

Oracle Life Sciences InForm

Reporting and Analysis Guide



Release 7.0.1
F56797-01
September 2024



Oracle Life Sciences InForm Reporting and Analysis Guide, Release 7.0.1

F56797-01

Copyright © 2019, 2024, Oracle and/or its affiliates.

Contents

1 Prerequisites

Configure your computer settings	1-1
Browser settings for Microsoft Edge	1-1
Browser settings for Mozilla Firefox	1-2
Windows Explorer settings	1-2
Access Cognos	1-2
Learn about Cognos	1-3
Element descriptions	1-3

2 Cognos Reporting reports

About Cognos Reporting	2-1
Converting Query Studio reports to Cognos Reporting reports	2-2
Tips for creating Cognos Reporting reports	2-2
Tips for creating reports that contain...	2-2
An indicator that a study object is deleted	2-2
Both clinical and study management data	2-3
Code values and text values	2-3
Columns that you can reuse in all of your studies	2-3
Counts from clinical visits, rather than all visits	2-3
Data from associated forms	2-3
Data from forms with itemsets	2-4
Data from multiple versions of the same study object	2-5
Data from repeating objects	2-5
Empty and duplicate data	2-6
Simple, meaningful data	2-6
Unit data for a study object	2-6
Tips for deciding what to include in a report	2-7
Use lineage information to identify report elements	2-7
Use naming conventions to decide what to add to your report	2-7
Cognos Reporting report elements	2-12
Study Info report elements	2-13
Study Info: Sponsor	2-13
Study Info: Study	2-15

Study Info: Study Versions	2-16
Sites report elements	2-17
Sites	2-17
Subject report elements	2-20
Subjects	2-21
Subjects: Subject Status (text)	2-22
Subjects: Subject Status Counts	2-24
Subjects: CRB Status Counts	2-29
Subjects: Subject Status Dates	2-30
Subjects: Subject Status by Month and Year	2-32
Visit report elements	2-33
Visits	2-34
Visits: Visit Properties	2-34
Visits: Visit Counts by Property	2-36
Visits: Visit Status Counts	2-37
Visits: Visit Dates	2-39
Forms report elements	2-40
Form elements and expected forms	2-41
Forms	2-42
Forms: Properties	2-43
Forms: Form Counts by Property	2-45
Forms: Form Status Counts	2-48
Forms: Review States	2-55
Forms: Review States Counts	2-55
Forms: Form Dates	2-56
Forms: Form Status by Month and Year	2-61
Forms: Aging	2-62
Forms: Cycle Times	2-63
Section report elements	2-69
Sections	2-70
Sections: Properties	2-70
Item report elements	2-70
Items	2-71
Items: Item Properties	2-72
Items: Item Counts by Property	2-74
Items: Item Status Counts	2-76
Items: Item Dates	2-77
Rule report elements	2-78
Rules	2-78
Query report elements	2-79
Queries	2-80
Queries: Properties	2-81

Queries: Query Counts	2-82
Queries: Query Dates	2-84
Queries: Query Status by Month, Year	2-85
Queries: Cycle Times	2-86
Queries: Aging	2-87
Comment report elements	2-88
Comments	2-88
User Info report elements	2-89
User Info: Users	2-89
User Info: Group Associations	2-91
User Info: Historical User Info	2-92
Predefined filters	2-94
Filters	2-94
Examples: Reporting on multi-instance forms and items	2-96
Example 1: One non-repeating section and one itemset	2-96
Example 2: Incomplete non-repeating section and one itemset	2-96
Example 3: Incomplete non-repeating section, one itemset, and an additional form	2-97
Example 4: One non-repeating section with multiple itemsets	2-98
Example 5: Incomplete non-repeating section with multiple itemsets	2-99

3 Oracle InForm standard reports

About standard reports	3-1
Tips for running standard reports	3-1
Select the correct standard report formats	3-1
Save large reports and run them locally	3-2
Choose a clear naming convention for saved reports	3-2
Save reports to the Team content folder sparingly	3-2
Standard report column descriptions	3-2
Audit Trail Reports	3-2
Historical Oracle InForm Access Report	3-2
Case Report Form (CRF) Reports	3-3
CRF Aging by Site	3-4
CRF Cycle Time Detail by Site	3-7
CRF Cycle Time Detail for a Site	3-13
CRF Frozen Status	3-19
CRF Signature Status Report	3-21
CRF Site Performance Summary by Site	3-23
CRF Status Detail by Site and Subject	3-29
CRF Status Detail by Visit and Site	3-36
CRF Status Summary by Site	3-42
CRF Status Summary by User	3-47

Item Reports	3-52
CRF Item Listing	3-52
Source Verification Listing	3-57
Query Reports	3-61
Outstanding Queries by Site and Visit	3-62
Query Aging by Site	3-64
Query Cycle Times by Site	3-66
Query Cycle Times by User	3-69
Query Performance Summary by Site	3-72
Query Performance Summary by User	3-76
Query Status by Site	3-80
Query Status by Site and Subject	3-83
Query Status by Site and Visit	3-86
Query Status by User	3-89
Query Volume by Month by Site	3-92
Query Volume by Rule	3-94
Subject Counts with Outstanding Queries	3-95
Study Administration Reports	3-97
Site Study Version History Report	3-97
Rights Group History Report	3-98
Subject Reports	3-99
Case Book Completion and Query Summary by Site	3-100
Cumulative Subject Enrollment by Month	3-103
Subject Dropout Count by Reason	3-105
Subject Enrollment Status by Site	3-106

4 FAQs

General reporting FAQs	4-1
Cognos Reporting report FAQs	4-2
Standard report FAQs	4-3

5 What if...

My report contains empty cells	5-1
My report contains N/A in some cells	5-2
My report contains extra rows with incomplete information	5-2
My standard report is missing data in a column	5-2
Cycle time columns show negative values	5-2
I can't see any clinical data	5-2
I accidentally closed or logged out of Oracle InForm	5-3
I accidentally logged out of Cognos	5-3

I am locked out of Oracle InForm or my session times out	5-3
A Cognos Reporting report element name has a suffix like ~1	5-3
I can't see date time information in my report	5-3
I can't see subject status information	5-3

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>.

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.

Related resources

All documentation and other supporting materials are available on the [Oracle Help Center](#).

Access to Oracle Support

Oracle customers that have purchased support have access to electronic support through Oracle Support Cloud.

Contact our Oracle Customer Support Services team by logging requests in one of the following locations:

- English interface Customer Support Portal (<https://hsgbu.custhelp.com/>)
- Japanese interface Customer Support Portal (<https://hsgbu-jp.custhelp.com/>)

You can also call our 24x7 help desk. For information, visit <https://www.oracle.com/life-sciences/support/> or visit <https://www.oracle.com/corporate/accessibility/learning-support.html#support-tab> if you are hearing impaired.

Additional copyright information

This documentation is for internal-use only.

This documentation may include references to materials, offerings, or products that were previously offered by Phase Forward Inc. Certain materials, offerings, services, or products may no longer be offered or provided. Oracle and its affiliates cannot be held responsible for any such references should they appear in the text provided.

1

Prerequisites

In this chapter:

- [Configure your computer settings](#)
- [Access Cognos](#)
- [Learn about Cognos](#)
- [Element descriptions](#)

Configure your computer settings

In this section:

- [Browser settings for Microsoft Edge](#)
- [Browser settings for Mozilla Firefox](#)
- [Windows Explorer settings](#)

Browser settings for Microsoft Edge

Configure the following browser settings to access Oracle InForm and Cognos.

- Specify the preferred browser language.
- To view reports in Microsoft Excel format:
 - Set the Oracle InForm website domain and the reporting website domain as trusted sites.
 - Enable automatic prompting for file downloads.
 - Enable notifications when downloads complete.
- Configure pop-up blocking to allow pop-ups for the InForm website domain and the reporting website domain.
- Prevent automatic password completion.
- Specify that you want to save encrypted files to disk.
- Automatically check for newer versions of stored pages.
- Set the amount of disk space to use to 6 MB.
- Set the HTTP and TLS options to use HTTP 1.1 and TLS 1.2.
- Disable the SSL settings.
- Enable printing background colors and images for graphics.
- Modify security settings:
 - Allow Cookies
 - Enable Active Scripting
 - Allow META REFRESH

- Run ActiveX controls and plug-ins
 - Mark Script ActiveX controls safe for scripting
 - Enable Binary and script behaviors
 - Allow programmatic clipboard access
 - Enable User data persistence.
 - If you are using Chromium Edge, enable this browser settings:
 - Allow local data (cookies) to be set
 - Show all images
 - Allow all sites to run JavaScript
 - Set up tabbed browsing to launch links in a new tab.
 - Disable the option Display intranet sites in Compatibility View.
 - Disable the option Automatically detect intranet network
- For more information, see the Microsoft Edge documentation.

Browser settings for Mozilla Firefox

Configure the following Firefox settings to access Oracle InForm and Cognos.

- Specify the preferred browser language.
- Configure pop-up blocking to allow pop-ups for the Oracle InForm website domain and the reporting website domain.
- Prevent Firefox from using stored passwords.
- Set the security protocol option to use TLS 1.2 or higher.
- Modify security settings:
 - Allow Cookies
 - Enable Java
 - Enable JavaScript
 - Load Images.
- Set up tabbed browsing to launch links in a new tab.

For more information, see the Mozilla Firefox documentation.

Windows Explorer settings

Configure the following Windows Explorer settings to access Oracle InForm and Cognos.

- Make sure the files with the XLS and XLSX extensions are not set to Browse in the same window.
- Associate files with the XLS and XLSX extensions with the Microsoft Excel spreadsheet software.

Access Cognos


1. Log in to Oracle InForm using Microsoft Edge, Mozilla Firefox or Google Chrome.

2. Click **Reports**.
3. If you want to run a standard report, on the left, select **Team content**, and select the folder where the standard reports are stored.

Or, if you want to create a report using Cognos Reporting, on the left click **New**, and click **Report**.

Learn about Cognos

Reporting capability for Oracle InForm is provided by Cognos. To learn more about Cognos:

1. Log in to Oracle InForm.
2. Click Oracle InForm.
3. To open the Cognos documentation, in the top right of the Cognos user interface, click **Help** ()

Element descriptions

The description of each element in this document might include the following:

- **Data displayed**—The type of data that is returned in the report. Possible values are:
 - Numeric
 - String (text)
 - Date/Time
 - Y/N
- **Description**—A brief description of the element.
- **How calculated**—Information about how data is calculated. (Included only for counts.)
- **Data source**—A description of where the data came from.

Data source	Description
Replicated from the Oracle InForm Transactional database to the Reporting and Analysis database (not a derived value).	This data resides in both the Oracle InForm Transactional database and in the Reporting and Analysis database.
Replicated from the Oracle InForm Transactional database to the Reporting and Analysis database. Database value has been decoded for display.	This data resides in both the Oracle InForm Transactional database and in the Reporting and Analysis database. The value has been derived for display. For example, a Y/N value that displays in a report may be stored as a 0/1 value in the database.
Derived by the workspace. Not stored in the Reporting and Analysis database.	This data is derived when you run a report. The data does not appear in any Oracle InForm database.
Derived and stored in the Reporting and Analysis database.	This data is derived by the Cognos Reporting workspace and resides only in the Reporting and Analysis database.

- **Date type**—A description of the type of date displayed. (Included only for dates.)

Date type	Description
System date (GMT).	A date recorded by the Oracle InForm application at data entry. All Oracle production servers are set to GMT time.
System date and time (GMT).	A date and time recorded by the Oracle InForm application at data entry.
System date (GMT), derived for display.	A date recorded by the Oracle InForm application, but derived for display. For example, the Form Status by Month, Year report element returns only the Month and Year portion of the date.
Reporting and Analysis database system date and time.	A system date on the Reporting and Analysis database server.
Clinical.	A date entered by an Oracle InForm user in local time.
Specified in study design code.	A date specified in the study MedML.
May be specified in study design code. If not, this is a system date.	A date that may be specified in the study MedML. If it is not, the date is a date recorded by the InForm application at data entry.

- **Example**—An example to help illustrate a calculation or concept.

2

Cognos Reporting reports

In this chapter:

- [About Cognos Reporting](#)
- [Converting Query Studio reports to Cognos Reporting reports](#)
- [Tips for creating Cognos Reporting reports](#)
- [Cognos Reporting report elements](#)
- [Item report elements](#)
- [Rule report elements](#)
- [Query report elements](#)
- [Comment report elements](#)
- [User Info report elements](#)
- [Predefined filters](#)
- [Examples: Reporting on multi-instance forms and items](#)

About Cognos Reporting

In Cognos Analytics 11, IBM re-named some components of functionality as compared to previous Cognos releases. The notable change in semantics for InForm usage of Cognos is that the IBM Cognos Feature historically referenced as 'Reports Studio' is now known as simply **Reporting** in Cognos 11 and onwards.

While Cognos 11 is used for prior Oracle InForm releases, product documentation for these earlier Oracle InForm versions remained unchanged and does not reflect these recent IBM terminology changes. As we introduced a Cognos feature access change to the Oracle InForm Reporting Group Ad Hoc users group in Oracle InForm 7.0, the associated documentation for this release was also updated to reflect the new IBM terminology. References to Reports Studio have been updated to 'Cognos Reporting' to reflect this.

Reports created with Query Studio still function and are editable even after the revocation of Query Studio access simply by converting these reports to Cognos Reporting. For more information, see [Converting Query Studio reports to Cognos Reporting reports](#).



Note:

If you need a detailed overview of the changes made from 'Report Studio' and 'Query Studio' to the new Cognos Reporting interface, see [IBM's website](#).

The Cognos Reporting workspace provides the flexibility to quickly create different types of reports:

- **List**—Data details in columns and rows.
- **Crosstab**—Summary data in columns and rows.

- **Chart**—Summary data using graphical presentations, such as pie charts and bar charts.

You create ad hoc reports on both clinical and study management data using the Cognos Reporting workspace, which is powered by the Cognos Reporting application. Ad hoc reports allow limited use of Cognos features such as data output styles, report layout and formatting, summarizations and aggregations, mathematical functions, and prompts.

Converting Query Studio reports to Cognos Reporting reports

Query Studio reports can still be run in the new Cognos Reporting interface simply by converting them to the new format.

To edit an existing Query Studio report to Cognos Reporting report:

1. Go to **My content** in the Cognos Reporting interface.
2. Select the Query Studio report you want to convert and right-click on it.
3. Select **Convert to report**.
4. Save the converted report in this new format.

Tips for creating Cognos Reporting reports

In this section:

- [Tips for creating reports that contain...](#)
- [Tips for deciding what to include in a report](#)

Tips for creating reports that contain...

In this section:

- [An indicator that a study object is deleted](#)
- [Both clinical and study management data](#)
- [Code values and text values](#)
- [Columns that you can reuse in all of your studies](#)
- [Counts from clinical visits, rather than all visits](#)
- [Data from associated forms](#)
- [Data from forms with itemsets](#)
- [Data from multiple versions of the same study object](#)
- [Data from repeating objects](#)
- [Empty and duplicate data](#)
- [Simple, meaningful data](#)
- [Unit data for a study object](#)

An indicator that a study object is deleted

By default, Cognos Reporting reports include data from deleted study objects. To indicate that a form, visit, subject and so forth is deleted, add the **Is Deleted** report element from the study object's Properties folder to the report.

Both clinical and study management data

If you create reports with clinical data and study management data, keep the following in mind:

- You can include data from only one clinical form.
- Do not use elements from the following study management report topics in reports that also contain clinical elements:
 - Sections
 - Items
 - Rules
 - Queries
 - Comments

Report results will be difficult to interpret if you include these report elements.

- For best results, include only one element from the study-specific clinical data model with no more than two elements from the Trial Management data model for each report that includes both clinical and study management data.



Note:

This suggestion does not apply to DOV elements.

Code values and text values

Some clinical data is represented both by a text value and a code in the Reporting and Analysis database. For example, a Yes answer to a question on a form is stored both as Yes and as 1 in the database.

To include a text value for your clinical data, include the report element from the Basic Data folder. To include the code value for your clinical data, include the report element from the Additional Data folder.

Columns that you can reuse in all of your studies

If you want to create a report that you can run for all of your studies, use only study management query elements and topics, which appear in the **<study name> InForm Trial Management** section of the tree. Since every study contains the same set of study management query elements and topics, you can reuse the report and run it against any study.

Counts from clinical visits, rather than all visits

Use a predefined filter to limit counts to clinical visits only. By default, all visit types are included in general visit counts for Cognos Reporting reports. Adding a predefined filter allows you to limit your reports to clinical visit counts only.

Data from associated forms

Use the report data in the Clinical Data by Associated Form package to create a Cognos Reporting report with associated form data.

You can create a Cognos Reporting report to show the relationship between data on two associated forms. For example, a report can accurately provide data on the adverse events and concomitant medications for a subject. For example, it can accurately illustrate the relationships between:

- The subject and each adverse event.
- The subject and each medication.
- The adverse event and its associated concomitant medication.

 **Tip:**

- The associated forms must be repeating.
- The forms must be marked as associated in Oracle Central Designer.
- The report must only contain data from two associated forms.

 **Note:**

You cannot create a Cognos Reporting report that contains data from both the Clinical Data by Form folder and the Clinical Data by Associated Form package.

- [Example: Adverse Events and Concomitant Medications association](#)

Example: Adverse Events and Concomitant Medications association

This example shows the report output for the association between an adverse event on the Adverse Events form and a drug on the Concomitant Medications form for subject PRE.

In this example, there is a one-to-one relationship between a single adverse event and a single concomitant medication for the subject. If, for example, the subject reported a second adverse event associated with the drug Anacin, an additional row would appear in the report listing the second Adverse Event (in the Event column), and Anacin listed in the Drug name column.

Subject Initials	Event	Drug name	Site Mnemonic
PRE	Diabetes	Anacin	01

1 2

- **1**—(Points to the **Event** column.) The Event column contains adverse event data for each subject.
- **2**—(Points to the **Drug name** column.) The Drug name column contains concomitant medication data for each subject.

Data from forms with itemsets

For forms that contain a non-repeating section and an itemset, an association exists between the itemset and non-repeating section. You can create Cognos Reporting reports to show the relationship between the data in a non-repeating section and its associated itemsets. The

report output contains columns with data from the non-repeating section, and columns with data from each itemset.

For more information, see [Examples: Reporting on multi-instance forms and items](#).

 **Tip:**

- You can only create reports with data from a non-repeating section and itemsets that exist on the same form.
- The form the non-repeating section and itemsets exist on can be repeating or non-repeating.
- There is no relationship between the itemsets on a form. Therefore, creating a report that only contains itemset data is not useful.
- During study versioning:
 - If you created a report with an itemset and a non-repeating section, and either of them was deleted, the columns in the report are empty for subjects that did not have data in the deleted study object before it was deleted.
 - An association is created between a non-repeating section and an itemset when:
 - * A non-repeating section is added to a form that contains an itemset.
 - * An itemset is added to a form that contains a non-repeating section.

Data from multiple versions of the same study object

Use the report elements in the Clinical Data by Form folder. The folder contains an report element for every form and item that has ever been used in any version of the study. When you add one of these report elements to a report, the report contains the most recent data entered for each version of the corresponding study object.

Data from repeating objects

When you create a report that contains clinical data, you need to include some kind of unique identifier so that you can determine which instance of each data point you're reporting on. For example, if you want to create a report about a particular subject, you need a way to identify the subject. You can use any of the following as identifiers:

- Subject Number, if your study requires unique subject numbers.
- Subject Number and Subject Initials, if your study doesn't require unique subject numbers.
- Internal IDs for:
 - Subjects

 **Tip:**

Use the SUBJECTID internal ID to identify a subject if your study doesn't require unique subject numbers. The SUBJECTID internal ID appears in the Internal IDs folder for the Subjects query report.

- Sites

- Study versions
- Visits
- Forms

 **Tip:**

Use the Form Index, Itemset Index, and Visit Index internal IDs to identify an instance of a repeating form, items, or visit. For example, to identify an instance of an Adverse Events form, add the FORMINDEX report element from the Internal IDs folder under the Adverse Events form report element.

Empty and duplicate data

By default, the following data does not appear in Cognos Reporting reports:

- Items or controls without data.
- Duplicate data.

However, you can create a Cognos Reporting report that includes this data by configuring the automatic summarization settings for a report. For more information, see IBM Reporting documentation.

 **Note:**

Calculations are performed before data is suppressed.

Simple, meaningful data

The Basic Data folder provides easy access to frequently-run reports. You can select the entire folder to create a basic report for a given form that includes easy-to-read, meaningful data and appropriate key elements to ensure report accuracy.

The Basic Data folder contains:

- Clinical data for a form.
- Text values of items rather than database codes, as well as most of the available date formats.
- Several query items that you can use to identify sites, subjects, and visits.

Unit data for a study object

For each question that requires a unit of measure, you can include the following information in your report:

- **Entered value**—Appears in the Basic Data folder.
- **Unit of measure**—Appears in the Basic Data folder.
- **Normalized value**—Appears in the Additional Data folder.
- **Unit code**—Appears in the Additional Data folder.

Tips for deciding what to include in a report

In this section:

- [Use lineage information to identify report elements](#)
- [Use naming conventions to decide what to add to your report](#)

Use lineage information to identify report elements

Before you add a report element to a Cognos Reporting report, you can view the report element's origin. The lineage information displays metadata such as the report package, visit, form, and so forth, associated with the report element. Use the lineage information to ensure that you include the correct report element in a report.

To view lineage information, right-click the report element, and click **Lineage**.

Use naming conventions to decide what to add to your report

The clinical data report elements that you can add to a Cognos Reporting report are named in a way that can help you determine which report element to use. In general, the labels use the following convention:

optional prefix~ control identifier~ item identifier

The control identifier and item identifier are specified in the study design, retrieved by InForm, and populated in the Clinical Data by Forms folder in Cognos Reporting.

Where the control identifier and item identifier come from

Label	Description
<i>optional prefix</i>	The type of element: <ul style="list-style-type: none"> • None • Code • Unit • Unit Code • Normalized • Date • Time • Month Yr • YYYY/MM/DD • HH24:MM:SS • Month • Year

Label	Description
<i>control identifier</i>	Text that identifies the specific control for the item. <ul style="list-style-type: none"> • Controls other than checkboxes—The Oracle InForm application uses the following properties: <ul style="list-style-type: none"> – Caption property for the control, if it exists. – RefName property for the control, if no caption exists. • Checkboxes—The Oracle InForm application uses the following properties: <ul style="list-style-type: none"> – Label property of the child control element, if it exists. – Caption property of the child control element, if no label exists. – RefName property for the child control element, if no label or caption exists.
<i>item reference</i>	Text that identifies the item as it appears in the study. The InForm application uses the following properties: <ul style="list-style-type: none"> • Short Question property for the item, if it exists and is not the default. • Question property for the item, if no short question exists.

Default labels by control type

Keep the following in mind as you create a report in Cognos Reporting.

Table 2-1 Report element (Default label)

Code report elements	Description	Default folder
[control identifier] Example: Cardiovascular ~ Cardiovascular	Returns the text value that was entered during data entry.	Basic Data
Code~ [control identifier] Example: Code ~ Cardiovascular ~ Cardiovascular	Returns the database code that corresponds to the value entered during data entry.	Additional Data

Table 2-2 Data that require units of measure

Code report elements	Description	Default folder
[control identifier] Example: Weight	Returns the value that was entered during data entry. For instance, if the Oracle InForm user entered 135 on the form, the Weight element returns 135.	Basic Data
Unit~ [control identifier] Example: Unit~ Weight	Returns the specific unit of measure that was selected at data entry. The label for this element has the prefix Unit ~ . For example, the Unit ~ Weight element might return these values: kg or lbs.	Basic Data

Table 2-2 (Cont.) Data that require units of measure

Code report elements	Description	Default folder
Normalized~ [control identifier] Example: Normalized~ Weight	Returns the normalized value; the Oracle InForm application converts measurements to the same, or normalized, unit of measure, based on a base unit of measure that is defined for your study. For example, if the base unit of measure is kilograms, the InForm application converts all entered values to kilograms and stores that value as a normalized value.	Additional Data
Unit Code~ [control identifier] Example: Unit Code ~Weight	Returns the code value for the unit of measure, as it is stored in the database. The label for this element has the prefix Unit Code~ .	Additional Data

Table 2-3 Date controls

Code report elements	Description	Default folder
Date ~ [control label] Example: Date~ Start Date	Returns a date that includes Month, Day, and Year. If data is not entered, or is marked as Unknown in the Oracle InForm application, data does not appear for this report element.	Basic Data
Month Yr ~ [control label] Example: Month Yr ~ Start Date	Returns a date that includes Month and Year. If data is not entered, or is marked as Unknown in the Oracle InForm application, data does not appear for this report element.	Basic Data
YYYYMMDD ~ [control label] Example: YYYYMMDD ~ Date Started	Returns a text string in YYYYMMDD format. Data displays here when a date control allows empty or unknown values.	Basic Data
Time ~ [control label] Example: Time ~ Date Taken	Returns a standard time (24-hour clock) in HH:MM:SS format. If data is not entered, or is marked as Unknown in the Oracle InForm application, data does not appear for this report element. This report element appears only for those Oracle InForm controls that collect the time portion of a date.	Basic Data

Table 2-3 (Cont.) Date controls

Code report elements	Description	Default folder
HH24:MM:SS ~ [control label] Example: HH24:MM:SS~ Date Taken	Returns a text value for time (24-hour clock). Data displays here when a date control allows empty or unknown values. This report element appears only for those Oracle InForm controls that collect the time portion of a date.	Basic Data
Year ~ [control label] Example: Year ~ Date Taken	Returns only the year portion of a date. If data is not entered, or is marked as Unknown in the Oracle InForm application, data does not appear for this report element.	Additional Data
Month ~ [control label] Example: Month ~ Date Taken	Returns only the Month portion of a date. If data is not entered, or is marked as Unknown in the Oracle InForm application, data does not appear for this report element.	Additional Data

Table 2-4 Itemsets, repeating visits, and repeating forms

Code report elements	Description	Default folder
Visit Index	Returns a numeric value that identifies an instance of a repeating visit.	Basic Data
Form Index	Returns a numeric value that identifies an instance of a repeating form.	Basic Data
Itemset Index	Returns a numeric value that identifies an instance of an itemset.	Basic Data

Table 2-5 Deleted itemsets and form instances

Code report elements	Description	Default folder
Deleted form	<p>Indicates whether the reported form instance was marked for deletion in the Oracle InForm application. Use this report element with the Form Index element to see form instances that are deleted. Values are:</p> <ul style="list-style-type: none"> • Y—Form was marked for deletion. • N—Form was not marked for deletion. 	Basic Data
Deleted itemset	<p>Indicates whether the reported Add Entry itemset was marked for deletion in the Oracle InForm application. Use this report element with the Itemset Index to see itemsets that are deleted. Values are:</p> <ul style="list-style-type: none"> • Y—Itemset was marked for deletion. • N—Itemset was not marked for deletion. 	Basic Data


 **Note:**
 You can not delete or undelete a Repeating Data item set.

Table 2-6 Incomplete data reasons

Code report elements	Description	Default folder
Not Done ~ [item label] Example: Not Done ~ Unit Dose	Returns a textual value that indicates why an item is marked Incomplete.	Incomplete Data Reasons

Table 2-6 (Cont.) Incomplete data reasons

Code report elements	Description	Default folder
Blank-[item label] Example: Blank~HeartRate	Indicates whether the reported item appears in a Repeating Data itemset, and is blank, as specified in the study design. <ul style="list-style-type: none"> • Y—Item is blank. • N—Item is not blank. 	Incomplete Data Reasons

Table 2-7 Transactional data

Code report elements	Description	Default folder
CREATEDBYUSERID	User ID of the user who started the form by entering data on the form or triggering a rule that entered data on the form. When the review schema is recreated, this column displays the system user ID.	Basic Data
CREATEDBYDATETIME	Date and time when the reported form was started; that is, when a user entered data on the form or triggered a rule that entered data on the form. When the review schema is recreated, this column displays the date and time when the review schema was recreated.	Basic Data
MODIFIEDBYUSERID	User ID of the user who started or modified the form by entering or modifying data or triggering a rule that entered or modified data on the form. When the review schema is recreated, this column displays the system user ID.	Basic Data
MODIFIEDBYDATETIME	Date and time when the reported form was most recently started or modified; that is, when a user entered or modified data on the form or triggered a rule that entered or modified data on the form. When the review schema is recreated, this column displays the date and time when the review schema was recreated.	Basic Data

Cognos Reporting report elements

In this section:

- [Study Info report elements](#)
- [Sites report elements](#)
- [Subject report elements](#)
- [Visit report elements](#)
- [Forms report elements](#)
- [Section report elements](#)

Study Info report elements

Use the Study Info report elements to include information about the study, the study sponsor, and study version in your reports.

 **Note:**

If an optional item is left blank in the Oracle InForm application, data does not appear in reports that contain the report element for that item.

- [Study Info: Sponsor](#)
- [Study Info: Study](#)
- [Study Info: Study Versions](#)

Study Info: Sponsor

Study Info: Sponsor report elements let you report on specifics about the sponsor of the study.

Report element	Description
Sponsor Name	<p>Data type: String</p> <p>Description: The name of the sponsor of the study.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Note	<p>Data type: String</p> <p>Description: An optional description of the study, as specified in the study design code.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Address 1	<p>Data type: String</p> <p>Description: The text stored in the Address 1 line for the study sponsor.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Report element	Description
Address 2	<p>Data type: String</p> <p>Description: The text stored in the Address 2 line for the sponsor.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
City	<p>Data type: String</p> <p>Description: The city in which the study sponsor is located.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
State/Province	<p>Data type: String</p> <p>Description: The state or province in which the study sponsor is located.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Country	<p>Data type: String</p> <p>Description: The country in which the study sponsor is located.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Postal Code	<p>Data type: String</p> <p>Description: The postal code for the sponsor location.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Phone	<p>Data type: String</p> <p>Description: The primary telephone number for the sponsor.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Alt Phone	<p>Data type: String</p> <p>Description: The secondary telephone number for the sponsor.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Fax	<p>Data type: String</p> <p>Description: The fax number for the sponsor.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Report element	Description
Email	<p>Data type: String</p> <p>Description: An email address specified by the sponsor for a primary contact related to the study.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Therapeutic Area	<p>Data type: String</p> <p>Description: The medical area being investigated by the study. Use of the Therapeutic Area field varies from sponsor to sponsor.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Program Name	<p>Data type: String</p> <p>Description: The name of the medical program into which the study can be categorized. Program names might be medical areas such as Oncology, Dermatology, and so forth. Use of the Program name field varies from sponsor to sponsor.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Study Info: Study

Study Info: Study report elements report on specifics of the study.

Report element	Description
Study Name	<p>Data type: String</p> <p>Description: The name associated with the study, as specified in the study design code.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Trade Drug/Device Name	<p>Data type: String</p> <p>Description: The proprietary, trademark-protected name under which the drug, device, biologic, or compound is being marketed. This name is specified in the study design code.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Generic Drug/Device Name	<p>Data type: String</p> <p>Description: The name used for the generic, therapeutic equivalent of the brand-name drug, device, biologic, or compound (if any). This name is specified in the study design code.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Report element	Description
Sponsor Drug/Device Name	<p>Data type: String</p> <p>Description: The name the sponsor uses to refer to the drug, device, biologic, or compound being studied. This name is specified in the study design code.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Refresh Time	<p>Data type: Date/Time</p> <p>Description: The last date and time the reporting data was refreshed. This time reflects the last time data was refreshed in the Reporting and Analysis database, regardless of whether data was changed.</p> <p>Data type: Reporting and Analysis database system date and time.</p>
Transaction Time	<p>Data type: Date/Time</p> <p>Description: The most current Oracle InForm transaction time.</p> <p>Data type: System date and time (GMT).</p>

Study Info: Study Versions

Study Info: Study Versions reporting elements allow you to report on data about the particular study versions.

Report element	Description
Version	<p>Data type: String</p> <p>Description: The name that is associated with a given study version, as specified in the study design code. This report element returns all study versions.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Version Date	<p>Data type: Date/Time</p> <p>Description: The date the study version was defined for the study.</p> <p>Date type: May be specified in study design code. If not, this is a system date.</p>
Description	<p>Data type: String</p> <p>Description: Text that describes what has changed in the study version. Study version description text is unique to each study version. Often, this field is used to reflect the iteration of a particular study. For example, a 2 in this field may indicate that the study version is the second revision.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Report element	Description
Design Note	<p>Data type: String</p> <p>Description: Optional notes for the study version entered in the study design code.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Sponsor Approval Date	<p>Data type: Date/Time</p> <p>Description: The projected date on which the sponsor approved the Oracle InForm study version. This date is set by the study designer. It does not necessarily reflect the actual date the study version goes live.</p> <p>Date type: Specified in study design code.</p>

Sites report elements

Site report elements and measures allow you to create reports that provide identifying and descriptive data for all sites in a given study. Use the Sites report topic when you want to see information broken out by each site participating in the study.

- [Sites](#)

Sites

Note:

If an optional item is left blank in the Oracle InForm application, data does not appear in reports that contain the report element for that item.

