

Reporting Database Schema Guide

Oracle[®] Health Sciences InForm 6.1



ORACLE[®]

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About this guide

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Overview of this guide

This guide describes the Reporting and Analysis database, the views that are used by the Cognos operational and clinical models, the views that are used for creating Reporting Data Extracts (RDEs), and procedures for creating a custom RDE.

Audience

This guide is for system and database administrators who are responsible for producing reports using the IBM Cognos 10 Business Intelligence software and working with RDEs.

Documentation

The product documentation is available from the following locations:

- **Oracle Software Delivery Cloud** (<https://edelivery.oracle.com>)—The complete documentation set.
- **My Oracle Support** (<https://support.oracle.com>)—*Release Notes* and *Known Issues*.
- **Oracle Technology Network** (<http://www.oracle.com/technetwork/documentation>)—The most current documentation set, excluding the *Release Notes* and *Known Issues*.

All documents may not be updated for every InForm release. Therefore, the version numbers for the documents in a release may differ.

| Document | Description |
|--|--|
| <i>Release Notes</i> | The <i>Release Notes</i> document describes enhancements introduced and problems fixed in the current release, upgrade considerations, release history, and other late-breaking information. |
| <i>Known Issues</i> | The <i>Known Issues</i> document provides detailed information about the known issues in this release, along with workarounds, if available. |
| <i>Secure Configuration Guide</i> | The <i>Secure Configuration Guide</i> provides an overview of the security features provided with the Oracle® Health Sciences InForm application, including details about the general principles of application security, and how to install, configure, and use the InForm application securely. |
| <i>Upgrade and Migration Guide</i> | The <i>Upgrade and Migration Guide</i> provides instructions for upgrading and migrating the InForm software and InForm Portal software to the current InForm release, and for upgrading the Cognos software for use with the Reporting and Analysis module. |
| <i>Installation Guide</i> | The <i>Installation Guide</i> describes how to install the software and configure the environment for the InForm application and Cognos software. |
| <i>Study and Reporting Setup Guide</i> | The <i>Study and Reporting Setup Guide</i> describes how to perform the tasks that are required to set up an InForm study and configure the Reporting and Analysis module for the study. |
| <i>User Guide</i> | The <i>User Guide</i> provides an overview of the InForm application including details on multilingual studies, how to navigate through the user interface, how to manage a study-specific Home page with the InForm Portal application, and how to accomplish typical tasks you perform while running a clinical study. |
| <i>Reporting and Analysis Guide</i> | The <i>Reporting and Analysis Guide</i> provides an overview of the Reporting and Analysis module. It includes a brief overview of the Reporting and Analysis interface, illustrates how to access the Ad Hoc Reporting feature, and describes the study management and clinical data packages available for Reporting and Analysis. It also provides detailed descriptions of each standard report that is included with your installation. |

| Document | Description |
|---|---|
| <i>Reporting Database Schema Guide</i> | The <i>Reporting Database Schema Guide</i> describes the Reporting and Analysis database schema, and provides information on creating Reporting Database Extracts (RDEs). |
| <i>Utilities Guide</i> | <p>The <i>Utilities Guide</i> provides information about and step-by-step instructions for using the following utilities:</p> <ul style="list-style-type: none"> • PFCConsole utility • MedML Installer utility • InForm Data Import utility • InForm Data Export utility • InForm Performance Monitor utility • InForm Report Folder Maintenance utility <p>This guide also provides reference information for the MedML elements and scripting objects that are used to import and export data to and from the InForm application, as well as sample data import XML.</p> |
| MedML Installer utility online Help | <p>The MedML Installer utility online Help provides information about, and step-by-step instructions for using, the MedML Installer utility, which is used to load XML that defines study components into the InForm database.</p> <p>This guide also provides reference information for the MedML elements and scripting objects that are used to import and export data to and from the InForm application, as well as sample data import XML.</p> <p>This document is also available from the user interface.</p> |
| InForm Data Export utility online Help | <p>The InForm Data Export utility online Help provides information about and step-by-step instructions for using the InForm Data Export utility, which is used to export data from the InForm application to the following output formats:</p> <ul style="list-style-type: none"> • Customer-defined database (CDD) • Name value pairs <p>This document is also available from the user interface.</p> |
| InForm Data Import utility online Help | <p>The InForm Data Import utility online Help provides information about and step-by-step instructions for using the InForm Data Import utility, which is used to import data into the InForm application.</p> <p>This document is also available from the user interface.</p> |
| <i>Clinical Data API Guide</i> | The <i>Clinical Data API Guide</i> provides information about submitting data to the InForm application in InForm ODM format. |
| <i>Third Party Licenses and Notices</i> | The <i>Third Party Licenses and Notices</i> document includes third party technology that may be included in or distributed with this product. |

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Finding InForm information and patches on My Oracle Support

The latest information about the InForm application is on the Oracle Support self-service website, My Oracle Support. Before you install and use the InForm application, check My Oracle Support for the latest information, including *Release Notes* and *Known Issues*, alerts, white papers, bulletins, and patches.

Creating a My Oracle Support account

You must register at My Oracle Support to obtain a user name and password before you can enter the site.

- 1 Open a browser to <https://support.oracle.com>.
- 2 Click the **Register** link.
- 3 Follow the instructions on the registration page.

Finding information and articles

- 1 Sign in to My Oracle Support at <https://support.oracle.com>.
- 2 If you know the ID number of the article you need, enter the number in the text box at the top right of any page, and then click the magnifying glass icon or press **Enter**.
- 3 To search the knowledge base, click the **Knowledge** tab, and then use the options on the page to search by:
 - Product name or family.
 - Keywords or exact terms.

Finding patches

You can search for patches by patch ID or number, product, or family.

- 1 Sign in to My Oracle Support at <https://support.oracle.com>.
- 2 Click the **Patches & Updates** tab.
- 3 Enter your search criteria and click **Search**.
- 4 Click the patch ID number.

The system displays details about the patch. You can view the Read Me file before downloading the patch.

- 5 Click **Download**, and then follow the instructions on the screen to download, save, and install the patch files.

Finding Oracle documentation

The Oracle website contains links to Oracle user and reference documentation. You can view or download a single document or an entire product library.

Finding Oracle Health Sciences documentation

For Oracle Health Sciences applications, go to the Oracle Health Sciences Documentation page at <http://www.oracle.com/technetwork/documentation/hsgbu-clinical-407519.html>.

Note: Always check the Oracle Health Sciences Documentation page to ensure you have the most up-to-date documentation.

Finding other Oracle documentation

- 1 Do one of the following:
 - Go to <http://www.oracle.com/technology/documentation/index.html>.
 - Go to <http://www.oracle.com>, point to the **Support** tab, and then click **Product Documentation**.
- 2 Scroll to the product you need, and click the link.

Finding prerequisite software for Oracle Health Sciences applications

Prerequisite software for Oracle Health Sciences applications is available from the following locations:

- Download the latest major or minor release from the Oracle Software Delivery Cloud (<https://edelivery.oracle.com/>).

For information on the credentials that are required for authorized downloads, click **FAQs** on the main page of the Oracle Software Delivery Cloud portal.

- Download subsequent patch sets and patches from My Oracle Support (<https://support.oracle.com>).

To find patch sets or patches, select the **Patches & Updates** tab.

If a previous version of prerequisite software is no longer available on the Oracle Software Delivery Cloud, log a software media request Service Request (SR). Previous versions of prerequisite software are archived and can usually be downloaded. After you open an SR, you can check its status:

- US customers: Call 1-800-223-1711.
- Outside the US: Check www.oracle.com/us/support/contact/index.html for your local Oracle Support phone number.

For more information on logging a media request SR, go to My Oracle Support for Document 1071023.1: Requesting Physical Shipment or Download URL for Software Media (<https://support.oracle.com/epmos/faces/DocumentDisplay?id=1071023.1>).

CHAPTER 1

The Reporting and Analysis database

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Overview of the Reporting and Analysis database

The Reporting and Analysis database is used with the Reporting and Analysis module. The Reporting and Analysis module is based on the IBM Cognos 10 Business Intelligence applications, which have been customized and integrated into the InForm application by Oracle, and embedded in the InForm user interface. The Reporting and Analysis module provides a library of configurable reports, predefined reports, and ad hoc reporting and charting tools. You use the Reporting and Analysis module to access both clinical and operational data in real time from the InForm database.

Naming conventions

The Reporting and Analysis database uses the following naming conventions for schema objects:

| Prefix | Schema object type |
|--------|---|
| CV_ | Subject data view (clinical view). |
| DI_ | Form and itemset clinical view with date and state information. |
| DV_ | Views used for the Data Viewer. |
| CD_ | Clinical data and metadata for form controls. |
| CT_ | Clinical data table. |
| IRV_ | View. |
| IRV_MD | View of study design metadata. |
| RT_ | Table. |
| IRI_ | Index. |
| IRC_ | Constraint. |
| PF_ | Table replicated from the InForm database. |

The Reporting and Analysis database is closely tied to the InForm study database. However, many of the items in the InForm database have different names in the Reporting and Analysis database, as shown in the following table.

| Object type | MedML type | InForm database name | Reporting and Analysis database name |
|---------------|--------------|----------------------|--------------------------------------|
| Study | | Volume | Study |
| Study Version | StudyVersion | VolumeEdition | StudyVersion |
| Visit | FormSet | VEChapter | StudyVersionVisit |
| Visit | | Chapter | Visit |
| Form | Form | VEChapterPage | StudyVersionForm |
| Form | | Page | Form |
| Subject | | Patient | Subject |
| Subject Visit | | SubjectVEChapter | SubjectVisit |

Locales in the Reporting and Analysis module

There are multiple locales that affect the languages that appear in the Reporting and Analysis environment.

- Default product locale
 - Set during the InForm installation.
 - Controls the language of the prefixes for clinical metadata, such as **Code~**, **Unit~**, and **Date~**, which appear in the Ad Hoc Reporting tree.
- Reporting product locale
 - Based on the default or user product locale settings in the InForm application.
 - Controls the language of Cognos commands and navigation controls.
 - Controls the language of the study metadata, such as the names of the report topics in the Ad Hoc Reporting tree, for the Trial Management data model.
- Review schema locale
 - Set automatically when you deploy your study to the InForm application.

Note: You can use the PFAAdmin utility to change the review schema locale after the Reporting and Analysis installation. For more information, see the *Study and Reporting Setup Guide*.

- Defines the language in which language-dependent resources such as clinical data are displayed.

Note: Make sure that the review schema locale that you select for the Reporting and Analysis module contains all the forms and data elements from all the study locales for the study.

CHAPTER 2

Operational view descriptions

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Study design metadata

IRV_STUDYVERSIONS

This view contains one row for each study version installed into the study (MedML StudyVersion element).

| IRV_STUDYVERSIONS | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| STUDYVERSIONID (PK) | Numeric identifier for the current study version. |
| STUDYID | Numeric identifier of the study. |
| STUDYREV | Revision number for the study. |
| REVTIME | Time the study version was entered into the database. |
| STUDYTYPE | Type of study (always 1 in reporting): 0 - system forms 1 - study forms |
| STUDYNAME | Name of the study associated with the study version. |
| TRADEDRUGNAME | Trade name for the drug associated with the study version. |
| GENERICDRUGNAME | Generic name for the drug associated with the study version. |
| SPONSORDRUGNAME | Name that the sponsor uses for the drug associated with the study version. |
| SPONSORAPPROVALDATE | Date when the sponsor approved the use of the study version. |
| EDITIONDESCRIPTION | Description of the study version. |
| STUDYVERSION | Study name. |
| PROTOCOLDESIGNNOTE | Design note for the protocol for the study version, as provided by the study designer. |

IRV_STUDYVERSION_VISITS

This view contains one row for each formset (visit) installed into the study (MedML FormSet element).

| IRV_STUDYVERSION_VISITS | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| STUDYVERSIONID (PK) | Numeric identifier for the current study version associated with the formset. |
| VISITID (PK) | Numeric identifier for the visit. |
| VISITREV | Revision number for the visit. |
| VISITREFNAME | RefName for the visit. |
| VISITNAME | Name of the visit. |
| VISITMNEMONIC | Abbreviated name for the visit. |
| VISITTYPE | Numeric value for the type of visit: 1 - Visit 2 - Enrollment 3 - Screening 4 - Monitor 5 - Status 6 - Common CRF 7 - Regdocs 8 - Visitreports 9 - Conflict 16 - Relation |
| VTSUBJECTVISIT | Visit type is CRF: 0 - No 1 - Yes |
| VTENROLLMENT | Visit type is Enrollment: 0 - No 1 - Yes |
| VTSCREENING | Visit type is Screening: 0 - No 1 - Yes |
| VTMONITOR | Visit type is Monitor: 0 - No 1 - Yes |

| IRV_STUDYVERSION_VISITS | |
|------------------------------------|---|
| Column Name (Key indicator) | Column Description |
| VTSTATUS | Visit type is Status: 0 - No 1 - Yes |
| VTCOMMONCRF | Visit type is Common CRF: 0 - No 1 - Yes |
| VTREGDOCS | Visit type is Regulatory Document: 0 - No 1 - Yes |
| VTVISITREPORT | Visit type is Visit Report: 0 - No 1 - Yes |
| VTCONFLICT | Visit type is Conflict: 0 - No 1 - Yes |
| VISITPROPERTIES | Contains the same data as the VISITTYPE column. For internal Oracle use only. |
| VISITSCHEDULED | Visit is scheduled: 0 - No 1 - Yes |
| VISITOPTIONAL | Visit is optional: 0 - No 1 - Yes |
| VISITSREPEATING | Visit can be repeated: 0 - No 1 - Yes |
| VISITDYNAMIC | Visit is dynamic: 0 - No 1 - Yes |
| VISITRELATION | Visit type is Relation: 0 - No 1 - Yes |
| HELPTTEXT | Help text for the visit. |

| IRV_STUDYVERSION_VISITS | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| DESIGNNOTE | Design note for the visit, as provided by the study designer. |
| VISITORORDER | Order of the visit in the study. |
| STARTHOURSFROMPREVIOUS | Number of hours from enrollment to when the visit is scheduled to start. |
| STARTHOURSFROMENROLL | Number of hours from enrollment to when the visit is scheduled to start. |

