinical container in the Project Explorer. If you do not create the forms, default versions are generated and deployed.
-	Repeating form	A form defined as repeating in the Oracle Central Designer application deploys as a repeating form in the Oracle InForm application.
-	Screening form	If you do not include a special Screening form, a default Screening form is deployed to the Oracle InForm application.
Global condition	Rule	The deployment process treats a global condition as a rule and creates rule attachments, arguments, and dependencies in the Oracle InForm application as necessary based on the items referenced in the global condition definition.

Oracle Central Designer study component	Corresponding Oracle InForm study component	Notes
Help text	CRF Help	Instructions and Help defined for forms or items in the Oracle Central Designer application deploy as CRF Help in the Oracle InForm application. Instructions and Help defined for other study objects (for example, study events) in the Oracle Central Designer application do not deploy to the Oracle InForm application.

Oracle Central Designer study component	Corresponding Oracle InForm study component	Notes
Item	Item	Item deployment considerations: • The Oracle Central Designer application includes the following custom properties for Oracle InForm deployment: – **Collapsible** (for items)—Defaults to False in the Oracle InForm application. Collapsed items in the Oracle Central Designer application become dynamic controls in the Oracle InForm application. – **Display Override** (for items)—Defaults to False in the Oracle InForm application. – **Required** (for items)—Defaults to True in the Oracle InForm application. – **SDV Critical** (for forms and items)—Defaults to False in the Oracle InForm application. – **SDV Required** (for items)—Defaults to True in the Oracle InForm application. – **Special Fields** (for items)—Identifies items that have a special meaning in the Oracle InForm application, including special Date of Visit and Randomization items and items that appear on special forms. • Layout specifications determine how controls appear in the Oracle InForm application. For date time items, layout specifications include the specification of year ranges.

Oracle Central Designer study component	Corresponding Oracle InForm study component	Notes
-	Date/time control	Date time items in the Oracle Central Designer application become date/time controls in the Oracle InForm application.
-	Group control	A compound item defined with child items in the Oracle Central Designer application deploys in the Oracle InForm application as a group control consisting of the child items.
-	Nested control	An item in the Oracle Central Designer application that is conditional on another item deploys in the Oracle InForm application as a nested control within the item on which it is conditional.
-	Text control	Text, integer, and float items in the Oracle Central Designer application become the appropriate text controls in the Oracle InForm application.
-	Unit	• A base unit or a base unit and a single conversion unit specified in an integer, float, or yes no item definition in the Oracle Central Designer application deploy as units in the Oracle InForm application. • If more than one conversion unit is selected in the item definition, the conversion units deploy in the Oracle InForm application as a radio or pulldown control, depending on the layout option selected.
Library	No corresponding component	This type of study object is not deployed to the Oracle InForm application.
Library project	No corresponding component	This type of study object is not deployed to the Oracle InForm application.
Mapping	CDD or CIS mapping definition object	-

Oracle Central Designer study component	Corresponding Oracle InForm study component	Notes
Rule	Rule	The deployment process creates rule attachments, arguments, and dependencies in the Oracle InForm application as necessary based on the items referenced in the rule definition.
Section	Section	• In the Oracle Central Designer application, a section note is specified in the layout definition. • If you do not create a section for a form in the Oracle Central Designer application, a section with the same title as the form is automatically generated when the study is deployed to the Oracle InForm application.
-	Itemset	The items in a section defined as repeating in the Central Designer application are grouped into an itemset in the InForm application.
-	Repeating Data itemset	The items in a section defined as fixed and repeating in the Oracle Central Designer application are grouped into a Repeating Data itemset in the Oracle InForm application.
Short Question	Itemset column header	• If a Short Question is specified, the value is used for the column header that appears in the itemset. • If a Short Question is not specified, the value of the Default Question is used.
Study	Study	The study version (VERSIONDESCRIPTION attribute in Oracle InForm MedML) is a concatenation of: • The Title property of the study object. • The revision number of the validation baseline used to create the deployment package. • An abbreviation for the locale, if the deployment package is created for multiple locales.

Oracle Central Designer study component	Corresponding Oracle InForm study component	Notes
Study element	No corresponding component	This type of study object is not deployed to the Oracle InForm application.
Study event	Visit	The Short Title of a study event is used as the visit mnemonic in the Oracle InForm application.
-	Dynamic visit	A study event for which the precondition is the outcome of a workflow rule or global condition deploys as a dynamic visit in the Oracle InForm application.
-	Enrollment visit	A special Oracle InForm visit that must be included in the Oracle Central Designer study design. • The enrollment form must belong to the enrollment visit. • The enrollment visit must be a standalone visit in the study workflow. • The enrollment visit must be the second visit in the workflow after the screening visit.
-	Regulatory report and visit report visits	The deployment process creates regulatory report and visit report visits.
-	Repeating visit	A study event defined as repeating in the Oracle Central Designer application deploys as a repeating visit in the Oracle InForm application.
-	Screening visit	A special Oracle InForm visit that must be included in the Oracle Central Designer study design. • The screening form must belong to the screening visit. • The screening visit must be a standalone visit in the workflow. The screening visit must be the first visit in the workflow and the enrollment visit must be second.
Study project	No corresponding component	This type of study object is not deployed to the Oracle InForm application.

Oracle Central Designer study component	Corresponding Oracle InForm study component	Notes
Task	No corresponding component	This type of study object is not deployed to the Oracle InForm application.
Template	No corresponding component	This type of study object is not deployed to the Oracle InForm application.
Type	No corresponding component	This type of study object is not deployed to the Oracle InForm application.
No corresponding component	Calculated control	You cannot create calculated controls in the Oracle Central Designer application. You can create a read-only control that serves the same purpose as a calculated control in that it uses a rule to fill in data.

Note:

Components in MedML are named based on the RefNames of study objects in the Oracle Central Designer application, with the following two exceptions:

- PFElements. The RefName from the codelist item is concatenated with an underscore and a 40-character identifier that the application creates using the RefName, code, and translations of the codelist label. If you modify the RefName, code, or codelist label, the application creates a new PFElement.
- Group controls are prefaced with "GC_" only when multiple items are conditional on the same item.

Validation

In this section:

- What is a baseline used for?
- What checks are performed during validation?
- What information is not validated?
- Can I delete a validation baseline?
- What happens to the baseline when you upgrade?

What is a baseline used for?

A baseline is a snapshot of all the components in a study. Validation creates the baseline.

A validation baseline is temporary until you make it public, either explicitly or by using it to create a deployment package. Subsequent validation jobs that you run create a

new temporary validation baseline and replace the previous one. Only you can view, edit, or delete a temporary validation baseline that you created, or use that baseline in a deployment package.

What checks are performed during validation?

For a study to be deployed to Oracle InForm, it must pass a series of validation checks. For more information, see:

General validation checks

Validation area	Must be true for successful validation
Study objects	• All study object RefNames are valid and unique. • Reserved words are not used as RefNames. • References to study objects are valid (for example, if you delete an item from a form, you make sure that the layout does not continue to refer to the deleted item). • The study does not contain: – Duplicate references to a study object (for example, if you import an archived study that contains duplicate references). – References to study objects that are not included in the study. – Empty string resources. • A study object is not a child of itself. • Parent/child study object relationships are valid.
Locale and translation	• At least one locale is selected in the Study Editor as a deployment target. • Translations to all study languages are complete. • Notes on sections are translated for all locales. If you provide a translation and then clear the value, the translation is considered valid.
Layout	• The study contains form layout definitions for all deployable locales. • You have provided translations for captions and notes for all supported locales for the study. • An error has not occurred with any layouts.

Validation area	Must be true for successful validation
Rules	• Rules compile successfully, including rule templates and workflow rules, whether or not they are used. • Rules do not refer to study objects that have been deleted. • Rules reference the current RefNames of study objects. If a RefName is not updated automatically, you must manually update the RefName in the rule. • Only one current instance of a repeating form is referenced in a rule. • If the Current() method is used in the rule expression, the target of the rule action is a child of the study object referenced by the Current() method. In addition, validation considers the lowest level of Current() that you use. For example, for Visit1 and Form1: – The following expression is valid only if you apply the rule to a child study object of Visit1. **this.Visit1.Current().Form1.I1 == 1** – The following expression is valid only if you apply the rule to a child study object of Section1. **this.Visit1.Current().Form1.Current().Section1.Current()I1 == 1** – The following expression is valid only if you apply the rule to a child study object of Form1. **this.Visit1.Current().Form1.Current().I1 == 1** For more information, see the *Rules Reference Guide*.

Validation checks for Oracle InForm deployment

Validation area	Must be true for successful deployment to the InForm application
Study	The study has at least one study event.
Study design	A warning occurs if the title or RefName of the study design, when appended with the version and locale of the study design, might exceed 63 characters. If the warning occurs, shorten the title or RefName, or the deployment process truncates the title or RefName in the Oracle InForm application.
Common visit	For studies with common forms, if you translate a title or short title of the common visit for one language, the title and short title are translated for all languages.
Study event	• Each study event has at least one form. • A study event is not used on both a study element and a study design.

Validation area	Must be true for successful deployment to the InForm application
Form	• Each form: – Contains at least one item. – Has a layout defined for each locale that is deployed. – Does not contain duplicate items. – Is included in a study event no more than once. • Each Study Completion form has a Completion Status item. • Checks for form associations: – Associated forms in a repeating study event must have the same type; that is, both are repeating forms or repeating, common forms. – Forms in repeating study events can only be associated with forms in the same repeating study event. – A repeating, common form can be associated with more than one form if the forms are repeating, common forms in the same study event. – A form that is not repeating or common can only have one form association. – A warning occurs when associated forms are in different study events, and indicates that this functionality is available for Oracle InForm release 6.0.1 or later.

Validation area	Must be true for successful deployment to the InForm application
Section	For a regular section: • The section has a layout defined for each locale that is deployed. • If the section was deployed to a LIVE study, it is not changed to a dynamic grid section during an in-place revision or study version change. For a dynamic grid section: • The source object is a repeating form or section. • The source visit referenced in the dynamic grid section appears in the study. • The source visit referenced in the dynamic grid section is included in the study design. • The source visit referenced in the dynamic grid section is not repeating. • The source form referenced in the dynamic grid section appears on the visit referenced in the dynamic grid. • The source form referenced in the dynamic grid section is not common. • The source section referenced in the dynamic grid section exists on the referenced source form. • The source section referenced in the dynamic grid section is not also a dynamic grid section. • The source items referenced in the dynamic grid section appear in the study. • The source items referenced in the dynamic grid section exist on the referenced source forms or sections. • The codelist subset selection for an item is the same on the source object as in the dynamic grid section; that is, for an item with an assigned codelist subset, you have not changed or removed the codelist subset assignment on the source form after mapping the item to the dynamic grid. • Either the source form or section referenced in the dynamic grid is repeating, but not both. • The dynamic grid section does not appear on a common form. • The dynamic grid section does not reference its own parent form. • If the dynamic grid section was deployed to a LIVE study, it is not changed to a different type of section during an in-place revision or study version change. • If the dynamic grid section was deployed to a LIVE study, its source visit, form,

Validation area	Must be true for successful deployment to the InForm application
	section, or item path is not changed during an in-place revision or study version change. • The dynamic grid section contains items.
Item	• Questions for top-level items are not blank. • Year range for date time items is valid (for example, start year cannot be later than end year). • The precision value of a float item is not longer than the specified length of the item. • The nesting of compound and conditional items is not greater than five. If an item holds more than one child control, a group control is created, and each group control counts as one level of nesting. • Each compound item has at least one child item. • An item that is designated as a key item is not: – Formatted as a checkbox. – An item on which other items are conditional. – Conditional on another item if the key item is a child of a compound item. • The study does not contain any items for which **NA** or **UNK** is the RefName. • An item that is designated as Personal/ Protected Health Information (PHI) is not included in the subject line or body of an email to be sent by a rule.

Validation area	Must be true for successful deployment to the InForm application
Codelist and codelist item	• Each codelist has codelist items. • Each codelist item has a label for the appropriate locale. • Each codelist item has a label for the appropriate locale. • The codes of codelist items are unique within a codelist. • The codes for codelist items on text items do not exceed the length that is specified for the text item. • The codes for codelist items match the type of the codelist. For example, the codes for an integer codelist cannot contain letters. • The code of a codelist item that is conditional on another item has not been modified since the codelist item was made conditional. • Codelist labels do not contain apostrophes. • The Study Completion Status Item custom property is not set for codelist items in multiple items. • Each instance of a copied or linked codelist item has the same codelist type.

Validation area	Must be true for successful deployment to the InForm application
Codelist subset	• Each codelist subset has one or more codelist items. • Each codelist item in a codelist subset exists under the parent codelist. • Each codelist subset exists under the item on which the codelist exists. • Codelist items used for conditional values belong to the subset assigned to the conditional item on the form or section. • When a fixed repeating section references a codelist subset, the codelist items selected as fixed columns must exist in the referenced codelist subset. • Each rule that references a codelist subset must only reference the codelist items that are part of the subset. • Each rule test for a rule that references a codelist subset must only reference the codelist items that are part of the subset. • A codelist subset is selected if for each item instance if: – The item has a codelist with defined subsets. – The **Require codelist subset selection** setting is enabled for the study. • If you import a study with an item that has a codelist subset that references a codelist that is not assigned to that item, during validation, you are prompted to select a valid codelist.

Validation area	Must be true for successful deployment to the InForm application
Review state	• The maximum number of review states is not exceeded, and there are no duplicate State values. • State, Label, and Mnemonic are defined for a review state. • Label and Mnemonic are defined for each review stage. • Label and Mnemonic fields for a review state and each of its review stages have values for each required product locale. Values for an Oracle InForm product locale (English [United States] or Japanese [Japan]) are required if the locales specified for the study include a locale with the same language. For example, English translations are required if the study includes en-US or en-GB locales. • Label and Mnemonic for each review state are unique across locales. • Label and Mnemonic for each review stage are unique for each review state across locales. • Review stage names exist for each review stage and are unique within a review state. • Each review state has three defined review stages.
Workflow	• A study object does not have multiple global conditions. • A workflow object does not have two outgoing arrows without a rule. • All study objects in a workflow reference study objects that still exist in the study. If validation fails due to an invalid workflow, go to the Workflow Diagram tab for the workflow with the issue, and right-click in the white space of the diagram and select **Refresh Workflow** to correct the issue. • A warning occurs if a rule contains the UpdateWorkflow action. The UpdateWorkflow action is not required for studies deployed to Oracle InForm release 6.1.1 or later. • Each workflow rule is connected to a study element or study event.

Validation area	Must be true for successful deployment to the InForm application
Data-entry rule	• No rules are created on a linked item that is in multiple compound items. • The query message of a rule has 255 characters or fewer, not including the parameters. • For each data-entry rule, an item that triggers the rule is selected. If an item is not selected, you receive a warning during validation. • Each constant has a value (the length of the value must be greater than 0). • No email rules refer to items designated as Personal/Protected Health Information (PHI) in the subject or body of the email message.

Note:

If two rules (on different study objects) have the same name, in release 7.0 of the Oracle Central Designer application, you receive a warning during validation. Using the same rule name for rules on different study objects is not recommended, and future releases may not support the practice.

Validation area	Must be true for successful deployment to the InForm application
Function	• All functions that are used in rules exist in the DLL file for user-defined functions. • A warning occurs if a study or library contains a user-defined function that uses an incorrect version of the Log4Net application. • A warning occurs if a study or library contains a user-defined function with an assembly that is: – Unsigned. – Not signed with a strong named signature. – Signed with an invalid or untrusted signature. **Note:** If you ignore the warning for a user-defined function with an assembly that requires signing with a strong named, valid, and trusted signature, an error occurs when the rule executes in the Oracle InForm application. For more information about user-defined function assemblies that require signing, see the *Rules Reference Guide*. – A warning occurs if a study or library contains a user-defined function with invalid references to ExternalFunctions.dll.
Unit	• All units that are used in the study are in the units file. The file must have a symbol for each unit in each locale that is deployed, and a conversion map must exist to convert between the base unit and the conversion unit. • All units are translated for all of the supported locales for a study. • In the units file, unit names are 31 characters or fewer.
In-place revision	• The study objects associated with in-place revisions exist. • No more than one in-place revision exists for each study object. • Every in-place revision is associated with an existing deployment instance and a study version.

Validation area	Must be true for successful deployment to the InForm application
Study administration data	General checks: • Each constant has a value (the length of the value must be greater than 0). Item group checks: • Each item group contains one or more item. • Each item in an item group is a top-level item on at least one form in the study design. • Each item in an item group exists on a form in the study design. • Each item in an item group exists in only one item group. Rights group checks: • Each rights group contains one or more item groups. • Each item group in a rights group exists in the study. Signature group checks: • Each signature group contains a form. • Each form in a signature group exists in the study design. • For each signature group, a translation is provided for the Signature Meaning and Signature Text for each locale in the study.
Other	Oracle reserved words are not used as RefNames of any study object or Aliases of data sets and data series.

Validation for special Oracle InForm forms and items

Validation area	Error or warning
All special forms (Screening, Enrollment, Patient Identification, and Study Completion)	Error if: • The study contains multiple instances of the form. • The form contains multiple instances of any item. • The form is marked as repeating or appears in a repeating study event. • Required fields are not on the form. • The Special Forms property is defined on a section that is on the form.

Validation area	Error or warning
Screening and Patient Identification forms	Error if: • (For a Screening form only) The form is used in multiple study events. • (For a Screening form only) The form contains a repeating section. • (For a Patient Identification form only) The Patient Number and Initials items are included on the form and are not together in either a section or the top-level form. • All items are not on the same section or form. • The item types for special items are not correct. Warning if the special items are on a non-special form.
Enrollment form	Error if the: • Form is used in multiple study events. • Item types for special items are not correct. • Form contains a repeating section. Warning if the special items are on a non-special form.
Study Completion form	• Error if all items are not in the same form. • Warning if the special items are on a non-special form.
DOV item	Error if the item: • Is used multiple times in a study, unless it was copied using Copy > Link. **Note:** You can use the Copy > Link option to reuse the DOV item in a study. However, an error occurs if you use the DOV item multiple times in a study event, even if you copied it using Copy > Link. • Was copied using the Copy > Link option and pasted onto a form in the same study event. • Has an incorrect item type. • Is not on the first form in a study event. • Is in a repeating section or form. • Is in a common form or a section of a common form. • Is in a section in a repeating study event.
Randomization item	• Error if the item appears multiple times in a study. • Error if the Patient Number and Randomization items are on the same section or form. If one item is on a section, the other item is allowed to be outside the section on the same form.

Validation area	Error or warning
Patient Initials item	Warning if the item has 4 characters.
Drop Out Reason item	Error if the code for its codelist item has more than 47 characters.

Validation for coding

To be valid, a study must pass the following coding-related checks:

- A form can contain only one copy of an item.
- Items in a coding map must all be either in or not in a repeating section.
- A coding map must include at least one target item.
- A target item must be a top-level item or a child of a top-level compound item. It cannot be a child of a nested compound item and cannot be conditional on another item.
- All query target items must be:
  - Top-level items.
  - Visible and available for editing in the Oracle InForm application. Items designated as query targets must not have the Display Override property set to ReadOnly or Hidden in the Oracle Central Designer application.
- All items in a coding map, except the query target item, must be text items.
- Each coding map is valid in the dictionary type from which it was created.
- The dictionary metadata in the study CSML must be in the dictionaries that are supported in the Oracle Central Designer application.

Validation for monitoring forms

If you create a custom regulatory document form and a visit report form, the following must be true for the study to pass validation:

- Only one regulatory document form and one visit report form exist in the study.
- (For visit report forms only) The form contains a Date of Visit item that is marked as a Date of Visit special item and is the first item on the form.
- If the study supports multiple locales, the regulatory document form and visit report form are translated for all locales. A warning occurs if the forms are missing translations for one or more locales.
- The visit report form is not repeating.

Validation for data mappings

The type of data mapping, either CDD, CIS, or rules, determines whether the data mapping definition is validated against criteria for CDD data mappings, CIS data mappings, or no data mappings, respectively.

Validation area	Must be true for successful validation
CDD data mappings	-

Validation area	Must be true for successful validation
Data type compatibility	• All components of a date time item must be required and must not allow unknowns if the date time item is mapped to a data series with a data type of DateTime. • If one or more parts of a date time item are not required or allowed to be unknown, the data series to which the item is mapped must have a type of Text. • The length of an item mapped to a data series must not be longer than the value set in the DB Format Length custom property of the data series. • The precision of a float item mapped to a float data series must not be greater than the value set in the DB Format Float Precision custom property of the data series. • If a float item is mapped to an integer data series, the precision must be 0.
Date part and split date	If any item is mapped to a data series with the split date option, all items mapped to the data series must use the split date option.
Target key types	• Data series mapped to items in a repeating section cannot have a pivot target key type. Pivot tables are not supported for itemset data. • If the target key type of the data set is a pivot target key type, one (and only one) data series must be identified as the pivot column.
Data sets and data series	Custom dimensions and custom dimension labels do not reference deleted codelists or codelist items.
CIS data mappings	-
Block key and page key	The block key and page key must conform to the specifications of the data series for the block key item or page key item in the context panel: • The data type must convert to a compatible data type. • The length must be within the length specified in the DB Format Length CIS custom property. • If the data type of the data series is float, the precision must be within the precision specified in the DB Format Float Precision CIS custom property.

Validation area	Must be true for successful validation
Context panel	• A data mapping can have only one custom context panel. • The data series in a context panel must have data types of Text, Fixed, or Float. • The value of the Context Type property of a data series in a context panel cannot be: – **Other context item** if the value of the Is Key property is True. – **Not a context item**. • A context panel can have only one: – Subject key item. – Block key item. – Page key item. – Block repeat key item. – Page repeat key item. • For a subject key item, if the data type of the data series is Text, the value of the DB Format Length custom property cannot be greater than 80. • Data set aliases used in a context panel cannot be used in data sets for noncontext panels. • If the study contains a data set that is a custom context panel, and the study contains a common form with one or more items that are mapped to any data series, you must specify a value in the Shared Form Block Key custom property on the study design.
Data type compatibility	• All components of a date time item must be required and must not allow unknowns if the date time item is mapped to a data series with a data type of DateTime. • If one or more parts of a date time item are not required or allowed to be unknown, the data series to which the item is mapped must have a type of Text. • The length of an item mapped to a data series must not be longer than the value set in the DB Format Length custom property of the data series. • The precision of a float item mapped to a float data series must not be greater than the value set in the DB Format Float Precision custom property of the data series. • If a float item is mapped to an integer data series, the precision must be 0.
Date part and split date	If any item is mapped to a data series with the split date option, all items mapped to the data series must use the split date option.
Enrollment panel	A data mapping can have only one enrollment panel.
Non-patient data panel	The data series in a non-patient data panel cannot have any mapped items.

Validation area	Must be true for successful validation
Other validation for CIS data mappings	• The following CIS custom data series properties must be mutually exclusive: – Checklist and CIS Codelist. – Derived and Item Required. • RefNames of data sets and data series that are used for: – CIS data mappings must not be longer than 20 characters. – CDD data mappings must not be longer than 25 characters. • Aliases for data sets and data series must not be longer than 20 characters. • RefNames and aliases for data sets must be unique within a data mapping, and RefNames and aliases for data series must be unique within a data set. Checking for RefName and alias uniqueness is case insensitive; for example, the names BP and bp are considered identical. • The RefName and alias of a custom data dimension that is used as a subset key must not be the same as the RefName or alias of any data series in the data dimension. • If the value of the Is Key custom property of a data series is True, the value of the Item Required custom property must also be True. • If you do not create mappings for a CIS enrollment panel, the Oracle Central Designer application creates an enrollment panel from the items in the special screening and enrollment forms. The RefNames of the special screening and enrollment items used to create the enrollment panel must not be longer than 20 characters. • If a data set is marked as an enrollment or non-patient data panel, the value of the Detail Key Item, Detail Panel, Master Item, and Master Panel custom properties of all data series in the data set must not be True.
Data sets and data series	Custom dimensions and custom dimension labels do not reference deleted codelists or codelist items.

Validation for in-place revisions

In order to validate an in-place revision, which compares the current potential baseline and previous baselines, baselines that have been deployed to LIVE/UAT must exist. For more information, see Delete a deployment package and Can I delete a validation baseline?

The following in-place revision changes cause validation warnings. If you make these changes using in-place revision, you must ensure that the changes do not result in data loss, do not compromise data integrity, and do not have regulatory impact.

- Reduce the length of an alphanumeric, numeric, or float study object.

- Reduce the minimum or maximum limit for a numeric or float study object.
- Remove an item for which data was entered in Oracle InForm.

> **Note:**
>
> Oracle Central Designer does not check whether data has been entered for a study in Oracle InForm. We recommend creating or using an existing manual process to determine whether data loss, data integrity or regulatory impact occurs.

- Modify the precision for a numeric or float study object.
- Modify a codelist label.
- Decrease the date range for a date control.
- Remove a date part such as hours or minutes from a date control.
- Modify item text to correct spelling or punctuation errors.
- Add an item to an existing section.
- Remove or modify the codelist subset for a codelist on a form.
- Select a codelist subset for a codelist on a form.
- Remove a codelist item from a subset that is assigned to a codelist on a form.
- Remove a source from a dynamic grid.

The following in-place revision changes cause validation errors. You cannot deploy your study successfully if you make these changes by performing an in-place revision.

- Remove a unit selection for an item.
- Modify a codelist selection value.
- Modify a fixed repeating section by doing the following:
  - Add an additional row.
  - Change a predefined value.
  - Remove a row.
  - Rearrange rows.
  - Change an existing item cell from non-blank to blank.
  - Change an existing item cell from blank to non-blank.
  - Add new items that have blank cells.
- Modify a dynamic grid section by doing the following:
  - Change the section from dynamic to not dynamic.
  - Remove an item from the source form or section referenced in the dynamic grid section, and apply the in-place revision to the source object, but not to the dynamic grid section.
  - On the Design tab of the form or the Properties tab for the form, modify an item on the source form or section referenced in the dynamic grid section, and apply the in-place revision to the source object, but not to the dynamic grid section.

> **Note:**
>
> If you make these changes on the forms' Layout tab, you need to apply the in-place revision to the source object or the dynamic grid section, but not both.

  - Modify an item on the source form or section referenced in the dynamic grid section, and apply the in-place revision to the dynamic grid section, but not to the source object.
  - Add an item to the source form or section referenced in the dynamic grid section, add the item to the dynamic grid section, and apply the in-place revision to the dynamic grid section, but not to the source object.
  - Add a source form or section to the study, add its items to the dynamic grid section, and apply an in-place revision to the dynamic grid section.

> **Note:**
>
> This is not possible because, even though adding an item to a dynamic grid section is a supported in-place revision change, adding a form or section must be done by creating a new study version. You cannot deploy a study with both types of changes.

  - Change the type of item mapping (item level or data point mapping).
  - Change the codelist item mapped for the source item, but that codelist item does not exist in a deployed version of the source, and in-place revision is applied to the dynamic grid but not the source.
  - Codelist item used by a dynamic grid was removed and in-place revision applied to the source but not on dynamic grid.
  - Codelist subset for an item in item level mapping does not match between source and target, and in-place revision is not applied both to the source and the dynamic grid.
- Modify the structure of a control by adding a level of nesting or changing a radio control to a pull-down control.
- Remove a special item.
- Add a section to a form.
- Remove a section from a form.

Validation for custom events

Validation area	Must be true for successful validation
Custom events	• A warning occurs if you're deploying the study with custom events to an Oracle InForm release prior to 6.2. • If a custom event has a prerequisite custom event, the prerequisite has a lower priority group number so that it runs first. • Each custom event has one or more triggers. • Each custom event has one or more results. • Each custom event has a destination name, endpoint name and priority group. • The trigger or result is mapped to an item that is nested fewer than six levels. • For a custom event with a selected Integration type, a warning occurs if the following values do not match. – Integration Type in Oracle Central Designer must match Integration Type in Oracle Central Designer Administrator. – Endpoint Name in Oracle Central Designer must match Endpoint Name in Oracle Central Designer Administrator. – Map to name in Oracle Central Designer must match a Map to name in Oracle Central Designer Administrator. – Result Custom Data Name in Oracle Central Designer must match a Custom Data Name in Oracle Central Designer Administrator. – Result Custom Data Value in Oracle Central Designer must match a Custom Data Value in Oracle Central Designer Administrator.

Validation area	Must be true for successful validation
Custom event triggers	• All study objects in each trigger exist in the study design. • The path for every study object in each trigger matches the study design. • For a trigger referencing a codelist, the selected codelist must have codelist items defined, and the codelist items must exist in the study design. • If a trigger in custom event references a repeating visit, all triggers in that custom event refer to the same repeating visit. • If a trigger in custom event references a repeating form, all triggers in that custom even refer to the same repeating form. • If a trigger in custom event references a repeating section, all triggers in that custom event should refer to the same repeating section. • Triggers only reference repeating sections. • For a trigger on a form with an Event type of Review State, the review state and review stage objects exist in the study design. • For a trigger with an Event type of ValueMatch on an integer or float item without a codelist, the value that you enter in the Value to Compare field must match the item type. For example, if you create the trigger on a float item, you must enter a float value in the Value to Compare field. • For a trigger on an item with an Event type of ValueMatch, the value that you enter in the Value to Compare field must not exceed the value of the Length property for the item. • For a trigger on a float item with an Event type of ValueMatch, the value that you enter in the Value to Compare field must include the exact precision specified in the Precision property for the item.
Custom event results	• All study objects in each result exist in the study design. • The path for every study object in a result matches the study design. • If a custom event has an Integration type, the specified Integration type, Map to name, Result data name, and Result data value in the result corresponds to the available options in the Oracle Central Designer Administrator. • Results only reference repeating sections.

Validation area	Must be true for successful validation
Custom event In-place revisions	• The path for study objects referenced in the custom event trigger is valid path in the target study version. • The path for study objects referenced in the custom event result is valid path in the target study version. • For a trigger on a codelist with an Event type of Value Match, the codelist item that you select in the Value to Compare field exists on the selected codelist item in the target study version. • The review state or review stage referenced in the custom event trigger is defined for the target study version.

Some information is not validated. For more information, see What information is not validated?

What information is not validated?

Validation area	Information not validated
Layout	• Non-EDC layouts. • Item layouts. • Layouts for a locale that is not supported in a study (for example, if a layout is created for a locale that is later deselected for the study).
Instructions and help	Instructions and help information for a locale that is not supported in a study.

Can I delete a validation baseline?

You can delete baselines to optimize performance of study validation and the deployment editor.

You can only delete a validation baseline if no deployment packages are associated with it. Baselines associated with a deployment package are retained for auditing as well as for critical functions of the in-place revision feature, such as IPR validation.

If a baseline is associated with a deployment package and you still want to delete it, see Delete a deployment package for more information.

What happens to the baseline when you upgrade?

- A baseline that is valid in a previous release is not necessarily valid after an upgrade. For example, the study might contain RefNames that were allowed in an earlier release but are not valid in the current release. A study that contains such RefNames does not pass validation.
- You cannot download deployment packages that are created in Oracle Central Designer release 2.1.

- If you are deploying a study to Oracle InForm release 6.1.1 or later and the most recent baseline for the study was created in a Oracle Central Designer release prior to 2.1.2, you must recreate and deploy the deployment package for the study.

Deployment

In this section:

- When can I create a deployment package?
- What types of deployment packages can I create?
- What happens when Oracle InForm processes the deployment package?
- When can I delete a deployment package?
- When can I cancel a deployment?
- What are the basics of automated deployment?
- What am I notified about during automated deployment?
- When should I use manual deployment?
- Can I edit or delete a deployment instance?
- How do I deploy an in-place revision?

When can I create a deployment package?

When a validation baseline is free from errors and warnings, or if you have indicated that warnings can be ignored, you can create a deployment package from it. A deployment package is a ZIP file that contains:

- Metadata that describes the study and the files required to create the MedML for the metadata.
- Deployment options specific to the target application.
- A list of all files in the deployment package.
- Oracle InForm rule engine assemblies.
- Rule assembly and user-defined functions.
- Assemblies required to deploy the study.

You install the deployment package on the computer where the Oracle InForm server is running.

What types of deployment packages can I create?

You can create three different deployment packages:

- **Full package**—Deployment package that contains everything needed to deploy a complete study, including study administration data.
  If you create or modify a coding map, use a full deployment package to deploy the changes. Changes to coding maps are not supported in incremental deployment packages.
- **Incremental package**—Deployment package that contains everything needed to deploy a complete study, including study administration data, plus additions and changes to the study, reflected in Alternate forms in the Oracle InForm application.

Alternate forms are not created when you install an incremental deployment package that contains additions to repeating forms, fixed repeating sections (Repeating Data itemsets in the Oracle InForm application), or dynamic grid sections.

- **Administration data**—Deployment package that contains only study administration data.

Full and incremental deployment packages both contain the definitions for every study object in the study.

What happens when Oracle InForm processes the deployment package?

Characteristic	Description
What the deployment process creates	• For a manual deployment, an Oracle InForm server and a study, if they do not already exist. The process of creating the Oracle InForm study creates an Oracle user for the study database tables. • MedML definitions for CDD or CIS mappings, if the deployment package includes CDD or CIS mappings. • A log file called StudyInstaller.log in the Oracle InForm installation folder. This log file contains information that can be used to debug problems with deployment. Messages from each subsequent deployment are appended to the log.
What the deployment process does not create	The Oracle user and system DSN for a CDD or for a Clintrial protocol that is the target of CIS mappings. You must create the CDD Oracle user and DSN through the Oracle InForm Service. The Oracle user and DSN for a Clintrial protocol are created through the Clintrial application or through CIS synchronization.

Characteristic	Description
Deployment package processing	The deployment process for deployment in the Oracle InForm application: 1. Creates the Oracle InForm application server, if it does not already exist. 2. Creates the Oracle InForm study database, if it does not already exist. 3. Installs the MedML (Oracle InForm-specific metadata XML) definitions for the Base study components, if the deployment package is for a full deployment. The Base study components include system resources, settings, and form definitions common to all Oracle InForm studies. **Note:** Do not create the Base study with the dbsetup utility before running the Deployment Wizard. Deployment processing does not succeed if the Base study already exists. If you install a deployment package using command-line options, you can override this restriction. You can follow the progress of the deployment in the message box on the last page of the Deployment Wizard.

When can I delete a deployment package?

You can delete a deployment package for a LIVE or UAT deployment instance when the following is true:

- The deployment package was not transferred to the Oracle InForm environment.

  Note:

  If the deployment package was transferred to the Oracle InForm environment but the deployment was cancelled you cannot delete the package.

- The deployment package is not associated with a rejected deployment request.
- The deployment package is not associated with a locked deployment request approval.

When you delete a deployment package, the following are also deleted:

- Any incremental deployment packages associated with the package.

- Any automated deployment data associated with the package, including deployment requests; deployment approvals and rejections; deployment cancellations and deployment request cancellations; and deployment logs.

When can I cancel a deployment?

After you create a deployment request, you can cancel the deployment request or deployment in the following two scenarios:

- If the deployment request requires an approval but it has not been approved or rejected yet, and you have the appropriate rights, you can cancel the deployment request.
- If the deployment request has been approved, or it does not require an approval, and you have the appropriate rights, you can cancel the deployment if the status of deployment is either Scheduled or Submitted.

What are the basics of automated deployment?

Automated deployment is the process through which a study design is moved directly from Oracle Central Designer to the Oracle InForm environment.

The deployment request is the basis of the automated deployment process.

What am I notified about during automated deployment?

The Oracle Central Designer application sends email notifications whenever one of the following events related to automated deployments occurs:

- Deployment request is created.
- Deployment request is canceled.
- Deployment request is approved or rejected.
- Deployment is canceled.
- Deployment starts.
- Deployment completes successfully or with failures.

You select the users who receive email notifications when you create the deployment request. For more information, see Create a deployment request.

> **Note:**
>
> An administrator must configure the Oracle Central Designer application to send email notifications. For more information, see the *Installation Guide*.

When should I use manual deployment?

You must use manual deployment to deliver and install a deployment package to a study in Oracle InForm release 6.0 or earlier. You can also use manual deployment as an alternative to automated deployment for studies in the Oracle InForm release 6.1 or later.

If you use manual deployment, you might notice differences in functionality when performing in-place revisions and viewing the differences between form versions.

Can I edit or delete a deployment instance?

- Editing or deleting an instance does not affect deployment requests created before the edit or deletion.
- You cannot delete an instance that is associated with in-place revisions. If you edit an instance with in-place revisions, the changes affect the in-place revisions.

How do I deploy an in-place revision?

You apply an in-place revision by deploying a package that contains the revision into Oracle InForm. In the Create deployment package wizard, you review the changes and confirm that you understand the implications of making in-place revisions before you can create a deployment package that contains in-place revisions.

> **Note:**
>
> After you deploy a study that contains an in-place revision change to a LIVE deployment instance, Oracle recommends that you remove all IPR configurations for the study. You can delete the IPR configurations manually using the IPR Summary Editor, or you can configure the Oracle Central Designer application to do so automatically. For more information, see the *Administrator Guide*.

Post-design activities

In this section:

- Decommissioning and archiving FAQs
- Reports and Annotated Study Book FAQs
- Translating text FAQs

Decommissioning and archiving FAQs

In this section:

- What's involved in decommissioning?
- What is the workflow for decommissioning studies and projects?
- What is archiving?
- What information is archived?
- How is deleting a study or project different from archiving?
- What information is deleted when you delete a study or project?
- What are the options for importing an archive?
- What information is imported from an archive?

What's involved in decommissioning?

Decommissioning is the process of archiving and deleting a study, study project, or library project.

Archiving and deleting allow you to decommission an entire study, study project, or library project, including all of its study objects.

> **Note:**
>
> The archiving functionality is not intended to be your only backup mechanism. You should also schedule regular database backups.

What is the workflow for decommissioning studies and projects?

Decommissioning is the process of archiving and deleting a study, study project, or library project.

1. Archive a study or project.
2. (Optional but highly recommended) Make a full database backup.
3. Delete the study or project.
4. (If you need to modify a decommissioned study, study project, or library project) Download and import an archived study or project.
5. (Optional) Delete an archived study or project from the database.