Report element	Description
Site Name	<p>Data type: String</p> <p>Description: The name of the site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Report element	Description
Address 1	<p>Data type: String</p> <p>Description: First line of the site address, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Address 2	<p>Data type: String</p> <p>Description: Second line of the site address, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
City	<p>Data type: String</p> <p>Description: The city in which a site is located, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
State/Province	<p>Data type: String</p> <p>Description: The state or province in which the site is located, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Country	<p>Data type: String</p> <p>Description: The country in which a site is located, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Postal Code	<p>Data type: String</p> <p>Description: The postal code for the site address, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Phone	<p>Data type: String</p> <p>Description: The primary telephone number for the study site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Report element	Description
Alt Phone	<p>Data type: String</p> <p>Description: The site secondary telephone number, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Fax	<p>Data type: String</p> <p>Description: The fax number for a study site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Email	<p>Data type: String</p> <p>Description: The email address for a site contact, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Time Zone	<p>Data type: String</p> <p>Description: The time zone in which a study site is located, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Date Format	<p>Data type: Numeric</p> <p>Description: The format used for all references to dates for the site. Valid values are:</p> <ul style="list-style-type: none"> • 1—Day/Month/Year • 2—Year/Month/Day • 3—Month/Day/Year <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Site Activation Date	<p>Data type: Date/Time</p> <p>Description: The projected date for the activation of the study by the site. It does not necessarily reflect the actual date on which the activation occurs.</p> <p>Date type: May be specified in study design code. If not, this is a system date.</p>

Report element	Description
Current Study Version	<p>Data type: String</p> <p>Description: Displays a description of the most current study version, as specified in the study design code. Many study designers use this field to indicate study version iteration. For example, 2 indicates the second version of the study. The value may also be a text description for the study version.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Current Site Acceptance Date	<p>Data type: Date/Time</p> <p>Description: The date on which the site was assigned to the current study version.</p> <p>Date type: May be specified in study design code. If not, this is a system date. The date that appears here depends on how the site was associated with the current study version:</p> <ul style="list-style-type: none">• If the site was associated with the study version through the Oracle InForm Administration interface, the Current Site Acceptance Date is the system date when the association took place.• If the site was associated with the study version through the MedML Installer utility, the Current Site Acceptance Date is the date specified in the MedML for the new study version.

Subject report elements

Subject report elements and measures allow you to create reports that provide metrics and status information about subjects during the course of the study.

Note:

The elements and measures in this report topic return study management data. You can use these elements and measures to access such data as current status, status dates, and counts. These elements and measures do not provide any clinical information about a subject. You can create reports that contain clinical data about subjects only if you have access to both study management and clinical items and measures in your reporting package.

- [Subjects](#)
- [Subjects: Subject Status \(text\)](#)
- [Subjects: Subject Status Counts](#)
- [Subjects: CRB Status Counts](#)
- [Subjects: Subject Status Dates](#)
- [Subjects: Subject Status by Month and Year](#)

Subjects

Subjects report elements return identifying information about the subject. This report element also includes a count item, which allows you to see totals for subjects, regardless of status.

Report element	Description
Subject Number	<p>Data type: String</p> <p>Description: The number that identifies the subject. This number can also be changed post-enrollment, if configured in the study.</p> <p>Note: Subject number might not be unique at your site.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Subject Initials	<p>Data type: String</p> <p>Description: The initials of the subject enrolled in the study. These initials can be changed post-enrollment.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Subject DOB (Screening)	<p>Data type: Date</p> <p>Description: The date of birth for the subject, as entered on the Screening form for the subject. The DOB field may or may not be used on the Screening form for your study.</p> <p>You cannot change this date after the subject is enrolled. You can change it after the Screening form is submitted, as long as the subject has not yet been enrolled.</p> <p>Many study designers also include a date of birth field for the subject on other clinical forms in the study to correct data entry errors that might have occurred when the subject was screened. Unlike the DOB field on the screening form, a DOB field on a clinical form can be changed at any time.</p> <p>As a result, a subject may have two different dates of birth recorded in the Reporting and Analysis database; one recorded on the Screening form, and one recorded on another clinical form in the study. These dates may or may not match.</p> <p>You can report on clinical DOB dates using report elements that appear in the Clinical Data by Form folder.</p> <p>Data type: Clinical</p>

Report element	Description
SV Selected	<p>Data type: Y/N</p> <p>Description: Indicates whether the subject is selected for source verification.</p> <ul style="list-style-type: none">• Y—The subject is selected for source verification. All forms for this subject must be source verified.• N—The subject is not selected for source verification. Forms for this subject do not require source verification. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Subjects: Subject Status (text)

The elements in the Subjects: Subject Status (text) reporting topic allow you to create reports that describe subject status.



Note:

The subject states listed here are states internal to the Oracle InForm application. They may or may not correlate with clinical state definition, since events like screening and randomization are often performed outside of the Oracle InForm application.

Report element	Description
Subject Status	<p>Data type: String</p> <p>Description: The current Oracle InForm subject status. Subjects can be in only one state at a time in the Oracle InForm application. Valid values are:</p> <ul style="list-style-type: none"> • Screened—The Screening form for the subject was started, but the subject is not enrolled. • Screen Failed—The subject has failed the Oracle InForm screening process. • Enroll Failed—The subject has passed the Oracle InForm screening process, but failed the enrollment process. • Enrolled—The subject was properly enrolled in the Oracle InForm application, but has not reached the status of randomized, completed, or dropped out. • Randomized—The subject was enrolled and has been randomized in the Oracle InForm application, but is not yet completed or dropped out. • Complete—The subject has completed the study, as recorded in the Complete control of the Study Completion form for that subject. • Dropped out—The subject has dropped out of the study, as recorded in the Complete control of the Study Completion form for that subject. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Screen Failure Reason	<p>Data type: String</p> <p>Description: Text that indicates why the subject failed the screening process.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Enroll Failure Reason	<p>Data type: String</p> <p>Description: Text that indicates why the subject failed enrollment.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Enroll Override Reason	<p>Data type: String</p> <p>Description: Text that indicates why the screening or enrollment failure was overridden for the subject.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Report element	Description
Drop Out Reason	<p>Data type: String</p> <p>Description: Text that indicates why the subject dropped out of the study. The dropout reason is clinical data that is specified on the Study Completion form for the subject.</p> <p>Note: This report displays only those reasons that were specified when a subject dropped out of the study. If a dropout reason was never used, the reason does not appear in this report.</p> <p>UUIDs: PF_SC_COMPLETECTL, PF_SC_REASONCTL_ <i>internal_reason_value</i></p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Subjects: Subject Status Counts

The Subjects: Subject Status Counts folder contains reporting elements that calculate subject counts that are based on subject state. The listed subject states are internal to InForm. Whether these states correlate to actual clinical states depends on your use of InForm features.

A subject can be in only one state at a time in InForm. Therefore, if a subject is randomized after being enrolled in InForm, the current state for the subject is Randomized, not Enrolled.

However, when you create reports on subjects who are still actively participating in the study, you will likely need to see totals that reflect the number of subjects who have ever been enrolled in the study. For example, a count of enrolled subjects should include all subjects who have ever been enrolled in InForm, even if their status changed to Randomized, because in clinical terms, a subject who has been randomized is still considered enrolled. Therefore, these subject status counts return totals of subjects who have ever had these states:

- Screened
- Enrolled
- Enrolled Override
- Randomized

To report on subjects who are no longer active in the study, use the Screened Failed, Enrolled Failed, Dropped Out, and Complete subject status counts. Unlike the other subject status counts, these report elements return totals of those subjects currently in any of these states. Subjects will have Dropped Out and Complete status only if your study uses the Study Completion form.

 **Note:**

The status assigned to a subject depends on the InForm features you use to set the status. For instance, for a subject to have a randomized state, you must perform subject randomization through the InForm application. For more information, see [I can't see subject status information](#).

You can use any of the predefined subject filters to further qualify the Subject Status Count totals.

Report element	Description
Subject Count	<p>Data type: Numeric</p> <p>Description: The number of subjects who enrolled at the site.</p> <p>How calculated: For each site, counts subjects who enrolled at the site, including subjects who are currently assigned other states.</p> <p>Note: The Enrollment form, designed according to Oracle InForm specifications, must be completed for the subject.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Status is determined by the value on the Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p> <p>Note: You can use any of the predefined subject filters to further qualify this count.</p>
Screened	<p>Data type: Numeric</p> <p>Description: The number of subjects who have ever been in the Screened state in the Oracle InForm application.</p> <p>How calculated: Counts subjects who have ever been assigned a Screened status in the Oracle InForm application. This count includes subjects whose states have changed from Screened to a new state.</p> <p>Data source: Status is determined by the Screening form and stored in the Reporting and Analysis database. The status count is derived from the status and is set to 1 when the subject enters that status.</p> <p>Note: The Screening form must be completed for the subject for the report to display this information.</p>

Report element	Description
Screen Failed	<p>Data type: Numeric</p> <p>Description: The number of subjects who have a current status of Screened Failed in the Oracle InForm application.</p> <p>How calculated: Counts subjects who were rejected by the Oracle InForm screening process, based on some screening eligibility requirement that was not met. Subjects can have a status of Screened Failed in the Oracle InForm application only if screening eligibility requirements are being used for your study.</p> <p>A subject is not counted if the screen failure was overridden for the subject.</p> <p>Data source: Status is determined by the Screening form and stored in the Reporting and Analysis database. The status count is derived from the status and is set to 1 when the subject enters that status.</p>
Enrolled	<p>Data type: Numeric</p> <p>Description: The number of subjects who have ever been enrolled in the study through the InForm application.</p> <p>How calculated: Counts subjects whose Enrollment form was completed and successfully submitted. This count includes:</p> <ul style="list-style-type: none"> • Subjects whose states have changed from Enrolled to a new state. • All subjects who have ever been in the Enrolled state. • Subjects who have gone through the enrollment override process. <p>Data source: Status is determined by the value on the Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p> <p>Note: The Enrollment form must be completed for the subject for the report to display this information.</p>

Report element	Description
Enrolled Failed	<p>Data type: Numeric</p> <p>Description: The number of subjects who have a current status of Enrolled Failed in the InForm application.</p> <p>How calculated: Counts subjects whose Enrollment form was rejected by the Oracle InForm application, based on some eligibility requirement that was not met. This count includes subjects whose current states have changed from Enrolled Failed to a new state.</p> <p>A subject is not counted if the enroll failure was overridden for the subject.</p> <p>Subjects can have this status only if the enrollment eligibility requirements are being used in the Oracle InForm application for your study.</p> <p>Data source: Status is determined by the value on the Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p> <p>Note: You can use any of the predefined subject filters to further qualify this count.</p>
Enrolled Override	<p>Data type: Numeric</p> <p>Description: The number of subjects who initially failed the Oracle InForm screening or enrollment process, but whose failure was overridden in the Oracle InForm application.</p> <p>How calculated: Counts subjects who were screened or enrolled successfully through the Oracle InForm Enrolled Override process. This count includes all subjects whose status has changed from Enrolled Override to a new status.</p> <p>Data source: Status is determined by the Oracle InForm Screening/Enrollment override process and stored in the Reporting and Analysis database. The status count is derived from the status and is set to 1 when the subject enters that status.</p>

Report element	Description
Randomized	<p>Data type: Numeric</p> <p>Description: The number of subjects in the study who have ever been randomized in the Oracle InForm application. Subjects have a status of Randomized immediately after they have been randomized with the Oracle InForm randomization feature.</p> <p>How calculated: Counts subjects who have ever been randomized in the Oracle InForm application. This count includes subjects whose status has changed from Randomized to a new status.</p> <p>If you randomize subjects outside of the Oracle InForm application, the randomized subject count will always be 0.</p> <p>Data source: Status is determined by the Oracle InForm Randomization feature and stored in the Reporting and Analysis database. The status count is derived from the status and is set to 1 when the subject enters that status.</p> <p>Note: The randomization process, as designed per Oracle InForm requirements, must be completed for the subject for the report to display this information.</p>
Dropped Out	<p>Data type: Numeric</p> <p>Description: The number of subjects who have a current status of Dropped Out.</p> <p>How calculated: Counts subjects who have dropped out of the study, as recorded in the Study Completion form for that subject.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p> <p>Note: The Study Completion form, as designed per Oracle InForm requirements, must be completed for the subject for the report to display this information.</p>
Subject Complete	<p>Data type: Numeric</p> <p>Description: The number of subjects who have a current status of Complete.</p> <p>How calculated: Counts subjects who have a current status of Complete, as recorded in the Study Completion form for that subject.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p> <p>Note: The Study Completion form, as designed per Oracle InForm requirements, must be completed for the subject for the report to display this information.</p>

Subjects: CRB Status Counts

The Subjects: CRB Status Counts return metrics on the number of case books in various states. CRB states are set at the case book level only. A CRB state is not set by actions performed on individual forms within the case book.

Report element	Description
CRB Started	<p>Data type: Numeric</p> <p>Description: The number of started case books in the Oracle InForm application.</p> <p>How calculated: Counts case books that have a started noncommon form from the first visit in the case book; that is, with any entered data, queries, or comments on the form.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
CRB SV Ready	<p>Data type: Numeric</p> <p>Description: The number of case books with a current status of SV ready.</p> <p>How calculated: Counts case books that have a current status of SV ready.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
CRB Frozen	<p>Data type: Numeric</p> <p>Description: The number of frozen case books.</p> <p>How calculated: Counts case books that have a current status of Frozen.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
CRB Signed	<p>Data type: Numeric</p> <p>Description: The number of case books that have been signed.</p> <p>How calculated: Counts case books that have a current status of Signed.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
CRB Locked	<p>Data type: Numeric</p> <p>Description: The number of locked case books.</p> <p>How calculated: Counts case books that have a current status of Locked.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Report element	Description
CRB w/ Query	<p>Data type: Numeric</p> <p>Description: The number of the case books that have at least one opened or unanswered query.</p> <p>How calculated: Counts case books that have at least one form with at least one opened or answered query. Does not count case books that only have an associated query in the Candidate state.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Subjects: Subject Status Dates

The Subjects: Subject Status Dates report elements return dates when subjects were assigned to particular states in the InForm application.

Subjects may be set to some states more than one time. For these states, First and Last date report elements appear in the Cognos Reporting interface tree. Use these report elements to identify when subjects are moved from one state to another, as follows:

- Use Last dates to determine the current status for a subject and the date on which the status change occurred.
- Use the First and Last dates together to identify subjects who were, but are no longer, in a given state.

Report element	Description
Subject Status Date	<p>Data type: Date/Time</p> <p>Description: The date on which the subject was assigned the current subject status. For example, if the current subject state is Complete, the Subject Status date indicates the date on which the subject status was set to Complete.</p> <p>Date type: System date (GMT).</p>
InForm Screened Date	<p>Data type: Date/Time</p> <p>Description: The date on which the subject was screened for the study in the Oracle InForm application. A Screened status indicates that the Screening form for the subject was started, but the subject is not yet enrolled. This covers these cases:</p> <ul style="list-style-type: none"> • The subject is fully screened, but the enrollment form has not been started. • The subject is fully screened and the enrollment process has started but not completed. <p>Data type: Clinical</p>

Report element	Description
InForm Enrolled Date	<p>Data type: Date/Time</p> <p>Description: The date on which the subject was enrolled in the Oracle InForm application. A status of enrolled indicates the subject was properly enrolled in the InForm application, but has not reached the status of randomized, completed, or dropped out.</p> <p>Date type: System date (GMT).</p>
InForm Screen Failure Date	<p>Data type: Date/Time</p> <p>Description: The date on which the subject failed the screening process.</p> <p>Date type: System date (GMT).</p>
InForm Randomized Date	<p>Data type: Date/Time</p> <p>Description: The date on which the subject was randomized through the Oracle InForm application. A status of randomized indicates that a subject was enrolled and randomized in the Oracle InForm application, but is not yet completed or dropped out.</p> <p>Note: If you perform randomization outside of the InForm application, the resulting report column does not contain randomization data.</p> <p>Date type: System date (GMT).</p>
First Dropped Date	<p>Data type: Date/Time</p> <p>Description: The date on which the subject first dropped out of the study, as recorded in the Study Completion form for that subject.</p> <p>Date type: System date (GMT).</p>
Last Dropped Date	<p>Data type: Date/Time</p> <p>Description: The date on which the subject most recently dropped out of the study, as recorded in the Study Completion form for that subject. If the subject is removed from the dropped out state, the resulting report column does not contain data.</p> <p>Date type: System date (GMT).</p>
Subject First Complete Date	<p>Data type: Date/Time</p> <p>Description: The first date on which the subject completed the study, as recorded in the Study Completion form as designed per Oracle InForm requirements.</p> <p>Date type: System date (GMT).</p>
Subject Last Complete Date	<p>Data type: Date/Time</p> <p>Description: The most recent date on which the subject completed the study, as recorded in the Study Completion form as designed per Oracle InForm requirements. If the subject is removed from the Complete state, the resulting report column is does not contain data.</p> <p>Date type: System date (GMT).</p>

Report element	Description
CRB SV Ready Date	<p>Data type: Date/Time</p> <p>Description: The date on which the case book was marked SV ready.</p> <p>Date type: System date (GMT).</p>
CRB Frozen Date	<p>Data type: Date/Time</p> <p>Description: The date on which the case book was frozen in the Oracle InForm application. If the CRB is unfrozen, the resulting report column does not contain data.</p> <p>Date type: System date (GMT).</p>
CRB Signed Date	<p>Data type: Date/Time</p> <p>Description: The date on which the case book was signed in the Oracle InForm application. If the CRB is not signed, the resulting report column does not contain data.</p> <p>Date type: System date (GMT).</p>
CRB Locked Date	<p>Data type: Date/Time</p> <p>Description: The date on which the case book was locked in the Oracle InForm application. If the CRB is not locked, the resulting report column does not contain data.</p> <p>Date type: System date (GMT).</p>

Subjects: Subject Status by Month and Year

The Subjects: Subject Status by Month and Year report elements let you create reports on subject status by month. Use these report elements with subject status counts to see the number of subjects who were assigned a particular status each month.

If the report is sorted by one of the Month/Year report elements. (You can apply a filter to specify a date range to one appropriate for your study.) You can then add the Subject Count element to see how many forms were assigned a particular status in each month.

Report element	Description
Subject Status Month, Year	<p>Data type: Date/Time</p> <p>Description: Each month/year combination from the start of the study to present day. Use this column with Subject Count to see the month and year each subject was assigned the current Oracle InForm status.</p> <p>Date type: System date (GMT), derived for display.</p>
Screened Month, Year	<p>Data type: Date/Time</p> <p>Description: Each month/year combination from the start of the study to present day. Use this column with Subject Count to see how many subjects were screened in the Oracle InForm application each month.</p> <p>Date type: System date (GMT), derived for display.</p>

Report element	Description
Enrolled Month, Year	<p>Data type: Date/Time</p> <p>Description: Each month/year combination from the start of the study to present day. Use this column with Subject Count to see how many subjects were enrolled each month.</p> <p>Date type: System date (GMT), derived for display.</p>
Randomized Month, Year	<p>Data type: Date/Time</p> <p>Description: Each month/year combination from the start of the study to present day. Use this column with Subject Count to see how many subjects were randomized in the Oracle InForm application each month.</p> <p>Date type: System date (GMT), derived for display.</p>
Subject Complete Month, Year	<p>Data type: Date/Time</p> <p>Description: Each month/year combination from the start of the study to present day. Use this column with Subject Count to see how many subjects were completed each month.</p> <p>Date type: System date (GMT), derived for display.</p>
Dropped Month, Year	<p>Data type: Date/Time</p> <p>Description: Each month/year combination from the start of the study to present day. Use this column with Subject Count to see how many subjects dropped out of the study each month.</p> <p>Date type: System date (GMT), derived for display.</p>

Visit report elements

Visit report elements allow you to create reports on visit properties, status, and dates.

Visit type	Description
Clinical visit types	
Subject Visit	A visit that contains clinical data within the case book for the subject.
Common Visit	An internal mechanism that contains common forms used in the study.
Non-clinical visit types	
Screening	The visit that contains the Screening form, which is used for Oracle InForm screening. Note that the Screening visit is not included in the case book for the subject.
Enrollment	The visit that contains the Enrollment form, which is used for Oracle InForm enrollment. Note that the Enrollment visit is not included in the case book for the subject.
Monitor (Reg Docs)	An internal mechanism that is used to record information about a review of the study documentation.
Monitor (Visit Report)	An internal mechanism that is used to record information about a visit to a site by a monitor.

All visit types are included in general visit counts for Cognos Reporting reports. To limit your reports to clinical visit counts only, use a predefined filter.

- [Visits](#)
- [Visits: Visit Properties](#)
- [Visits: Visit Counts by Property](#)
- [Visits: Visit Status Counts](#)
- [Visits: Visit Dates](#)

Visits

Visits report elements return identifying information about the visit.

Report element	Description
Visit Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation of the visit title, as specified in the study design. For CRF visits, this title appears at the top of a collection of forms in the visit timeline and may not be a unique identifier.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Visit Name	<p>Data type: String</p> <p>Description: The complete name that identifies the visit in the Oracle InForm application, as specified in study design code. The visit name is not a unique identifier.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Visits: Visit Properties

Visits: Visit Properties report elements return information about the type of visit.

Report element	Description
Visit Type	<p>Data type: String</p> <p>Description: The type of visit. Valid types are:</p> <ul style="list-style-type: none"> • Subject Visit—A visit used to gather clinical data within the case book for the subject. • Common Visit—An internal mechanism used to contain common forms used in the study. • Screening—The visit that contains the Screening form, used for Oracle InForm screening. The Screening visit is not included in the case book for the subject. • Enrollment—The visit that contains the Enrollment form, used for Oracle InForm enrollment. The Enrollment visit is not included in the case book for the subject. • Monitor (Reg Docs)—An internal mechanism used to record information about a review of the study documentation. • Monitor (Visit Report)—An internal mechanism used to record information about a visit to a site by a monitor. <p>Note: To report only on clinical data, filter this column to include only common and subject visits.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>
Start Hours	<p>Data type: Numeric</p> <p>Description: Number of hours from the subject enrollment to the start of the visit. This number is specified in the study design code and is used to create the proposed schedule of visits shown in the Visit Calculator when a subject is enrolled.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Is Scheduled Visit	<p>Data type: Y/N</p> <p>Description: Indicates whether the visit is a scheduled visit. Scheduled visits occur in a fixed relationship to the beginning of enrollment in a study by a subject. Scheduled visits start a specified number of hours after enrollment. Valid values are:</p> <ul style="list-style-type: none"> • Y—The visit is scheduled. • N—The visit is not a scheduled visit. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>

Report element	Description
Is Repeating Visit	<p>Data type: Y/N</p> <p>Description: Indicates whether the visit is a repeating visit. Repeating visits are those that occur multiple times within a study. Repeating visits are always unscheduled. Valid values are:</p> <ul style="list-style-type: none"> • Y—The visit is a repeating visit. • N—The visit is not a repeating visit. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>
Is Dynamic Visit	<p>Data type: Y/N</p> <p>Description: Indicates whether the visit is a dynamic visit. Dynamic visits are created automatically when subject data satisfies certain criteria that you test by attaching a rule to a form item. Valid values are:</p> <ul style="list-style-type: none"> • Y—The visit is dynamic. • N—The visit is not dynamic. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>
Dynamic Projected Start Hours	<p>Data type: Numeric</p> <p>Description: The number of hours after the study starts that this visit is scheduled to take place. This value is used for dynamic visit scheduling.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Visit Order	<p>Data type: Numeric</p> <p>Description: A number that indicates the relative order of the visit within the study.</p> <p>Note: Use Visit Order to sort visits in a report. This is helpful when the visit order is not implied in the Visit Mnemonic or Visit Name.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Design Note	<p>Data type: String</p> <p>Description: Optional text containing special information about the visit, specified in the study design code. This information is for documentation only and is not displayed in the Oracle InForm application.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Visits: Visit Counts by Property

Visits: Visit Counts by Property report elements return totals of different types of visits.

 **Note:**

These visit counts are totals of all subject visits, regardless of visit type. To report on clinical visits only, use the Clinical Visits filter in the Predefined Filters folder.

Report element	Description
Scheduled Visit	<p>Data type: Numeric</p> <p>Description: The number of scheduled subject visits, regardless of visit type.</p> <p>How calculated: This calculation includes:</p> <ul style="list-style-type: none"> • All scheduled visits. • All started dynamic visits. • All started unscheduled visits. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Repeating Visit	<p>Data type: Numeric</p> <p>Description: The number of started repeating (unscheduled) visits.</p> <p>How calculated: A visit is counted if it is repeating (unscheduled) and has been started.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Dynamic	<p>Data type: Numeric</p> <p>Description: The number of started dynamic visits.</p> <p>How calculated: A visit is counted if it is dynamic and has been started.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Visits: Visit Status Counts

Visits: Visit Status Count report elements return visit totals by their status. Visit states are derived from the state of each form within each visit. For example, a visit is considered completed only if all forms within the visit have a status of complete.

 **Note:**

Visit status does not correlate to status indicators on the Oracle InForm subject list.

Report element	Description
Visit Count (Across subjects)	<p>Data type: Numeric</p> <p>Description: The total number of subject visits for the study.</p> <p>How calculated: Counts all subject visit instances, regardless of visit type or status. This count includes non-clinical visits. (You can apply a predefined filter if you want to limit visit counts to clinical visits only.)</p> <p>In addition to counting Visits that have expected forms (including activated dynamic visits), this count includes unscheduled visits.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Visit Started	<p>Data type: Numeric</p> <p>Description: The number of visits that have a non-common form that has been started in the Oracle InForm application.</p> <p>How calculated: A visit is counted as started if at least one non-common expected form in the visit has been started.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Visit Complete	<p>Data type: Numeric</p> <p>Description: The number of visits where each expected form has a current status of Complete.</p> <p>How calculated: Counts visits that have all expected forms marked Complete.</p> <p>Note: Visit status reported here differs from visit status indicated by the status icon in the Oracle InForm user interface.</p> <ul style="list-style-type: none"> • Visit complete in Cognos Reporting—All expected forms must be complete for the visit to be considered complete. • Visit complete in the InForm user interface—At least one started form must be complete for the visit to be considered complete. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Visit Frozen	<p>Data type: Numeric</p> <p>Description: The number of visits where each expected form has a current status of Frozen.</p> <p>How calculated: Counts visits that have all expected forms marked Frozen.</p> <ul style="list-style-type: none"> • Visit complete in Ad Hoc Reporting—All expected forms must be frozen for the visit to be considered frozen. • Visit complete in the InForm user interface—At least one started form must be frozen for the visit to be considered frozen. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Report element	Description
Visit SV Complete	<p>Data type: Numeric</p> <p>Description: The number of visits where each expected form has been source verified in the Oracle InForm application.</p> <p>How calculated: Counts visits that have all expected forms marked SV complete.</p> <p>Note: Visit status reported here differs from visit status indicated in the Oracle InForm user interface.</p> <ul style="list-style-type: none"> • Visit Source Verified in Ad Hoc Reporting—All expected forms must be source verified for the visit to be considered source verified. • Visit Source Verified in the InForm user interface—At least one started form must be source verified for the visit to be considered source verified. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Visit Locked	<p>Data type: Numeric</p> <p>Description: The number of visits where each expected form has a status of Locked.</p> <p>How calculated: Counts visits that have all expected forms marked Locked.</p> <p>Note: Visit status reported here differs from visit status indicated in the Oracle InForm user interface.</p> <ul style="list-style-type: none"> • Visit Locked in Ad Hoc Reporting—All expected forms must be locked for the visit to be considered locked. • Visit Locked in the InForm user interface—At least one expected form must be locked for the visit to be considered locked. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Visits: Visit Dates

Visits: Visit Dates report elements return dates associated with visits.

Report element	Description
Scheduled Date	<p>Data type: Date</p> <p>Description: The date on which the visit is scheduled.</p> <p>How calculated: Calculates the date by adding the value in the Start Hour property for the visit to the enrollment date.</p> <p>Date type: System date (GMT), derived for display.</p>

Report element	Description
Actual Date (DOV)	<p>Data type: Date</p> <p>Description: The date that is recorded in a standard Date of Visit control in the Oracle InForm application.</p> <p>Data type: Clinical</p> <p>Note: This report element assumes that your study was developed using a specific design for the DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 <p>Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674</p>
Data Entry Date	<p>Data type: Date</p> <p>Description: The date on which data was entered for the visit. This date is equal to the first date that any form is submitted for the visit.</p> <p>Date type: System date (GMT).</p>

Forms report elements

Forms report elements and measures allow you to create reports that provide metrics and status information about forms in your study. Use this report topic to include:

- Counts of different form types.
- Information about form properties and states.
- Information about custom review states and stages associated with forms.
- Information on when forms were initially created and changed.
- [Form elements and expected forms](#)
- [Forms](#)
- [Forms: Properties](#)
- [Forms: Form Counts by Property](#)
- [Forms: Form Status Counts](#)
- [Forms: Review States](#)
- [Forms: Review States Counts](#)
- [Forms: Form Dates](#)
- [Forms: Form Status by Month and Year](#)
- [Forms: Aging](#)
- [Forms: Cycle Times](#)

Form elements and expected forms

Unless otherwise noted, all of the calculations and dates that the elements in the Forms report topic return are based on expected form counts.

A form is counted as expected if it meets any of the following criteria:

- It appears within a scheduled visit (regardless of whether the form is started).
- It appears within a started unscheduled visit.
- It is a dynamic form that has been activated.

 **Note:**

Non-started common forms are not counted as expected.

Expected forms are counted for subjects in the following states:

- Enrolled
- Randomized
- Complete
- Dropped-out

 **Note:**

For subjects that have completed or dropped-out (as indicated by the Study Completion form), only forms in started visits or dynamic started forms are counted.

The expected forms calculation assumes the following:

Only CRFs are counted. Other special CRFs (such as screening and enrollment) are not included.

- **Alternate forms**—One form in each visit is counted.
- **Common forms**—A common form is counted only once for the study, regardless of the number of visits in which it occurs.
 - For enrolled or randomized subjects, common forms are considered expected.
 - For complete or dropped-out subjects, only started common forms are considered expected.
- **Common dynamic forms**—Each activated or started instance is counted once.
- **Common dynamic repeating forms**—Each activated or started instance is counted once.
- **Common repeating forms**—Each instance is counted once.
- **Dynamic forms**—One activated dynamic form is counted for each visit in which it exists. Deleted (removed) form instances are not counted as expected.
- **Dynamic repeating forms**—Each activated or started instance is counted once.
- **Regular forms**—One form is counted for each visit.

- **Repeating forms**—For repeating forms that have not been started, one instance of the form is counted as expected. For repeating forms that have been started, each started instance counts as expected. Deleted (removed) form instances are not counted as expected.

Only subject visits and common visits are counted. Other special visits (such as screening/enrollment or monitor) are not included.

- **Started visits (scheduled and unscheduled)**
 - Regular and repeating forms are counted as expected.
 - All activated dynamic forms are counted as expected.
 - All alternate forms are counted as expected.
- **Unstarted scheduled visits**
 - For enrolled or randomized subjects:
 - * Regular and repeating forms are counted as expected.
 - * All activated dynamic forms are counted as expected.
 - * Started alternate forms are counted as expected.
 - For complete or dropped-out subjects:
 - * No forms are counted as expected.
- **Unstarted unscheduled visits**
 - No forms are counted as expected.

Forms

Form report elements return identifying information about forms.

Report element	Description
Form Mnemonic	<p>Data type: String</p> <p>Description: A short name or abbreviation for the form, as specified in the study design code. This name appears in the Visit ruler and along the left side of certain pages for use with the form selectors, and is used to access a specific form in the Oracle InForm application.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Form Name	<p>Data type: String</p> <p>Description: The complete name that identifies the form in the Oracle InForm application.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Report element	Description
SV Selected	<p>Data type: Y/N</p> <p>Description: Indicates whether the form is selected for source verification.</p> <ul style="list-style-type: none"> • Y—The form is selected for source verification. • N—The form is not selected for source verification. <p>A form has been selected for source verification if one of the following is true:</p> <ul style="list-style-type: none"> • The form contains one or more critical items. • The form is on the Critical Forms list. • The subject with which the form is associated is in the SV Pool. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Forms: Properties

Forms: Properties report elements return information about the properties associated with forms.

Report element	Description
Form Type	<p>Data type: String</p> <p>Description: Displays the type of form. Valid values are:</p> <ul style="list-style-type: none"> • CRF—Identifies a form that is used in a clinical subject visit. • Enrollment—Identifies forms that are used in Screening and Enrollment visits. • Monitor RegDoc—Identifies forms that are used in Regulatory Documentation visits. • Monitor Visit Report—Identifies forms that are used for Visit Reports. <p>Use the predefined form filters with this element to limit the data on your report to a particular form type.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database. Value decoded for display.</p>
Is Dynamic	<p>Data type: Y/N</p> <p>Description: Specifies whether the form is dynamic. Valid values are:</p> <ul style="list-style-type: none"> • Y—The form is dynamic. • N—The form is not dynamic. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>

Report element	Description
Is Repeating	<p>Data type: Y/N</p> <p>Description: Specifies whether the form is a repeating form. Valid values are:</p> <ul style="list-style-type: none"> • Y—The form is a repeating form. • N—The form is not a repeating form. <p>A repeating form occurs multiple times in the same visit or study. For example, if a protocol calls for multiple blood draws at intervals after administering a medication, you can capture the repeating data on multiple instances of a repeating form.</p> <p>Data source: Replicated from the InForm transactional database to the Reporting and Analysis database and decoded for display.</p>
Is Common	<p>Data type: Y/N</p> <p>Description: Specifies whether the form is a common form. Valid values are:</p> <ul style="list-style-type: none"> • Y—The form is a common form. • N—The form is not a common form. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>
Is Alternate Form	<p>Data type: Y/N</p> <p>Description: Specifies whether the form is an alternate form. Valid values are:</p> <ul style="list-style-type: none"> • Y—The form is an alternate form. • N—The form is not an alternate form. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>
Contains SV Required Items	<p>Data type: Y/N</p> <p>Description: Specifies whether the form contains items that require Source Verification.</p> <ul style="list-style-type: none"> • Y—The form contains SV Required items. • N—The form does not contain SV Required items. <p>An item is considered SV Required only if it is marked SV Required.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>
Contains Required Items	<p>Data type: Y/N</p> <p>Description: Specifies whether the form contains items that require data entry for the form to be complete. Valid values are:</p> <ul style="list-style-type: none"> • Y—The form contains required items. • N—The form does not contain required items. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>

Report element	Description
Form Order	<p>Data type: Numeric</p> <p>Description: An ordinal that specifies the position of the form within the visit. For example, 3 indicates that the form is the third form in the visit.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>
Design Note	<p>Data type: String</p> <p>Description: Optional text, as specified in the study design code, that is used by study designers for documentation purposes only. This note does not appear in the Oracle InForm interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Form Note	<p>Data type: String</p> <p>Description: Optional text, as specified in the study design code, that appears on the form.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Is SV Selected	<p>Data type: Y/N</p> <p>Description: Indicates whether the form has been selected for source verification.</p> <ul style="list-style-type: none"> • Y—The form has been selected for source verification. • N—The form has not been selected for source verification. A form has been selected for source verification if one of the following is true: <ul style="list-style-type: none"> • The form contains one or more critical items. • The form is on the Critical Forms list. • The subject with which the form is associated is in the SV Pool. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>

Forms: Form Counts by Property

Forms: Form Counts by Property report elements return totals of different types of forms. Form counts here are expected form counts.