IRV_STUDYVERSION_FORMS

This view contains one row for each form installed into the study (MedML FormRef element).

| IRV_STUDYVERSION_FORMS | |
|-----------------------------|--|
| Column Name (Key Indicator) | Column Description |
| STUDYID | Numeric identifier for the study in which the form exists. |
| STUDYVERSIONID (PK) | Numeric identifier for the current study version for the study in which the form exists. |
| VISITID (PK) | Numeric identifier for the visit in which the form exists. |
| VISITREV | Revision number for the visit in which the form exists. |
| FORMID (PK) | Numeric identifier for the form. |
| FORMREV | Revision number for the form. |
| FORMREFNAME | RefName for the form. |
| FORMNAME | Form name. |
| FORMMNEMONIC | Abbreviated name for the form. |
| FORMNOTE | Form note, as displayed below the form name in the user interface. |

| IRV_STUDYVERSION_FORMS | |
|-----------------------------|--|
| Column Name (Key Indicator) | Column Description |
| FORMTYPE | Form type: 1 - CRF 3 - Enrollment 4 - Custom 5 - Custom study 6 - Custom Admin 7 - Custom Rules 8 - Custom Auth 101 - Monitor Regdoc 102 - Monitor Visit Report |
| FORMHELPURL | URL for the sponsor-provided form Help. |
| QUESTIONWIDTH | Question width for the items on the form. |
| CONTROLWIDTH | Width for the controls on the form. |
| REPEATINGFORM | Form can appear multiple times in a visit: 0 - No 1 - Yes |
| COMMONFORM | Form is a common form: 0 - No 1 - Yes |
| FORMUNIQUEKEY | Each combination of forms having KEYFORM=1. Must be unique within the visit: 0 - No 1 - Yes |
| FORMDESIGNNOTE | Design note for the form, as provided by the study designer. |
| FORMORDER | Order of the form in the visit. |
| DYNAMICFORM | Form is dynamic: 0 - No 1 - Yes |
| ALTFORM | Form is an alternate form: 0 - No 1 - Yes |

| IRV_STUDYVERSION_FORMS | |
|------------------------------------|--|
| Column Name (Key Indicator) | Column Description |
| EXPECTINGALTFORM | Form is expected, and has an alternate form: 0 - No 1 - Yes |
| ALTFORMID | Numeric identifier for the alternate form. |
| ALTFORMREV | Revision number for the alternate form. |
| ASSOCVISIT | Form is repeating, with one or more instances associated with one or more visits: 0 - No 1 - Yes |
| ASSOCVISITID | Numeric identifier for the visit associated with an instance of the repeating form. |
| ASSOCVISITREV | Revision number for the visit associated with an instance of the repeating form. |
| FORMINCOMMONVISIT | Form appears in the Common CRF visit: 0 - No 1 - Yes |

IRV_FORM_REVS

This view contains one row for each form installed into the study (MedML Form element).

| IRV_FORM_REVS | |
|------------------------------------|---|
| Column Name (Key indicator) | Column Description |
| FORMID (PK) | Numeric identifier for the form. |
| FORMREV (PK) | Revision number for the form. |
| FIRSTREV | This is the first revision of the form: 0 - No 1 - Yes |
| CURRENTREV | This is the most current revision of the form: 0 - No 1 - Yes |
| FORMREFNAME | RefName for the form. |
| FORMNAME | Form name. |
| FORMMNEMONIC | Abbreviated name for the form. |

| IRV_FORM_REVS | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| FORMNOTE | Form note, as displayed below the form name in the user interface. |
| FORMTYPE | Form type: 1 - CRF 3 - Enrollment 4 - Custom 5 - Custom study 6 - Custom Admin 7 - Custom Rules 8 - Custom Auth 101 - Monitor Regdoc 102 - Monitor Visit Report |
| FORMHELPUURL | URL for the sponsor-provided form Help. |
| QUESTIONWIDTH | Question width for the items on the form. |
| CONTROLWIDTH | Width for the controls on the form. |
| REPEATINGFORM | Form can appear multiple times in a visit: 0 - No 1 - Yes |
| FORMUNIQUEKEY | Each combination of forms having KEYFORM=1. Must be unique within the visit: 0 - No 1 - Yes |
| FORMDESIGNNOTE | Design note for the form, as provided by the study designer. |

IRV_SECTION_REVS

This view contains one row for each section installed into the study (MedML Section element).

| IRV_SECTION_REVS | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| SECTIONID (PK) | Numeric identifier for the section. |
| SECTIONREV (PK) | Revision number for the section. |
| FIRSTREV | This is the first revision of the section: 0 - No 1 - Yes |
| CURRENTREV | This is the most current revision of the section: 0 - No 1 - Yes |
| SECTIONREFNAME | RefName for the section. |
| SECTIONHEADER | Section title. |
| SECTIONNOTE | Section note, as displayed below the section name in the user interface. |
| REPEATINGSECTION | Section contains an itemset: 0 - No 1 - Yes |
| SECTIONDESIGNNOTE | Design note for the section, as provided by the study designer. |

IRV_ITEM_REVS

This view contains one row for each item installed into the study (MedML Item element).

| IRV_ITEM_REVS | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| ITEMID (PK) | Numeric identifier for the item. |
| ITEMREV (PK) | Revision number for the item. |
| FIRSTREV | This is the first revision of the item: 0 - No 1 - Yes |

| IRV_ITEM_REVS | |
|------------------------------------|--|
| Column Name (Key indicator) | Column Description |
| CURRENTREV | This is the most current revision of the item: 0 - No 1 - Yes |
| ITEMLAYOUT | Layout for the item, as set in the Central Designer application at the control level. |
| ITEMLABEL | Abbreviation for the item, which appears in itemsets or as a column heading in repeating page summaries. |
| ITEMQUESTION | Item question, as displayed on a form. |
| CONTROLID | Numeric identifier for the control with which the item is associated. |
| CONTROLREV | Revision number for the control with which the item is associated. |
| CALCULATED | Item is calculated: 0 - No 1 - Yes |
| SDVREQUIRED | Item is marked SV Required. 0 - No 1 - Yes |
| RANDOMIZE | Not used. |
| ITEMREQUIRED | Item is required. |
| ITEMREFNAME | RefName for the item. |
| DISPLAYOVERRIDE | Item display mode: 1 - Read-only 2 - Editable 3 - Hidden |
| ITEMHELPURL | URL for the sponsor-provided item Help. |
| ITEMDESIGNNOTE | Design note for the item, as provided by the study designer. |

IRV_ITEMSET_REVS

This view contains one row for each itemset installed into the study (MedML ItemSet element).

| IRV_ITEMSET_REVS | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| ITEMSETID (PK) | Numeric identifier for the itemset. |
| ITEMSETREV (PK) | Revision number for the itemset. |
| ITEMSETREFNAME | RefName for the itemset. |
| SDVREQUIRED | Itemset requires source verification: 0 - No 1 - Yes |
| ITEMSETREQUIRED | Itemset is required: 0 - No 1 - Yes |
| DISPLAYOVERRIDE | Itemset display mode: 1 - Read-only 2 - Editable 3 - Hidden |
| ITEMSETHelpURL | URL for the sponsor-provided itemset Help. |
| ITEMSETDESIGNNOTE | Design note for the itemset, as provided by the study designer. |

IRV_CONTROL_REVS

This view contains one row for each control installed into the study.

| IRV_CONTROL_REVS | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| CONTROLID | Numeric identifier for the control. |
| CONTROLREV | Revision number for the control. |
| FIRSTREV | This is the first revision of the control: 0 - No 1 - Yes |
| CURRENTREV | This is the most current revision of the control: 0 - No 1 - Yes |
| CONTROLREFNAME | RefName for the control. |
| CONTROLNAME | Control name. |
| CONTROLCAPTION | Control caption. |
| CONTROLTABLE | Name of the table containing attributes specific to the type of control. |
| CONTROLTYPE | Control type: 1 - Simple control 2 - Drop-down list 3 - Listbox control 5 - Text control 6 - Calculated control 7 - Group control 8 - Radio control 9 - Checkbox group 10 - Date control |
| CONTROLLAYOUT | Control layout: 1 - Horizontal 2 - Vertical 3 - No wrapping |
| CONTROLALIGNMENT | Control alignment: 1 - Left 2 - Center 3 - Right 4 - Top 5 - Middle 6 - Bottom |

| IRV_CONTROL_REVS | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| CAPTIONALIGNMENT | Caption alignment with respect to the control: 1 - Left 2 - Center 3 - Right 4 - Top 5 - Middle 6 - Bottom |
| HEIGHT | Control height. |
| UNTDISPLAYTYPE | Units display as: 1 - A single element 2 - Radio buttons 3 - Drop-down list |
| CONTROLDESIGNNOTE | Design note for the control, as provided by the study designer. |

IRV_MD_FORMS_CONTROLS

This view contains one row for each control in every form installed into the study.

If (itemset = 0):

- **ItemID**—ItemID (ItemType 0).
- **RootcontrolID**—Root control for the item on which the control exists.
- **I_ and C_ attributes**—Attribute columns for item on which the control exists, and the item's root control.
- **ChildItemID, CI**—Null. (Only itemsets have child items.)
- **ChildID and CC_**—Attributes of the control described by the row.
- **Child1-4**—Nested controls of the item on which the control exists. (For example, if child1-4 is an array, then ChildID is the control ID located at array index ChildDepth.)

If (itemset = 1):

- **ItemID**—ItemID (ItemType 1).
- **I_**—Attribute columns for the itemset in which the control exists.
- **ChildItemID/ChildItemOrder**—Determines which item in the itemset is described by the row.
- **CI_ attributes**—Attributes for the itemset item on which the control exists.
- **C_ attributes**—Attributes of the root control of the itemset item on which the control exists.
- **Child controls**—Described the same as they are for non-itemset items.

Note: ItemID always refers to the ultimate parent item, which is the item that comes from the PF_SECTIONITEM table. ItemID refers to either an item or an itemset.

IRV_MD_FORMS_CONTROLS

| Column Name (Key indicator) | Column Description |
|-----------------------------|--|
| MDFCID (secondary PK) | Unique numerical identifier. |
| FORMID (PK) | Numeric identifier for the form on which the control exists. |
| FORMREV (PK) | Revision number for the form on which the control exists. |
| FORMREFNAME | RefName for the form on which the control exists. |
| FORMNAME | Name of the form on which the control exists. |
| FORMMNEMONIC | Abbreviated name for the form on which the control exists. |

| IRV_MD_FORMS_CONTROLS | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| FORMTYPE | Type of form on which the control exists: 1 - CRF 3 - Enrollment 4 - Custom 5 - Custom trial 6 - Custom Admin 7 - Custom Rules 8 - Custom Auth 101 - Monitor Regdoc 102 - Monitor Visit Report |
| FORMNOTE | Form note, as displayed below the form name in the user interface, for the form on which the control exists. |
| FORMHELPURL | URL for the sponsor-provided form Help. |
| QUESTIONWIDTH | Question width for the item on which the control exists. |
| FORMCONTROLWIDTH | Width of the control. |
| REPEATINGFORM | Form on which the control exists appears multiple times in a visit: 0 - no 1 - yes |
| FORMUNIQUEKEY | Each combination of forms having KEYFORM=1. Must be unique within the visit: 0 - No 1 - Yes |
| FORMDESIGNNOTE | Design note for the form on which the control exists, as provided by the study designer. |
| SECTIONID (PK) | Numeric identifier for the section in which the control exists. |
| FORMSECTIONORDER (PK) | Order within the form for the section in which the control exists. |
| SECTIONID | Numeric identifier for the section in which the control exists. |
| SECTIONREV (PK) | Revision number for the section in which the control exists. |
| NUMBERSTART | Indicates where to start numbering the items within the section in which the control exists. |

| IRV_MD_FORMS_CONTROLS | |
|------------------------------------|---|
| Column Name (Key indicator) | Column Description |
| NUMBERTYPE | Identifies the numbering scheme used for items within the section in which the control exists: 0 - Numeric 1 - Alphanumeric |
| SECTIONREFNAME | RefName for the section in which the control exists. |
| SECTIONHEADER | Title of the section in which the control exists. |
| SECTIONNOTE | Section note, as displayed below the section name in the user interface, for the section in which the control exists. |
| REPEATINGSECTION | Section in which the control exists contains an itemset: 0 - no 1 - yes |
| SECTIONDESIGNNOTE | Design note for the section in which the control exists, as provided by the study designer. |
| ITEMID (PK) | Numeric identifier for the item on which the control exists. |
| ITEMREV (PK) | Revision number for the item on which the control exists. |
| SECTIONITEMORDER (PK) | Order of the item in which the control exists within the section. |
| ITEMSET | Item on which the control exists is an itemset: 0 - No 1 - Yes |
| CI_ITEMTYPE | Type of the study object on which the control exists: 0 - item 1 - itemset |
| CI_ITEMLAYOUT | Layout for the item or itemset on which the control exists, as set in the Central Designer application at the control level. |
| CI_ITEMQUESTION | Question, as displayed on a form, for the item or itemset on which the control exists. (Always NULL for itemsets.) |
| CI_ITEMLABEL | Abbreviation in itemsets or as a column heading in repeating page summaries for the item or itemset on which the control exists. |
| CI_CALCULATED | Item or itemset on which the control exists is calculated: 0 - No 1 - Yes |

| IRV_MD_FORMS_CONTROLS | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| CI_SDVREQUIRED | Item or itemset on which the control exists is marked SV Required: 0 - No 1 - Yes |
| CI_RANDOMIZE | Item or itemset on which the control exists is randomized. |
| CI_ITEMREQUIRED | Item or itemset on which the control exists is required. |
| CI_ITEMREFNAME | RefName for the item or itemset on which the control exists. |
| CI_ITEMHELPURL | URL for the sponsor-provided Help for the item or itemset on which the control exists. |
| CI_DISPLAYOVERRIDE | Display mode for the item or itemset on which the control exists: 1 - Read-only 2 - Editable 3 - HiddenItem or itemset |
| CHILDITEMID (PK) | Numeric identifier for the child item on which the control exists. |
| CHILDITEMREV (PK) | Revision number for the child item in which the control exists. |
| KEYITEM | Child item on which the control exists is part of unique key (see ITEMSETUNIQUEKEY): 0 - No 1 - Yes |
| ITEMSETUNIQUEKEY | Each combination of items having KEYITEM=1 must be unique within the itemset: 0 - No 1 - Yes |
| CI_ITEMTYPE | Type for the itemset on which the control exists. (Always 0 for items.) |
| CI_ITEMLAYOUT | Layout for the itemset on which the control exists, as set in the Central Designer application at the control level. |
| CI_ITEMQUESTION | Question for the itemset on which the control exists, as displayed on a form. |
| CI_ITEMLABEL | Abbreviation for the itemset on which the control exists, which appears in the itemset or as a column heading in repeating page summaries. |