> **Note:**
>
> You also can archive without deleting and delete without archiving.

What is archiving?

Archiving and deleting allow you to decommission an entire study, study project, or library project, including all of its study objects. The archiving functionality is not intended to be your only backup mechanism. You should also schedule regular database backups.

An archive contains the components that reconstruct a study, study project, or library project. All archives are saved on the database server, and you can copy them to another location and delete them from the database.

The archive process locks the study or project, but not the study objects in it. Therefore, Oracle recommends that you schedule archive processes for a time when no one is using the application.

> **Note:**
>
> You cannot delete or archive the System Library or its project.

What information is archived?

Component	Information that is saved in an archive
Attachments	Attachments on: • The study or library. • The study project or library project.
Baselines	• All baselines. • Most recent revision of any study objects that the most recent baseline does not contain.
Categorizations	• System and user keywords. • Automatically generated and manually generated categories. • The mappings that connect keywords and categories to study objects.
Collaboration notes and tasks	All collaboration notes and tasks in the study, study project, or library project.
Custom properties	• Custom properties and their corresponding keywords and categories. • Values of the custom properties.
Functions	All functions in the study, study project, or library project.
Study objects	• All study objects, including their revisions and ancestry information that connects a study object to its parent and children. • Information about whether a study object is a copy of another study object, as well as the study object from which it was copied. • Information about whether a study object is published, including the revisions that were published.
Teams	• Teams in the study or library. • Information about users in the team, such as user name, first name, and last name, but not the roles for the users.
Units	The units file.
Validation results (Studies only)	Validation results for the most recent baseline only.

Component	Information that is saved in an archive
Direct deployment records (for successful UAT and LIVE deployment type instances only)	• Information about deployment requests and approvals. • Deployment packages. • Information about users associated with the request, including the user who created the deployment package, the user who created the deployment request, the user who approved or rejected the request, and the users in the email distribution list for the request. • Deployment logs created for the deployment.

Note:

Deployment packages that are associated with manual deployments are not included, as only autodeployments can have a status of Successful. Use caution importing an archive if there is a chance you may do any in-place revisions on the study. In order to validate an in-place revision, which compares the current potential baseline and previous baselines, baselines that have been deployed to LIVE/UAT must exist. In this case, it would be possible to delete the baseline, as it would not be associated with a deployment package.

How is deleting a study or project different from archiving?

Deleting an archive file decreases the size of the database by removing unwanted studies, study projects, and library projects.

Before you delete a study, study project, or library project, Oracle recommends that you perform a full database backup. You can also archive a study or project.

When you download an archive file, you have the option of permanently deleting it from the database.

> **Note:**
>
> You cannot delete or archive the System Library or its project.

What information is deleted when you delete a study or project?

Component	Information that is deleted
Attachments	Attachments on: • The study or library. • The study project or library project. **Note:** Attachments are not deleted if they are referenced by study objects that are not deleted. For example, study objects are not deleted if they are shared with another library.
Baselines	All baselines.
Categorizations	The mappings that connect keywords and categories to study objects. **Note:** The actual keywords and categories are not deleted.

Component	Information that is deleted
Collaboration notes and tasks	All collaboration notes and tasks in the study, study project, or library project.
Custom Properties	The mappings that connect custom properties and their hierarchy to study objects. **Note:** The actual custom properties are not deleted.
Study objects	• All study objects, including their revisions. **Note:** When the repository contains children or a parent of a deleted study object, the children and parent are connected. • Information about whether a study object is a copy of another study object, as well as the study object from which it was copied. • Information about whether a study object is published, including the revisions that were published.
Teams	The teams in the study or library. **Note:** Users are not deleted from the Oracle Central Designer application, and their corresponding roles are not deleted from the Oracle Central Designer Administrator application.
Validation results (Studies only)	All validation results.

What are the options for importing an archive?

You have the following options for importing an archive:

- Import an archived study into a study project.
- Import an archived study project or library project and create a new project.

You can import an archive into the database in which it was created or into another database. You cannot import an archived study, study project, or library project if it still exists in the target database—first you must delete the existing study, study project, or library project.

Before you can import an archived study or project, you must download it from the database. Optionally, you can delete the file from the database after downloading it.

What information is imported from an archive?

Component	Information that is imported
Attachments	Attachments on: • The study or library. • The study project or library project. Files with the same name are overwritten.
Baselines	All baselines.
Categorizations	• System and user keywords. • Automatically generated and manually generated categories. • The mappings that connect keywords and categories to study objects. **Note:** If categories or keywords already exist in the target database, they are not overwritten.
Collaboration notes and tasks	All collaboration notes and tasks in the study, study project, or library project.

Component	Information that is imported
Custom properties	• Custom properties and their corresponding keywords and categories. • Values of the custom properties. **Note:** If custom properties with the same name and on the same study object already exist in the target database, they are not overwritten.
Functions	All functions in the study, study project, or library project. **Note:** Functions with the same file name in the target database are overwritten.

Component	Information that is imported
Study objects	• All study objects are imported with their original identifiers. Archived study objects are re-inserted so the family tree is restored. • Information about whether a study object is a copy of another study object, as well as the study object from which it was copied. • Information about whether a study object is published, including the revisions that were published. **Note:** The identifiers for study objects are maintained after an import. Linked study objects are overwritten in the target database only if the archive contains a newer revision of the study object.
Validation results (Studies only)	All validation results.

Note:

- The units file is not imported. If you need to recover this file from an archive, contact Oracle Services.
- Users and teams are not imported. When study objects in the archive refer to a user that does not exist in the target database, **archiveimporter** is inserted for the user's name. For example, if the user JohnSmith modified a study object in the archive but does not exist in the database, the History Viewer lists **archiveimporter** in place of JohnSmith after the archive is imported.

Reports and Annotated Study Book FAQs

In this section:

- What reports can I generate?
- What is an Annotated Study Book?
- What is in the Schedule of Events table in the Annotated Study Book?

- What do the RDE Analytics tables in the Annotated Study Book contain?
- How are layouts handled in an Annotated Study Book versus a deployment package?
- What are the RD Column names in RDE Analytics tables?
- What does the Custom Events table in the Annotated Study Book contain?

What reports can I generate?

You can generate reports to check the progress of work for the following study objects:

- Studies.
- Libraries.
- All study objects in a library.

Reports provide information about study objects, such as:

- Study objects that have been copied from a library to a study and then modified and saved in either the study or library.
- Number of times a study object was copied to a study or library.
- Data-entry rule action/locale combinations in a study.
- RefName paths for all deployed items (Oracle InForm controls) in a study.

> **Note:**
>
> You can open the Reports dialog box for all study objects. If no reports are available for the study object, There are no reports for the selected object appears in the drop-down list.

Study object	Report	Oracle InForm-specific
Studies	Data Entry Rule Actions Report.	Yes
-	Oracle InForm RefName Report.	Yes
-	Library Objects Modified in the Study.	No
-	Library Objects Modified in the Library.	No
-	Workflow Rules and Global Conditions Report	Yes
Libraries	Number of Studies Containing Library Objects.	No
	Library Objects Modified in Studies.	No
Study objects in a library	Studies Containing Selected Library Object.	No

What is an Annotated Study Book?

An Annotated Study Book is a form-by-form summary of the design of a study. Optionally, it includes a time and events schedule, a preview of each form, and selected annotations that list design details. Optionally, it includes a schedule of events, a preview of each form, and

selected annotations that list design details. You can print an Annotated Study Book or save it to a PDF file and use it as a tool for reviewing the study design.

For details about how design information is displayed in an Annotated Study Book, see:

Annotated Study Book Options dialog box

Schedule of Events table in the Annotated Study Book:

Field	Description
Element	If the study design uses study elements, they appear in the first row, and the study events in each study element are grouped under the study element columns. **Note:** The study element name for the special Screening and Enrollment visits is System.
Assessment	Study events are listed in study workflow order, as they appear in the workflow editor for the study design or study element. The heading of each visit column shows the study event title, short title (in parentheses), and visit type (in square brackets). Visit types: • S—Scheduled • D—Dynamic • U—Unscheduled • R—Repeating
CRF	Short title of each form, or blank if the ShortTitle property is not defined.
Visit Start Hours	The visit start hour appears for study events. The visit start hour is a calculated value based on the scheduling specified for the study workflow. The start hour for the special Screening and Enrollment visits is zero. If the first visit after the Screening and Enrollment visits is not scheduled in the study workflow, its start hour is also zero.

Field	Description
Forms	• Identified with their translated names in the language in which the annotated study book is generated. If the translated name is not specified, the form title appears. This form identifier also appears on each annotated form in the annotated study book. • Forms are listed in study workflow order, except that: – Forms that occur in more than one visit are not duplicated. – If a study design includes a Regulatory Documents or Visit Report form, those forms appear in the form listing but do not appear in the Time and Events table. A number in each visit column where the form appears indicates the order in which the form occurs in the visit. Special form types are indicated by a code that follows the form order number: • C—Common • DF—Dynamic • RF—Repeating
Key	Codes used for special types of forms and visits.

RDE Analytics tables

RDE Analytics tables are listings of the column names that are generated when study data is extracted to the Oracle InForm reporting database.

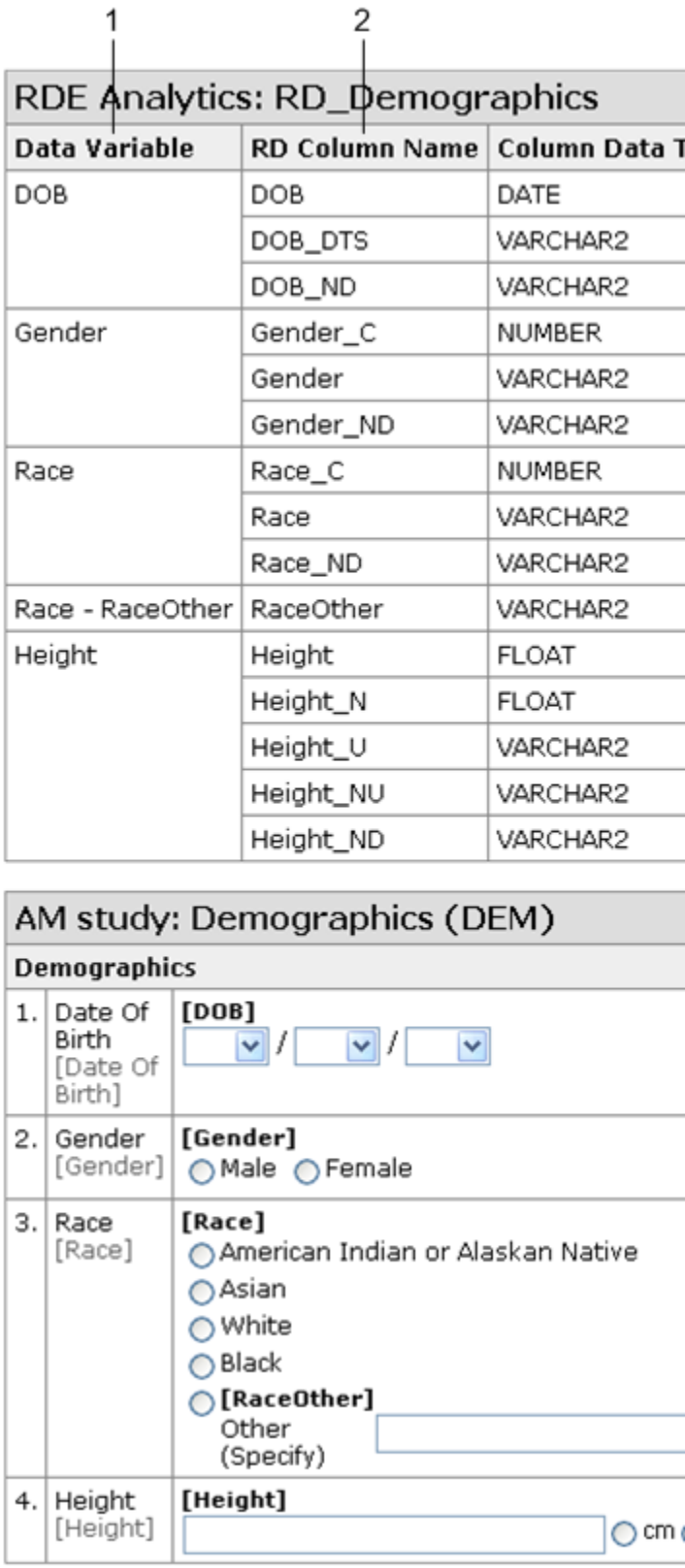
Field	Description
Data Variable	Title of the item for which the column names are generated, or RefName if **Show Object RefNames** is selected in the Annotated Study Book Options dialog box.

Field	Description
RD Column Name	Name of the column in the reporting database where the data will be inserted. • Column names consist of the item RefName or the RefName concatenated with a suffix. • All types of top-level items have a column with the suffix _ND to hold the reason that an item is not done or incomplete. The format of the other column names generated for an item depends on the type of item. • For child items of compound items, the RefName of the parent and child items are concatenated before the suffix. • If the RefName part of the generated column name exceeds 25 characters, an asterisk appears in front of the column name to indicate that it will not match the actual RDE output. A footnote explains the asterisk. • If an item is used multiple times on a form, an asterisk appears in front of the column name to indicate that it might not match the actual RDE output. A footnote explains the asterisk.
Column Data Type -	Data type of the column.

Note:

For each form, items that are outside of a section on a form and items that are in a nonrepeating section are included in a table. If a form contains a repeating section, each repeating section has its own table and the items in the repeating section are listed in the corresponding table for the repeating section.

Example of an RDE Analytics table and its annotated form:

Description	Illustration
1—Study object RefName or Title. **2**—Column name as it is generated in the InForm reporting database. **a**—Complete date time item. No suffix. **b**—Date time item with only date parts. **c**—Comment on item, reason why item was not done, or reason why item is incomplete. **d**—In an item with radio or checkbox controls or a drop-down list, the coded value for the selected control. **e**—In an item with radio or checkbox controls or a drop-down list, the label for the selected control. **f**—Child item in a compound or conditional item. RaceOther is a text item within the Race radio group. The column name contains the RefName of the parent item, a hyphen, and the RefName of the child item. **g**—Entered value of an item with units. **h**—Normalized value of an item with units. **i**—Unit symbol for an item with units. **j**—Normalized unit symbol for an item with units.	

What is in the Schedule of Events table in the Annotated Study Book?

Field	Description
Element	If the study design uses study elements, they appear in the first row, and the study events in each study element are grouped under the study element columns. **Note:** The study element name for the special Screening and Enrollment visits is System.
Assessment	Study events are listed in study workflow order, as they appear in the workflow editor for the study design or study element. The heading of each visit column shows the study event title, short title (in parentheses), and visit type (in square brackets). Visit types: • S—Scheduled • D—Dynamic • U—Unscheduled • R—Repeating
CRF	Short title of each form, or blank if the ShortTitle property is not defined.
Visit Start Hours	The visit start hour appears for study events. The visit start hour is a calculated value based on the scheduling specified for the study workflow. The start hour for the special Screening and Enrollment visits is zero. If the first visit after the Screening and Enrollment visits is not scheduled in the study workflow, its start hour is also zero.

Field	Description
Forms	• Identified with their translated names in the language in which the annotated study book is generated. If the translated name is not specified, the form title appears. This form identifier also appears on each annotated form in the annotated study book. • Forms are listed in study workflow order, except that: – Forms that occur in more than one visit are not duplicated. – If a study design includes a Regulatory Documents or Visit Report form, those forms appear in the form listing but do not appear in the Time and Events table. A number in each visit column where the form appears indicates the order in which the form occurs in the visit. Special form types are indicated by a code that follows the form order number: • C—Common • DF—Dynamic • RF—Repeating
Key	Codes used for special types of forms and visits.

What do the RDE Analytics tables in the Annotated Study Book contain?

RDE Analytics tables are listings of the column names that are generated when study data is extracted to the InForm reporting database.

Field	Description
Data Variable	Title of the item for which the column names are generated, or RefName if **Show Object RefNames** is selected in the Annotated Study Book Options dialog box.

Field	Description
RD Column Name	Name of the column in the reporting database where the data will be inserted. • Column names consist of the item RefName or the RefName concatenated with a suffix. • All types of top-level items have a column with the suffix _ND to hold the reason that an item is not done or incomplete. The format of the other column names generated for an item depends on the type of item. • For child items of compound items, the RefName of the parent and child items are concatenated before the suffix. • If the RefName part of the generated column name exceeds 25 characters, an asterisk appears in front of the column name to indicate that it will not match the actual RDE output. A footnote explains the asterisk. • If an item is used multiple times on a form, an asterisk appears in front of the column name to indicate that it might not match the actual RDE output. A footnote explains the asterisk.
Column Data Type -	Data type of the column.

Note:

For each form, items that are outside of a section on a form and items that are in a nonrepeating section are included in a table. If a form contains a repeating section, each repeating section has its own table and the items in the repeating section are listed in the corresponding table for the repeating section.

Example of an RDE Analytics table and its annotated form

Description	Illustration
1—Study object RefName or Title. **2**—Column name as it is generated in the InForm reporting database. **a**—Complete date time item. No suffix. **b**—Date time item with only date parts. **c**—Comment on item, reason why item was not done, or reason why item is incomplete. **d**—In an item with radio or checkbox controls or a drop-down list, the coded value for the selected control. **e**—In an item with radio or checkbox controls or a drop-down list, the label for the selected control. **f**—Child item in a compound or conditional item. RaceOther is a text item within the Race radio group. The column name contains the RefName of the parent item, a hyphen, and the RefName of the child item. **g**—Entered value of an item with units. **h**—Normalized value of an item with units. **i**—Unit symbol for an item with units. **j**—Normalized unit symbol for an item with units.	1 2 RDE Analytics: RD_Demographics Data Variable | RD Column Name | Column Data T DOB | DOB | DATE DOB_DTS | VARCHAR2 DOB_ND | VARCHAR2 Gender | Gender_C | NUMBER Gender | VARCHAR2 Gender_ND | VARCHAR2 Race | Race_C | NUMBER Race | VARCHAR2 Race_ND | VARCHAR2 Race - RaceOther | RaceOther | VARCHAR2 Height | Height | FLOAT Height_N | FLOAT Height_U | VARCHAR2 Height_NU | VARCHAR2 Height_ND | VARCHAR2 AM study: Demographics (DEM) Demographics 1. Date Of Birth [Date Of Birth] [DOB] / / 2. Gender [Gender] [Gender] Male Female 3. Race [Race] [Race] American Indian or Alaskan Native, Asian, White, Black, [RaceOther] Other (Specify) 4. Height [Height] [Height] cm

How are layouts handled in an Annotated Study Book versus a deployment package?

When you generate an annotated study book for a study that supports multiple locales, you specify the layout and locale to use. When you generate a deployment package, you specify the default layout locale for the deployment package. These settings are independent of each other.

- **Annotated Study Book**—When you specify a layout and generate an annotated study book, the annotated study book reflects the layout customizations that you have made for the layout.
- **Deployment package**—In Oracle InForm release 4.7 and later, a single study version contains the layout information for all locales in the study, and you specify a default layout locale, from which all layouts, regardless of locale, inherit customizations in the Oracle InForm application.
  The site locale language in the Oracle InForm application determines the language in which forms appear.

  For example, a study contains layouts for the French (France) and the English (United Kingdom) locales. Radio buttons are horizontal in the French (France) layout but are vertical in the England (United Kingdom) layout. If French (France) is the default layout locale, then all layout customizations for the France (French) layout, including the alignment of radio buttons, are deployed to the Oracle InForm application and appear for all users, regardless of their site locale. Therefore, if your site locale in the Oracle InForm application is English (United Kingdom), the forms appear in English but with the customizations that were made in the French (France) layout in the Oracle Central Designer application.

What are the RD Column names in RDE Analytics tables?

RD Column Name	Source of data	Column data type
Text, integer, or float item without units:	-	-
Item_RefName	Entered value	VARCHAR2, NUMBER, or FLOAT, depending on the data type of the item.
*Item_RefName*_ND	Reason why an item is incomplete (Not Done, Not Applicable, or Unknown).	VARCHAR2
Integer or float item with units:	-	-
Item_RefName	Entered value	NUMBER or FLOAT
*Item_RefName*_N	Normalized value	NUMBER or FLOAT
*Item_RefName*_U	Entered unit symbol	VARCHAR2
*Item_RefName*_NU	Normalized unit symbol	VARCHAR2
*Item_RefName*_ND	Reason why an item is incomplete (Not Done, Not Applicable, or Unknown).	VARCHAR2
Radio buttons or drop-down lists:	-	-
Item_RefName	Label	VARCHAR2

RD Column Name	Source of data	Column data type
*Item_RefName*_C	Coded value	VARCHAR2, NUMBER, or FLOAT, depending on the data type of the item.
*Item_RefName*_ND	Reason why an item is incomplete (Not Done, Not Applicable, or Unknown).	VARCHAR2
Checkboxes	-	-
Two columns for each checkbox:	-	-
RefName_of_parent_item - RefName_of_child_item_or_control	Label of codelist item control in child item.	VARCHAR2
RefName_of_parent_item - *RefName_of_child_control*_C	Coded value of codelist item control in child item.	VARCHAR2, NUMBER, or FLOAT, depending on the data type of the item.
Dates and times:	-	-
Item_RefName	Valid, complete date time or complete date plus hours and minutes (A complete date time can include UNK or ND entries).	DATE
*Item_RefName*_DTS	Date string	VARCHAR2
*Item_RefName*_DTR	Appears when: • The Item_RefName_DTS column name appears for an item. • The value of any date part that appears is not required, or an unknown value is allowed for the date part.	VARCHAR2
*Item_RefName*_TMS	Time string	VARCHAR2
*Item_RefName*_TMR	Appears when: • The *Item_RefName*_TMS column appears for an item. • The value of any date part that appears is not required, or an unknown value is allowed for the date part.	VARCHAR2
*Item_RefName*_ND	Reason why an item is incomplete (Not Done, Not Applicable, or Unknown).	VARCHAR2
Compound items (parent item):	-	-
*RefName_of_parent_item*_ND	Reason why an item is incomplete (Not Done, Not Applicable, or Unknown).	VARCHAR2
Compound items (child item):	-	-

RD Column Name	Source of data	Column data type
RefName_of_parent_item - RefName_of_child_item_Suffix One or more columns for each child item, based on the item type. The value of *Suffix* is based on the type of the child item or control, as described in this table.	Based on the type of the child item or control.	Based on the type of the child item or control.

What does the Custom Events table in the Annotated Study Book contain?

Field	Description
Title	The title you gave the custom event.
RefName	The custom event's RefName. The RefName corresponds to the Custom Event Name in Oracle InForm Publisher.
Description	The description you gave the custom event.
Integration type	The integration type that you selected for the custom event. Integration types are added in the Oracle Central Designer Administrator.
Destination name	The destination application where Oracle InForm sends the exported data.
Endpoint name	The endpoint name corresponds to the Endpoint Alias in Oracle InForm Publisher.
Active	The custom event's active status.
Evaluate on	Indicates whether to run the custom event against new data only, or new data and existing data.
Priority group	The order to run the custom events in.
Prerequisite	The name of the custom event that needs to run before the current custom event can be triggered.
Trigger operator	• AND if you want the custom event result to occur if all of the triggers are satisfied. • OR if you want the custom event result to occur if any of the triggers is satisfied.
Trigger data	-
Trigger type	Subject or study object the custom event trigger is created on.
Mapped object path (RefName)	The RefName path of the study object that you created the custom event trigger on.
Event type	The type of event that causes the custom event result to be triggered.
Additional values	Information in addition to the event type that you entered for the trigger.
Result data	-
Result type	The type of data you want to export when the custom event is triggered.

Field	Description
Map to name	The destination where you want to save the exported data.
Mapped object path (RefName)	The RefName path of the study object whose data you want to export when the custom event is triggered.
Custom data	The additional data that you want to export when the custom event is triggered.

Translating text FAQs

In this section:

- How can I switch between locales and provide translations?

How can I switch between locales and provide translations?

Every layout supports all locales. You do not need to create a unique layout for every form and locale in the study. Use the Locales drop-down list on the toolbar in the Layout tab to switch between locales and provide translations.

Translations are not layout-specific. Every layout supports every locale that is supported by the study. For example, if you have two layouts, you can view the translations for every supported locale in each layout.

You can provide translations for the following components in a layout:

- Captions.
- Section notes.
- Form and section titles.
- Questions.
- Codelist item label overrides.

> **Note:**
>
> You can also provide translations for questions in the Design tab of the Item Editor.

You can translate codelist item labels in the Codelist Editor.

Oracle InForm to Oracle Argus Safety integration

In this section:

- What data does the integration require?
- Why would I make the Safety Case form dynamic?
- When might an Oracle InForm site user include multiple adverse events when sending data to Oracle Argus Safety?

- What is a dynamic grid?
- What are item level mapping and data point mapping in a dynamic grid?
- What is an editable item in a dynamic grid?
- When will an Oracle InForm site user use a Safety Case form?
- How do I include the unit of measurement with items I create in Oracle Central Designer?
- What's in the data sets used to process data transmissions?
- What is the syntax of the _SavetoDB function?
- How does a calculation rule work?
- Are there rules that are not supported for items in the dynamic grid?
- What happens in Oracle InForm when a source form with a dynamic grid is deleted?
- What kind of queries should I include on a dynamic grid item?
- What is data mapping?
- Are there fields that I don't need to map?
- When and how are data mappings validated?
- Which items have data series for transmitting coded or verbatim data?
- What alias names should I use when creating custom data series?
- How do I trigger Oracle InForm Publisher to send adverse event data to Oracle Argus Safety based on an onset date?

What data does the integration require?

For an E2B file to be accepted into Oracle Argus Safety as a new case, you must send the following data, at a minimum:

Adverse Event description—The site user can enter verbatim text to describe the adverse event triggering the case. If the site user does not supply text, the integration sends this description: "Event Description not Filled in by Oracle InForm User."

Report type—This is sent as "Report from Study."

Patient information—The SubjectNumber from Oracle InForm is sent as the Patient ID.

Reporter —The full name of the user that marked the adverse event as serious is sent as the Reporter. The Site Mnemonic and Name are sent as the reporter organization (displays in Institution field in Oracle Argus Safety) and the site address is the reporter address.

Suspect Product—You must send one. This can be collected on a form and mapped to MedicinalProductName. If not filled in or mapped, the value stored in the Oracle InForm database as SponsorStudyDrug is sent. If this is not populated and items were mapped to the SuspectDrug data series of the Safety Logical Schema, the string "StudyDrug" is sent.

Study Drug—The study drug must be sent to Oracle Argus Safety. You can add it to a form as and map it to Suspect Product in Oracle Argus Safety. Or, you can enter the

study drug name under Sponsor Drug Name as a property of a Study Design object. Oracle InForm Publisher will send it automatically.

Country of Incidence or Reporter—Send either Country of Incidence or Reporter (also known as Primary Source Country).

- Country of Incidence can be mapped in the SafetyCase data series of the Logical schema.
- Primary Source Country comes from the country specified in the site address in InForm.
- If neither of these is available when the message is sent, Oracle Argus Safety rejects the E2B file.

Why would I make the Safety Case form dynamic?

A form for which the precondition is the outcome of a workflow rule or global condition deploys as a dynamic form in the Oracle InForm application.

You can make the Safety Case form dynamic dependent on the Serious or Reportable item being True or False on the Adverse Event form.

When might an Oracle InForm site user include multiple adverse events when sending data to Oracle Argus Safety?

You can design the study so that Oracle InForm site users include all the adverse event information on a single Adverse Event form and each form opens an Oracle Argus Safety Case.

You can also allow Oracle InForm site users to group multiple related adverse events entered into multiple Adverse Event forms to be reported together in a single Oracle Argus Safety case.

- If you choose to have one adverse event per case, you have two form setup options:
  - Include a Safety case form and associate it with that AE.
  - Don't include a Safety Case form (all AE information would be on the AE form).
- If you include multiple adverse events per case:
  - If all adverse events need to be selected by the site, you need a Safety Case form.
  - If some adverse events need to be sent via time frames, you can choose whether to include a Safety Case form.

> **Note:**
>
> Be mindful that all adverse event data included in a Safety Case form will not be sent to Oracle Argus Safety until the Safety Case form is filled out by the site.

Including multiple adverse events for a single Oracle Argus Safety case is useful when a subject has experienced several adverse events that are related to each other and you need to submit them together as one safety case to Oracle Argus Safety. Multiple versions of the Adverse Event form are also allowable if you are not including a Safety Case form. For example, there might be one Adverse Event form for typical adverse and serious events and

a different version of the Adverse Event form for pregnancies. Also, if needed, you can include all the different adverse events in a single dynamic grid.

What is a dynamic grid?

A dynamic grid section is a type of repeating section on a form, which contains a pointer to one or more repeating forms or sections, and a set of items from that source repeating forms or sections. By adding a dynamic grid section, when the study is deployed the site user can select which items from the itemset to include relying on clinical judgment.

For example, in Oracle InForm, a site user might want to use one form to collect all of the information about a serious adverse event (SAE) that needs to be submitted to a safety application such as Oracle Argus Safety. Consider a scenario in which a subject suffers a heart attack while taking an investigational medication. Then, while in the hospital, the subject is prescribed a blood thinner, and develops a fever.

The Oracle InForm site user has determined that the data entered about the heart attack, the investigational product the subject was taking, the blood thinner, and the subsequent fever is all related to the SAE heart attack. He wants to submit all of this information to Oracle Argus Safety.

To facilitate the collection and transmission of this data, which is entered on multiple forms over the course of multiple visits, you can include a single form in the study design.

The form contains dynamic grid sections with all of the items from existing forms that might contain data that the Oracle InForm site user wants to send to Oracle Argus Safety.

For example, a dynamic grid section to collect related adverse events and their onset and end dates, a dynamic grid section to collect concomitant medications, and a dynamic grid section to collect data from lab reports created during the subject's hospital stay.

When the study is deployed to Oracle InForm, the dynamic grid sections become itemsets in which the site user is presented with the most up-to-date data entered in the items you added to the dynamic grid sections. The site user can select all or some of the data presented in the dynamic grid section to send to Oracle Argus Safety.

What are item level mapping and data point mapping in a dynamic grid?

You can map multiple sources for a single target item in a dynamic grid, but depending on the needs of your study, there are two ways to do it.

- Item level: At this mapping level, items are shared between source and target, and all their attributes will remain the same. In the case of nested items, only the top level item can be selected, making all nested items automatically selected as well.
- Data point: At this mapping level, items are not shared between source and target, and all their attributes must be designed on the dynamic grid itself. In the case of nested items, you can select an individual nested item instead of the top item that contains it.

What is an editable item in a dynamic grid?

An editable item in a dynamic grid is a top-level item section which has no mapping to any source objects. Once deployed, it will become an editable field on dynamic grid in Oracle InForm.

When including an editable item in a dynamic grid, consider that:

- Editable items can be a text, integer, float, date time or compound item, and it can have nested items. You can also write rules against it.
- Editable items supports all display override types: Read Only, Editable and Hidden.

When will an Oracle InForm site user use a Safety Case form?

If all the adverse event data for an Oracle Argus Safety case is on a single Adverse Event form, a Safety Case form isn't needed, unless you want Oracle InForm site users to be able to select which items to send to Oracle Argus Safety. If you allow adverse events for the same Oracle Argus Safety case to be entered on multiple Adverse Event forms, you must include a Safety Case form so the site user can associate the Adverse Event forms and other forms, such as Medical History and Concomitant Medications, with the Oracle Argus Safety case.

How do I include the unit of measurement with items I create in Oracle Central Designer?

In Oracle Central Designer, you can enter the unit of measurement used to report the items you enter. The unit definition can be part of the item definition, or you can create a separate item to hold the unit selection. Oracle Argus Safety integration accommodates both models, using two data series for each item with units.

A data series to hold the value of the item

The following illustration shows an item in which the unit is specified as part of the item definition. When you map this type of item, you use only the data series for the item value.

A data series to hold the units in which the value is entered

The following illustration shows an item in which a separate item is designed to hold the unit selection. When you map this type of item, you use both the data series for the item value and the data series for the unit.

Oracle InForm Publisher sends the data value for an item and the units in which it is reported to the same field in Oracle Argus Safety.

What's in the data sets used to process data transmissions?

The Oracle InForm and Oracle Argus Safety integration software uses the following data set definitions and system data sets to process data transmissions:

- Safety_Config
- Safety_Significant

Safety_Config

The Safety_Config data set identifies items and forms used by Oracle InForm Publisher for safety processing. For example, the Safety_Config data set includes a required data series mapped to a control in the AE form so that Oracle InForm Publisher can identify the AE forms in the study.

Characteristics	Description
Any AE Form Control	Use to identify the AE form. Map this data series to any item on the AE form. Required.
Any SE Form Control	Use to identify the Safety Case form in a design with separate AE and Safety Case forms. Map this data series to any item on the Safety Case form. Required in a design with separate AE and Safety Case forms.
SE Related AE Sequence Number Control	Item on the Safety Case form containing the sequence number of the AE instance for which the Safety Case was entered. Required in a design with separate AE and Safety Case forms. Map the item on the Safety Case form. This form collects the sequence ID of the AE form. If this is mapped to an item in a repeating itemset, then time frames will not be used for related AEs.
AE Start Date Control	Onset date of the AE. This data series is used to identify by date range the related safety event data that appears on other forms.
AE IsSerious Control	Shows where the IsSerious checkbox resides on the form.
AE IsReportable Control	Shows where the IsReportable checkbox resides on the form.

Safety_Significant

The Safety_Significant data set is an empty data set in which you must create the data series and mappings for items that are monitored for changes after initial transmission to determine whether follow-up transmissions are needed. The items mapped to data series in the Safety_Significant data set are considered significant for safety and trigger a follow-up transmission when changed.

> **Note:**
>
> Compound items can include both items that are mapped as significant in the Safety_Significant data set and items that are not mapped as significant. When any item in a compound item is updated, all items in the compound item are updated, and, therefore, even an update to a non-significant item triggers a follow-up transmission.

The data series in the Safety_Significant data set are a subset of the data series in the data sets that make up the main message body sent to Oracle Argus Safety. Every item that is mapped in the Safety_Significant data set must also be mapped in the message body data sets.

Additionally, the data series in the Safety_Significant data set must have the same aliases as the corresponding data series in the message body data sets. Therefore, copy and pasting data series from the message body data sets into the Safety_Significant data set is recommended.

What is the syntax of the _SavetoDB function?

The _SavetoDB function is called in rules that determine whether to send data to the Oracle InForm Publisher queue.

```
Syntax:    _SaveToDB(<Message>,<Trialname>);
```

Where:

- **Message (string)**—Parameter that triggers Oracle InForm Publisher to do one of the actions listed below. The rule expression loads the message parameter with a value based on the value of specific items in the form.
  The text of the message parameter is fixed. The library in the Oracle InForm to Oracle Argus Safety integration package includes the following constants defining enumerations for the required strings. We recommend that you use these SafetyConstants enumerations to specify the required strings.
  - **IsReadyToSend**¾If the site never completes the item, it will be sent to Oracle Argus Safety within after a time interval configured in Oracle InForm Publisher.
  - **IsReportableOrSerious**¾Marks the safety event as serious and sends it to Oracle Argus Safety after a time interval configured in Oracle InForm Publisher.
- **Trialname (string)**¾Name of the study, populated by the GetTrialName() predefined function.

Sample call to _SaveToDB:

```
_SaveToDB('SafetyConstants.IsReportableOrSerious',GetTrialName());
```

How does a calculation rule work?

To create a calculation rule, use the **SetValue** action.

In the following example, when the Labs Local Hematology form is submitted, a calculation rule populates the hidden HemoglobinLabNameLL2 item with the value Hemoglobin if a value is entered in the HemoglobinValueLL2 item.

Rule Part	Specification
Precondition	Evaluate on Form Submission
Expression	`value = (this.sctHemoglobin.HemoglobinValueLL2.Empty) && ! this.sctHemoglobin.HemoglobinLabNameLL2.Empty ? 2 : (! this.sctHemoglobin.HemoglobinValueLL2.Empty) && (this.sctHemoglobin.HemoglobinLabNameLL2.Empty || ("Hemoglobin" != this.sctHemoglobin.HemoglobinLabNameLL2.Value)) ? 1 : 3`
Action	`Set Value check box is selected. Set Value clause: when value == 1 set this.sctHemoglobin.HemoglobinLabNameLL2.Value = "Hemoglobin" when value == 2 set this.sctHemoglobin.HemoglobinLabNameLL2.Empty = true`

Are there rules that are not supported for items in the dynamic grid?

Yes. Batch rules are not supported.

What happens in Oracle InForm when a source form with a dynamic grid is deleted?

If you delete a form that has an adverse event in a dynamic grid, the relationship between the form and the adverse event is removed. If you undelete the form, the relationship with the dynamic grid is not restored. You must add the adverse event to the dynamic grid.

What kind of queries should I include on a dynamic grid item?

Any rules having to do with event selection; for example, which adverse events should go to Oracle Argus Safety, should be written on the dynamic grid items.

Any rules regarding the data entry itself; for example, an out-of-range AE onset date, should be written on the source form.

In both cases, the rule should point to a specific form and section.

What is data mapping?

The Oracle InForm and Oracle Argus Safety integration uses the data mapping feature of Oracle Central Designer to configure how safety event data items on Oracle InForm forms correspond to safety event entities in Oracle Argus Safety.

A data mapping is made up of data sets, and each data set is made up of data series:

- A data set is a grouping of one or more related data series.
- A data series is a grouping of one or more items with the same clinical meaning, such as or more items that collect medical history.

When you design a study, you map the data series in each data set to the Oracle InForm items that provide the source data to transmit to Oracle Argus Safety. Mappings for almost all of the data series are optional; you map only the data series that provide applicable safety event information for your study.

Are there fields that I don't need to map?

Some fields will be sent by Oracle InForm Publisher itself without being mapped in the Logical Schema.