Note:

When used by themselves, these report elements return form totals multiplied by the number of subjects participating in the study. You can add other report elements to see different totals for specific subjects.

Report element	Description
Dynamic Form	<p>Data type: Numeric</p> <p>Description: The number of expected dynamic forms.</p> <p>How calculated: Counts forms that are dynamic and have been activated or started. Does not count dynamic forms that have been removed.</p> <p>Example: A subject (who is pregnant) is participating in a study that requires the collection of additional information for subjects who are pregnant. A dynamic form is activated for the subject when entered data indicates that she is pregnant.</p> <p>Dynamic form count for this example = 1.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Repeating Form	<p>Data type: Numeric</p> <p>Description: The number of started, non-started, and deleted repeating forms within the study.</p> <p>How calculated: Counts not started repeating once. Counts each started instance of a repeating form.</p> <p>Example: Two subjects are participating in a study with a repeating form that records blood draws at different intervals within the study. Subject A has had one blood draw; therefore one instance of the repeating form has been started for the subject. Subject B has had two blood draws; therefore two instances of the repeating form have been started for Subject B.</p> <p>Repeating form count for this example =3.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Common Form	<p>Data type: Numeric</p> <p>Description: The number of possible common forms across all subjects.</p> <p>How calculated: Counts each common form one time, regardless of the number of visits in which the form appears.</p> <p>Example: A study contains a common form for Adverse Events, which appears in each visit. This form has been completed for a subject in three different visits.</p> <p>Common form count for this example = 1.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Report element	Description
Alternate Form	<p>Data type: Numeric</p> <p>Description: The number of possible alternate forms across all subjects.</p> <p>How calculated: Counts forms that are started alternate forms.</p> <p>Example: An alternate form is completed for two subjects who are enrolled in the study. Alternate form count for this example=2.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Has Required Items	<p>Data type: Numeric</p> <p>Description: The number of possible expected forms across all subjects that contain required items.</p> <p>How calculated: Counts forms that could be expected or started and that contain required items. This calculation includes dynamic and repeating forms with required items, as follows:</p> <ul style="list-style-type: none"> • Dynamic form <ul style="list-style-type: none"> – Counted if it contains required items and it is activated or started. – Not counted if it has been removed. • Repeating form <ul style="list-style-type: none"> – Not started—Counted one time if it contains required items. – Started—Counts each instance that contains required items. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Has SV Required Items	<p>Data type: Numeric</p> <p>Description: The number of possible expected forms across all subjects that contain items marked SV Required.</p> <p>How calculated: Counts forms that are expected or started, and that contain items marked SV Required. This calculation includes dynamic and repeating forms with items marked SV Required, as follows:</p> <ul style="list-style-type: none"> • Dynamic form <ul style="list-style-type: none"> – Counted if it contains items marked SV Required, and is activated or started. – Not counted if it has been removed. • Repeating form <ul style="list-style-type: none"> – Not started—Counted one time if it contains items marked SV Required. – Started—Counts each instance that contains items marked SV Required. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Report element	Description
SV Selected	<p>Data type: Numeric</p> <p>Description: The number of forms that have been selected for source verification.</p> <p>How calculated: Counts forms that have been selected for source verification.</p> <p>A form has been selected for source verification if one of the following is true:</p> <ul style="list-style-type: none"> • The form contains one or more critical items. • The form is on the Critical Forms list. • The subject with which the form is associated is in the SV Pool. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Forms: Form Status Counts

Forms: Form Status Counts report elements return totals of forms according to their status.

Report element	Description
Form Count	<p>Data type: Numeric</p> <p>Description: The total number of forms.</p> <p>How calculated: This calculation includes all forms, including expected forms, forms that have not been started, and unscheduled forms. Use this report element in combination with other predefined filters to narrow report results.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Report element	Description
Expected	<p>Data type: Numeric</p> <p>Description: The number of expected forms in the study.</p> <p>How calculated: Counts forms that meet any of the following criteria:</p> <ul style="list-style-type: none"> • Appear within a scheduled visit (regardless of whether the form is started). • Appear within a started unscheduled visit. • Are activated dynamic forms. <p>Counts expected forms only for subjects who have been enrolled in the InForm application (includes enrolled, randomized, completed, and dropped subjects).</p> <p>For subjects that have completed or dropped (as indicated by the Study Completion form), only forms in started visits or dynamic started forms are counted. Non-started common forms are not counted as expected.</p> <p>Only CRFs are counted. Other special CRFs (such as screening and enrollment) are not included.</p> <ul style="list-style-type: none"> • Alternate forms—One form in each visit is counted. • Common forms—A common form is counted only once for the study, regardless of the number of visits in which it occurs. <ul style="list-style-type: none"> – For enrolled or randomized subjects, common forms are considered expected. – For complete or dropped-out subjects, only started common forms are considered expected. • Common dynamic forms—Each activated or started instance is counted one time. • Common dynamic repeating forms—Each activated or started instance is counted one time. • Common repeating forms—Each instance is counted one time. • Dynamic forms—One activated dynamic form is counted for each visit in which it exists. Deleted (removed) form instances are not counted as expected. • Dynamic repeating forms—Each activated or started instance is counted one time. • Regular forms—One form is counted for each visit. • Repeating forms—For repeating forms that have not been started, one instance of the form is counted as expected. For repeating forms that have been started, each started instance counts as expected. Deleted (removed) form instances are not counted as expected. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Report element	Description
Started	<p>Data type: Numeric</p> <p>Description: Total count of all forms that are started across all subjects, by visit and by site.</p> <p>How calculated: An expected form is considered started if any type of data entry activity (form data, queries, or comments) has started on the form.</p> <p>Data source: Replicated from the InForm transactional database to the Reporting and Analysis database.</p> <p>Note: To report on forms that are started but incomplete, subtract the complete count (Complete report element) from the started count (Started report element).</p>
Missing Required Items	<p>Data type: Numeric</p> <p>Description: The number of started forms for which at least one required item is empty.</p> <p>How calculated: Counts forms that:</p> <ul style="list-style-type: none"> • Are started. • Contain required items. • Have at least one required item that does not contain data. <p>Data source: Replicated from the InForm transactional database to the Reporting and Analysis database.</p>
Complete	<p>Data type: Numeric</p> <p>Description: Total count of all forms that are complete across all subjects, by visit and by site.</p> <p>How calculated: An expected form is considered complete if all of the required items for the form are supplied. For repeating forms, the form cannot be in a deleted state.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Frozen	<p>Data type: Numeric</p> <p>Description: The number of expected forms that are currently marked Frozen.</p> <p>How calculated: Counts forms that are expected and have been frozen using any of the following Oracle InForm features:</p> <ul style="list-style-type: none"> • Freeze CRF • Freeze CRB • Freeze Visit <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Report element	Description
SV Ready	<p>Data type: Numeric</p> <p>Description: The number of forms that are currently marked SV Ready.</p> <p>How calculated: Counts forms that are marked SV Ready, and are selected for source verification.</p> <p>A form has been selected for source verification if one of the following is true:</p> <ul style="list-style-type: none"> • The form contains one or more critical items. • The form is on the Critical Forms list. • The subject with which the form is associated is in the SV Pool. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
SV Partial	<p>Data type: Numeric</p> <p>Description: The number of forms that are currently marked SV Partial.</p> <p>How calculated: Counts forms that are in the SV Partial state.</p> <p>A form is considered SV Partial if one of the following is true:</p> <ul style="list-style-type: none"> • The form contains unverified critical items. • The form is on the Critical Forms list, and contains unverified items that are marked SV Required. • The subject with which the form is associated is in the SV Pool, and the form contains unverified items that are marked SV Required. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject, and the form contains unverified items that are marked SV Required. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Report element	Description
SV Complete	<p>Data type: Numeric</p> <p>Description: The number of verified forms.</p> <p>How calculated: Counts forms that are marked Verified.</p> <p>A form is considered Verified if the form is selected for source verification, and if one of the following is true:</p> <ul style="list-style-type: none"> • The form does not contain critical items, and all items on the form that are marked SV Required are verified. • The form contains critical items, and all critical items on the form are verified. • The form is on the Critical Forms list, and all items on the form that are marked SV Required are verified. • The subject with which the form is associated is in the SV Pool, and all items marked SV Required are verified. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject, and all items marked SV Required are verified. <p>If none of the items on the form require source verification, the Oracle InForm application marks the form Verified.</p> <p>Note: For more information on source verification, see the <i>User Guide for Sponsor Users</i>.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Signed	<p>Data type: Numeric</p> <p>Description: The number of signed forms and the percentage of expected forms that are currently signed in the Oracle InForm application.</p> <p>How calculated: Counts forms that have been signed by all groups that are required to sign the form. This value appears as a whole number and as a percentage of expected forms that are signed:</p> $[\text{signed, \% of expected}] = [\text{signed forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Report element	Description
Locked	<p>Data type: Numeric</p> <p>Description: The number of locked forms.</p> <p>How calculated: Counts forms that:</p> <ul style="list-style-type: none"> • Have been locked in the Oracle InForm application at the form level or visit level. • Are contained within a case book that has been locked in the Oracle InForm application. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Marked Incomplete	<p>Data type: Numeric</p> <p>Description: The number of forms that have been marked Incomplete.</p> <p>How calculated: Counts forms that have an existing form comment(s) with an Incomplete Reason of Not Done, Not Applicable, or Unknown.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Has Data	<p>Data type: Numeric</p> <p>Description: The number of forms on which some data has been entered.</p> <p>How calculated: Counts forms that have entered data in at least one item. The item with data does not need to be a required item.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Has Open Query	<p>Data type: Numeric</p> <p>Description: The number of forms with open queries.</p> <p>How calculated: Counts forms that contain items with open queries. This count does not include forms that contain items with queries in states other than Open.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Has Answered Query	<p>Data type: Numeric</p> <p>Description: The number of forms with answered queries.</p> <p>How calculated: Counts forms that contain items with open queries. This count does not include forms that contain items with queries in states other than Answered.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Report element	Description
Candidate Query	<p>Data type: Numeric</p> <p>Description: The number of candidate queries. Use with the Form Name report element to see the number of candidate queries that are associated with a particular form.</p> <p>How calculated: A query is counted if it is currently a candidate query.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Open Query	<p>Data type: Numeric</p> <p>Description: The number of open queries. Use with the Form Name report element to see the number of open queries that are associated with a particular form.</p> <p>How calculated: A query is counted if it is currently open. This count includes reissued queries.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Answered Query	<p>Data type: Numeric</p> <p>Description: The number of answered queries. Use with the Form Name report element to see the number of answered queries that are associated with a particular form.</p> <p>How calculated: A query is counted if it is currently answered.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Has Form Comment	<p>Data type: Numeric</p> <p>Description: The number of forms that contain form-level comments.</p> <p>How calculated: Counts forms that contain at least one form-level comment. This calculation includes forms that have been marked Incomplete. This count does not include forms with only item-level comments.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Has Item Comment	<p>Data type: Numeric</p> <p>Description: The number of forms that contain items with item-level comments.</p> <p>How calculated: Counts forms that contain at least one item-level comment. This calculation includes items that have been marked Incomplete. This calculation does not include forms that include only form-level comments.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Report element	Description
Deleted Repeating	<p>Data type: Numeric</p> <p>Description: The number of repeating forms that have been deleted.</p> <p>How calculated: Counts forms that are repeating forms that have been deleted.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Forms: Review States

Forms: Review States report elements return the custom review state with which each form in the report is associated.

You create custom review states and stages for the Data Viewer using the Oracle Central Designer application. You can define as many as five custom review states, and each custom review state must include three stages. If you do not define custom review states and stages for your study, the associated report elements do not appear in the Cognos Reporting tree. For more information, see the Oracle Central Designer *User Guide*.

Note:

This folder contains study-specific clinical data. It only appears for the Forms report topic if you select the study-specific clinical package on the **Select a package** page when accessing the Cognos Reporting workspace.

Report element	Description
<i>Review state name</i>	<p>Data type: String</p> <p>Description: The custom review state associated with the form, if custom review states are defined for the study.</p> <p>Data source: Calculated in the clinical data model.</p>

Forms: Review States Counts

Forms: Review States Counts report elements return the number of forms that are associated with each custom review state and stage in a study. The folder contains one measure element for each custom review state and stage combination.

You create custom review states and stages for the Data Viewer using the Oracle Central Designer application. You can define as many as five custom review states, and each custom review state must include three stages. If you do not define custom review states and stages for your study, the associated report elements do not appear in the Cognos Reporting tree. For more information, see the Oracle Central Designer *User Guide*.

Note: This folder contains study-specific clinical data. It only appears for the Forms report topic if you select the study-specific clinical package on the **Select a package** page when accessing the Cognos Reporting workspace.

Report element	Description
<i>Review state name ~ Review stage name</i>	<p>Data type: Numeric</p> <p>Description: The number of forms associated with a stage in a custom review state.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Forms: Form Dates

Forms: Form Dates report elements allow you to report on dates associated with form status.

Forms may be set to some states more than one time. For these states, First and Last date report elements appear in the Cognos Reporting interface tree. Use these report elements to identify when a form moved from one state to another, as follows:

- Use Last dates to determine the current status for a form, and the date on which the status change occurred.
- Use the First and Last dates together to identify forms that were, but are no longer in a given state. You can also use these dates to identify forms that changed after being assigned a given state. For example, you can compare the Data Last Modified Date to the Last SV Complete date to see whether the form changed after it was marked SV Complete.

If a form has been in a particular state only one time, the First and Last dates for that state display the same date.

If a form has never been assigned a particular status, the columns for the First and Last dates for that state do not contain data.

Report element	Description
Current Status Date	<p>Data type: Date/Time</p> <p>Description: The date on which the form was assigned its current state. For instance, if the current state of a form is Started, this element would return the date on which the form was started.</p> <p>Date type: System date (GMT).</p>
Data Last Modified Date	<p>Data type: Date/Time</p> <p>Description: The date on which data was last entered or modified on the form.</p> <p>Date type: System date (GMT).</p>
Form's Scheduled Visit Date	<p>Data type: Date</p> <p>Description: The date on which the scheduled visit that contains the form should occur.</p> <p>Date type: System date (GMT).</p>
Form's Visit Data Entry Date	<p>Data type: Date/Time</p> <p>Description: The date on which data was first entered for the visit that contains the form.</p> <p>Date type: System date (GMT).</p>

Report element	Description
DOV	<p>Data type: Date/Time</p> <p>Description: The date that is recorded in a standard Date of Visit control in the InForm application.</p> <p>Data type: Clinical</p> <p>Note: This report element assumes that your study was developed using a specific design for the DOV controls.</p> <p>UIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674
Started Date	<p>Data type: Date/Time</p> <p>Description: The date on which the form was started.</p> <p>Date type: System date (GMT).</p>
Complete Date	<p>Data type: Date/Time</p> <p>Description: The date on which the form was completed. Counts forms that are expected and meet the following criteria:</p> <ul style="list-style-type: none"> • Are started. • Contain data for all required items. <p>Date type: System date (GMT).</p>
Deleted Date	<p>Data type: Date/Time</p> <p>Description: The date on which the form was deleted.</p> <p>Date type: System date (GMT).</p>
First Frozen Date	<p>Data type: Date/Time</p> <p>Description: The date on which the status of the form was first set to Frozen. A form is frozen if it has been frozen using any of these InForm features:</p> <ul style="list-style-type: none"> • Freeze CRF • Freeze CRB • Freeze Visit <p>This report element retrieves only those dates for forms frozen at the form or visit level. It does not retrieve a first frozen date for forms that were frozen at the case book level.</p> <p>Date type: System date (GMT).</p>
Last Frozen Date	<p>Data type: Date/Time</p> <p>Description: The most recent date on which the status of the form was set to Frozen. This report element retrieves only those dates for forms that were frozen at the form or visit level. It does not retrieve a last frozen date for forms that were frozen at the case book level.</p> <p>Date type: System date (GMT).</p>

Report element	Description
First SV Ready Date	<p>Data type: Date/Time</p> <p>Description: The date on which the status of the form was first considered SV Ready.</p> <p>A form is considered SV Ready if it has a status of SV Ready, and is selected for source verification.</p> <p>A form has been selected for source verification if one of the following is true:</p> <ul style="list-style-type: none"> • The form contains one or more critical items. • The form is on the Critical Forms list. • The subject with which the form is associated is in the SV Pool. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject. <p>Date type: System date (GMT).</p>
Last SV Ready Date	<p>Data type: Date/Time</p> <p>Description: The most recent date on which the status of the form was set to SV Ready.</p> <p>A form is considered SV Ready if it has a status of SV Ready, and is selected for source verification.</p> <p>A form has been selected for source verification if one of the following is true:</p> <ul style="list-style-type: none"> • The form contains one or more critical items. • The form is on the Critical Forms list. • The subject with which the form is associated is in the SV Pool. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject. <p>Date type: System date (GMT).</p>
First SV Partial Date	<p>Data type: Date/Time</p> <p>Description: The date on which the form status was first set to SV Partial.</p> <p>A form is considered SV Partial if one of the following is true:</p> <ul style="list-style-type: none"> • The form contains unverified critical items. • The form is on the Critical Forms list, and contains unverified items that are marked SV Required. • The subject with which the form is associated is in the SV Pool, and the form contains unverified items that are marked SV Required. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject, and the form contains unverified items that are marked SV Required. <p>Date type: System date (GMT).</p>

Report element	Description
Last SV Partial Date	<p>Data type: Date/Time</p> <p>Description: The date on which the form was last considered SV Partial.</p> <p>A form is considered SV Partial if one of the following is true:</p> <ul style="list-style-type: none"> • The form contains unverified critical items. • The form is on the Critical Forms list, and contains unverified items that are marked SV Required. • The subject with which the form is associated is in the SV Pool, and the form contains unverified items that are marked SV Required. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject, and the form contains unverified items that are marked SV Required.
First SV Complete Date	<p>Date type: System date (GMT).</p> <p>Data type: Date/Time</p> <p>Description: The date on which the form was first considered Verified.</p> <p>A form is considered Verified if one of the following is true:</p> <ul style="list-style-type: none"> • The form does not contain critical items, and all items on the form that are marked SV Required are verified. • The form contains critical items, and all critical items on the form are verified. • The form is on the Critical Forms list, and all items on the form that are marked SV Required are verified. • The subject with which the form is associated is in the SV Pool, and all items marked SV Required are verified. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject, and all items marked SV Required are verified. <p>If none of the items on the form require source verification, the InForm application marks the form Verified.</p> <p>Date type: System date (GMT).</p>

Report element	Description
Last SV Complete Date	<p>Data type: Date/Time</p> <p>Description: The most recent date on which the form was marked Verified.</p> <p>A form is considered Verified if one of the following is true:</p> <ul style="list-style-type: none"> • The form does not contain critical items, and all items on the form that are marked SV Required are verified. • The form contains critical items, and all critical items on the form are verified. • The form is on the Critical Forms list, and all items on the form that are marked SV Required are verified. • The subject with which the form is associated is in the SV Pool, and all items marked SV Required are verified. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject, and all items marked SV Required are verified. <p>If none of the items on the form require source verification, the InForm application marks the form Verified.</p>
First Signed Date	<p>Date type: System date (GMT).</p> <p>Data type: Date/Time</p> <p>Description: The date on which the form was first signed.</p>
Last Signed Date	<p>Date type: System date (GMT).</p> <p>Data type: Date/Time</p> <p>Description: The date on which the form was last signed.</p>
First Locked Date	<p>Date type: System date (GMT).</p> <p>Data type: Date/Time</p> <p>Description: The date on which the form was first locked. This report element retrieves only those dates for forms that were locked at the form or visit level. It does not retrieve a first locked date for forms that were locked at the case book level.</p>
Last Locked Date	<p>Date type: System date (GMT).</p> <p>Data type: Date/Time</p> <p>Description: The date on which the form was last locked. This report element retrieves only those dates for forms that were locked at the form or visit level. It does not retrieve a last locked date for forms that were locked at the case book level.</p> <p>Date type: System date (GMT).</p>

Report element	Description
<i>Review state name</i> Date Changed	<p>Data type: Date/Time</p> <p>Description: The date on which the review state for the form was last updated.</p> <p>Date type: System date (GMT).</p> <p>Notes:</p> <p>You create custom review states and stages for the Data Viewer using the Central Designer application. You can define as many as five custom review states, and each custom review state must include three stages. If you do not define custom review states and stages for your study, the associated report elements do not appear in the Cognos Reporting interface tree. For more information, see the Central Designer <i>InForm Design Guide</i>.</p> <p>The <i>Review state name</i> Date report element contains study-specific clinical data. It only appears in the Form Dates folder for the Forms report topic if you select the study-specific clinical package on the Select a package page when accessing the Cognos Reporting interface workspace.</p>

Forms: Form Status by Month and Year

Forms: Form Status by Month and Year report elements let you create reports on form status by month. Use these report elements with form status counts to see the number of forms that were set to a particular status each month.

If the report is sorted by one of the Month/Year report elements. You can add the Form Count element to see how many forms were assigned a particular status in each month.

Report element	Description
Started Month, Year	<p>Data type: Date</p> <p>Description: Each month/year combination from the start of the study to present day. Use with the Form Count report element to see how many forms were started each month.</p> <p>Date type: System date (GMT), derived for display.</p>
Completed Month, Year	<p>Data type: Date/Time</p> <p>Description: Each month/year combination from the start of the study to present day. Use with the Form Count report element to see how many forms have been completed each month.</p> <p>Date type: System date (GMT), derived for display.</p>
Frozen Month, Year	<p>Data type: Date/Time</p> <p>Description: Each month/year combination from the start of the study to present day. Use with the Form Count report element to see how many forms were frozen each month.</p> <p>Date type: System date (GMT), derived for display.</p>

Report element	Description
SV Complete Month, Year	<p>Data type: Date/Time</p> <p>Description: Each month/year combination from the start of the study to present day. Use with the Form Count report element to see how many forms were source verified each month.</p> <p>A form is considered Verified if one of the following is true:</p> <ul style="list-style-type: none"> • The form does not contain critical items, and all items on the form that are marked SV Required are verified. • The form contains critical items, and all critical items on the form are verified. • The form is on the Critical Forms list, and all items on the form that are marked SV Required are verified. • The subject with which the form is associated is in the SV Pool, and all items marked SV Required are verified. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject, and all items marked SV Required are verified. <p>If none of the items on the form require source verification, the InForm application marks the form Verified.</p> <p>Date type: System date (GMT), derived for display.</p>
Signed Month, Year	<p>Data type: Date/Time</p> <p>Description: Each month/year combination from the start of the study to present day. Use with the Form Count report element to see how many forms were signed each month.</p> <p>Date type: System date (GMT), derived for display.</p>
Locked Month, Year	<p>Data type: Date/Time</p> <p>Description: Each month/year combination from the start of the study to present day. Use with the Form Count report element to see how many forms were locked each month.</p> <p>Date type: System date (GMT), derived for display.</p>

Forms: Aging

Forms: Aging report elements allow you to report on how long forms have been in an incomplete state.

Report element	Description
Days Incomplete from DOV	<p>Data type: Numeric</p> <p>Description: The number of days the status of an incomplete form has been incomplete, beginning with the recorded date of visit.</p> <p>How calculated: This calculation begins on the recorded date of visit on the form and ends on the most recent date that the status of the form was set to Incomplete.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Days Incomplete from Started	<p>Data type: Numeric</p> <p>Description: The number of days the status of an incomplete form has been incomplete, beginning with the date on which the form was started.</p> <p>How calculated: This calculation begins on the date the form was started and ends on the most recent date that the status of the form was set to Incomplete.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Forms: Cycle Times

Forms: Cycle times report elements let you report on the amount of time it takes for forms to move from one state to another. These elements may return a specific value or an average, depending on other elements used in your report.

Report element	Description
DOV to Form Started	<p>Data type: Numeric</p> <p>Description: The number of days from the recorded date of visit to when the form was started.</p> <p>Note: The date entered on the DOV form could be different from the date of data entry recorded in the database. The date that is entered on the DOV form will most commonly reflect the time zone for the site, and the date of data entry that is recorded in the database is in UTC.</p> <p>How calculated: This calculation begins on the recorded date of visit for the form and ends on the date when the form status was set to Started.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p> <p>Note: This report element assumes that your study was developed using a specific design for the DOV controls.</p>

Report element	Description
Started to Complete	<p>Data type: Numeric</p> <p>Description: The number of days from when the form was started to when it was completed.</p> <p>How calculated: This calculation begins on the date when the form status was set to Started and ends on the most recent date when the form status was set to Complete. Counts forms that are expected and meet the following criteria:</p> <ul style="list-style-type: none"> • Are started. <p>Contain data for all required items.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Complete to Frozen	<p>Data type: Numeric</p> <p>Description: The number of days from when a form was completed to when it was frozen.</p> <p>How calculated: This calculation begins on the first date when the form status was set to Complete and ends on the most recent date when the form status was set to Frozen.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Complete to SV Ready	<p>Data type: Numeric</p> <p>Description: The number of days from when a form was completed to when it became SV Ready.</p> <p>How calculated: This calculation begins on the first date when the form status was set to Complete and ends on the most recent date when the form status was set to SV Ready.</p> <p>A form is considered SV Ready if it has a status of SV Ready, and is selected for source verification.</p> <p>A form has been selected for source verification if one of the following is true:</p> <ul style="list-style-type: none"> • The form contains one or more critical items. • The form is on the Critical Forms list. • The subject with which the form is associated is in the SV Pool. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Report element	Description
Complete to SV Complete	<p>Data type: Numeric</p> <p>Description: The number of days from when a form was completed to when it became verified.</p> <p>How calculated: This calculation begins on the first date when the form status was set to Complete and ends on the most recent date when the form status was set to Verified.</p> <p>A form is considered Verified if one of the following is true:</p> <ul style="list-style-type: none"> • The form does not contain critical items, and all items on the form that are marked SV Required are verified. • The form contains critical items, and all critical items on the form are verified. • The form is on the Critical Forms list, and all items on the form that are marked SV Required are verified. • The subject with which the form is associated is in the SV Pool, and all items marked SV Required are verified. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject, and all items marked SV Required are verified. <p>If none of the items on the form require source verification, the Oracle InForm application marks the form Verified.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Complete to Signed	<p>Data type: Numeric</p> <p>Description: The number of days from when a form was completed to when it was signed.</p> <p>How calculated: This calculation begins on the first date when the form status was set to Complete and ends on the most recent date when the form status was set to Signed.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Report element	Description
Signed to SV Complete	<p>Data type: Numeric</p> <p>Description: The number of days from when a form was signed to when it became verified.</p> <p>How calculated: This calculation begins on the first date when the form status was set to Signed and ends on the most recent date when the form status was set to Verified.</p> <p>A form is considered Verified if one of the following is true:</p> <ul style="list-style-type: none"> • The form does not contain critical items, and all items on the form that are marked SV Required are verified. • The form contains critical items, and all critical items on the form are verified. • The form is on the Critical Forms list, and all items on the form that are marked SV Required are verified. • The subject with which the form is associated is in the SV Pool, and all items marked SV Required are verified. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject, and all items marked SV Required are verified. <p>If none of the items on the form require source verification, the Oracle InForm application marks the form Verified.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Report element	Description
SV Ready to SV Complete	<p>Data type: Numeric</p> <p>Description: The number of days from when a form became SV Ready to when it became verified.</p> <p>How calculated: This calculation begins on the first date when the form status was SV Ready and ends on the most recent date when the form status form was set to Verified.</p> <p>A form is considered SV Ready if it has a status of SV Ready, and is selected for source verification.</p> <p>A form has been selected for source verification if one of the following is true:</p> <ul style="list-style-type: none"> • The form contains one or more critical items. • The form is on the Critical Forms list. • The subject with which the form is associated is in the SV Pool. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject. <p>A form is considered Verified if one of the following is true:</p> <ul style="list-style-type: none"> • The form does not contain critical items, and all items on the form that are marked SV Required are verified. • The form contains critical items, and all critical items on the form are verified. • The form is on the Critical Forms list, and all items on the form that are marked SV Required are verified. • The subject with which the form is associated is in the SV Pool, and all items marked SV Required are verified. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject, and all items marked SV Required are verified. <p>If none of the items on the form require source verification, the Oracle InForm application marks the form Verified.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Report element	Description
Frozen to SV Complete	<p>Data type: Numeric</p> <p>Description: The number of days from when a form was frozen to when it became verified.</p> <p>How calculated: This calculation begins on the first date when the form was frozen and ends on the most recent date when the form status was set to Verified.</p> <p>A form is considered Verified if one of the following is true:</p> <ul style="list-style-type: none"> • The form does not contain critical items, and all items on the form that are marked SV Required are verified. • The form contains critical items, and all critical items on the form are verified. • The form is on the Critical Forms list, and all items on the form that are marked SV Required are verified. • The subject with which the form is associated is in the SV Pool, and all items marked SV Required are verified. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject, and all items marked SV Required are verified. <p>If none of the items on the form require source verification, the Oracle InForm application marks the form Verified.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Report element	Description
SV Complete to Signed	<p>Data type: Numeric</p> <p>Description: The number of days from when a form became verified to when it was signed.</p> <p>How calculated: This calculation begins on the first date when the form status was set to Verified and ends on the most recent date when the form was signed.</p> <p>A form is considered Verified if one of the following is true:</p> <ul style="list-style-type: none"> • The form does not contain critical items, and all items on the form that are marked SV Required are verified. • The form contains critical items, and all critical items on the form are verified. • The form is on the Critical Forms list, and all items on the form that are marked SV Required are verified. • The subject with which the form is associated is in the SV Pool, and all items marked SV Required are verified. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject, and all items marked SV Required are verified. <p>If none of the items on the form require source verification, the Oracle InForm application marks the form Verified.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Signed to Locked	<p>Data type: Numeric</p> <p>Description: The number of days from when a form was signed to when it was locked.</p> <p>How calculated: This calculation begins on the first date when the form status was set to Signed and ends on the most recent date when the form status was set to Locked.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Complete to Locked	<p>Data type: Numeric</p> <p>Description: The number of days from when a form was completed to when it was locked.</p> <p>How calculated: This calculation begins on the first date the form became complete and ends on the most recent date when the form status was set to Locked.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Section report elements

Forms in your study may be designed in sections. Section report elements let you report on these form sections in study design.

- [Sections](#)
- [Sections: Properties](#)

Sections

Section report elements let you report on sections of forms in your study.

Report element	Description
Section Title	<p>Data type: String</p> <p>Description: The title of a section in a form, as specified in the study design code.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Sections: Properties

Sections: Properties report elements return information about the properties associated with sections.

Report element	Description
Grid Itemset	<p>Data type: Y/N</p> <p>Description: Specifies whether the section contains a Repeating Data itemset. Valid values are:</p> <ul style="list-style-type: none"> • Y—The section contains a Repeating Data itemset. • N—The section does not contain a Repeating Data itemset. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>
Initial Row Count	<p>Data type: Numeric</p> <p>Description: Counts the initial number of rows in the itemset.</p> <ul style="list-style-type: none"> • 0—If the section contains an Add Entry itemset. • NULL—If the section does not contain an itemset. • n—If the section contains a Repeating Data itemset, displays the number of rows in the itemset. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Item report elements

The Items report topic contains elements and measures that provide metrics and status information about items on forms in the study. Use this report topic to include counts of

different item types, information about item properties, and information on when items were initially created and changed.

- Items may be set to some states more than one time. For these states, First and Last date report elements appear in the Cognos Reporting tree. Use these report elements to identify when an item moved from one state to another, as follows:
 - Use Last dates to determine the current status for an item and the date on which the status change occurred.
 - Use the First and Last dates together to identify items that were, but are no longer in a given state. You can also use these dates to identify items that changed after being assigned a given state. For example, you can compare the Last Modified Date to the Last SV date to see whether the form was changed after it was last source verified.
- If an item has been in a particular state only one time, the First and Last dates for that state display the same date.
- If an item has never been assigned a particular status, the columns for the First and Last dates for that state do not contain data.
- [Items](#)
- [Items: Item Properties](#)
- [Items: Item Counts by Property](#)
- [Items: Item Status Counts](#)
- [Items: Item Dates](#)

Items

Items report elements return metrics on the items in your study.

Report element	Description
Item Name	<p>Data type: String</p> <p>Description: The itemset header text, as specified in the study design code. Access to this data can be restricted in the Oracle InForm application. When users who do not have access to this data run a report with this report element, the resulting report displays a series of asterisks (*****) rather than the actual itemset header text.</p> <p>Oracle InForm items that have never had data will not appear on reports that pair Item Name with Form Mnemonic or Form Name.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Report element	Description
Item Question	<p>Data type: String</p> <p>Description: Text of the question or prompt that instructs the user to enter specific clinical data. Access to this data can be restricted in the Oracle InForm application. When users who do not have access to this data run a report with this report element, the resulting report displays a series of asterisks (*****) rather than the actual item question.</p> <p>Oracle InForm items that have never contained data will not appear on reports that pair Item Question with Form Name or Form Mnemonic.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Reason for Change	<p>Data type: String</p> <p>Description: Text that explains the reason for the most recent clinical data change (if any) for the item. Text appears here only when the clinical data for the item has been changed since initial entry.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Incomplete Reason	<p>Data type: String</p> <p>Description: Text that explains why the item was marked Incomplete. Text appears here only when the item has been marked Incomplete. Use this report element with the Subject Number report element to see incomplete reason text broken out by subject.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Status Change User	<p>Data type: String</p> <p>Description: The user name of the Oracle InForm user who made the most recent change to the status of the item. A change to the SV status of the item is considered a status change for the item.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Data Change User	<p>Data type: String</p> <p>Description: The user name of the Oracle InForm user who made the most recent change to the item.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Items: Item Properties

Items: Item Properties report elements let you report on types of items.