| IRV_MD_FORMS_CONTROLS | |
|------------------------------------|---|
| Column Name (Key indicator) | Column Description |
| CI_CALCULATED | Itemset on which the control exists is calculated: 0 - No 1 - Yes |
| CI_SDVREQUIRED | Itemset on which the control exists requires source verification: 0 - No 1 - Yes |
| CI_RANDOMIZE | Itemset on which the control exists is randomized. |
| CI_ITEMREQUIRED | Itemset on which the control exists is required: 0 - No 1 - Yes |
| CI_ITEMREFNAME | RefName for the itemset on which the control exists. |
| CI_ITEMHELPURL | URL for the sponsor-provided Help for the itemset on which the control exists. |
| CI_DISPLAYOVERRIDE | Display mode for the itemset on which the control exists (overridden by itemset property): 1 - Read-only 2 - Editable 3 - Hidden |
| CI_ITEMDESIGNNOTE | Design note for the child item on which the control exists, as provided by the study designer. |
| C_CONTROLID (PK) | Numeric identifier for the control (root control for nested controls). |
| C_CONTROLREV (PK) | Revision number for the root control. |
| C_CONTROLREFNAME | RefName for the root control. |
| C_CONTROLNAME | Name of the root control. |
| C_CONTROLTABLE | Name of the table containing attributes specific to the type of control. |

| IRV_MD_FORMS_CONTROLS | |
|------------------------------------|--|
| Column Name (Key indicator) | Column Description |
| C_CONTROLTYPE | Root control type: 1 - Simple control 2 - Drop-down list 3 - Listbox control 5 - Text control 6 - Calculated control 7 - Group control 8 - Radio control 9 - Checkbox group 10 - Date control |
| C_CONTROLLAYOUT | Root control layout: 1 - Horizontal 2 - Vertical 3 - No wrapping |
| C_CAPTION | Root control caption. |
| C_CONTROLALIGNMENT | Root control alignment: 1 - Left 2 - Center 3 - Right 4 - Top 5 - Middle 6 - Bottom |
| C_CAPTIONALIGNMENT | Caption alignment with respect to the root control: 1 - Left 2 - Center 3 - Right 4 - Top 5 - Middle 6 - Bottom |
| C_HEIGHT | Root control height. |
| C_UNITDISPLAYTYPE | Units within the control display as: 1 - A single element 2 - Radio buttons 3 - Drop-down list |
| C_CONTROLDESIGNNOTE | Design note for the root control, as provided by the study designer. |
| CC_CONTROLID | Numeric identifier for the control (for nested control). |
| CC_CONTROLREV | Revision number for the control. |
| CHILDDEPTH | Level (0-4) at which the child control is nested within the item. |

| IRV_MD_FORMS_CONTROLS | |
|------------------------------------|---|
| Column Name (Key indicator) | Column Description |
| CHILDORDER | Order in which the child control appears in the itemset. |
| CHILDSELECT | Value to associate with the parent control when this child control is selected. (If blank, the InForm application generates a value of the format "!pf!{CONTROLGUID}"). |
| CC_CONTROLREFNAME | Child control RefName. |
| CC_CONTROLNAME | Child control name. |
| CC_CONTROLTABLE | Name of the table containing attributes specific to the type of control. |
| CC_CONTROLTYPE | Child control type: 1 - Simple control 2 - Drop-down list 3 - Listbox control 5 - Text control 6 - Calculated control 7 - Group control 8 - Radio control 9 - Checkbox group 10 - Date control |
| CC_CONTROLLAYOUT | Child control layout: 1 - Horizontal 2 - Vertical 3 - No wrapping |
| CC_CAPTION | Child control caption. |
| CC_CONTROLALIGNMENT | Child control alignment: 1 - Left 2 - Center 3 - Right 4 - Top 5 - Middle 6 - Bottom |
| CC_CAPTIONALIGNMENT | Child caption alignment with respect to the child control: 1 - Left 2 - Center 3 - Right 4 - Top 5 - Middle 6 - Bottom |
| CC_HEIGHT | Child control height. |

| IRV_MD_FORMS_CONTROLS | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| CC_UNITDISPLAYTYPE | Units within the child control display as: 1 - A single element 2 - Radio buttons 3 - Drop-down list |
| CC_CONTROLDESIGNNOTE | Child control design note, as provided by the study designer. |
| CHILD1ID (PK) | Numeric identifier for the first child control. |
| CHILD1REV (PK) | Revision number for the first child control. |
| CHILD1ORDER (PK) | Order in which the first child control appears in the itemset. |
| CHILD1SELECT | First child control value to associate with the parent control when this child control is selected. (If blank, the InForm application generates a value of the format "!pf!{CONTROLGUID}"). |
| CHILD2ID (PK) | Numeric identifier for the second child control. |
| CHILD2REV (PK) | Revision number for the second child control. |
| CHILD2ORDER (PK) | Order in which the second child control appears in the itemset. |
| CHILD2SELECT | Second child control value to associate with the parent control when this child control is selected. (If blank, the InForm application generates a value of the format "!pf!{CONTROLGUID}"). |
| CHILD3ID (PK) | Numeric identifier for the third child control. |
| CHILD3REV (PK) | Revision number for the third child control. |
| CHILD3ORDER (PK) | Order in which the third child control appears in the itemset. |
| CHILD3SELECT | Third child control value to associate with the parent control when this child control is selected. (If blank, the InForm application generates a value of the format "!pf!{CONTROLGUID}"). |
| CHILD4ID (PK) | Numeric identifier for the fourth child control. |
| CHILD4REV (PK) | Revision number for the fourth child control. |
| CHILD4ORDER (PK) | Order in which the fourth child control appears in the itemset. |
| CHILD4SELECT | Fourth child control value to associate with the parent control when this child control is selected. (If blank, the InForm application generates a value of the format "!pf!{CONTROLGUID}"). |

| IRV_MD_FORMS_CONTROLS | |
|------------------------------------|--|
| Column Name (Key indicator) | Column Description |
| CREATEDATETIME | <p>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.</p> <p>When the review schema is recreated, this column displays the date and time when the review schema was recreated.</p> |
| CREATEDBYUSERID | <p>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.</p> <p>When the review schema is recreated, this column displays the system user ID.</p> |
| MODIFIEDDATETIME | <p>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.</p> <p>When the review schema is recreated, this column displays the date and time when the review schema was recreated.</p> |
| MODIFIEDBYUSERID | <p>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.</p> <p>When the review schema is recreated, this column displays the system user ID.</p> |

Study objects and administrative data

IRV_CUR_CONFIG

This view contains current configuration settings for the study (MedML SysConfig element).

| IRV_CUR_CONFIG | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| CONFIGID (PK) | Numeric identifier for the configuration setting. |
| ALLOWCPRESIZE | Not supported. Indicates whether the InForm application permits a user to minimize the navigation panel on the left side of the screen, including the user picture. 0 - no (default) 1 - yes |
| ALLOWPASSWORDREUSE | Indicates whether users can change to a previously used password when performing password updates. 0 - No 1 - Yes (default) |
| AUTOCLOSEMANUALQUERIES | Indicates whether the InForm application automatically answers a manual query when a data item change satisfies the rules on the data item. 0 - No 1 - Yes (default) |
| COOKSERVER | Name of the server used for installing MedML metadata definitions. |
| DAYSPASSWORDEXPIRATION | Number of days that can pass before the InForm application requires users to change their passwords. The default is 30. |
| DEFAULTCPMAXIMIZED | Not supported. Indicates whether or not the navigation pane in the InForm application window is maximized upon login. 0 - No 1 - Yes (default) |
| ENABLEFORGOTPASSWORD | Indicates whether to enable the feature that allows users to request a password reset if they have forgotten their password. 0 - No 1 - Yes (default) |

| IRV_CUR_CONFIG | |
|------------------------------------|--|
| Column Name (Key indicator) | Column Description |
| ENFORCEVISITDATE | Indicates whether to require the use of the Date of Visit item on the first form of every visit. 0 - no (default) 1 - yes |
| ENROLLWITHINCOMPLETEFORMS | Indicates whether the InForm application permits a subject to be enrolled with incomplete screening or enrollment information, after override authorization. 0 - no (default) 1 - yes |
| EXEPLANSERVER | The name of the server(s) that are defined as the server(s) on which execution plans run. |
| INACTIVATERETRYCOUNT | Number of failed login attempts to allow before inactivating the user account. The default is 3. |
| MAXNUMOFRESUBMISSIONS | Maximum number of times to retry submission of a failed execution plan before it is logged as an error in the event log and removed from the queue of execution plans to be run. The default is 2. |
| MINPASSWORDLENGTH | Minimum number of characters required for passwords. The default is 6. |
| MINUTESREAUTHENTICATE | Number of minutes of inactivity that can pass before the InForm application requires a user to log in again. The default is 5. |
| MINUTESREIDENTIFICATION | Number of minutes that a session can be active before the InForm application requires a user to log in again. The default is 120. |
| NAVIGATIONMODE | Not supported. Indicates whether to enable or disable special navigation modes for a study. 0 - Disable (default) 1 - Enable |
| NUMCHARSCRFLNGTH | Maximum number of lines on a CRF to create a readable PDF. The default is 100. |
| NUMOFEXEPLANLISTENTHREADS | Number of threads running in the background to process pending execution plans. The default is 4; at least 1 is required for an execution plan to run. |
| ONENONALPHANUMERICCHARACTER | Indicates whether passwords must include at least one special character. 0 - no (default) 1 - yes |

| IRV_CUR_CONFIG | |
|--------------------------------|---|
| Column Name (Key indicator) | Column Description |
| ONENUMERICALCHARACTER | Indicates whether passwords must include at least one numeric character. 0 - no (default) 1 - yes |
| ONEUPPERCASECHARACTER | Indicates whether passwords must include at least one uppercase character. 0 - no (default) 1 - yes |
| POSTQUERYFORCONFLICTRESOLUTION | Not supported. Indicates whether to create a query when during synchronization data is found to be entered into a data item by two different servers. 0 - No 1 - Yes (default) |
| QUERYMAXLENGTH | Maximum number of characters of query text displayed for an item on a CRF. The default is 80. |
| RANDOMIZATIONSRC | Name of the randomization source manager (COM object) who accesses the default randomization source database. The default name is Inform.PFRandomization.1. |
| RANSIMPLECENTRAL | Sequence number format for Simple Central randomization schemes (one central drug kit list from which numbers are assigned sequentially). For information about sequence number formats, see the <i>Study and Reporting Setup Guide</i> . |
| REQUIRECOMMENTFORNA | Indicates whether the InForm application requires a user to enter a comment when entering N/A, Unknown, or Not Done in response to a question on a form. 0 - no (default) 1 - yes |
| SCREENINGSEQUENCE | Sequence number format for assigning screening numbers. For information about sequence number formats, see the <i>Study and Reporting Setup Guide</i> . |
| SPONSOREDITFROZEN | Indicates whether sponsors are able to edit a form after it has been marked Frozen. 0 - no (default) 1 - yes |

| IRV_CUR_CONFIG | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| SSLFLAG | Indicates whether Secure Socket Layer should be enabled to provide encryption of data. 0 - no (default) 1 - yes |
| TRIALDATEFORMAT | Month_Day_Year, Day_Month_Year or Year_Month_Day, indicating the format in which you want the date to appear in the study. The default is Month_Day_Year. |
| UNIQUEINTLDOBSWTCH | Indicates whether the InForm application requires a unique combination of subject initials and date of birth for a study, a site or not at all: 0 (default) - Initials and DOB combination does not have to be unique. 1 - Initials and DOB combination must be unique within a site. 2 - Initials and DOB combination must be unique within a study. |
| UNIQUEPATIDSWTCH | Indicates whether the InForm application requires a unique subject identifier for a study, a site or not at all: 0 (default) - Subject identifier does not have to be unique. 1 - Subject identifier must be unique within a site. 2 - Subject identifier must be unique within a study. |
| VIEWCRFSIGNLIST | Indicates whether a list of required signatures should appear on each CRF for which a signature is required. 0 - No 1 - Yes (default) |

IRV_CUR_RULE

This view contains the most recent definition of each rule installed into the study.

| IRV_CUR_RULE | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| RULECOUNT | Always 1; indicates that the row represents one rule. |
| RULEID (PK) | Numeric identifier for the rule. |
| RULEREV | Current revision number for the rule. |
| RREVS | Number of times the rule has been revised. |
| MINRREV | Revision number for the first time the rule was revised. |
| MAXRREV | Revision number for the most recent time the rule was revised. |
| RULEREFNAME | RefName for the rule. |
| RULEDESCRIPTION | Rule description. |
| RULEENABLED | Rule enabled status: 0 - Disabled 1 - Enabled |
| EVENTTYPEID | Numeric identifier for the rule event type. |
| ETINITIALREVISIONNUMBER | Revision number for the first time the event type was revised. |
| SCRIPTTYPE | Rule type: 0 - Unknown 1 - Server rule 2 - Browser 3 - Server calculation 4 - Conversion 5 - Randomization 6 - Clintrial rule 7 - Clintrial derivation 8 - Server rule calculation 9 - Server rule calculated randomization |
| HELPTEXTID | Numeric identifier for the rule Help text. |
| DESIGNNOTE | Design note for the rule, as provided by the study designer. |
| CTMSGTEXT | Rule message text; Clintrial rules only. |
| CTRULEACTION | Rule action; Clintrial rules only. |
| CTRULEOPTIONS | Rule options; Clintrial rules only. |

IRV_CUR_RULEITEM

This view contains associations between rules and items on forms (MedML AttachRuleSet element).