If you don't include:	Oracle InForm Publisher sends:
Product Name	Value stored in StudySponsorDrug or StudyDrug.
Primary Reporter	Full name of user who marked the AE as serious or for follow-up, user who made last significant change.
Institution	Site Mnemonic and Name.
Reporter’s address	Site Address.
Qualification code	Physician (if not mapped or entered).
Report Type	2 (Report from Study)
Patient ID	Subject Number.
Initial Received Date	Date AE was marked as Serious.
Follow-up Date	Date the last significant data changed.

When and how are data mappings validated?

When the Oracle InForm Publisher service starts, an optional validation runs on the mappings defined to make sure that no required mappings are missing and that the data mapping does not contain mappings that are unsupported by Oracle InForm Publisher. This validation is useful for catching common mapping mistakes in the data mapping that could cause unexpected results in the data published by Oracle InForm Publisher. The validation checks that:

- All required mappings have been defined.
- Every item that is mapped in the Safety_Significant data set is also mapped in the message body data sets.
- Data series in non-repeating data sets are mapped to a specific instance of an item.
- Data series in repeating data sets are not mapped to both flat items and itemset items within the same repeating form.

To enable or disable the validation, set the RunStartupValidation attribute when configuring Oracle InForm Publisher. For more information, see *Oracle InForm Installation Guide*.

Which items have data series for transmitting coded or verbatim data?

Item	Data Set	Data Series
AE description (verbatim)	Subject_AdverseEventSubject_AdverseEvent	AE_VerbatimTerm
AE description (coded to MedDRA lower-level term)	Subject_AdverseEvent	AE_LowLevelTerm
AE description (coded to MedDRA preferred term)	Subject_AdverseEvent	AE_PreferredTerm
Indication for concomitant medication	Subject_ConMed	ConMed_indication
Indication for suspect drug user	Subject_SuspectDrug	SuspectDrug_Indication
Indication for past drug use	Subject_PastDrugHistory	PastDrugHistory_Indication
Reaction to past drug use	Subject_PastDrugHistory	PastDrugHistory_Reaction
Medical history condition	Subject_MedicalHistory	MedicalHistory_Name
Cause of death	Subject_CauseOfDeath	CauseOfDeath
Autopsy cause of death	Subject_Autopsy	AutopsyCauseOfDeath

What alias names should I use when creating custom data series?

These are the alias names to use when creating custom data series.

Data Set Title	Tab in Argus Safety	Alias Naming Convention
Safety_Case	General	String fields: Cust_General_Str_<1...12> Number fields: Cust_General_Num_<1...12> Date fields: Cust_General_Dt_<1...12>
Subject	Patient	String fields: Cust_Patient_Str_<1...12> Number fields: Cust_Patient_Num_<1...12> Date fields: Cust_Patient_Dt_<1...12>
Subject_AdverseEvent	Event	String fields: Cust_Reaction_Str_<1...12> Number fields: Cust_Reaction_Num_<1...12> Date fields: Cust_Reaction_Dt_<1...12>

Example

In the sample studies delivered with the Oracle InForm and Oracle Argus Safety integration package, the Subject_AdverseEvent data set has a custom data series with the following properties:

- RefName - DSRReaction_Cust_float_1
- Title - AE_Cust_float_1
- Alias - Cust_Reaction_Num_1

This mapping means that in the Event tab of Oracle Argus Safety, the user-defined float field 1 receives data from the Oracle InForm item mapped to the AE_Cust_ float_1 data series.

How do I trigger Oracle InForm Publisher to send adverse event data to Oracle Argus Safety based on an onset date?

Oracle InForm Publisher watches for and collects serious adverse events to send to Oracle Argus Safety.

The before and after onset dates for an adverse event can be used to associate the adverse event with related safety data based on date ranges you configure in Oracle InForm Publisher. Configure the Oracle Argus Safety only attributes in the Oracle InForm Publisher configuration file, as described in the *Configuration Guide for Oracle InForm Publisher*.

If an instance of a related form has a start date within the specified range of the AE onset date, the safety event data from the related form is transmitted to Oracle Argus Safety with the AE data. For example, if the AE Start Date is March 1, 2018 and the time frame for collecting related adverse events is 14 days, an AE that occurred on Feb 25, 2018 would be sent to Oracle Argus Safety.

> **Note:**
>
> If you map the Safety Case-related AE Sequence Number Control to an item in a repeating itemset, the time frame for related AEs will not be used.

General

In this section:

- What is a project?
- What happens when I delete a study object?
- What happens when I delete a study or project?
- What happens when I protect a study or library?
- How are study objects sorted in the Project Explorer?
- What are local locks and remote locks?
- What is the primary layout of a study?

What is a project?

A project is a container that holds studies and libraries. You can create two types of projects:

- **Study project**—A project containing one or more studies that are related to each other. There is no limit on the number of studies you can create in a study project. However, you might experience performance degradation if you have multiple studies in a single project, especially if the number of study objects is large.
- **Library project**—A project containing a library. You can create one library in each library project.

What happens when I delete a study object?

The way that study objects are deleted depends on whether they are instances or links. If you delete a study object that has been copied as a link, only the selected study object is deleted. No copies of it are deleted.

Type	Description	Appearance in the Project Explorer
Instance	An actual study object in a study	Study objects that are **instances** appear in study object containers. For example, all study elements in the Elements container are instances.

Type	Description	Appearance in the Project Explorer
Link	A link to a study object in a study.	Study objects that are **links** appear as children in study object containers. For example, if a study event is a child of a study element in the Elements container, the study element is an instance, and the study event is a link.

For more information, see:

- What is the difference between an instance and a link?

What is the difference between an instance and a link?

Type	Description	Appearance in the Project Explorer
Instance	An actual study object in a study	Study objects that are **instances** appear in study object containers. For example, all study elements in the Elements container are instances.
Link	A link to a study object in a study.	Study objects that are **links** appear as children in study object containers. For example, if a study event is a child of a study element in the Elements container, the study element is an instance, and the study event is a link.

For more information, see:

- What happens when an instance is deleted?
- What happens when a link is deleted?

What happens when an instance is deleted?

Description	Example	When you delete the Gender item
No child study objects. Not used by other study objects in the study.	Item name—PregnancyTest • No codelist. • Not used on any form.	The instance of the PregnancyTest item is removed from the study.

Description	Example	When you delete the Gender item
No child study objects. Used by one or more study objects in the study.	Item name—PregnancyTest • No codelist. • Used on the Visit1 and Visit2 forms.	A dialog box informs you that the delete will remove all links to the instance. You can continue or cancel. If you continue: • The instance of the PregnancyTest item is removed from the study. • The links to the PregnancyTest item are removed from the Visit1 and Visit2 forms.
One or more child study objects that are not used by any other study object. Not used by other study objects in the study.	Item name—PregnancyTest • Has a codelist. • Not used on any form.	The instance of the PregnancyTest item is removed from the study. You are asked if you want to include the child study objects in the delete. • If you select Yes, the codelist is deleted. • If you select No, the codelist is not deleted.
One or more child study objects that are used by one or more other study objects. Not used by other study objects in the study.	Item name—PregnancyTest • Has a codelist. • Not used on any form.	The instance of the PregnancyTest item is removed from the study. The codelist on the item is not affected because it is being used by one or more other study objects in the study.
One or more child study objects that are not used by any other study object. Used by one or more study objects in the study.	Item name—PregnancyTest • Has a codelist. • Used on the Visit1 and Visit2 forms.	A dialog box informs you that the delete will remove all links to the instance. You can continue or cancel. If you continue: • You are asked if you want to include the child study objects in the delete. – If you select Yes, the codelist is removed from the study. – If you select No, the codelist is not affected. In addition: • The instance of the PregnancyTest item is removed from the study. • The links to the PregnancyTest item are removed from the Visit1 and Visit2 forms

What happens when a link is deleted?

Description	Example	Results of deleting the item
Has child study objects or has no child study objects. Is used by multiple study objects.	Item name—PregnancyTest • Has a codelist or has no codelist. • Used on the Visit1 and Visit2 forms.	When you delete the PregnancyTest item from a form (for example, the Visit2 form): • The link to the PregnancyTest item is deleted from the Visit2 form. • The link to the PregnancyTest item remains on the Visit1form. The PregnancyTest item can be used on other forms.
Has no child study objects. Is used by a single study object.	Item name—PregnancyTest • No codelist. • Used on the Visit2 form only.	The link to the PregnancyTest item is deleted from the Visit2 form, and the instance of the PregnancyTest item is removed from the study.
Has one or more child study objects. Is used by a single study object.	Item name—PregnancyTest • Has a codelist. • Used on the Visit2form only.	The link to the PregnancyTest item is removed from the Visit2 form. If the codelist on the item is used by only the PregnancyTest item, then you are asked if the child study objects should be included in the delete: • If you select Yes, the instances of the codelist and its codelist items are removed from the study. • If you select No, only the PregnancyTest item is removed from the study. The codelist still exists and can be used by other items.

Note:

When you delete the final link of a study object, you receive a message that only a single link to the study object exists in the study or library, and you are asked if you want to delete the study object from the study or library after the link is removed. If you click:

- Yes—Both the link to the study object and the study object itself are deleted from the study or library.
- No—The link to the study object is removed from the study or library, but the study object remains in the study or library.

What happens when I delete a study or project?

When you delete a study, study project, or library project, the contents are permanently removed from the database. You cannot delete or archive the System Library or its project.

What happens when I protect a study or library?

You cannot:

- Modify objects in the study.
- Change the structure of the study or library.

However, you can:

- Validate, create, and delete baselines.
- Create and delete deployment packages.
- Copy and paste a protected study object onto an unprotected study object. The protected study object remains protected.
- Delete a study object that is not the direct child of a protected study object.

How are study objects sorted in the Project Explorer?

By default, study objects appear in the following order in the Project Explorer:

- Study objects added to a Study Design, Study Element, or Study Event appear in workflow order.
- Study objects added to a form appear in the order in which they are added.
- Study objects without children appear in alphabetical order.

You can sort the study objects in ascending (alphabetical) order or descending (reverse alphabetical) order. You can also drag and drop study objects to change their order in the Project Explorer.

What are local locks and remote locks?

You can filter the study objects that appear in the Project Explorer by the type of lock applied to them. Local locks are study objects that you locked. Remote locks are study objects that are locked by other users.

What is the primary layout of a study?

Every study requires a primary layout, or validation fails. You set the primary layout for a study at the study level. The first layout that you create for a form or item is given the name of the primary layout.

If you change the name of the primary layout, the change affects all forms. For example, if a form has a layout named Main, and you choose to use the layout named Spanish as the primary layout, then all layouts named Spanish become the primary layouts.

13

What if...

In this chapter:

- Study administrators
- Library users
- Setting your machine for different locales
- Dynamic grid
- I can't import a project archive
- I export and re-import the same study CSML
- I can't create an item from a user-created type
- I can't mark a project as a template
- Deployment with an in-place revision change fails
- I delete a rule
- I deactivate a rule
- I disable a rule
- I can't disable a rule
- I cut a data-entry rule from a study object, but nothing happened
- A rule test case fails
- Validation produces errors and warnings
- A rule in Oracle InForm is deactivated
- I edit or delete a deployment instance
- There are blank pages in the PDF file created for my annotated study book

Study administrators

In this section:

- There are no locales listed on the Languages tab for my study
- I can't add a user to a study team
- I can't archive a study or project
- I was added to a study team, but still don't have the associated rights
- I can't find the dictionary type I want in the Dictionary Types list
- I can't find the verbatim type I want in the Verbatim Types list
- I can't deselect a dictionary type
- I can't add a library object to my study

- I can't search for study objects in a library that I want to search
- There aren't any sponsors listed in the study administration data
- I can't add a form to a signature group

There are no locales listed on the Languages tab for my study

An application administrator must select locales in Oracle Central Designer Administrator to populate the list.

I can't add a user to a study team

If you don't see the user you want to add to a study team in the Users Browser, the user might not be assigned to the role that corresponds to the study team.

Contact a Oracle Central Designer administrator to get the user added to the correct role.

I can't archive a study or project

If you can't archive a study or a project, one of the following might be the cause:

- The project might contain studies for which you are not a team member. **Solution:** Contact a Oracle Central Designer administrator to get access to the hidden studies.
- A deployment to a LIVE or UAT deployment instance is scheduled or in progress. **Solution:** Archive after the deployment process is complete.

I was added to a study team, but still don't have the associated rights

Log out and log on again to have the privileges associated with the team.

I can't find the dictionary type I want in the Dictionary Types list

Only enabled dictionary types appear in the Dictionary Types list. Contact a Oracle Central Designer administrator to import and enable additional dictionary types in the Oracle Central Designer Administrator.

I can't find the verbatim type I want in the Verbatim Types list

Only enabled verbatim types appear in the Verbatim Types list. Contact a Oracle Central Designer administrator to import and enable additional verbatim types in the Oracle Central Designer Administrator.

I can't deselect a dictionary type

The dictionary type might be used in a coding map. If it's used in a coding map, **(in use)** appends the dictionary type, and you can't deselect it.

I can't add a library object to my study

The library is likely disabled. Contact a library administrator to enable it.

I can't search for study objects in a library that I want to search

The library is likely disabled. Contact a library administrator to enable it.

There aren't any sponsors listed in the study administration data

Contact an application administrator to add sponsors in the Oracle Central Designer Administrator. The sponsors in the Oracle Central Designer Administrator are used to populate the Sponsor name drop-down list.

I can't add a form to a signature group

If a signature group is a case report book type, the following restrictions apply to forms that you add to the signature group:

- You cannot add a repeating form to the signature group.
- You can add only one form to the signature group.
- The form can belong to only one study event.
- The form cannot be used in a repeating study event.

Library users

In this section:

- I was added to a library team, but still don't have the associated rights
- I can't archive a library or library project
- I can't edit a library object
- I can't add a library to the Library List for a study
- I can't close a library that I'm not using anymore
- I can't delete an object

I was added to a library team, but still don't have the associated rights

Log out and log on again to have the privileges associated with the team.

I can't archive a library or library project

If you can't archive a library or a project, one of the following might be the cause:

- The project might contain studies for which you are not a team member.
  Solution: Contact a Oracle Central Designer administrator to get access to the hidden studies.
- You are attempting to archive the System Library project.
  Solution: This project cannot be archived or deleted.

I can't edit a library object

The library is likely disabled. To enable a library, in the Project Explorer, right-click the library, and select **Enable Library**.

I can't add a library to the Library List for a study

The library is likely disabled. To enable a library, in the Project Explorer, right-click the library, and select **Enable Library**.

I can't close a library that I'm not using anymore

The library is likely disabled. To enable a library, in the Project Explorer, right-click the library, and select **Enable Library**.

I can't delete an object

This can happen if:

- The object is protected, or is the child of a protected object.
  Review the object's protected status and try again.
- The object is an item that is used in a dynamic grid section. (If you try to delete an item that is used in a dynamic grid section, an error appears and tells you why you can't delete the item.)
  Remove the item from the dynamic grid section, and then try again to delete it from the form.
- The object is a visit, form, or section that is used in a dynamic grid section.
  Remove the item from the dynamic grid section, and then try again to delete it from the form.
- The object is a child of an item that is used in a dynamic grid section.
  Remove the item from the dynamic grid section, and then try again to delete it from the form.
- The object is conditional on an item that is used in a dynamic grid section.
  Remove the item from the dynamic grid section, and then try again to delete it from the form.

Setting your machine for different locales

In this section:

- Viewing Japanese characters
- Setting up a keyboard to use different locales
- Additional locale settings

Viewing Japanese characters

Perform these steps if you are unable to view Japanese characters.

1. Select **Start** > **Control Panel** > **Regional and Language Options**.

2. Select the **Languages** tab.
3. Select **Install files for East Asian languages**.
4. Click **OK**.
5. Restart your computer.

Setting up a keyboard to use different locales

When the Windows operating system starts in a specific locale, it updates the keyboard settings for that locale. If you will develop a study in a language other than the locale in which you are located, use this procedure to switch your keyboard settings and shortcuts between locales.

In each locale, set up the Windows operating system to support multiple text input languages —the local language and the language in which the study is developed:

1. Select **Control Panel** > **Regional and Language Options** > **Languages** tab > **Details**.
2. In the **Settings** tab of the **Text Services and Input Languages** dialog box, make sure that both the local language and the study development language are included in the list of supported text input languages.
3. Activate the **Language Bar**.
4. Use the **Language Bar** to switch between the local language and the study development language. Always log on to the Oracle Central Designer application in the study development language.

Additional locale settings

You set the default locale for a study in the Oracle Central Designer application.

The Microsoft Windows operating system also provides the following language-related options.

Option location	Purpose
Control Panel >Regional and Language Options >Regional Options tab >Standards and formats section	Controls the formatting conventions for numeric data, including dates, times, numbers, and currencies.
Control Panel >Regional and Language Options >Languages tab >Language used in menus and dialogs	Controls the language of text in menus and dialog boxes. The option appears only if you have one or more Multiple User Interface (MUI) packs installed. The Oracle Central Designer user interface supports only English.
Control Panel >Regional and Language Options >Languages tab >Details button >Default input language	Controls the language that you use to type information on the computer. For example, if the default locale for a study is set to French (France), all study metadata is saved as French metadata. Even if the input language is English (United States) and you type information in the English language, the information is saved as information entered for the French locale.

Note:

If you do not set the default locale for a study in the Oracle Central Designer application, this setting is used as the default locale for a study. If you modify the regional setting, you must close and reopen the Oracle Central Designer application to use the new locale.

Dynamic grid

In this section:

- I want to add one or more source items to a single target item
- Source items and target items have different data configurations
- The source item configuration differs from its parent form configuration
- I'm data mapping with a source item that has a codelist

- Source items have units
- I want to create multiple dynamic grids that have the same source form
- I'm using an item-level mapping for nested items
- I want to map multiple items in a repeating form to a single target item
- The year range differs between the source item and target item or form

I want to add one or more source items to a single target item

When adding one or multiple sources to a dynamic grid, source items for a single target item must have the same data type.

Source items and target items have different data configurations

When adding one or multiple sources to a dynamic grid, target items should encompass all possible source item data configurations.

For example, a target text item's character limit should be equal to the source text item with the largest character limit. Likewise, different lengths or precision in a target item should be large enough on all aspects to include all source items.

The source item configuration differs from its parent form configuration

A target item in a dynamic grid only matches source item data configurations and ignores configurations for its parent form layout. If there is a mismatch between the source item and its parent form (for example, if the original source item configurations were overridden by its parent form layout), a validation error may occur. To avoid this:

- For item-level mapping, update the target form layout to match the parent form layout of the source item.
- For data point mapping, either update the target item or its parent form layout to match the parent form layout of the source item.

I'm data mapping with a source item that has a codelist

For data point mapping with a source item that has a codelist, the data type of a target item must be text type.

For a codelist as radio or menu control, all the selections can be mapped to the same target item; for a codelist as a check box, each selection must be mapped to an individual target item.

Source items have units

For items with units, the data type and base unit must match between source and target items. Also, the target item must have all the conversion units that source items have.

I want to create multiple dynamic grids that have the same source form

You can create multiple dynamic grids that have the same source form. For example, an Adverse Event form can be linked to both an Adverse Event dynamic grid and a medical history dynamic grid.

I'm using an item-level mapping for nested items

If you're using an item-level mapping for nested items, the nested structure must be identical between sources.

I want to map multiple items in a repeating form to a single target item

You cannot have multiple objects within the same repeating ancestor mapped to the same target item. For example, multiple items on the same repeating form cannot be the source for a single target item.

The year range differs between the source item and target item or form

The year range for a target date time item and how it appears on a target form depend on the following criteria:

- If the **inherit** option under **Year range** in Control Styles is checked and the source date time item doesn't have a specific year range on its design, the target item uses the year range from study style.
- If the **inherit** option under **Year range** in Control Styles is checked and the source date time item has a specific year range on its design, the target item uses the year range specified by the source item's design.
- On the item layout, if the **inherit** option under **Year range** in Control Styles is unchecked (overridden) and the user specifies a different year range, this year range is used as default when creating a new form layout. Existing form layouts with the item are not affected.
- On the form layout, if the **inherit** option under **Year range** in Control Styles is unchecked (overridden) and the user specifies a different year range, this year range is used as the year range for the item on that form.

To confirm the effective year range for the item, use the Preview Annotated Form in the form layout editor.

I can't import a project archive

If your project archive contains functions, you need super-user rights to import the archive.

During the import process, the study doesn't yet exist, so you don't yet have the right to import functions into that study, and won't be granted that right until the import finishes. However, because a user with super-user rights has all rights by default, he can complete the import.

Contact your application administrator to be granted super-user rights, or to locate a user who has the rights to complete the import.

I export and re-import the same study CSML

If you export and then re-import a study using the CSML format, the Study Design object is overwritten. (Each study has only one Study Design object.) The following rules apply when an imported study object and an existing study object have the same object ID.

Import target	Imported study object has the same ID as a study object in...	Result
Study	Any other study.	The ID of the imported study object is changed to a new ID. All references to the imported study object in the import are updated to refer to the new ID.
Study	The same study.	The ID of the imported object does not change.
Library	Any library.	The ID of the imported object does not change.
Library	Any study.	The ID of the imported study object is changed to a new ID. All references to the imported study object in the import are updated to refer to the new ID.

I can't create an item from a user-created type

The item type might not exist in the libraries that are included in the Library List for your study. Ask your company's librarian to add the item type to one of your study's libraries.

I can't mark a project as a template

You cannot mark a project as a template if it contains hidden studies, which are studies you are not a team member on. Contact your study administrator to be added to the studies.

Deployment with an in-place revision change fails

You might have requested an in-place revision for a study version that doesn't exist in the target deployment instance. In this case, Oracle Central Designer ignores the request, and the in-place revision change is not completed for the study version that does not exist. A warning appears in the deployment package, but the deployment fails.

This can occur when you copy an in-place revision Configuration from one deployment instance to another. You can only copy an in-place revision Configuration from one deployment instance to another if the source and target deployment instances do not use the same study version number and contain the same path information for the study object on which you made an in-place revision change.

You must manually ensure that this criterion is met, as Oracle Central Designer does not validate this information before you copy the in-place revision Configuration.

> **Note:**
>
> When a study designer performs an in-place revision, Oracle Central Designer provides a list of available study versions in Oracle InForm that are eligible for in-place revision. However, if an Oracle InForm user does a trial copy or trial reset before the in-place revision, the study versions in Oracle InForm and the ones in Oracle Central Designer are out of sync. Make sure that you refresh your in-place revision in Oracle Central Designer before deploying. To refresh your in-place revision, go to the IPR Configuration dialog box (where you create an in-place revision change), and click the **Refresh Versions** button.

I delete a rule

For a rule that you no longer want to use with a study, you can delete, deactivate, or disable the rule. The behavior of the rule in the Oracle InForm application depends on the action that you choose.

> **Tip:**
>
> When deploying to Oracle InForm release 6.1.1 or later, you must create a deployment instance in order to see the behavior described in this topic. The deployment instance allows Oracle Central Designer to communicate with Oracle InForm to determine the rule states and update them accordingly.

When you delete a rule, Oracle Central Designer removes the rule from the study. Deleted rules are not validated or deployed to Oracle InForm.

- If you deploy to an Oracle InForm release prior to release 6.1.1, the rule is not deleted in Oracle InForm.
- If you deploy to Oracle InForm release 6.1.1 or later, Oracle InForm marks the rule as Inactive when you deploy your study. The rule does not appear in the Oracle InForm user interface.

  > **Note:**
  >
  > If you deactivate a rule in any release of Oracle InForm after deployment, it is not deleted in Oracle Central Designer. As a result, if you do not delete, deactivate, or disable the rule in Central Designer, the next time you deploy the study, the rule is deployed to Oracle InForm in the Active state.

- If you create the deployment instance after the baseline, the change will not be applied to Oracle InForm and the rule will remain in the state it was in previous to it being deleted in Central Designer.
  If you are using manual deployment, the deployment instance must be created prior to creating the baseline in order for the deletion of the rule to take effect in Oracle InForm.

I deactivate a rule

For a rule that you no longer want to use with a study, you can delete, deactivate, or disable the rule. The behavior of the rule in the Oracle InForm application depends on the action that you choose.

> **Tip:**
>
> When deploying to Oracle InForm release 6.1.1 or later, you must create a deployment instance in order to see the behavior described in this topic. The deployment instance allows Oracle Central Designer to communicate with Oracle InForm to determine the rule states and update them accordingly.

When you deactivate a rule, Oracle Central Designer retains the rule in the database, but prevents the rule from running in the Oracle InForm application. Deactivating a rule also allows you suspend execution of the rule on a temporary basis.

Deactivated rules are:

- Validated in the Oracle Central Designer application.
- Deployed to the Oracle InForm application in the Inactive state.
- Run only manually in the Oracle InForm application.

> **Note:**
>
> To deactivate a rule, set the Evaluate on Event precondition to **On demand (batch mode)**.

I disable a rule

For a rule that you no longer want to use with a study, you can delete, deactivate, or disable the rule. The behavior of the rule in the Oracle InForm application depends on the action that you choose.

> **Tip:**
>
> When deploying to Oracle InForm release 6.1.1 or later, you must create a deployment instance in order to see the behavior described in this topic. The deployment instance allows Oracle Central Designer to communicate with Oracle InForm to determine the rule states and update them accordingly.

When you disable a rule, Oracle Central Designer allows you to more easily perform testing for a study during a development process in which forms and rules are being developed collaboratively by different users, by viewing the study in the Oracle InForm application, without having to validate rules.

Disabling a rule does not prohibit you from performing rule-related tasks, such as editing the rule, and creating and running test cases for the rule. You can successfully run a test case for a single disabled rule. However, if you run more than one rule at a time, the Oracle Central Designer application will not run the test cases for disabled rules.

- If you deploy to an Oracle InForm release prior to release 6.1.1:
  - Disabled rules are not validated in the Oracle Central Designer application.
  - Disabled rules are excluded from the deployment package.
  - A validation warning appears and indicates that the study contains disabled rules.
- If you deploy a study to Oracle InForm release 6.1.1 or later:
  - Disabled rules are deployed to the Oracle InForm application as read-only.
  - A validation warning appears and indicates that the study contains disabled rules.

> **Note:**
>
> If you disable a rule in any release of Oracle InForm after deployment by marking it Inactive, it is not disabled in Oracle Central Designer. As a result, if you do not delete, deactivate, or disable the rule in Oracle Central Designer, the next time you deploy the study, the rule is deployed to Oracle InForm in the Active state.

I can't disable a rule

The Oracle Central Designer application disables or enables all unlocked and unprotected rules. The rule might be locked or protected.

I cut a data-entry rule from a study object, but nothing happened

When you select Cut, the data-entry rule is not immediately deleted from its parent study object. The rule is only deleted when you paste it onto another study object. If you do not paste a cut rule, it remains associated with its original parent study object. This behavior is different from the cut and paste functionality that is used when you move a study object in the Project Explorer. In the Project Explorer, when you cut a study object, it is immediately deleted from its parent study object.

A rule test case fails

A test case fails when the parameters that you enter are run in the rule, and the result that you expected does not occur. To troubleshoot failed test cases, consider the following:

- Does the test case reflect the expected behavior of the rule?
- Is the rule written correctly?

Validation produces errors and warnings

Validation can produce errors and warnings, as well as informational messages. You can read the errors and warnings to find out if any modifications are necessary for your study to pass validation and be deployed.

You can deploy a study that has received validation warnings, but you must acknowledge the warnings to indicate that you understand them and choose to ignore them in order to proceed with building the deployment package.

A validation baseline can have the following statuses:

- **Invalid**—One or more errors. The validation baseline cannot be used in a deployment package.
- **Invalid with warnings**—One or more warnings. A user must indicate that the warnings can be ignored before using the validation baseline in a deployment package.
- **Pending**—Validation is in process.
- **Valid**—No errors. The validation baseline can be used in a deployment package.
- **Valid with warnings**—One or more warnings. A user has indicated that the warnings can be ignored, and the validation baseline can be used in a deployment package.

A rule in Oracle InForm is deactivated

If you deactivate a rule in Oracle InForm, do one of the following in Oracle Central Designer before creating a new deployment package:

- Remove the rule from the study.
- Disable the rule.
- Change the triggering event to On Demand (Batch Mode).

Rule-related changes that you make in Oracle InForm are overridden when you install a new deployment package.

Before you can create a deployment package, you must specify deployment options for the study in the Study Editor. Deployment options indicate the target applications, format, and languages or locales for which the study is being designed.

I edit or delete a deployment instance

Editing or deleting an instance does not affect deployment requests created before the edit or deletion.

You cannot delete an instance that is associated with in-place revisions. If you edit an instance with in-place revisions, the changes affect the in-place revisions.

There are blank pages in the PDF file created for my annotated study book

Each form appears on its own page in the PDF output.

However, because of how the PDF is generated by Windows, which Oracle Central Designer cannot control, if a form is large enough that when printed it goes all the way to the bottom of the page, generating the PDF creates an extra page break, leading to random blank pages in the PDF.

If you see blank pages in the PDF, change the scaling before printing to PDF.

1. Instead of clicking the Print button in the Annotated Study Book Options dialog box, right click anywhere in the Annotated Study Book window, and select Print Preview.
   The preview will first scale the output to 100%, and then Shrink to Fit. This shrinking is what causes the blank page.
2. Change the scaling, for example to 60%, until you can see there are no blank pages.
   You may have to change the scaling based on the content of the study.
3. After you're satisfied with the appearance of the PDF, click the printer button and select your PDF printer driver as you'd normally do.
   The resulting PDF should have no blank pages.

14

Option and property descriptions

In this chapter:

- Setting up and administering a study
- Study elements and study events
- Study objects
- Forms, items, codelists, and codelist items
- Layouts
- Study workflow
- Import and export
- Tasks and notes
- Custom events
- Rules
- Data mappings
- Validation and deployment
- Post-design
- Properties

Setting up and administering a study

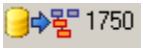
In this section:

- Home page—Section descriptions
- Status toolbar—Option descriptions
- Coding tab—Option descriptions
- Coding Map dialog boxes—Option descriptions
- Libraries tab—Section descriptions
- Libraries tab—Button descriptions
- References tab—Option descriptions
- Review State editor—Option descriptions
- Review State editor—Option descriptions
- Study General tab—Option descriptions
- Teams tab—Field descriptions
- Deployment Setup tab—Option descriptions
- Study administration data

Home page—Section descriptions

Section	Description
Recent Projects List	Projects you opened recently.
Pending Approvals Tab	Deployment requests that you can approve. Use the toolbar buttons to approve or reject requests, and view a history of automated deployments.
Recent Tasks Tab	Tasks that are open and assigned to you. Use the drop-down list to see tasks added since yesterday, in the last three days, in the last week, and so on.
My Tasks	All tasks assigned to you.

Status toolbar—Option descriptions

Option	Description
	Appears when study objects are loading.
	You are logged on, and the application is connected to the application server.
 or 	• (Green circle icon)—The application is pulling information from the application server. • (Yellow circle icon)—The application is unable to pull information from the application server. For example, network connectivity might be unavailable, or the server might have stopped responding.
 or 	• (Gray circle icon)—The server is not processing information, and you can work. • (Blue circle icon)—The server is processing information. Wait until the process completes before performing another activity.

Coding tab—Option descriptions

> **Note:**
>
> This tab appears only after you have defined context information for a coding map and when the coding map is selected in the top panel. Not all dictionaries allow you to define context information.

Field	Description
Top panel	–
Assign queries to Item	Title of the item to which to assign queries for the verbatim in the Oracle Health Sciences InForm application.
Assign queries to Question	(Optional) Question associated with the item to which to assign queries for the verbatim in the Oracle Health Sciences InForm application.
Assign queries to RefName	(Optional) RefName of the item to which to assign queries for the verbatim in the Oracle Health Sciences InForm application.
Coding Map RefName	RefName of the coding map.
Dictionary Type	Name of the dictionary type for which the coding map is created.
Form Name	Form on which the verbatim item exists.
Verbatim Item	Title of the verbatim item for which a coding map is created.
Verbatim Type	Verbatim type that was specified for the coding map.
Verbatim Question	Default question of the verbatim item.
Verbatim RefName	RefName of the item.
Bottom panel—Coding Results tab	–
Dictionary Level	Dictionary level for which the coding map is defined.
Level Type	Information that indicates whether the target item is for: • Code • Term • Additional information, which appears as **Additional Info for [Level Name]**, where [Level Name] is the name of the dictionary level (available only for the WHO-DD dictionary type and in custom dictionary types in which additional information is defined).
Target Item	Title of the item that is specified for the dictionary level in the coding map.
Target Question	Default question of the item that is specified for the dictionary level in the coding map.
Target RefName	RefName of the target item.

Field	Description
Bottom panel—Context Information tab	–
Context Meaning	Descriptive text for the context information. This information is displayed exactly as it is defined in the dictionary.
Context Item	Title of the context item.
Context Question	Default question of the context item.
Context RefName	RefName of the context item.

Coding Map dialog boxes—Option descriptions

Option	Description
Dictionary type	List of all dictionary types (including custom dictionary types, if any) that have been installed, enabled, and selected for the given study or library. For more information, see: • Importing and overwriting a dictionary type (in the *Administrator Guide*). • Enabling and disabling a dictionary type (in the *Administrator Guide*). After you select a dictionary type, additional fields in the dialog box (including Verbatim Type and the information in the grids) are populated with data from the dictionary.
Item to code	List of titles for all text items that can be coded. **Note:** • If you are creating a coding map, you can change the selected item but you cannot clear it. • If you are modifying a coding map, this field is read-only.
Verbatim type	List of verbatim types that are enabled for the selected dictionary type. The field is enabled after you select a dictionary type.

Option	Description
Assign queries to	List of items that are eligible for query assignment, including the verbatim item. Each item in the list is: • A top-level item. • Visible and available for editing in the InForm application. Items designated as query targets must not have the Display Override property set to ReadOnly or Hidden in the Central Designer application. **Note:** You can select **<use verbatim>** in the **Assign queries to** drop-down list to select the verbatim item as the query target if the verbatim satisfies the requirements for a query target item.
Coding Results tab	–
Dictionary Level	Dictionary level for which the coding map is defined.
Level Type	Information that indicates whether the target item is for: • Code • Term • Additional information, which appears as **Additional Info for [Level Name]**, where [Level Name] is the name of the dictionary level (available only for the WHO-DD dictionary type and in custom dictionary types in which additional information is defined).

Option	Description
Target Item	List of titles for all text items that can be selected as target items for a dictionary level in the coding map. If you select an item, the Target Question field is populated with its question. The list does **not** contain items that are already a verbatim, text item, or context item for the specified dictionary type, unless you are modifying a coding map. In that situation, the list includes the item that is currently assigned to the row, so you can review the list of options and reselect the item if you decide not to change the assignment.
Target Question	List of default questions for all text items that can be selected as target items for a dictionary level in the coding map. If you select a question, the Target Item field is populated with the item name.
Context Information tab	–
Context Meaning	Descriptive text for the context information. This information is displayed exactly as it is defined in the dictionary.
Context Item	List of titles for all text items that can be selected as context items for a dictionary level in the coding map. If you select an item, the Context Question field is populated with its question. The list does **not** contain items that are already a verbatim, text item, or context item for the specified dictionary type, unless you are modifying a coding map. In that situation, the list includes the item that is currently assigned to the row, so you can review the list of options and reselect the item if you decide not to change the assignment.
Context Question	List of default questions for all text items that can be selected as context items for a dictionary level in the coding map. If you select a question, the Target Item field is populated with the item name.

Libraries tab—Section descriptions

Section	Description	For more information, see...
Library List (In Search Order)	Libraries with study objects that can be copied to the study. The order of the libraries indicates the order in which search results are displayed in the Libraries Browser (results from the first library appear first, followed by results from the second library, and so on).	Create and configure a library

Libraries tab—Button descriptions

Button	Description	For more information, see...
Add	Add an existing library to the Libraries list. When users in the study search for study objects in libraries, only the libraries in the Libraries list are searched.	Create and configure a library.
Remove	Remove a library from the Libraries list.	–
Up	Move a library up in the Libraries list.	Create and configure a library.

> **Note:**
>
> Libraries are searched in the order in which they are listed.

Button	Description	For more information, see...
Down	Move a library down in the Libraries list.	–

References tab—Option descriptions

Option	Description
Top section	-
Title	Name of the file or URL attachment.
Preview	Text that appears in the Description section.
(Paper clip button)	Indicates whether the reference has an attachment (a file, shortcut to a file, or URL address).
Details section	-
Description	Description of the attachment.
Attachments	All file and URL attachments.

Note:

The default maximum file size is 10 MB. This value can be configured.

Review State editor—Option descriptions

Field	Description
RefName, Title, Description	RefName, title, and description of the review state. In a study, review state RefNames must be unique. In a library, duplicate RefNames are allowed.
Activated	If selected, indicates that the review state is visible in the Oracle InForm application.
State	Number of the review state, indicating the order in which the review state is displayed in the Oracle InForm user interface. You can define a maximum of five review states for a study. In a library, the number of review states is unlimited.

Field	Description
English (United States), Japanese (Japan)	Oracle InForm product locales. Each tab contains the locale-specific names for the review state and each of its three stages. The Label and Mnemonic fields for the review state and each review stage are required for each Oracle InForm product locale (English and Japanese). If a required value is missing in a product locale tab, the value from the other locale (if it is defined) appears in the field in red, and an icon appears in the tab to indicate that translation is required. Study validation also checks for missing translated values. Because both English and Japanese locales are always required for review states, the study definition does not need to have the Japanese locale selected, and you do not need the Japanese language skill to translate the review state fields.
Label	Name for the review state, which appears in hover Help and drop-down lists in the Oracle InForm application.
Mnemonic	Abbreviated name for the review state, which appears in column headings in the Data Viewer of the Oracle InForm application.
Stage 1, Stage 2, Stage 3	Indicates the stage for which to specify the name, label, and mnemonic. You must create three review stages for each review state.
Name	RefName of the review stage. Each RefName must be unique within its review state.
Label	Name for the review stage, which appears in hover Help and drop-down lists in the Oracle InForm application.
Mnemonic	Abbreviated name for the review stage, which appears in column headings in the Data Viewer of the Oracle InForm application.