Report element	Description
Is Required	<p>Data type: Y/N</p> <p>Description: Indicates whether the item requires a value for the form to be considered data entry complete. Valid values are:</p> <ul style="list-style-type: none">• Y—The item is required.• N—The item is not required. <p>Note: Itemset items cannot be required.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>
Is SV Required	<p>Data type: Y/N</p> <p>Description: Indicates whether the item requires source verification.</p> <ul style="list-style-type: none">• Y—The item requires InForm source verification.• N—The item does not require source verification. <p>An item is considered SV Required only if it is marked SV Required.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>
Is SV Selected	<p>Data type: Y/N</p> <p>Description: Indicates whether the item has been selected for source verification.</p> <ul style="list-style-type: none">• Y—The item has been selected for source verification.• N—The item has not been selected for source verification. <p>An item has been selected for source verification if one of the following is true:</p> <ul style="list-style-type: none">• The item is marked SV Required and SV Critical.• The form on which the item exists is on the Critical Forms list.• The subject with which the item is associated is part of the SV Pool.• The subject with which the item is associated is not part of the SV Pool, but the item is marked critical for that subject. <p>Data source: Replicated from the InForm transactional database to the Reporting and Analysis database and decoded for display.</p>

Report element	Description
Is Critical Override	<p>Data type: Y/N</p> <p>Description: Indicates whether the critical setting for the item in the study design was overridden using the Oracle Central Designer application or the InForm user interface.</p> <ul style="list-style-type: none"> • Y—The critical setting for the item in the study design was overridden using the Oracle Central Designer application or the Oracle InForm user interface. • N—The critical setting for the item in the study design was not overridden using the Oracle Central Designer application or the Oracle InForm user interface. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>
Is Blank	<p>Data type: Y/N</p> <p>Description: Indicates whether the item is blank.</p> <ul style="list-style-type: none"> • Y—The item is in a Repeating Data itemset and is blank. • N—The item is in a Repeating Data itemset and is not blank, or the item is not in a Repeating Data itemset. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>

Items: Item Counts by Property

Items: Item Counts by Property report elements let you report item totals based on their design characteristics.

Note:

All item counts include only items that have at one time contained clinical data. These counts do not include items for which clinical data has never been entered.

Report element	Description
Required	<p>Data type: Y/N</p> <p>Description: Indicates whether the item is required.</p> <ul style="list-style-type: none"> • Y—A value must be entered for the item. • N—Data entry is not required for the item. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Report element	Description
SV Required	<p>Data type: Numeric</p> <p>Description: The total number of items that require source verification and have ever contained clinical data.</p> <p>How calculated: Counts items that:</p> <ul style="list-style-type: none"> • Are marked SV Required. • Contain (or have ever contained) clinical data. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Calculated	<p>Data type: Numeric</p> <p>Description: The total number of calculated items, as specified in the study design code.</p> <p>How calculated: Counts items that:</p> <ul style="list-style-type: none"> • Have the item property set as a calculated control. • Have ever contained clinical data. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Blank	<p>Data type: String</p> <p>How calculated:</p> <ul style="list-style-type: none"> • For a Repeating Data itemset, counts the number of blank items in the itemset. • For an item, indicates whether the item is blank, as designed in the study. <ul style="list-style-type: none"> – 0—Item is not in a Repeating Data itemset, or is in a Repeating Data itemset, but is not blank. – 1—Item is in a Repeating Data itemset, and is blank. <p>Data source: Replicated from the InForm transactional database to the Reporting and Analysis database.</p>
SV Selected	<p>Data type: Numeric</p> <p>How calculated: Counts items that have been selected for source verification.</p> <p>An item has been selected for source verification if one of the following is true:</p> <ul style="list-style-type: none"> • The item is marked SV Required and SV Critical. • The form on which the item exists is on the Critical Forms list. • The subject with which the item is associated is part of the SV Pool. • The subject with which the item is associated is not part of the SV Pool, but the item is marked critical for that subject. <p>Data source: Replicated from the InForm transactional database to the Reporting and Analysis database and decoded for display.</p>

Items: Item Status Counts

Items: Item Status Counts return totals of items (relative to the number of subjects) in various states.

Report element	Description
Item Count	<p>Data type: Numeric</p> <p>Description: The total number of items, relative to the subjects participating in the study.</p> <p>How calculated: Counts each item for each subject if it contains (or ever has contained) clinical data.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Empty	<p>Data type: Numeric</p> <p>Description: The total number of items that currently have no data.</p> <p>How calculated: Counts items for each subject if both of the following are true:</p> <ul style="list-style-type: none"> • The item currently contains no clinical data. • The item contained clinical data at one time. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Source Verified	<p>Data type: Numeric</p> <p>Description: The total number of items with a current status of Verified.</p> <p>How calculated: Counts items that have a current status of Verified.</p> <p>Data source: Replicated from the InForm transactional database to the Reporting and Analysis database.</p>
Marked Incomplete	<p>Data type: Numeric</p> <p>Description: The total number of items that are currently marked Incomplete.</p> <p>How calculated: Counts items that have comments with an Incomplete Reason of Not Done, Not Applicable, or Unknown.</p> <p>Data source: Replicated from the InForm transactional database to the Reporting and Analysis database.</p>
Deleted	<p>Data type: Numeric</p> <p>Description: The total number of items that have been deleted in the InForm application.</p> <p>How calculated: Counts items that are add-entry items and have been removed.</p> <p>Data source: Replicated from the InForm transactional database to the Reporting and Analysis database.</p>

Report element	Description
Has Item Comment	<p>Data type: Numeric</p> <p>Description: The total number of items that have had an item-level comment associated with them.</p> <p>How calculated: Counts items that:</p> <ul style="list-style-type: none"> • Have item-level comments (item-level comments are manually entered by user). • Are marked Not Done (item-level comments are autogenerated). <p>Data source: Replicated from the InForm transactional database to the Reporting and Analysis database.</p>
Has Query	<p>Data type: Numeric</p> <p>Description: The total number of items that have at least one associated open query.</p> <p>How calculated: Counts items that have at least one associated open query. Does not count items whose only associated query is a candidate query.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Source Verified Targeted	<p>Data type: Numeric</p> <p>How calculated: Counts items that have been source verified and have been selected for source verification.</p> <p>An item has been selected for source verification if one of the following is true:</p> <ul style="list-style-type: none"> • The item is marked SV Required and SV Critical. • The form on which the item exists is on the Critical Forms list. • The subject with which the item is associated is part of the SV Pool. • The subject with which the item is associated is not part of the SV Pool, but the item is marked critical for that subject. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Items: Item Dates

Items: Item Dates report elements let you report on when items were completed and modified.

Report element	Description
Original Value Date	<p>Data type: Date</p> <p>Description: The date on which data was originally entered into the item.</p> <p>Date type: System date (GMT).</p>
Last Modified Date	<p>Data type: Date</p> <p>Description: The date on which data was most recently entered into the item.</p> <p>Date type: System date (GMT).</p>

Report element	Description
First SV Date	<p>Data type: Date</p> <p>Description: The date on which the item was first source verified. An item is considered source verified if it is in the Verified state.</p> <p>Date type: System date (GMT).</p>
Last SV Date	<p>Data type: Date</p> <p>Description: The most recent date on which the item was source verified. An item is considered source verified if it is in the Verified state.</p> <p>Date type: System date (GMT).</p>

Rule report elements

Rule report elements and measures allow you to create reports using information about rules that are attached to the study. Use this report topic to include information about rule types and the number of times rules have been triggered.

- [Rules](#)

Rules

Rules report elements return information on rules in your study.

Report element	Description
Rule Item RefName	<p>Data type: String</p> <p>Description: The name that uniquely identifies the item to which the rule is attached in the study design code. This corresponds to the Short Question in the Oracle Central Designer application or Itemset Column Header in the Oracle InForm application. Access to this data can be restricted in the Oracle InForm application. When users who do not have access to this data run a report with this report element, the resulting report displays a series of asterisks (*****) rather than the actual text.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Rule RefName	<p>Data type: String</p> <p>Description: The name that uniquely identifies the rule in the study design code. This is the rule RefName.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Report element	Description
Rule Description	<p>Data type: String</p> <p>Description: Description of the rule.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Rule Type	<p>Data type: String</p> <p>Description: The type of rule. Valid values are:</p> <ul style="list-style-type: none"> • Server Rule—Executes on the server. • Browser Rule—Executes on the browser. Two browser-side rule activities are supported in the Oracle InForm application: <ul style="list-style-type: none"> – Checks for text entries in a numeric field or numeric entries in an alphabetic field. – Smart controls, which provide automatic selection of radio buttons and checkboxes when a user enters or selects a value in an associated text control or list. • Server Calc Rule—Provides the result for a calculated control whose value is based on the value of one or more other items. • Server conversion—Converts units from one standard to another standard. • Server Rand Rule—Determines the randomized drug kit number to assign in a calculated control. • Clintrialderivation—Used in a Clintrial study to provide the result for a derived data item whose value is based on the value of one or more other items in the Clintrial database. • Clintrialrule—Used in a Clintrial study. • Workflow—Determines the visit or form to which a subject progresses next. A workflow rule prevents study objects in the workflow from appearing until the rule is evaluated. • Global Condition—Determines whether a visit, form, or item appears for a subject. A global condition does not affect other study objects in the workflow. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Query report elements

Query report elements allow you to include information about the queries that have been issued against clinical data. Use these report elements to see query text and type, to gather counts on manual and automatic queries, and to see query status.

- [Queries](#)
- [Queries: Properties](#)
- [Queries: Query Counts](#)
- [Queries: Query Dates](#)

- [Queries: Query Status by Month, Year](#)
- [Queries: Cycle Times](#)
- [Queries: Aging](#)

Queries

Query report items return identifying information about queries and status.

Report element	Description
Query Text	<p>Data type: String</p> <p>Description: The selected reason or entered text when a query was issued against an item.</p> <p>If the query state is Open, Answered, or Closed, this element returns the text that is associated with the last time the query was opened. If the query is a candidate query, this element returns the text that is associated with the last candidate query.</p> <p>For automatic queries, query text is defined in the rule that triggers the query. Therefore, query text for automatic queries will be consistent. For manual queries, the query text reflects what an Oracle InForm user entered when issuing the query. Therefore, query text for manual queries will vary.</p> <p>Access to this data can be restricted in the Oracle InForm application. When users who do not have access to this data run a report with this report element, the data is blinded in the resulting report.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Query Response	<p>Data type: String</p> <p>Description: The text for the most recent query response. This text is entered when the query is answered. If the query is reopened after it is answered, the resulting column is blank in the report.</p> <p>Access to this data can be restricted in the Oracle InForm application. When users who do not have access to this data run a report with this report element, the data is blinded in the resulting report.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Query Closure Text	<p>Data type: String</p> <p>Description: The text that was entered when the query was closed.</p> <p>Access to this data can be restricted in the Oracle InForm application. When users who do not have access to this data run a report with this report element, the data is blinded in the resulting report.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Report element	Description
Query Status	<p>Data type: String</p> <p>Description: The current status of the query. Valid values are:</p> <ul style="list-style-type: none"> • Open • Answered • Closed • Candidate • Deleted <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>
Originating User	<p>Data type: String</p> <p>Description: The user name of the user who first entered the query. If the query has been reissued, this report element returns the user name of the user who reissued the query.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Queries: Properties

Queries: Properties report elements let you report on different types of queries.

Report element	Description
Query Type	<p>Data type: String</p> <p>Description: The type of query. Valid values are:</p> <ul style="list-style-type: none"> • Automatic—An automatic query is a query that the Oracle InForm application automatically generates when a rule in the study design detects a discrepancy in entered data. • Manual—A manual query is a query that an Oracle InForm user enters. • Conflict—A conflict query is a query that the Oracle InForm application automatically generates when it detects a discrepancy between different copies of the same study when users synchronize them, or that is entered in the Oracle InForm Adapter query interface. This query type exists only when the Oracle InForm application is used with the CIS application. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>

Report element	Description
Is Automatic	<p>Data type: Y/N</p> <p>Description: Indicates whether the Oracle InForm application automatically generated the query. Valid values are:</p> <ul style="list-style-type: none"> • Y—The query is automatic. • N—The query is either a manual or conflict query. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>
Is Manual	<p>Data type: Y/N</p> <p>Description: Indicates whether an Oracle InForm user entered the query manually. Valid values are:</p> <ul style="list-style-type: none"> • Y—The query is manual. • N—The query is either an automatic or a conflict query. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>

Queries: Query Counts

Queries: Query Counts report elements return totals of different types of queries.

Report element	Description
Query Count	<p>Data type: Numeric</p> <p>Description: The number of unique queries, regardless of status or type.</p> <p>How calculated: Counts all queries that have ever been triggered, regardless of status and type.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Automatic	<p>Data type: Numeric</p> <p>Description: The number of queries that the InForm application automatically generates.</p> <p>How calculated: Counts all automatic queries that have ever been triggered, regardless of status. An automatic query is a query that the InForm application automatically generates when a rule in the study design detects a discrepancy in entered data.</p> <p>This calculation does not include manual or conflict queries.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Report element	Description
Manual	<p>Data type: Numeric</p> <p>Description: The number of queries entered manually by InForm users.</p> <p>How calculated: Counts all manual queries that have ever been triggered, regardless of status. A manual query is a query that an InForm user enters. This calculation does not include automatic or conflict queries.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Conflict	<p>Data type: Numeric</p> <p>Description: The number of conflict queries that have ever been triggered.</p> <p>How calculated: Counts all conflict queries that have ever been triggered, regardless of status. A conflict query is a query that the InForm application automatically generates when it detects a discrepancy between different copies of the same study when users synchronize them, or that is entered in the InForm Adapter query interface. This query type exists only when the InForm application is used with the CIS application.</p> <p>This calculation does not include automatic or manual queries.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Candidate	<p>Data type: Numeric</p> <p>Description: The number of queries with a current status of Candidate.</p> <p>How calculated: Counts queries with a current status of Candidate, regardless of query type.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Open	<p>Data type: Numeric</p> <p>Description: The number of queries with a current status of Open.</p> <p>How calculated: Counts queries with a current status of Open, regardless of query type. Note that this total includes queries that have been reissued and are currently open.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p> <p>Note: To see the total number of newly opened queries, create a calculation that subtracts the number of reissued queries from the number of open queries.</p>

Report element	Description
Reissued	<p>Data type: Numeric</p> <p>Description: The number of currently open queries that were reissued.</p> <p>How calculated: Counts all reissued queries that are currently open. A query is reissued if it has been answered and then re-opened.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Answered	<p>Data type: Numeric</p> <p>Description: The number of queries with a current status of Answered.</p> <p>How calculated: Counts queries with a current status of Answered, regardless of query type.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Deleted	<p>Data type: Numeric</p> <p>Description: The number of queries with a current status of Deleted.</p> <p>How calculated: Counts queries with a current status of Deleted, regardless of query type.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Closed	<p>Data type: Numeric</p> <p>Description: The number of queries with a current status of Closed.</p> <p>How calculated: Counts queries with a current status of Closed, regardless of query type.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Status Changes	<p>Data type: Numeric</p> <p>Description: The number of state changes for a query.</p> <p>How calculated: Counts each status change for each triggered query. This count includes the initial entry of the query.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Queries: Query Dates

Query Dates report elements let you report query activity by date. You can also use this information to calculate how long queries have been in a particular state.

Report element	Description
Query Status Date	<p>Data type: Date</p> <p>Description: The date when a query was assigned its current status in the Oracle InForm application.</p> <p>Date type: System date (GMT).</p>

Report element	Description
First Candidate Date	Data type: Date Description: The date when the query was first issued a Candidate status. Date type: System date (GMT).
Last Candidate Date	Data type: Date Description: The date when the query was last issued a Candidate status. Date type: System date (GMT).
Opened Date	Data type: Date Description: The date when the query was first opened in the Oracle InForm application. Date type: System date (GMT).
First Reissued Date	Data type: Date Description: The date when the query was first reissued. Date type: System date (GMT).
Last Reissued Date	Data type: Date Description: The date when the query was last reissued. Date type: System date (GMT).
First Answered Date	Data type: Date Description: The date when the query was first answered. Date type: System date (GMT).
Last Answered Date	Data type: Date Description: The date when the query was last answered. Date type: System date (GMT).
Closed Date	Data type: Date Description: The date when the query was closed. Date type: System date (GMT).

Queries: Query Status by Month, Year

Queries: Query Status by Month, Year report elements let you create reports on query status by month. Use this report element with query counts to see the number of queries that were set to a particular status each month.

If the report is sorted by one of the Month/Year report elements, the resulting report displays each month within a specified range. You can then add the Query Count element to see how many queries were assigned a particular status in each month.

Report element	Description
Query Status, Month, Year	<p>Data type: Date/Time</p> <p>Description: Each month/year combination within a specified range. Use with the Query Count report element to see how many queries were opened each month.</p> <p>Date type: System date (GMT), derived for display.</p>
Opened Month, Year	<p>Data type: Date/Time</p> <p>Description: Each month/year combination within a specified range. Use with the Query Count report element to see how many queries were opened each month.</p> <p>Date type: System date (GMT), derived for display.</p>
Answered Month, Year	<p>Data type: Date/Time</p> <p>Description: Each month/year combination within a specified range. Use with the Query Count report element to see how many queries were answered each month.</p> <p>Date type: System date (GMT), derived for display.</p>
Closed Month, Year	<p>Data type: Date/Time</p> <p>Description: Each month/year combination within a specified range. Use with the Query Count report element to see how many queries were closed each month.</p> <p>Date type: System date (GMT), derived for display.</p>

Queries: Cycle Times

Queries: Query Cycle Times report elements let you report on how long it takes for queries to move from one state to another.

Report element	Description
Days Opened to Answered	<p>Data type: Numeric</p> <p>Description: The number of days from when a query was first opened to the last time it was answered.</p> <p>How calculated: The calculation begins on the first day when the status of a query was set to Open and ends on the most recent day when the status of a query was set to Answered. This value is calculated in multiples of 24 (hours) and is rounded down to the nearest whole number.</p> <p>For example, if a query is opened on day 1 at 10 AM and answered on day 3 at 9 AM, the Open to Answered value is 2 days.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Report element	Description
Days Opened to Closed	<p>Data type: Numeric</p> <p>Description: The number of days from when a query was first opened to last time it was closed.</p> <p>How calculated: The calculation begins on the first day when the status of a query was set to Open and ends on the most recent day when the status of a query was set to Closed. This value is calculated in multiples of 24 (hours) and is rounded down to the nearest whole number.</p> <p>For example, if a query is opened on day 1 at 10 AM and closed on day 3 at 9 AM, the Answered to Closed value is 2 days.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Days Answered to Closed	<p>Data type: Numeric</p> <p>Description: The number of days from when a query was last answered to the last time it was closed.</p> <p>How calculated: The calculation begins on the first day when the status of a query was set to Answered and ends on the most recent day when the status of a query was set to Closed. This value is calculated in multiples of 24 (hours) and is rounded down to the nearest whole number.</p> <p>For example, if a query is answered on day 1 at 10 AM and closed on day 3 at 9 AM, the Answered to Closed value is 2 days.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Queries: Aging

Queries: Aging report elements let you report the length of time that queries have been in particular states.

Report element	Description
Days Candidate	<p>Data type: Numeric</p> <p>Description: The number of days a candidate query has been in the Candidate state.</p> <p>How calculated: This calculation only applies to queries that currently have a Candidate status. The returned value is either an exact count or an average, depending on other elements in the report.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Report element	Description
Days Open	<p>Data type: Numeric</p> <p>Description: The number of days an open query has been in the Open state.</p> <p>How calculated: This calculation only applies to queries that currently have an Open status, including reissued queries. The returned value is either an exact count or an average, depending on other elements in your report. The calculation begins on the last date when a query had a status of Open and ends on the current date. The number of days is always rounded to the nearest whole number.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Days Answered	<p>Data type: Numeric</p> <p>Description: The number of days an answered query has been in the Answered state.</p> <p>How calculated: This report element returns values only for those queries that currently have an Answered status. The returned value is either an exact count or an average, depending on other elements in your report. The calculation begins on the last date when a query had a status of Answered, and ends on the current date. The number of days is always rounded to the nearest whole number.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Comment report elements

Comment report elements allow you to report on comments in your study. You can report on both item-level and form-level comments.

- [Comments](#)

Comments

Report element	Description
Comment Date	<p>Data type: Date</p> <p>Description: The date when the comment was entered in the Oracle InForm application.</p> <p>Data source: Entered in the InForm application.</p>
Comment Text	<p>Data type: String</p> <p>Description: The comment text (limited to 255 characters).</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Report element	Description
Comment Type	<p>Data type: Text</p> <p>Description: The comment type. Valid values are:</p> <ul style="list-style-type: none"> • Form—The comment is a form-level comment. • Item—The comment is an item-level comment. <p>Data source: Derived for the report; not stored in the Reporting and Analysis database. Database value decoded for display.</p>
Comment Count	<p>Data type: Numeric</p> <p>Description: The number of comments.</p> <p>How calculated: Counts all item-level and form-level comments.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Item Count	<p>Data type: Numeric</p> <p>Description: The number of item-level comments only. Item comments can be manually entered by an Oracle InForm user or automatically generated when an item is marked Incomplete.</p> <p>How calculated: Counts item-level comments only. Does not count form-level comments.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Form Count	<p>Data type: Numeric</p> <p>Description: The number of form-level comments only.</p> <p>How calculated: Counts form-level comments only. Does not count item-level comments.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

User Info report elements

In this section:

- [User Info: Users](#)
- [User Info: Group Associations](#)
- [User Info: Historical User Info](#)

User Info: Users

User Info report elements allow you to gather information on your InForm users. Many of these elements are optional in your study design; report elements may return blank values.

Report element	Description
User Name	<p>Data type: String</p> <p>Description: The user name of the Oracle InForm user.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
First Name	<p>Data type: String</p> <p>Description: The first name of the Oracle InForm user.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Last Name	<p>Data type: String</p> <p>Description: The last name of the Oracle InForm user.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Title	<p>Data type: String</p> <p>Description: The job title of the Oracle InForm user.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Description	<p>Data type: String</p> <p>Description: Text that describes details about the Oracle InForm user. If no description has been entered for the user, this column does not contain any data.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Rights Group	<p>Data type: String</p> <p>Description: The Oracle InForm rights group to which the Oracle InForm user belongs.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Email	<p>Data type: String</p> <p>Description: The email address of the Oracle InForm user.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Phone	<p>Data type: String</p> <p>Description: The phone number of the Oracle InForm user.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Report element	Description
User Count	<p>Data type: Numeric</p> <p>Description: The number of Oracle InForm users.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
User Type	<p>Data type: String</p> <p>Description: The Oracle InForm user type.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>
Creation Date	<p>Data type: Date/Time</p> <p>Description: The date the user record was created in the Oracle InForm application.</p> <p>Date type: System date (GMT).</p>
Activation Date	<p>Data type: Date/Time</p> <p>Description: The date the user was activated in the Oracle InForm application.</p> <p>Date type: System date (GMT).</p>
User Status	<p>Data type: String</p> <p>Description: The current status of the Oracle InForm user. Valid values are:</p> <ul style="list-style-type: none"> • Active • Inactive • Terminated <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
User Status Date	<p>Data type: String</p> <p>Description: The date when the current status was assigned to the InForm user.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

User Info: Group Associations

Group Associations report elements let you report on the Oracle InForm groups with which users are associated.

Report element	Description
Group Name	<p>Data type: String</p> <p>Description: The Oracle InForm rights group to which the user belongs.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Report element	Description
Group Type	<p>Data type: String</p> <p>Description: The type of the group with which the Oracle InForm user is associated. Valid values are:</p> <ul style="list-style-type: none"> • Query • Signature • Reporting • ItemGroup • ManageUser <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

User Info: Historical User Info

Historical User Info report elements allow you to see status information and group membership changes for users.



Note:

To include the current first name, last name, and rights group for a user, use report elements from the User Info: Users folder.

There is also a standard report that shows the login history for a study within a selected date range.

For more information, see [Historical Oracle InForm Access Report](#).

Report element	Description
User ID	<p>Data type: String</p> <p>Description: The user ID of the Oracle InForm user whose status or group membership changed.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Change Type	<p>Data type: String</p> <p>Description: Displays the following text, describing the type of change the user has undergone:</p> <ul style="list-style-type: none"> • Group Change—The user has been added or removed from a group. • Status Change—The user has been activated, deactivated, terminated, or reinstated. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Report element	Description
Change Type Description	<p>Data type: String</p> <p>Description: Additional information about the type of change the user has undergone.</p> <ul style="list-style-type: none"> • If the Change Type is Group Change, one of the following appears: <ul style="list-style-type: none"> – Addition – Deletion • If the Change Type is Status Change, one of the following appears: <ul style="list-style-type: none"> – Created – Activated – Deactivated – Terminated – Reinstated <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Change Date	<p>Data type: Date/Time</p> <p>Description: Date and time when the user status or group membership change took place.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Change Username	<p>Data type: String</p> <p>Description: User name of the user who updated the status or group membership information for the user whose status or group membership changed.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Reason for Change	<p>Data type: String</p> <p>Description: The reason for the user status or group membership change, as generated by the Oracle InForm application.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Change Group Name	<p>Data type: String</p> <p>Description: For users whose group membership information changed, the group name to which the user was added or from which the user was removed.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p> <p>Note: If the user group membership information did not change, data does not appear in this column.</p>

Report element	Description
Change Group Type	<p>Data type: String</p> <p>Description: For users whose group membership information changed, the group type of the group to which the user was added or from which the user was removed.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p> <p>Note: If the user group membership information did not change, data does not appear in this column.</p>

Predefined filters

Use predefined filters to narrow results in your Cognos Reporting reports. These filters are shipped with the Oracle InForm application and can be used in all reports.



Note:

You can also create filters to be used within reports. Each user-created filter is saved with the report in which it was created. The filter can be used only with that report and cannot be used globally across multiple reports.

- [Filters](#)

Filters

Predefined filters let you limit your report to specific subjects, visits, and forms.

Filter	Description
All Enrolled Subjects	<p>Limits the report to subjects who have been enrolled in the study. The resulting report includes all active subjects who were ever enrolled in any of these states:</p> <ul style="list-style-type: none"> • Enrolled • Enroll Override • Randomized • Dropped Out • Complete
All Enrolled Subjects except Dropped	<p>Limits the report to subjects who were ever enrolled in the study, excluding those subjects who dropped out. The resulting report includes data about subjects in any of these states:</p> <ul style="list-style-type: none"> • Enrolled • Enroll Override • Randomized • Complete

Filter	Description
Active Subjects	Limits the report to active subjects; that is, all subjects who have been enrolled in the study, excluding those who have dropped out or completed the study. The resulting report includes data about subjects in any of these states: <ul style="list-style-type: none"> • Enrolled • Enroll Override • Randomized
Clinical Visit	Limits the report to data about only clinical, or subject, visits. Use this filter to include information only about clinical visits in your report. This filter excludes data for these visit types: <ul style="list-style-type: none"> • Screening • Enrollment • Reg Docs • Visit Report
Clinical Form	Limits the report to information on clinical forms (forms whose type is CRF). This filter excludes these types of forms: <ul style="list-style-type: none"> • Enrollment • Monitor RegDoc • Monitor Visit Report
Expected Forms: Scheduled Visits	Limits the report to those clinical forms that are expected because they appear in scheduled visits.
Expected Forms: Scheduled or Started Visits	Limits the report to expected forms that are expected because they appear in scheduled or started visits.
Expected Forms: Scheduled or Started Visits to Date	Limits the report to forms that are expected because they appear in visits that are scheduled to occur or have started by a particular date. (This filter prompts the report user to enter a date.)
Expected Forms: Scheduled Visits or Started Forms to Date	Limits the report to forms that have started by a given date or are expected because they appear in visits that are scheduled to occur by a given date. (This filter prompts the report user to enter a date.)
Data Complete (Queries Allowed)	Limits the report to forms that are data complete; that is, forms for which all required items have been completed. Note that this filter includes forms that have associated queries in any state.
Data Complete, No Open Queries	Limits the report to data for forms that are data complete; that is, forms for which all required items have been completed. This filter excludes forms that have associated open queries and candidate queries.
Data Clean: Complete and SV	Limits the report to forms that are data complete and clean. This filter includes forms for which: <ul style="list-style-type: none"> • All required items have been completed. • All SV Required items have been source verified using the Oracle InForm application. The filter excludes forms with open and answered queries associated with them.

Examples: Reporting on multi-instance forms and items

In this section:

- Example 1: One non-repeating section and one itemset
- Example 2: Incomplete non-repeating section and one itemset
- Example 3: Incomplete non-repeating section, one itemset, and an additional form
- Example 4: One non-repeating section with multiple itemsets
- Example 5: Incomplete non-repeating section with multiple itemsets

Example 1: One non-repeating section and one itemset

This example shows the report output for subjects AAA and AAB. In this example, the non-repeating section appears on a repeating form. Therefore, more than one instance of the non-repeating section exists in the study.

Subject Number from Flat portion >	Subject Initials	Form Index▲	Deleted Form	Treatment Name	Subject Initials from Itemset	Itemset Index▲	Deleted Itemset	Date ~ New Dose Start	New Dose
100	AAA	1	N	Treat1	AAA	1	N	Jan 13, 2006 12:00:00 AM	10
100	AAA	1	N	Treat1	AAA	2	N	Jan 27, 2006 12:00:00 AM	20
100	AAA	2	N	Treat2	AAA	1	N	Jan 26, 2006 12:00:00 AM	40
100	AAA	2	N	Treat2	AAA	2	N	Jan 25, 2006 12:00:00 AM	41
100	AAA	2	N	Treat2	AAA	3	N	Jan 26, 2006 12:00:00 AM	42
101	AAB	1	N	Treat5	AAB	1	N	Jan 12, 2006 12:00:00 AM	60
101	AAB	1	N	Treat5	AAB	2	N	Jan 27, 2006 12:00:00 AM	61

1—Data from the non-repeating section on each form for subjects AAA and AAB.

2—Data for the itemsets on each form for subjects AAA and AAB.

3—The Form Index column indicates that the non-repeating section appears on two forms for subject AAA, and one form for subject AAB.

4—The Itemset Index column indicates that:

- For subject AAA, the non-repeating section is associated with two itemset instances on Form 1 (rows 1 and 2), and three itemset instances on Form 2 (rows 3-5).
- For subject AAB, the non-repeating section is associated with two itemset instances on Form 1 only (rows 6 and 7).

Example 2: Incomplete non-repeating section and one itemset

This example shows the report output for subjects AAA, AAB, and AAC when the data in the non-repeating section is incomplete for subject AAC.

Subject Number from Flat portion^	Subject Initials	Form Index^	Deleted Form	Treatment Name	Subject Initials from Itemset	Itemset Index^	Deleted Itemset	Date ~ New Dose Start	New Dose
100	AAA	1	N	Treat1	AAA	1	N	Jan 13, 2006 12:00:00 AM	10
100	AAA	1	N	Treat1	AAA	2	N	Jan 27, 2006 12:00:00 AM	20
100	AAA	2	N	Treat2	AAA	1	N	Jan 26, 2006 12:00:00 AM	40
100	AAA	2	N	Treat2	AAA	2	N	Jan 25, 2006 12:00:00 AM	41
100	AAA	2	N	Treat2	AAA	3	N	Jan 26, 2006 12:00:00 AM	42
101	AAB	1	N	Treat5	AAB	1	N	Jan 12, 2006 12:00:00 AM	60
101	AAB	1	N	Treat5	AAB	2	N	Jan 27, 2006 12:00:00 AM	61
					AAC	1	N	Jan 6, 2006 12:00:00 AM	80
					AAC	2	N	Jan 25, 2006 12:00:00 AM	81

1—The Form Index column indicates that the non-repeating section appears on two forms for subject AAA, and one form for subject AAB. For subject AAC, the non-repeating section does not contain data. However, its associated itemsets for subject AAC appear in rows 8 and 9.

2—The Itemset Index column indicates that:

- For subject AAA, the non-repeating section is associated with two itemset instances on Form 1 (rows 1 and 2), and three itemset instances on Form 2 (rows 3-5).
- For subject AAB, the non-repeating section is associated with two itemset instances on Form 1 (rows 6 and 7).
- For subject AAC, the non-repeating section is associated with two itemset instances (rows 8 and 9).

3—For subject AAC, the non-repeating section that is associated with Itemset Instance 1 and Itemset Instance 2 does not contain data. Therefore, blank cells appear for the columns that correspond to the data for the non-repeating section.

Example 3: Incomplete non-repeating section, one itemset, and an additional form

This example shows the report output for subjects AAA, AAB, and AAC when the data in the non-repeating section is incomplete for subject AAC, and data from the Subject Identification (SI) form is included in the report.

For subjects AAA and AAB, the itemset data is associated with the data in the non-repeating section, and the data in the non-repeating section is associated with the data on the SI form. Therefore, in this instance, the itemset data is associated with the data on the SI form for subjects AAA and AAB. Because data is not entered in the non-repeating section for subject AAC, the data that exists for subject AAC on the SI form is not associated with the itemset data, and therefore does not appear in the report, even if data for subject AAC exists on the SI form.