| IRV_CUR_RULEITEM | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| RULEITEMCOUNT | Always 1; indicates that the row represents one rule item. |
| RULEITEMID (PK) | Numeric identifier for the rule-item association. |
| RIREVS | Number of times the rule item has been revised. |
| MINRIREV | First time the rule item was revised. |
| MAXRIREV | Most recent time the rule item was revised. |
| RULEITEMREFNAME | RefName for the item with which the rule is associated. |
| APPLYEVENT | Rule dependency type: 0 - DEPENDENCY 1 - APPLIED 2 - TRIGGER |
| ACTIVE | Rule active status: 0 - Rule is not run for this item. 1 - Rule is run for this item. |
| RULEID | Numeric identifier for the rule. |
| CHAPTERID | Numeric identifier (VISITID) for the visit in which the rule item exists. |
| PAGEID | Numeric identifier (FORMID) for the form on which the rule item exists. |
| SECTIONID | Numeric identifier for the section in which the rule item exists. |
| ITEMSETID | Numeric identifier for the itemset in which the rule item exists. |
| ITEMID | Numeric identifier for the item with which the rule is associated. |
| RULESETID | Rule item identifier of parent rule item. If blank, this rule item is a key context. Child rule items are additional dependencies for the rule. |
| ITEMSETEVENTID | Numeric identifier for the itemset event with which the rule is associated. |
| ITEMSETHELPID | Numeric identifier for the Help for the itemset with which the rule is associated. |

IRV_CUR_SITE

This view contains the most recent definition of each site (MedML Site element).

| IRV_CUR_SITE | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| SITECOUNT | Always 1; indicates that the row represents one site. |
| SITETYPEID | Numeric identifier for the site type. |
| SITEID (PK) | Numeric identifier for the site. |
| SITEREV | Revision number for the site. |
| SITENAME | Name of the site. |
| SITEADDRESS1 | First line of the site address. |
| SITEADDRESS2 | Second line of the site address. |
| SITEALTPHONENUMBER | Site alternate telephone number. |
| SITECITY | City in which the site address is located. |
| SITECOUNTRY | Country in which the site address is located. |
| SITEDATEFORMAT | The format of the dates displayed for the site, if a format is not specified at the user level. |
| SITEDAYPHONENUMBER | Daytime telephone number for the site. |
| SITEEMAILADDRESS | Email address used for contacting the site. |
| SITEFAXNUMBER | Site fax number. |
| SITEMNEMONIC | Abbreviated name with which to refer to the site. Required. |
| SITEPOSTALCODE | Site postal code. |
| SITESERVER | Name of the server designated as the site server. |
| SITESTATEPROVINCE | State or province in which the site address is located. |
| SITESTUDYINITIATIONDATE | Date the site came online. The following date and time formats are valid: <ul style="list-style-type: none"> • DD/MONTH/YYYY—25 January 1996 • HH:MM:SS (12-hour clock)—8:30:00 • HH:MM:SS (24-hour clock)—20:30:00 • MONTH/DD/YYYY/HH:MM:SS—January 25, 1996 8:30:00 • HH:MM:SS/MON/DD/YYYY—8:30:00 Jan. 25, 1996 • MM/DD/YYYY/HH:MM:SS—1/25/1996 8:30:00 |

| IRV_CUR_SITE | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| SITESTUDYTERMINATIONDATE | Date the site came offline; for example, date that the last subject was signed and locked. |
| SITETIMEZONE | Time zone in which the site is located, used to convert from internal universal system time to local time. |

IRV_CUR_SPONSOR

This view contains the most recent information for each sponsor in the study.

| IRV_CUR_SPONSOR | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| SPONSORID (PK) | Numeric identifier for the sponsor. |
| SPONSORREVISIONNUMBER | Revision number for the sponsor. |
| SPONSORCONTACTUSERID | User identifier for the primary sponsor contact. |
| SPONSORNAME | Name of the sponsor. |
| ADDRESS1 | First line of the sponsor address. |
| ADDRESS2 | Second line of the sponsor address. |
| CITY | City in which the sponsor address is located. |
| STATE_PROVINCE | State or province in which the sponsor address is located. |
| ZIPCODE_POSTCODE | Sponsor zip or postal code. |
| COUNTRY | Country in which the sponsor address is located. |
| PHONE | Sponsor telephone number. |
| FAX | Sponsor fax number. |
| ALTPHONE | Sponsor alternate telephone number. |
| EMAILADDRESS | Email address for the sponsor. |
| LOGOID | Login identifier for the sponsor. |
| THERAPUTICAREA | Therapeutic area of the study with which the sponsor is associated. |
| PROGRAMNAME | Name of the study with which the sponsor is associated. |
| NOTE | Description of the study with which the sponsor is associated. |

IRV_CUR_SUBJECT

This view contains the most recent information for each subject.

| IRV_CUR_SUBJECT | |
|------------------------------|---|
| Column Name (Key indicator) | Column Description |
| SUBJECTCOUNT | Always 1; indicates that the row represents one subject. |
| SUBJECTID (PK) | Numeric identifier for the subject. |
| SUBJECTREV | Revision number for the subject. |
| SUBJECTNUMBERSTR | Subject number. |
| SUBJHIST | Subject HISTORICALORDER. |
| SUBJTIME | Date and time when the subject was last modified. |
| USERID | Numeric identifier for the user who last modified the subject information. |
| TRANSACTIONID | Numeric identifier for the transaction that last modified the subject information. |
| SITEID | Numeric identifier for the site to which the subject is assigned. |
| SITEREV | Revision number for the site with which the subject is associated. |
| STUDYVERSIONID | Numeric identifier for the study version associated with the subject's site. |
| SUBJECTINITIALS | Subject initials. |
| SUBJECTDOB | Subject date of birth. |
| SUBJECTDOBVALIDMAP | Indicates valid date components that comprise the date of birth. Sum of the following values for each valid date part: Year (0x01) 1, Month (0x02) 2, Day (0x04) 4, Hour (0x08) 8, Minute (0x10) 16, Second (0x20) 32. |
| SUBJECTSCREENINGDATE | Subject screening date. |
| SUBJECTSCREENINGDATEVALIDMAP | Indicates valid date components that comprise the screening date. Sum of the following values for each valid date part: Year (0x01) 1, Month (0x02) 2, Day (0x04) 4, Hour (0x08) 8, Minute (0x10) 16, Second (0x20) 32. |
| CURSUBJECTSTATUSTIME | Time the subject state was last changed. |

| IRV_CUR_SUBJECT | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| SUBJECTSTATETEXT | Text value description of subject state: <ul style="list-style-type: none"> • Screened • Screening Failure • Enrollment Failure • Enrolled • Randomized • Completed • Dropped Out |
| SUBJECTSTATE | Numeric value for the subject state: <ul style="list-style-type: none"> 1 - Screened 2 - Screening Failure 3 - Enrollment Failure 4 - Enrolled 5 - Randomized 6 - Completed 7 - Dropped Out |
| SUBJECTSCREENED | Subject is currently Screened: <ul style="list-style-type: none"> 0 - No 1 - Yes |
| SUBJECTEVERSCREENED | Subject has ever been screened: <ul style="list-style-type: none"> 0 - No 1 - Yes |
| MINSCREEN | First system screening date for the subject. |
| MAXSCREEN | Most recent system screening date for the subject. |
| SUBJECTSCREENFAIL | Subject is currently Screen Failed: <ul style="list-style-type: none"> 0 - No 1 - Yes |
| SUBJECTEVERSCREENFAIL | Subject has ever failed screening: <ul style="list-style-type: none"> 0 - No 1 - Yes |
| MINSCREENFAIL | First system screening failure date for the subject. |
| MAXSCREENFAIL | Most recent system screening failure date for the subject. |
| SUBJECTSCREENFAILTEXT | Screening failure reason for the subject. |

| IRV_CUR_SUBJECT | |
|------------------------------------|--|
| Column Name (Key indicator) | Column Description |
| SUBJECTENROLLFAIL | Subject is currently Enrollment Failed: 0 - No 1 - Yes |
| SUBJECTEVERENROLLFAIL | Subject has ever failed enrollment: 0 - No 1 - Yes |
| MINENROLLFAIL | First system enrollment failure date for the subject. |
| MAXENROLLFAIL | Most recent system enrollment failure date for the subject. |
| SUBJECTENROLLFAILTEXT | Enrollment failure reason for the subject. |
| SUBJECTENROLLED | Subject is currently Enrolled: 0 - No 1 - Yes |
| SUBJECTEVERENROLLED | Subject has ever been enrolled: 0 - No 1 - Yes |
| SUBJECTENROLLDATE | First system enrollment date for the subject. |
| MAXENROLLED | Most recent system enrollment date for the subject. |
| SUBJECTENROLLOVERRIDETEXT | Enrollment override reason for the subject. |
| SUBJECTRANDOMIZED | Subject is currently Randomized: 0 - No 1 - Yes |
| SUBJECTEVERRANDOMIZED | Subject has ever been randomized: 0 - No 1 - Yes |
| MINRANDOMIZED | First system randomization date for the subject. |
| MAXRANDOMIZED | Most recent system randomization date for the subject. |
| SUBJECTCOMPLETED | Subject is currently Complete: 0 - No 1 - Yes |

| IRV_CUR_SUBJECT | |
|------------------------------------|---|
| Column Name (Key indicator) | Column Description |
| SUBJECTEVERCOMPLETED | Subject has ever been complete: 0 - No 1 - Yes |
| MINCOMPLETED | System date when the subject was first completed. |
| MAXCOMPLETED | System date for the most recent time the subject was completed. |
| SUBJECTINCOMPLETE | Subject is currently Not Complete: 0 - No 1 - Yes |
| SUBJECTEVERINCOMPLETE | Subject has ever been Not Complete: 0 - No 1 - Yes |
| MINNOTCOMPLETED | First system dropout date for the subject. |
| MAXNOTCOMPLETED | Most recent subject dropout date for the subject. |
| BOOKSIGNED | Date subject CRB was signed. |
| BOOKFROZEN | Date subject CRB was frozen. |
| BOOKLOCKED | Date subject CRB was locked. |
| BOOKSDVREADY | Date subject CRB was ready for source verification. |
| COUNTBOOKSIGNED | Subject CRB has been signed. |
| COUNTBOOKFROZEN | Subject CRB has been frozen. |
| COUNTBOOKLOCKED | Subject CRB has been locked. |
| COUNTBOOKSDVREADY | Subject CRB has been SV Ready. |

IRV_CUR_SUBJECT_DIM

This view is a subset of IRV_CUR_SUBJECT. It contains the most recent attributes for each subject; it does not contain facts or measures.

| IRV_CUR_SUBJECT_DIM | |
|------------------------------|---|
| Column Name (Key indicator) | Column Description |
| SUBJECTID (PK) | Numeric identifier for the subject. |
| SUBJECTREV | Revision number for the subject. |
| SUBJECTNUMBERSTR | Subject number. |
| SUBJHIST | Subject HISTORICALORDER. |
| SUBJTIME | Date and time when the subject was last modified. |
| USERID | Numeric identifier for the user who last modified the subject information. |
| TRANSACTIONID | Numeric identifier for the transaction that last modified the subject information. |
| SITEID | Numeric identifier for the site to which the subject is assigned. |
| SITEREV | Revision number for the site with which the subject is associated. |
| STUDYVERSIONID | Numeric identifier for the study version associated with the subject's site. |
| SUBJECTINITIALS | Subject initials. |
| SUBJECTDOB | Subject date of birth. |
| SUBJECTDOBVALIDMAP | Indicates valid date components that comprise the date of birth. Sum of the following values for each valid date part: Year (0x01) 1, Month (0x02) 2, Day (0x04) 4, Hour (0x08) 8, Minute (0x10) 16, Second (0x20) 32. |
| SUBJECTSCREENINGDATE | Subject screening date. |
| SUBJECTSCREENINGDATEVALIDMAP | Indicates valid date components that comprise the screening date. Sum of the following values for each valid date part: Year (0x01) 1, Month (0x02) 2, Day (0x04) 4, Hour (0x08) 8, Minute (0x10) 16, Second (0x20) 32. |
| CURSUBJECTSTATUSTIME | Time the subject state was last changed. |

| IRV_CUR_SUBJECT_DIM | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| SUBJECTSTATETEXT | Text value description of subject state: <ul style="list-style-type: none"> • Screened • Screening Failure • Enrollment Failure • Enrolled • Randomized • Completed • Dropped Out |
| SUBJECTSTATE | Numeric value for the subject state: <ul style="list-style-type: none"> 1 - Screened 2 - Screening Failure 3 - Enrollment Failure 4 - Enrolled 5 - Randomized 6 - Completed 7 - Dropped Out |
| MINSCREEN | First system screening date for the subject. |
| MAXSCREEN | Most recent system screening date for the subject. |
| MINSCREENFAIL | First system screening failure date for the subject. |
| MAXSCREENFAIL | Most recent system screening failure date for the subject. |
| SUBJECTSCREENFAILTEXT | Screening failure reason for the subject. |
| MINENROLLFAIL | First system enrollment failure date for the subject. |
| MAXENROLLFAIL | Most recent system enrollment failure date for the subject. |
| SUBJECTENROLLFAILTEXT | Enrollment failure reason for the subject. |
| SUBJECTENROLLDATE | First system enrollment date for the subject. |
| MAXENROLLED | Most recent system enrollment date for the subject. |
| SUBJECTENROLLOVERRIDETEXT | Enrollment override reason for the subject. |
| MINRANDOMIZED | First system randomization date for the subject. |
| MAXRANDOMIZED | Most recent system randomization date for the subject. |
| MINCOMPLETED | System date when the subject was first completed. |
| MAXCOMPLETED | System date for the most recent time the subject was completed. |
| MINNOTCOMPLETED | First system dropout date for the subject. |

| IRV_CUR_SUBJECT_DIM | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| MAXNOTCOMPLETED | Most recent subject dropout date for the subject. |
| BOOKSIGNED | Date subject CRB was signed. |
| BOOKFROZEN | Date subject CRB was frozen. |
| BOOKLOCKED | Date subject CRB was locked. |
| BOOKSDVREADY | Date subject CRB was ready for source verification. |

IRV_SUBJECT_STATE_CHANGES

This view contains a history of subject state changes.