Review State editor—Option descriptions

Field	Description
Activated	If selected, indicates that the review state is visible in the Oracle InForm application.
Description	Description of the review state.
Identifier	Internal identifier of the review state.
Published (libraries only)	If True, indicates that the review state is published.
RefName	RefName of the review state.

Field	Description
State	Number of the review state, indicating the order in which the review state is displayed in the Oracle InForm user interface. You can define a maximum of five review states for a study. In a library, the number of review states is unlimited. READ-ONLY.
Title	Title of the review state.

Study General tab—Option descriptions

Field	Description
Study Name	Name of the study.
Targets	Target applications to which you will deploy the study.
Phase	Phase of the study.
Sponsor	Sponsor associated with the study.
Protocol	Name of the protocol associated with the study.
Study Restrictions	–
Restrict study designers from creating new forms or sections in a study	Study designers can drag and drop library forms and sections into the study, but cannot create new forms or add sections to forms in the study.
Restrict study designers from creating new items on forms from libraries	Study designers can drag and drop library forms into the study, but cannot add items to those forms.
Restrict study designers from modifying certain properties of items from libraries	Study designers can drag and drop library items into the study, but cannot modify the item Length, RefName, Short Question, Signed Value (integer items only), or Precision (float items only).
Restrict study designers from modifying codelists from libraries	Study designers can drag and drop library codelists into the study, but cannot modify the codelist, its codelist items, or its codelist subsets.
Require codelist subset selection	When study designers drag and drop codelists with defined subsets into the study, they must select a codelist subset for each item instance they drag and drop the codelist on. The restriction applies to items that exist in the study design, have one or more codelists, and have subsets defined for the codelists.

Teams tab—Field descriptions

When you select a user in the left section or double-click a user in the right section of the Teams tab, the right section has the following fields.

Field	Description
Team Name	The study team to which the selected user is assigned *for the selected study only*.
Must Approve	Reserved for future use.

Deployment Setup tab—Option descriptions

Option	Description
Buttons	–
Test URL	Test the URL of the selected deployment instance. If the test fails, automated deployment fails. The test is successful when: • The URL and port are valid for the Oracle InForm web service that is associated with the deployment instance. • The Oracle Central Designer deployment certificate is installed on the Oracle InForm server. • The Oracle Central Designer application can connect with the Oracle InForm web service. • The type of the deployment instance matches the type selected for the Oracle InForm web service. • The Approval Required setting for the deployment instance matches the setting for the Oracle Health Sciences InForm web service. • The rule engine that is installed on the Oracle Central Designer server is also installed on the Oracle InForm server. For more information, see the Oracle InForm *Installation Guide*.
Audit History	Display all the revisions of the selected deployment instance study object.
Columns	Select the columns to display.
Lock and Protect	Lock or protect the selected study object.
Columns	–

Option	Description
Icon (first column)	Status of the study object: •  —New. •  —Locked. •  —Protected. When a study object is protected, you cannot: – Update or lock it. – Add child study objects to it by pasting or dragging and dropping. • Delete its child study objects.
Description	Description of the deployment instance.
Type	Type of deployment instance: • **UAT—**User acceptance testing • **QA—**Quality assurance • **DEV—**Development • **LIVE—**Production • **TRN—**Training
URL	URL address of the deployment instance.
Port	Port number of the web service used to query deployment status.
Approval Required	Indicates whether deployments to the server must be approved by a user with the appropriate right, as configured in the Oracle Central Designer Administrator application.

Study administration data

In this section:

- Sponsor tab of the Administration editor—Option descriptions
- System settings tab of the Administration editor—Option descriptions
- Item Groups tab of the Administration editor—Option descriptions
- Query Groups tab of the Administration Editor—Option descriptions
- Rights Groups tab of the Administration Editor—Option descriptions
- Signature Groups tab of the Administration editor—Option descriptions

Sponsor tab of the Administration editor—Option descriptions

Option	Description
Sponsor Name	Name of the organization that is sponsoring the study.
Program	Name of the program.
Therapeutic area	Medical area that is being investigated by the study.
Note	Additional information you may want to include.
Address 1	Sponsor street address.
Address 2	Additional address information.
City	City.
State	State (United States).
Zip code	Zip code (United States).
Province	Province (outside the United States).
Postcode	Postcode (outside the United States).
Country	Country.
Phone	Telephone number.
Alt phone	Alternate telephone number.
Fax	Fax number.
Email address	Email address.

System settings tab of the Administration editor—Option descriptions

Field	Description
AutoAnswerManualQueries	Whether the Oracle InForm application automatically answers a manual query when a data item change satisfies the rules on the data item.
EmailForNewSiteAndUserNotification	Email address of an administrator who receives notification when a new site or new user is added.
EnforceVisitDate	Whether to require the use of Date of Visit on the first form of every visit.
EnrollWithIncompleteForms	Whether an Oracle InForm user can override a failed screening and enrollment.
FormSaveMode	Location and format of the message that appears when a form is submitted successfully.
InlineDuration	Number of seconds that the "Form submitted successfully" message remains visible in the header of the form before it fades. Must be a value from 1 to 9.
NavigationMode	Whether to allow users to change the order in which subjects appear in the Oracle InForm UI.
PatientSequence	Format for assigning subject numbers (read-only).
QueryMaxLength	Maximum number of characters of query text. Maximum characters: 350.
QuerySelection	State in which queries are created.

Field	Description
RequireCommentsForNA	Whether a comment is required when NA is used.
ScreeningSequence	Sequence number format for assigning screening numbers (read-only).
SponsorEditFrozen	Whether a sponsor can edit a form after it is marked frozen.
TrialDateFormat	Format of the date that appears in the study.
UniqueIntDOBSwitch	Requirements for a subject initial/date of birth combination settings. • Initials and DOB combination must be unique within a site. • Initials and DOB combination must be unique within a study.
UniquePatIDSwitch	Requirements for a subject ID. • Subject ID must be unique with a site. • Subject ID must be unique within a study.
UserNameOrder	Order in which subjects appear in the Signature Details view.
ViewCRFSignList	Whether a list of required signatures is included on each form.
VisitCalculatorEnabled	Whether to enable the visit calculator.
ShowUnscheduled	Whether to show the word Unscheduled in the visit title of unscheduled visits. This setting is only applicable to studies that are deployed to Oracle InForm release 6.2 or higher.
FreeCommentTextBox	Whether to enable a text box where users can enter a comment for a form or item. If you select Yes for **RequireCommentsForNA**, you can't select No for FreeCommentTextBox. If you select **No**, existing comments appear as read-only text, and the option to select Not Applicable, Unknown, or Not Done in the Reason incomplete field is available only for forms and items without data. This setting is only applicable to studies that are deployed to Oracle InForm release 6.2 or higher.
ItemsetUnsvRequired	Whether to specify when to set a Verified itemset to Not Verified in Oracle InForm. • If you select **When any item is changed (Default)**, a Verified itemset is set to Not Verified any time an item in the itemset is modified. • If you select **When any SV Required item is changed**, a Verified itemset is set to Not Verified any time an item in the itemset that is marked SV Required is modified. Setting this option in Oracle Central Designer sets the corresponding Oracle InForm option called **Set itemset to Not Verified**.
SVAutoSelectRate	Percentage of subjects that will be automatically selected for Partial SDV. The default is 100.
SVFirstNSubjects	Default value for the first n number of subjects that will be automatically selected for Partial SDV. The default is 0.
SVDefaultInclude	Include or exclude subjects from the SDV pool by default. The default is Include.

> **Note:**
>
> The system default settings that represent 100% SDV are:
>
> - SVAutoSelectRate = 100
> - SVFirstNSubjects = 0
> - SVDefaultInclude = Include
>
> The SVAutoSelectRate percentage starts after the SVFirstNSubjects is fulfilled.

Item Groups tab of the Administration editor—Option descriptions

Option	Description
Group Name	Name of the item group.
Description	Description of the item group.
Item Name	Name of an item that is associated with the item group.
Question	Question associated with the item group.
Owner Form (s)	Form or forms in which the item group is defined.

Query Groups tab of the Administration Editor—Option descriptions

Option	Description
Group Name	Name of the query group.
Description	Description of the query group.

Rights Groups tab of the Administration Editor—Option descriptions

Option	Description
Group Name	Name of the item group.
Description	Description of the item group.
Item Group Name	Name of an item group that is associated with the rights group.
Description	Description of an item group that is associated with the rights group.
Display Override	Whether the group of items that make up an item group is hidden, editable, or read-only.

Signature Groups tab of the Administration editor—Option descriptions

Option	Description
Group Name	Name of the signature group.
Description	Description of the signature group.
Type	Type of document a signature group can sign.

Option	Description
Reset Form State	Whether associating a new signature group with a form that is signed resets the state of the form to unsigned.
Invalidation Level	Invalidates a signature if items change after signoff.
Title	Name of the form a signature group can sign.
Description	Description of the form a signature group can sign.
Language	Language to use for meaning and signature text.
Signature Meaning	Whether the signature indicates that the form is Reviewed, Approved, or in a user-specified state.
Signature Text	The affidavit text.

Study elements and study events

In this section:

- Study Elements editor—Option descriptions
- Study Events Editor

Study Elements editor—Option descriptions

Columns common to all study object editors

> **Note:**
>
> Not all fields appear in the default view. Optionally, you can add the other fields and rearrange the browser view.

Property	Description
Icon (first column)	Study object's status.
Description	Study object's description.
Identifier	Unique internal identifier of the study object.
IPR Status	Indicates whether the study object has an IPR configuration.
Published (only in libraries)	Indicates that the study object has been published.

Property	Description
RefName	RefName of the study object. **Note:** We recommend that you don't use Conflict for a study event RefName, as there is a default Conflict visit created for Oracle InForm.
Revision	Revision number of the study object. The revision number is incremented each time the study object is changed and saved.
Title	Title of the study object.
Version	Version number of the study object. The version number is incremented only when a user explicitly updates it.

Optional fields for the default view

Note:

Not all fields appear in the default view. Optionally, you can add the other fields and rearrange the browser view.

Option	Description
Drop point	Data type of the codelist. The data type of a codelist must be compatible with the data type of any items in which it is included.

Study Events Editor

Columns common to all study object editors

Note:

Not all fields appear in the default view. Optionally, you can add the other fields and rearrange the browser view.

Property	Description
Icon (first column)	Status of the study object: •  —New. •  —Locked. •  —Protected. When a study object is protected, you cannot : – Update or lock it. – Add child study objects to it by pasting or dragging and dropping. – Delete its child study objects.
Description	Description of the study object. The description can have 0-255 characters.
Identifier	Unique internal identifier of the study object.
Published (only in libraries)	Indicates that the study object has been published.
RefName	RefName of the study object. The RefName can have 1-63 characters.
Revision	Revision number of the study object. The revision number is incremented each time the study object is changed and saved.
Title	Title of the study object. The title can have 1-63 characters.
Version	Version number of the study object. The version number is incremented only when a user explicitly updates it.

Optional fields for the default view

> **Note:**
>
> Not all fields appear in the default view. Optionally, you can add the other fields and rearrange the browser view.

Option	Description
Block key value	Value of the Clintrial block key, used for data transfer to the Clintrial application through CIS mappings. If you specify this value, it overrides the visit RefName as the block key.
Optional	Indicates whether the study event is optional or required.
Repeating	Indicates whether the study event is repeating.
Short Title	Short title for the study event.
Special Visits	Indicates whether the study event is an InForm special visit.

Study objects

In this section:

- Export Translations dialog box—Option descriptions
- Export Wizard options
- History Viewer dialog box—Option descriptions
- Import Wizard options—CSML or ODM file
- Import Wizard options—Oracle InForm resources
- References tab—Option descriptions

Export Translations dialog box—Option descriptions

Option	Description
Field	-
Locale to translate from	Name of the locale in which the text strings to translate have been defined. **Note:** The Locale to translate from is not the global default locale that is defined in the Tools > Options dialog box, but rather any locale in which the text strings to export exist.
Translate <locale name> to	Locale into which strings will be translated.
Target	Target application for which to translate strings.
Export file location	Location and file name in which to store the file of strings to translate. By default the file name has the format: <*StudyName*>_ExportTranslations_<*TargetSystem*>_<SelectedLocale>.csv For example: TestStudy_ExportTranslations_InForm_fr-FR.csv The Browse button enables you to browse to the location.
Include empty locale values	• **If selected**, the file of strings to translate includes strings that are empty in the locale to translate from. • **If not selected**, the export process skips empty strings.

Option	Description
Export log results	Displays messages that are generated during the export. Optionally, you can save these results to a file by clicking the Save Log Results As button.
Button	-
Check for Empty Strings	Opens a window listing all strings that are empty in the locale to translate from.
Save Log Results As	Specifies the location of a log file containing the messages that are generated in the Export log results box during the export.

Export Wizard options

Page	Option	Description
Welcome	-	Introduction page.
Export Type	-	Select the output format and export type.
-	Data Type	**CSML**—Export in Clinical Study Markup Language format. **ODM**—Export in Operational Data Model-compliant format. The Oracle Central Designer application supports the ODM 1.3 standard. **Administration data**—Export only study administration data for the Oracle InForm User Management Tool application.
-	Export Type	**Local**—Export to the computer where the Oracle Central Designer application is installed.
Export File Path	Export Directory	Specify the path name and file in which to save the export file, or click Browse to browse for the path name and file in which to save the export file.
Ready to Export Central Designer Data	-	View a summary of the parameters that will be used for the export.

History Viewer dialog box—Option descriptions

Field	Description
Top section	-
Object	Name of the study object.

Field	Description
Unlocked or Locked icon	Indicates whether study object is locked or unlocked.
Object [name of study object] section	-
Revision/Version	Revision or version number of the study object, with either *Version* or *Revision* in parentheses to indicate if it is a version or revision. **Note:** This value is for the selected study object only, not for the study in which the study object exists. This value may differ from the value that appears for the Revision property at the bottom of the History Viewer dialog box.
Label	• **If you are viewing versions**—Label given to the version when it was created. • **If you are viewing revisions**—Study Revision.
Altered By	Name of the user who modified the study object for the version or revision.
Date	Day and time when the study object was modified for the version or revision.
Description	• **If the last save created a version**—The label and description applied for the version. • **If the last saved created a revision**—Auto-generated description text.
View changing radio buttons	-
View Versions	All versions of the selected study object appear in the top grid.
View Every Edit	All revisions of the study object appear in the top grid.
Buttons	-
Differences	(Enabled when you select two versions or revisions.) View the differences between two versions or revisions of a study object.
Revert to	Revert to a previous version or revision of a study object.

Import Wizard options—CSML or ODM file

Page	Option	Description
Welcome	-	Introduction page.
Import Type	-	Select the source of the data to import.
-	Import CSML or ODM file	Generate study objects from a file in CSML or ODM format.
-	Harvest InForm Resources	Generate study objects from the components of an Oracle InForm study.
File Location	Path of file to import	Specify the path of the CSML or ODM import file, or click Browse to locate the import file.
Study Administration Import Mode	-	This page appears only for the CSML import type, if the CSML file contains study administration objects.
-	Import study objects and administration data.	Import both study objects and study administration objects.
-	Import administration data only.	Import only study administration objects.
-	Import study objects only.	Import only study objects.
Rule Import Mode	Rule Import Mode	Only the Import as Collaboration Notes option is supported. With this option, each imported rule is converted to a collaboration note in the Oracle Central Designer application. **Note:** This option applies only if the Import Type is ODM; if the Import Type is CSML, the import process creates a Oracle Central Designer rule for each imported rule.
IPR Import Mode	Import IPR data	Select whether to import in-place revision objects. **Note:** This page appears only if the file contains in-place revision objects.
Ready to Import Data to Central Designer	-	View a summary of the import options selected in the wizard.

Import Wizard options—Oracle InForm resources

Page	Option	Description
Welcome	-	Introduction page.
Import Type	-	Select the source of the data to import.

Page	Option	Description
-	Import CSML or ODM file	Generate study objects from a file in CSML or ODM format.
-	Harvest Oracle InForm Resources	Generate study objects from the components of an Oracle InForm study.
Oracle InForm File Location	-	Select the file or trial from which to harvest resources.
-	RSP or XML file	Specify the full path of the RSP or XML file containing MedML definitions of Oracle InForm trial components to import, or click Browse to browse to the file.
Rule Import Mode	Rule Import Mode	Only the Import as Collaboration Notes option is supported. With this option, each imported rule is converted to a collaboration note in the Oracle Central Designer application.
Ready to Import Data to Oracle Central Designer	-	View a summary of the import options selected in the wizard.

References tab—Option descriptions

Option	Description
Top section	-
Title	Name of the file or URL attachment.
Preview	Text that appears in the Description section.
(Paper clip button)	Indicates whether the reference has an attachment (a file, shortcut to a file, or URL address).
Details section	-
Description	Description of the attachment.
Attachments	All file and URL attachments.

Note:

The default maximum file size is 10 MB. This value can be configured.

Forms, items, codelists, and codelist items

In this section:

- Codelists Editor—Option descriptions
- Codelist Items Editor—Option descriptions
- Design tab of the Codelist Editor—Option descriptions
- Design tab of the Form Editor or Section Editor—Option descriptions
- Design tab of the Item Editor—Option descriptions
- Forms and sections editor—Option descriptions
- General tab of the Form Editor or Section Editor—Option descriptions
- Oracle InForm Items Editor—Option descriptions
- Item Properties dialog box—Option descriptions
- Keys dialog box
- Languages tab of the Codelist Item Editor—Option descriptions

Codelists Editor—Option descriptions

Columns common to all study object editors

> **Note:**
>
> Not all fields appear in the default view. Optionally, you can add the other fields and rearrange the browser view.

Property	Description
Icon (first column)	Study object's status.
Description	Study object's description.
Identifier	Unique internal identifier of the study object.
IPR Status	Indicates whether the study object has an IPR configuration.
Published (only in libraries)	Indicates that the study object has been published.

Property	Description
RefName	RefName of the study object. **Note:** We recommend that you don't use Conflict for a study event RefName, as there is a default Conflict visit created for Oracle InForm.
Revision	Revision number of the study object. The revision number is incremented each time the study object is changed and saved.
Title	Title of the study object.
Version	Version number of the study object. The version number is incremented only when a user explicitly updates it.

Optional fields for the default view

Note:

Not all fields appear in the default view. Optionally, you can add the other fields and rearrange the browser view.

Option	Description
CodeListType	Data type of the codelist. The data type of a codelist must be compatible with the data type of any items in which it is included.

Note:

To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add HTML formatting characters to a text field to control its appearance when deployed.

Codelist Items Editor—Option descriptions

Columns common to all study object editors

> **Note:**
>
> Not all fields appear in the default view. Optionally, you can add the other fields and rearrange the browser view.

Property	Description
Icon (first column)	Study object's status.
Description	Study object's description.
Identifier	Unique internal identifier of the study object.
IPR Status	Indicates whether the study object has an IPR configuration.
Published (only in libraries)	Indicates that the study object has been published.
RefName	RefName of the study object.

> **Note:**
>
> We recommend that you don't use Conflict for a study event RefName, as there is a default Conflict visit created for Oracle InForm.

Revision	Revision number of the study object. The revision number is incremented each time the study object is changed and saved.
Title	Title of the study object.
Version	Version number of the study object. The version number is incremented only when a user explicitly updates it.

Optional fields for the default view

> **Note:**
>
> Not all fields appear in the default view. Optionally, you can add the other fields and rearrange the browser view.

Option	Description
Code	Code of the codelist item.
CodeListType	Data type of the codelists in which the codelist item is included.
Label	Label of the codelist item. The label can have 1-255 characters.
Study Completion Status Item	Function of the codelist item in the codelist that is used in the special Completion status item of the Study Completion form: • None—The codelist item is not part of the codelist in the Completion status item. • Complete Study (Study Completion). • Incomplete Study (Study Completion).

Note:

To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add HTML formatting characters to a text field to control its appearance when deployed.

Design tab of the Codelist Editor—Option descriptions

Option	Description
Title (codelist)	Title of the codelist. The title can have 1-63 characters.
Description	Description of the codelist.
Data type	Data type of the codelist; must be compatible with the values specified for codelist item codes: • Float • Integer • String
Pulldown display order	Determines how the codelist will be displayed to the end user. The available options are: • Entered (default) • Alphabetical Ascending • Alphabetical Descending
Fields	-
Title (codelist item)	Title of the codelist item. The title can have 1-63 characters.
Code	Value stored in the repository for the codelist item. The value can have 1-2000 characters.
Label	Default label that appears on the form for the codelist item. The label can have 1-255 characters.
Description	Description of the codelist item. The description can have 0-255 characters.

> **Note:**
>
> To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add HTML formatting characters to a text field to control its appearance when deployed.

Design tab of the Form Editor or Section Editor—Option descriptions

Option	Description
Repeating	Indicates that the form or section is repeating. Multiple instances of the same set of data appear in the form or section.
Common (forms only)	Indicates that the form is common. The same data is visible in all study events that contain the form.
Fixed (sections only)	Indicates that the section is a fixed repeating section containing static text that repeats for each instance of the item.
Keys (toolbar button and icon for repeating forms and sections only)	• For a repeating form with no sections, opens the Keys dialog box, in which you can define key items. • For a form with one or more repeating sections, displays a drop-down list of repeating sections. Selecting a section opens the Keys dialog box, in which you can define key items.
Fields	-
Codelist	Applies to text, float, and integer items only. Drop-down list with available codelists for the item. Available codelists are all of the codelists in the study or library with the same type as the item.
Codelist Subset	Select a subset of codelist items to add to the codelist.
Conditional On	Title of the item on which the current item is conditional. The drop-down list in this column contains items that contain a codelist. If the current item is conditional on one of the items in this column, the current item provides additional data about one of the options in the codelist.
Conditional Value	Code and label of the codelist item on which the current item is conditional.
Data Label	-
Description	Description of the item. The description can have 0-255 characters.
Display Override	-

Option	Description
Item Properties	Contains an **Edit** link, which you can click to open the Item Properties dialog box. If you navigate to the field using the Tab button, you can open the dialog box by pressing the spacebar.
Item Required	Indicates that the item is required.
Key	For key items, displays icons and numbers that indicate: • Type of key item uniqueness (None, Individual, or Group). • Order of the items in the drop-down navigation list that appears in the summary view of a repeating form in the Oracle InForm application. In the Oracle InForm application, key items are used to make it easier to navigate among the instances of a repeating form and to enforce data uniqueness in specific items.
Length	Applies to text, float, and integer items only. Length of the item. Allowed values: • Text items—1 to 2000. • Float items—1 to 18. • Integer items—1 to 10.
Locked	Indicates that the item is locked.
MaxProperty	If a MaxValue is specified for the item, indicates whether the value can be less than or less than or equal to the MaxValue.
MaxValue	Maximum value that the Oracle InForm application will allow to be typed for the item.
MinProperty	If a MinValue is specified for the item, indicates whether the value can be greater than or greater than or equal to the MinValue.
MinValue	Minimum value that the InForm application will allow to be typed for the item.
Modified	Indicates that the item has been modified and has not yet been saved.
New	Indicates that the item is new and has not yet been saved.
Protected	Indicates that the item is protected.
Question	Default question for the item. This question appears on the form if no customized label or translation is defined for the item. The question can have 0-1000 characters. Certain words may be reserved for this field.
RefName	RefName of the item.
Revision	Revision number of the study object.
SDV Critical	Indicates that the study object is considered critical for source verification. If you select SDV Critical, SDV Required becomes selected as well.

Option	Description
SDV Required	Indicates that the study object must be source verified in the Oracle InForm application.
ShortQuestion	Text of a short version of the item question. In the Oracle InForm application, the short question appears as a column heading in a repeating form, an itemset, and in reports generated by the Reporting and Analysis application. The short question can have 0-255 characters. Certain words may be reserved for this field.
Special Fields	Type of special InForm field, or None, indicating that the item is not a special InForm field. Available special fields, along with the forms in which they appear, are: • Initials (Screening). • DOB (Screening). • Screening date (Screening). • Patient No. (Enrollment). • Initials (Patient Identification. Completion status (Study Completion). • Drop-out reason (Study Completion). • DOV (Date of Visit). • Randomization field (Randomization).
Title	Title of the item. The title can have 1-63 characters.
Type	Item type; one of the following, or a custom item type defined in a library to which the study has access: • Blood pressure • Compound • Date time • Float • Integer • Text • Yes No
Version	Version number of the study object. The version number is incremented only when a user explicitly updates it.

Note:

To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add HTML formatting characters to a text field to control its appearance when deployed.

Design tab of the Item Editor—Option descriptions

Compound or blood pressure item options

Option	Description
Compound Properties section	-
Default question	Default question for the item. This question appears on the form if no customized label or translation is defined for the item. The question can have 0-1000 characters. Certain words may be reserved for this field.
Title	Title of the item. The title can have 1-63 characters.
Child Items section	-
Child Items section	List the items that make up the compound item. For a blood pressure item, the predefined child items Systolic Variable and Diastolic Variable appear in this list.
Type	Item type. For a blood pressure item, the item type of the two child items is Integer.
Title	Title of the child item. The title can have 1-63 characters.
RefName	RefName of the child item.
Question	Caption that appears with the child item on the form.
Languages section	-
Languages section	Translate item questions. This section is active if: • More than one language and locale have been selected for the study in the Study Editor. • You have been associated with one of the languages for the study in your user skills profile. An administrator user sets up this profile in the Oracle Central Designer Administrator application.
Language	Language in which the question appears.
Question	Text of the question in the specified language. The question can have 0-1000 characters.
Short Question	Text of a short version of the item question. In the Oracle InForm application, the short question appears as a column heading in a repeating form, an itemset, and in reports generated by the Reporting and Analysis application. The short question can have 0-255 characters. Certain words may be reserved for this field.

> **Note:**
>
> To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add HTML formatting characters to a text field to control its appearance when deployed.

Date time item options

Option	Description
Date Time Properties section	-
Default question	Default question for the item. This question appears on the form if no customized label or translation is defined for the item. The question can have 0-1000 characters. Certain words may be reserved for this field.
Title	Title of the item. The title can have 1-63 characters. The title can have 1-63 characters.
Year Month Day Hour Minute Second	When selected, this part of the date time item (Year, Month, Day, Hour, Minute, or Second) can be made visible on the form if it is marked as visible in the Layout tab. • **Required**—(Selected by default for Year, Month, and Day) When selected, this part of the date time item (Year, Month, Day, Hour, Minute, or Second) is required. • **Allow unknown**—A data-entry user can mark this part of the date time item (Year, Month, Day, Hour, Minute, or Second) unknown. An entry marked unknown is considered completed.
Languages section	-
Languages section	Translate item questions. This section is active if: • More than one language and locale have been selected for the study in the Study Editor. • You have been associated with one of the languages for the study in your user skills profile. An administrator user sets up this profile in the Oracle Central Designer Administrator application.
Language	Language in which the question appears.
Question	Text of the question in the specified language. The question can have 0-1000 characters. Certain words may be reserved for this field.
Short Question	Text of a short version of the item question. In the Oracle InForm application, the short question appears as a column heading in a repeating form, an itemset, and in reports generated by the Reporting and Analysis application. The short question can have 0-255 characters. Certain words may be reserved for this field.

> **Note:**
>
> To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add HTML formatting characters to a text field to control its appearance when deployed.

> **Note:**
>
> The Required and Allow unknown fields are not available until you select the corresponding Allow fields.

Float item options

Option	Description
Float Properties section	-
Default question	Default question for the item. This question appears on the form if no customized label or translation is defined for the item. The question can have 0-1000 characters. Certain words may be reserved for this field.
Title	Title of the item. The title can have 1-63 characters.
Base Unit	The unit for which a measurement is stored in the repository.
Conversion Units	One or more optional units in which a user can enter a measurement. A conversion unit value is converted to the base unit when stored in the study database.

Option	Description
Length	Maximum length of the data that a user can enter into the item, including the values before and after the decimal point. **Note:** When a float item is deployed to an Oracle InForm study, the decimal point counts in the length, and you must account for the decimal point when designing the float item. For example, in the Oracle InForm application, the largest number that can be entered in a field that has a length of 4 and a precision of 1 is 99.9.
Precision	Number of required characters following the decimal point.
Codelist Settings	• **Select Single Value**—A user must select only one codelist item. • **Select Multiple Values**—A user can select multiple codelist items.
Codelist section	
Codelist section	Select or define a codelist for the item. A codelist consists of a group of codelist items, each containing a code and a label.
Codelist	List of existing codelists or the name of a new codelist that you type.
New	Create a codelist in the repository, using the name entered in the Codelist field.
Code	Value stored in the repository for the codelist item. The value can have 1-2000 characters.
Label	Default label that appears on the form for the codelist item. The label can have 1-255 characters.
Languages section	-

Option	Description
Languages section	Translate item questions. This section is active if: • More than one language and locale have been selected for the study in the Study Editor. • You have been associated with one of the languages for the study in your user skills profile. An administrator user sets up this profile in the Oracle Central Designer Administrator application.
Language	Language in which the question appears.
Question	Text of the question in the specified language. The question can have 0-1000 characters. Certain words may be reserved for this field.
Short Question	Text of a short version of the item question. In the Oracle InForm application, the short question appears as a column heading in a repeating form, an itemset, and in reports generated by the Reporting and Analysis application. The short question can have 0-255 characters. Certain words may be reserved for this field.

> **Note:**
>
> To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add HTML formatting characters to a text field to control its appearance when deployed.

Integer or yes no item options

Option	Description
Integer Properties section	-
Default question	Default question for the item. This question appears on the form if no customized label or translation is defined for the item. The question can have 0-1000 characters. Certain words may be reserved for this field.
Title	Title of the item. The title can have 1-63 characters.
Base Unit	The unit for which a measurement is stored in the repository.
Conversion Units	One or more optional units in which a user can enter a measurement. A conversion unit value is converted to the base unit when stored in the study database.
Length	Maximum length of the data that a user can enter into the item, including the values before and after the decimal point.
Signed Value	Reserved for future use.

Option	Description
Codelist settings	• **Select Single Value**—A user must select only one codelist item. • **Select Multiple Values**—A user can select multiple codelist items.
Codelist section	-
Codelist section	Select or define a codelist for the item. A codelist consists of a group of codelist items, each containing a code and a label. **Note:** A yes no item includes a predefined codelist named YesNo Codelist. This codelist has the values 0 (No) and 1 (Yes).
Codelist	List of existing codelists or the name of a new codelist that you type.
New	Create a codelist in the repository, using the name entered in the Codelist field.
Code	Value stored in the repository for the codelist item. The value can have 1-2000 characters.
Label	Default label that appears on the form for the codelist item. The label can have 1-255 characters.
Languages section	-
Languages section	Translate item questions. This section is active if: • More than one language and locale have been selected for the study in the Study Editor. • You have been associated with one of the languages for the study in your user skills profile. An administrator user sets up this profile in the Oracle Central Designer Administrator application.
Language	Language in which the question appears.
Question	Text of the question in the specified language. The question can have 0-1000 characters. Certain words may be reserved for this field.
Short Question	Text of a short version of the item question. In the Oracle InForm application, the short question appears as a column heading in a repeating form, an itemset, and in reports generated by the Reporting and Analysis application. The short question can have 0-255 characters. Certain words may be reserved for this field.

> **Note:**
>
> To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add HTML formatting characters to a text field to control its appearance when deployed.

Text item options

Option	Description
Text Properties	Specify text item properties.
Default question	Default question for the item. This question appears on the form if no customized label or translation is defined for the item. The question can have 0-1000 characters. Certain words may be reserved for this field.
Title	Title of the item. The title can have 1-63 characters.
Length	Maximum length of the data that a user can enter into the item, including the values before and after the decimal point.
Codelist Settings	• **Select Single Value**—A user must select only one codelist item. • **Select Multiple Values**—A user can select multiple codelist items.
Codelist section	Select or define a codelist for the item. A codelist consists of a group of codelist items, each containing a code and a label.
Codelist	List of existing codelists or the name of a new codelist that you type.
New	Create a codelist in the repository, using the name entered in the Codelist field.
Code	Value stored in the repository for the codelist item. The value can have 1-2000 characters.
Label	Default label that appears on the form for the codelist item. The label can have 1-255 characters.
Languages section	Translate item questions. This section is active if: • More than one language and locale have been selected for the study in the Study Editor. • You have been associated with one of the languages for the study in your user skills profile. An administrator user sets up this profile in the Oracle Central Designer Administrator application.
Language	Language in which the question appears.
Question	Text of the question in the specified language. The question can have 0-1000 characters. Certain words may be reserved for this field.

Option	Description
Short Question	Text of a short version of the item question. In the Oracle InForm application, the short question appears as a column heading in a repeating form, an itemset, and in reports generated by the Reporting and Analysis application. The short question can have 0-255 characters. Certain words may be reserved for this field.

> **Note:**
>
> To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add HTML formatting characters to a text field to control its appearance when deployed.

Default maximum input field lenghts

When you create an item, you specify the length of the input field. The Oracle Central Designer application supports the following maximum field lengths as a default.

Type of input field	Maximum length
Text item	2000
Integer item	10
Float item	18
Float precision	10

Forms and sections editor—Option descriptions

Columns common to all study object editors

All study object editors have the following columns.

> **Note:**
>
> Not all fields appear in the default view. Optionally, you can add the other fields and rearrange the browser view.

Property	Description
Icon (first column)	Study object's status.
Description	Study object's description.
Identifier	Unique internal identifier of the study object.
IPR Status	Indicates whether the study object has an IPR configuration.
Published (only in libraries)	Indicates that the study object has been published.

Property	Description
RefName	RefName of the study object. **Note:** We recommend that you don't use Conflict for a study event RefName, as there is a default Conflict visit created for Oracle InForm.
Revision	Revision number of the study object. The revision number is incremented each time the study object is changed and saved.
Title	Title of the study object.
Version	Version number of the study object. The version number is incremented only when a user explicitly updates it.

Note:

To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add HTML formatting characters to a text field to control its appearance when deployed.

Field	Description
AssociatedForm	Title of the associated form, or None, if the form is not associated with another form.
Common	Indicates that the form is common. The same data is visible in all study events that contain the form.
Fixed (sections only)	Indicates that the section is a repeating section containing items for which the text is fixed and repeated in each instance of the item.
Item Required	Indicates that a value must be entered for the item for the form to be considered complete.
Page Key Value	Value of the Clintrial page key, used for transferring data to the Clintrial application through CIS mappings. If you specify the Page Key Value, it overrides the form RefName as the page key.
Repeating	Indicates that the form or section is repeating. Multiple instances of the same set of data appear in the form or section.
SDV Critical	Indicates that the study object is considered critical for source verification. If you select SDV Critical, SDV Required becomes selected as well.

Field	Description
SDV Required	Indicates that the study object must be source verified in the Oracle InForm application.
Short Title	Short title of the form. The short title is deployed to the Oracle InForm application as the form mnemonic. The short title can have 1-63 characters.
Special Forms	Type of special Oracle InForm form, or None, indicating that the form is not a special Oracle InForm form. Available special forms are: • Screening • Enrollment • Patient Identification • Study Completion

General tab of the Form Editor or Section Editor—Option descriptions

Option	Description
Setting section	-
Title	Title of the form or section. The title can have 1-63 characters.
Short Title (Form Editor only)	Short title of the form. The short title is deployed to the Oracle InForm application as the form mnemonic. The short title can have 1-63 characters.
RefName	RefName of the form or section. The RefName can have 1-63 characters.
Description	Description of the form or section. The description can have 0-255 characters.
Behavior section	-
Repeating	Indicates that the form or section is repeating. Multiple instances of the same set of data appear in the form or section.
Common (Form Editor only)	Indicates that the form is common. The same data is visible in all study events that contain the form.
Short Title Languages section (Form Editor only)	-
Language	Language and locale to which the short title is translated.
Short Title	Translated text of the short title. The short title can have 1-63 characters.

Note:

To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add HTML formatting characters to a text field to control its appearance when deployed.

Oracle InForm Items Editor—Option descriptions

Columns common to all study object editors

All study object editors have the following columns.

> **Note:**
>
> Not all fields appear in the default view. Optionally, you can add the other fields and rearrange the browser view.

Property	Description
Icon (first column)	Study object's status.
Description	Study object's description.
Identifier	Unique internal identifier of the study object.
IPR Status	Indicates whether the study object has an IPR configuration.
Published (only in libraries)	Indicates that the study object has been published.
RefName	RefName of the study object.

> **Note:**
>
> We recommend that you don't use Conflict for a study event RefName, as there is a default Conflict visit created for InForm.

Revision	Revision number of the study object. The revision number is incremented each time the study object is changed and saved.
Title	Title of the study object.
Version	Version number of the study object. The version number is incremented only when a user explicitly updates it.

Optional fields for the default view

> **Note:**
>
> Not all fields appear in the default view. Optionally, you can add the other fields and rearrange the browser view.

Option	Description
Data Label	Text label for the item, enabling access to the item in a target table with the Patient To Control key type or any of the pivot key types.
Display Override	Determines the default behavior of an item when a layout is generated. • **ReadOnly**—The item is visible but not editable. • **Editable**—The item is visible and editable by any user, regardless of the rights assigned to the user. • **Hidden**—The item is not visible. • **None**—The item is visible to all users, and visible and editable by any user who has the rights to view and/or edit the item. This is a custom property for items deployed in a study in the Oracle InForm application.
Item Required	**True** (default) or **False**, indicating whether the item is required for data entry on the form to be complete. This is a custom property for items deployed in a study in the Oracle InForm application.
MaxProperty	If a MaxValue is specified for the item, indicates whether the value can be less than or less than or equal to the MaxValue.
MaxValue	Maximum value that the Oracle InForm application will allow to be typed for the item.
MinProperty	If a MinValue is specified for the item, indicates whether the value can be greater than or greater than or equal to the MinValue.
MinValue	Minimum value that the Oracle InForm application will allow to be typed for the item.
PHI	**True** or **False** (default), indicating whether an Oracle InForm user might enter Personal/ Protected Health Information (PHI) for the item.
Question	Default question for the item. This question appears on the form if no customized label or translation is defined for the item. The question can have 0-1000 characters. Certain words may be reserved for this field.
SDV Critical	**True** or **False** (default), indicating whether the item is considered critical for source verification. If you select True, SDV Required changes to True.
SDV Required	**True** (default) or **False**, indicating whether the item requires source document verification. This is a custom property for items deployed in a study in the Oracle InForm application.