Subject Number from Flat portion	Subject Number from SI form	Subject Initials	Form Index	Deleted Form	Treatment Name	Subject Initials from Itemset	Itemset Index	Deleted Itemset	Date ~ New Dose Start	New Dose
100	AAA	AAA	1	N	Treat1	AAA	1	N	Jan 13, 2006 12:00:00 AM	10
100	AAA	AAA	1	N	Treat1	AAA	2	N	Jan 27, 2006 12:00:00 AM	20
100	AAA	AAA	2	N	Treat2	AAA	1	N	Jan 26, 2006 12:00:00 AM	40
100	AAA	AAA	2	N	Treat2	AAA	2	N	Jan 25, 2006 12:00:00 AM	41
100	AAA	AAA	2	N	Treat2	AAA	3	N	Jan 26, 2006 12:00:00 AM	42
101	AAB	AAB	1	N	Treat5	AAB	1	N	Jan 12, 2006 12:00:00 AM	60
101	AAB	AAB	1	N	Treat5	AAB	2	N	Jan 27, 2006 12:00:00 AM	61
						AAC	1	N	Jan 6, 2006 12:00:00 AM	80
						AAC	2	N	Jan 25, 2006 12:00:00 AM	81

1—Non-repeating section data.

2—SI form data.

3—Non-repeating section data, continued.

4—For subject AAC, the non-repeating section that is associated with Itemset Instance 1 and Itemset Instance 2 does not contain data. Therefore, blank cells appear for the columns that correspond to the data for the non-repeating section, and the columns that correspond to the data for the SI form. An association cannot be made between the itemset data and the data on the SI form without data in the non-repeating section.

5—The Itemset Index column indicates that:

- For subject AAA, the non-repeating section is associated with two itemset instances on Form 1 (rows 1 and 2), and three itemset instances on Form 2 (rows 3-5).
- For subject AAB, the non-repeating section is associated with two itemset instances on Form 1 (rows 6 and 7).
- For subject AAC, the non-repeating section is associated with two itemset instances (rows 8 and 9).

6—The Form Index column indicates that the non-repeating section appears on two forms for subject AAA, and one form for subject AAB. For subject AAC, the non-repeating section does not contain data. Therefore, data from the SI form does not appear for subject AAC; however, the itemset instances associated with the non-repeating section for subject AAC appear in rows 8 and 9.

Example 4: One non-repeating section with multiple itemsets

This example shows the report output for subject TTT when data in the non-repeating section is associated with multiple itemsets.



Note:

No relationship exists between the itemsets.

Subject Number	Subject Initials	rdcSTDR ~ Is the subject currently on study drug Rivaroxaban Placebo	rdcSTDR2 ~ Is the subject currently on study drug Warfarin Placebo	Subject Initials	Itemset Index	Date ~ Stop date	Adverse Event Is this a serious Adverse Event ~ Reason	Subject Initials	Itemset Index	Date ~ Stop date	Is this a serious adverse event ~ Reason
200	TTT	Yes	Yes	TTT	1	Dec 28, 2010 12:00:00 AM	Yes. Bleeding or Non-Bleeding?	TTT	1	Dec 28, 2010 12:00:00 AM	Adverse Event
200	TTT	Yes	Yes	TTT	2	Dec 31, 2010 12:00:00 AM	Yes. Bleeding or Non-Bleeding?	TTT	2	Dec 29, 2010 12:00:00 AM	Adverse Event
200	TTT	Yes	Yes	TTT	3	Dec 17, 2010 12:00:00 AM	Yes. Bleeding or Non-Bleeding?				

1

2

3

1—Non-repeating section data.

2—Data for the first itemset that is associated with the non-repeating section. Three instances of the itemset exist in the study.

3—Data for the second itemset that is associated with the non-repeating section. Two instances of the itemset exist in the study.

Example 5: Incomplete non-repeating section with multiple itemsets

This example shows the report output for subjects BBA and AQW when data in a non-repeating section is complete for subject BBA, and incomplete for subject AQW.

- When the non-repeating section that is associated with an itemset is complete, the report contains the minimum number of rows required to display the data for each instance of each itemset.
- When the non-repeating section that is associated with an itemset does not contain data, or contains incomplete data, the report contains a separate row for each instance of each itemset.



Note:

No relationship exists between the itemsets.

Subject Number	Subject Initials from flat portion	Accession I (flat portion item)	Subject Initials from Itemset1	Itemset 1			Subject Initials from Itemset2	Itemset 2		
				Low	High	Itemset Index from Itemset1		Low	High	Itemset Index from Itemset2
300	BBA	I	BBA	10	20	1	BBA	100	101	1
300	BBA	I	BBA	11	12	2	BBA	110	111	2
300	BBA	I					BBA	115	117	3
301	AQW		AQW	200	201	1				
301	AQW		AQW	202	203	2				
301	AQW		AQW	204	205	3				
301	AQW						AQW	300	301	1
301	AQW						AQW	301	303	2

2

3

1—For subject BBA, all three items from the non-repeating section that appear in the report are complete, and data for five instances appears for two itemsets. Three instances of Itemset 1 exist, and two instances of Itemset 2 exist.

Because data in the non-repeating section is complete for subject BBA, the data for all five itemset instances appears in three rows in the report output. The data for the two instances of Itemset 1 and the first two instances of Itemset 2 appears in the first two rows, and the data for the additional instance of Itemset 2 appears in the third row.

2—For subject AQW, at least one of the three items that appear in the non-repeating section for the report is incomplete.

3—For subject AQW, data for five itemset instances appears for two itemsets. Three instances of Itemset 1 exist, and two instances of Itemset 2 exist.

Because the data from the non-repeating section that appears in the report is incomplete for subject AQW, the data for all five itemset instances appears in five rows in the report output, with each row corresponding to an itemset instance. The data for the three instances of Itemset 1 appears in the first three rows, and the data for the two instances of Itemset 2 appears in the last two rows.



Note:

If a non-repeating section contains incomplete data items, but the incomplete items are not included in the report, the report does not have a row for each instance of each itemset.

3

Oracle InForm standard reports

In this chapter:

- [About standard reports](#)
- [Tips for running standard reports](#)
- [Standard report column descriptions](#)

About standard reports

Oracle InForm includes a set of management reports that provide information about the progress of a study. These reports contain several categories of information, and several views of each report are available. For example, you can display the query status reports by site and by user; month by month or study-to-date; and in text or graphical formats. Standard reports are created using the Cognos Reporting application and are validated and optimized for InForm.

There are six categories of standard reports:

- Audit Trail Reports provide login history in your Oracle InForm studies.
- Case Report Form (CRF) Reports provide information about the progress of data entry and query activity on started case books.
- Item Reports provide information about the progress of item source verification, as well as listings of items on forms.
- Query Reports provide information about query aging, status, and cycle time.
- Study Administration Reports provide information about Oracle InForm study administration objects such as sites and rights groups.
- Subject Reports provide information on the progress of case book completion for individual subjects. These reports also provide subject enrollment and dropout counts, as well as subject enrollment status.

Tips for running standard reports

In this section:

- [Select the correct standard report formats](#)
- [Save large reports and run them locally](#)
- [Choose a clear naming convention for saved reports](#)
- [Save reports to the Team content folder sparingly](#)

Select the correct standard report formats

CSV, XML and Excel data formats are not supported for standard reports.

After you click the link for a report, you can select the format when you click the **Run as Options** menu for the report to specify additional options.

Save large reports and run them locally

If your report contains a lot of data, save the report and open it from your local machine.

Choose a clear naming convention for saved reports

To save a report, when you view a report, tap the **disk icon** or the **ellipsis icon**. The location of the save option depends on the type of report you view. You also have the **Save as** option of saving the report version under a different name or in a different location.

To avoid overwriting saved data, choose a naming convention that allows you to differentiate between the contents of different reports.

For example, name one report Report1, and name the other report Report1_WithData_<date report was created>.

Save reports to the Team content folder sparingly

When you save a report to the Team content folder, anyone with access to your reporting instance can see the data in the report, regardless of whether the user has the rights to see the data in Oracle InForm.

To protect study data, we recommend that you save reports to the Team content folder only when the reports contain data that can be shared with all users. If a report contains site-specific or subject-specific data, do not save it to the Team content folder.

Standard report column descriptions

In this section:

- [Audit Trail Reports](#)
- [Case Report Form \(CRF\) Reports](#)
- [Item Reports](#)
- [Query Reports](#)
- [Study Administration Reports](#)
- [Subject Reports](#)

Audit Trail Reports

In this section:

- [Historical Oracle InForm Access Report](#)

Historical Oracle InForm Access Report

This report shows the login history within a selected date range. There are also Cognos Reporting report topics that you can use to create a report that shows user status and group membership information.

For more information, see [User Info: Historical User Info](#)

Table 3-1 Column descriptions

Column	Description
Session Start Date/Time	<p>Data type: String</p> <p>Description: Session start date/time value. The data identifies when an SSO user logs into InForm (versus logging in to their SSO account).</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Username	<p>Data type: String</p> <p>Description: User name of the user.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
First name	<p>Data type: String</p> <p>Description: First name of the user.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Last name	<p>Data type: String</p> <p>Description: Last name of the user.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Country	<p>Data type: String</p> <p>Description: Country in which a user is located, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Rights Group	<p>Data type: String</p> <p>Description: Rights group to which the user belongs.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
User Type	<p>Data type: String</p> <p>Description: User type. For example, Sponsor.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Case Report Form (CRF) Reports

In this section:

- [CRF Aging by Site](#)
- [CRF Cycle Time Detail by Site](#)

- [CRF Cycle Time Detail for a Site](#)
- [CRF Frozen Status](#)
- [CRF Signature Status Report](#)
- [CRF Site Performance Summary by Site](#)
- [CRF Status Detail by Site and Subject](#)
- [CRF Status Detail by Visit and Site](#)
- [CRF Status Summary by Site](#)
- [CRF Status Summary by User](#)

CRF Aging by Site

This report shows:

- The number of forms that are expected at any point in the study.
- The number of forms that are incomplete.
- The length of time that incomplete forms have been incomplete, beginning with the date of visit.



Note:

This calculation relies on the use of the DOV controls specified in the form design.

CRAs use this report to stay current on the CRF activity within their site.

Subtotals and totals

- **Subtotals**—By Country.
- **Totals**—Overall form count totals.

Table 3-2 Column descriptions

Column	Description
Country	<p>Data type: String</p> <p>Description: The country in which a site is located, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Table 3-2 (Cont.) Column descriptions

Column	Description
Subject Count	<p>Data type: Numeric</p> <p>Description: The number of subjects who enrolled at the site.</p> <p>How calculated: For each site, counts subjects who enrolled at the site, including subjects who are currently assigned other states.</p> <p>Note: The Enrollment form, designed according to Oracle InForm specifications, must be completed for the subject.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Status is determined by the value on the Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p>
Form Counts: Expected	<p>Data type: Numeric</p> <p>Description: The number of expected forms in the study.</p> <p>How calculated: This number reflects the number of expected forms for the site based on the option selected for the Expected forms for filter on the report prompt page. For more information, see Form elements and expected forms.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Form Counts: Complete	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of completed forms, and the percentage of expected forms that are complete in the Oracle InForm application.</p> <p>How calculated: Counts forms that are expected and meet the following criteria:</p> <ul style="list-style-type: none"> • Are started. • Contain data for all required items. • For a repeating form, the form is not in a deleted state. • For an itemset form, the form is complete even if all the instances are deleted. <p>This value displays as a whole number and as a percentage of the total number of expected forms that are complete:</p> $[\text{completed, \% of expected}] = \frac{[\text{completed forms}] * 100}{[\text{expected forms}]}$ <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database. Percentage is derived for display.</p>

Table 3-2 (Cont.) Column descriptions

Column	Description
Form Counts: Incomplete	<p>Data type: Numeric</p> <p>Description: The number of expected forms that are started but not complete.</p> <p>How calculated: For each site, this calculation is: <i>[count of started forms] - [count of completed forms]</i></p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Form Counts: Not Started	<p>Data type: Numeric (Percentage)</p> <p>Description: The number (and percentage) of expected forms that are not started in the Oracle InForm application.</p> <p>How calculated: A form is started if any data, queries, or comments have been entered. Each instance of a repeating form counts as a separate started form. A dynamic form may be Activated, but not Started.</p> <p>This value displays as a whole number and as the percentage of expected forms that are not started: <i>[not started, % of expected] = [not started forms count] * 100 / [expected forms count]</i></p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Table 3-2 (Cont.) Column descriptions

Column	Description
Incomplete (from DOV) Form Count (% of Incomplete)	<p>Data type: Numeric (Percentage)</p> <p>Description: The total count of all forms across all subjects that have been incomplete for specific ranges of calendar days after the date of visit. You specify the aging interval (in days) on the report prompt page.</p> <p>For example, if you specify 7, the resulting report shows the number of forms that have been incomplete for:</p> <ul style="list-style-type: none"> • Seven or fewer days. • More than 7 but equal to or fewer than 14 days. • More than 14 but equal to or fewer than 21 days. • More than 21 but equal to or fewer than 28 days. • More than 28 days. <p>How calculated: This value displays as a whole number, followed by a percentage of the total incomplete form count. The percentage is calculated as follows:</p> <p><i>[count of incomplete forms within the aging interval] * 100 / [count of incomplete forms]</i></p> <p>Note: This report element assumes that your study was developed using a specific design for the DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674 <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

CRF Cycle Time Detail by Site

This report shows the measures of data-entry performance, by site and visit, by showing the number of days from:

- Date of visit to form started.
- Date of visit to form completed.
- Form completed to form source verified.
- Form completed to form locked.



Note:

This calculation relies on the use of the DOV controls specified in the form design.



Tip:

For the best performance, do not select any optional filters on the Selection Criteria page.

Subtotals and totals

- **Subtotals**—By site and country.
 - Min—Lowest minimum value for any site in the country.
 - Max—Highest maximum value for any site in the country.
 - Median—No value.
- **Totals**—Overall form count totals.
 - Min—Lowest minimum value for any site in the country.
 - Max—Highest maximum value for any site in the country.
 - Median—No value.

Table 3-3 Column descriptions

Column	Description
Country	<p>Data type: String</p> <p>Description: The country in which a site is located, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Visit Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation of the visit title, as specified in the study design. For CRF visits, this title appears at the top of a collection of forms in the visit timeline and may not be a unique identifier.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Table 3-3 (Cont.) Column descriptions

Column	Description
Form Counts: Expected	<p>Data type: Numeric</p> <p>Description: The total count of all forms that are expected across all subjects, by visit and by site.</p> <p>How calculated: This number reflects the number of expected forms for the site based on the definition of Expected forms. For more information, see Form elements and expected forms.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Form Counts: Started	<p>Data type: Numeric</p> <p>Description: Total count of all forms that are started across all subjects, by visit and by site.</p> <p>How calculated: An expected form is considered started if any type of data entry activity (form data, queries, or comments) has started on the form.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Form Counts: Completed	<p>Data type: Numeric</p> <p>Description: Total count of all forms that are complete across all subjects, by visit and by site.</p> <p>How calculated: Counts forms that are expected and meet the following criteria:</p> <ul style="list-style-type: none">• Are started.• Contain data for all required items.• For a repeating form, the form is not in a deleted state.• For an itemset form, the form is complete even if all the instances are deleted. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Table 3-3 (Cont.) Column descriptions

Column	Description
DOV to Form Started (Days): Min, Max, Median	<p>Data type: Numeric</p> <p>Description: The number of days from the date entered on the DOV form to the first day on which any data entry activity (item data, comments, or queries) started. For each visit, this section displays:</p> <ul style="list-style-type: none"> • Minimum number of days taken by Oracle InForm users, across all forms and all subjects for each visit at every site, to start a form from the date entered in the DOV form. • Maximum number of days taken by Oracle InForm users, across all forms and all subjects for each visit at every site, to start a form from the date entered in the DOV form. • Median value for the number of days taken by Oracle InForm users, across all forms and all subjects for each visit at every site, to start a form from the date entered in the DOV form for all forms in the visit. <p>Note: This report element assumes that your study was developed using a specific design for the DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674 <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>

Table 3-3 (Cont.) Column descriptions

Column	Description
DOV to Form Completed (Days): Min, Max, Median	<p>Data type: Numeric</p> <p>Description: The number of days from the date entered on the DOV form to the most recent date on which all of the required items on the form contain data. For each visit, this section displays:</p> <ul style="list-style-type: none"> • Minimum number of days taken by Oracle InForm users, across all forms and all subjects for each visit at every site, to complete a form from the date entered in the DOV form. • Maximum number of days taken by Oracle InForm users, across all forms and all subjects for each visit at every site, to complete a form from the date entered in the DOV form. • Median value for the number of days taken by Oracle InForm users, across all forms and all subjects for each visit at every site, to complete a form from the date entered in the DOV form for all forms in the visit. <p>Note: This report element assumes that your study was developed using a specific design for the DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674 <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>

Table 3-3 (Cont.) Column descriptions

Column	Description
Form Completed to SV Complete (Days): Min, Max, Median	<p>Data type: Numeric</p> <p>Description: The number of days from the earliest date on which the form was complete to the most recent date when the form was marked Verified. A form is considered Verified if one of the following is true:</p> <ul style="list-style-type: none"> • The form does not contain critical items, and all items on the form that are marked SV Required are verified. • The form contains critical items, and all critical items on the form are verified. • The form is on the Critical Forms list, and all items on the form that are marked SV Required are verified. • The subject with which the form is associated is in the SV Pool, and all items marked SV Required are verified. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject, and all items marked SV Required are verified. <p>If none of the items on the form require source verification, the Oracle InForm application marks the form Verified.</p> <p>For each visit, this section displays:</p> <ul style="list-style-type: none"> • Minimum number of days, across all forms and all subjects for each visit at every site, to complete the source verification process from the date of form completion. • Maximum number of days, across all forms and all subjects for each visit at every site, to complete the source verification process from the date of form completion. • Median value of number of days, across all forms and all subjects for each visit at every site, to complete the source verification process from date of form completion. <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>

Table 3-3 (Cont.) Column descriptions

Column	Description
Form Completed to Form Locked (Days): Min, Max, Median	<p>Data type: Numeric</p> <p>Description: The number of days from the earliest date on which the form was complete to the most recent date on which the form was locked. For each visit, this section displays:</p> <ul style="list-style-type: none"> • Minimum number of days, across all forms and all subjects for each visit at every site, to lock the form from the date of form completion. • Maximum of days, across all forms and all subjects for each visit at every site, to lock the form from the date of form completion. • Median value of number of days, across all forms and all subjects for each visit at every site, to lock the form from the date of form completion. <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>

CRF Cycle Time Detail for a Site

This report shows the measures of data-entry performance, by site and visit, by showing the number of days from:

- Date of visit to form started.
- Date of visit to form completed.
- Form completed to form source verified.
- Form completed to form locked.



Note:

This calculation relies on the use of the DOV controls specified in the form design.



Tip:

For the best performance, do not select any optional filters on the Selection Criteria page.

Graphs

A combination line/bar graph appears on the first page of the CRF Cycle Time Detail by Site report, plotting the median time from DOV to form complete against expected forms.

Subtotals and totals

- **Subtotals**—By site and country.
 - Min—Lowest minimum value for any site in the country.

- Max—Highest maximum value for any site in the country. Median—No value.
- **Totals**—Overall form count totals.
 - Min—Lowest minimum value for any site in the country.
 - Max—Highest maximum value for any site in the country. Median—No value.

Table 3-4 Column descriptions

Column	Description
Country	<p>Data type: String</p> <p>Description: The country in which a site is located, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Visit Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation of the visit title, as specified in the study design. For CRF visits, this title appears at the top of a collection of forms in the visit timeline and may not be a unique identifier.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Form Counts: Expected	<p>Data type: Numeric</p> <p>Description: The total count of all forms that are expected across all subjects, by visit and by site.</p> <p>How calculated: This number reflects the number of expected forms for the site based on the definition of Expected forms. For more information, see Form elements and expected forms.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Form Counts: Started	<p>Data type: Numeric</p> <p>Description: Total count of all forms that are started across all subjects, by visit and by site.</p> <p>How calculated: An expected form is considered started if any type of data entry activity (form data, queries, or comments) has started on the form.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Table 3-4 (Cont.) Column descriptions

Column	Description
Form Counts: Completed	<p>Data type: Numeric</p> <p>Description: Total count of all forms that are complete across all subjects, by visit and by site.</p> <p>How calculated: Counts forms that are expected and meet the following criteria:</p> <ul style="list-style-type: none">• Are started.• Contain data for all required items.• For a repeating form, the form is not in a deleted state.• For an itemset form, the form is complete even if all the instances are deleted. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Table 3-4 (Cont.) Column descriptions

Column	Description
DOV to Form Started (Days): Min, Max, Median	<p>Data type: Numeric</p> <p>Description: The number of days from the date entered on the DOV form to the first day on which any data entry activity (item data, comments, or queries) started. For each visit, this section displays:</p> <ul style="list-style-type: none"> • Minimum number of days taken by Oracle InForm users, across all forms and all subjects for each visit at every site, to start a form from the date entered in the DOV form. • Maximum number of days taken by InForm users, across all forms and all subjects for each visit at every site, to start a form from the date entered in the DOV form. • Median value for the number of days taken by Oracle InForm users, across all forms and all subjects for each visit at every site, to start a form from the date entered in the DOV form for all forms in the visit.



Note:

This report element assumes that your study was developed using a specific design for the DOV controls.

UUIDs:

- DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674
- Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674
- Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674

Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.

Table 3-4 (Cont.) Column descriptions

Column	Description
DOV to Form Completed (Days): Min, Max, Median	<p>Data type: Numeric</p> <p>Description: The number of days from the date entered on the DOV form to the most recent date on which all of the required items on the form contain data. For each visit, this section displays:</p> <ul style="list-style-type: none"> • Minimum number of days taken by InForm users, across all forms and all subjects for each visit at every site, to complete a form from the date entered in the DOV form. • Maximum number of days taken by InForm users, across all forms and all subjects for each visit at every site, to complete a form from the date entered in the DOV form. • Median value for the number of days taken by Oracle InForm users, across all forms and all subjects for each visit at every site, to complete a form from the date entered in the DOV form for all forms in the visit. <p>Note: This report element assumes that your study was developed using a specific design for the DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674 <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>

Table 3-4 (Cont.) Column descriptions

Column	Description
Form Completed to SV Complete (Days): Min, Max, Median	<p>Data type: Numeric</p> <p>Description: The number of days from the earliest date on which the form was complete to the most recent date when the form was marked Verified. A form is considered Verified if one of the following is true:</p> <ul style="list-style-type: none"> • The form does not contain critical items, and all items on the form that are marked SV Required are verified. • The form contains critical items, and all critical items on the form are verified. • The form is on the Critical Forms list, and all items on the form that are marked SV Required are verified. • The subject with which the form is associated is in the SV Pool, and all items marked SV Required are verified. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject, and all items marked SV Required are verified. <p>If none of the items on the form require source verification, the InForm application marks the form Verified.</p> <p>For each visit, this section displays:</p> <ul style="list-style-type: none"> • Minimum number of days, across all forms and all subjects for each visit at every site, to complete the source verification process from the date of form completion. • Maximum number of days, across all forms and all subjects for each visit at every site, to complete the source verification process from the date of form completion. • Median value of number of days, across all forms and all subjects for each visit at every site, to complete the source verification process from date of form completion. <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>

Table 3-4 (Cont.) Column descriptions

Column	Description
Form Completed to Form Locked (Days): Min, Max, Median	<p>Data type: Numeric</p> <p>Description: The number of days from the earliest date on which the form was complete to the most recent date on which the form was locked. For each visit, this section displays:</p> <ul style="list-style-type: none"> • Minimum number of days, across all forms and all subjects for each visit at every site, to lock the form from the date of form completion. • Maximum of days, across all forms and all subjects for each visit at every site, to lock the form from the date of form completion. • Median value of number of days, across all forms and all subjects for each visit at every site, to lock the form from the date of form completion. <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>

CRF Frozen Status

This report shows the current frozen status of forms.

Link to form items

Click the value in the **Form** column to link directly to the form in Oracle InForm.

Table 3-5 Column descriptions

Column	Description
Country	<p>Data type: String</p> <p>Description: The country in which a site is located, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies the site associated with the form, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Table 3-5 (Cont.) Column descriptions

Column	Description
Subject Number	<p>Data type: String</p> <p>Description: Number that identifies the subject associated with the form. This number may be changed after the subject is enrolled, if the study is configured to require a unique subject ID for a study or site.</p> <p>Data source: Replicated from the Oracle InForm Transactional Database to the Reporting and Analysis database.</p>
Visit Mnemonic	<p>Data type: String</p> <p>Description: Abbreviation of the visit title for the visit the form was filled out in, as specified in study design code. For CRF visits, this name appears at the top of a collection of forms in the visit timeline. The visit mnemonic may not be a unique identifier.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
DOV	<p>Data type: Date/Time</p> <p>Description: The date that is recorded in a standard Date of Visit control in the Oracle InForm application.</p> <p>Data type: Clinical</p> <p>Note: This report element assumes that your study was developed using a specific design for the DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674
Form Mnemonic	<p>Data type: String</p> <p>Description: A short name or abbreviation for the form, as specified in the study design code. Short name or abbreviation for the form, as specified in the study design code. This name appears on the Visit Navigation tab and is used to access a specific form in the Oracle InForm application.</p> <p>To open the form in InForm, log in to Oracle InForm if prompted, then click the link in this column.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Table 3-5 (Cont.) Column descriptions

Column	Description
Form Index	<p>Data type: String</p> <p>Description: For repeating forms, a numeric ordinal value that identifies the instance of the form. For non-repeating forms, the value is 1.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Details	<p>Data type: String</p> <p>Description: The following information about the current frozen status of the form.</p> <ul style="list-style-type: none"> • Current Frozen Status—The form's frozen status. Options are Frozen, Unfrozen, or Never Frozen. • Date Updated—For Frozen or Unfrozen forms, the date and time the form was most recently frozen or unfrozen. • Updated by—For Frozen or Unfrozen forms, the user name of the user who froze or unfroze the form. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

CRF Signature Status Report

This report shows the signature status of forms, case report books, and visits that require signatures.

Column descriptions


Table 3-6 Column descriptions

Column	Description
Country	<p>Data type: String</p> <p>Description: The country in which a site is located, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies the site associated with the form, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Table 3-6 (Cont.) Column descriptions

Column	Description
Subject Number	<p>Data type: String</p> <p>Description: Number that identifies the subject associated with the form. This number may be changed after the subject is enrolled, if the study is configured to require a unique subject ID for a study or site.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Visit Mnemonic	<p>Data type: String</p> <p>Description: Abbreviation of the visit title for the visit the form was filled out in, as specified in study design code. For CRF visits, this name appears at the top of a collection of forms in the visit timeline. The visit mnemonic may not be a unique identifier.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
DOV	<p>Data type: Date/Time</p> <p>Description: The date that is recorded in a standard Date of Visit control in the Oracle InForm application.</p> <p>Data type: Clinical</p> <p>Note: This report element assumes that your study was developed using a specific design for the DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674
Form Mnemonic	<p>Data type: String</p> <p>Description: Short name or abbreviation for the form, as specified in the study design code. This name appears on the Visit Navigation tab and is used to access a specific form in the Oracle InForm application.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Form Index	<p>Data type: String</p> <p>Description: For repeating forms, a numeric ordinal value that identifies the instance of the form. For non-repeating forms, the value is 1.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Table 3-6 (Cont.) Column descriptions

Column	Description
Type	<p>Data type: String</p> <p>Description: The Signature Type for the given report row:</p> <ul style="list-style-type: none"> • CRF (Form Level Signature) <div style="border: 1px solid #0070C0; padding: 10px; margin: 10px 0;"> <p> Note:</p> <p>Visit Level Signatures will be denoted as Type CRF in the Report Output. To view only Visit-level Signatures, use the pre-execution Report Filters to limit the output to CRF Signatures and the Form selection to Form(s) defined specifically for Visit Level Signatures.</p> </div> <ul style="list-style-type: none"> • CRB (Book Level Signature) <p>Data source: Replicated from the InForm transactional database to the Reporting and Analysis database.</p>
Details	<p>Data type: String</p> <p>Description: The following information about the signature status of the form.</p> <ul style="list-style-type: none"> • Group Name—Name of the signature group the signer belongs to. • Signed Date—Date the form was signed. • Signed By—User who signed the form. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

CRF Site Performance Summary by Site

This report shows the average amount of time between study milestones, such as from visit start, to initial data entry, to form complete, and includes aging information for incomplete forms organized by site.



Tip:

For the best performance, do not select any optional filters on the Selection Criteria page.

Graphs

Two bar graphs appear on the first page of the CRF Site Performance Summary by Site report. The first graph plots, for the selected sites, the median number of days from DOV to form started and the median number of days from DOV to form completed. The second graph plots the number of incomplete forms, by time period, for the selected sites.

Subtotals and totals

- **Subtotals**—By Country.
 - Min—Lowest minimum value for any site in the country.
 - Max—Highest maximum value for any site in the country.
 - Median—No value.
- **Totals**—Overall cycle time totals.
 - Min—Lowest minimum value for any site in the country.
 - Max—Highest maximum value for any site in the country.
 - Median—No value.

Drill-down reports

You can click a value in the Site Mnemonic column to drill down to the CRF Cycle Time Detail by Site report.

Table 3-7 Column descriptions

Column	Description
Country	<p>Data type: String</p> <p>Description: The country in which a site is located, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Table 3-7 (Cont.) Column descriptions

Column	Description
DOV to Forms Started (Days): Min, Max, Median	<p>Data type: Numeric</p> <p>Description: The number of days from the date entered on the DOV form to the first day on which any data entry activity (item data, comments, or queries) started. For each visit, this section displays:</p> <ul style="list-style-type: none"> • Minimum number of days taken by Oracle InForm users, across all forms and all subjects for each visit at every site, to start a form from the date entered in the DOV form. • Maximum number of days taken by Oracle InForm users, across all forms and all subjects for each visit at every site, to start a form from the date entered in the DOV form. • Median value for the number of days taken by Oracle InForm users, across all forms and all subjects for each visit at every site, to start a form from the date entered in the DOV form for all forms in the visit.



Note:

This report element assumes that your study was developed using a specific design for the DOV controls.

UUIDs:

- DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674
- Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674
- Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674

Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.

Table 3-7 (Cont.) Column descriptions

Column	Description
DOV to Forms Completed (Days): Min, Max, Median	<p>Data type: Numeric</p> <p>Description: The number of days from the date entered on the DOV form to the most recent date on which all of the required items on the form contain data. For each visit, this section displays:</p> <ul style="list-style-type: none"> • Minimum number of days taken by Oracle InForm users, across all forms and all subjects for each visit at every site, to complete a form from the date entered in the DOV form. • Maximum number of days taken by Oracle InForm users, across all forms and all subjects for each visit at every site, to complete a form from the date entered in the DOV form. • Median value for the number of days taken by Oracle InForm users, across all forms and all subjects for each visit at every site, to complete a form from the date entered in the DOV form for all forms in the visit. <p>Note: This report element assumes that your study was developed using a specific design for the DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674 <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>

Table 3-7 (Cont.) Column descriptions

Column	Description
Forms Completed to Forms SV Complete (Days): Min, Max, Median	<p>Data type: Numeric</p> <p>Description: The number of days from the earliest date on which the form was complete to the most recent date when the form was marked Verified. A form is considered Verified if one of the following is true:</p> <ul style="list-style-type: none"> • The form does not contain critical items, and all items on the form that are marked SV Required are verified. • The form contains critical items, and all critical items on the form are verified. • The form is on the Critical Forms list, and all items on the form that are marked SV Required are verified. • The subject with which the form is associated is in the SV Pool, and all items marked SV Required are verified. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject, and all items marked SV Required are verified. <p>If none of the items on the form require source verification, the Oracle InForm application marks the form Verified.</p> <p>For each visit, this section displays:</p> <ul style="list-style-type: none"> • Minimum number of days, across all forms and all subjects for each visit at every site, to complete the source verification process from the date of form completion. • Maximum number of days, across all forms and all subjects for each visit at every site, to complete the source verification process from the date of form completion. • Median value of number of days, across all forms and all subjects for each visit at every site, to complete the source verification process from date of form completion. <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>

Table 3-7 (Cont.) Column descriptions

Column	Description
Forms Completed to Forms Locked (Days): Min, Max, Median	<p>Data type: Numeric</p> <p>Description: The number of days from the earliest date on which the form was complete to the most recent date when the form was locked.</p> <p>For each visit, this section displays:</p> <ul style="list-style-type: none"> • Minimum number of days, across all forms and all patients for each visit at every site, to lock the form from the date of form completion. • Maximum of days, across all forms and all patients for each visit at every site, to lock the form from the date of form completion. • Median value of number of days, across all forms and all patients for each visit at every site, to lock the form from the date of form completion. <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>

Table 3-7 (Cont.) Column descriptions

Column	Description
Incomplete (from DOV) Forms Count (Days)	<p>Data type: Numeric (Percentage)</p> <p>Description: The total count of all forms across all subjects that have been incomplete for specific ranges of calendar days after the date of visit. You specify the aging interval (in days) on the report prompt page.</p> <p>For example, if you specify 7, the resulting report shows the number of forms that have been incomplete for:</p> <ul style="list-style-type: none"> • Seven or fewer days. • More than 7 but equal to or fewer than 14 days. • More than 14 but equal to or fewer than 21 days. • More than 21 but equal to or fewer than 28 days. • More than 28 days. <p>How calculated: This value displays as a whole number, followed by a percentage of the total incomplete form count. The percentage is calculated as follows:</p> $[\text{count of incomplete forms within the aging interval}] * 100 / [\text{count of incomplete forms}]$ <p>Note: This report element assumes that your study was developed using a specific design for the DOV controls.</p> <p>UIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674 <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

CRF Status Detail by Site and Subject

This report shows the number of forms in each possible status. Forms can be counted based on the definition selected for Expected.



Tip:

For the best performance, do not select any optional filters on the Selection Criteria page.

Subtotals and totals

- **Subtotals**—By Subject, Site, and Country.

- **Totals**—Overall form count totals.