| IRV_SUBJECT_STATE_CHANGES | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| SUBJECTID (PK) | Numeric identifier for the subject. |
| SUBJECTREV (PK) | Revision number for the subject. |
| SUBJECTSTATE | Current subject state. |
| SUBJECTSTATETIME | Time when the subject state was changed to the current state. |
| PREVSUBJECTSTATE | Previous subject state. |
| PREVSUBJECTSTATETIME | Time of previous state change for the subject (NULL if first revision). |
| NEXTSUBJECTSTATE | Next subject state for the subject. |
| NEXTSUBJECTSTATETIME | Time of next state change for the subject (NULL if current revision). |

IRV_CUR_SYSTEMVERSION

This view contains current InForm version information.

| IRV_CUR_SYSTEMVERSION | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| SYSTEMID (PK) | Numeric identifier for the current InForm software version. |
| SYSTEMREV | Revision number for the current InForm software version. |
| REVTIME | Time the system revision was entered into the database. |
| SYSTEMTYPE | Type of study (always 1 in reporting): 0 - system forms 1 - study forms |
| SYSTEMNAME | Study name associated with the InForm version. |
| SYSTEMVERSIONID | Numeric identifier for the current InForm version. |
| SPONSORAPPROVALDATE | Date when the sponsor approved the version change. |
| VERSIONDESCRIPTION | InForm version description. |
| SYSTEMVERSION | Protocol version associated with the current InForm version. |

IRV_SYSTEMVERSIONS

This view contains information about all the InForm versions against which the study has been run.

| IRV_SYSTEMVERSIONS | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| SYSTEMID (PK) | Numeric identifier for the InForm software version. |
| SYSTEMREV (PK) | Revision number for the InForm software version. |
| FIRSTSYSTEMVERSION | First system version: 0 - No 1 - Yes |
| CURRENTSYSTEMVERSION | Most recent system version: 0 - No 1 - Yes |
| REVTIME | Time the system revision was entered into the database. |
| SYSTEMTYPE | Type of InForm version. |

| IRV_SYSTEMVERSIONS | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| SYSTEMNAME | Study name associated with the InForm version. |
| SYSTEMVERSIONID | Numeric identifier for the current InForm version. |
| SPONSORAPPROVALDATE | Date when the sponsor approved the version change. |
| VERSIONDESCRIPTION | InForm version description. |
| SYSTEMVERSION | Protocol version associated with the InForm version. |

IRV_CUR_USER

This view contains the most recent information for each InForm user.

| IRV_CUR_USER | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| USERCOUNT | Always 1; indicates that the row represents one user. |
| USERTYPEID | Numeric identifier for the user type. |
| USERID (PK) | Numeric identifier for the user. |
| USERREV | Revision number for the user. |
| USERCREATETIME | Date the user was created. |
| USERACTIVESTATETIME | Most recent date the user was assigned the Active state. |
| USERDELETESTATETIME | Most recent date the user was assigned the Deleted state. |
| USERREVTIME | Time of last user revision. |
| USERNAME | Account name for the user. |
| RIGHTSGROUPID | Numeric identifier of the rights group to which the user is currently assigned. |
| RIGHTSGROUP | Name of the rights group to which the user is currently assigned. |
| USERACTIVESTATE | User is currently activated: 0 - No 1 - Yes |
| USERADDRESS1 | First line of the user address. |
| USERADDRESS2 | Second line of the user address. |
| USERALTPHONENUMBER | User alternate telephone number. |
| USERAUTHTYPE | Indicates whether or not the user has authority to reset passwords. |
| USERCITY | City in which the user address is located. |

| IRV_CUR_USER | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| USERCONFLICT | Used by synchronization to identify sync conflicts. |
| USERCOUNTRY | Country in which the user address is located. |
| USERDATEFORMAT | Desired date format for viewable InForm pages for the user. |
| USERDAYPHONENUMBER | User daytime telephone number. |
| USERDELETESTATE | Indicates whether the user has been terminated. Options are true or false. Note: Terminated users remain in the database. |
| USERDESCRIPTION | Description of the user; for example, user's role in the study. |
| USERDISPLAYNAME | User name, as displayed in the InForm application window. Maximum length is 63 characters; shorter strings are recommended. |
| USEREMAILADDRESS | User email address. |
| USERFAXNUMBER | User fax number. |
| USERFIRSTNAME | Given name of the user. |
| USERHOMESCREENURL | Local or external URL identifying the initial screen that appears when a user logs in to the InForm application. |
| USERIMAGEID | Name of the image file that appears in the InForm application above the user name. |
| USERLANGID | User preferred language. |
| USERLASTNAME | Surname of the user. |
| USERPOSTALCODE | User postal code. |
| USERRESETPASSWORD | Set to 1 if a user must reset a password. |
| USERSTATEPROVINCE | State or province where the user is located. |
| USERSUBJECTGUID | GUID for the user identifier. |
| USERTITLE | User title. |
| USERTYPE | User type. For example, Sponsor. |

IRV_CUR_USERLIST

This view contains user-group associations.

| IRV_CUR_USERLIST | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| GROUPID (PK) | Numeric identifier for the group with which the user is associated. |
| GROUPNAME | Name of the group with which the user is associated. |
| GROUPTYPE | Type of the group with which the user is associated. |
| GROUPTYPENAME | UUID for the group type with which the user is associated. |
| USERID (PK) | Numeric identifier for the user. |

IRV_USERS_SITES

This view contains user-site associations.

| IRV_USERS_SITES | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| USERID (PK) | Numeric identifier for the user. |
| SITEID (PK) | Numeric identifier for the site with which the user is associated. |
| RIGHTSGROUPID | Numeric identifier of the rights group to which the user is currently assigned. |
| USERNAME | Account name for the user. |
| RIGHTSGROUP | Name of the rights group to which the user is currently assigned. |
| SITEMNEMONIC | Abbreviated name for the site with which the user is associated. |
| SITENAME | Name of the site with which the user is associated. |
| SITECOUNTRY | Country in which the site address with which the user is associated is located. |

IRV_USER_ACTIVESTATE_CHANGES

This view contains a history of each time a user's Active state has changed.

| IRV_USER_ACTIVESTATE_CHANGE S | |
|----------------------------------|---|
| Column Name (Key indicator) | Column Description |
| USERID (PK) | Numeric identifier for the user. |
| USERREV (PK) | Revision number for the user. |
| FIRSTREV | First user revision: 0 - No 1 - Yes |
| CURRENTREV | Most recent user revision: 0 - No 1 - Yes |
| USERACTIVESTATE | New active state: 0 - inactive 1 - active |
| ENTEREDBY | Numeric identifier of the user who made the state change. |
| ENTEREDDATE | Time of the state change. |
| ENTEREDREASON | Action that caused the state change. |

RT_USER_BLIINDED_ITEMS

This view contains a row for each user and item combination with its blinding status.

| RT_USER_BLIINDED_ITEMS | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| USERID (PK) | User ID associated with the item. |
| USERNAME (PK) | Account name for the user associated with the item. |
| ITEMID (PK) | Numeric identifier for the item. |
| ITEMREV (PK) | Revision number for the item. |
| ITEMBLINDED | Blind flag. 0 - item is visible to the user 1 - item is not visible to the user |

| RT_USER_BLIINDED_ITEMS | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| CREATEDDATETIME | <p>Date and time when the item was started; that is, when a user entered data on the item or triggered a rule that entered data on the item.</p> <p>When the review schema is recreated, this column displays the date and time when the review schema was recreated.</p> |
| CREATEDBYUSERID | <p>User ID of the user who started the item by entering data on the item or triggering a rule that entered data on the item.</p> <p>When the review schema is recreated, this column displays the system user ID.</p> |
| MODIFIEDDATETIME | <p>Date and time when the item was most recently modified; that is, when a user most recently entered data on the item or triggered a rule that entered data on the item.</p> <p>When the review schema is recreated, this column displays the date and time when the review schema was recreated.</p> |
| MODIFIEDBYUSERID | <p>User ID of the user who most recently modified the item by entering data on the item or triggering a rule that entered data on the item.</p> <p>When the review schema is recreated, this column displays the system user ID.</p> |

Study operational data

IRV_SUBJECT_DROPOUT_REASON

This view contains information about subjects who have dropped out of the study and the reason they dropped out.

| IRV_SUBJECT_DROPOUT_REASON | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| SUBJECTID (PK) | Numeric identifier for the subject. |
| DROPOUTREASON | Drop out reason text, depending on usage of the suggested Study Completion Form design practice. |

IRV_SV_SUBJECTVISITS

This view contains the most current information about started and expected visits for each subject.

| IRV_SV_SUBJECTVISITS | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| SUBJECTVISITCOUNT | Always 1; indicates that the row represents one subject visit. |
| SUBJECTID (PK) | Numeric identifier for the subject. |
| SUBJECTSTATE | Numeric value for the subject state: 1 - Screened 2 - Screening Failure 3 - Enrollment Failure 4 - Enrolled 5 - Randomized 6 - Completed 7 - Dropped Out |
| STUDYID | Numeric identifier for the study with which the subject and visit are associated. |
| SITEID | Numeric identifier for the site with which the subject and visit are associated. |
| STUDYVERSIONID | Numeric identifier for the current study version with which the subject and visit are associated. |
| VISITID (PK) | Numeric identifier for the visit with which the subject and visit are associated. |
| VISITREV | Revision number for the visit with which the subject and visit are associated. |

| IRV_SV_SUBJECTVISITS | |
|------------------------------------|---|
| Column Name (Key indicator) | Column Description |
| VISITINDEX (PK) | Instance identifier for the visit with which the subject is associated: 0 - expected visit 1 - started, non-repeating visit <revisionnumber> - repeating visit |
| VISITORDINAL | Visit ordinal (0, 1, 2, 3...n ordered by visit index). |
| SUBJECTVISITID | Subject visit numeric identifier. |
| SUBJECTVISITREV | Revision number for the subject visit. |
| VISITACTIVATED | Visit is started: 0 - No 1 - Yes |
| VISITINCURSV | Visit is in current study version: 0 - No 1 - Yes |
| VISITORDER | Order of the visit in the study. |
| STARTHOURSFROMPREVIOUS | Number of hours from enrollment to when the visit is scheduled to start. |
| STARTHOURSFROMENROLL | Number of hours from enrollment to when the visit is scheduled to start. |
| VISITTYPE | Numeric value for the type of visit: 1 - Visit 2 - Enrollment 3 - Screening 4 - Monitor 5 - Status 6 - Common CRF 7 - Regdocs 8 - Visitreports 9 - Conflict 16 - Relation |
| VTSUBJECTVISIT | Visit type is CRF: 0 - No 1 - Yes |
| VTCOMMONCRF | Visit type is Common CRF: 0 - No 1 - Yes |

| IRV_SV_SUBJECTVISITS | |
|------------------------------------|--|
| Column Name (Key indicator) | Column Description |
| VISITPROPERTIES | Contains the same data as the VISITTYPE column. For internal Oracle use only. |
| VISITSCHEDULED | Visit is scheduled: 0 - No 1 - Yes |
| VISITSREPEATING | Visit can be repeated: 0 - No 1 - Yes |
| VISITDYNAMIC | Visit is dynamic: 0 - No 1 - Yes |
| EXPECTEDSTARTDATE | Visit expected start date: (STARTHOURSFROMENROLL + subject enrolled date) |
| VISIT_FIRST_ENTRY | Date when data was first entered for the visit. |
| VISIT_LAST_ENTRY | Date when data was most recently modified for the visit. |
| PROJECTEDSTARTHOURS | Not used. |
| STARTDATETIME | Not used. |
| DOV | Date of visit, as entered in the InForm user interface. |
| DOVDTMASK | Indicates valid date components that comprise the DOV. Sum of the following values for each valid date part: Year (0x01) 1, Month (0x02) 2, Day (0x04) 4, Hour (0x08) 8, Minute (0x10) 16, Second (0x20) 32. |
| DELETED | Visit has been deleted: 0 - No 1 - Yes |
| USERID | Numeric identifier of the user who last modified the visit. |
| SVTIME | Time of last visit revision. |
| TRANSACTIONID | Transaction associated with last visit revision. |
| REASON | Reason for last visit revision. |
| VISITCOMPLETE | All expected forms in the visit are complete: 0 - No 1 - Yes |

| IRV_SV_SUBJECTVISITS | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| VISITFROZEN | All expected forms in the visit are frozen: 0 - No 1 - Yes |
| VISITSDVCOMPLETE | All expected forms in the visit are Verified: 0 - No 1 - Yes |
| VISITSIGNED | All expected forms in the visit are signed: 0 - No 1 - Yes |
| VISITLOCKED | All expected forms in the visit are locked: 0 - No 1 - Yes |

IRV_AF_SUBJECT_FORMS

This view contains information about forms that are in visits that have been started or activated in the InForm application. Each row in this view corresponds to one row in the InForm table PF_SUBJECTVECHAPTERPAGE.