Option	Description
ShortQuestion	Text of a short version of the item question. In the Oracle InForm application, the short question appears as a column heading in a repeating form, an itemset, and in reports generated by the Reporting and Analysis application. The short question can have 0-255 characters. Certain words may be reserved for this field.
Special Fields	Type of special Oracle InForm field, or None, indicating that the item is not a special Oracle InForm field. Available special fields, along with the forms in which they appear, are: • Initials (Screening). • DOB (Screening). • Screening date (Screening). • Patient No. (Enrollment). • Initials (Patient Identification. Completion status (Study Completion). • Drop-out reason (Study Completion). • DOV (Date of Visit). • Randomization field (Randomization).
Type	Item type; one of the following, or a custom item type defined in a library to which the study has access: • Blood pressure • Compound • Date time • Float • Integer • Text • Yes No

Note:

To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add HTML formatting characters to a text field to control its appearance when deployed.

Item Properties dialog box—Option descriptions

Options for the compound or blood pressure item type

Option	Description
Title	Title of the item. The title can have 1-63 characters.
RefName	RefName of the study object. The RefName can have 1-63 characters.

Option	Description
Default Question	Default question for the item. This question appears on the form if no customized label or translation is defined for the item. The question can have 0-1000 characters. Certain words may be reserved for this field.

Options for the float item type

Option	Description
Title	Title of the item. The title can have 1-63 characters.
RefName	RefName of the study object. The RefName can have 1-63 characters.
Default Question	Default question for the item. This question appears on the form if no customized label or translation is defined for the item. The question can have 0-1000 characters. Certain words may be reserved for this field.
Base Unit	The unit for which a measurement is stored in the repository.

Note:

If you are using RDEs in Oracle InForm, do not edit the unit definition for an item that was already deployed to Oracle InForm. Instead, to prevent downstream RDE issues, create a new item with the updated unit definition, and replace each instance of the existing item with the new item.

Option	Description
Conversion Units	One or more optional units in which a user can enter a measurement. A conversion unit value is converted to the base unit when stored in the study database.

Note:

If you are using RDEs in Oracle InForm, do not edit the unit definition for an item that was already deployed to Oracle InForm. Instead, to prevent downstream RDE issues, create a new item with the updated unit definition, and replace each instance of the existing item with the new item.

Option	Description
Length	Maximum length of the data that a user can enter into the item, including the values before and after the decimal point. **Note:** When a float item is deployed to an Oracle InForm study, the decimal point counts in the length, and you must account for the decimal point when designing the float item. For example, in the Oracle InForm application, the largest number that can be entered in a field that has a length of 4 and a precision of 1 is 99.9.
Precision	Number of required characters following the decimal point.
Codelist Settings	-
Codelist	List of existing codelists or the name of a new codelist that you type.
Subset	Assign a codelist subset to the codelist selected in the Codelist drop-down list for the item.
New	Create a new codelist on the item.
Edit	Edit the codelist on the item. If the item does not have a codelist, this option is not available.
Subset	Select a subset of codelist items to add to the codelist.
Codelist Settings	• **Select Single Value**—A user must select only one codelist item. • **Select Multiple Values**—A user can select multiple codelist items.

Options for the date time item type

Option	Description
Title	Title of the item. The title can have 1-63 characters.
RefName	RefName of the study object. The RefName can have 1-63 characters.
Question	Text of the question in the specified language. The question can have 0-1000 characters. Certain words may be reserved for this field.
Date Time Component Setting	-
Year Month Day Hour Minute Second	When selected, this part of the date time item (Year, Month, Day, Hour, Minute, or Second) can be made visible on the form if it is marked as visible in the Layout tab. • **Required**—(Selected by default for Year, Month, and Day) When selected, this part of the date time item (Year, Month, Day, Hour, Minute, or Second) is required. • **Allow unknown**—A data-entry user can mark this part of the date time item (Year, Month, Day, Hour, Minute, or Second) unknown. An entry marked unknown is considered completed.
Year Range	-
Start Year End Year	First and last year in the drop-down list for the year range for the item. The year range is available only when the **Year** component is selected.

Options for the integer or yes no item type

Option	Description
Title	Title of the item. The title can have 1-63 characters.
RefName	RefName of the study object. The RefName can have 1-63 characters.
Default Question	Default question for the item. This question appears on the form if no customized label or translation is defined for the item. The question can have 0-1000 characters. Certain words may be reserved for this field.

Option	Description
Base Unit	The unit for which a measurement is stored in the repository. **Note:** If you are using RDEs in Oracle InForm, do not edit the unit definition for an item that was already deployed to Oracle InForm. Instead, to prevent downstream RDE issues, create a new item with the updated unit definition, and replace each instance of the existing item with the new item.
Conversion Units	One or more optional units in which a user can enter a measurement. A conversion unit value is converted to the base unit when stored in the study database. **Note:** If you are using RDEs in Oracle InForm, do not edit the unit definition for an item that was already deployed to Oracle InForm. Instead, to prevent downstream RDE issues, create a new item with the updated unit definition, and replace each instance of the existing item with the new item.
Length	Maximum length of the data that a user can enter into the item, including the values before and after the decimal point.
Signed Value	Reserved for future use.

Option	Description
Codelist Settings	-
Codelist	List of existing codelists or the name of a new codelist that you type.
Subset	Assign a codelist subset to the codelist selected in the Codelist drop-down list for the item.
New	Create a new codelist on the item.
Edit	Edit the codelist on the item. If the item does not have a codelist, this option is not available.
Codelist Settings	• **Select Single Value**—A user must select only one codelist item. • **Select Multiple Values**—A user can select multiple codelist items.

Options for the text item type

Option	Description
Title	Title of the item. The title can have 1-63 characters.
RefName	RefName of the study object. The RefName can have 1-63 characters.
Default Question	Default question for the item. This question appears on the form if no customized label or translation is defined for the item. The question can have 0-1000 characters. Certain words may be reserved for this field.
Length	Maximum length of the data that a user can enter into the item, including the values before and after the decimal point.

Note:

Enter a value of less than 4,000 characters if you anticipate that this item's data will be sent to Data Management Workbench.

Codelist Settings	-
Codelist	List of existing codelists or the name of a new codelist that you type.
Subset	Assign a codelist subset to the codelist selected in the Codelist drop-down list for the item.
New	Create a new codelist on the item.
Edit	Edit the codelist on the item. If the item does not have a codelist, this option is not available.

Option	Description
Subset	Select a subset of codelist items to add to the codelist.
Codelist Settings	• **Select Single Value**—A user must select only one codelist item. • **Select Multiple Values**—A user can select multiple codelist items.

Keys dialog box

Field	Description
Data uniqueness for selected keys	-
None	Key items appear in a drop-down list in the summary view of a repeating form as navigation aids. The key items are not used to enforce uniqueness of key values across instances of the repeating form.
Individual	Each key item must be unique across all instances of the repeating form or itemset in the Oracle InForm application.
Group	The combination of all key items evaluated together must be unique across all instances of the repeating form or itemset in the Oracle InForm application.
Key selection	-
Items available as keys	The list of items in the repeating form or section that have not been selected as keys.
Section	Name of the section in which an available item occurs; blank for repeating forms.
Item	Title of the available item.
Selected keys	The list of items in the repeating form or section that have been selected as keys.
Section	Name of the section in which the key item occurs; blank for repeating forms.
Item	Title of the key item.
Unique	Selected if the item is an individually or group unique key.
Button	-
>, <	Moves one or more selected items between the Items available as keys list and the Selected keys list.
>>, <<	Moves all items between the Items available as keys list and the Selected keys list.
Move Up, Move Down	Moves the selected key item up or down in the Selected keys list. The resulting order determines the order in which key items appear in a drop-down list on a repeating form in the Oracle InForm application.

Languages tab of the Codelist Item Editor—Option descriptions

Option	Description
Language	Language and locale into which the codelist item label is translated. The default language appears in the first row.
Label	Label of the codelist item. The label can have 1-255 characters.

Layouts

In this section:

- Control Styles dialog box—Option descriptions
- Layout tab options and deployment to the Oracle InForm application
- Study Level Styles and Form Level Styles dialog boxes—Option descriptions

Control Styles dialog box—Option descriptions

General tab

Option	Description
Item name	Display name (either the title or RefName) of the item that is associated with the control. READ-ONLY
Caption	Caption for the control. Limit: 4000 characters.
Inherit all styles	When selected, all control styles are inherited from the study-level styles or the form-level styles, if they are defined. This setting does not affect the caption. The caption that you specify appears, regardless of whether you selected **Inherit all styles**.

> **Note:**
>
> Click **Apply** to save your changes and close the dialog box. Click **Apply/Next** to apply your changes (if you made any) and advance to the next control.

Basic Styles tab

The options that are available depend on the type of control that is selected in the Layout tab.

Option	Description
Caption alignment	(Available for all controls.) Align the caption to the left, top, right, or bottom of the control.
Textbox size	(Available for controls on text, float, and integer items.) • **Width**—Width of the text box, in characters. • **Height** (Available for text items only)—Height of the text box, in lines.
Control orientation	(Available for compound items.) Align the controls of the compound item either horizontally or vertically.

> **Note:**
>
> The **Inherit** checkbox is available for each option. When **Inherit** is selected, the value for the option is inherited from the study-level styles or, if it is used, the form-level styles. To override the study-level or form-level styles, deselect **Inherit**, and provide a different value.

> **Note:**
>
> Click **Apply** to save your changes and close the dialog box. Click **Apply/Next** to apply your changes (if you made any) and advance to the next control.

Date Time Settings tab

The following options are available when you select a Date Time item in the Layout tab.

Option	Description
Visible fields	Select the fields to set as visible for the date time item.
Year range	Select the year range for the date time item.

> **Note:**
>
> The **Inherit** checkbox is available for each option. When **Inherit** is selected, the value for the option is inherited from the study-level styles or, if it is used, the form-level styles. To override the study-level or form-level styles, deselect **Inherit**, and provide a different value.

> **Note:**
>
> Click **Apply** to save your changes and close the dialog box. Click **Apply/Next** to apply your changes (if you made any) and advance to the next control.

Control Type tab

The Control Type tab appears when a control is:

- A float, integer, or text item with a codelist.
- A float or integer item with units.

For other controls, this tab is hidden.

Option	Description
Unit control type	• **For a float or integer item with units**—Format the units as either radio buttons or pulldowns. • **For a float, integer, or text item with a codelist**—Format the controls for the codelist items as either radio buttons or pulldowns.

> **Note:**
>
> The **Inherit** checkbox is available for each option. When **Inherit** is selected, the value for the option is inherited from the study-level styles or, if it is used, the form-level styles. To override the study-level or form-level styles, deselect **Inherit**, and provide a different value.

> **Note:**
>
> Click **Apply** to save your changes and close the dialog box. Click **Apply/Next** to apply your changes (if you made any) and advance to the next control.

Advanced tab

Option	Description
Display Override	You can override the item's Display Override value for the control only. • **Inherit**—Use the item's Display Override value. • **Read only**—Make the control read only. (In the Oracle InForm software, corresponds to the Hidden value of the Display Override property of an item.) • **Hidden**—Make the control hidden. (In the Oracle InForm software, corresponds to the Read-Only value of the Display Override property of an item.)

Option	Description
Character set restriction	(Available for text items without codelists.) • **Unrestricted** (Default)—Do not restrict the entry of values in text fields without codelists. • **ASCII Only**—In release 5.0 and later of the Oracle InForm application, restrict the entry of values in text fields without codelists to the complete ASCII character set (byte range 0 to 127). Items with restricted values are marked with a star («) in the Annotated Study Book.

> **Note:**
>
> Click **Apply** to save your changes and close the dialog box. Click **Apply/ Next** to apply your changes (if you made any) and advance to the next control.

Layout tab options and deployment to the Oracle InForm application

The following table lists the options that are available in the right-click menus, toolbar, and form and control styles for the Layout tab. The table describes the effect of each option when the study objects are deployed in the Oracle InForm application.

Option	Sub-option	Deployment in the InForm application
Align Caption	Left, Right, Top, or Bottom	Specifies the position of the caption relative to the control. Corresponds to the Caption Alignment property.
Align Question	• Left, Center, or Right • Top, Middle, or Bottom	N/A
Control Type	• Radio Button • Pulldown	For codelist items: • Radio control • Pulldown control For units: • Specifies how unit selections are displayed. Corresponds to the Unit Display Type property. If an item definition has only one unit with no conversion units, the Unit Display Type property has a value of **Element**.
Edit Caption	-	Specifies the text of the caption that appears with the control. Corresponds to the Caption property.

Option	Sub-option	Deployment in the InForm application
Edit Textbox Size	-	For text controls: • **Width**—Specifies the number of characters that can be entered into a text box with the data type of Text. Corresponds to the Length property of a text box control. • **Height**—Specifies the number of lines displayed in a text box. Corresponds to the Height property of a text box control. For integer controls: • Number of characters that can be entered into a text box with a data type of Integer. Corresponds to the Length property of an integer text control. For float controls: • Number of characters that can be entered into a text box with a data type of Float. Corresponds to the Length plus the Precision properties of a float text control, plus the decimal point.
Edit Question	-	Question text. Corresponds to the Question property of an item.
Edit Question Column Width	-	Width of the question column. Corresponds to the Question Width property.
Orientation	• Horizontal • Vertical	Specifies how the controls included as children of the grouped control are oriented. Corresponds to the Layout property.
Section Header	-	Form or section title. Corresponds to the Title property of a form or section.
Section Note	-	Specifies the text of a note that appears immediately below a form or section heading. Corresponds to the Note property of a form or section.
Preview Annotated Form	-	N/A
Preview Form	-	N/A
Reset	-	N/A
Remove Caption	-	N/A

Option	Sub-option	Deployment in the InForm application
IPR Configuration	-	Opens the IPR Configuration dialog box so that you can specify a change as an in-place revision.

Note: This button only appears when you access the Lay

Option	Sub-option	Deployment in the InForm application
		outtabforaformthroughtheVisitScheduleExplorerbar.

Study Level Styles and Form Level Styles dialog boxes—Option descriptions

Form Styles page

Option	Description
Question column width	The percentage of the width of the layout table to use for the question column. **Default**—50 percent.

> **Note:**
>
> The **Inherit** checkbox is not available for the options on the Study Level Styles dialog box. When **Inherit** is selected, all values for the set of options are inherited from the study styles. To override the study styles, deselect **Inherit**, and provide different values.

Codelist Control Styles page

Option	Description
Control orientation	Display codelist items either horizontally or vertically. **Default**—Horizontal.
Single selection settings	The settings in this section apply only to items that require a single selection (set on the Design tab for an item, when **Select Single Value** is selected). Multiple-selection codelists are always formatted as checkboxes.
Radio buttons	(Default) Format single-selection codelists as radio buttons. • **Use pulldown when item count exceeds**—Format single-selection codelists as radio buttons, except when the number of codelist items exceeds the specified number, and then format as pulldowns. **Default**—5. • **Display vertically when item count exceeds**—When the number of codelist items exceeds the specified number, display the codelist items as vertical radio buttons. **Default**—5.
Pulldown	Format single-selection codelists as pulldowns.

> **Note:**
>
> The **Inherit** checkbox is not available for the options on the Study Level Styles dialog box. When **Inherit** is selected, all values for the set of options are inherited from the study styles. To override the study styles, deselect **Inherit**, and provide different values.

Compound Items Control Styles page

Option	Description
Caption alignment	Align the caption to the left, top, right, or bottom of an item's controls. **Default**—Left.
Control orientation	Display nested controls either horizontally or vertically. **Default**—Vertically.

> **Note:**
>
> The **Inherit** checkbox is not available for the options on the Study Level Styles dialog box. When **Inherit** is selected, all values for the set of options are inherited from the study styles. To override the study styles, deselect **Inherit**, and provide different values.

Date Time Item Control Styles page

Option	Description
Year range	The default year range for all date time items. **Default**—Current year for both fields.
Caption alignment	Align the caption to the left, top, right, or bottom of an item's controls. **Default**—Left.

> **Note:**
>
> The **Inherit** checkbox is not available for the options on the Study Level Styles dialog box. When **Inherit** is selected, all values for the set of options are inherited from the study styles. To override the study styles, deselect **Inherit**, and provide different values.

Float Item and Integer Item Control Styles pages

Option	Description
Caption alignment	Align the caption to the left, top, right, or bottom of an item's controls. **Default**—Left.
Textbox width	Specify the width of the text boxes. • **Use the item variable's length as the width** (Default)—Use each item's length as the width of the text box. • **Use this width**—Use a specified width for the text box.
Unit control type	Display the controls for the units for a float or integer item as either radio buttons or pulldowns. **Default**—Radio buttons.

> **Note:**
>
> The **Inherit** checkbox is not available for the options on the Study Level Styles dialog box. When **Inherit** is selected, all values for the set of options are inherited from the study styles. To override the study styles, deselect **Inherit**, and provide different values.

Text Item Control Styles page

Option	Description
Caption alignment	Align the caption to the left, top, right, or bottom of an item's controls.
Textbox size	Specify the width and height of the text boxes. • **Use the item variable's length as the width** (Default)—Use each item's length as the width of the text box. – **Increase the height by one line for every __ chars**—Increment the height of the text box by one line for every 50 characters. For example, the height for 1-50 characters is 1; the height for 51-100 characters is 2; and so on. **Default**—50. • **Use the following width and height**—Use a specified width and height for the textbox. Specify the width using the number of characters and the height using the number of lines.

Option	Description
Character set restriction	• **Unrestricted** (Default)—Do not restrict the entry of values in text fields without codelists. • **ASCII Only**—In release 5.0 and later of the InForm application, restrict the entry of values in text fields without codelists to the complete ASCII character set (byte range 0 to 127). Items with restricted values are marked with a star (★) in the Annotated Study Book.

Note:

The **Inherit** checkbox is not available for the options on the Study Level Styles dialog box. When **Inherit** is selected, all values for the set of options are inherited from the study styles. To override the study styles, deselect **Inherit**, and provide different values.

Study workflow

In this section:

- Common Visit tab of the Study Design Editor—Option descriptions
- General tab of the Study Event Editor—Option descriptions
- Schedule of Events tab—Option descriptions
- Workflow Diagram tab—Option descriptions
- Workflow Grid tab—Option descriptions

Common Visit tab of the Study Design Editor—Option descriptions

You must have the appropriate language skills to edit the fields, including the skill for the primary locale of the study. Changes are not sorted automatically.

Option	Description
Common Visit settings	-
Title	Title of the common visit in the language of the primary locale. If you do not provide a value and the study contains common forms, **Common CRF** is used. Limit: 63 characters.
Short Title	Short title of the common visit in the language of the primary locale. If you do not provide a value and the study contains common forms, **Common** is used. Limit: 63 characters.

Option	Description
Languages grid	-
Language	Language and locale to which information is translated.
Title	Translated text of the title of the common visit.
Short Title	Translated text of the short title of the common visit.

Note:

- If you do not specify localized values, the title and short title are used during deployment.
- If you specify localized values, you must specify values for all of the study's supported locales, or validation fails.

General tab of the Study Event Editor—Option descriptions

Option	Description
Settings	-
Title	Title of the study event. The title can have 1-63 characters.
Short Title	Short title of the study event. The short title is deployed to the Oracle InForm application as the visit mnemonic.
RefName	RefName of the study event. The RefName can have 1-63 characters.
Description	Description of the study event. The description can have 0-255 characters.
Behavior	-
Repeating	Indicates that the study event is repeating.
Title Languages	-
Language	Language and locale to which information is translated.
Short Title	Translated text of the short title. The short title can have 1-63 characters.

Option	Description
Title	Translated text of the title. The Title field (in the Settings section) is not localizable and does not change, regardless of what you enter in the Title column in the Title Languages grid. To enter a localized value for a study object's title, use the Title column. Providing a value in the Title column is optional: • If you do not specify a localized value, the title of the study object is used during deployment. • If you specify a localized title, you must specify a localized value for all of the study's supported locales, or validation fails.

Schedule of Events tab—Option descriptions

Field	Description
Activity/Observation	Title of each form in the study. Each form creates one row of the table, in the order in which it was added to the study. A selected checkbox at the intersection of a Form row and an Event column indicates that the form is included in that study event.
Short Title	Short title (mnemonic) of the form.
Event columns	Title of each study event in the study. Each study event creates one column in the table, in the order in which it was added to the study. A selected checkbox at the intersection of a Form row and an Event column indicates that the form is included in that study event.

Workflow Diagram tab—Option descriptions

Option	Description
New Element (Study Editor and Study Design Editor only)	Create a new study element.
New Event (Study Design Editor and Study Element Editor)	Create a new study event.
New (Study Event Editor only)	Create a new form.
Global Conditions	Create a global condition.
Rule Tests	Create test cases for a workflow rule.
Select All	Select all study objects in the workspace.

Option	Description
Layout	Arrange the layout of the workflow diagram by using the following options: • **Grid Layout**—Align all study objects along a grid. • **Horizontal Layout**—Align all connected study objects horizontally. • **Spring Layout**—Place all connected study objects so that the connecting lines do not need to bend. • **Tree Layout**—Align all connected study objects in a tree format. • **Vertical Layout**—Align all connected study objects vertically.
Zoom	Adjust the size of the workflow diagram by using the following options: • **Zoom In**—Increase the diagram size. • **Zoom Out**—Reduce the diagram size. • **Fit to Page**—Adjust the diagram size to fill the workspace.
Enable/Disable Workflow	Enable or disable the workflow. The text on the button changes depending on the workflow state.

Workflow Grid tab—Option descriptions

Option	Description
Status	Icon indicating the status of a study object, including Locked, Protected, and so on.
Type	Study object type. On a study design, where you can create either study elements or study events, the available types appear in a drop-down list.
Title	Title of the study object.

Import and export

In this section:

- Import Wizard options—CSML or ODM file
- Import Wizard options—Oracle InForm resources
- Translation file format
- Translation file requirements
- Export Wizard options
- Export Translations dialog box—Option descriptions

Import Wizard options—CSML or ODM file

Page	Option	Description
Welcome	-	Introduction page.
Import Type	-	Select the source of the data to import.
-	Import CSML or ODM file	Generate study objects from a file in CSML or ODM format.
-	Harvest InForm Resources	Generate study objects from the components of an Oracle InForm study.
File Location	Path of file to import	Specify the path of the CSML or ODM import file, or click Browse to locate the import file.
Study Administration Import Mode	-	This page appears only for the CSML import type, if the CSML file contains study administration objects.
-	Import study objects and administration data.	Import both study objects and study administration objects.
-	Import administration data only.	Import only study administration objects.
-	Import study objects only.	Import only study objects.
Rule Import Mode	Rule Import Mode	Only the Import as Collaboration Notes option is supported. With this option, each imported rule is converted to a collaboration note in the Oracle Central Designer application. **Note:** This option applies only if the Import Type is ODM; if the Import Type is CSML, the import process creates a Oracle Central Designer rule for each imported rule.
IPR Import Mode	Import IPR data	Select whether to import in-place revision objects. **Note:** This page appears only if the file contains in-place revision objects.
Ready to Import Data to Central Designer	-	View a summary of the import options selected in the wizard.

Import Wizard options—Oracle InForm resources

Page	Option	Description
Welcome	-	Introduction page.
Import Type	-	Select the source of the data to import.

Page	Option	Description
-	Import CSML or ODM file	Generate study objects from a file in CSML or ODM format.
-	Harvest Oracle InForm Resources	Generate study objects from the components of an Oracle InForm study.
Oracle InForm File Location	-	Select the file or trial from which to harvest resources.
-	RSP or XML file	Specify the full path of the RSP or XML file containing MedML definitions of Oracle InForm trial components to import, or click Browse to browse to the file.
Rule Import Mode	Rule Import Mode	Only the Import as Collaboration Notes option is supported. With this option, each imported rule is converted to a collaboration note in the Oracle Central Designer application.
Ready to Import Data to Oracle Central Designer	-	View a summary of the import options selected in the wizard.

Translation file format

The translation export and import CSV file consists of a header and translation records in the following formats.

Header

The header contains the following values: RefName,OwnerType,SrType, Id,Revision,<*ReferenceLocaleValue*>,< *LocaleToTranslate*>

- <*ReferenceLocaleValue*>—Locale of the strings from which to translate, as specified in the Locale to translate from field of the Export Translations dialog box. Example: en-US.
- <*LocaleToTranslate* >—Locale to which text strings are being translated, as specified in the Locale to translate field of the Export Translations dialog box. Example: fr-FR.

Example of file header

```
RefName,OwnerType,SrType,Id,Revision,en-US,fr-FR
```

Records

Each translation record contains the following fields: <RefName>,<OwnerType>,<SrType, <Id>,<Revision>,<*ReferenceLocaleValue*>,< *LocaleToTranslate*>, as described in the following table.

Field	Description
RefName	RefName of the study object that owns the string.

Field	Description
OwnerType	Internal type of the study object that owns the string resource.
SrType	Internal type of the field that references the string resource.
Id	GUID of the string resource in CSML.
Revision	Revision number of the study object for which the text string is defined.
ReferenceLocaleValue	Text string in the locale to translate.
LocaleToTranslate	Translated text string. This value is empty when you export the file. The translator fills in the value before you import the file.

Note:

The LocaleToTranslate is the only value that may be changed in each record.

Examples of file records

```
Layout_5fxx,LayoutPlan,ItemCaption,d067b170-8885-11e1-b0c4-0800200c9a66,12,
"DOV
      Form","Forme pour la date de visite"
Itm_DOB,DateTime,Question,26beca46-663e-4841-ab8b-03ff6b7a78f9,5,"Date of
Birth","Date de
      naissance"
```

Translation file requirements

- Do not change any values in the translation file except the strings in the LocaleToTranslate position (last field in each record).
- The header record must be present.
- Each record must conform to the following standards:
  - All records must have the same number of fields.
  - RefName and Id fields must not be empty.
  - RefName length must be less than or equal to 63 characters.
  - Revision and OwnerType lengths must be less than or equal to 255 characters.
  - ReferenceLocaleValue and LocaleToTranslate lengths must be less than or equal to 32000 characters.
- Double quotation marks (") are required for any field that contains a line break, double quote, or comma and are optional for any other field.

- If a field contains a double quotation mark character [for example, Dizzy ("Groggy")], you must include another double quotation mark as an escape character, as follows: "Dizzy (""Groggy"")"
- Lines must end with a Windows-style (CRLF) line terminator.

Export Wizard options

Page	Option	Description
Welcome	-	Introduction page.
Export Type	-	Select the output format and export type.
-	Data Type	**CSML**—Export in Clinical Study Markup Language format. **ODM**—Export in Operational Data Model-compliant format. The Oracle Central Designer application supports the ODM 1.3 standard. **Administration data**—Export only study administration data for the User Management Tool application.
-	Export Type	**Local**—Export to the computer where the Oracle Central Designer application is installed.
Export File Path	Export Directory	Specify the path name and file in which to save the export file, or click Browse to browse for the path name and file in which to save the export file.
Ready to Export Central Designer Data	-	View a summary of the parameters that will be used for the export.

Export Translations dialog box—Option descriptions

Option	Description
Field	-

Option	Description
Locale to translate from	Name of the locale in which the text strings to translate have been defined. **Note:** The Locale to translate from is not the global default locale that is defined in the Tools > Options dialog box, but rather any locale in which the text strings to export exist.
Translate <*locale name*> to	Locale into which strings will be translated.
Target	Target application for which to translate strings.
Export file location	Location and file name in which to store the file of strings to translate. By default the file name has the format: <*StudyName*>_ExportTranslations_<*TargetSystem*>_<SelectedLocale>.csv For example: TestStudy_ExportTranslations_InForm_fr-FR.csv The Browse button enables you to browse to the location.
Include empty locale values	• **If selected**, the file of strings to translate includes strings that are empty in the locale to translate from. • **If not selected**, the export process skips empty strings.
Export log results	Displays messages that are generated during the export. Optionally, you can save these results to a file by clicking the Save Log Results As button.
Button	-
Check for Empty Strings	Opens a window listing all strings that are empty in the locale to translate from.
Save Log Results As	Specifies the location of a log file containing the messages that are generated in the Export log results box during the export.

Tasks and notes

In this section:

- What are tasks and how do I work with them?
- Where do the task types come from?
- How are task statuses used?
- Who does what with tasks?
- What is a collaboration note?
- Task Editor dialog box—Option descriptions
- Collaboration Notes Browser—Option descriptions
- Collaboration Note Editor dialog box—Option descriptions
- Task areas—Field descriptions
- Tasks Browser—Option descriptions

Task Editor dialog box—Option descriptions

The second tab that appears in the Task Editor dialog box depends on the type of task that is selected. For standard tasks, the dialog box has an Instructions tab, and for translation tasks, the dialog box has an Assignment tab.

Option	Description
Top toolbar	-
Accept, Complete,Close, Reopen,Unaccept	Accept, complete, close, reopen, and unaccept a task.
Top section	-
Study	(READ-ONLY) Study with the study object to which the task is attached.
Object Name	(READ-ONLY) Study object to which the task is attached.
Object Type	(READ-ONLY) Type of study object on which the task was created.
Created	(READ-ONLY) Date and time the task was created.
Requested By	(READ-ONLY) User who created the task.
Status	(READ-ONLY) Status of the task (Open, Accepted, Completed, or Closed).
Task Type	(REQUIRED.) Type of the task. An administrator defines task types in the Central Designer Administrator application.
Priority	(REQUIRED.) Priority of the task. Options are Critical, High, Medium, and Low.
Due	(REQUIRED.) Deadline for when the task must be completed. **Default value**—Current date and time.

Option	Description
Owner	(READ-ONLY) Person or team to which the task is assigned.
Completed By	(READ-ONLY) User who completed the task.
Completed Date	(READ-ONLY) Date and time the task was completed.
Instructions tab	-
Instructions text field	Text for the task.
Assignment tab	-
[List of roles]	List of roles to which the task can be assigned. If an administrator specified a default role to which the task type is assigned, the role is selected.

> **Note:**
>
> Use the buttons on the toolbar to add an attachment and format the text.

Collaboration Notes Browser—Option descriptions

Option	Description
Fields	-
Author	Person who created the collaboration note.
Created Date	Date and time the collaboration note was created. READ-ONLY
Description	Description of the collaboration note.
ID	Unique identifier of the collaboration note.
Object Name	Study object to which the collaboration note is attached.
Object Type	Type of study object (such as form or study event) to which the collaboration note is attached.
Type	Collaboration note type on which the collaboration note was based. Collaboration note types are defined in theOracle Central Designer Administrator application.
Toolbar options	-
New Note Edit Print Delete	Create, edit, print, or delete the selected collaboration note.
Show Children	• **Selected**—You see all collaboration notes attached to the selected study object and its children. • **Not selected**—You see the collaboration notes that are attached to the selected study object only.

Option	Description
Refresh	Refresh the information in the Collaboration Notes Browser with information from the database.

Collaboration Note Editor dialog box—Option descriptions

Option	Description
Study	(READ-ONLY.) Study with the study object to which the collaboration note is attached.
Object Name	(READ-ONLY.) Study object to which the collaboration note is attached.
Object Type	(READ-ONLY.) Type of study object to which you are attaching the collaboration note, such as a form or study event.
Note Type	(REQUIRED.) Type of the collaboration note. An administrator defines collaboration note types in the Central Designer Administrator application.
Author	(READ-ONLY.) User who created the collaboration note.
Instructions text field	Text for the collaboration note.

Task areas—Field descriptions

The following fields appear in:

- Recent Tasks tab of the Home Page.
- My Tasks section of the Home Page.
- Tasks Browser.

> **Note:**
>
> Some fields appear on the Home page, but not in the Tasks Browser. In addition, not all fields appear in the default view. Optionally, you can add the other fields to the browser view, and you can rearrange the order of fields.

Field	Description
Completed By	Person who completed the task.
Completed Date	Date and time the task was completed. READ-ONLY
Created Date	Date and time the task was created.
Description	Description of the task.
Due Date	Deadline for the task, selected by the task requester. If the task is overdue, the date is red. READ-ONLY

Field	Description
Id	Unique identifier for the task.
Object Name	Study object to which the task is attached.
Object Type	Task type.
Owner	User or team responsible for the task: • Assigned task—The assignee (or assignees). • Accepted task—The accepter. • Completed task—The creator.
Priority	Priority of the task. Options are Critical, High, Medium, and Low.
Project Id	Unique identifier for the project that contains the task.
Project Name	Project that contains the task.
Requested By	Person who created the task.
Status	Status of the task.
Study Id	Unique identifier for the study that contains the task.
Study Name	Study that contains the task.
Type	Task type on which the task is based. An administrator defines task types in the Oracle Central Designer Administrator application.

Tasks Browser—Option descriptions

> **Note:**
>
> Some fields appear on the Home page, but not in the Tasks Browser. In addition, not all fields appear in the default view. Optionally, you can add the other fields to the browser view, and you can rearrange the order of fields.

Fields	Description
Completed By	Person who completed the task.
Completed Date	Date and time the task was completed. READ-ONLY
Created Date	Date and time the task was created.
Description	Description of the task.
Due Date	Deadline for the task, selected by the task requester. If the task is overdue, the date is red. READ-ONLY
Id	Unique identifier for the task.
Object Name	Study object to which the task is attached.
Object Type	Task type.

Fields	Description
Owner	User or team responsible for the task: • Assigned task—The assignee (or assignees). • Accepted task—The accepter. • Completed task—The creator.
Priority	Priority of the task. Options are Critical, High, Medium, and Low.
Project Id	Unique identifier for the project that contains the task.
Project Name	Project that contains the task.
Requested By	Person who created the task.
Status	Status of the task.
Study Id	Unique identifier for the study that contains the task.
Study Name	Study that contains the task.
Type	Task type on which the task is based. An administrator defines task types in the Oracle Central Designer Administrator application.

Option	Description
New Task Edit Print Delete	Create, edit, print, or delete a task.
Accept Complete Close Reopen Unaccept	Accept, complete, close, reopen, and unaccept a task.
Show Children	• **Selected**—You see all tasks attached to the selected study object and its children. • **Not selected**—You see the tasks that are attached to the selected study object only.
Refresh	Refresh the information in the Tasks Browser with information from the database.

Custom events

In this section:

- What are the limitations on triggers?
- Custom Events editor—Option descriptions

Custom Events editor—Option descriptions

All study object editors have the following columns.

Note:

Not all fields appear in the default view. Optionally, you can add the other fields and rearrange the browser view.

Property	Description
Icon (first column)	Study object's status.
Description	Study object's description.
Identifier	Unique internal identifier of the study object.
IPR Status	Indicates whether the study object has an IPR configuration.
Published (only in libraries)	Indicates that the study object has been published.
RefName	RefName of the study object.

Note:

We recommend that you don't use Conflict for a study event RefName, as there is a default Conflict visit created for Oracle InForm.

Title	Title of the study object.

Field	Description
Active	The custom event's active status.
Destination Name	The destination application where InForm sends the exported data.
Endpoint Name	The endpoint name corresponds to the Endpoint Alias in Oracle InForm Publisher.
Evaluate On	Indicates whether to run the custom event against new data only, or new data and existing data.
Integration Type	The integration type that you selected for the custom event. Integration types are added in the Oracle Central Designer.
Prerequisite	The name of the custom event that needs to run before the current custom event can be triggered.
Priority Group	The order to run the custom events in.

Note:

To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add HTML formatting characters to a text field to control its appearance when deployed.

Rules

In this section:

- What types of rules can I create?
- How should I name my rules?
- Can I schedule rules to run in a certain order?
- Can I create a rule with more than one action?
- What happens when I reuse a study object with a data-entry rule?
- What happens when I reuse a study object with a global condition?
- Which object should I add a rule to?
- What happens if I create a rule on a repeating study object?
- Should I use a workflow rule or a global condition?
- What happens if I disable a workflow?
- View all rules for a study object and its children
- Can I cause a subject to fail screening and enrollment?
- Assign Conditions dialog box—Option descriptions
- Define Test Values for Repeating Instances dialog box—Option descriptions
- Design tab of the Rule Test Cases dialog box—Option descriptions
- Edit Global Conditions dialog box—Option descriptions
- Edit Schedule dialog box—Option descriptions
- Edit Schedule and Rule Action dialog box—Option descriptions
- Edit Workflow Rules dialog box—Option descriptions
- Email Action dialog box—Option descriptions
- Invoke Function dialog box—Option descriptions
- Query Action dialog box—Option descriptions
- New Rule Template dialog box—Option descriptions
- Rule Templates tab—Option descriptions
- Rule Wizard—Option descriptions
- Rules tab—Option descriptions
- Run tab of the Rule Test Cases dialog box—Option descriptions
- Set Review State Action dialog box
- Set Value Action dialog box—Option descriptions
- Workflow Expression Editor dialog box—Option descriptions

Assign Conditions dialog box—Option descriptions

Use the Assign Conditions dialog box to add a global condition to or remove a global condition from a study object in a workflow. In this dialog box, you specify the terms under which the next object in a workflow appears in a study, when the next object in a workflow depends on the outcome of a global condition.

Option	Description
Global Conditions	Available global conditions.
Assigned Conditions	Global condition that has been added to the selected study object.
Add (>>) Remove (<<)	Assign the global condition to the study object, and remove the assigned global condition.
Expression box	Text of the global condition expression.

Option	Description
If the value is	Specify how the result of the selected global condition determines the study workflow. Indicates when the next object in the workflow appears in a study: • **False**—Only if the global condition evaluates to false. • **True**—Only if the global condition evaluates to true. • **Always**—Regardless of the result of the global condition. This option is disabled for a workflow rule. • **Only if no other action executes**—Only if no other workflow object is in effect. This option is disabled for a workflow rule. • **Relational statement**—Only if the value returned by the global condition satisfies the condition specified in the drop-down list and the text fields for this option. The following additional information is required for this selection: – **Drop-down list**—Specifies how the value returned by the workflow rule is compared with the values in the two text fields. – **First text field**—Specifies the value to compare with the value returned by the global condition. If Between is selected in the drop-down list, the first text field specifies the first of two values that delineate a range. The global condition result is checked to determine if it is between the two values. – **Second text field**—Available if Between is selected in the drop-down list. The second text field specifies the second of two values that delineate a range. The global condition result is checked to determine whether it is between the two values. – **Inclusive**—Available if Between is selected in the drop-down list. If selected, indicates that the range of values delineated in the two text fields includes the values entered in those fields. **Note:** Do not use the relational statement fields for string values, or a validation error occurs.