Table 3-8 Column descriptions

Column	Description
Country	<p>Data type: String</p> <p>Description: The country in which a site is located, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Subject Number	<p>Data type: String</p> <p>Description: The subject number, followed by the subject initials.</p> <p>The subject number identifies the subject. The subject number and subject initials can be changed post enrollment, if this is configured in the study.</p> <p>Note: Subject number might not be unique at your site.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Visit Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation of the visit title, as specified in the study design. For CRF visits, this title appears at the top of a collection of forms in the visit timeline and may not be a unique identifier.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
DOV	<p>Data type: Date/Time</p> <p>Description: The date that is recorded in a standard Date of Visit control in the Oracle InForm application.</p> <p>Data type: Clinical</p> <p>Note: This report element assumes that your study was developed using a specific design for the DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674

Table 3-8 (Cont.) Column descriptions

Column	Description
Form Count (% of Expected): Expected	<p>Data type: Numeric</p> <p>Description: The number of expected forms in the study.</p> <p>How calculated: This number reflects the number of expected forms for the site based on the option selected for the Expected forms for filter on the report prompt page. For more information, see Form elements and expected forms.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Form Count (% of Expected): Not Started	<p>Data type: Numeric (Percentage)</p> <p>Description: The number (and percentage) of expected forms that are not started in the Oracle InForm application.</p> <p>How calculated: Calculated based on your selection in the Expected forms for filter on the report prompt page. The Oracle InForm application calculates the forms that are not started by taking the total number of expected forms, based on the filter you select, and then subtracting from that the number of all forms that have been started.</p> <p>A form is started if any data, queries or comments have been entered. Each instance of a repeating form counts as a separate started form. A deleted repeating form is also counted as a started form. A dynamic form may be Activated but not Started. This value displays as a whole number and as the percentage of expected forms that are not started:</p> $[not\ started,\ \%\ of\ expected] = [not\ started\ forms\ count] * 100 / [expected\ forms\ count]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Form Count (% of Expected): Incomplete	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of expected forms that are started but incomplete, and the percentage of expected forms that are incomplete.</p> <p>How calculated: For each site, calculates the following:</p> $[incomplete\ forms\ count] = [started\ forms\ count] - [completed\ forms\ count]$ $[incomplete,\ \%\ of\ expected] = [incomplete\ forms\ count] * 100 / [expected\ forms\ count]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Table 3-8 (Cont.) Column descriptions

Column	Description
Form Count (% of Expected): Completed	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of completed forms, and the percentage of expected forms that are complete in the InForm application.</p> <p>How calculated: Counts forms that are expected and meet the following criteria:</p> <ul style="list-style-type: none"> • Are started. • Contain data for all required items. • For a repeating form, the form is not in a deleted state. • For an itemset form, the form is complete even if all the instances are deleted. <p>This value displays as a whole number and as a percentage of the total number of expected forms that are complete:</p> $[\text{completed, \% of expected}] = [\text{completed forms}] * 100 / [\text{expected forms}]$ <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database. Percentage is derived for display.</p>
Form Count (% of Expected): Frozen	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of frozen forms, and the percentage of expected forms that are currently marked frozen in the InForm application.</p> <p>How calculated: Counts expected forms that have been frozen using any of these Oracle InForm features:</p> <ul style="list-style-type: none"> • Freeze CRF • Freeze CRB • Freeze Visit <p>This value displays as a whole number (number of frozen forms), followed by the percentage of expected forms that are currently marked frozen:</p> $[\text{frozen, \% of expected}] = [\text{frozen forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database. Percentage is derived for display.</p>

Table 3-8 (Cont.) Column descriptions

Column	Description
Form Count (% of Expected): SV Partial	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of forms marked SV Partial, and the percentage of expected forms where source verification is not complete.</p> <p>How calculated: Counts partially verified forms. A form is considered SV Partial if one of the following is true:</p> <ul style="list-style-type: none">• The form contains unverified critical items.• The form is on the Critical Forms list, and contains unverified items that are marked SV Required.• The subject with which the form is associated is in the SV Pool, and the form contains unverified items that are marked SV Required.• The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject, and the form contains unverified items that are marked SV Required. <p>This value is displayed as a whole number and as a percentage of the total number of expected forms that are marked SV Partial:</p> $[SV\ Partial, \% \text{ expected}] = [SV\ Partial\ forms\ count] * 100 / [expected\ forms\ count]$ <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database. Percentage is derived for display.</p>

Table 3-8 (Cont.) Column descriptions

Column	Description
Form Count (% of Expected) SV Complete	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of verified forms, and the percentage of expected forms where source verification is complete.</p> <p>How calculated: Counts forms marked Verified. A form is considered Verified if one of the following is true:</p> <ul style="list-style-type: none"> • The form does not contain critical items, and all items on the form that are marked SV Required are verified. • The form contains critical items, and all critical items on the form are verified. • The form is on the Critical Forms list, and all items on the form that are marked SV Required are verified. • The subject with which the form is associated is in the SV Pool, and all items marked SV Required are verified. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject, and all items marked SV Required are verified. <p>If none of the items on the form require source verification, the Oracle InForm application marks the form Verified.</p> <p>This value displays as a whole number and as a percentage of the total number of expected forms that are marked Verified.</p> $[\text{Verified, \% of expected}] = \frac{[\text{Verified forms count}] * 100}{[\text{expected forms count}]}$ <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Form Count (% of Expected): Signed	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of signed forms and the percentage of expected forms that have been signed in the Oracle InForm application.</p> <p>How calculated: Counts forms that have been signed. This value displays as a whole number and as a percentage of the total number of expected forms that are signed.</p> $[\text{signed, \% of expected}] = \frac{[\text{signed forms count}] * 100}{[\text{expected forms count}]}$ <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database. Percentage is derived for display.</p>

Table 3-8 (Cont.) Column descriptions

Column	Description
Form Count (% of Expected): Locked	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of locked forms, and the percentage of expected forms that are locked.</p> <p>How calculated: Counts forms for which any of the following conditions is true:</p> <ul style="list-style-type: none"> • The form has been locked. • The form is contained within a case book that has been locked. • The form is contained within a visit that has been locked. <p>This value displays as a whole number and as a percentage:</p> $[\text{locked, \% of expected}] = [\text{locked forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database. Percentage is derived for display.</p>
Form Counts (% of Expected): Forms with Comments	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of expected forms with form-level comments, and the percentage of expected forms that have form-level comments.</p> <p>How calculated: Counts forms that contain form-level comments. Does not count forms with item-level comments only. This value displays as a whole number and a percentage of the total number of expected forms that have comments:</p> $[\text{forms with comments, \% of expected}] = [\text{forms with comments}] * 100 / [\text{expected forms count}]$ <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database. Percentage is derived for display.</p>
Form Counts (% of Expected): Forms with Queries	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of forms with open queries, and the percentage of expected forms that contain open queries.</p> <p>How calculated: Counts forms that contain an item with an open query. This value displays as a whole number and a percentage of the total number of expected forms that have open queries:</p> $[\text{forms with open queries, \% of expected}] = [\text{forms with open queries}] * 100 / [\text{expected forms count}]$ <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database. Percentage is derived for display.</p>

CRF Status Detail by Visit and Site

This report shows the number of forms in each possible status, organized by visit across sites. Use the report to help focus on cleaning specific visits.



Tip:

For the best performance, do not select any optional filters on the Selection Criteria page.

Subtotals and totals

- **Subtotals**—By Site, Visit, and Country.
- **Totals**—Overall form count totals.

Table 3-9 Column descriptions

Column	Description
Country	<p>Data type: String</p> <p>Description: The country in which a site is located, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Visit Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation of the visit title, as specified in the study design. For CRF visits, this title appears at the top of a collection of forms in the visit timeline and may not be a unique identifier.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Subject Number	<p>Data type: String</p> <p>Description: The number that identifies the subject. This number can also be changed post-enrollment, if configured in the study.</p> <p>Note: Subject number might not be unique at your site.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Table 3-9 (Cont.) Column descriptions

Column	Description
DOV	<p>Data type: Date/Time</p> <p>Description: The date that is recorded in a standard Date of Visit control in the Oracle InForm application.</p> <p>Data type: Clinical</p> <p>Note: This report element assumes that your study was developed using a specific design for the DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674
Form Count (% of Expected): Expected	<p>Data type: Numeric</p> <p>Description: The number of expected forms in the study.</p> <p>How calculated: This number reflects the number of expected forms for the site based on the option selected for the Expected forms for filter on the report prompt page. For more information, see Form elements and expected forms.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Form Count (% of Expected): Incomplete	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of expected forms that are started but incomplete, and the percentage of expected forms that are incomplete.</p> <p>How calculated: For each site, calculates the following:</p> $[incomplete\ forms\ count] = [started\ forms\ count] - [completed\ forms\ count]$ $[incomplete,\ \%\ of\ expected] = [incomplete\ forms\ count] * 100 / [expected\ forms\ count]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Table 3-9 (Cont.) Column descriptions

Column	Description
Form Count (% of Expected): Completed	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of completed forms, and the percentage of expected forms that are complete in the Oracle InForm application.</p> <p>How calculated: Counts forms that are expected and meet the following criteria:</p> <ul style="list-style-type: none"> • Are started. • Contain data for all required items. • For a repeating form, the form is not in a deleted state. • For an itemset form, the form is complete even if all the instances are deleted. <p>This value displays as a whole number and as a percentage of the total number of expected forms that are complete:</p> $[\text{completed, \% of expected}] = \frac{[\text{completed forms}] * 100}{[\text{expected forms}]}$ <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database. Percentage is derived for display.</p>
Form Count (% of Expected): Frozen	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of frozen forms, and the percentage of expected forms that are currently marked frozen in the Oracle InForm application.</p> <p>How calculated: Counts expected forms that have been frozen using any of these Oracle InForm features:</p> <ul style="list-style-type: none"> • Freeze CRF • Freeze CRB • Freeze Visit <p>This value displays as a whole number (number of frozen forms), followed by the percentage of expected forms that are currently marked frozen:</p> $[\text{frozen, \% of expected}] = \frac{[\text{frozen forms count}] * 100}{[\text{expected forms count}]}$ <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database. Percentage is derived for display.</p>

Table 3-9 (Cont.) Column descriptions

Column	Description
Form Count (% of Expected): SV Partial	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of forms marked SV Partial, and the percentage of expected forms where source verification is not complete.</p> <p>How calculated: Counts partially verified forms. A form is considered SV Partial if one of the following is true:</p> <ul style="list-style-type: none"> • The form contains unverified critical items. • The form is on the Critical Forms list, and contains unverified items that are marked SV Required. • The subject with which the form is associated is in the SV Pool, and the form contains unverified items that are marked SV Required. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject, and the form contains unverified items that are marked SV Required. <p>This value is displayed as a whole number and as a percentage of the total number of expected forms that are marked SV Partial:</p> $[SV\ Partial, \% \text{ expected}] = [SV\ Partial\ forms\ count] * 100 / [expected\ forms\ count]$ <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database. Percentage is derived for display.</p>

Table 3-9 (Cont.) Column descriptions

Column	Description
Form Count (% of Expected): SV Completed	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of verified forms, and the percentage of expected forms where source verification is complete.</p> <p>How calculated: Counts forms marked Verified. A form is considered Verified if one of the following is true:</p> <ul style="list-style-type: none"> • The form does not contain critical items, and all items on the form that are marked SV Required are verified. • The form contains critical items, and all critical items on the form are verified. • The form is on the Critical Forms list, and all items on the form that are marked SV Required are verified. • The subject with which the form is associated is in the SV Pool, and all items marked SV Required are verified. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject, and all items marked SV Required are verified. <p>If none of the items on the form require source verification, the Oracle InForm application marks the form Verified.</p> <p>This value displays as a whole number and as a percentage of the total number of expected forms that are marked Verified.</p> $[\text{Verified, \% of expected}] = \frac{[\text{Verified forms count}] * 100}{[\text{expected forms count}]}$ <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Form Count (% of Expected): Signed	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of signed forms and the percentage of expected forms that have been signed in the Oracle InForm application.</p> <p>How calculated: Counts forms that have been signed. This value displays as a whole number and as a percentage of the total number of expected forms that are signed.</p> $[\text{signed, \% of expected}] = \frac{[\text{signed forms count}] * 100}{[\text{expected forms count}]}$ <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database. Percentage is derived for display.</p>

Table 3-9 (Cont.) Column descriptions

Column	Description
Form Count (% of Expected): Locked	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of locked forms, and the percentage of expected forms that are locked.</p> <p>How calculated: Counts forms for which any of the following conditions is true:</p> <ul style="list-style-type: none"> • The form has been locked. • The form is contained within a case book that has been locked. • The form is contained within a visit that has been locked. <p>This value displays as a whole number and as a percentage:</p> $[\text{locked, \% of expected}] = [\text{locked forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database. Percentage is derived for display.</p>
Form Counts (% of Expected): Forms with Comments	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of expected forms with form-level comments, and the percentage of expected forms that have form-level comments.</p> <p>How calculated: Counts forms that contain form-level comments. Does not count forms with item-level comments only. This value displays as a whole number and a percentage of the total number of expected forms that have comments:</p> $[\text{forms with comments, \% of expected}] = [\text{forms with comments}] * 100 / [\text{expected forms count}]$ <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database. Percentage is derived for display.</p>
Form Counts (% of Expected): Forms with Queries	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of forms with open queries, and the percentage of expected forms that contain open queries.</p> <p>How calculated: Counts forms that contain an item with an open query. This value displays as a whole number and a percentage of the total number of expected forms that have open queries:</p> $[\text{forms with open queries, \% of expected}] = [\text{forms with open queries}] * 100 / [\text{expected forms count}]$ <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database. Percentage is derived for display.</p>

CRF Status Summary by Site

This report shows, by site, the number and percentage of expected forms that are incomplete, complete, frozen, and locked.

Tip:

For the best performance, do not select any optional filters on the Selection Criteria page.

Graphs

A bar graph appears on the first page of the CRF Status Summary by Site report, plotting a summary of form completion status across all subjects, visits, and sites in each country.

Subtotals and totals

- **Subtotals**—By Country.
- **Totals**—Overall form count totals.

Drill-through reports

- Click a value in the Site Mnemonic column to drill through to the [CRF Status Detail by Visit and Site](#) report for the selected site.
- Click a value in the Subject Count column to drill through to the [CRF Status Detail by Site and Subject](#) report for the subjects included in the subject count

Table 3-10 Column descriptions

Column	Description
Country	<p>Data type: String</p> <p>Description: The country in which a site is located, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Table 3-10 (Cont.) Column descriptions

Column	Description
Subject Count	<p>Data type: Numeric</p> <p>Description: The number of subjects who enrolled at the site.</p> <p>How calculated: For each site, counts subjects who enrolled at the site, including subjects who are currently assigned other states.</p> <p>Note: The Enrollment form, designed according to Oracle InForm specifications, must be completed for the subject.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Status is determined by the value on the Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p>
Form Count (% of Expected): Expected	<p>Data type: Numeric</p> <p>Description: The number of expected forms in the study.</p> <p>How calculated: This number reflects the number of expected forms for the site based on the option selected for the Expected forms for filter on the report prompt page. For more information, see Form elements and expected forms.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Form Count (% of Expected): Not Started	<p>Data type: Numeric (Percentage)</p> <p>Description: The number (and percentage) of expected forms that are not started in the InForm application.</p> <p>How calculated: A form is started if any data, queries, or comments have been entered. Each instance of a repeating form counts as a separate started form. A dynamic form may be Activated, but not Started.</p> <p>This value displays as a whole number and as the percentage of expected forms that are not started:</p> $[not\ started, \% \ of\ expected] = [not\ started\ forms\ count] * 100 / [expected\ forms\ count]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Table 3-10 (Cont.) Column descriptions

Column	Description
Form Count (% of Expected): Incomplete	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of expected forms that are started but incomplete, and the percentage of expected forms that are incomplete.</p> <p>How calculated: For each site, calculates the following: $[incomplete\ forms\ count] = [started\ forms\ count] - [completed\ forms\ count]$ $[incomplete,\ \%\ of\ expected] = [incomplete\ forms\ count] * 100 / [expected\ forms\ count]$</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Form Count (% of Expected): Completed	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of completed forms, and the percentage of expected forms that are complete in the InForm application.</p> <p>How calculated: Counts forms that are expected and meet the following criteria:</p> <ul style="list-style-type: none"> • Are started. • Contain data for all required items. • For a repeating form, the form is not in a deleted state. • For an itemset form, the form is complete even if all the instances are deleted. <p>This value displays as a whole number and as a percentage of the total number of expected forms that are complete: $[completed,\ \%\ of\ expected] = [completed\ forms] * 100 / [expected\ forms]$</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database. Percentage is derived for display.</p>

Table 3-10 (Cont.) Column descriptions

Column	Description
Form Count (% of Expected): Frozen	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of frozen forms, and the percentage of expected forms that are currently marked frozen in the Oracle InForm application.</p> <p>How calculated: Counts expected forms that have been frozen using any of these Oracle InForm features:</p> <ul style="list-style-type: none"> • Freeze CRF • Freeze CRB • Freeze Visit <p>This value displays as a whole number (number of frozen forms), followed by the percentage of expected forms that are currently marked frozen:</p> $[\text{frozen, \% of expected}] = [\text{frozen forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database. Percentage is derived for display.</p>

Table 3-10 (Cont.) Column descriptions

Column	Description
Form Count (% of Expected): SV Complete	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of verified forms, and the percentage of expected forms where source verification is complete.</p> <p>How calculated: Counts verified forms.</p> <p>A form is considered Verified if one of the following is true:</p> <ul style="list-style-type: none"> • The form does not contain critical items, and all items on the form that are marked SV Required are verified. • The form contains critical items, and all critical items on the form are verified. • The form is on the Critical Forms list, and all items on the form that are marked SV Required are verified. • The subject with which the form is associated is in the SV Pool, and all items marked SV Required are verified. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject, and all items marked SV Required are verified. <p>If none of the items on the form require source verification, the Oracle InForm application marks the form Verified.</p> <p>This value displays as a whole number and as a percentage of the total number of expected forms that are marked Verified:</p> $[\text{Verified, \% of expected}] = [\text{Verified forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Form Count (% of Expected): Signed	<p>Data type: Numeric</p> <p>Description: The number of signed forms and the percentage of expected forms that are currently signed in the Oracle InForm application.</p> <p>How calculated: Counts forms that have been signed by all groups that are required to sign the form. This value appears as a whole number and as a percentage of expected forms that are signed:</p> $[\text{signed, \% of expected}] = [\text{signed forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Table 3-10 (Cont.) Column descriptions

Column	Description
Form Count (% of Expected): Locked	<p>Data type: Numeric</p> <p>Description: The number of locked forms and the percentage of expected forms that are locked in the Oracle InForm application.</p> <p>How calculated: Counts forms that meet one of the following criteria:</p> <ul style="list-style-type: none"> • Have been locked. • Are contained within a case book that has been locked. • Are contained within a visit that has been locked. <p>This value displays as a whole number and as a percentage:</p> $[\text{locked, \% of expected}] = [\text{locked forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

CRF Status Summary by User

This report shows the total number and percentage of expected forms that are incomplete, complete, frozen, locked, SV complete, and signed. This report is grouped by user within a rights group.



Tip:

For the best performance, do not select any optional filters on the Selection Criteria page.

Subtotals and totals

- **Subtotals**—one.
- **Totals**—Overall form count totals.

Drill-down reports

- Click a value in the Site Mnemonic column to drill down to the [CRF Status Detail by Visit and Site](#) report for the selected site.
- Click a value in the Subject Count column to drill down to the [CRF Status Detail by Site and Subject](#) report for the selected user.

Table 3-11 Column descriptions

Column	Description
Rights Group	<p>Data type: String</p> <p>Description: The Oracle InForm rights group to which the InForm user belongs.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
User Name	<p>Data type: String</p> <p>Description: The user name of the Oracle InForm user.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Subject Count	<p>Data type: Numeric</p> <p>Description: The number of subjects who enrolled at the site.</p> <p>How calculated: For each site, counts subjects who enrolled at the site, including subjects who are currently assigned other states.</p> <p>Note: The Enrollment form, designed according to Oracle InForm specifications, must be completed for the subject.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Status is determined by the value on the Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p>
Form Count (% of Expected): Expected	<p>Data type: Numeric</p> <p>Description: The number of expected forms in the study.</p> <p>How calculated: This number reflects the number of expected forms for the site based on the option selected for the Expected forms for filter on the report prompt page. For more information, see Form elements and expected forms.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Table 3-11 (Cont.) Column descriptions

Column	Description
Form Count (% of Expected): Not Started	<p>Data type: Numeric (Percentage)</p> <p>Description: The number (and percentage) of expected forms that are not started in the Oracle InForm application.</p> <p>How calculated: A form is started if any data, queries, or comments have been entered. Each instance of a repeating form counts as a separate started form. A dynamic form may be Activated, but not Started.</p> <p>This value displays as a whole number and as the percentage of expected forms that are not started: $[not\ started, \%\ of\ expected] = [not\ started\ forms\ count] * 100 / [expected\ forms\ count]$</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Form Count (% of Expected): Incomplete	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of expected forms that are started but incomplete, and the percentage of expected forms that are incomplete.</p> <p>How calculated: For each site, calculates the following: $[incomplete\ forms\ count] = [started\ forms\ count] - [completed\ forms\ count]$ $[incomplete, \%\ of\ expected] = [incomplete\ forms\ count] * 100 / [expected\ forms\ count]$</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Form Count (% of Expected): Completed	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of completed forms, and the percentage of expected forms that are complete in the InForm application.</p> <p>How calculated: Counts forms that are expected and meet the following criteria:</p> <ul style="list-style-type: none"> • Are started. • Contain data for all required items. • For a repeating form, the form is not in a deleted state. • For an itemset form, the form is complete even if all the instances are deleted. <p>This value displays as a whole number and as a percentage of the total number of expected forms that are complete: $[completed, \%\ of\ expected] = [completed\ forms] * 100 / [expected\ forms]$</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database. Percentage is derived for display.</p>

Table 3-11 (Cont.) Column descriptions

Column	Description
Form Count (% of Expected): Frozen	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of frozen forms, and the percentage of expected forms that are currently marked frozen in the Oracle InForm application.</p> <p>How calculated: Counts expected forms that have been frozen using any of these Oracle InForm features:</p> <ul style="list-style-type: none"> • Freeze CRF • Freeze CRB • Freeze Visit <p>This value displays as a whole number (number of frozen forms), followed by the percentage of expected forms that are currently marked frozen:</p> $[\text{frozen, \% of expected}] = [\text{frozen forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database. Percentage is derived for display.</p>

Table 3-11 (Cont.) Column descriptions

Column	Description
Form Count (% of Expected): SV Complete	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of verified forms, and the percentage of expected forms where source verification is complete.</p> <p>How calculated: Counts verified forms.</p> <p>A form is considered Verified if one of the following is true:</p> <ul style="list-style-type: none"> • The form does not contain critical items, and all items on the form that are marked SV Required are verified. • The form contains critical items, and all critical items on the form are verified. • The form is on the Critical Forms list, and all items on the form that are marked SV Required are verified. • The subject with which the form is associated is in the SV Pool, and all items marked SV Required are verified. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject, and all items marked SV Required are verified. <p>If none of the items on the form require source verification, the Oracle InForm application marks the form Verified.</p> <p>This value displays as a whole number and as a percentage of the total number of expected forms that are marked Verified:</p> $[\text{Verified, \% of expected}] = \frac{[\text{Verified forms count}] * 100}{[\text{expected forms count}]}$ <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Form Count (% of Expected): Signed	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of signed forms and the percentage of expected forms that have been signed in the Oracle InForm application.</p> <p>How calculated: Counts forms that have been signed. This value displays as a whole number and as a percentage of the total number of expected forms that are signed.</p> $[\text{signed, \% of expected}] = \frac{[\text{signed forms count}] * 100}{[\text{expected forms count}]}$ <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database. Percentage is derived for display.</p>

Table 3-11 (Cont.) Column descriptions

Column	Description
Form Count (% of Expected): Locked	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of locked forms, and the percentage of expected forms that are locked.</p> <p>How calculated: Counts forms for which any of the following conditions is true:</p> <ul style="list-style-type: none"> • The form has been locked. • The form is contained within a case book that has been locked. • The form is contained within a visit that has been locked. <p>This value displays as a whole number and as a percentage:</p> $[\text{locked, \% of expected}] = [\text{locked forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database. Percentage is derived for display.</p>

Item Reports

In this section:

- [CRF Item Listing](#)
- [Source Verification Listing](#)

CRF Item Listing

This report shows a list of form items that are in a given state or that entered a given state as of a specified point in time. The report is organized by site, subject, visit, and form. You can filter for missing items or for items that were changed after a given time.

Tip:

- You must select a visit in the Visits drop-down list on the Selection Criteria page before you can access the More Options page or run the report.
- For the best performance, do not select any optional filters on the Selection Criteria page.

Column descriptions

Table 3-12 Column descriptions

Column	Description
Site	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Subject Number/Initials	<p>Data type: String</p> <p>Description: The subject number, followed by the subject initials.</p> <p>The subject number identifies the subject. The subject number and subject initials can be changed post enrollment, if this is configured in the study.</p> <p>Note: Subject number might not be unique at your site.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Visit	<p>Data type: String</p> <p>Description: An abbreviation of the visit title, as specified in the study design. For CRF visits, this title appears at the top of a collection of forms in the visit timeline and may not be a unique identifier.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
DOV	<p>Data type: Date/Time</p> <p>Description: The date that is recorded in a standard Date of Visit control in the Oracle InForm application.</p> <p>Data type: Clinical</p> <p>Note: This report element assumes that your study was developed using a specific design for the DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674

Table 3-12 (Cont.) Column descriptions

Column	Description
Form	<p>Data type: String</p> <p>Description: A short name or abbreviation for the form, as specified in the study design code. Short name or abbreviation for the form, as specified in the study design code. This name appears on the Visit Navigation tab and is used to access a specific form in the Oracle InForm application.</p> <p>To open the form in Oracle InForm, log in to Oracle InForm if prompted, then click the link in this column.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Form index	<p>Data type: Numeric</p> <p>Description: For repeating forms, a numeric ordinal value that identifies an iteration of a form. For non-repeating forms, the value is 1.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Item Question	<p>Data type: String</p> <p>Description: Text of the question or prompt that instructs the user to enter specific clinical data.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Form State Dates: SV Ready	<p>Data type: Date/Time</p> <p>Description: The most recent date on which the status of the form was set to SV Ready.</p> <p>A form is considered SV Ready if it has a status of SV Ready, and is selected for source verification.</p> <p>A form has been selected for source verification if one of the following is true:</p> <ul style="list-style-type: none"> • The form contains one or more critical items. • The form is on the Critical Forms list. • The subject with which the form is associated is in the SV Pool. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject. <p>Date type: System date (GMT).</p>
Form State Dates: Frozen	<p>Data type: Date/Time</p> <p>Description: The most recent date on which the status of the form was set to Frozen in the Oracle InForm application. Note that a value displays here only if the form has a current status of Frozen.</p> <p>Date type: System date (GMT).</p>

Table 3-12 (Cont.) Column descriptions

Column	Description
Form State Dates: SV Complete	<p>Data type: Date/Time</p> <p>Description: The most recent date on which the form was marked Verified.</p> <p>A form is considered Verified if one of the following is true:</p> <ul style="list-style-type: none"> • The form does not contain critical items, and all items on the form that are marked SV Required are verified. • The form contains critical items, and all critical items on the form are verified. • The form is on the Critical Forms list, and all items on the form that are marked SV Required are verified. • The subject with which the form is associated is in the SV Pool, and all items marked SV Required are verified. • The subject with which the form is associated is not in the SV Pool, but an item on the form is marked critical for that subject, and all items marked SV Required are verified. If none of the items on the form require source verification, the InForm application marks the form Verified. <p>Date type: System date (GMT).</p>
Form State Dates: Signed	<p>Data type: Date/Time</p> <p>Description: The most recent date on which the form was signed in the InForm application. Note that a value displays here only if the form has a current status of Signed.</p> <p>Date type: System date (GMT).</p>
Form State Dates: Locked	<p>Data type: Date/Time</p> <p>Description: The most recent date on which the form was locked in the Oracle InForm application. Note that a value displays here only if the form has a current status of Locked.</p> <p>Date type: System date (GMT).</p>
Item Properties: Required	<p>Data type: Y/N</p> <p>Description: Indicates whether the item requires a value for the form to be considered data entry complete. Valid values are:</p> <ul style="list-style-type: none"> • Y—The item is required. • N—The item is not required. <p>Note: Itemset items cannot be required.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>

Table 3-12 (Cont.) Column descriptions

Column	Description
Item Properties: SV Selected	<p>Data type: Y/N</p> <p>Description: Indicates whether the item has been selected for source verification.</p> <ul style="list-style-type: none"> • Y—The item has been selected for source verification. • N—The item has not been selected for source verification. <p>An item has been selected for source verification if one of the following is true:</p> <ul style="list-style-type: none"> • The item is marked SV Required and SV Critical. • The form on which the item exists is on the Critical Forms list. • The subject with which the item is associated is part of the SV Pool. • The subject with which the item is associated is not part of the SV Pool, but the item is marked critical for that subject. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>
Item Properties: SV Required	<p>Data type: Y/N</p> <p>Description: Indicates whether the item requires source verification.</p> <ul style="list-style-type: none"> • Y—The item requires InForm source verification. • N—The item does not require source verification. <p>An item is considered SV Required only if it is marked SV Required.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>
Item Properties: Verified	<p>Data type: Y/N</p> <p>Description: Indicates whether the item is source verified.</p> <ul style="list-style-type: none"> • Y—The item is source verified. • N—The item is not source verified. <p>An item is considered source verified if it is in the Verified state.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>

Table 3-12 (Cont.) Column descriptions

Column	Description
Item Properties: Has Query	<p>Data type: Y/N</p> <p>Description: Indicates whether the item has an open query associated with it.</p> <ul style="list-style-type: none"> • Y—The item has an open query. • N—The item has no open queries. <p>Note: This field is not supported in itemsets.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>
Item Properties: Has Comment	<p>Data type: Y/N</p> <p>Description: Indicates whether the item has a comment associated with it.</p> <ul style="list-style-type: none"> • Y—The item has a comment. • N—The item does not have a comment. <p>Note: This field is not supported in itemsets.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>
Item Properties: Data Modified	<p>Data type: Date</p> <p>Description: The date on which data was most recently modified.</p> <p>Date type: System date (GMT).</p>
Item Properties: Original Value Date	<p>Data type: Date</p> <p>Description: The date on which data was originally entered into the item.</p> <p>Date type: System date (GMT).</p>
Item Properties: Data Change User	<p>Data type: String</p> <p>Description: The user name of the Oracle InForm user who made the most recent change to the item.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Source Verification Listing

This report shows, for the specified date range:

- Form items for which the SV status changed.
- Form items for which data was entered (regardless of if a form status change or SV action is taken).
- Form items not source verified if other items on the same form were source verified in the specified date range:
 - This scenario is indicated in the report by an item row having a status of Verified = N and the Last Verified column being blank as the item has never been verified. The Status Change User column records the user that verified other items on the form.
 - This behaviour is observed inclusive of items with and without a value (blank), unless the item is part of an itemset, in which case blank items are not listed in the report.

CRAAs use this report to compile a list of items to source verify when visiting a site, or to view those items that were source verified/un-source verified in a given time period.

 **Tip:**

- You must select a visit and at least one form on the Selection Criteria page.
- If you use the Limit to filter on the Selection Criteria page, the report displays data items that have all of the selected criteria. For example, if you select Unverified Items and No Longer Verified Items, the report contains only forms that have both unverified and no longer verified items.

Table 3-13 Column descriptions

Column	Description
Site	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Subject Number	<p>Data type: String</p> <p>Description: The number that identifies the subject. This number can also be changed post-enrollment, if configured in the study.</p> <p>Note: Subject number might not be unique at your site.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Visit	<p>Data type: String</p> <p>Description: An abbreviation of the visit title, as specified in the study design. For CRF visits, this title appears at the top of a collection of forms in the visit timeline and may not be a unique identifier.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Table 3-13 (Cont.) Column descriptions

Column	Description
DOV	<p>Data type: Date</p> <p>Description: The date that is recorded in a standard Date of Visit control in the Oracle InForm application.</p> <p>Data type: Clinical</p> <p>Note: This report element assumes that your study was developed using a specific design for the DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674
Form	<p>Data type: String</p> <p>Description: A short name or abbreviation for the form, as specified in the study design code. Short name or abbreviation for the form, as specified in the study design code. This name appears on the Visit Navigation tab and is used to access a specific form in the Oracle InForm application.</p> <p>To open the form in Oracle InForm, log in to Oracle InForm if prompted, then click the link in this column.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Form Index	<p>Data type: Numeric</p> <p>Description: For repeating forms, a numeric ordinal value that identifies an iteration of a form. For non-repeating forms, the value is 1.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Item Question	<p>Data type: String</p> <p>Description: Text of the question or prompt that instructs the user to enter specific clinical data. Access to this data can be restricted in the Oracle InForm application. When users who do not have access to this data run a report with this report element, the resulting report displays a series of asterisks (*****) rather than the actual item question.</p> <p>Oracle InForm items that have never contained data will not appear on reports that pair Item Question with Form Name or Form Mnemonic.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Table 3-13 (Cont.) Column descriptions

Column	Description
Status Change User	<p>Data type: String</p> <p>Description: The user name of the Oracle InForm user who made the most recent change to the status of the item. A change to the SV status of the item is considered a status change for the item.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Verified	<p>Data type: Y/N</p> <p>Description: Indicates whether the item is source verified.</p> <ul style="list-style-type: none">• Y—The item is source verified.• N—The item is not source verified. <p>An item is considered source verified if it is in the Verified state.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>
Last Verified	<p>Data type: Date</p> <p>Description: The most recent date on which the item was source verified. An item is considered source verified if it is in the Verified state.</p> <p>Date type: System date (GMT).</p>
Data Change User	<p>Data type: String</p> <p>Description: The user name of the Oracle InForm user who made the most recent change to the item.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Data Last Modified	<p>Data type: Date</p> <p>Description: The date on which data was most recently entered into the item.</p> <p>Date type: System date (GMT).</p>

Table 3-13 (Cont.) Column descriptions

Column	Description
Is SV Selected	<p>Data type: Y/N</p> <p>Description: Indicates whether the item has been selected for source verification.</p> <ul style="list-style-type: none"> • Y—The item has been selected for source verification. • N—The item has not been selected for source verification. <p>An item has been selected for source verification if one of the following is true:</p> <ul style="list-style-type: none"> • The item is marked SV Required and SV Critical. • The form on which the item exists is on the Critical Forms list. • The subject with which the item is associated is part of the SV Pool. • The subject with which the item is associated is not part of the SV Pool, but the item is marked critical for that subject. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>
Source Verified Targeted	<p>Data type: Y/N</p> <p>Description: Indicates whether the item has been source verified and selected for source verification.</p> <ul style="list-style-type: none"> • Y—The item has been source verified and selected for source verification. • N—The item has not been source verified and selected for source verification. <p>An item has been selected for source verification if one of the following is true:</p> <ul style="list-style-type: none"> • The item is marked SV Required and SV Critical. • The form on which the item exists is on the Critical Forms list. • The subject with which the item is associated is part of the SV Pool. • The subject with which the item is associated is not part of the SV Pool, but the item is marked critical for that subject. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database and decoded for display.</p>

Query Reports

In this section:

- [Outstanding Queries by Site and Visit](#)
- [Query Aging by Site](#)
- [Query Cycle Times by Site](#)

- [Query Cycle Times by User](#)
- [Query Performance Summary by Site](#)
- [Query Performance Summary by User](#)
- [Query Status by Site](#)
- [Query Status by Site and Subject](#)
- [Query Status by Site and Visit](#)
- [Query Status by User](#)
- [Query Volume by Month by Site](#)
- [Query Volume by Rule](#)
- [Subject Counts with Outstanding Queries](#)

Outstanding Queries by Site and Visit

This cross-tab report shows the number of open or answered queries for each visit (columns) and each site (rows). The report displays information only for countries that have sites with outstanding queries.