| IRV_AF_SUBJECT_FORMS | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| FORMCOUNT | Always 1; indicates that the row represents one form. |
| SUBJECTID (PK) | Numeric identifier for the subject for whom the form exists in a started or activated visit. |
| SUBJECTSTATE | Numeric value for the state of the subject for whom the form exists in a started or activated visit: 1 - Screened 2 - Screening Failure 3 - Enrollment Failure 4 - Enrolled 5 - Randomized 6 - Completed 7 - Dropped Out |
| SITEID | Numeric identifier for the site with which the form in a started visit is associated. |
| STUDYID | Numeric identifier for the study with which the form in a started visit is associated. |

| IRV_AF_SUBJECT_FORMS | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| STUDYVERSIONID | Numeric identifier for the current study version. |
| VISITID (PK) | Numeric identifier for the started or activated visit in which the form exists. |
| VISITREV | Revision number for the started or activated visit in which the form exists. |
| VISITORDER | Order in the study of the started or activated visit with which the form is associated. |
| VISITTYPE | Numeric value for the type of started or activated visit in which the form exists: 1 - Visit 2 - Enrollment 3 - Screening 4 - Monitor 5 - Status 6 - Common CRF 7 - Regdocs 8 - Visitreports 9 - Conflict 16 - Relation |
| VISITINDEX (PK) | Instance identifier for the started or activated visit in which the form exists: 0 - expected visit 1 - started, non-repeating visit <revisionnumber> - repeating visit |
| SUBJECTVISITID | Numeric identifier for the started or activated subject visit in which the form exists. |
| SUBJECTVISITREV | Revision number for the started or activated subject visit in which the form exists. |
| FORMID (PK) | Numeric identifier for the form. |
| FORMREV (PK) | Revision number for the form. |
| FORMINDEX (PK) | Identifier for the form instance: 0 - unstarted form 1 - non-repeating form <revisionnumber> - repeating form |
| INFORMACTIVATIONTIME | Date and time the form was activated. |
| DOV | Date of visit, as entered in the InForm user interface. |
| DOVDTMASK | Indicates valid date components that comprise the DOV. Sum of the following values for each valid date part: Year (0x01) 1, Month (0x02) 2, Day (0x04) 4, Hour (0x08) 8, Minute (0x10) 16, Second (0x20) 32. |

| IRV_AF_SUBJECT_FORMS | |
|------------------------------------|---|
| Column Name (Key indicator) | Column Description |
| VISIT_FIRST_ENTRY | Date when data was first entered on the form. |
| VISITDELETED | Started or activated visit in which the form exists has been deleted: 0 - No 1 - Yes |
| EXPECTEDSTARTDATE | Expected start date for the started or activated visit with which the form is associated: (STARTHOURSFROMENROLL + subject enrolled date) |
| FORMORDER | Order of the form in the visit. |
| FORMDYNAMIC | Form is a dynamic form: 0 - No 1 - Yes |
| FORMREPEATING | Form is a repeating form: 0 - No 1 - Yes |
| FORMCOMMON | Form is a common form: 0 - No 1 - Yes |
| ALTFORM | Form is an alternate form: 0 - No 1 - Yes |
| EXPECTINGALTFORM | Form is expected, and has an alternate form: 0 - No 1 - Yes |
| ALTFORMID | Numeric identifier for the alternate form associated with the form. |
| ALTFORMREV | Revision number for the alternate form associated with the form. |
| HASREQUIREDITEMS | Form has one or more required items. |
| HASDVREQUIREDITEMS | Form has one or more items marked SV Required. |
| FHREVS | Count of times the form state has changed. |
| MINFORMHISTORYID | Date of the first form history revision. |
| MINFORMHISTORYREV | Most recent form history revision. |

| IRV_AF_SUBJECT_FORMS | |
|------------------------------------|--|
| Column Name (Key indicator) | Column Description |
| MAXFORMHISTORYID | Numeric identifier for the first form history revision. |
| MAXFORMHISTORYREV | Numeric identifier for the most recent form history revision. |
| HISTORICALORDER | Sequential numeric identifier that corresponds to the current form state revision transaction. |
| USERID | Numeric identifier of the user who last changed the form state. |
| FORMHISTORYTIME | Time of the most recent form state change. |
| TRANSACTIONID | Numeric identifier of the most recent transaction to change the form state. |
| REASON | Reason for most recent form state change. |
| STATEHIST | Current form state. |
| ORIGINALSTATE | Previous form state. |
| ACTION | Action that may have occurred in conjunction with the last form state change. |
| STARTEDSTATE | Form is in the Started state: 0 - No 1 - Yes |
| FMINSTARTEDSTATE | First time the form was placed in the Started state. |
| FMAXSTARTEDSTATE | Most recent time the form was placed in the Started state. |
| SDVREADYSTATE | Form is in the SV Ready state: 0 - No 1 - Yes |
| FMINSDVREADYSTATE | First time the form was placed in the SV Ready state. |
| FMAXSDVREADYSTATE | Most recent time the form was placed in the SV Ready state. |
| SDVPARTIALSTATE | Form is in the Not Complete state: 0 - No 1 - Yes |
| FMINSDVPARTIALSTATE | First time the form was placed in the Not Complete state. |
| FMAXSDVPARTIALSTATE | Most recent time the form was placed in the Not Complete state. |

| IRV_AF_SUBJECT_FORMS | |
|------------------------------------|---|
| Column Name (Key indicator) | Column Description |
| SDVCOMPLETESTATE | Form is in the Verified state: 0 - No 1 - Yes |
| FMINSDVCOMPLETESTATE | First time the form was placed in the Verified state. |
| FMAXSDVCOMPLETESTATE | Most recent time the form was placed in the Verified state. |
| LOCKEDSTATE | Form is in the Locked state: 0 - No 1 - Yes |
| FMINLOCKEDSTATE | First time the form was placed in the Locked state. |
| FMAXLOCKEDSTATE | Most recent time the form was placed in the Locked state. |
| FROZENSTATE | Form is in the Frozen state: 0 - No 1 - Yes |
| FMINFROZENSTATE | First time the form was placed in the Frozen state. |
| FMAXFROZENSTATE | Most recent time the form was placed in the Frozen state. |
| SIGNEDSTATE | Form is in the Signed state: 0 - No 1 - Yes |
| FMINSIGNEDSTATE | First time the form was placed in the Signed state. |
| FMAXSIGNEDSTATE | Most recent time the form was placed in the Signed state. |
| COMPLETESTATE | Form is in the Complete state: 0 - No 1 - Yes |
| FMINCOMPLETESTATE | First time the form was placed in the Complete state. |
| FMAXCOMPLETESTATE | Most recent time the form was placed in the Complete state. |
| HASQUERIESSTATE | Form has queries: 0 - No 1 - Yes |
| FMINHASQUERIESSTATE | First time the form had queries. |
| FMAXHASQUERIESSTATE | Most recent time the form had queries. |

| IRV_AF_SUBJECT_FORMS | |
|------------------------------------|--|
| Column Name (Key indicator) | Column Description |
| HASCOMMENTSSTATE | Form has comments: 0 - No 1 - Yes |
| FMINHASCOMMENTSSTATE | First time the form had comments. |
| FMAXHASCOMMENTSSTATE | Most recent time the form had comments. |
| HASDATASTATE | Form has data: 0 - No 1 - Yes |
| FMINHASDATASTATE | First time the form had data. |
| FMAXHASDATASTATE | Most recent time the form had data. |
| MISSINGITEMSSTATE | Form is missing required items: 0 - No 1 - Yes |
| FMINMISSINGITEMSSTATE | First time the form was considered to have missing items. |
| FMAXMISSINGITEMSSTATE | Most recent time the form was considered to have missing items. |
| NOTDONESTATE | Form has been marked Not Done: 0 - No 1 - Yes |
| FMINNOTDONESTATE | First time the form was marked Not Done. |
| FMAXNOTDONESTATE | Most recent time the form was marked Not Done. |
| DELETEDSTATE | Form has been deleted: 0 - No 1 - Yes |
| FMINDELETEDSTATE | First time the form was deleted. |
| FMAXDELETEDSTATE | Most recent time the form was deleted. |
| DELETEDDYNAMICFORMSTATE | Form is a dynamic form that has been deleted: 0 - No 1 - Yes |
| FMINDELETEDDYNAMICFORMS TATE | First time the dynamic form was deleted. |
| FMAXDELETEDDYNAMICFORM STATE | Most recent time the dynamic form was deleted. |

| IRV_AF_SUBJECT_FORMS | |
|------------------------------------|--|
| Column Name (Key indicator) | Column Description |
| BOOKSIGN | Form represents a CRB signature form: 0 - No 1 - Yes |
| FMINBOOKSIGN | First time this form was a CRB signature form. |
| FMAXBOOKSIGN | Most recent time this form was a CRB signature form. |
| INFORMPARTIALURL_CRFVIEW | Partial InForm URL for the form. |
| FDAYSSINCEDOV | Number of days since the date of visit for the visit containing this form. |
| FDAYSSINCESTART | Count of days since the form was started. |
| FDAYSDOVTOSTART | Count of days from DOV to form started. |
| FDAYSDOVTOCOMPLETE | Count of days from DOV to form complete. |
| FDAYSSSTARTTOCOMPLETE | Count of days from form started to form complete. |
| FDAYSCOMPLETETEOFROZEN | Count of days from form complete to form frozen. |
| FDAYSCOMPLETETOSDVREADY | Count of days from form complete to SV Ready. |
| FDAYSCOMPLETETOSDVCOMPL ETE | Count of days from form complete to Verified. |
| FDAYSCOMPLETETOSIGNED | Count of days from form complete to signed. |
| FDAYSSIGNTOSDVCOMPLETE | Count of days from form signed to Verified. |
| FDAYSSDVREADYTOSDVCOMPL ETE | Count of days from form SV Ready to Verified. |
| FDAYSFROZENTOSDVCOMPLET E | Count of days from form frozen to Verified. |
| FDAYSSDVCOMPLETETOSIGN | Count of days from form frozen to Verified. |
| FDAYSSIGNTOLOCK | Count of days from form signed to locked. |
| FDAYSCOMPLETETOLOCK | Count of days from form complete to locked. |
| LASTDATATIME | Last time the form's data was modified. |
| QUERIES | Count of queries against the form. |
| QTYPEAUTO | Count of autoqueries against the form. |
| QTYPEMANUAL | Count of manual queries against the form. |
| QTYPECONFLICT | Count of conflict queries against the form. |
| QREISSUED | Count of reissued queries against the form. |
| QCANDIDATE | Count of candidate queries against the form. |
| QOPENED | Count of opened queries against the form. |

| IRV_AF_SUBJECT_FORMS | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| QANSWERED | Count of answered queries against the form. |
| QCLOSED | Count of closed queries against the form. |
| QDELETED | Count of deleted queries against the form. |
| HASANSWEREDQUERY | Form has one or more answered queries: 0 - No 1 - Yes |
| ITEMCOMMENTS | Count of item- or itemset-level comments associated with the form. |
| FORMCOMMENTS | Count of form-level comments associated with the form. |
| HASITEMCOMMENT | Form has one or more item- or itemset-level comments: 0 - No 1 - Yes |

IRV_SV_SUBJECT_FORMS

This view contains information about forms. It contains all of the forms from IRV_AF_SUBJECT_FORMS and it contains information about expected forms that do not yet exist.

| IRV_SV_SUBJECT_FORMS | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| FORMCOUNT | Always 1; indicates that the row represents one form. |
| SUBJECTID (PK) | Numeric identifier for the subject with whom the form is associated. |
| SUBJECTSTATE | Numeric value for state of the subject with whom the form is associated: 1 - Screened 2 - Screening Failure 3 - Enrollment Failure 4 - Enrolled 5 - Randomized 6 - Completed 7 - Dropped Out |
| SITEID | Numeric identifier for the site with which the form is associated. |
| STUDYID | Numeric identifier for the study with which the form is associated. |

| IRV_SV_SUBJECT_FORMS | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| STUDYVERSIONID | Numeric identifier for the study version of the study with which the form is associated. |
| VISITID (PK) | Numeric identifier for the visit with which the form is associated. |
| VISITREV | Revision number for the visit with which the form is associated. |
| VISITINDEX (PK) | Instance identifier for the visit with which the form is associated: 0 - expected visit 1 - started, non-repeating visit <revisionnumber> - repeating visit |
| SUBJECTVISITID | Numeric identifier for the subject visit with which the form is associated. |
| SUBJECTVISITREV | Revision number for the subject visit with which the form is associated. |
| FORMID (PK) | Numeric identifier for the form. |
| FORMREV (PK) | Revision number for the form. |
| FORMINDEX (PK) | Identifier for the form instance: 0 - unstarted form 1 - non-repeating form <revisionnumber> - repeating form |
| INFORMACTIVATIONTIME | Date and time the form was activated. |
| DOV | Date of visit, as entered in the InForm user interface. |
| DOVDTMASK | Indicates valid date components that comprise the DOV. Sum of the following values for each valid date part: Year (0x01) 1, Month (0x02) 2, Day (0x04) 4, Hour (0x08) 8, Minute (0x10) 16, Second (0x20) 32. |
| VISIT_FIRST_ENTRY | Date when data was first entered for the visit with which the form is associated. |
| VISITDELETED | Visit associated with the form has been deleted: 0 - No 1 - Yes |
| EXPECTEDSTARTDATE | Expected start date for the visit associated with the form: (STARTHOURSFROMENROLL + subject enrolled date) |
| FORMORDER | Order of the form in the visit. |

| IRV_SV_SUBJECT_FORMS | |
|------------------------------------|--|
| Column Name (Key indicator) | Column Description |
| FORMDYNAMIC | Form is a dynamic form: 0 - No 1 - Yes |
| FORMREPEATING | Form is a repeating form: 0 - No 1 - Yes |
| FORMCOMMON | Form is a common form: 0 - No 1 - Yes |
| ALTFORM | Form is an alternate form: 0 - No 1 - Yes |
| EXPECTINGALTFORM | Form is expected, and has an alternate form: 0 - No 1 - Yes |
| ALTFORMID | Numeric identifier for the alternate form associated with the form. |
| ALTFORMREV | Revision number for the alternate form associated with the form. |
| HASREQUIREDITEMS | Form has one or more required items. |
| HASSDVREQUIREDITEMS | Form has one or more items marked SV Required. |
| EXPECTEDFORM | Form is expected: 0 - No 1 - Yes |
| FHREVS | Count of times the form state has changed. |
| MINFORMHISTORYID | First form history revision. |
| MINFORMHISTORYREV | Most recent form history revision. |
| MAXFORMHISTORYID | Numeric identifier for the first form history revision. |
| MAXFORMHISTORYREV | Numeric identifier for the most recent form history revision. |
| HISTORICALORDER | Sequential numeric identifier that corresponds to the current form state revision transaction. |
| USERID | Numeric identifier of the user who last changed the form state. |