Define Test Values for Repeating Instances dialog box—Option descriptions

When an item is on a repeating section, form, or study event, you must provide test values for all of the instances of the item.

Option	Description
Buttons	-
Add Repeating Instance	Add an instance of the selected repeating study object to create test cases for each instance.
Copy Repeating Instance	Adds an instance with the value of the selected instance.
Remove Repeating Instance	Delete the selected instance.
-	**Note:** When you add, copy, or delete instances, the indexing of the repeating instances is reordered. For example, if you delete the second of four instances, the third instance becomes the second and the fourth becomes the third. Adding an instance increases all subsequent instance numbers.
Sections	-
Selected Item tree	Tree that contains the study objects in the rule. Use the buttons to create or remove instances. **Note:** You can create instances only for repeating study objects, which appear in the Repeating Items list.
Grid	Path and value of items that are on repeating study objects. Provide a testing value in the Item Value field.

Option	Description
Repeating Items list	List of all items in the rule that are children of repeating study objects. Select an item to provide its test values in the grid.
Rule Details tab	Text representation and description of the rule.
Item Properties tab	Properties for the test name, item, or expected result that you point to in the grid.
Form Preview tab	Preview of the form on which the repeating item exists.

Design tab of the Rule Test Cases dialog box—Option descriptions

In the Design tab, you write, modify, and delete test cases for rules.

Fields	Description
Grid	-
Test Name	Name of the test case. By default, test cases are named **Test**<*incrementing number*>, where <*incrementing number*>is a number that starts with 1 and counts upward.
<*item name*>	Each item that is used in the rule expression appears as a field. You can provide test values for each item.
Expected Result	The expected result of the test case. Multiple fields appear for data-entry rules with multiple actions. For data-entry rules: • **Rule issues a query**—Select **QUERY** or **NOQUERY**. • **Rule sends an email message**—Select **Sent** or **Not Sent**. • **Rule sets a value**—Calculate and type the expected value. For example, for a BMI rule, use the Height and Weight values in the test case to calculate the value. – For workflow rules, you select the study object that you expect to appear next in the workflow, based upon the test case. – For global conditions, you select True or False, depending on whether the specified condition is true or false.
Rule Details tab	Text representation and description of the rule.
Site Info tab	Information appears in this tab when a locale is defined for a study.
Site name (or mnemonic)	Name of the site. This information is returned when you use the GetSiteMnemonic() function.
Site locale	Drop-down list of supported locales for a study. The selected locale is returned when you use the GetSiteLocale() function.

Fields	Description
Site locale date and time	Drop-down list for selecting a date and time. The selected date and time is returned when you use the GetSiteTime() function.
Form Associations tab	Information appears in this tab if an item path contains an associated form.
Associated Data View item paths	If you used data from associated forms in the rule, select the item paths that you used so that the Rule Test Cases dialog box can use the information when running the test cases.
Test Properties tab	Properties for the test name, item, or expected result that you point to in the grid.
Test Description tab	Optionally, type a description of the test case.

Edit Global Conditions dialog box—Option descriptions

Use the Edit Global Conditions dialog box to:

- Create, edit, and delete a global condition.
- View the locations in which a global condition is used.

Option	Description
Global Conditions list	-
Name	Name of the global condition.
Description	Description of the global condition. This field is not deployed. Maximum characters: 2000.
Target	Target application specified for the global condition. The target application determines the study objects that are visible in the References section.
Add, Edit, Delete	Create a new global condition, or edit or delete the selected global condition.
Expression tab	Used for developing the expression for the global condition by typing or by dragging in components displayed in the tabs of the References section. When you drag in a component, the reference to the component is converted to the standard Oracle Central Designer expression syntax. Typically an expression might contain a combination of typed values (such as operators) and dragged-in components (such as functions or references to study objects).
Assignments tab	View the locations in the study in which the selected global condition is used.
Workflow Name	Name of the study object with the workflow that contains the global condition.
Workflow Type	Type (such as study design) of study object with the workflow that contains the global condition.
Object Name	Name of the study object to which the global condition is assigned.

Option	Description
Object Type	Type (such as study event) of the study object to which the global condition is assigned.
Rule Action	Action for the global condition assignment, such as **when value is true**.
Reference tabs—Available components	List of the components that are available for use in the global condition being defined. By default, these tabs appear on the right side of the dialog box. When you select a tab, the Reference section appears, with tabs along the bottom edge.
Data tab	The available study objects appear in a tree structure similar to the Project Explorer.
Functions tab	The available functions appear in a tree structure organized by class. **Note:** Functions are defined in the Study Editor or Library Editor.
Constants tab	The available constants appear in a tree structure organized by class. **Note:** Constants are defined in the Study Editor or Library Editor.
Data Mappings tab	The components of the available mappings appear in a tree structure similar to the Project Explorer.
Show All checkbox	When selected, all available study objects as well as their properties appear. When not selected, only the available study objects appear.

Edit Schedule dialog box—Option descriptions

Use the Edit Schedule dialog box to specify the interval before the next study event in a study workflow. This dialog box appears when you:

- Connect a study element or study event to a study element or study event in the Workflow Diagram tab.
- Double-click an outgoing connector from a study element or study event to a study element or study event in the Workflow Diagram tab.

Option	Description
Target event interval	Amount of time to elapse between the connected study object and study event. This amount is specified as the number of weeks, days, and hours.
After event	Indicates the study event that the current study event follows.
Clear Schedule	Resets the target event interval to zero.

Edit Schedule and Rule Action dialog box—Option descriptions

Use the Edit Schedule and Rule Action dialog box to specify the conditions under which the next object in a workflow appears in a study, when the next study object in a workflow depends on the outcome of a workflow rule. This dialog box appears when you:

- Connect a rule to a study event in the Workflow Diagram tab.
- Double-click an outgoing connector from a rule in the Workflow Diagram tab.
- Specify a workflow rule outcome as a precondition in the Workflow Diagram tab.

The Edit Schedule and Rule Action dialog box appears when you connect a workflow rule and a study object. The dialog box allows you to define a schedule at the same time that you define a workflow action.

Option	Description
Event Schedule tab	-
Target event interval	Amount of time to elapse between the connected study object and study event. This amount is specified as the number of weeks, days, and hours.
After event	Indicates the study event that the current study event follows.
Clear Schedule	Resets the target event interval to zero.
Rule Action tab	-

Option	Description
If the value is	Indicates when the next object in the workflow appears in a study: • **False**—Only if the rule or global condition evaluates to false. • **True**—Only if the rule or global condition evaluates to true. • **Always**—Regardless of the result of the rule or global condition. This option is disabled for a workflow rule. • **Only if no other action executes**—Only if no other workflow object is in effect. This option is disabled for a workflow rule. • **Relational statement**—Only if the value returned by the rule or global condition satisfies the condition specified in the drop-down list and the text fields for this option. The following additional information is required for this selection: – **Drop-down list**—Specifies how the value returned by the workflow rule is compared with the values in the two text fields. – **First text field**—Specifies the value to compare with the value returned by the rule or global condition. If Between is selected in the drop-down list, the first text field specifies the first of two values that delineate a range. The rule or global condition result is checked to determine if it is between the two values. – **Second text field**—Available if Between is selected in the drop-down list. The second text field specifies the second of two values that delineate a range. The rule or global condition result is checked to determine whether it is between the two values. – **Inclusive**—Available if Between is selected in the drop-down list. If selected, indicates that the range of values delineated in the two text fields includes the values entered in those fields. **Note:** Do not use the relational statement fields for string values, or a validation error occurs.

Edit Workflow Rules dialog box—Option descriptions

Option	Description
Rule Name	Name of the workflow rule.
Owner Object	RefName of the object the rule exists on.
Predecessor	The object that appears before the workflow rule in the study design.
Description	Description of the workflow rule. This field is not deployed. Maximum characters: 2000.
Target	The application you're deploying the study to.
Buttons	-
Edit	Edit the rule.
Go to rule	Locate the rule in the study workflow.
Expression section	Used for developing the expression for the rule by typing or by dragging in components displayed in the tabs of the References section. When you drag in a component, the reference to the component is converted to the standard Oracle Central Designer expression syntax. Typically an expression might contain a combination of typed values (such as operators) and dragged-in components (such as functions or references to study objects).
Reference tabs—Available components	List of the components that are available for use in the rule being defined. By default, these tabs appear on the right side of the dialog box. When you select a tab, the Reference section appears, with tabs along the bottom edge.
Data tab	The available study objects appear in a tree structure similar to the Project Explorer.
Functions tab	The available functions appear in a tree structure organized by class.

> **Note:**
>
> Functions are defined in the Study Editor or Library Editor.

Option	Description
Constants tab	The available constants appear in a tree structure organized by class. **Note:** Constants are defined in the Study Editor or Library Editor.
Data Mappings tab	The components of the available mappings appear in a tree structure similar to the Project Explorer.

Email Action dialog box—Option descriptions

Option	Description
Item	Item that triggers the email action. Optionally, drag an item from the Data tab.
To	(Required) Email address of the person to receive the email. Separate multiple email addresses with a semicolon. The email address must be in a valid format, such as name@address.value.
From	Email address of the person to send the email. The email address must be in a valid format, such as name@address.value. If you do not provide an email address, an address is taken from the registry. If the registry does not contain an email address, **<***studyname***>@<default_webserver>** is used.
Locale	Locale for the email subject and message. **Note:** To translate information, you must have the necessary language skills defined in theOracle Central Designer Administrator application.

Option	Description
Subject	Subject of the email message. You can type a value or drag information from the Data, Functions, Constants, and Globals tabs. **Note:** Do not add an item for which the PHI item property is set to True.

Option	Description
Message	Email message. You can type a value or drag information from the Data, Functions, Constants, and Globals tabs. **Note:** • Do not add an item for which the PHI item property is set to True. • A parameterized string in an email message or query that is generated in the Oracle InForm application follows the formatting that is specified for the site in the Oracle InForm application. Not allowed and unknown components of a date time value appear as asterisks (*). Leading and following underscores in the value are removed automatically.
Message and Subject Parameters	Optional parameters that you can create and use in the Subject field, Message field, and Parameter Value field. Type a value or drag information from the Data, Functions, Constants, and Globals tabs.

Option	Description
Reference tabs—Available components	List of the components that are available for use in the rule being defined. By default, these tabs appear on the right side of the dialog box. When you select a tab, the Reference section appears, with tabs along the bottom edge.
Data tab	The available study objects appear in a tree structure similar to the Project Explorer.
Functions tab	The available functions appear in a tree structure organized by class. **Note:** Functions are defined in the Study Editor or Library Editor.
Constants tab	The available constants appear in a tree structure organized by class. **Note:** Constants are defined in the Study Editor or Library Editor.
Data Mappings tab	The components of the available mappings appear in a tree structure similar to the Project Explorer.
Show All checkbox	When selected, all available study objects as well as their properties appear. When not selected, only the available study objects appear.

Invoke Function dialog box—Option descriptions

Use the Invoke Function dialog box to assign values to the parameters named in a function that you are invoking in a rule or global condition definition.

Option	Description
Function	Name and description of the function being invoked.
Return Type	Data type of the value returned by the function.

Option	Description
Reference tabs—Available components	List of the components that are available for use in the rule being defined. By default, these tabs appear on the right side of the dialog box. When you select a tab, the Reference section appears, with tabs along the bottom edge.
Data tab	The available study objects appear in a tree structure similar to the Project Explorer.
Functions tab	The available functions appear in a tree structure organized by class. **Note:** Functions are defined in the Study Editor or Library Editor.
Constants tab	The available constants appear in a tree structure organized by class. **Note:** Constants are defined in the Study Editor or Library Editor.
Data Mappings tab	The components of the available mappings appear in a tree structure similar to the Project Explorer.
Show All checkbox	When selected, all available study objects as well as their properties appear. When not selected, only the available study objects appear.
Parameter description section	Lists the parameters that have been defined for the function, along with spaces in which to specify their values in the rule or global condition expression.
Parameter	Name of the parameter.
Data Type	Data type of the parameter.
Value	Value the parameter takes in the rule or global condition expression: • An explicit number or string. • A study object, constant, or data series dragged from the Data, Constants, or Data Mappings tab of the References section. • A function that returns a value of the required data type (for example, the GetValue() function).

Query Action dialog box—Option descriptions

Option	Description
Initial Query State	Initial state of the query. • **Open**—The query is visible on the form and available for response. • **Candidate**—The query is not visible on the form until someone reviews and explicitly opens it.
Item	Item on which the query will be issued. You can: • Type the name of the item. • Drag an item from the Data tab to the field. • Type an expression that satisfies the requirements of the rule expression language.
Locale	Locale of the query message. **Note:** To translate information, you must have the necessary language skills defined in the Oracle Central Designer Administrator application.

Option	Description
Message	Query message that appears. The query message must be 255 characters or fewer. The following errors occur for query messages that have 256 characters or more: • If the query message has parameters and the message is 255 characters or fewer without the parameters, you receive a warning during validation, and the query is truncated to 255 characters in the Oracle InForm application. • If the query message does not have parameters, you receive an error during validation. **Note:** A parameterized string in an email message or query that is generated in the Oracle InForm application follows the formatting that is specified for the site in the Oracle InForm application. Not allowed and unknown components of a date time value appear as asterisks (*). Leading and following underscores in the value are removed automatically.
Message Parameters	Optional parameters that you can create and use in the query message. Type a value or drag information from the Data, Functions, Constants, and Globals tabs.
Reference tabs—Available components	List of the components that are available for use in the rule being defined. By default, these tabs appear on the right side of the dialog box. When you select a tab, the Reference section appears, with tabs along the bottom edge.
Data tab	The available study objects appear in a tree structure similar to the Project Explorer.

Option	Description
Functions tab	The available functions appear in a tree structure organized by class. **Note:** Functions are defined in the Study Editor or Library Editor.
Constants tab	The available constants appear in a tree structure organized by class. **Note:** Constants are defined in the Study Editor or Library Editor.
Data Mappings tab	The components of the available mappings appear in a tree structure similar to the Project Explorer.
Show All checkbox	When selected, all available study objects as well as their properties appear. When not selected, only the available study objects appear.

New Rule Template dialog box—Option descriptions

Option	Description
Properties tab	-
Name	Name of the rule template.
Classification	User-defined term used to organize rule templates.
Description	Description of the rule template.
Display Text	Text that appears in the Rule Summary section of the Rule wizard after the **When Value Is** information. If this field is blank, the contents of the Expression workspace are used. If the expression contains parameters, the name of the parameter and the value of the parameter appear. For example, if the expression is **value must be between {a} and {b}**, and the value of **a** is 10 and the value of **b** is 100, the parameters appear as **a:10** and **b:100**.
Definition tab	-

Option	Description
Return Type drop-down list	Return type of the rule template; one of the following: Integer, Float, String, Boolean, Date/Time, or Array (A list of values, all of the same type).
Expression	Expression of the rule.
Parameters (Optional)	-
Parameter	Name of the parameter.
Data Type	Return type of the parameter; one of the following: Integer, Float, String, Boolean, Date/Time, or Array (A list of values, all of the same type).
Default Value	Specified value of the parameter.
References	-
Data tab	Lists study objects in the scope of the rule. Optionally, to view the rule model properties of all of the study objects, select **Show all**.
Functions tab	Lists functions registered in a study and the libraries that appear in the Libraries List in the Study Editor. Any rule in the study can reference a function.
Constants tab	Lists constants created in the study and the libraries that appear in the Libraries List in the Study Editor. Any rule in the study can reference a constant.
Data Mappings tab	Lists: • RefNames of the data mappings, data sets, and data series in the study or library. • Rule model properties for data series. A data series has the properties of the item that is mapped to it. If a data series contains an item that collects more than one value, the rule model properties for repeating study objects appear so you can access an array of all of the values of the item. • Methods for data sets. A method appears if you select the corresponding standard data dimension of the data set. You can use data set methods to return a subset of the data in the data set. • Study events, forms, sections, and items that are mapped to each data set. • Study objects appear if you select the corresponding standard data dimension of the data set. The properties of the study objects are used as parameters of data set methods.

Rule Templates tab—Option descriptions

The grid displays rule templates created on the study object selected in the Project Explorer.

Option	Description
Rule templates grid	-
Data Type	Return type of the rule template.
Description	Description of the rule template.
Display Text	Text that appears in the Rule Summary section of the Rule wizard after the **When Value Is** information.
Id	Identification information for the rule.
Expression	Rule expression of the rule template.
Parameters	Specified parameters of the rule template, separated by semicolons.
Template Name	Name of the rule template.
Type	Indicates that the rule was created using the Oracle Central Designer rule expression language.

Rule Wizard—Option descriptions

The Rule Wizard provides a simple interface for creating data-entry rules, including specifying the type of rule, preconditions, expression, and actions.

Navigate through the wizard using:

- The tabs at the top of the wizard.
- The Next button.
- The links in the Rule Summary section.

The Rule Wizard has the following tabs.

Quick Start tab

In the Quick Start tab, you choose the type of rule to create.

> **Note:**
>
> The tab appears when you create a rule but not when you view an existing rule.

Option	Description
Intrinsic Rule	An intrinsic rule is a constraint rule or calculation rule based on a predefined rule template. Rule templates can be created for constraint rules and calculation rules. If no rule templates have been defined for the selected study object, then you cannot create an intrinsic rule for the study object.
Constraint Rule	A constraint rule checks whether data is valid.
Calculation Rule	A calculation rule sets the value of an item based on a calculation.

Properties tab

In the Properties tab, you provide a name and a brief description for the rule.

Option	Description
Name	The name of the rule: • Cannot contain spaces. • Must begin with a letter and can contain letters, numbers, and underscores (_) but no other special characters. • Must be no longer than 63 characters. • Must be unique for the study object. For example, you can create a rule called rulCalcBMI on a form and an item, but you cannot create two rulCalcBMI rules on two different forms.
Description	Description of the rule. The Description field can contain a description of the rule or the formal specification that is used by the actual rule developer. The limit is 2000 characters.

Preconditions tab

In the Preconditions tab, you select from the options in the Evaluate on Event drop-down list to specify when the rule will be evaluated.

Options	Description
Evaluate on Event	Event that causes the rule to execute: • **On demand (batch mode)**—Rule is validated and deployed to the Oracle InForm application with a deactivated status, so the rule does not run in the Oracle InForm application. • **Form submission**—Rule runs on form submission. The Oracle InForm application uses the study objects on which the rule depends to determine rule dependencies and the form that causes the rule to run.
Select the rules which should execute before this rule	Reserved for future use.
Execute this rule only if the following expression is true	Reserved for future use.

Expression tab

The Expression tab has two views, one for creating an intrinsic rule and another for creating a calculation or constraint rule.

Option	Description
Expression workspace	(Read-only for intrinsic rules) Provide the expression of the rule.
Parameters section	(Visible only for intrinsic rules) Provide the parameters for the function.

Option	Description
Data Mappings tab	Lists: • RefNames of the data mappings, data sets, and data series in the study or library. • Rule model properties for data series. A data series has the properties of the item that is mapped to it. If a data series contains an item that collects more than one value, the rule model properties for repeating study objects appear so you can access an array of all of the values of the item. • Methods for data sets. A method appears if you select the corresponding standard data dimension of the data set. You can use data set methods to return a subset of the data in the data set. • Study events, forms, sections, and items that are mapped to each data set. • Study objects appear if you select the corresponding standard data dimension of the data set. The properties of the study objects are used as parameters of data set methods.
Constants tab	Lists constants created in the study and the libraries that appear in the Libraries List in the Study Editor. Any rule in the study can reference a constant.
Functions tab	Lists functions registered in a study and the libraries that appear in the Libraries List in the Study Editor. Any rule in the study can reference a function. **Note:** This tab does not appear for intrinsic rules.
Data tab	Lists study objects in the scope of the rule. Optionally, to view the rule model properties of all of the study objects, select **Show all**.

Actions tab

In the Actions tab, you specify the action, or actions, that occur as a result of executing the rule.

Options	Description
Add Action button	Add an action to the rule. **Note:** Click the **Add Action** button after defining an action only if you need to add another action.
Delete Action button	Delete the action selected in the Actions grid.
Grid	-
Fire Event	Event that causes the action to occur. You select the event in the **If The Value Is** section.
Actions	Action that occurs.
If the value is section	-
False	If the rule calculates a False value, the action occurs.
Always	(Default for calculation rules) The action always occurs.
True	If the rule calculates a True value, the action occurs.
Only if no other action executes	The action occurs only if no other action occurs. Select this option only if you define at least two actions.

Options	Description
Values to specify	• **Equals**—If the rule calculates a value that is equal to the provided value, the action occurs. • **Not Equals**—If the rule calculates a value that is not equal to the provided value, the action occurs. • **Less Than**—If the rule calculates a value that is less than the provided value, the action occurs. • **Greater Than**—If the rule calculates a value that is greater than the provided value, the action occurs. • **Between**—If the rule calculates a value that is between the provided values, the action occurs. **Note:** You can include string values in the Equals and Not Equals fields. Enclose the string in double quotes. For example, **"text"**.
(Inclusive) checkbox	Select this option to make the number comparisons inclusive. For example, **Less Than** becomes **Less Than or Equal To**.
Execute these actions grid	-
Action	Available actions. **Note:** Actions appear after you select the event that causes the rule to execute.

Rule Summary section

As you create a rule, the Rule Summary reflects the structure of the rule, including precondition, action, and expression information. Click a link in the Rule Summary to navigate through the Rule Wizard.

Rules tab—Option descriptions

Option	Description
Toolbar buttons	-
New Rule Edit Delete	Create, edit, or delete a data-entry rule.
Check Syntax	Check the syntax of a rule.
Cut Copy Paste	Cut, copy, or paste a data-entry rule.
Enable Disable	Enable all disabled rules or disable all enabled rules for a study object. To enable or disable only parent rules for a study object, deselect the Show Child Rules checkbox before clicking the button.
Show Errors/Hide Errors	View the errors associated with the rule. You must check syntax before you can view errors.
Rule Tests	Open the Rule Test Cases dialog box and create rule test cases.
Top section	-
Show Child Rules checkbox	When selected, all data-entry rules on the selected study object and its children appear in the grid.
Summary grid	-
Description	Description of the rule.
Expression	Expression of the rule.
Id	Identification information for the rule.
Lock icon	Appears if the rule is locked.
Parameters	Parameters for the rule template.
Parent	Title of the study object to which the rule is attached.
Parent RefName	RefName of the study object to which the rule is attached.
Parent Type	Type of study object (such as a form) to which the rule is attached.
RefName	RefName of the rule.
Syntax icon	Indicates the validity of the rule syntax. •  —Rule syntax is valid. •  —Rule syntax has one or more warnings associated with it, or the rule could not be compiled. •  —Rule syntax contains one or more errors and is not valid.
Target	Target application to which the rule is deployed.

Option	Description
When	Event that triggers the rule (you select this option from the **Evaluate** on **Event** drop-down list in the Rule Wizard).
Rule Summary section	A structured specification of the rule appears, with links that open the Rule Wizard.

Run tab of the Rule Test Cases dialog box—Option descriptions

In the Run tab, you run validate rules, run test cases, and view the results.

Field	Description
Top section	-
Check Syntax	Check syntax for the selected rules.
Execute Tests	Run the selected test cases and check syntax for the selected rules.
Stop	Stop the action.
Go to Rule	You are brought to the following location: • **Data-entry rules**—The study object on which the rule is created. • **Workflow rules**—The Workflow Diagram tab that contains the workflow rule. The workflow rule is selected in the diagram. • **Global conditions**—The study object on which the global condition was created (in a study, the study design). The Edit Global Conditions dialog box opens with the global condition selected.
Progress indicator	If the action is successful, the indicator is green. If one or more rules or test cases is invalid, the indicator is red.
Passed Failed Skipped	Metrics for the test cases that you ran. **Note:** If the IgnoreTest property for a test case (set in the Test Properties tab) is set to True, the test case is skipped.
Grid	-
Status	• **Red circle**—Test case or rule is not valid. • **Green circle**—Test case or rule is valid. • **Yellow circle**—(Can appear only after you run test cases) Test case was skipped.
Object Name	Study object on which the rule was created.
Rule Name	Name of the rule.

Field	Description
Validation	Indicates whether the rule is **valid**, **invalid**, or **incomplete** (for rules or global conditions that have valid syntax but are not complete; for example, if the rule has no action defined).
Test Name	• **Run test cases**—Name of the test case. • **Check syntax**—n/a appears
Results	• **Run test cases**—Passed or Failed. • **Check syntax**—n/a appears.
Expected	• **Run test cases**—Expected result of the test case. • **Check syntax**—n/a appears.
Actual	• **Run test cases**—Actual result of the test case. If the test case fails, error appears. • **Check syntax**—n/a appears.
Time	• **Run test cases**—Time (in milliseconds) • **Check syntax**—n/a appears.
Execution Results section	Select a result in the grid to view additional information.

Set Review State Action dialog box

Use the Set Value Action dialog box to set the review stage of a form based on the outcome of a rule.

Option	Description
Form	Form for which the review state is set. You can type a name or drag a form from the Data tab.
ReviewState	Review state to set.
Review Stage	Review stage to set in the review state.
Review Stage expression	Expression for the review stage to set in the review state.
Comment (optional)	Optional text describing the action.
Reference tabs—Available components	List of the components that are available for use in the rule being defined. By default, these tabs appear on the right side of the dialog box. When you select a tab, the Reference section appears, with tabs along the bottom edge.
Data tab	The available study objects appear in a tree structure similar to the Project Explorer.

Option	Description
Functions tab	The available functions appear in a tree structure organized by class. **Note:** Functions are defined in the Study Editor or Library Editor.
Constants tab	The available constants appear in a tree structure organized by class. **Note:** Constants are defined in the Study Editor or Library Editor.
Data Mappings tab	The components of the available mappings appear in a tree structure similar to the Project Explorer.
Show All checkbox	When selected, all available study objects as well as their properties appear. When not selected, only the available study objects appear.

Set Value Action dialog box—Option descriptions

Use the Set Value Action dialog box to set the value of an item based on the outcome of a rule.

Option	Description
Item	Item for which the value is set. You can type a name or drag an item from the Data tab.
Value to set the Item	Value for the item. You can type a value or drag information from any of the tabs.
Reference tabs—Available components	List of the components that are available for use in the rule being defined. By default, these tabs appear on the right side of the dialog box. When you select a tab, the Reference section appears, with tabs along the bottom edge.
Data tab	The available study objects appear in a tree structure similar to the Project Explorer.

Option	Description
Functions tab	The available functions appear in a tree structure organized by class. **Note:** Functions are defined in the Study Editor or Library Editor.
Constants tab	The available constants appear in a tree structure organized by class. **Note:** Constants are defined in the Study Editor or Library Editor.
Data Mappings tab	The components of the available mappings appear in a tree structure similar to the Project Explorer.
Show All checkbox	When selected, all available study objects as well as their properties appear. When not selected, only the available study objects appear.

Workflow Expression Editor dialog box—Option descriptions

Use the Workflow Expression Editor dialog box to create the expression for a workflow rule in a Workflow Diagram tab.

Option	Description
Rule Name	Name of the workflow rule.
Rule Description	Description of the workflow rule. This field is not deployed. Maximum characters: 2000.
Expression section	Used for developing the expression for the rule by typing or by dragging in components displayed in the tabs of the References section. When you drag in a component, the reference to the component is converted to the standard Oracle Central Designer expression syntax. Typically an expression might contain a combination of typed values (such as operators) and dragged-in components (such as functions or references to study objects).

Option	Description
Reference tabs—Available components	List of the components that are available for use in the rule being defined. By default, these tabs appear on the right side of the dialog box. When you select a tab, the Reference section appears, with tabs along the bottom edge.
Data tab	The available study objects appear in a tree structure similar to the Project Explorer.
Functions tab	The available functions appear in a tree structure organized by class. **Note:** Functions are defined in the Study Editor or Library Editor.
Constants tab	The available constants appear in a tree structure organized by class. **Note:** Constants are defined in the Study Editor or Library Editor.
Data Mappings tab	The components of the available mappings appear in a tree structure similar to the Project Explorer.
Show All checkbox	When selected, all available study objects as well as their properties appear. When not selected, only the available study objects appear.

Data mappings

In this section:

- Custom Dimension Labels - Select Codelist dialog box—Option descriptions
- Data Series Editor—Field descriptions
- Data Series Properties dialog box—Option descriptions
- Data Series Summary tab—Option descriptions
- Data Set Editor—Field descriptions
- Data Set Properties dialog box—Field descriptions

- Date-Time Data Point dialog box—Option descriptions
- Item has units dialog box—Option descriptions
- Mapping Editor—Field descriptions
- Select Custom Dimension dialog box—Option descriptions

Custom Dimension Labels - Select Codelist dialog box—Option descriptions

In the Custom Dimension Labels - Select Codelist dialog box, you select or create a codelist for the labels for custom data dimensions created with a data set.

> **Note:**
>
> The dialog box appears when you define a custom data dimension and then click the button in the Codelist Lookup column.

Option	Description
[Codelist drop-down list]	List of available codelists.
New	Create a codelist.
Code	List of codes for the selected codelist.
Label	List of labels for the selected codelist.
Use only listed labels checkbox	Indicates whether users are required to choose from the custom dimension labels that you provide, or if they can provide their own values. • **Selected**—When defining the value of the custom data dimension, users are required to choose from the codelist items you type in the Custom Dimension Labels section. • **Not selected**—When defining the value of the custom data dimension, user can choose from the values you type or provide a value. **Note:** If you select **Use only listed labels**, the codelist must have at least one codelist item.

Data Series Editor—Field descriptions

Field	Description
Item	Name of the item that has been added to the selected data series.
Form	Indicates the forms that are included in the mapping of the item to the data series. • **{All}**—The item is always mapped to the data series, on every form, in every study, and in the library. • **[Form names]**—The item is mapped to the data series only when the item appears on the listed forms. • **[blank]**—The item is not added to the data series.
Study Event	Indicates which study events are included in the mapping of the item to the data series. • **{All}**—The item is always mapped to the data series, on every form, in every study, and in the library. • **[Form names]**—The item is mapped to the data series only when the item appears on the listed forms. • **[blank]**—The item is not added to the data series.
State	Indicates if the association between the item and data series is currently mapped. • **Mapped**—The item is mapped to the data series. • **Unmapped**—The item is part of the data series but is not mapped to the data series for the study. You might add an item to a data series but not want the mapping to exist in a particular study.
Labels	All specified values for custom data dimensions.

Data Series Properties dialog box—Option descriptions

Option	Description
Title	Name of the data series in the data set.
RefName	RefName of the data series in the data set.
Description	Description of the data series in the data set.

Option	Description
Alias	Alias for the data series. If an alias is present, it is used as the column name in the customer-defined database (CDD) or as the Clintrial item name in CIS mappings. If an alias is not present, the RefName is used as the column header. Because RefNames must be unique throughout a study, you must create an alias if the RefName is used by a study object. Data series aliases must be unique within a data set. Checking for RefName and alias uniqueness is case insensitive; for example, the names BP and bp are considered identical.
Type	Data type of the data series.

The data types of an item and data series must be compatible for you to add the item to the data series. The following table indicates the item types that you can add to each data series type.

Item type	Text	Integer	Float	Date time
Text item	Yes	No	No	No
Integer item	Yes	Yes	Yes	No
Float item	Yes	No	Yes	No
Date time item	Yes. You are asked if you want to choose part of the date or the whole date.	Yes. You are asked to choose the part of the date.	No	Yes

Data Series Summary tab—Option descriptions

The Data Series Summary tab appears in the editors for study events and forms.

Option	Description
Filtering bar	-
Mapping	View data series in the selected mapping.
Data Set	View data series in the selected data set.
Filter	• **Show All**—View all items • **Associated**—View items that are part of a data series. • **Not Associated**—View items that are NOT part of a data series.
Compatible types only	When selected, items that cannot be added to any data series are hidden.
CardView	View each item grouped individually.
Fields	-

Option	Description
Forms and Items columns	Forms and items appear as the left-most column headers. The Forms column appears only when a study event is selected. The columns list all forms and items in the study.
[Data series names] columns	Data series appear as column headers in the grid beneath column headers of their data sets. The cells where an item meets with the data series have one of the following background colors: • Gray—You cannot map the item to the data series. • White—You can map the item to the data series. The following mapping types are available: – **[No value]**—The item is not in the data series. Selecting [No value] for an item that previously was mapped to the data series removes the item from the data series. – **Always**—The item is always mapped to the data series, on every form, in every study, and in the library. – **Form**—The item is mapped to the data series only when the item appears on a specific section (or form, if the form has no sections). You can select this option for multiple sections or forms. – **Study event**—(Available only when a study event is selected.) The item is mapped to the data series only when it appears on any form in a specific study event. You can select this option for multiple study events. – **Study event & Form**—(Available only when a study event is selected.) The item is mapped to the data series only when it appears on a specific form in a specific study event.

Data Set Editor—Field descriptions

Field	Description
Title	Title of the data series in the data set.
Description	Description of the data series in the data set.
Type	Data type of the data series.

Field	Description
Alias	Alias for the data series. If an alias is present, it is used as the column name in the customer-defined database (CDD) or as the Clintrial item name in CIS mappings. If an alias is not present, the RefName is used as the column header. Because RefNames must be unique throughout a study, you must create an alias if the RefName is used by a study object. Data series aliases must be unique within a data set. Checking for RefName and alias uniqueness is case insensitive; for example, the names BP and bp are considered identical.

Data Set Properties dialog box—Field descriptions

In the Data Set Properties dialog box, you can define the name and description of a data set and choose the standard dimensions that you want to create for the data set. You have the option of defining custom dimensions for the data set, as well.

Field	Description
Title	Title of the data set.
RefName	RefName of the data set.
Description	Description of the data set.
Alias	Alias for the data set. If an alias is present, it is used as the column name in the customer-defined database (CDD) or as the Clintrial item name in CIS mappings. If an alias is not present, the RefName is used as the column header. Because RefNames must be unique throughout a study, you must create an alias if the RefName is used by a study object. Data series aliases must be unique within a data set. Checking for RefName and alias uniqueness is case insensitive; for example, the names BP and bp are considered identical.
Standard Dimensions section	In this section, you view the standard data dimensions that were selected when the data set was created.
Study	RefName of the study.
Subject	Subject ID.
Section	RefName of the section.
Section Index	Instance of a repeating section.
Event	RefName of the study event.
Event Index	Instance of a repeating study event.
Form	RefName of the form.
Form Index	Instance of a repeating form.
Item	RefName of the item.
Custom Dimensions section	In this section, you view the custom data dimensions, if any, for the data set.

Field	Description
Name	Name of the custom dimension for the selected data set.
Description	Description of the custom dimension created with the selected data set.
Data Type	Data type of the custom dimension created with the selected data set. The following types are available: • **Text**—Contains alphanumeric characters. • **Integer**—Contains only numbers.
Codelist Lookup	Click the button to choose or create a codelist to use for the custom data dimension labels.

Date-Time Data Point dialog box—Option descriptions

Use the Date-Time Data Point dialog box to specify custom mappings for date time items. The dialog box appears when you map a date to a data series that has a type of Integer or Text or when you modify the date part of a mapped date time item.

> **Note:**
>
> When you map a date time item to an integer data series in a CDD mapping, the item is mapped as a split date, with a separate column for each date time part.

Option	Description
All in one column	Map the date to a single database column. This option is available only if the date item is mapped to a data series with a type of Text.
Split columns	Split the date parts into multiple database columns. If the mapping is for: • CDD—The Oracle Central Designer application splits the date parts into multiple database columns. • CIS—You must create a different mapping for each date part that you want to map to a different panel item.
CIS Date Part	Date part to map. This option is available for rule and CIS mappings but not for CDD mappings.

Item has units dialog box—Option descriptions

Option	Description
Normalized Value	Map the normalized value of the item with the data series. Normalization is the process of converting data to a required format. The normalized units appear in parentheses.

Option	Description
Entered Value	Map the entered value of the item with the data series. The entered value can be the same as or different from the normalized value.
Entered Unit	Map the unit in which a value is entered.

Mapping Editor—Field descriptions

Field	Description
Grid section	-
Title	Name of the data set.
Description	Description of the data set.
Alias	Alias for the data set. If an alias is present, it is used as the CDD table name in CDD mappings and as the Clintrial panel name in CIS mappings. If an alias is not present, the RefName is used as the column header. Because RefNames must be unique throughout a study, you must create an alias if the RefName is used by another study object. Data set aliases must be unique within a mapping.
Standard Dimensions section	In this section, you view the standard data dimensions that were selected when the data set was created.
Study	RefName of the study.
Subject	Subject ID.
Section	RefName of the section.
Section Index	Instance of a repeating section.
Event	RefName of the study event.
Event Index	Instance of a repeating study event.
Form	RefName of the form.
Form Index	Instance of a repeating form.
Item	RefName of the item.

Note:

Checking for RefName and alias uniqueness is case insensitive; for example, the names BP and bp are considered identical.

Field	Description
Custom Dimensions section	In this section, you view the custom data dimensions, if any, for the data set.
Name	Name of the custom dimension for the selected data set.
Description	Description of the custom dimension created with the selected data set.
Data Type	Data type of the custom dimension created with the selected data set. The following types are available: • **Text**—Contains alphanumeric characters. • **Integer**—Contains only numbers.
Codelist Lookup	Click the button to choose or create a codelist to use for the custom data dimension labels.

> **Note:**
>
> The Standard Dimensions and Custom Dimensions sections are read-only.

Select Custom Dimension dialog box—Option descriptions

The Select Custom Dimension dialog box appears when you add an item to a data series, and the item is in a data series that is in a data set with one or more custom data dimensions defined.