Use this report to quickly assess how clean current data is relative to visits or subjects.

Subtotals and totals

- **Subtotals**—By Country.
- **Totals**—Overall query count totals.

Column descriptions

Table 3-14 Column descriptions

Report element	Description
Country	<p>Data type: String</p> <p>Description: The country in which a site is located, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Table 3-14 (Cont.) Column descriptions

Report element	Description
Visit Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation of the visit title, as specified in the study design. For CRF visits, this title appears at the top of a collection of forms in the visit timeline and may not be a unique identifier.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Open query counts by visit	<p>Data type: Numeric</p> <p>Description: For each site and visit, the number of queries with a current status of Open.</p> <p>How calculated: Counts all open queries for each site and visit that are associated with items on any form in the visit. This calculation counts manual, automatic, or both types of open queries, based on your selection for the Query Type filter on the report prompt page. Note that this total includes queries that were opened, answered, and then reissued.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Answered query counts by visit	<p>Data type: Numeric</p> <p>Description: For each site and visit, the number of queries with a current status of Answered.</p> <p>How calculated: Counts all answered queries for each site and visit that are associated with items on any form in the visit. This calculation counts manual, automatic, or both types of answered queries, based on your selection for the Query Type filter on the report prompt page.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Total query counts by visit	<p>Data type: Numeric</p> <p>Description: For each site and visit, the total number of open and answered queries.</p> <p>How calculated: The sum of the values in the Open and Ans'd columns.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Totals - Open query counts by visit	<p>Data type: Numeric</p> <p>Description: For each site, the number of queries with a current status of Open.</p> <p>How calculated: The sum of the values for open queries for all visits at a given site.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Table 3-14 (Cont.) Column descriptions

Report element	Description
Totals - Answered query counts by visit	<p>Data type: Numeric</p> <p>Description: For each site, the number of queries with a current status of Answered.</p> <p>How calculated: The sum of the values for answered queries for all visits at a given site.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Totals - Total query counts by visit	<p>Data type: Numeric</p> <p>Description: For each site, the number of queries with a current status of Open or Answered.</p> <p>How calculated: The sum of the values for open or answered queries for all visits at a given site.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Query Aging by Site

This report shows the number of queries that are open, by site, for a given number of days.

Use this report to help identify sites that are falling behind.

Subtotals and totals

- **Subtotals**—By Country.
- **Totals**—Overall query aging totals.

Table 3-15 Column descriptions

Column	Description
Country	<p>Data type: String</p> <p>Description: The country in which a site is located, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Table 3-15 (Cont.) Column descriptions

Column	Description
Subject Count	<p>Data type: Numeric</p> <p>Description: The number of subjects who enrolled at the site.</p> <p>How calculated: For each site, counts subjects who enrolled at the site, including subjects who are currently assigned other states.</p> <p>Note: The Enrollment form, designed according to Oracle InForm specifications, must be completed for the subject.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Status is determined by the value on the Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p>
Total Open	<p>Data type: Numeric</p> <p>Description: For each site, the number of queries with a current status of Open.</p> <p>How calculated: For each site, all queries with a current status of Open are counted, regardless of query type. Note that this total includes queries that were opened, answered, and then reissued.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Average Age of Open	<p>Data type: Numeric</p> <p>Description: For each site, the average number of days that a query is in the Open state.</p> <p>How calculated: This calculation only applies to queries with a current status of Open. The number of days is calculated by subtracting the date when a query was last opened from the current date.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Table 3-15 (Cont.) Column descriptions

Column	Description
Queries Open (% of Total Open for Country)	<p>Data type: Numeric (Percentage)</p> <p>Description: The number of open queries that have been open for specific intervals of time. You specify the aging interval (in days) on the report prompt page.</p> <p>For example, if you specify 7, the resulting report shows the number of queries that have been open for:</p> <ul style="list-style-type: none"> • Seven or fewer days. • More than 7 but equal to or fewer than 14 days. • More than 14 but equal to or fewer than 21 days. • More than 21 but equal to or fewer than 28 days. • More than 28 days. <p>How calculated: This value is calculated in multiples of 24 (hours). For example, if the query is opened at 10 AM on day 1 and the report is run 10 days later at 9 AM., the days open is 9.</p> <p>The number of queries in the date range is followed by a percentage of the total open query count per country. For each country, the percentage is calculated as follows:</p> $[\text{open queries within aging interval}] * 100 / [\text{total number of open queries}]$ <p>Data source: Derived and stored in the Reporting and Analysis database. Percentage derived for display.</p>

Query Cycle Times by Site

This report shows the minimum, maximum, and median number of days for queries to move from open to answered to closed. This report is grouped by site or sponsor. The report includes only sites that have queries.

Use this report to help you see whether a given site or sponsor is having issues resolving queries in a timely way.



Tip:

For the best performance, do not select any optional filters on the Selection Criteria page.

Graphs

A combination line/bar graph appears on the first page of the Query Cycle Times by Site report, plotting the median time from query open to answered, and the minimum time answered to closed, by sites within countries.

Subtotals and totals

- **Subtotals**—By country.
 - Min—Lowest minimum value for any site in the country.
 - Max—Highest maximum value for any site in the country.
 - Median—No value.
- **Totals**—Overall query cycle time totals.
 - Min—Lowest minimum value for any site in the country.
 - Max—Highest maximum value for any site in the country.
 - Median—No value.

Column descriptions

Table 3-16 Column descriptions

Column	Description
Country	<p>Data type: String</p> <p>Description: The country in which a site is located, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Subject Count	<p>Data type: Numeric</p> <p>Description: The number of subjects who enrolled at the site.</p> <p>How calculated: For each site, counts subjects who enrolled at the site, including subjects who are currently assigned other states.</p> <p>Note: The Enrollment form, designed according to InForm specifications, must be completed for the subject.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Status is determined by the value on the Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p>

Table 3-16 (Cont.) Column descriptions

Column	Description
Query Count	<p>Data type: Numeric</p> <p>Description: The total number of number of open, answered, and closed queries.</p> <p>How calculated: This calculation counts all open, closed, and answered queries, based on your selection in the Query Type filter on the report prompt page. This count does not include queries that have never been opened (candidate queries or deleted candidate queries).</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Open to Answered (Days): Min, Max, Median	<p>Data type: Numeric</p> <p>Description: Data on the number of days from when queries are opened to when they are answered. For each site, columns display:</p> <ul style="list-style-type: none">• Minimum—The fewest number of days for an opened query to be answered at the site.• Maximum—The greatest number of days for an opened query to be answered at the site.• Median—The median of the opened-to-answered range for all answered queries at the site. <p>How calculated: The calculation begins on the first day when the status of a query was set to Open and ends on the most recent day when the status of a query was set to Answered. This value is calculated in multiples of 24 (hours) and is rounded down to the nearest whole number.</p> <p>For example, if a query is opened on day 1 at 10 AM and answered on day 3 at 9 AM, the Open to Answered value is 2 days.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Table 3-16 (Cont.) Column descriptions

Column	Description
Answered to Closed (Days): Min, Max, Median	<p>Data type: Numeric</p> <p>Description: Data on the number of days from when queries are answered to when they are closed. For each site, columns display:</p> <ul style="list-style-type: none"> • Minimum—The fewest number of days for an answered query to be closed at the site. • Maximum—The greatest number of days for an answered query to be closed at the site. • Median—The median of the answered-to-closed range for all closed queries at the site. <p>How calculated: The calculation begins on the first day when the status of a query was set to Answered and ends on the most recent day when the status of a query was set to Closed. This value is calculated in multiples of 24 (hours) and is rounded down to the nearest whole number.</p> <p>For example, if a query is answered on day 1 at 10 AM and closed on day 3 at 9 AM, the Answered to Closed value is 2 days.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Open to Closed (Days): Min, Max, Median	<p>Data type: Numeric</p> <p>Description: Data on the number of days from when queries are opened to when they are closed. For each site, columns display:</p> <ul style="list-style-type: none"> • Minimum—The fewest number of days for an open query to be closed at the site. • Maximum—The greatest number of days for an open query to be closed at the site. • Median—The median of the opened-to-closed range for all closed queries at the site. <p>How calculated: The calculation begins on the first day when the status of a query was set to Open and ends on the most recent day when the status of a query was set to Closed. This value is calculated in multiples of 24 (hours) and is rounded down to the nearest whole number.</p> <p>For example, if a query is opened on day 1 at 10 AM and closed on day 3 at 9 AM, the Answered to Closed value is 2 days.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Query Cycle Times by User

This report shows the minimum, maximum, and median number of days for queries to move from open to answered to closed. This report is grouped by site or sponsor.

Use this report to help you see whether a given site or sponsor is having issues efficiently resolving queries.



Tip:

For the best performance, do not select any optional filters on the Selection Criteria page.

Subtotals and totals

- **Subtotals**—By User Name and Rights Group.
 - Min—Lowest minimum value for any site for this user.
 - Max—Highest maximum value for any site for this user.
 - Median—No value.
- **Totals**—Overall query cycle time totals.
 - Min—Lowest minimum value for any site for this user.
 - Max—Highest maximum value for any site for this user.
 - Median—No value.

Table 3-17 Column descriptions

Column	Description
Rights Group	<p>Data type: String</p> <p>Description: The Oracle InForm rights group to which the user belongs.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
User Name	<p>Data type: String</p> <p>Description: The user name of the Oracle InForm user.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Table 3-17 (Cont.) Column descriptions

Column	Description
Subject Count	<p>Data type: Numeric</p> <p>Description: The number of subjects who enrolled at the site.</p> <p>How calculated: For each site, counts subjects who enrolled at the site, including subjects who are currently assigned other states.</p> <p>Note: The Enrollment form, designed according to InForm specifications, must be completed for the subject.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Status is determined by the value on the Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p>
Query Count	<p>Data type: Numeric</p> <p>Description: The total number of number of open, answered, and closed queries.</p> <p>How calculated: This calculation counts all open, closed, and answered queries, based on your selection in the Query Type filter on the report prompt page. This count does not include queries that have never been opened (candidate queries or deleted candidate queries).</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Open to Answered (Days): Min, Max, Median	<p>Data type: Numeric</p> <p>Description: Data on the number of days from when queries are opened to when they are answered. For each user, columns display:</p> <ul style="list-style-type: none"> • Minimum—The fewest number of days for an opened query to be answered for this user. • Maximum—The greatest number of days for an opened query to be answered for this user. • Median—The median of the opened-to-answered range for all answered queries for this user. <p>How calculated: The calculation begins on the first day when the status of a query was set to Open and ends on the most recent day when the status of a query was set to Answered. This value is calculated in multiples of 24 (hours) and is rounded down to the nearest whole number.</p> <p>For example, if a query is opened on day 1 at 10 AM and answered on day 3 at 9 AM, the Open to Answered value is 2 days.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Table 3-17 (Cont.) Column descriptions

Column	Description
Answered to Closed (Days): Min, Max, Median	<p>Data type: Numeric</p> <p>Description: Data on the number of days from when queries are answered to when they are closed. For each user, columns display:</p> <ul style="list-style-type: none"> • Minimum—The fewest number of days for an answered query to be closed for this user. • Maximum—The greatest number of days for an answered query to be closed for this user. • Median—The median of the answered-to-closed range for all closed queries for this user. <p>How calculated: The calculation begins on the first day when the status of a query was set to Answered and ends on the most recent day when the status of a query was set to Closed. This value is calculated in multiples of 24 (hours) and is rounded down to the nearest whole number.</p> <p>For example, if a query is answered on day 1 at 10 AM and closed on day 3 at 9 AM, the Answered to Closed value is 2 days.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Open to Closed (Days): Min, Max, Median	<p>Data type: Numeric</p> <p>Description: Data on the number of days from when queries are opened to when they are closed. For each user, columns display:</p> <ul style="list-style-type: none"> • Minimum—The fewest number of days for an opened query to be closed for this user. • Maximum—The greatest number of days for an opened query to be closed for this user. • Median—The median of the opened- to-closed range for all closed queries for this user. <p>How calculated: The calculation begins on the first day when the status of a query was set to Open and ends on the most recent day when the status of a query was set to Closed. This value is calculated in multiples of 24 (hours) and is rounded down to the nearest whole number.</p> <p>For example, if a query is opened on day 1 at 10 AM and closed on day 3 at 9 AM, the Answered to Closed value is 2 days.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Query Performance Summary by Site

This report provides a summary collection of query statistics: the volume of queries by CRF and CRB, the average and range of days to resolve, and the current ages of unresolved queries. The report lists only sites that have open queries.

Study managers and lead CRAs use this report to review performance, track key metrics, and develop comprehensive action plans.



Tip:

For the best performance, do not select any optional filters on the Selection Criteria page.

Graphs

- A bar graph appears on the first page of the Query Performance Summary by Site report, plotting the median query count for case books and forms, by site within country.
- A second graph shows the median days to resolve queries, by site within country.
- A third graph shows the median days queries have been open, by site within country.

Subtotals and totals

- **Subtotals**—By Country.
- **Totals**—Overall query count totals.

Table 3-18 Column descriptions

Column	Description
Country	<p>Data type: String</p> <p>Description: The country in which a site is located, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Enrolled	<p>Data type: Numeric</p> <p>Description: The number of subjects who enrolled at the site.</p> <p>How calculated: For each site, counts subjects who enrolled at the site, including subjects who are currently assigned other states.</p> <p>Note: The Enrollment form, designed according to Oracle InForm specifications, must be completed for the subject.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Status is determined by the value on the Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p>

Table 3-18 (Cont.) Column descriptions

Column	Description
Queries per CRB	<p>Data type: Numeric</p> <p>Description: The maximum and median number of all queries per casebook for all enrolled subjects in each site.</p> <p>How calculated: For each site, counts manual, automatic, or both types of queries, based on your selection in the Query Type filter on the report prompt page. This count includes all queries, regardless of status, and all subjects who were ever enrolled, regardless of current status.</p> <p>For each site, columns display:</p> <ul style="list-style-type: none"> • Maximum—The maximum number of all queries per case book for all enrolled subjects at the site. • Median—The median number of all queries per case book for all enrolled subjects at the site. <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Queries per CRF	<p>Data type: Numeric</p> <p>Description: The maximum and median number of all queries per form for all started forms for all enrolled subjects in each site.</p> <p>How calculated: For each site, counts manual, automatic, or both types of queries, based on your selection in the Query Type filter on the report prompt page. This count includes all queries, regardless of status on all started clinical forms.</p> <p>For each site, columns display:</p> <ul style="list-style-type: none"> • Maximum—The maximum number of all queries per form for all started forms at the site. • Median—The median number of all queries per form for all started forms at the site. <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Table 3-18 (Cont.) Column descriptions

Column	Description
Days to Resolve (Open to Close)	<p>Data type: Numeric</p> <p>Description: The minimum, maximum, and median number of days for queries to be opened and closed.</p> <p>How calculated: For each query, the calculation starts on the first date when the status of the query was set to Open and ends on the most recent date when the status of the query was set to Closed. The number of days from the Open to the Closed state is rounded down to the nearest whole number.</p> <p>How calculated: The calculation begins on the first day when the status of a query was set to Open and ends on the most recent day when the status of a query was set to Closed. This value is calculated in multiples of 24 (hours) and is rounded down to the nearest whole number.</p> <p>For example, if a query is opened on day 1 at 10 AM and closed on day 3 at 9 AM, the Answered to Closed value is 2 days.</p> <p>For each site, columns display:</p> <ul style="list-style-type: none">• Minimum—The fewest number of days taken for a query to be opened and closed at the site.• Maximum—The maximum number of days taken for a query to be opened and closed at the site.• Median—The median number of days for all queries to be opened and closed at the site. <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Table 3-18 (Cont.) Column descriptions

Column	Description
Days Open	<p>Data type: Numeric</p> <p>Description: For each site, the number of queries that have been open for a specific number of days.</p> <p>How calculated: This calculation applies only to queries with a current status of Open. The calculation begins on the date when a query was last opened and ends on the current date.</p> <p>This value is calculated in multiples of 24 (hours). For example, if the query is opened at 10 a.m. on day 1 and the report is run 10 days later at 9 a.m., the days open is 9.</p> <p>You specify the aging interval (in days) on the report prompt page.</p> <p>For example, if you specify 7, the resulting report shows the number of queries that have been open for:</p> <ul style="list-style-type: none"> • Seven or fewer days. • More than 7 but equal to or fewer than 14 days. • More than 14 but equal to or fewer than 21 days. • More than 21 but equal to or fewer than 28 days. • More than 28 days. <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Query Performance Summary by User

This report provides a summary collection of query statistics: the volume of queries by CRF and CRB, the average and range of days to resolve, and the current ages of unresolved queries. The report lists only users that have open queries.

Study managers and lead CRAs use this report to filter by user and direct query-related inquiries to appropriate study personnel.



Tip:

For the best performance, do not select any optional filters on the Selection Criteria page.

Subtotals and totals

- **Subtotals**—By User Name and Rights Group.
- **Totals**—Overall query count totals.

Table 3-19 Column descriptions

Column	Description
Rights Group	<p>Data type: String</p> <p>Description: The Oracle InForm rights group to which the user belongs.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
User Name	<p>Data type: String</p> <p>Description: The user name of the Oracle InForm user.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Enrolled	<p>Data type: Numeric</p> <p>Description: The number of subjects who enrolled at the site.</p> <p>How calculated: For each site, counts subjects who enrolled at the site, including subjects who are currently assigned other states.</p> <p>Note: The Enrollment form, designed according to Oracle InForm specifications, must be completed for the subject.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Status is determined by the value on the Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p>

Table 3-19 (Cont.) Column descriptions

Column	Description
Queries per CRB	<p>Data type: Numeric</p> <p>Description: The maximum and median number of all queries per casebook for all enrolled subjects in each site.</p> <p>How calculated: For each site, counts manual, automatic, or both types of queries, based on your selection in the Query Type filter on the report prompt page. This count includes all queries, regardless of status, and all subjects who were ever enrolled, regardless of current status.</p> <p>For each site, columns display:</p> <ul style="list-style-type: none"> • Maximum—The maximum number of all queries per case book for all enrolled subjects at the site. • Median—The median number of all queries per case book for all enrolled subjects at the site. <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Queries per CRF	<p>Data type: Numeric</p> <p>Description: The maximum and median number of all queries per form for all started forms for all enrolled subjects in each site.</p> <p>How calculated: For each site, counts manual, automatic, or both types of queries, based on your selection in the Query Type filter on the report prompt page. This count includes all queries, regardless of status on all started clinical forms.</p> <p>For each site, columns display:</p> <ul style="list-style-type: none"> • Maximum—The maximum number of all queries per form for all started forms at the site. • Median—The median number of all queries per form for all started forms at the site. <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Table 3-19 (Cont.) Column descriptions

Column	Description
Days to Resolve (Open to Close)	<p>Data type: Numeric</p> <p>Description: The minimum, maximum, and median number of days for queries to be opened and closed.</p> <p>How calculated: For each query, the calculation starts on the first date when the status of the query was set to Open and ends on the most recent date when the status of the query was set to Closed. The number of days from the Open to the Closed state is rounded down to the nearest whole number.</p> <p>How calculated: The calculation begins on the first day when the status of a query was set to Open and ends on the most recent day when the status of a query was set to Closed. This value is calculated in multiples of 24 (hours) and is rounded down to the nearest whole number.</p> <p>For example, if a query is opened on day 1 at 10 AM and closed on day 3 at 9 AM, the Answered to Closed value is 2 days.</p> <p>For each site, columns display:</p> <ul style="list-style-type: none">• Minimum—The fewest number of days taken for a query to be opened and closed at the site.• Maximum—The maximum number of days taken for a query to be opened and closed at the site.• Median—The median number of days for all queries to be opened and closed at the site. <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Table 3-19 (Cont.) Column descriptions

Column	Description
Days Open	<p>Data type: Numeric</p> <p>Description: For each site, the number of queries that have been open for a specific number of days.</p> <p>How calculated: This calculation applies only to queries with a current status of Open. The calculation begins on the date when a query was last opened and ends on the current date.</p> <p>This value is calculated in multiples of 24 (hours). For example, if the query is opened at 10 a.m. on day 1 and the report is run 10 days later at 9 a.m., the days open is 9.</p> <p>You specify the aging interval (in days) on the report prompt page.</p> <p>For example, if you specify 7, the resulting report shows the number of queries that have been open for:</p> <ul style="list-style-type: none"> • Seven or fewer days. • More than 7 but equal to or fewer than 14 days. • More than 14 but equal to or fewer than 21 days. • More than 21 but equal to or fewer than 28 days. • More than 28 days. <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Query Status by Site

This report shows the current total queries in each state for each site, with the option to drill down into the list of queries for visits or subjects for a specific site.

Sponsor personnel use this report to determine whether particular sites are generating many queries, which might indicate potential problems.



Tip:

For the best performance, do not select any optional filters on the Selection Criteria page.

Subtotals and totals

- **Subtotals**—By Country
- **Totals**—Overall query count totals

Drill-through reports

This report contains links to two drill-through reports:

- Click the value in the **Site Mnemonic** column to drill down to the Query Status by Site and Visit report for the site.
- Click the value in the **Subject Count** column to drill down to the Query Status by Site and Subject report for the subject.

Table 3-20 Column descriptions

Column	Description
Country	<p>Data type: String</p> <p>Description: The country in which a site is located, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Subject Count	<p>Data type: Numeric</p> <p>Description: The number of subjects who enrolled at the site.</p> <p>How calculated: For each site, counts subjects who enrolled at the site, including subjects who are currently assigned other states.</p> <p>Note: The Enrollment form, designed according to InForm specifications, must be completed for the subject.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Status is determined by the value on the Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p>
Avg Queries per Patient	<p>Data type: Numeric</p> <p>Description: The average number of queries associated with each subject at the site.</p> <p>How calculated: Counts the average number of unique queries per subject for the site, regardless of status, by dividing the number of queries for the site by the subject count for the site. This calculation counts manual, automatic, or both types of queries, based on your selection for the Query Types prompt.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Table 3-20 (Cont.) Column descriptions

Column	Description
Query Count: Candidate	<p>Data type: Numeric</p> <p>Description: For each site, the number of queries with a current status of Candidate.</p> <p>How calculated: Counts queries with the current status of Candidate. Counts manual, automatic, or both types of candidate queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Deleted	<p>Data type: Numeric</p> <p>Description: For each site, the number of queries with a current status of Deleted.</p> <p>How calculated: Counts queries with a current status of Deleted. Counts manual, automatic, or both types of deleted queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Open	<p>Data type: Numeric</p> <p>Description: For each site and visit, the number of queries with a current status of Open.</p> <p>How calculated: Counts all open queries for each site. Counts manual, automatic, or both, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Answered	<p>Data type: Numeric</p> <p>Description: For each site, the number of queries with a current status of Answered.</p> <p>How calculated: Counts all answered queries for each site. Counts manual, automatic, or both types of answered queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Closed	<p>Data type: Numeric</p> <p>Description: For each site, the number of queries with a current status of Closed.</p> <p>How calculated: Counts all closed queries for each site. Counts automatic, manual, or both types of closed queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Table 3-20 (Cont.) Column descriptions

Column	Description
Query Count: Total (% of Total within Country)	<p>Data type: Numeric (Percentage)</p> <p>Description: The total number of queries at the site, regardless of status. For each site total, this column also displays the percentage of total queries for the country at the site.</p> <p>How calculated: Counts automatic, manual, or both types of closed queries, based on your selection in the Query Type filter on the report prompt page. The percentage is calculated as follows:</p> $[\% \text{ of total within country}] = [\text{query count for the site}] * 100 / [\text{query count for the country}]$ <p>Data source: Derived and stored in the Reporting and Analysis database. Percentage derived for display.</p>

Query Status by Site and Subject

This report is a drill-down report from the link in the Site Mnemonic column in the Query Status by Site and Query Status by User reports and can also be run as a stand-alone report.

This report shows CRAs and study managers the number of queries to date in each query state for one or more subjects within selected sites.



Tip:

For the best performance, do not select any optional filters on the Selection Criteria page.

Subtotals and totals

- **Subtotals**—By Site and Country.
- **Totals**—Overall query count totals.

Table 3-21 Column descriptions

Column	Description
Country	<p>Data type: String</p> <p>Description: The country in which a site is located, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Table 3-21 (Cont.) Column descriptions

Column	Description
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Subject Number	<p>Data type: String</p> <p>Description: The subject number, followed by the subject initials.</p> <p>The subject number identifies the subject. The subject number and subject initials can be changed post enrollment, if this is configured in the study.</p> <p>Note: Subject number might not be unique at your site.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Current Status	<p>Data type: String</p> <p>Description: The current status of the subject. Subjects can be in only one state at a time.</p> <ul style="list-style-type: none"> • Screened—The Screening form for the subject was started, but the subject is not enrolled for one of the following reasons: <ul style="list-style-type: none"> – The subject has been fully screened, but the enrollment form has not been started. – The subject is fully screened and the enrollment process has started, but is not complete. • Screen Failed—The subject failed the InForm screening process. • Enroll Failed—The subject passed the Oracle InForm screening process, but failed the enrollment process. • Enrolled—The subject was properly enrolled in the Oracle InForm application, but has not reached the status of randomized, completed, or dropped out. • Randomized—The subject was enrolled and has been randomized in the Oracle InForm software, but is not yet completed or dropped out. • Complete—The subject has completed the study, as recorded in the Complete control of the Study Completion form for the subject. • Dropped out—The subject has dropped out of the study, as recorded in the Complete control of the Study Completion form for the subject. <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Table 3-21 (Cont.) Column descriptions

Column	Description
Started Visits Count	<p>Data type: Numeric</p> <p>Description: For each subject, the number of visits that have a current status of Started.</p> <p>How calculated: For each subject, a visit is counted as started if at least one expected form in the visit is started. A form is started when any data, queries, or comments have been entered on the form.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Candidate	<p>Data type: Numeric</p> <p>Description: For each site, the number of queries with a current status of Candidate.</p> <p>How calculated: Counts queries with the current status of Candidate. Counts manual, automatic, or both types of candidate queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Deleted	<p>Data type: Numeric</p> <p>Description: For each site, the number of queries with a current status of Deleted.</p> <p>How calculated: Counts queries with a current status of Deleted. Counts manual, automatic, or both types of deleted queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Open	<p>Data type: Numeric</p> <p>Description: For each site and visit, the number of queries with a current status of Open.</p> <p>How calculated: Counts all open queries for each site. Counts manual, automatic, or both, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Answered	<p>Data type: Numeric</p> <p>Description: For each site, the number of queries with a current status of Answered.</p> <p>How calculated: Counts all answered queries for each site. Counts manual, automatic, or both types of answered queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Table 3-21 (Cont.) Column descriptions

Column	Description
Query Count: Closed	<p>Data type: Numeric</p> <p>Description: For each site, the number of queries with a current status of Closed.</p> <p>How calculated: Counts all closed queries for each site. Counts automatic, manual, or both types of closed queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Total (% of Queries within Country)	<p>Data type: Numeric (Percentage)</p> <p>Description: The total number of queries at the site, regardless of status. This count is a sum of Candidate, Deleted, Open, Answered, and Closed queries plus the count of Conflict queries (which are not part of this report). For each site total, this column also displays the percentage of total queries for the country at the site.</p> <p>How calculated: Counts automatic, manual, or both types of closed queries, based on your selection in the Query Type filter on the report prompt page. The percentage is calculated as follows:</p> $[\% \text{ of total within country}] = [\text{query count for the site}] * 100 / [\text{query count for the country}]$ <p>Data source: Derived and stored in the Reporting and Analysis database. Percentage derived for display.</p> <p>Note: A conflict query is a query that the InForm application automatically generates when it detects a discrepancy between different copies of the same study when users synchronize them. This query type exists when the Oracle InForm application is used with the CIS application. Conflict queries can also be entered using the Oracle InForm Adapter query interface.</p>

Query Status by Site and Visit

This report is a drill-down report and uses the Subject Count as the link from the Query Status by Site and Query Status by User reports. It can also be run as a stand-alone report.

This report shows CRAs and study managers the number of queries to date in each query state for one or more visits for selected sites. CDMs use this report to review current query status by visit to help close out open queries in advance of an interim analysis or other study milestone.

 **Tip:**

For the best performance, do not select any optional filters on the Selection Criteria page.

Subtotals and totals

- **Subtotals**—By Site and Country.
- **Totals**—Overall query count totals.

Table 3-22 Column descriptions

Column	Description
Country	<p>Data type: String</p> <p>Description: The country in which a site is located, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Subject Count	<p>Data type: Numeric</p> <p>Description: The number of subjects who enrolled at the site.</p> <p>How calculated: For each site, counts subjects who enrolled at the site, including subjects who are currently assigned other states.</p> <p>Note: The Enrollment form, designed according to Oracle InForm specifications, must be completed for the subject.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Status is determined by the value on the Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p>
Visit Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation of the visit title, as specified in the study design. For CRF visits, this title appears at the top of a collection of forms in the visit timeline and may not be a unique identifier.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Table 3-22 (Cont.) Column descriptions

Column	Description
Query Count: Candidate	<p>Data type: Numeric</p> <p>Description: For each site, the number of queries with a current status of Candidate.</p> <p>How calculated: Counts queries with the current status of Candidate. Counts manual, automatic, or both types of candidate queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Deleted	<p>Data type: Numeric</p> <p>Description: For each site, the number of queries with a current status of Deleted.</p> <p>How calculated: Counts queries with a current status of Deleted. Counts manual, automatic, or both types of deleted queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Opened	<p>Data type: Numeric</p> <p>Description: For each site and visit, the number of queries with a current status of Open.</p> <p>How calculated: Counts all open queries for each site. Counts manual, automatic, or both, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Answered	<p>Data type: Numeric</p> <p>Description: For each site, the number of queries with a current status of Answered.</p> <p>How calculated: Counts all answered queries for each site. Counts manual, automatic, or both types of answered queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Closed	<p>Data type: Numeric</p> <p>Description: For each site, the number of queries with a current status of Closed.</p> <p>How calculated: Counts all closed queries for each site. Counts automatic, manual, or both types of closed queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Table 3-22 (Cont.) Column descriptions

Column	Description
Query Count: Total (% Queries within Country)	<p>Data type: Numeric (Percentage)</p> <p>Description: The total number of queries at the site, regardless of status. This count is a sum of Candidate, Deleted, Open, Answered, and Closed queries plus the count of Conflict queries (which are not part of this report). For each site total, this column also displays the percentage of total queries for the country at the site.</p> <p>How calculated: Counts automatic, manual, or both types of closed queries, based on your selection in the Query Type filter on the report prompt page. The percentage is calculated as follows:</p> $[\% \text{ of total within country}] = [\text{query count for the site}] * 100 / [\text{query count for the country}]$ <p>Data source: Derived and stored in the Reporting and Analysis database. Percentage derived for display.</p> <p>Note: A conflict query is a query that the InForm application automatically generates when it detects a discrepancy between different copies of the same study when users synchronize them. This query type exists when the Oracle InForm application is used with the CIS application. Conflict queries can also be entered using the Oracle InForm Adapter query interface.</p>

Query Status by User

This report shows CRAs and study managers the raw numbers of queries to date in each query state for one or more sites, by user, with the option to drill down into the list of queries for visits or subjects for a specific site.



Tip:

For the best performance, do not select any optional filters on the Selection Criteria page.

Subtotals and totals

- **Subtotals**—None.
- **Totals**—Overall query count totals.

Drill-through reports

This report contains links to two drill-through reports:

- Click a value in the Site Mnemonic column to drill down to the Query Status by Site and Visit report for the selected site.

- Click a value in the Subject Count column to drill down to the Query Status by Site and Subject report for the subjects included in the count.