| IRV_SV_SUBJECT_FORMS | |
|------------------------------------|---|
| Column Name (Key indicator) | Column Description |
| FORMHISTORYTIME | Time of the most recent form state change. |
| TRANSACTIONID | Numeric identifier of the most recent transaction to change the form state. |
| REASON | Reason for most recent form state change. |
| STATEHIST | Current form state. |
| ORIGINALSTATE | Previous form state. |
| ACTION | Action that may have occurred in conjunction with the last form state change. |
| STARTEDSTATE | Form is in the Started state: 0 - No 1 - Yes |
| FMINSTARTEDSTATE | First time the form was placed in the Started state. |
| FMAXSTARTEDSTATE | Most recent time the form was placed in the Started state. |
| SDVREADYSTATE | Form is in the SV Ready state: 0 - No 1 - Yes |
| FMINSDVREADYSTATE | First time the form was placed in the SV Ready state. |
| FMAXSDVREADYSTATE | Most recent time the form was placed in the SV Ready state. |
| SDVPARTIALSTATE | Form is in the Not Complete state: 0 - No 1 - Yes |
| FMINSDVPARTIALSTATE | First time the form was placed in the Not Complete state. |
| FMAXSDVPARTIALSTATE | Most recent time the form was placed in the Not Complete state. |
| SDVCOMPLETESTATE | Form is in the Verified state: 0 - No 1 - Yes |
| FMINSDVCOMPLETESTATE | First time the form was placed in the Verified state. |
| FMAXSDVCOMPLETESTATE | Most recent time the form was placed in the Verified state. |

| IRV_SV_SUBJECT_FORMS | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| LOCKEDSTATE | Form is in the Locked state: 0 - No 1 - Yes |
| FMINLOCKEDSTATE | First time the form was placed in the Locked state. |
| FMAXLOCKEDSTATE | Most recent time the form was placed in the Locked state. |
| FROZENSTATE | Form is in the Frozen state: 0 - No 1 - Yes |
| FMINFROZENSTATE | First time the form was placed in the Frozen state. |
| FMAXFROZENSTATE | Most recent time the form was placed in the Frozen state. |
| SIGNEDSTATE | Form is in the Signed state: 0 - No 1 - Yes |
| FMINSIGNEDSTATE | First time the form was placed in the Signed state. |
| FMAXSIGNEDSTATE | Most recent time the form was placed in the Signed state. |
| COMPLETESTATE | Form is in the Complete state: 0 - No 1 - Yes |
| FMINCOMPLETESTATE | First time the form was placed in the Complete state. |
| FMAXCOMPLETESTATE | Most recent time the form was placed in the Complete state. |
| HASQUERIESSTATE | Form has associated queries: 0 - No 1 - Yes |
| FMINHASQUERIESSTATE | First time the form had associated queries. |
| FMAXHASQUERIESSTATE | Most recent time the form had associated queries. |
| HASCOMMENTSSTATE | Form has associated comments: 0 - No 1 - Yes |
| FMINHASCOMMENTSSTATE | First time the form had associated comments. |

| IRV_SV_SUBJECT_FORMS | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| FMAXHASCOMMENTSSTATE | Most recent time the form had associated comments. |
| HASDATASTATE | Form has data: 0 - No 1 - Yes |
| FMINHASDATASTATE | First time the form had data. |
| FMAXHASDATASTATE | Most recent time the form had data. |
| MISSINGITEMSSTATE | Form is missing required items: 0 - No 1 - Yes |
| FMINMISSINGITEMSSTATE | First time the form was considered to have missing items. |
| FMAXMISSINGITEMSSTATE | Most recent time the form was considered to have missing items. |
| NOTDONESTATE | Form has been marked Not Done: 0 - No 1 - Yes |
| FMINNOTDONESTATE | First time the form was marked Not Done. |
| FMAXNOTDONESTATE | Most recent time the form was marked Not Done. |
| DELETEDSTATE | Form has been deleted: 0 - No 1 - Yes |
| FMINDELETEDSTATE | First time the form was deleted. |
| FMAXDELETEDSTATE | Most recent time the form was deleted. |
| DELETEDDYNAMICFORMSTATE | Form is a dynamic form that has been deleted: 0 - No 1 - Yes |
| FMINDELETEDDYNAMICFORMSTATE | First time the dynamic form was deleted. |
| FMAXDELETEDDYNAMICFORMSTATE | Most recent time the dynamic form was deleted. |
| BOOKSIGN | Form represents a CRB signature form: 0 - No 1 - Yes |
| FMINBOOKSIGN | First time the form was a CRB signature form. |

| IRV_SV_SUBJECT_FORMS | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| FMAXBOOKSIGN | Most recent time the form was a CRB signature form. |
| INFORMPARTIALURL_CRFVIEW | Partial InForm URL for the form. |
| FDAYSSINCEDOV | Number of days since DOV for the visit containing this form. |
| FDAYSSINCESTART | Count of days since the form was started. |
| FDAYSDOVTOSTART | Count of days from DOV to form started. |
| FDAYSDOVTOCOMPLETE | Count of days from DOV to form complete. |
| FDAYSSSTARTTOCOMPLETE | Count of days from form started to form complete. |
| FDAYSCOMPLETETOFROZEN | Count of days from form complete to form frozen. |
| FDAYSCOMPLETETOSDVREADY | Count of days from form complete to SV Ready. |
| FDAYSCOMPLETETOSDVCOMPLETE | Count of days from form complete to Verified. |
| FDAYSCOMPLETETOSIGNED | Count of days from form complete to signed. |
| FDAYSSIGNTOSDVCOMPLETE | Count of days from form signed to Verified. |
| FDAYSSDVREADYTOSDVCOMPLETE | Count of days from form SV Ready to Verified. |
| FDAYSFROZENTOSDVCOMPLETE | Count of days from form frozen to Verified. |
| FDAYSSDVCOMPLETETOSIGN | Count of days from form frozen to Verified. |
| FDAYSSIGNTOLOCK | Count of days from form signed to locked. |
| FDAYSCOMPLETETOLOCK | Count of days from form complete to locked. |
| LASTDATATIME | Last time the form's data was modified. |
| QUERIES | Count of queries against the form. |
| QTYPEAUTO | Count of autoqueries against the form. |
| QTYPEMANUAL | Count of manual queries against the form. |
| QTYPECONFLICT | Count of conflict queries against the form. |
| QREISSUED | Count of reissued queries against the form. |
| QCANDIDATE | Count of candidate queries against the form. |
| QOPENED | Count of opened queries against the form. |
| QANSWERED | Count of answered queries against the form. |
| QCLOSED | Count of closed queries against the form. |
| QDELETED | Count of deleted queries against the form. |

| IRV_SV_SUBJECT_FORMS | |
|------------------------------------|--|
| Column Name (Key indicator) | Column Description |
| HASANSWEREDQUERY | Form has one or more associated answered queries: 0 - No 1 - Yes |
| ITEMCOMMENTS | Count of item- or itemset-level comments associated with the form. |
| FORMCOMMENTS | Count of form-level comments associated with the form. |
| HASITEMCOMMENT | Form has one or more associated item- or itemset-level comments: 0 - No 1 - Yes |
| REVIEWSTATE1STAGE1 | Form is in the first stage of the first custom review state in the study: 0 - No 1 - Yes |
| REVIEWSTATE1STAGE2 | Form is in the second stage of the first custom review state in the study: 0 - No 1 - Yes |
| REVIEWSTATE1STAGE3 | Form is in the third stage of the first custom review state in the study: 0 - No 1 - Yes |
| REVIEWSTATE2STAGE1 | Form is in the first stage of the second custom review state in the study: 0 - No 1 - Yes |
| REVIEWSTATE2STAGE2 | Form is in the second stage of the second custom review state in the study: 0 - No 1 - Yes |
| REVIEWSTATE2STAGE3 | Form is in the third stage of the second custom review state in the study: 0 - No 1 - Yes |

| IRV_SV_SUBJECT_FORMS | |
|------------------------------------|--|
| Column Name (Key indicator) | Column Description |
| REVIEWSTATE3STAGE1 | Form is in the first stage of the third custom review state in the study: 0 - No 1 - Yes |
| REVIEWSTATE3STAGE2 | Form is in the second stage of the third custom review state in the study: 0 - No 1 - Yes |
| REVIEWSTATE3STAGE3 | Form is in the third stage of the third custom review state in the study: 0 - No 1 - Yes |
| REVIEWSTATE4STAGE1 | Form is in the first stage of the fourth custom review state in the study: 0 - No 1 - Yes |
| REVIEWSTATE4STAGE2 | Form is in the second stage of the fourth custom review state in the study: 0 - No 1 - Yes |
| REVIEWSTATE4STAGE3 | Form is in the third stage of the fourth custom review state in the study: 0 - No 1 - Yes |
| REVIEWSTATE5STAGE1 | Form is in the first stage of the fifth custom review state in the study: 0 - No 1 - Yes |
| REVIEWSTATE5STAGE2 | Form is in the second stage of the fifth custom review state in the study: 0 - No 1 - Yes |

| IRV_SV_SUBJECT_FORMS | |
|------------------------------------|--|
| Column Name (Key indicator) | Column Description |
| REVIEWSTATE5STAGE3 | Form is in the third stage of the fifth custom review state in the study: 0 - No 1 - Yes |
| REVIEWSTATE1 | Form is in the first custom review state. 0 - No 1 - Yes |
| REVIEWSTATE2 | Form is in the second custom review state. 0 - No 1 - Yes |
| REVIEWSTATE3 | Form is in the third custom review state. 0 - No 1 - Yes |
| REVIEWSTATE4 | Form is in the fourth custom review state. 0 - No 1 - Yes |
| REVIEWSTATE5 | Form is in the fifth custom review state. 0 - No 1 - Yes |
| REVIEWSTATE1DATECHANGED | Date and time when the form was assigned the first custom review state. |
| REVIEWSTATE2DATECHANGED | Date and time when the form was assigned the second custom review state. |
| REVIEWSTATE3DATECHANGED | Date and time when the form was assigned the third custom review state. |
| REVIEWSTATE4DATECHANGED | Date and time when the form was assigned the fourth custom review state. |
| REVIEWSTATE5DATECHANGED | Date and time when the form was assigned the fifth custom review state. |

IRV_CRF_STATUS_REPORT

This view contains information about forms. It contains a subset of the data for all of the forms from the IRV_SV_SUBJECT_FORMS table with labels such as Site Name, and Visit Name joined in to simplify the task of writing reports.

| IRV_CRF_STATUS_REPORT | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| INFORMPARTIALURL_CRFVIEW | Partial InForm URL for the form. |
| STUDYID | Numeric identifier for the study with which the form is associated. |
| STUDYVERSIONID | Numeric identifier for the study version with which the form is associated. |
| SUBJECTID (PK) | Numeric identifier for the subject for whom the form exists. |
| SITEID | Numeric identifier for the site with which the form is associated. |
| VISITID (PK) | Numeric identifier for the visit in which the form exists. |
| VISITREV | Revision number for the visit in which the form exists. |
| VISITORDER | Order in the study of the visit with which the form is associated. |
| VISITTYPE | Numeric identifier for the type of visit in which the form exists: 1 - Visit 2 - Enrollment 3 - Screening 4 - Monitor 5 - Status 6 - Common CRF 7 - Regdocs 8 - Visitreports 9 - Conflict 16 - Relation |
| VISITINDEX (PK) | Instance identifier for the visit in which the form exists: 0 - expected visit 1 - started, non-repeating visit <revisionnumber> - repeating visit |
| FORMID (PK) | Numeric identifier for the form. |
| FORMREV (PK) | Revision number for the form. |

| IRV_CRF_STATUS_REPORT | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| FORMINDEX (PK) | Identifier for the form instance: 0 - unstarted form 1 - non-repeating form <revisionnumber> - repeating form |
| INFORMACTIVATIONTIME | Date and time the form was activated. |
| SITENAME | Name of the site with which the form is associated. |
| SITEMNEMONIC | Mnemonic of the site with which the form is associated. |
| SITECOUNTRY | Country of the site with which the form is associated. |
| SUBJECTNUMBERSTR | Subject number for the subject with whom the form is associated. |
| SUBJECTSTATE | State of the subject with whom the form is associated. |
| SUBJECTENROLLED | Subject is currently Enrolled: 0 - No 1 - Yes |
| SUBJECTEVERENROLLED | Subject has ever been enrolled: 0 - No 1 - Yes |
| SUBJECTRANDOMIZED | Subject is currently Randomized: 0 - No 1 - Yes |
| SUBJECTEVERRANDOMIZED | Subject has ever been randomized: 0 - No 1 - Yes |
| SUBJECTCOMPLETED | Subject is currently complete: 0 - No 1 - Yes |
| SUBJECTEVERCOMPLETED | Subject has ever been complete: 0 - No 1 - Yes |
| SUBJECTINCOMPLETE | Subject is currently not complete: 0 - No 1 - Yes |

| IRV_CRF_STATUS_REPORT | |
|------------------------------------|--|
| Column Name (Key indicator) | Column Description |
| SUBJECTEVERINCOMPLETE | Subject has ever been not complete: 0 - No 1 - Yes |
| VISITREFNAME | RefName for the visit in which the form exists. |
| VISITNAME | Name of the visit in which the form exists. |
| VISITMNEMONIC | Abbreviated name for the visit in which the form exists. |
| EXPECTEDSTARTDATE | Expected start date for the visit in which the form exists: (STARTHOURSFROMENROLL + subject enrolled date) |
| VISIT_FIRST_ENTRY | Date when data was first entered for the visit in which the form exists. |
| DOV | Date of visit, as entered in the InForm user interface. |
| DOVDTMASK | Indicates valid date components that comprise the DOV. Sum of the following values for each valid date part: Year (0x01) 1, Month (0x02) 2, Day (0x04) 4, Hour (0x08) 8, Minute (0x10) 16, Second (0x20) 32. |
| FORMREFNAME | RefName for the form. |
| FORMNAME | Form name. |
| FORMMNEMONIC | Abbreviated name for the form. |
| FORMORDER | Order of the form in the visit. |
| ACTUALFORM | Form actually exists within the InForm application: 0 - No 1 - Yes |
| EXPECTEDFORM | Form is expected: 0 - No 1 - Yes |
| HASREQUIREDITEMS | Form has required items: 0 - No 1 - Yes |
| HASDVREQUIREDITEMS | Form has items marked SV Required: 0 - No 1 - Yes |

| IRV_CRF_STATUS_REPORT | |
|------------------------------------|---|
| Column Name (Key indicator) | Column Description |
| STARTEDDATE | Date the form was started: 0 - No 1 - Yes |
| STARTEDSTATE | Form is in the Started state: 0 - No 1 - Yes |
| SDVREADYSTATE | Form is in the SV Ready state: 0 - No 1 - Yes |
| SDVPARTIALSTATE | Form is in the Not Complete state: 0 - No 1 - Yes |
| SDVCOMPLETESTATE | Form is in the Verified state: 0 - No 1 - Yes |
| LOCKEDSTATE | Form is in the Locked state: 0 - No 1 - Yes |
| FROZENSTATE | Form is in the Frozen state: 0 - No 1 - Yes |
| SIGNEDSTATE | Form is in the Signed state: 0 - No 1 - Yes |
| COMPLETESTATE | Form is in the Complete state: 0 - No 1 - Yes |
| HASDATASTATE | Form has data: 0 - No 1 - Yes |
| MISSINGITEMSSTATE | Form is missing required items: 0 - No 1 - Yes |

| IRV_CRF_STATUS_REPORT | |
|------------------------------------|--|
| Column Name (Key indicator) | Column Description |
| NOTDONESTATE | Form is marked Not Done: 0 - No 1 - Yes |
| DELETEDSTATE | Form is deleted: 0 - No 1 - Yes |
| DELETEDDYNAMICFORMSTATE | Form is a deleted dynamic form: 0 - No 1 - Yes |
| BOOKSIGN | Form contains a CRB signature: 0 - No 1 - Yes |
| HASQUERIESSTATE | Form has queries: 0 - No 1 - Yes |
| HASCOMMENTSSTATE | Form has comments: 0 - No 1 - Yes |
| QUERYCOUNT | Count of queries against the form. |
| QTYPEAUTO | Count of autoqueries against the form. |
| QTYPEMANUAL | Count of manual queries against the form. |
| QTYPECONFLICT | Count of conflict queries against the form. |
| QREISSUED | Count of reissued queries against the form. |
| QCANDIDATE | Count of candidate queries against the form. |
| QOPENED | Count of opened queries against the form. |
| QANSWERED | Count of answered queries against the form. |
| QCLOSED | Count of closed queries against the form. |
| QDELETED | Count of deleted queries against the form. |
| COMMENTCOUNT | Count of comments associated with the form. |
| CITEMCOMMENT | Count of item comments associated with the form. |
| CFORMCOMMENT | Count of form comments associated with the form. |