Option	Description
X	When checkbox is selected, custom data dimension is selected.
Dimension Name, Dimension Description	Name and description of the custom data dimension.
Data Type	Data type of the custom data dimension
Labels	Drop-down list containing the codelist item labels for the custom data dimension.

> **Note:**
>
> If you type a label or modify an existing label, a new codelist item is created for the codelist.

Validation and deployment

In this section:

- Baselines Browser—Option descriptions
- Create Deployment Package Wizard—Full deployment package
- Create Deployment Package Wizard—Incremental deployment package
- Create Deployment Package Wizard—Administration data deployment package
- Create Deployment Package Wizard—Custom events
- Deployment Editor—Option descriptions
- Pending Approvals tab on the Home Page—Option descriptions
- Deployment History dialog box—Option descriptions
- Deployment Package History dialog box—Option descriptions
- Deployment Request dialog box—Option descriptions
- Deployment Wizard for Oracle InForm deployment
- Jobs Browser—Option descriptions

Baselines Browser—Option descriptions

Option	Description
Buttons	-
Edit	Edit the name and description of the selected baseline.
Delete	Delete the selected baseline. You can only delete a baseline that does not have a deployment package associated with it.
Ignore Warnings	View warning messages and either update the study to correct them or indicate that you will ignore the warnings.
Make Public	Mark a baseline as public so that other users can view and work with it.
Show Validation/Hide Validation	• **Show Validation**—Change from a grid to a tree structure that you can expand to view the validation messages generated during baseline creation. • **Hide Validation**—Change from a tree structure back to a grid that lists only baselines without validation messages.
Refresh	Refresh the display of baselines from the Oracle Central Designer database. Job results for baselines that are expanded are also refreshed from the database.
Save As	Save the contents of the Baselines Browser to a comma-separated value (CSV) file that can be opened in a Microsoft Excel spreadsheet.

Option	Description
Columns	Not all fields appear in the default view. Optionally, you can add the other fields and rearrange the browser view.
Baseline ID	Unique identifier of the baseline.
Date Created	Date and time that the baseline was created.
Deployed	Yes or No, indicating whether the baseline has been processed for deployment.
Description	Description of the baseline, updated if you edit the baseline.
Job ID	Unique identifier of the job in which the baseline was created.
Name	Name of the baseline. By default, the name consists of the string Validation baseline, along with the date and time it was created.
Public	Yes or No, indicating whether the validation baseline has been made public.
Revision	Revision number of the baseline. The revision consists of three numbers: "Major.Minor.Revision," such as 1.0.2. • **Major and minor number**—The version number of the study design study object. If the study design does not have a version number, the first two numbers are 0.0, such as 0.0.4. • **Revision number**—The number of revisions made to the study since the most recent version label (either major or minor) was created.
Status	Status of the baseline: • **Valid**—No warnings and no errors. A baseline with this status can be processed for deployment. • **Valid with Warnings**—One or more warnings exist, but a user has updated them with the Ignore Warnings menu command. A baseline with this status can be processed for deployment. • **Pending**—Validation is in process. • **Invalid with Warnings**—One or more warnings exist and have not been updated with the Ignore Warnings menu command. A baseline with this status cannot be processed for deployment. • **Invalid**—One or more errors exist. A baseline with this status cannot be processed for deployment.
Status Icon	Icon that corresponds to the status of the baseline.
Study ID	Unique identifier of the study for which the baseline is generated.
Targets	The target application(s) for which you validated the study and to which you deploy the study.

Option	Description
Sub-columns	The following columns are in the grid that appears when you click Show Job Results and expand the results for a job.
Code	Unique identifier for the validation error or warning. You can provide the code when submitting issues to Oracle Support.
Description	Description of the baseline message.
Date Created	Date and time the validation message was created.
Issue Name	Type of issue for which the job result is reporting. This field contains a value only if the job result is a validation error on a rule. Options include Rule Name and sometimes Function Name.
Job Id	Unique identifier of the job in which the baseline was created.
Job Result Id	Unique identifier of the baseline message.
Object RefName	RefName of the study object that is reported in the validation message. This field contains a value only if the job result is a validation error on a rule.
Object Title	Title of the study object that is reported in the validation message. This field contains a value only if the job result is a validation error on a rule.
Path	Path of the study object that is reported in the validation message. This field contains a value only if the job result is a validation error on a rule.
Target	Target application for which you validate the study and to which you deploy the study.
Type Icon	Icon that corresponds to the status of the validation type.
Validation Type	Type of message: • **Information**—Description of the processing step being performed during validation. • **Warning**—Irregularity that should be investigated. Further processing (for example, creation of a deployment package) can be performed if you explicitly choose to ignore warnings. • **Error**—Fatal problem. No further processing (for example, creation of a deployment package) can be performed until all errors are corrected.
Warning Ignored	Indicates if you have chosen to ignore a warning.

Create Deployment Package Wizard—Full deployment package

Page	Option	Description
Welcome	-	Introduction page.

Page	Option	Description
Select a Deployment Package Type	-	Specify the type of deployment package to create. **Note:** To deactivate a rule in the Oracle InForm application, do one of the following in the Central Designer application before creating a new deployment package:

Page	Option	Description
		• Remove the rule from the study. • Disable the rule. • Change the trigg

Page	Option	Description
		ering event to On Demand (Batch Mode). Rule-related changes that you make in the Oracle InForm application are ove

Page	Option	Description
		rridden when you install a new deployment package. **Note:** If you create or modify a coding map, use a full deployment package to deploy the changes. Changes

Page	Option	Description
		to coding maps are not supported in incremental deployment packages.
-	Full package	Deployment package that contains everything needed to deploy a complete study.
-	Incremental package	Deployment package that contains everything needed to deploy a complete study, plus additions and changes to the study, reflected in Alternate forms in the Oracle InForm application. Alternate forms are not created when you install an incremental deployment package that contains additions to repeating forms or fixed repeating sections (Repeating Data itemsets in the Oracle InForm application).
-	Administration data	Deployment package that contains only study administration data.

Page	Option	Description
-	Custom events	Deployment package that contains one or more in-place revisions on custom events. **Note:** The Custom Events option is for updating existing events. You can not use it to add a new custom event to a study.

Page	Option	Description
Select a Baseline	-	Specify the baseline to use for creating the deployment package. Validation baselines with a status of Valid or Valid with Warnings are eligible. **Note:** If you select an unpublished validation baseline, the baseline is made public during deployment package creation.
-	Please select a baseline	Drop-down list of validated baselines available for creating a deployment package.
In-Place Revisions	-	If the specified baseline contains in-place revisions, review the changes and confirm you understand the risks of deploying before proceeding.

Page	Option	Description
-	View IPR Summary	Open the IPR Summary dialog box to review the revisions included in the baseline.
-	Confirmation text	Select the checkbox to confirm that you understand the risks involved in deploying to the Oracle InForm application. Select the checkbox to confirm that you understand the risks involved in deploying to the Oracle InForm application.

Page	Option	Description
Select Locales	-	Specify the locale or locales for which to create the deployment package. You must select at least one locale.

Note:

Each option is applicable for different releases of the Oracle InForm application, and only one option is used for each release. However, you must st

Page	Option	Description
		select values for both options.
-	Please select one or more locales	List of locales available to be supported by the deployment package. **Note:** This option is used when you deploy to Oracle InForm release 4.6.

Page	Option	Description
-	Apply layout from	Specify the default layout locale for the deployment package. In Oracle InForm release 4.7 and later, a single study version contains the layout information for all locales in the study, and you specify a default layout locale, from which all layouts, regardless of locale, inherit customizations in the Oracle InForm application. The site locale language in the Oracle InForm application determines the language in which forms appear. For example, a study contains layouts for the French (France) and the English (United Kingdom) locales. Radio buttons are horizontal in the French (France) layout but are vertical in the England (United Kingdom) layout. If French (France) is the default layout locale, then all layout customizations for the France (French) layout, including the alignment of radio buttons, are deployed to the Oracle InForm application and appear for all users, regardless of their site locale. Therefore, if your site locale in the Oracle InForm application is English (United Kingdom), the forms appear in English but with the customizations that were made in the French (France) layout in the Oracle Central Designer application. **Note:** This option is used when you dep

Page	Option	Description
		loy to Ora cle InF or m rele ase 4.7 and late r.
Select Layouts	-	Choose the layout to deploy. If the layout does not exist for a form, the primary layout for the form is deployed instead. The list contains only the registered layout names in the study, which appear in the Tools > Layout Names Manager dialog box.
Select Customer Defined Database (CDD) Mappings (optional)	-	Specify the mappings used to generate mappings for a CDD. This page appears only if at least one CDD mapping is defined for the study. Only CDD mappings appear in the list.

Page	Option	Description
-	Optionally, select one or more mappings for CDD mapping	List of CDD mappings.

Note:

If you are deploying a study version change, and the study version includes new visits with items used in mappings, you must include the mappings wh

Page	Option	Description
		en you cre ate the dep loy me nt pac kag e.
-	Select All	Select all mappings in the list.
-	Unselect All	Deselect all mappings in the list.
Select Clintrial Integration Solution (CIS) Mappings (optional)	-	Specify the mappings used to generate mappings for the CIS application. This page appears only if at least one CIS mapping is defined for the study. Only CIS mappings appear in the list.

Page	Option	Description
-	Optionally, select one or more mappings for CIS mapping	List of CIS mappings.

Note:

If you are deploying a study version change, and the study version includes new visits with items used in mappings, you must include the mappings wh

Page	Option	Description
		en you cre ate the dep loy me nt pac kag e.
-	Select All	Select all mappings in the list.
-	Unselect All	Deselect all mappings in the list.
Specify a Name and Description	-	Specify a name and description for the deployment package.
-	Please specify a name for your deployment package	Name of the deployment package.
-	Package description	Description of the deployment package.
-	Apply new study version to all sites	Select to apply the study to all sites.
-	Email dropbox location	Specify the location to which to send an email triggered by a rule.

Page	Option	Description
MedML Files (optional)	-	Attach MedML files to the deployment package. The order in which the files are deployed is determined by their order in the grid. **Note:** The MedML files are validated by the Oracle InForm application prior to execution.
-	Add	Add a MedML file to the grid.
-	Remove	Remove selected MedML file from the grid.
-	Move Up	Move selected file higher in the grid.
-	Move Down	Move selected file lower in the grid.
-	Select All	Select all files in the grid.
Ready to Create Deployment Package	-	View a summary of the deployment options selected in the wizard.
-	Options summary	Summary of options selected for the deployment package.

Create Deployment Package Wizard—Incremental deployment package

Page	Option	Description
Welcome	-	Introduction page.

Page	Option	Description
Select a Deployment Package Type	-	Specify the type of deployment package to create.

Note:

To deactivate a rule in the Oracle InForm application, do one of the following in the Oracle Central Designer application before creating a new deployment pac

Page	Option	Description
		kage: • Remove the rule from the study. • Disable the rule. • Change the stri

Page	Option	Description
		gggeringeventtoOnDemand(BatchMode). Rule-related changes that you make in the Oracle InForm application

Page	Option	Description
		are overridden when you install a new deployment package.
		Note: If you create or modify a coding map, use a full deployment package to deploy the changes. Ch

Page	Option	Description
		ang es to cod ing ma ps are not sup por ted in incr em ent al dep loy me nt pac kag es.
-	Full package	Deployment package that contains everything needed to deploy a complete study.
-	Incremental package	Deployment package that contains everything needed to deploy a complete study, plus additions and changes to the study, reflected in Alternate forms in the Oracle InForm application. Alternate forms are not created when you install an incremental deployment package that contains additions to repeating forms or fixed repeating sections (Repeating Data itemsets in the Oracle InForm application).
-	Administration data	Deployment package that contains only study administration data.

Page	Option	Description
-	Custom events	Deployment package that contains one or more in-place revisions on custom events. **Note:** The Custom Events option is for updating existing events. You cannot use it to add a new custom event to a study.
Select a Previously Created Deployment Package	-	Specify the previously created deployment package for which this is an incremental package.
-	Please select a deployment package	Drop-down list of previously created deployment packages.

Page	Option	Description
Select a Baseline	-	Specify the validation baseline to use for creating the incremental deployment package. This baseline must have a date and time that is later than the validation baseline used to create the deployment package selected on the previous page.
-	Deployment Package	Name of the deployment package selected on the previous page.
-	Package Baseline	Validation baseline used to create the selected deployment package.
-	Please select a baseline for the incremental package	Drop-down list of validated baselines available for creating the incremental deployment package.
In-Place Revisions	-	If the specified baseline contains in-place revisions, review the changes and confirm you understand the risks of deploying before proceeding.
-	View IPR Summary	Open the IPR Summary dialog box to review the revisions included in the baseline.
-	Confirmation text	Select the checkbox to confirm that you understand the risks involved in deploying to the Oracle InForm application.
Add Locales (Optional)	-	Specify the additional locale or locales for which to create the incremental deployment package. This page appears only if you have added new locales to the validation baseline.
-	Optionally, select one or more locales	List of locales available to be supported by the deployment package.
-	Select All	Select all locales in the list.
-	Unselect All	Deselect all locales in the list.
Add Customer Defined Database (CDD) Mappings (Optional)	-	Specify the additional mapping or mappings, if any, to use in the incremental package for generation of CDD mappings. This page appears only if you have added new CDD mappings to the validation baseline. If you have made changes to existing CDD mappings, those mappings are used in the deployment package to update the CDD mappings.

Page	Option	Description
-	Optionally, select one or more CDD mappings	List of CDD mappings.

Note:

If you are deploying a study version change, and the study version includes new visits with items used in mappings, you must include the mappings wh

Page	Option	Description
		en you cre ate the dep loy me nt pac kag e.
-	Select All	Select all mappings in the list.
-	Unselect All	Deselect all mappings in the list.
Add Clintrial Integration Solution (CIS) Mappings (Optional)	-	Specify the additional mapping or mappings, if any, to use in the incremental package for generation of CIS mappings. This page appears only if you have added new CIS mappings to the validation baseline. If you have made changes to existing CIS mappings, those mappings are used in the deployment package to update the CIS mappings.

Page	Option	Description
-	Optionally, select one or more CIS mappings	List of CIS mappings.

> **Note:**
>
> If you are deploying a study version change, and the study version includes new visits with items used in mappings, you must include the mappings wh

Page	Option	Description
		en you cre ate the dep loy me nt pac kag e.
-	Select All	Select all mappings in the list.
-	Unselect All	Deselect all mappings in the list.
Specify a Name and Description	-	Specify a name and description for the incremental deployment package
-	Please specify a name for your deployment package	Name of the incremental deployment package.
-	Package description	Description of the incremental deployment package.
-	Apply new study version to all sites	Select to apply the study to all sites.
-	Email dropbox location	Specify the location to which to send an email triggered by a rule.

Page	Option	Description
MedML Files (optional)	-	Attach MedML files to the deployment package. The order in which the files are deployed is determined by their order in the grid.
-	Add	Add a MedML file to the grid.
-	Remove	Remove selected MedML file from the grid.
-	Move Up	Move selected file higher in the grid.
-	Move Down	Move selected file lower in the grid.
-	Select All	Select all files in the grid.
Ready to Create Deployment Package	-	View a summary of the deployment options selected in the wizard.
-	Options summary	Summary of options selected for the incremental deployment package.

Note:

The MedML files are validated by the Oracle InForm application prior to execution.

Create Deployment Package Wizard—Administration data deployment package

Page	Option	Description
Welcome	-	Introduction page.

Page	Option	Description
Select a Deployment Package Type	-	Specify the type of deployment package to create. **Note:** To deactivate a rule in the Oracle Inline Form application

Page	Option	Description
		, d o o n e o f t h e f o l l o w i n g i n t h e O r a c l e C e n t r a l D e s i g n e r a p p l i c a t i o n b

Page	Option	Description
		for recreating a new deployment package: • Remove the rule from the es

Page	Option	Description
		tudy. • Disable the rule. • Change the trigger ing event to On Demand (

Page	Option	Description
		BatchMode). Rule-relatedchangesthatyoumakeintheOracleInF

Page	Option	Description
		or map plication area overridden when you install a new deployment pack

Page	Option	Description
		age.
		Note: If you create or modify a coding map, use a full deployment

Page	Option	Description
		oymentpackagetodeployth echhangges.Chhangestocodingmapsaren

Page	Option	Description
		otsupportedininincrementaldeployment packages.
-	Full package	Deployment package that contains everything needed to deploy a complete study.

Page	Option	Description
-	Incremental package	Deployment package that contains everything needed to deploy a complete study, plus additions and changes to the study, reflected in Alternate forms in the Oracle InForm application. Alternate forms are not created when you install an incremental deployment package that contains additions to repeating forms or fixed repeating sections (Repeating Data itemsets in the Oracle InForm application).
-	Administration data	Deployment package that contains only study administration data.

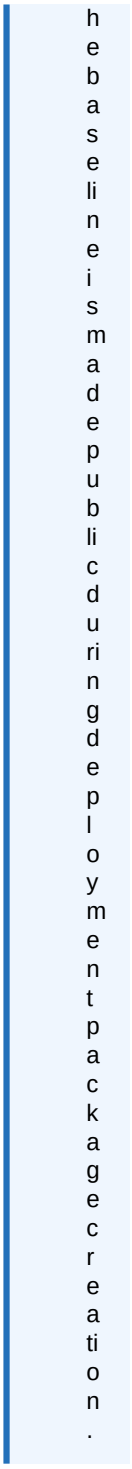
Page	Option	Description
-	Custom events	Deployment package that contains one or more in-place revisions on custom events.

Note:

The Custom Events option is for updating existing ev

Page	Option	Description
		ents. You can not use it to add a new custom event to a study.

Page	Option	Description
Select a Baseline	-	Specify the baseline to use for creating the deployment package. Validation baselines with a status of Valid or Valid with Warnings are eligible. **Note:** If you select an unpublished validation baseline, t

Page	Option	Description
		
-	Please select a baseline	Drop-down list of validated baselines available for creating a deployment package.

Page	Option	Description
Specify a Name and Description	-	Specify a name and description for the deployment package.
-	Please specify a name for your deployment package	Name of the deployment package.
-	Package description	Description of the deployment package.
Ready to Create Deployment Package	-	View a summary of the deployment options selected in the wizard.
-	Options summary	Summary of options selected for the deployment package.

Create Deployment Package Wizard—Custom events

Page	Option	Description
Welcome	-	Introduction page.

Page	Option	Description
Select a Deployment Package Type	-	Specify the type of deployment package to create.

Note:

To deactivate a rule in the Oracle InForm application, do one of the following in the Oracle Central Designer application before creating a new deployment pac

Page	Option	Description
		kage: • Remove the rule from the study. • Disable the rule. • Change the stri

Page	Option	Description
		gggeringeventtoOnDemand(BatchMode). Rule-related changes that you make in the Oracle InForm application

Page	Option	Description
		are overridden when you install a new deployment package.
		Note: If you create or modify a coding map, use a full deployment package to deploy the changes. Ch

Page	Option	Description
		ang es to cod ing ma ps are not sup por ted in incr em ent al dep loy me nt pac kag es.
-	Full package	Deployment package that contains everything needed to deploy a complete study.
-	Incremental package	Deployment package that contains everything needed to deploy a complete study, including study administration data, plus additions and changes to the study, reflected in Alternate forms in the Oracle InForm application. Alternate forms are not created when you install an incremental deployment package that contains additions to repeating forms or fixed repeating sections (Repeating Data itemsets in the Oracle InForm application).
-	Administration data	Deployment package that contains only study administration data.

Page	Option	Description
-	Custom events	Deployment package that contains one or more in-place revisions on custom events.

> **Note:**
>
> The Custom Events option is for updating existing events. You can not use it to add a new custom event to a study.

Page	Option	Description
Select a Baseline	-	Specify the baseline to use for creating the deployment package. Validation baselines with a status of Valid or Valid with Warnings are eligible. **Note:** If you select an unpublished validation baseline, the baseline is made public during deployment package creation.
-	Please select a baseline	Drop-down list of validated baselines available for creating a deployment package.
In-Place Revisions	-	If the specified baseline contains in-place revisions, review the changes and confirm you understand the risks of deploying before proceeding.

Page	Option	Description
-	View IPR Summary	Open the IPR Summary dialog box to review the revisions included in the baseline.
-	Confirmation text	Select the checkbox to confirm that you understand the risks involved in deploying to the Oracle InForm application. Select the checkbox to confirm that you understand the risks involved in deploying to the Oracle InForm application.
Specify a Name and Description	-	Specify a name and description for the deployment package.
-	Name	Name of the deployment package.
-	Description	Description of the deployment package.
-	Email dropbox	Specify the location to which to send an email triggered by a rule.
-	Apply new study version to all sites	Select to apply the study to all sites.
Ready to Create Deployment Package	-	View a summary of the deployment options selected in the wizard.
-	Options summary	Summary of options selected for the deployment package.

Deployment Editor—Option descriptions

> **Note:**
>
> Not all fields appear in the default view. Optionally, you can add the other fields and rearrange the browser view.

Option	Description
Buttons	-
New Package	Create a deployment package from a validation baseline by using the Create Deployment Package Wizard.
Save as	Deliver a deployment package to a location from which it can be deployed. Available for deployment packages created in Oracle Central Designer release 2.1 and later.
Delete	Delete a deployment package.

Option	Description
Deployment	• **Request**—Create a deployment request for the selected deployment package. • **History**—Open the Deployment History dialog box to view a history of deployment requests for the selected package.
Columns	Select the columns to display in the Deployment Editor.
Refresh	Refresh the display of deployment packages.
Columns	-
Apply to All Sites	Apply the study version to all sites that use the study.
Base Layout	Layout that was created in the Oracle Central Designer 1.3 release or earlier and is used with a multilingual study that was deployed to the Oracle InForm 4.7 release or later.
Baseline	Name of the validation baseline on which the deployment package is based.
Contains IPR	Indicate that the study contains in-place revision changes.
Deployment Counts	Number of deployments performed for the deployment package.
Description	Description of the deployment package.
Main Layout	Primary layout that appears if a layout is not specified.
Name	Name of the deployment package.
Package Created By	User name of the user who created the deployment package.
Package Creation Date	Date and time when the deployment package was created.
Targets	The target application(s) for which you validated the study and to which you deploy the study.
Type	Type of deployment package: • Full • Incremental • Administration data
Version	Version of the study that you are deploying.

Pending Approvals tab on the Home Page—Option descriptions

Option	Description
Buttons	-
Approve/Reject Request	Open the Approve Deployment Request dialog box to view detailed information about the selected deployment request, and approve or reject the request.

Option	Description
Deployment History	Open the Deployment History dialog box to view a detailed list of deployment data that includes: • Deployment requests waiting for your approval and deployment requests for studies on which you are a team member. • Deployment requests from all studies, if you are assigned to a role with the View deployments across studies right.
Locking	Display the lock options for pending deployment requests.
Columns	Select the columns to display in the Approvals tab.
Columns	-
Additional Reason Info	Additional information about the reason for the approval request.
Approval ID	Unique identifier of the deployment.
Deployment Type	One of the following: • **Modify an existing trial**—Deploy modified content to an existing study. • **Deploy to new trial**—Deploy content to a new study.
Has IPR	Indicates that the deployment contains in-place revision changes.
Package Name	Name of the deployment package.
Package Type	Type of deployment package: • Full • Incremental • Administration data
Port Number	Port used to query for deployment status.
Project	Name of the project containing the study.
Reason	Reason for deployment provided when the deployment request was created.
Requested By	User name of the user who created the deployment request.
Requested Date	Date when the deployment request was created.
Schedule	Date and time when to perform package deployment. Configured when the deployment request was created.
Status URL	URL used to query for the deployment status of the study.
Study	Name of the study for which the deployment package was created.
Trial Server Name	Name of the machine on which to deploy the study.

Option	Description
Trial Type	Type of study server to which the deployment package was deployed. One of the following: • **UAT**—User acceptance testing • **QA**—Quality assurance • **DEV**—Development • **LIVE**—Production • **TRN**—Training
Trial URL	URL used to log on to the machine on which to deploy the study.

Deployment History dialog box—Option descriptions

Option	Description
Buttons	-
Package History	Open the Deployment History dialog box for the selected deployment package.
View Log	Open the Deployment Log dialog box.
Export	Save approval history information to a comma-separated value (CSV) file that can be opened in a Microsoft Excel spreadsheet.
Columns	Select the columns to display. Not all columns appear in the default view.
Columns	-
Additional Information	Additional information provided in the deployment request.
Approval Required	Whether the deployment of the package requires approval.
Approval Status	Approval status for the deployment request. One of the following: • **Not Required**—Request does not re quire an approval. • **Requested**—Request has been created, and it has not been approved or rejected yet. • **Approved**—Request has been approved. • **Rejected**—Request has been rejected.
Archived	Whether the deployment package is archived.
Date Completed	Date and time when the deployment process completed.
Date Performed	One of the following: • If the approval status is Not Required or Requested, date and time when the deployment request was created. • If the approval status is Approved or Rejected, date and time when the request was approved or rejected.
Date Started	Date and time when the deployment process started.
Deployment ID	Unique identifier of the deployment.

Option	Description
Deployment Instance	RefName of the deployment instance to which the deployment package was deployed.
Deployment Option Type	One of the following: • **Modify an existing trial**—Deploy modified content to an existing study. • **Deploy to new trial**—Deploy content to a new study.
Deployment Status	Deployment status for the deployment request. One of the following: • **Not Applicable**—Deployment has not been initiated. • **Unknown**—Deployment has been initiated, but the InForm application has either not detected the deployment package, or has not located it. • **Submitted**—Deployment has been initiated, the package has been transferred to the InForm server, but the InForm application has not detected it yet. • **Scheduled**—Deployment has been initiated, the package has been transferred to the InForm server, and the InForm application has scheduled it for installation. • **In Progress**—Deployment is currently being executed. • **Succeeded**—Deployment has completed successfully. • **Failed**—Deployment has failed. • **Canceled**—Deployment has been canceled.
Deployment Type	Type of study server to which the deployment package was deployed. One of the following: • **UAT**—User acceptance testing • **QA**—Quality assurance • **DEV**—Development • **LIVE**—Production • **TRN**—Training
Deployment URL	URL address of the deployment instance.
Has IPR	Indicates that the deployment contains in-place revision changes.
Is Immediate	Whether the deployment schedule option selected in the deployment request was Immediate.
Package Name	Name of the deployment package.
Package Type	Type of deployment package: • Full • Incremental • Administration data

Option	Description
Performed By	One of the following: • If the approval status is Not Required or Requested, user name of the user who created the deployment request. • If the approval status is Approved or Rejected, user name of the user who approved or rejected the deployment request.
Project	Name of the project containing the study.
Reason for Deployment	Reason for deployment provided when the deployment request was created.
Schedule	Date and time when to perform package deployment. Configured when the deployment request was created.
Status URL	URL used to query for the deployment status of the study.
Study	Name of the study for which the deployment package was created.

Deployment Package History dialog box—Option descriptions

Option	Description
Buttons	-
Cancel Request	Cancel the selected deployment request. Available only if the deployment request has not been approved or rejected yet. You cannot cancel a request if the deployment does not require an approval. **Note:** Cancelled deployment requests are not archived.
Cancel Deployment	Cancel the selected deployment. Available only if the deployment status is Scheduled or Submitted.
View Log	Open the deployment log for the selected deployment. Available if the deployment status is either Succeeded, Failed, or Canceled.
Save as	Open the Save as dialog box to save the deployment package as a zip file. Available only for deployment packages created in Oracle Central Designer release 2.1 and later.
Export	Save the deployment package history to a comma-separated value (CSV) file that can be opened in a Microsoft Excel spreadsheet.

Option	Description
Columns	Select the columns to display. Not all columns appear in the default view.
Filter by Deployment Id field	Enter a Deployment Id to display information only for that deployment.
Fields	-
Package	Name of the deployment package.
Baseline	Name of the validation baseline on which the deployment package is based.
Package Type	Type of deployment package: • Full • Incremental • Administration data
Columns	-
Additional Information	Additional information provided in the deployment request.
Approval Required	Whether the deployment of the package requires approval.
Approval Status	Approval status for the deployment request. One of the following: • **Not Required**—Request does not re quire an approval. • **Requested**—Request has been created, and it has not been approved or rejected yet. • **Approved**—Request has been approved. • **Rejected**—Request has been rejected.
Archived	Whether the deployment package is archived.
Date Completed	Date and time when the deployment process completed.
Date Performed	One of the following: • If the approval status is Not Required or Requested, date and time when the deployment request was created. • If the approval status is Approved or Rejected, date and time when the request was approved or rejected.
Date Started	Date and time when the deployment process started.
Deployment Id	Unique identifier of the deployment.
Deployment Instance	RefName of the deployment instance to which the deployment package was deployed.
Deployment Option Type	One of the following: • **Modify an existing trial**—Deploy modified content to an existing study. • **Deploy to new trial**—Deploy content to a new study.

Option	Description
Deployment Status	Deployment status for the deployment request. One of the following: • **Not Applicable**—Deployment has not been initiated. • **Unknown**—Deployment has been initiated, but the InForm application has either not detected the deployment package, or has not located it. • **Submitted**—Deployment has been initiated, the package has been transferred to the InForm server, but the InForm application has not detected it yet. • **Scheduled**—Deployment has been initiated, the package has been transferred to the InForm server, and the InForm application has scheduled it for installation. • **In Progress**—Deployment is currently being executed. • **Succeeded**—Deployment has completed successfully. • **Failed**—Deployment has failed. • **Canceled**—Deployment has been canceled.
Deployment Type	Type of study server to which the deployment package was deployed. One of the following: • **UAT**—User acceptance testing • **QA**—Quality assurance • **DEV**—Development • **LIVE**—Production • **TRN**—Training
Deployment URL	URL address of the deployment instance.
Has IPR	Indicates that the deployment contains in-place revision changes.
Is Immediate	Whether the deployment schedule option selected in the deployment request was Immediate.
Performed By	One of the following: • If the approval status is Not Required or Requested, user name of the user who created the deployment request. • If the approval status is Approved or Rejected, user name of the user who approved or rejected the deployment request.
Project	Name of the project containing the study.
Reason for Deployment	Reason for deployment provided when the deployment request was created.
Schedule	Date and time when to perform package deployment. Configured when the deployment request was created.
Status URL	URL used to query for the deployment status of the study.

Option	Description
Study	Name of the study for which the deployment package was created.

Deployment Request dialog box—Option descriptions

Use the Deployment Request dialog box to initiate the automated deployment of a package.

Settings tab

Option	Description
Deployment instance	Select a deployment instance from the Name drop-down list. The following information will be displayed for the selected instance: type, URL, and whether approvals are required.
Deployment schedule	Select when to perform the deployment: • **Time**—Select the time when to deploy the package (local time of the client). • **Immediate (after approval)**—Deploy the package immediately after the deployment request is approved.
Deployment option	One of the following: • **Modify an existing trial**—Deploy modified content to an existing study. • **Deploy to new trial**—Deploy content to a new study.
Reason for deployment	Select a reason for the deployment. The reason is included in the email notification sent to the deployment approvers.
Additional information	Optionally, provide more information about the deployment request. The information is not included in the email notification sent to the deployment approvers.
Email distribution list	Users who receive email notifications when the deployment request is created, approved or rejected, and when the deployment is completed. **Note:** The user who requests the deployment and all the users who have the right to approve the request are automatically added to the list.

Advanced tab

You can configure advanced options if overriding the settings is allowed for the server type in the Oracle Central Designer Administrator application. For more information, see the *Administrator Guide*.

Option	Description
Deployment start day	Time to wait (in milliseconds) for the Oracle InForm caches to initialize.

Deployment Wizard for Oracle InForm deployment

Page	Option	Description
Welcome	-	Introduction page.
Connecting to Oracle InForm	-	Connect to the Oracle InForm application and requests server and study information.
-	Message section	Informational and error messages.
-	Reconnect	Reconnect to the Oracle InForm application after correcting any error conditions.
Oracle InForm Trial Parameters	-	Specify information about the Oracle InForm application server and study to which to deploy the package. If either the server or the study does not already exist, subsequent pages collect additional information needed to create them.
-	Server Name	Name of the Oracle InForm application server.
-	Trial Name	Name of the Oracle InForm study.
-	Strict Mode	If selected (default)—Only complete MedML definitions of study components can be loaded into the study; an incomplete definition causes the installation to fail. If not selected—Incomplete study component definitions are permitted.
Create a New Oracle InForm Server	-	Specify whether the Oracle InForm server should start automatically when the Oracle InForm Service starts. This page appears if the specified Oracle InForm server does not yet exist.

Page	Option	Description
-	Startup Server Automatically on Oracle InForm Startup	If selected—The Oracle InForm server starts automatically when the InForm Service starts. If not selected—The Oracle InForm server must be started manually.
Create a New Oracle InForm Trial	-	Specify information needed to create the study. This page appears if the specified Oracle InForm study does not yet exist.
-	User Name	Oracle user name for the study database.
-	User Password	Oracle password for the study database.
-	Please specify a database for creating a new Oracle InForm study	One of the following: • **Connect String**—Connection string for the Oracle instance. • **TriDSN**—ODBC System DSN for the Oracle InForm study.
-	Startup Trial Automatically on Oracle InForm Startup	If selected—The Oracle InForm study starts automatically when the Oracle InForm Service starts. If not selected—The Oracle InForm study must be started manually.
Ready for Deployment	-	View a summary of the parameters that will be used for deployment.
Deployment Results	-	View messages generated during deployment processing, along with the elapsed time. These messages are also collected in the StudyInstaller.log file in the directory where you execute the deployment package.

Jobs Browser—Option descriptions

> **Note:**
>
> Not all fields appear in the default view. Optionally, you can add the other fields and rearrange the browser view.

Option	Description
Buttons	-
Hide Job Results/ Show Job Results	• **Show Job Results**—Change from a grid to a tree structure that you can expand to view the job results for each job. • **Hide Job Results**—Change from a tree structure back to a grid that lists only jobs without job results.
Refresh	Refresh the display of jobs from the dOracle Central Designer database. When you refresh, the job results for expanded jobs are also refreshed.
Save As	Save the contents of the Jobs Browser to a comma-separated value (CSV) file that can be opened in a Microsoft Excel spreadsheet.
Jobs Since	Drop-down list specifying how far back the display of job results goes.
Columns	-
Finish Time	Date and time at which the job ended.
Job State	Run status of the job, either Started or Finished.
Job Id	Unique identifier of the job that generated the listing.
Job Result	Indicates whether the job scheduler ran successfully for the specified job. This field is not an indication of the status of the job. • SucceededFailed
Name	Name of the job: • **For deployment package jobs**—Name of the deployment package. • **For library import jobs**—[Import to], plus the name of the target library. • **For validation jobs**—[Validation baseline], plus the date and time of job submission.
Start Time	Date and time when the job started.
Status	Overall status of the job results for the selected job. • **Information**—Job results contain only informational messages. This status also appears if the job has started but no job results have been reported yet. • **Warning**—Job results contain at least one warning (but no errors). • **Error**—Job results contain at least one error.
Status Icon	Icon that corresponds to the status of the job.
Study Id	Unique identifier of the study for which the job was run.
Type	Type of job, either Import, Validation, or BuildDeploymentPackage.

Option	Description
Sub-columns	The following columns are in the grid that appears when you click Show Job Results and expand the results for a job.
Code	Unique identifier for the validation error or warning. You can provide the code when submitting issues to Oracle Support.
Date Created	Date and time the message was generated.
Description	Text of the message.
Issue Name	Type of issue for which the job result is reporting. This field contains a value only if the job result is a validation error on a rule. Options include Rule Name and sometimes Function Name.
Job Id	Unique identifier of the job that generated the listing.
Job Result Id	Unique identifier of the job result.
Object RefName	RefName of the study object that is reported in the job result. This field contains a value only if the job result is a validation error on a rule.
Object Title	Title of the study object that is reported in the job result. This field contains a value only if the job result is a validation error on a rule.
Path	Path of the study object that is reported in the job result. This field contains a value only if the job result is a validation error on a rule.
Target	Target application for which you validate the study and to which you deploy the study.
Type	Type of message: • **Information**—Description of the processing step being performed in the job. • **Warning**—Irregularity that should be investigated. Further processing (for example, creation of a deployment package) can be performed if you explicitly choose to ignore warnings. • **Error**—Fatal problem. No further processing (for example, creation of a deployment package) can be performed until all errors are corrected.
Type Icon	Icon that corresponds to the type of message.
Warning Ignored	True or False, indicating whether you have chosen to ignore the warning message for the purpose of performing additional processing.

Post-design

In this section:

- In-place revisions
- Annotated Study Book

In-place revisions

In this section:

- IPR Configuration dialog box
- In-Place Revision Summary Editor—Option descriptions
- View Differences dialog box—Option descriptions
- IPR History dialog box—Option descriptions

IPR Configuration dialog box

Use the IPR Configuration dialog box to configure the settings of an in-place revision.

The dialog box is read-only if you do not have the right to make in-place revisions, or if the object or in-place revision is locked or protected.

Option	Description
Description of the change	Description of the change. Optional.
Add	Open the Add Deployment Instance dialog box to add a deployment instance.
Remove	Remove the selected deployment instance.
Refresh Versions	Retrieve the latest study version information for the selected deployment instance.
Apply to All	Apply a change to all study versions.
Copy Association	Open the Copy IPR Configurations dialog box to copy the in-place revision association from the selected deployment instance to another deployment instance.
View Differences	Open the View Differences dialog box to compare the latest version of the object with the object from a selected study version.
Columns (Select a deployment instance section, at the top of the dialog box)	-
Deployment Instance	RefName of the deployment instance.
Type	Server type for the deployment instance: • **UAT**—User acceptance testing • **QA**—Quality assurance • **DEV**—Development • **LIVE**—Production • **TRN**—Training
Description	Description of the deployment instance.
URL	URL address of the deployment instance.
Columns (Select study versions section, at the bottom of the dialog box)	-
Checkbox	When selected, associates the change to the study version on that row.
Oracle InForm Study Version	Oracle InForm study version.
Deployed	Indicates whether the study version was deployed to Oracle InForm.