Table 3-23 Column descriptions

Column	Description
Rights Group	<p>Data type: String</p> <p>Description: The Oracle InForm rights group to which the user belongs.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
User Name	<p>Data type: String</p> <p>Description: The user name of the Oracle InForm user.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Subject Count	<p>Data type: Numeric</p> <p>Description: The number of subjects who enrolled at the site.</p> <p>How calculated: For each site, counts subjects who enrolled at the site, including subjects who are currently assigned other states.</p> <p>Note: The Enrollment form, designed according to InForm specifications, must be completed for the subject.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Status is determined by the value on the Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p> <p>Note: You can use any of the predefined subject filters to further qualify this count.</p>
Avg Queries per Patient	<p>Data type: Numeric</p> <p>Description: The average number of queries associated with each subject at the site.</p> <p>How calculated: Counts the average number of unique queries per subject for the site, regardless of status, by dividing the number of queries for the site by the subject count for the site. This calculation counts manual, automatic, or both types of queries, based on your selection for the Query Types prompt.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Table 3-23 (Cont.) Column descriptions

Column	Description
Query Count: Candidate	<p>Data type: Numeric</p> <p>Description: For each site, the number of queries with a current status of Candidate.</p> <p>How calculated: Counts queries with the current status of Candidate. Counts manual, automatic, or both types of candidate queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Deleted	<p>Data type: Numeric</p> <p>Description: For each site, the number of queries with a current status of Deleted.</p> <p>How calculated: Counts queries with a current status of Deleted. Counts manual, automatic, or both types of deleted queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Open	<p>Data type: Numeric</p> <p>Description: For each site and visit, the number of queries with a current status of Open.</p> <p>How calculated: Counts all open queries for each site. Counts manual, automatic, or both, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Answered	<p>Data type: Numeric</p> <p>Description: For each site, the number of queries with a current status of Answered.</p> <p>How calculated: Counts all answered queries for each site. Counts manual, automatic, or both types of answered queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Closed	<p>Data type: Numeric</p> <p>Description: For each site, the number of queries with a current status of Closed.</p> <p>How calculated: Counts all closed queries for each site. Counts automatic, manual, or both types of closed queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Table 3-23 (Cont.) Column descriptions

Column	Description
Query Count: Total (% of all Queries)	<p>Data type: Numeric (Percentage)</p> <p>Description: The total number of queries at the site, regardless of status. For each site total, this column also displays the percentage of total queries for the country at the site.</p> <p>How calculated: Counts automatic, manual, or both types of closed queries, based on your selection in the Query Type filter on the report prompt page. The percentage is calculated as follows:</p> $[\% \text{ of total within country}] = [\text{query count for the site}] * 100 / [\text{query count for the country}]$ <p>Data source: Derived and stored in the Reporting and Analysis database. Percentage derived for display.</p>

Query Volume by Month by Site

This report shows the number of queries opened, answered, and closed in each month for a range of months.

Site managers use this report to see if query volume or query handling is changing negatively over the course of a study.



Tip:

For the best performance, do not select any optional filters on the Selection Criteria page.

Graphs

A bar graph appears on the first page of the report, plotting the query volume by month and site.

Subtotals and totals

- **Subtotals**—By Country.
- **Totals**—Overall query count totals

Table 3-24 Column descriptions

Column	Description
Country	<p>Data type: String</p> <p>Description: The country in which a site is located, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Table 3-24 (Cont.) Column descriptions

Column	Description
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Month, Year	<p>Data type: String</p> <p>Description: Month, Year for each month in which there is query activity (queries opened, answered, or closed).</p> <p>How calculated: For each query, extracts month and year portion of the date the query was first opened, first answered, and last closed.</p>
Open	<p>Data type: Numeric</p> <p>Description: The number of queries that were opened in a given month.</p> <p>How calculated: Counts queries that were opened in a given month, based on your selections in the Query Status, Query State, and Limit to Reissued prompts on the report prompt page.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Answered	<p>Data type: Numeric</p> <p>Description: The number of queries that were answered in a given month.</p> <p>How calculated: Counts queries that were answered in a given month, based on your selections in the Query Status, Query State, and Limit to Reissued prompts on the report prompt page.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Closed	<p>Data type: Numeric</p> <p>Description: For each site, the number of queries that were closed in a given month.</p> <p>How calculated: Counts queries that were closed in a given month, based on your selections in the Query Status, Query State, and Limit to Reissued prompts on the report prompt page.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Table 3-24 (Cont.) Column descriptions

Column	Description
Total	<p>Data type: Numeric</p> <p>Description: For each site and visit, the total number of open, answered, and closed queries in a given month.</p> <p>How calculated: The sum of the values in the Open, Ans'd, and Closed columns.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Query Volume by Rule

This report shows the number of times that each rule triggered a query.

Study designers use this report to help identify problem areas and find unnecessary query rules.

Tip:

- We recommend specifying From and To values in the Rule trigger count selection criteria field before running this report. If you don't select anything in that field, the bar graph might be hard to read if rule names are long.
- For the best performance, do not select any optional filters on the Selection Criteria page.

Graphs

A bar graph appears on the first page of the Query Volume by Rule report, illustrating the number of times each rule triggered a query.

Subtotals and totals

- **Subtotals**—By rule.
- **Totals**—Overall rule trigger count totals.

Table 3-25 Column descriptions

Column	Description
Rule name	<p>Data type: String</p> <p>Description: The name that uniquely identifies the rule in the study design code. This is the rule RefName.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Table 3-25 (Cont.) Column descriptions

Column	Description
Form Mnemonic	<p>Data type: String</p> <p>Description: A short name or abbreviation for the form, as specified in the study design code. This name appears in the Visit ruler and along the left side of certain pages for use with the form selectors, and is used to access a specific form in the Oracle InForm application.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Item Name	<p>Data type: String</p> <p>Description: The name that uniquely identifies the item to which the rule is attached in the study design code. This corresponds to the Short Question in the Central Designer application or Itemset Column Header in the Oracle InForm application. Access to this data can be restricted in the Oracle InForm application. When users who do not have access to this data run a report with this report element, the resulting report displays a series of asterisks (*****) rather than the actual text.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Trigger Count	<p>Data type: Text</p> <p>Description: The total number of times that the rule triggered a query.</p> <p>How calculated: Counts rules that have triggered a query.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Subject Counts with Outstanding Queries

This report shows the number of subjects at each site that have open or answered queries at a specified time. The report includes countries and sites regardless of whether they have subjects or queries.

Study managers and CDMs use this report to obtain detailed subject counts with outstanding queries in order to resolve queries and ensure site readiness.



Tip:

For the best performance, do not select any optional filters on the Selection Criteria page.

Subtotals and totals

- **Subtotals**—By Country.

- **Totals**—Overall subject count totals.

Table 3-26 Column descriptions

Column	Description
Country	<p>Data type: String</p> <p>Description: The country in which a site is located, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Subjects	<p>Data type: Numeric</p> <p>Description: The number of subjects who enrolled at the site.</p> <p>How calculated: For each site, counts subjects who enrolled at the site, including subjects who are currently assigned other states.</p> <p>Note: The Enrollment form, designed according to Oracle InForm specifications, must be completed for the subject.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Status is determined by the value on the Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p>
Subjects with Open Queries	<p>Data type: Numeric</p> <p>Description: The number of subjects with open queries.</p> <p>How calculated: Counts subjects with at least one open query against the entered data for the subject. The open query must have been open for at least the number of days that you specified in the Minimum Days Opened or Answered filter on the report prompt page. The calculation begins on the date when the query was last opened and ends on today's date. The number of days is rounded down to the nearest whole number.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Table 3-26 (Cont.) Column descriptions

Column	Description
Subjects with Answered Queries	<p>Data type: Numeric</p> <p>Description: The number of subjects with answered queries.</p> <p>How calculated: Counts subjects with at least one answered query against the entered data for the subject. The answered query must have been answered for at least the number of days that you specified in the Minimum Days Opened or Answered filter on the report prompt page. The calculation begins on the date when the query was last answered and ends on today's date. The number of days is rounded down to the nearest whole number.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Study Administration Reports

In this section:

- [Site Study Version History Report](#)
- [Rights Group History Report](#)


Site Study Version History Report

This report provides details on the sites in your Oracle InForm studies and their associated study version at the time the report is generated. It does not include the historic Site Name or Site Mnemonic values.

Table 3-27 Column descriptions

Column	Description
Site Mnemonic	An abbreviation that identifies a site.
Site Name	The full name of the site.
Study Version Change Type	<ul style="list-style-type: none"> • Initial—The first study version applied for the given site. • Update—Any subsequent study versions applied to the given site.
Study Version	The Study Version applied to the Site for the given report row.

Table 3-27 (Cont.) Column descriptions

Column	Description
Username	The user account the Study Version was applied by.
	<div data-bbox="1149 443 1192 478" style="display: inline-block; vertical-align: middle;"></div> Note: The user name system will appear for most scenarios, including Study Versions applied to Sites through Oracle Central Designer auto deployment.
Date Applied	The date/time the Study Version was applied to the Site.

Rights Group History Report

This report provides details on the audit trail for the addition and revocation of rights to a rights group in your InForm studies at the time the report is generated.

When a rights group is initially created, it will always have at least one right associated to it. As such, the date a given rights group was created is represented in this report by the earliest chronological record of any right being associated to that rights group.

Table 3-28 Column descriptions

Column	Description
Rights Group	Shows the Rights Group, as listed in Oracle InForm user interface.
Right Category	Lists the Right Category a given Right belongs to.
Right	Shows the Right being described in the report, as listed in the Oracle InForm user interface.
Right Action	Describes the action taken against the given Right for the given Rights Group. <ul style="list-style-type: none"> • Added—The Right was added to the Rights Group. That is, the checkbox for the Right is selected in the Oracle InForm user interface and the Rights Group change is submitted. • Revoked—The Right was revoked (removed) from the Rights Group. That is, the checkbox for the right is unselected in the Oracle InForm user interface and the Rights Group change is submitted.

Table 3-28 (Cont.) Column descriptions

Column	Description
Right Change Type	<p>Describes the type of change the listed Right has gone through within the Rights Group at the time of reporting.</p> <ul style="list-style-type: none"> • Initial—The Right was Added to the Rights Group during its initial configuration. • Update—The Right was either Revoked from the Rights Group after its initial configuration, or it was Added back into it after being previously removed.
Username	<p>The user that performed the change to the Rights Group.</p>
Date Applied	<p>The date and time the change to the Rights Group was saved.</p>



Note:

When a new Rights Group is created by installing MedML with the MedML Installer utility, the username is the name of the user account for the study. The system name may have a tenant prefix (for example, tenant13.system) or not have the word "system" in it.



Note:

The format for the date is DD-MMM-YYYY HH:MM:SS (where time is 24-hour clock). The timezone for the date is the same timezone as that of the Reporting database.

Subject Reports

In this section:

- [Case Book Completion and Query Summary by Site](#)

- [Cumulative Subject Enrollment by Month](#)
- [Subject Dropout Count by Reason](#)
- [Subject Enrollment Status by Site](#)

Case Book Completion and Query Summary by Site

This report shows how many case books are complete and how many have no outstanding queries.



Tip:

For the best performance, do not select any optional filters on the Selection Criteria page.

Subtotals and totals

- **Subtotals**—By Country. Numeric columns—Total for each country. % columns—Percent for each country.
 - Numeric columns—Total for each country.
 - % columns—Percent for each country.
- **Totals**—Overall subject count totals.
 - Numeric columns—Total for all countries.
 - % columns—Percent for all countries.

Table 3-29 Column descriptions

Column	Description
Country	<p>Data type: String</p> <p>Description: The country in which a site is located, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Table 3-29 (Cont.) Column descriptions

Column	Description
Enrolled Subject Count	<p>Data type: Numeric</p> <p>Description: The number of subjects with started CRBs who have enrolled at the site and have not dropped out.</p> <p>How calculated: For each site, counts subjects with started CRBs who have been enrolled in the Oracle InForm application and have not dropped out of the study.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Incomplete CRBs (% of Incomplete CRBs)	<p>Data type: Numeric</p> <p>Description: The number of started CRBs that are not complete.</p> <p>How calculated: Counts Case Report Books that have been started and have at least one expected form without a status of Data Entry Completed. This value displays as both a total and a percentage of all started CRBs for subjects that have not dropped out:</p> $[\% \text{ incomplete CRBs}] = [\text{incomplete CRBs}] * 100 / [\text{started CRBs}]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Incomplete CRBs with Queries (% of Incomplete CRBs with Queries)	<p>Data type: Numeric</p> <p>Description: The number of started CRBs that are not complete and that have open queries.</p> <p>How calculated: Counts Case Report Books that meet all of the following criteria:</p> <ul style="list-style-type: none"> • Have been started. • Have at least one expected form without a status of Data Entry Completed. • Have at least one expected form with at least one open or answered query. <p>This value displays as both a total and a percentage of all started CRBs for subjects that have not dropped out:</p> $[\% \text{ incomplete CRBs with queries}] = [\text{incomplete CRBs with queries}] * 100 / [\text{started CRBs}]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Table 3-29 (Cont.) Column descriptions

Column	Description
Incomplete CRBs without Queries (% of Incomplete CRBs without Queries)	<p>Data type: Numeric</p> <p>Description: The number of started CRBs that are not complete and that have no outstanding queries.</p> <p>How calculated: Counts Case Report Books that meet all of the following criteria:</p> <ul style="list-style-type: none"> • Have been started. • Have at least one expected form without a status of Data Entry Completed. • Do not have any expected forms with any open or answered queries. <p>This value displays as both a total and a percentage of all started CRBs for subjects that have not dropped out:</p> $[\text{incomplete CRBs without queries}] = [\text{incomplete CRBs}] - [\text{incomplete CRBs with queries}]$ $[\% \text{ incomplete CRBs without queries}] = [\text{incomplete CRBs without queries}] * 100 / [\text{started CRBs}]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Completed CRBs (% of Completed CRBs)	<p>Data type: Numeric</p> <p>Description: The number of started CRBs that are complete.</p> <p>How calculated: Counts Case Report Books that meet all of the following criteria:</p> <ul style="list-style-type: none"> • Have been started. • Have all expected forms with a status of Data Entry Completed. <p>This value displays as both a total and a percentage of all started CRBs for subjects that have not dropped out:</p> $[\text{complete CRBs}] = [\text{CRB count}] - [\text{incomplete CRBs}]$ $[\% \text{ complete CRBs}] = [\text{complete CRBs}] * 100 / [\text{started CRBs}]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Table 3-29 (Cont.) Column descriptions

Column	Description
Completed CRBs with Queries (% of Completed CRBs with Queries)	<p>Data type: Numeric</p> <p>Description: The number of started CRBs that are complete and that have open or answered queries.</p> <p>How calculated: Counts Case Report Books that meet all of the following criteria:</p> <ul style="list-style-type: none"> • Have been started. • Have all expected forms with a status of Data Entry Completed. • Have at least one expected form with at least one open or answered query. <p>This value displays as both a total and a percentage of all started CRBs for subjects that have not dropped out:</p> $[\text{completed CRBs with queries}] = [\text{total CRBs with queries}] - [\text{incomplete CRBs with queries}]$ $[\% \text{ complete CRBs with queries}] = [\text{complete CRBs with queries}] * 100 / [\text{started CRBs}]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Completed CRBs without Queries	<p>Data type: Numeric</p> <p>Description: The number of started CRBs that are complete and that have no open or answered queries.</p> <p>How calculated: Counts Case Report Books that meet all of the following criteria:</p> <ul style="list-style-type: none"> • Have been started. • Have all expected forms with a status of Data Entry Completed. • Do not have any expected forms with any open or answered queries. <p>This value displays as both a total and a percentage of all started CRBs for subjects that have not dropped out:</p> $[\text{complete CRBs without queries}] = [\text{complete CRBs}] - [\text{complete CRBs with queries}]$ $[\% \text{ complete CRBs without queries}] = [\text{complete CRBs without queries}] * 100 / [\text{started CRBs}]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Cumulative Subject Enrollment by Month

This report charts the cumulative counts of enrolled, dropped, and completed subjects at each site over time.



Tip:

For the best performance, do not select any optional filters on the Selection Criteria page.

Graphs

A bar graph appears on the first page of the Cumulative Subject Enrollment by Month report, illustrating the enrolled, dropped, and completed subject count by month.

Subtotals and totals

- **Subtotals**—None.
- **Totals**—Overall subject count totals.

Table 3-30 Column descriptions

Column	Description
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Enrolled count by month	<p>Data type: Numeric</p> <p>Description: The number of subjects who were enrolled at the site within a given month.</p> <p>How calculated: For each site, counts the number of enrolled subjects for the month. If no new subjects are enrolled during a particular month, the count is the same as the previous month.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Dropped count by month	<p>Data type: Numeric</p> <p>Description: The number of subjects in each site who dropped out of the study during a given month.</p> <p>How calculated: For each site, counts the number of subjects who dropped out of the study during the month. If no subjects drop out during a particular month, the count is the same as the previous month.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Completed count by month	<p>Data type: Numeric</p> <p>Description: The number of subjects at the site who completed the study during a given month.</p> <p>How calculated: For each site, counts the number of subjects who complete the study in a particular month. If no subjects complete the study in a given month, the count is the same as the previous month.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Subject Dropout Count by Reason

This report shows the number of subjects who have left the study for each reason used in the study design.

Graphs

A bar graph appears on the first page of the Subject Dropout Count by Reason report, illustrating how many subjects dropped out, organized by drop out reason.

Subtotals and totals

- **Subtotals**—By Country and Site.
- **Totals**—Overall subject count totals.

Table 3-31 Column descriptions

Column	Description
Country	<p>Data type: String</p> <p>Description: The country in which a site is located, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Enrolled	<p>Data type: Numeric</p> <p>Description: The number of subjects that were enrolled at the site in the Oracle InForm application during the specified date range.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Table 3-31 (Cont.) Column descriptions

Column	Description
Dropout Reason	<p>Data type: String</p> <p>Description: Text that indicates why the subject dropped out of the study. The dropout reason is clinical data that is specified on the Study Completion form for the subject.</p> <p>Note: This report displays only those reasons that were specified when a subject dropped out of the study. If a dropout reason was never used, the reason does not appear in this report.</p> <p>UUIDs: PF_SC_COMPLETECTL, PF_SC_REASONCTL_ <i>internal_reason_value</i></p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Total Dropouts	<p>Data type: Numeric</p> <p>Description: The total number of subjects that dropped out of the study, by site. This total is a sum of all dropout counts in the row plus the count of subjects who dropped out but for whom the reason was not specified.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Subject Enrollment Status by Site

This report shows the number and percentage of subjects screened, enrolled, randomized, active, completed, or dropped by site.

Graphs

A bar graph appears on the first page of the Subject Enrollment Status by Site report, illustrating the number of screened, enrolled, and dropped subjects at each site.

Subtotals and totals

- **Subtotals**—By Country.
- **Totals**—Overall subject count totals.

Table 3-32 Column descriptions

Column	Description
Country	<p>Data type: String</p> <p>Description: The country in which a site is located, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Table 3-32 (Cont.) Column descriptions

Column	Description
Site Mnemonic	<p>Data type: String</p> <p>Description: An abbreviation that identifies a site, as entered in the Oracle InForm Administration interface.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Screened	<p>Data type: Numeric</p> <p>Description: The number of subjects who have been successfully screened in the Oracle InForm application without a screen failure during the screening process.</p> <p>How calculated: For each site, counts each subject who was successfully screened without a screen failure during the screening process and who meets one of the following conditions:</p> <ul style="list-style-type: none"> • The enrollment process was not started. • The enrollment process was started but not completed because either an enrollment failure occurred or the user completed the enrollment form but chose not to enroll the subject. • The enrollment process was completed successfully and the subject moved on to another state (Enrolled, Randomized, Dropped Out, or Incomplete). <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Screen Failure	<p>Data type: Numeric</p> <p>Description: The number of subjects who failed the screening process in the Oracle InForm application. These subjects have screen failure text generated.</p> <p>How calculated: For each site, counts the number of subjects that were failed during the Oracle InForm screening process. This count excludes the Screen Override values.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Table 3-32 (Cont.) Column descriptions

Column	Description
Enroll Failure	<p>Data type: Numeric</p> <p>Description: The number of subjects who were successfully screened (no screen failure reason generated), but failed the enrollment process by entering an invalid character (hyphen or a slash). The failure generates the enroll failure reason in the InForm application.</p> <p>How calculated: For each site, counts the number of subjects who failed the Oracle InForm enrollment process. This count excludes the Enroll Override values.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Screen Override	<p>Data type: Numeric</p> <p>Description: For each site, the number of subjects who have been screened in the Oracle InForm application due to the screening override process.</p> <p>How calculated: For each site, counts the number of subjects who failed the Oracle InForm screening process and subsequently were screened through the Oracle InForm screening override process. This count includes subjects who may have moved on to other states (such as Enrolled, Randomized, Dropped out, or Complete).</p> <p>Subjects screened and enrolled through PF Admin Import: Subjects who were added to the study through PF Admin Import are not counted in Screen/Enroll Override counts, even if they initially failed screening or enrollment.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>

Table 3-32 (Cont.) Column descriptions

Column	Description
Enroll Override	<p>Data type: Numeric</p> <p>Description: For each site, the number of subjects who have been enrolled in the Oracle InForm application due to the enrollment override process within the specified date range on the report prompt page.</p> <p>How calculated: For each site, counts subjects who have ever failed the Oracle InForm enrollment process, but have subsequently been enrolled through the Oracle InForm enroll override process. This count includes subjects who may have moved on to other states (such as Randomized, Dropped out, or Complete).</p> <p>Subjects screened and enrolled through PF Admin Import: Subjects who were added to the study through PF Admin Import are not counted in Screen/Enroll Override counts, even if they initially failed screening or enrollment.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Enrolled	<p>Data type: Numeric</p> <p>Description: The number of subjects that were ever enrolled at the site.</p> <p>How calculated: For each site, the count includes subjects who were initially screen failed or enroll failed but subsequently enrolled or moved from the Enrolled state to other states (Randomized, Dropped out, or Completed).</p> <p>Subjects screened and enrolled through PF Admin Import: Subjects who were added to the study via PF Admin Import are not counted in Screen/Enroll Override counts, even if they initially failed screening or enrollment.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database. Percentage is derived for display.</p>
Randomized	<p>Data type: Numeric</p> <p>Description: The number of enrolled subjects who have been randomized in the Oracle InForm application.</p> <p>How calculated: For each site, counts subjects who have ever been in the randomized state.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database. Percentage is derived for display.</p>

Table 3-32 (Cont.) Column descriptions

Column	Description
Active in Trial	<p>Data type: Numeric</p> <p>Description: For each site, the number of subjects currently participating in the study as of the report run date.</p> <p>How calculated: For each site, counts every subject in the Enrolled or Randomized state within the specified date range. Excludes subjects in the Completed or Dropped out state.</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database.</p>
Completed	<p>Data type: Numeric</p> <p>Description: The number of enrolled subjects who have completed the study.</p> <p>How calculated: For each site, counts subjects who have completed the study, as recorded on the Subject Completion in the InForm application.</p> <p>UUIDs: PF_SC_COMPLETECTL, PF_SC_STUDY_COMPLETE, PF_SC_STUDY_INCOMPLETE</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database. Percentage is derived for display.</p>
Dropped	<p>Data type: Numeric</p> <p>Description: The number of enrolled subjects who have dropped out of the study.</p> <p>How calculated: For each site, counts subjects who have dropped out of the study, as recorded on the Subject Completion form in the Oracle InForm application.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Replicated from the Oracle InForm transactional database to the Reporting and Analysis database. Percentage is derived for display.</p>

4

FAQs

In this chapter:

- [General reporting FAQs](#)
- [Cognos Reporting report FAQs](#)
- [Standard report FAQs](#)

General reporting FAQs

Can I create my own reports?

Yes, you can use the Cognos Reporting application to create reports.

Can I access reporting for two studies at a time?

No. If you open two Oracle InForm studies, and access reporting for one of the studies, clicking **Reports** to access reporting for the second study logs you out of reporting for the first study, and your changes are lost.

How are data access rights controlled in Oracle InForm Reporting?

Data access rights in the Reporting and Analysis module are inherited from the Oracle InForm study and adhere to the site associations and item blinding permissions that are in place for each user.

Additionally, to access the Reporting and Analysis module, an InForm user must be:

- Assigned to a rights group that includes the InForm **Reports** right. The Oracle InForm **Reports** right gives users access to the Reporting and Analysis module.
- A member of either the **Sponsor Users** or **Site Users** reporting group. This conveys the Cognos Analytics Consumer permissions that allow users only to run reports.

You can give users access to additional reporting rights by making sure that the users are assigned to one of the default reporting groups installed with the Oracle InForm software. For more information, see the *Study and Reporting Setup Guide*.

Are my reports run against real-time data?

Yes. Data in the Reporting and Analysis database is updated in real time, so reports contain up-to-date information for your study. When you run a report, it contains the most recent data for every item or control.

How do my Oracle InForm locale settings impact Reporting and Analysis?

The languages that appear in the reporting environment are determined by the locales that are set for your study.

- Prefixes for clinical metadata report elements, such as **Code~**, **Unit~**, and **Date~**.
 - Determined by: Default product locale, set during the Oracle InForm installation.
- Names of the Trial Management report elements in Cognos Reporting.

- Determined by: Reporting product locale, which is based on the default or user product locale settings in Oracle InForm.
- Cognos commands and navigation controls.
 - Determined by: Reporting product locale, which is based on the default or user product locale settings in Oracle InForm.
- Clinical data, and other language-dependent resources.
 - Determined by: Review schema locale, which is set automatically when you deploy your study to Oracle InForm.

How can I monitor site progress over time?

Save a report as a report view, which is a version of a report that contains the data at the time that you ran it. To save a report, when you view a report, tap the **disk icon** or the **ellipsis icon**. The location of the save option depends on the type of report you view. You also have the **Save as** option of saving the report version under a different name or in a different location. .

Can I schedule my reports to run automatically?

Yes. You can use Cognos to schedule individual or batches of both Report Studio and standard reports. For more information, see the Cognos documentation.

Can I email reports to other people?

Only if your study is self-hosted. If your study is hosted by Oracle, you cannot email reports to other people.

In previous releases, you could schedule a job to run in the background, and send an email that contained the report link. Users with report access could open the report from the link. However, a configuration option was available so that your organization could decide whether emailing reports was allowed. The configuration option was removed from Cognos Analytics 11. As a result, to protect subject data, we no longer allow anyone to send reports in an email.

Cognos Reporting report FAQs

What kind of data can I use in my reports?

The Reporting and Analysis database contains two types of data:

- **Study management data**—Stored in the operational data model, and includes metrics and status data for a study. Use study management data to report on the completion status of your study. You can report on things like the number of visits that are complete for a study or the number of forms that are frozen or locked.
The Reporting and Analysis database study management schema is installed with each Oracle InForm installation. It is not specific to your study.
- **Clinical reporting data**—Stored in the clinical data model, and includes data about each subject visit. Use clinical data to report on specific clinical questions and responses. You can report on things like adverse events, vital signs information, and dosing records.

I'm filtering a report with more than one repeating form and itemset. How is my data affected?

You can apply filters to reports that contain data from more than one repeating form. However, results will vary depending on where you apply the filter.

You can filter on	For these results
A report element from a non-repeating form	<p>Rows for filtered-out items are removed.</p> <p>Example: Report contains: SubjectID, Gender, Adverse events, and Concomitant Medications.</p> <p>Filter: Gender column = Male</p> <p>Results: Report removes all rows for female subjects.</p>
A report element from a repeating form	<p>Rows for filtered-out items contain the text N/A, but are not removed.</p> <p>Example: Report contains: SubjectID, Gender, Adverse events, and Concomitant Medications.</p> <p>Filter: Adverse event = Depression</p> <p>Results: Report does not remove rows for other adverse events. Instead, N/A appears in the Adverse Events column for all other adverse events.</p>

Standard report FAQs

Why can't I see lineage information for standard reports?

Lineage information is not available for reports that are created in Cognos Reporting and include an if-then-else-if-then-else construct. This includes, but is not limited to, most Oracle InForm standard reports, and Oracle custom reports.

5

What if...

In this chapter:

- My report contains empty cells
- My report contains N/A in some cells
- My report contains extra rows with incomplete information
- My standard report is missing data in a column
- Cycle time columns show negative values
- I can't see any clinical data
- I accidentally closed or logged out of Oracle InForm
- I accidentally logged out of Cognos
- I am locked out of Oracle InForm or my session times out
- A Cognos Reporting report element name has a suffix like ~1
- I can't see date time information in my report
- I can't see subject status information

My report contains empty cells

Cells in reports might be blank because:

- Data was entered for an item, then deleted.
- Data wasn't entered for an item.
- An item is set to be populated by a calculation rule, but data wasn't entered for an item that the rule requires.
For example, if the DOV item does not contain data, the DOV to Form Started column in the CRF Cycle Time Detail by Site standard report is blank.
- You created a report on associated forms, and:
 - The report elements in the report are not from associated forms.
 - The report contains data from more than two associated forms.
- You created a report with an itemset and a non-repeating section, and either of them was deleted. When this happens, the columns in the report are empty for subjects that did not have data in the deleted study object before it was deleted.
- You created a report with report elements that are stored in different database tables, and data wasn't entered for one of the report elements for one of the subjects in the report.
For example, if you add items from the Demography form and an item from the Baseline Vital Signs form, but for one subject in the report, data has not been entered for the Vital signs item on the Baseline Vital Signs form, you might see blank columns or columns populated with **N/A**.

My report contains N/A in some cells

When you create a report with clinical data, the text **N/A** might appear for the following:

- Items or controls that are not started.
- Items or controls that are blank; that is, data for the item or control has been cleared.
- Items or controls that are blinded; that is, you don't have the right to see the data.
- Items or controls that are marked as Unknown.
- Items or controls with data entered for sites you are not associated with.
- Items or controls that exist on a repeating form, if you applied a filter to exclude their data. For example, if you applied a filter on an Adverse Event form so that only the Depression adverse event appears in the report, **N/A** appears in the rows for all other adverse events.

My report contains extra rows with incomplete information

When the same form is used in multiple visits, if a subject does not have any instances of the form, the resulting report may display extra rows that contain incomplete information.

My standard report is missing data in a column

This most likely occurred because the Oracle InForm special fields were not specified when the study was created in Oracle Central Designer. To fix this issue, you must update your study design in Oracle Central Designer and re-deploy the study.

Cycle time columns show negative values

If an Oracle InForm user enters a Date Of Visit that is later than the data entry date, reports show negative values in cycle time columns. To fix this issue, open a query on the incorrect data and re-run your report when the query is resolved.

I can't see any clinical data

A reserved word might have been incorrectly used in your study design. There are several reserved words that cannot be used for the following item properties in your study design:

- Short question.
- Default question or Question if a Short question is not provided, or is populated with a reserved word.

If a reserved word is used for the item Default question or Question, you must provide a Short question that is not a reserved word, or the clinical model in the Reporting and Analysis module fails to generate.

To fix this issue, you must remove reserved words from your study design in Oracle Central Designer and re-deploy the study. For a list of reserved words for reporting, see the Oracle Central Designer documentation.

I accidentally closed or logged out of Oracle InForm

For SSO and non-SSO studies, when you close or log out of Oracle InForm, your Cognos session, which is in a separate tab in the same browser window, is invalidated as a result. There is no notification provided for this. Any unsaved changes in Cognos are lost. When you attempt to perform an action in Cognos, the Cognos log in page appears and you need to enter your Oracle InForm study credentials (user name and password) and the Oracle InForm study name.

I accidentally logged out of Cognos

Your Oracle InForm session remains active. To access Cognos again:

1. In the Oracle InForm user interface, click **Reports**.
2. If you are prompted, log in to Oracle InForm again to access Cognos.

I am locked out of Oracle InForm or my session times out

In Oracle InForm, a dialog box appears, asking you to log in again.

For SSO and non-SSO studies, if you are locked out of Oracle InForm or your session times out, your Cognos session, which is in a separate tab in the same browser window, is invalidated as a result. There is no notification provided for this. Any unsaved changes in Cognos are lost. When you attempt to perform an action in Cognos, the Cognos log in page appears and you need to enter your Oracle InForm study credentials (user name and password) and the Oracle InForm study name.

A Cognos Reporting report element name has a suffix like ~1

If a study designer accidentally assigned more than one item in a repeating section with the same Short Question value, Cognos Reporting appends each value with a suffix to uniquely identify it. For example, if two itemsets share the Short Question **VSItemset**, Cognos Reporting identifies them as **VSItemset** and **VSItemset-1**.

As a best practice, study designers should make sure that each item in a study has a unique Short Question value.

I can't see date time information in my report

A site user might have selected Unknown for one of the date time items you included in your report.

If a site user selected Unknown for one or more parts of a date time item, Oracle InForm stores the date values in a date string column only. To fix this issue, add the string value (the report item named **YYYYMMDD ~ [control label]**) to your report to see data for the date time item.

I can't see subject status information

The subject status that appears in reports depends on which Oracle InForm features you use to set the state. For instance, to display status data for a subject in the Randomized state, you must perform subject randomization through Oracle InForm.

To see subject status information in a report, make sure that your study meets the following criteria.

Subject status	Required action in the Oracle InForm application
Screened	Oracle InForm Screening form (as designed per Oracle InForm requirements) must be successfully submitted for the subject.
Enrolled	Oracle InForm Enrollment form (as designed per Oracle InForm requirements) must be successfully submitted for the subject.
Screened Failed	Oracle InForm Screening form (as designed per Oracle InForm requirements) must be submitted for the subject. The subject subsequently fails the Oracle InForm screening process.
Enrolled Failed	Oracle InForm Enrollment form (as designed per InForm requirements) must be submitted for the subject. The subject subsequently fails the Oracle InForm enrollment process.
Enrolled Override	Oracle InForm Enrollment Override process must be successfully completed after the subject initially fails screening or enrollment.
Randomized	Subject must be randomized in Oracle InForm.
Dropped Out	Oracle InForm Study Completion form (as designed per Oracle InForm requirements) must be completed for the subject. The form must indicate that the subject has dropped out of the study.
Completed	Oracle InForm Study Completion form (as designed per Oracle InForm requirements) must be completed for the subject. The form must indicate that the subject has completed the study.