In-Place Revision Summary Editor—Option descriptions

Option	Description
Buttons	-
Edit	Edit the IPR configuration for the selected in-place revision.
Delete	Delete the selected in-place revision.
IPR Configurations	Copy IPR configurations from one deployment instance to another, or remove IPR configurations from selected deployment instances.
Select All	Select all in-place revisions.
Lock and Protect	Lock or protect the selected in-place revision objects.
History	Open the IPR History dialog box to view a history of in-place revisions for all baselines with in-place revisions that were successfully deployed to LIVE deployment instances. **Note:** The IPR History dialog box only contains information about IPRs applied through automated deployments.
Columns	-
RefName	RefName of the in-place revision study object.
Type	Type of revised study object.
Deployment Instance	Deployment instance to which to deploy the in-place revision.
Description	Description of the change.

View Differences dialog box—Option descriptions

Option	Description
Buttons	-
Show Differences	View the differences between the selected versions of the form.
Root	Select the study object at the top-level in the Modified Objects tree.
Back	Select the previously-selected study object in the Modified Objects tree.
Preview Form	View the current and previous layouts for the selected form.
Fields (for a form change)	-

Option	Description
Form	Form for which to view differences.
Preexisting version	Deployed study version in which the form exists. Select the study version to view the design of the form that you selected in the Form drop-down list that existed in that study version.
Locale	Locale for which to view form data.
Modified Objects	Explorer tree that displays a list of study objects that were modified in the most current version of the study.
Difference	Modification that was made to the study object selected in the Modified Objects tree in the most current version of the study.
Source	Study object that was modified.
Target	New study object that was created by the in-place revision change.
Fields (for a custom event change)	-
General tab	-
Property	The property of the custom event that was added, modified, or deleted from one study version to the other.
Preexisting Version	The deployed study version that contained the custom event.
Latest Version On Study	The latest study version that contained the custom event.
Triggers tab	-
Identifier	An identifier created by Oracle Central Designer for the trigger.
Trigger Type	The type of event (Subject or Study object) that triggers the custom event.
Event Type	The trigger event, which corresponds to the value that you entered in the Event type field in the New Custom Event Trigger dialog box.
Mapped Object	-
Additional Values	The values that you entered in the fields in the New Custom Event Trigger dialog box, other than the Event Type field, and the label of the item the trigger is on.
Results tab	-

Note:

If you create the trigger on a codelist item, the title of the codelist item appears in this column instead of the label.

Option	Description
Identifier	An identifier created by Oracle Central Designer for the result.
Result Type	The type of subject or study object status to include in the result.
Mapped Object	The name of the study object you selected in the result.
Map To Name	The Oracle InForm Publisher alias to map the result to.
Custom Data	The additional data to send with the result data.

IPR History dialog box—Option descriptions

Option	Description
Buttons	-
Show IPRs	View a list of in-place revision changes for the selected baseline.
View Configuration	View the in-place revision configuration for the study object that you select in the bottom of the dialog box.
Fields at the top of the dialog box	-
Baseline	Baseline for a study that was deployed to a LIVE deployment instance with in-place revision changes.
Package Name	Deployment package name.
Deployment Date	Date when the study was deployed.
Fields at the bottom of the dialog box	-
RefName	RefName of the study object that was modified using an in-place revision change.
Type	Study object type.
Deployment Instance	Type of deployment instance to which the study was deployed.
Description	Description of the in-place revision change that was made to the study object.

Note:

You can only view the in-place revision changes for a baseline for a study that was deployed to the Oracle InForm application using automated deployment.

Annotated Study Book

In this section:

- Annotated Study Book Options dialog box

Annotated Study Book Options dialog box

> **Note:**
>
> Items with restricted values are marked with a star (★) in the Annotated Study Book.

Option	What appears in the annotated study book when you select the option
Select Display Options section	• **No Annotated Information**—Form previews without annotations. – **Display Hidden Items**—Form previews without annotations, but with all items visible, including those that are hidden using the Display Override property. Hidden items include the annotation for the hidden display override setting. **Note:** When you select No Annotated Information and Display Hidden Items, hidden items do not appear when you generate an annotated preview of a form from the form layout editor. • **Selected Annotated Information**—Only the selected annotation information. If you choose **Selected Annotated Information**, select the specific information to include in the checkboxes that appear under that radio button. • **All Annotated Information**—All annotated information.
Time and Events Schedule	A listing of the Schedule of Events table.
Forms	Selected information about each form in the study.

Option	What appears in the annotated study book when you select the option
Inline CRF annotations	• **If selected**—The annotations described below. • **If not selected**—Titles or RefNames that appear in square brackets. The annotated forms display RefNames if Show Object RefNames is selected and titles if Show Object RefNames is not selected.
Item formats	• **Text**—A plus maximum character length (for example, A128). • **Integer**—N plus maximum field length (for example, N3). • **Float**—Significant digits and decimal places. The decimal point is included as a character in the length of an item. For example, if the length of a float item is 5 and the precision is 0, the annotation appears as **xxxx**. (the decimal point appears).
Captions on compound items	A caption for the parent item of a compound item appears with the alignment specified on the Layout tab.
Hidden, ReadOnly, or Editable display overrides	The word **hidden**, **read-only**, or **editable** appears in square brackets below the item question.
Minimums and maximums for integer and float items	Specifications set in the MinProperty, MinValue, MaxProperty, and MaxValue item properties are represented as values and operators and listed along with the item format. For example, the notation is 2.0 <= xx.xx < 100.0 if: • **MinProperty**—GREATERTHANEQUAL • **MinValue**—2.0 • **Float length**—5 • **Float precision**—2 • **MaxProperty**—LESSTHAN • **MaxValue**—100.0
Date time items	Required and unknown specifications appear in the date and time controls, and year ranges appear in parentheses following the controls.
Date format	The date format that you select in the Select date variable format field appears in parentheses before the controls.
Required items	An asterisk appears after the item number. In the grid view of fixed repeating sections, an asterisk appears in the column header for each required item.
Items that require source verification	For an item in a form or non-repeating section, a check mark appears under the item number.

Option	What appears in the annotated study book when you select the option
Repeating sections that require source verification	A check mark appears in the following locations: • **For a repeating section**—Under the number in the repeating section header row. • **For a fixed repeating section**—Under the # symbol in the fixed-item section header.
Forms and items that are critical for source verification	For an item in a form or non-repeating section, a check mark inside a circle appears under the item number. For a form, a check mark inside a circle appears to the right of the form name. Forms and items that are source-verification critical are also source-verification required, so these forms and items show only the check mark inside the circle and not an additional check mark denoting their source-verification required status. A footnote indicates that settings for critical source verification that are made in the Oracle InForm application override settings made in the Oracle Central Designer application.
Collapsible items	A collapsible item icon (⊟) appears after the item RefName. **Note:** In the Oracle InForm application, a collapsible item is called a dynamic control.
Key items	A key icon appears under the item number.
Base units	A superscript b in square brackets appears to the right of the control for the base unit.
Repeating forms and sections	A summary item layout containing top-level items appears (for example, the children of compound items and conditional items do not appear), followed by a form layout.

Option	What appears in the annotated study book when you select the option
Fixed repeating sections	A fixed item icon () appears after the item number. The following views appear: • Grid view containing a column for each top-level item and, for each fixed item, a row for each combination of item and codelist items. Depending on the definitions that exist in the study, column headers show the short question in the specified locale, the long question in the specified locale, or an empty cell. – For a hidden item, the text in the column header is grayed out. – The cell for a blank instance of a fixed or non-fixed item is grayed out and includes a blank icon (). • Data entry preview containing controls for each fixed item.
Associated forms	The name of the associated form, if it exists, appears at the bottom of the annotated form.
Codelist Values and Tables	Annotations on forms for codelists that are formatted as radio or checkbox groups. The data type and value appears in square brackets and italic font to the left of each option (for example, [N:1] indicates an integer data type and a codelist item value of 1). Data types are: • A—Text • F—Float • N—Integer Additionally, the annotated study book includes tables that list the specifications of each codelist and codelist item along with the title or RefName of the item with which they are associated. The tables display RefNames if **Show Object RefNames** is selected and titles if **Show Object RefNames** is not selected. For codelists that are pulldown controls, the display order can be set to alphabetical ascending, alphabetical descending, or entered order (Default). Next to the codelist dropdown, an indicator of ↑ **A...Z** will be shown for ascending, and an indicator of ↓ **Z...A** will be shown for descending. Default entered order will not have any indicator.
Include All Codelist Control Types	Available if Codelist Values and Tables is selected: • **If selected**—The codelist tables include all formats of codelists. • **If not selected**—The codelist tables include only codelists that are formatted as a drop-down list.

Option	What appears in the annotated study book when you select the option
Study Object Description Tables	Tables that list the type (Form, Section, or Item), title or RefName, and description for each form, section, and item. The tables display RefNames if **Show Object RefNames** is selected and titles if **Show Object RefNames** is not selected.
Only Show Properties With Values	Available if **Study Object Description Tables** is selected. If selected, the study object description tables list only study objects that have descriptions. **Note:** If you select All Annotated Information, **Only Show Properties With Values** is not available.
Key Items Tables	Tables that list the following information for items in a repeating form or section that are defined as key items for navigation assistance (repeating forms only) or to enforce data uniqueness: • Item name. • Uniqueness (None, Individual, or Group). • Order in which the items appear in the drop-down summary list of a repeating form. The tables display RefNames if **Show Object RefNames** is selected and titles if **Show Object RefNames** is not selected.
Coding Summary Tables	Tables that list verbatim, dictionary, coding item, and context item data for each item on a form that is coded. The tables display RefNames if **Show Object RefNames** is selected and titles if **Show Object RefNames** is not selected.

Option	What appears in the annotated study book when you select the option
RDE Analytics Tables	Tables that display the titles or RefNames, database table column names, and database types that are generated in the InForm Reporting Database Extract (RDE) Analytics offering for each data entry object in a form. The format of each table column name consists of the RefName of the item or the RefName plus a suffix that depends on the type of item and the format of the data entry control. The special characters **_-()/",+ %@#$&*!~|{}[]<>:;?** are removed from each study object RefName before it is appended with the appropriate suffix. The Data Variable column of the RDE Analytics tables displays RefNames if **Show Object RefNames** is selected and displays titles if **Show Object RefNames** is not selected.
Data Series Summary Tables	Tables that list the following information for each data series that has mappings for items contained in the form: • Item number, based on the order of the item in the form. • Item title or RefName, depending on whether **Show Object RefNames** is selected. • Mapping RefName. • Data set alias if available, otherwise RefName. • Data series alias if available, otherwise RefName. • Data series type.
Library Objects Table	For each form, the table lists the form and the library objects on the form, including: • FormsSections • Items of any type • Codelists • Codelist items

Option	What appears in the annotated study book when you select the option
Dynamic Grid Summary Table	For each form, the table lists relevant information about target items, including: • Target item • Mapped source objects • Mapping type **Note:** Editable items within the dynamic grid will not be displayed in this table.
Display Forms in Workflow Order	• **If selected**—Forms appear in study workflow order, except that: – Forms that occur in more than one study event are not duplicated. – Nonclinical forms (Regulatory Documents and Visit Reports) appear at the end of the listing. • **If not selected**—Forms appear in alphabetical order. **Note:** In the Time and Events Table, forms always appear in workflow order, regardless of the setting of the **Display Forms in Workflow Order** option.
Display Hidden Items	• **If selected**—Hidden items are included. • **If not selected**—Hidden items are not included. If a form contains one or more hidden items, the footer of the table indicates that hidden items on the table are not displayed.

Option	What appears in the annotated study book when you select the option
InForm Special Properties Table	A table that lists the values of the Oracle InForm Special Visit, Special Form, and Special Item properties, along with the property type and the study objects to which the properties are assigned. If a special property has not been assigned to a study object, the table shows the value as Unassigned.
Personal/Protected Health Information Table	A table that lists each item in the study for which the PHI custom property is set to True, along with the section (if the item exists in a section) and form on which the item exists.
Unit Conversions Table	A table that lists the unit type and unit conversion formulas for items that have units and appear in one or more forms.
Review States Table	A table that lists information about the review states defined for the study, along with information about the review stages defined for each review state. If a review state is not activated, only the review state header appears. If translations are missing for one of the product locales but present for the other, the locale for which translations have been defined appears in the table in the place of the other locale. An asterisk and footnote appear for translations that have been replaced in this manner.
In-place Revisions Summary Table	A table that lists the following information about the in-place revisions associated with a deployment instance: • Deployment instance to which the in-place revision applies. • RefName of the in-place revision study object. • Type of the revised study object. • Description of the change. • Study version to which the revision applies. • Path in the study hierarchy where the revised study object appears.
Custom Events Summary Table	Describes the properties for each custom event in the study, and the properties for each trigger and result defined on the custom event.

Option	What appears in the annotated study book when you select the option
Library Objects Table for Non-CRF Objects	For each study, the table lists the RefName, title, and type of each library object in the study other than forms and objects on forms, including: • Study elements • Study events • Data mappings • Data sets • Custom dimension codelists and codelist items • Data series • Constants • Functions • Help • Coding maps • Review states • Custom events
Show Object RefNames	• The annotated study book uses study object RefNames, rather than titles, to identify study objects. The following areas are affected: • The RefName for a form or section is appended to the form or section title that is displayed in the annotated form header. RefNames are enclosed in square brackets. • In annotated forms, items are identified with RefNames. • With the following exceptions, data tables that follow the annotated form use a column header of RefName instead of Title, and the column contains RefNames. – The Time and Events table is not affected by this option. – The Data Series Summary Table always uses RefName to identify mappings and data sets, regardless of whether this option is selected.

Option	What appears in the annotated study book when you select the option
Select Cover Page Options section	• **Include Cover Page**—Cover page with the study design properties selected from the **Display the following in addition to the study title** list, along with the study design title. If you select a user-defined custom property, the property must have a value and be visible, or it does not appear on the cover page. • **Do Not Include Cover Page**—No cover page. **Note:** The values of cover page options are set in the Properties Browser for the study design.
Select Date Variable Format	Format of date time items in the annotated forms.

Properties

In this section:

- CDD data mapping properties
- CIS data mapping properties
- Codelist properties
- Codelist item properties
- Data mapping properties
- Data series standard properties
- Data set properties
- Form and section properties
- Item properties
- Study and library standard properties
- Study design properties
- Study element properties
- Study event properties
- Study project and library project properties
- Properties in the Rule Test Cases dialog box

CDD data mapping properties

Study object	Option	Description
Item	Data Label	User-defined string to use for searching on data in the column. Maximum length is 30 characters. This label is included in the CDD data mapping control path definition in the Oracle InForm database. For CDD data mappings, it also appears in target CDD data mapping tables that have any of the following key types: Patient to Control, Pivot Patient, Pivot Visit, Pivot Form, and Pivot Section.
Data set	Associated Forms	Names of pairs of forms for which associations have been created. Selecting a pair of associated forms results in the generation of CDD data mappings for that association.

Study object	Option	Description
-	Target Key Type	For the following key types, the target key type specifies the composition of the primary key columns of the target table. Each time a component of the primary key changes from the previous primary key submitted, the Oracle InForm application inserts a new row in the target table. Primary keys consist of the following DBUIDs and indexes: • **Patient Only**—PatientID, FormIndex, ItemsetIndex. • **Patient Visit (default)**—PatientID, VisitID, FormIndex, ItemsetIndex, and VisitIndex. • **Patient to Form**—PatientID, VisitID, FormIndex, ItemsetIndex, VisitIndex, and FormID. • **Patient to Section**—PatientID, VisitID, FormIndex, ItemsetIndex, VisitIndex, FormID, and SectionID. • **Patient to Itemset**—PatientID, VisitID, FormIndex, ItemsetIndex, VisitIndex, FormID, SectionID, and ItemsetID. • **Patient to Item**—PatientID, VisitID, FormIndex, ItemsetIndex, VisitIndex, FormID, SectionID, ItemsetID, and ItemID. • **Patient to Control**—PatientID, VisitID, FormIndex, ItemsetIndex, VisitIndex, FormID, SectionID, ItemsetID, ItemID and five ControlIDs. A target table with this key type also contains a data label that can be used for data selection. For the following key types, the primary key columns are PatientID, VisitID, ItemsetIndex, VisitIndex, FormID, SectionID, ItemsetID, ItemID and five ControlIDs. The key type

Study object	Option	Description
		selection determines the composition of a pivot set. Within a pivot set, data points mapped to non-pivot columns are repeated in each row. Target tables with these key types also contain a data label that can be used for data selection. Pivot set keys consist of the following DBUIDs and indexes: • **Pivot Patient**—PatientID and VisitIndex • **Pivot Visit**—PatientID, VisitID, and VisitIndex • **Pivot Form**—PatientID, VisitID, FormID, and VisitIndex • **Pivot Section**—PatientID, VisitID, FormID, SectionID, and VisitIndex

Study object	Option	Description
Data series	Pivot Column	Identifies the column to use as the pivot column, if the key type is Pivot Form, Pivot Patient, Pivot Section, or Pivot Visit.

Note:

Only one column can be the pivot column, and it mu

Study object	Option	Description
		s t b e t h e fi r s t c o l u m n i n t h e t a b l e .
-	Target Column Max Length	Maximum length of a column, in the range 1-255. This property is applicable for columns with a type of STRING.

CIS data mapping properties

Use the following custom properties for CIS data mappings to specify how the data that is passed from the Oracle InForm application should be used in the Clintrial application. The custom properties have default values or are required only when you want to support specific Clintrial features, such as master-detail panel relationships.

Study object	Option	Description
Study event	Block Key Value	Value of the Clintrial block key. If you specify this value, it overrides the study event RefName as the block key.
Form	Page Key Value	Value of the Clintrial page key. If you specify this value, it overrides the form RefName as the page key.

Study object	Option	Description
Data set	Detail Key Item	Name of the item identified as the detail key item, if the panel definition is part of a detail page section.
-	Detail Panel	True or False (default), indicating whether the panel definition participates in a detail page section in a master-detail relationship. A master-detail relationship is a relationship between two page sections on a study page, in which each record in one page section (the master page section) can have one or more associated records in the other section (the detail page section). During data entry the displayed records in the detail page section are associated with the selected record in the master page section.
-	Master Item	Name of the item on the master panel that corresponds to the detail key item specified in the Detail Key Item property. This property applies only if the value of the Detail Panel property is True.
-	Master Panel	Name of the master panel with which this panel definition participates in a master-detail relationship. This property applies only if the value of the Detail Panel property is True.

Study object	Option	Description
-	Panel Type	A specification of how the database tables associated with the panel are structured: • **Panel Type 1**—One record per subject, collected once during the study. • **Panel Type 2**—Multiple records for each subject, collected once during the study. • **Panel Type 3**—One record per subject, collected at multiple visits. • **Panel Type 4 (default)**—Multiple records for each subject, collected at multiple visits. • **Context Panel**—One record containing custom context items that are associated with each record in a clinical data table. Use this type to specify a custom context panel. • **Enrollment Panel**—One record of enrollment data for each enrolled subject. • **Non-Patient Data**—Data not related to a study subject, for example, lab normals or standard coding thesauruses.
-	Protected	True or False (default), indicating whether access rights to the panel are limited in the Clintrial application.
-	SAS Name	Name of the panel when data is sent to SAS through the Clintrial SAS interface. OPTIONAL; if entered, the name must be 8 characters or fewer and conform to SAS naming requirements. **Note:** Panel SAS names must be unique within a protocol.
-	Verifiable	True or False (default), indicating whether double-entry of data in panel items is required for verification.

Study object	Option	Description
Data series	Checklist	Name of a Clintrial checklist associated with the item. A checklist is a type of codelist used to view suggested entries for a field. The checklist name must be 20 characters or fewer. Checklist and CIS Codelist are mutually exclusive properties.
-	CIS Codelist	Name of a Clintrial codelist associated with the item. A codelist encodes entered values. The codelist name must be 20 characters or fewer. Checklist and CIS Codelist are mutually exclusive properties. **Note:** When CIS synchronization processes data mappings and autogenerates codelists, it does *not* autogenerate codelists for items that have a value in the Code List property. The CIS Codelist property refers to an existing codelist. Therefore, if you want CIS to autogenerate a codelist for an item, leave the Code List property blank.

Study object	Option	Description
-	Context Type	Specifies the usage of a user-defined context item: • Not a context item (default). • Subject-related context item. • Visit-related context item. • Page-related context item. • Other context item. **Note:** Data series with a Context Type of Other context item are designed to be used in hybrid studies in which users can enter data using either the Clintrial or the Oracle InForm application. When you deploy a study that contains a data series with a Context type property of Other context item, the item definition for that data series is created in the Clintrial context panel, but the CIS application does not synchronize data from the Oracle InForm application to that context item. To enter data into a context panel item that is defined using the Other context item Context type property, users must use the Clintrial Enter module.
-	Copy With Panel	True (default) or False, indicating whether the item should be included with the panel if the panel is copied.
-	DB Format Float Precision	Number of characters that can be added after the decimal place in an item with a type of FLOAT. This value can be a number between 1 and 15. The default is 10.
-	DB Format Length	Number of characters that can be entered in this item. The default is 2000 for text items, 18 for numeric items.
-	Derived	True or False (default), indicating whether the value of the item is determined from a derivation associated with the panel.

Study object	Option	Description
-	Is Key	True or False (default), indicating whether the item mapped to the data series is a subject key, block key, block repeat key, page key, or page repeat key item in the context panel.
-	Item Required	True or False (default), indicating whether the item is required.
-	Key Order	The order in which the item appears in the concatenation of key items, if the item is part of the panel's key. 0 (not a key item) is the default.
-	Max	Maximum value that can be entered for the value of the item.
-	Min	Minimum value that can be entered for the value of the item.
-	Repeated	True or False (default), indicating whether an item is one for which multiple values can be entered within a page section.
-	SAS Name	(Optional) Name of the item when data is sent to SAS through the Clintrial SAS interface. If entered, the name must be eight characters or fewer and conform to SAS naming requirements. **Note:** Item SAS names must be unique within a panel.

Codelist properties

Property	Description
Description	Description of the study object. The description can have 0-255 characters.
Identifier	Unique internal identifier of the study object.
Locked	When True, the study object is locked.
Modified	When True, the study object has not been saved since the last modification.
New	When True, the study object has not been saved yet. When False, the study object has been saved at least one time.

Property	Description
Protected	When true, the study object is protected. When a study object is protected, you cannot: • Update or lock it. • Add child study objects to it by pasting or dragging and dropping. • Delete its child study objects.
RefName	RefName of the study object. The RefName can have 1-63 characters.
Revision	Revision number of the study object.
Title	Title of the study object. The title can have 1-63 characters.
Version	Version number of the study object. The version number is incremented only when a user explicitly updates it.
CodeListType	Type of codelist; integer, float, or text.

Codelist item properties

Properties common to all study objects

All study objects have the following properties.

Property	Description
Description	Description of the study object. The description can have 0-255 characters.
Identifier	Unique internal identifier of the study object.
Locked	When True, the study object is locked.
Modified	When True, the study object has not been saved since the last modification.
New	When True, the study object has not been saved yet. When False, the study object has been saved at least one time.
Protected	When true, the study object is protected. When a study object is protected, you cannot: • Update or lock it. • Add child study objects to it by pasting or dragging and dropping. • Delete its child study objects.
RefName	RefName of the study object. The RefName can have 1-63 characters.
Revision	Revision number of the study object.
Title	Title of the study object. The title can have 1-63 characters.
Version	Version number of the study object. The version number is incremented only when a user explicitly updates it.

Properties related to Oracle InForm.

Property	Description
Study Completion Status Items	Codelist items in the codelist for the Completion Status item on the Study Completion form, which is used in reporting in the Oracle InForm application to determine whether a subject dropped out of a study. Options include: • **None**—(default) The codelist item is not part of the codelist for the Completion Status item. • **Complete Study (Study Completion)**—Indicates that the subject has completed the study. • **Incomplete Study (Study Completion)**—Indicates that the subject has not completed the study.

Properties related to the standard codelist

Properties	Description
Code	Code of the codelist item.
CodeListType	Type of codelist; integer, float, or text. The value of this property is populated with the value for the CodeListType property of the codelist parent of the codelist item. READ-ONLY
Label	Label of the codelist item.

Data mapping properties

Property	Description
Description	Description of the study object. The description can have 0-255 characters.
Identifier	Unique internal identifier of the study object.
Locked	When True, the study object is locked.
Modified	When True, the study object has not been saved since the last modification.
New	When True, the study object has not been saved yet. When False, the study object has been saved at least one time.
RefName	RefName of the study object. The RefName can have 1-63 characters.
Revision	Version or revision number of the study object.
Title	Title of the study object. The title can have 1-63 characters.

Data series standard properties

Property	Description
Alias	Alias for the data series.
Classification	Type of the data series: • Integer • Float • Boolean • Text Date • Time
Description	Description of the study object. The description can have 0-255 characters.
Identifier	Unique internal identifier of the study object.
Locked	When True, the study object is locked.
Modified	When True, the study object has not been saved since the last modification.
New	When True, the study object has not been saved yet. When False, the study object has been saved at least one time.
RefName	RefName of the study object. The RefName can have 1-63 characters.
Revision	Version or revision number of the study object.
Title	Title of the study object. The title can have 1-63 characters.

Data set properties

Property	Description
Description	Description of the study object. The description can have 0-255 characters.
Identifier	Unique internal identifier of the study object.
Locked	When True, the study object is locked.
Modified	When True, the study object has not been saved since the last modification.
New	When True, the study object has not been saved yet. When False, the study object has been saved at least one time.
RefName	RefName of the study object. The RefName can have 1-63 characters.
Revision	Version or revision number of the study object.
Title	Title of the study object. The title can have 1-63 characters.

Form and section properties

Properties common to all study objects

All study objects have the following properties.

Property	Description
Description	Description of the study object. The description can have 0-255 characters.
Identifier	Unique internal identifier of the study object.
Locked	When True, the study object is locked.
Modified	When True, the study object has not been saved since the last modification.
New	When True, the study object has not been saved yet. When False, the study object has been saved at least one time.
Protected	When true, the study object is protected. When a study object is protected, you cannot: • Update or lock it. • Add child study objects to it by pasting or dragging and dropping. • Delete its child study objects.
RefName	RefName of the study object. The RefName can have 1-63 characters.
Revision	Revision number of the study object.
Title	Title of the study object. The title can have 1-63 characters.
Version	Version number of the study object. The version number is incremented only when a user explicitly updates it.

Form and Section properties

Property	Description
CIS properties	-
Page Key Value	Value of the Clintrial page key, used for transferring data to the Clintrial application through CIS mappings. If you specify the Page Key Value, it overrides the form RefName as the page key.
Oracle InForm properties	-
Item Required	True (default) or False, indicating whether the item is required.
SDV Required	**True** (default) or **False**, indicating whether the item requires source document verification.
SDV Critical	**True** or **False** (default), indicating whether the item is considered critical for source verification. If you select **True**, SDV Required changes to True.

Property	Description
Special Forms	Type of special Oracle InForm field, or None, indicating that the item is not a special Oracle InForm field. Available special fields, along with the forms in which they appear, are: • Initials (Screening). • DOB (Screening). • Screening date (Screening). • Patient No. (Enrollment). • Initials (Patient Identification. • Completion status (Study Completion). • Drop-out reason (Study Completion). • DOV (Date of Visit). • Randomization field (Randomization).
Standard properties	-
AssociatedForm	Indicates whether the form is an associated form. • **None**—Form is not an associated form. • **[Form name]**—Name of the form with which the form is associated.
Common	When True, the form is a common form. **Note:** Do not change this setting for a form that was already deployed. Instead, to avoid potential negative downstream impact, create a new form with the updated setting.
Fixed	For sections only. When True (used for repeating sections), the section contains items that are deployed as a Repeating Data itemset.

Property	Description
Repeating	When True, the study object is repeating. **Note:** Do not change this setting for a form that was already deployed. Instead, to avoid potential negative downstream impact, create a new form with the updated setting.
Short Title	Short title of the form, used as a mnemonic when deployed.

Item properties

Properties common to all study objects

All study objects have the following properties.

Property	Description
Description	Description of the study object. The description can have 0-255 characters.
Identifier	Unique internal identifier of the study object.
Locked	When True, the study object is locked.
Modified	When True, the study object has not been saved since the last modification.
New	When True, the study object has not been saved yet. When False, the study object has been saved at least one time.
Protected	When true, the study object is protected. When a study object is protected, you cannot: • Update or lock it. • Add child study objects to it by pasting or dragging and dropping. • Delete its child study objects.
RefName	RefName of the study object. The RefName can have 1-63 characters.
Revision	Revision number of the study object.
Title	Title of the study object. The title can have 1-63 characters.
Version	Version number of the study object. The version number is incremented only when a user explicitly updates it.

Item properties

Property	Description
CDD properties	-
Data Label	Text label for the item, enabling access to the item in a target table with the Patient To Control key type or any of the pivot key types.
Component Settings	(The following settings are used only for date time items.)
DayAllow, HourAllow, MinuteAllow, MonthAllow, SecondAllow, YearAllow	When True, indicates that the date time item includes a control for the component of the date time.
DayAllowUnknown, HourAllowUnknown, MinuteAllowUnknown, MonthAllowUnknown, SecondAllowUnknown, YearAllowUnknown	When True, indicates that the date time item includes a control for the component of the date time and allows a user to mark the value unknown.
DayRequired, HourRequired, MinuteRequired, MonthRequired, SecondRequired, YearRequired	When true, indicates that the component of the date time item is required.
Oracle InForm properties	-
Collapsible	**True** or **False** (default), indicating whether the item is always visible on the form in the InForm application, or is collapsed and not visible until a condition is met.
Display Override	Determines the default behavior of an item when a layout is generated. • **ReadOnly**—The item is visible but not editable. • **Editable**—The item is visible and editable by any user, regardless of the rights assigned to the user. • **Hidden**—The item is not visible. • **None**—The item is visible to all users, and visible and editable by any user who has the rights to view and/or edit the item.
Item Required	**True** (default) or **False**, indicating whether the item is required for data entry on the form to be complete.
MaxProperty	If a MaxValue is specified for the item, indicates whether the value can be less than or less than or equal to the MaxValue.

Property	Description
MaxValue	Maximum value that the Oracle InForm application will allow to be typed for the item.
MinProperty	If a MinValue is specified for the item, indicates whether the value can be greater than or greater than or equal to the MinValue.
MinValue	Minimum value that the Oracle InForm application will allow to be typed for the item.
PHI	**True** or **False** (default), indicating whether an Oracle InForm user might enter Personal/ Protected Health Information (PHI) for the item. If you select True:
SDV Critical	**True** or **False** (default), indicating whether the item is considered critical for source verification. If you select True, SDV Required changes to True. **Note:** The SDV Critical setting for an item can be overridden in the Oracle InForm application.
SDV Required	**True** (default) or **False**, indicating whether the item requires source document verification.
Special Fields	Fields used on the special forms for the Oracle InForm application. • **None**—Field is not a special Oracle InForm field. • **Screening form**: – Initials – DOB – Screening date • **Enrollment form**: Patient No. • **Patient Identification form**: Initials • **Study Completion form**: – Completion status – Drop out reason • **Date of Visit form**: DOV • **Randomization form**: Randomization field
Standard properties	-
Question	Question for the item. The question can have 0-1000 characters.
ShortQuestion	Short question for the item. The short question can have 0-255 characters.
Miscellaneous properties	-

Property	Description
Change assigned codelist	Available only in libraries. **True** or **False** (default), allow users to choose a different codelist for the item in a study. If set to **True**, Change assigned subset is also set to **True**.
Change assigned subset	Available only in libraries. **True** or **False** (default), allow users to choose a different codelist subset for the item in a study. If set to **False**, Change assigned codelist is also set to **False**.

Study and library standard properties

Property	Description
Enabled	For libraries only. Indicates whether the library is enabled or disabled.
Description	Description of the study object. The description can have 0-255 characters.
Identifier	Unique internal identifier of the study object.
Locked	When True, the study object is locked.
Modified	When True, the study object has not been saved since the last modification.
New	When True, the study object has not been saved yet. When False, the study object has been saved at least one time.
Protected	True or False, indicating whether the study or library is protected.
Title	Title of the study object. The title can have 1-63 characters.
Version	Study or library version.

Study design properties

Properties common to all study objects

All study objects have the following properties.

Property	Description
Description	Description of the study object. The description can have 0-255 characters.
Identifier	Unique internal identifier of the study object.
Locked	When True, the study object is locked.
Modified	When True, the study object has not been saved since the last modification.
New	When True, the study object has not been saved yet. When False, the study object has been saved at least one time.

Property	Description
Protected	When true, the study object is protected. When a study object is protected, you cannot: • Update or lock it. • Add child study objects to it by pasting or dragging and dropping. • Delete its child study objects.
RefName	RefName of the study object. The RefName can have 1-63 characters.
Revision	Revision number of the study object.
Title	Title of the study object. The title can have 1-63 characters.
Version	Version number of the study object. The version number is incremented only when a user explicitly updates it.

Study Design properties

Property	Description
Oracle InForm properties	-
Shared Form Block Key	Block key to use for a shared form; used for data transfers to the Clintrial application through CIS mappings. You must use this property if the block key in the Clintrial application is defined as a numeric field. The block key that you specify overrides the internal text block key (CommonCRF) that the Oracle Central Designer application creates during deployment from the system RefName of the special visit for shared forms.
Standard properties	-
Generic Drug Name	Generic name for a drug.
Protocol	Name of the study protocol.
Sponsor	Name of the sponsor of the study.
Sponsor Date	Date specified by the sponsor of the study.
Sponsor Drug Name	Code name given to a drug by a sponsor.
Study Name	Name of the study.
Trade Drug Name	Commercial name of a drug.

Study element properties

All study objects have the following properties.

Property	Description
Description	Description of the study object. The description can have 0-255 characters.
Identifier	Unique internal identifier of the study object.
Locked	When True, the study object is locked.

Property	Description
Modified	When True, the study object has not been saved since the last modification.
New	When True, the study object has not been saved yet. When False, the study object has been saved at least one time.
Protected	When true, the study object is protected. When a study object is protected, you cannot: • Update or lock it. • Add child study objects to it by pasting or dragging and dropping. • Delete its child study objects.
RefName	RefName of the study object. The RefName can have 1-63 characters.
Revision	Revision number of the study object.
Title	Title of the study object. The title can have 1-63 characters.
Version	Version number of the study object. The version number is incremented only when a user explicitly updates it.

Study event properties

Properties common to all study objects

All study objects have the following properties.

Property	Description
Description	Description of the study object. The description can have 0-255 characters.
Identifier	Unique internal identifier of the study object.
Locked	When True, the study object is locked.
Modified	When True, the study object has not been saved since the last modification.
New	When True, the study object has not been saved yet. When False, the study object has been saved at least one time.
Protected	When true, the study object is protected. When a study object is protected, you cannot: • Update or lock it. • Add child study objects to it by pasting or dragging and dropping. • Delete its child study objects.
RefName	RefName of the study object. The RefName can have 1-63 characters.
Revision	Revision number of the study object.
Title	Title of the study object. The title can have 1-63 characters.
Version	Version number of the study object. The version number is incremented only when a user explicitly updates it.

Study Event properties

Property	Description
CIS	-
Block Key Value	Value of the Clintrial block key, used for data transfer to the Clintrial application through CIS mappings. If you specify this value, it overrides the visit RefName as the block key.
Oracle InForm	-
Optional	True or False (default), indicating whether the formset (visit) is optional or required.
Special Visits	When a special visit type is selected, the study event is deployed as a special Oracle InForm visit.
Standard properties	-
Repeating	When True, the study object is repeating.
Short Title	Short title of the study event. The short title deploys to the Oracle InForm application as the visit mnemonic. The short title can have 1-63 characters.

Study project and library project properties

Property	Description
Description	Description of the study object. The description can have 0-255 characters.
Locked	When True, the study object is locked.
Modified	When True, the study object has not been saved since the most recent modification.
Name	Name of the study object.
New	When True, the study object has not been saved yet. When False, the study object has been saved at least one time.
Title	Title of the study object. The title can have 1-63 characters.

Properties in the Rule Test Cases dialog box

The following properties appear in the Test Properties tab, which you can select in the Design tab of the Rule Test Cases dialog box.

When you point to a component of a test case, its properties appear.

Property	Description
Properties for test names	-
Ignore test	When False, the test case is run. When True, the test case is not run.
Rule name	Name of the rule or global condition.
Rule type	Type of rule (data-entry rule, global condition, or workflow rule).

Property	Description
Properties for item names—Item Settings grouping	**Note:** If the item is repeating, the grouping is called Repeating Item Settings. **Note:** Not all properties are available for all types of items.
Codelist choices	Indicates the type of the codelist. Expand the property to view the code and label for each codelist item in the right column. **Note:** The numbers in the left column are for ordering purposes only and do not necessarily correspond to the codes for the codelist items. **Note:** If a codelist subset is selected for the codelist instance, only the codelist items in the selected subset appear.
Codelist type	The type of codelist on the item, such as float or integer.
Float length	Length of the float item.
Float precision	Precision of the float item.
Item object path	Path of the item in the context of the rule scope.

Property	Description
Object RefName	RefName of the item. **Note:** Oracle recommends that you do not update the Object RefName.
Object Title	Title of the item.
Repeating objects	List of repeating study objects that are in the item's path, including the type of study object (such as form or section).
Properties for item names—Test Settings grouping	-
Ignore test	When False, the test case is run. When True, the test case is not run.
Properties for expected results—Repeating Objects grouping	-
Repeating Form Index Repeating Section Index Repeating Event Index	Properties appear in this section when an item path contains a repeating study object. For example, if the only repeating study object in the item path is a section, only Repeating Section Index appears. The number of the repeating instance that you are testing.
Properties for expected results—Test Settings grouping	-
Ignore test	When False, the test case is run. When True, the test case is not run. Default: False.
Item object path	Path of the item in the context of the rule scope.
Rule action type	• Data-entry rules—Value, Query, or Email. • Global conditions—Condition. • Workflow rules—NextStep.
Rule name	Name of the rule or global condition.
Rule type	Type of rule (data-entry rule, global condition, or workflow rule).