IRV_FORM_ITEMS

This view contains information about items on activated forms. This view does not contain information about expected forms.

| IRV_FORM_ITEMS | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| ITEMCOUNT | Always 1; indicates that the row represents one item on a form. |
| CONTEXTID (PK) | Numeric identifier for the item context. |
| SUBJECTID | Numeric identifier for the subject for which the item exists on an activated form. |
| STUDYID | Numeric identifier for the study in which the item exists on an activated form. |
| STUDYVERSIONID | Numeric identifier for the study version in which the item exists on an activated form. |
| SITEID | Numeric identifier for the site for which the item exists on an activated form. |
| SUBJECTVISITID | Numeric identifier for the subject visit in which the item exists on an activated form. |
| VISITID | Numeric identifier for the visit in which the item exists on an activated form. |
| VISITREV | Revision number for the visit in which the item exists on an activated form. |
| VISITINDEX | Instance identifier for the visit in which the item exists on an activated form: 0 - expected visit 1 - started, non-repeating visit <revisionnumber> - repeating visit |
| FORMID | Numeric identifier for the activated form on which the item exists. |
| FORMREV | Revision number for the activated form on which the item exists. |
| FORMINDEX | Identifier for the form instance on which the item exists: 0 - unstarted form 1 - non-repeating form <revisionnumber> - repeating form |
| SECTIONID | Numeric identifier for the section in which the item exists on an activated form. |
| SECTIONREV | Revision number for the section in which the item exists on an activated form. |

| IRV_FORM_ITEMS | |
|------------------------------------|--|
| Column Name (Key indicator) | Column Description |
| FORMSECTIONORDER | Order of the section in which the item exists on an activated form. |
| ITEMSETID | Numeric identifier for the itemset in which the item exists on an activated form. |
| ITEMSETREV | Revision number for the itemset in which the item exists on an activated form. |
| ITEMSETINDEX | Itemset instance identifier for the itemset in which the item exists on an activated form. |
| ITEMID | Numeric identifier for the item. |
| ITEMREV | Revision number for the item. |
| SECTIONITEMORDER | Item/itemset order within the section in which the item exists on an activated form. |
| ITEMSETITEMORDER | Item order within itemset in which the item exists on an activated form. |
| INFORMPARTIALURL_CRFVIEW | Partial InForm URL for the activated form on which the item exists. |
| SECTIONITEM | Item is the child of a section: 0 - No 1 - Yes |
| ITEMSETITEM | Item is the child of an itemset: 0 - No 1 - Yes |
| IHREVS | Count of times the item state has changed. |
| MINCONTEXTREV | First item state change revision. |
| MAXCONTEXTREV | Most recent item state change revision. |
| STATEUSERID | Numeric identifier of the user who made the most recent item state change. |
| STATETIME | Time of the most recent item state change. |
| STATETRANSACTIONID | Transaction numeric identifier associated with the most recent item state change. |
| STATEREASON | Reason for the most recent item state change. |
| ITEMDELETED | Item has been deleted: 0 - No 1 - Yes |

| IRV_FORM_ITEMS | |
|------------------------------------|--|
| Column Name (Key indicator) | Column Description |
| ITEMSDVED | Item has been source verified: 0 - No 1 - Yes |
| ITEMFIRSTSDV | First time the item was source verified. |
| SDVTIME | Most recent time the item was source verified. |
| IDREVS | Count of times the item data has changed. |
| MAXAUDITORDER | Most recent item data change revision. |
| DATAUSERID | Numeric identifier of the user that made the most recent item data change. |
| DATATIME | Time of the most recent item data change. |
| DATATRANSACTIONID | Transaction numeric identifier associated with the most recent item data change. |
| DATAREASON | Reason for the most recent item data change. |
| ITEMFIRSTDATA | First time the item had data. |
| ITEMHASQUERIES | Item has queries: 0 - No 1 - Yes |
| QUERIES | Count of queries against the item. |
| QTYPEAUTO | Count of autoqueries against the item. |
| QTYPEMANUAL | Count of manual queries against the item. |
| QTYPECONFLICT | Count of conflict queries against the item. |
| QREISSUED | Count of reissued queries against the item. |
| QCANDIDATE | Count of candidate queries against the item. |
| QOPENED | Count of open queries against the item. |
| QANSWERED | Count of answered queries against the item. |
| QCLOSED | Count of closed queries against the item. |
| QDELETED | Count of deleted queries against the item. |
| ITEMHASCOMMENTS | Item has comments: 0 - No 1 - Yes |
| ITEMCOMMENTS | Count of comments associated with the item. |
| CONTROLS | Count of controls in the item. |
| CONTROLSWITHDATA | Count of controls in the item that contain data. |

| IRV_FORM_ITEMS | |
|------------------------------------|--|
| Column Name (Key indicator) | Column Description |
| ITEMEMPTY | Item has no data in any controls: 0 - No 1 - Yes |
| NOTDONE | Item has queries: 0 - No 1 - Yes |
| NOTDONEREASON | Reason entered when item was marked Not Done. |
| ITEMBLANK | The item exists in a Repeating Data itemset, and is blank in the itemset. 0 - No 1 - Yes |
| ITEMSDVCRITICAL | Item is marked critical: 0 - No 1 - Yes |
| ITEMSDVOVERRIDE | Critical setting for the item is overridden: 0 - No 1 - Yes |
| ITEMSDVSELECTED | Item is selected for source verification: 0 - No 1 - Yes |

IRV_CUR_COMMENT

This view contains the most recent information about each form and item comment.

| IRV_CUR_COMMENT | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| COMMENTCOUNT | Always 1; indicates that the row represents one comment. |
| COMMENTID (PK) | Numeric identifier for the comment. |
| COMMENTTIME | Time of the most recent comment revision. |
| COMMENTUSERID | Numeric identifier of the user who last revised the comment. |
| COMMENTHIST | Sequential numeric identifier that corresponds to the revision transaction of the last comment revision. |
| CONTEXTID | Numeric identifier of the item or form context associated with the comment. |
| SUBJECTVISITID | Numeric identifier for the subject visit with which the comment is associated. |
| SUBJECTID | Numeric identifier for the subject with which the comment is associated. |
| SITEID | Numeric identifier for the site with which the comment is associated. |
| STUDYVERSIONID | Numeric identifier for the study version with which the comment is associated. |
| VISITID | Numeric identifier for the visit in which the comment exists. |
| VISITREV | Revision number for the visit in which the comment exists. |
| VISITINDEX | Instance identifier for the visit in which the comment exists: 0 - expected visit 1 - started, non-repeating visit <revisionnumber> - repeating visit |
| FORMID | Numeric identifier for the form with which the comment is associated. |
| FORMREV | Revision number for the form with which the comment is associated. |

| IRV_CUR_COMMENT | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| FORMINDEX | Identifier for the form instance with which the comment is associated: 0 - unstarted form 1 - non-repeating form <revisionnumber> - repeating form |
| SECTIONID | Numeric identifier for the section with which the comment is associated. |
| SECTIONREV | Revision number for the section with which the comment is associated. |
| ITEMSETID | Numeric identifier for the itemset with which the comment is associated. |
| ITEMSETREV | Revision number for the itemset with which the comment is associated. |
| ITEMSETINDEX | Identifier for the itemset instance with which the comment is associated. |
| ITEMID | Numeric identifier for the item with which the comment is associated. |
| ITEMREV | Revision number for the item with which the comment is associated. |
| CREVS | Number of times the comment has been revised. |
| MINCOMMENTREV | First time the comment was revised. |
| MAXCOMMENTREV | Most recent time the comment was revised. |
| COMMENTTYPE | Type of comment: 0 - Form Comment 1 - Item Comment |
| CITEMCOMMENT | Comment is an item comment: 0 - No 1 - Yes |
| CFORMCOMMENT | Comment is a form comment: 0 - No 1 - Yes |
| COMMENTTEXT | Comment text. |

IRV_CUR_QUERY

This view contains the most recent information about each query.

| IRV_CUR_QUERY | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| QUERYCOUNT | Always 1; indicates that the row represents one query. |
| QUERYID (PK) | Numeric identifier for the query. |
| QUERYTIME | Time of most recent query revision. |
| QUERYUSERID | Numeric identifier of the user who last revised the query. |
| QUERYHIST | Sequential numeric identifier that corresponds to the state revision transaction of the last query revision. |
| CONTEXTID | Numeric identifier of the item context with which the query is associated. |
| SUBJECTVISITID | Numeric identifier for the subject visit with which the query is associated. |
| SUBJECTID | Numeric identifier for the subject with whom the query is associated. |
| STUDYID | Numeric identifier for the study with which the query is associated. |
| SITEID | Numeric identifier for the site with which the query is associated. |
| STUDYVERSIONID | Numeric identifier for the study version with which the query is associated. |
| VISITID | Numeric identifier for the visit in which the query exists. |
| VISITREV | Revision number for the visit in which the query exists. |
| VISITINDEX | Instance identifier for the visit in which the query exists: 0 - expected visit 1 - started, non-repeating visit <revisionnumber> - repeating visit |
| FORMID | Numeric identifier for the form with which the query is associated. |
| FORMREV | Revision number for the form with which the query is associated. |
| FORMINDEX | Identifier for the form instance with which the query is associated: 0 - unstarted form 1 - non-repeating form <revisionnumber> - repeating form |

| IRV_CUR_QUERY | |
|------------------------------------|--|
| Column Name (Key indicator) | Column Description |
| SECTIONID | Numeric identifier for the section with which the query is associated. |
| SECTIONREV | Revision number for the section with which the query is associated. |
| ITEMSETID | Numeric identifier for the itemset with which the query is associated. |
| ITEMSETREV | Revision number for the itemset with which the query is associated. |
| ITEMSETINDEX | Instance identifier for the itemset with which the query is associated. |
| ITEMID | Numeric identifier for the item with which the query is associated. |
| ITEMREV | Revision number for the item with which the query is associated. |
| QREVS | Number of times the query has been revised. |
| MINQUERYREV | First time the query was revised. |
| MAXQUERYREV | Most recent time the query was revised. |
| QUERYTYPE | Query type: 0 - Auto 1 - Manual 2 - Conflict |
| QTYPEAUTO | Query type is Autoquery: 0 - No 1 - Yes |
| QTYPEMANUAL | Query type is Manual: 0 - No 1 - Yes |
| QTYPECONFLICT | Query type is Conflict: 0 - No 1 - Yes |
| QUERYSTATE | Query state: 0 - Candidate 1 - Opened 2 - Answered 3 - Closed 4 - Deleted |

| IRV_CUR_QUERY | |
|------------------------------------|--|
| Column Name (Key indicator) | Column Description |
| QREISSUED | Query is reissued: 0 - No 1 - Yes |
| QCANDIDATE | Query state is Candidate: 0 - No 1 - Yes |
| QOPENED | Query state is Open: 0 - No 1 - Yes |
| QANSWERED | Query state is Answered: 0 - no 1 - yes |
| QCLOSED | Query state is Closed: 0 - No 1 - Yes |
| QDELETED | Query state is Deleted: 0 - No 1 - Yes |
| QUERYGROUP | Numeric identifier for the query group with which the query is associated. |
| QUERYDATA | Current query text. |
| RULEITEMID | Numeric identifier of the rule item that generated the query. |
| RULEID | Numeric identifier of the rule that generated the query. |
| CONFLICTSTATE | Contains an explanation of a query that is in conflict. |
| INFORMPARTIALURL_QUERY | Partial InForm URL for the query. |
| QORIGUSER | Numeric identifier of the user who generated the query. |
| QSTATUSTIME | Time of current query revision. |
| QDAYSINSTATE | Number of days the query has been in its current state. |
| QDAYSOPENTOANSWER | Number of days from query open to answered. |
| QDAYSANSWERTOCLOSE | Number of days from query answered to closed. |
| QDAYSOPENTOCLOSE | Number of days from query opened to closed. |
| QCOUNTREISSUED | Count of times the query was reissued. |

| IRV_CUR_QUERY | |
|------------------------------------|---|
| Column Name (Key indicator) | Column Description |
| QMINREISSUED | First time the query was reissued. |
| QMAXREISSUED | Most recent time the query was reissued. |
| FIRSTREISSUEDTEXT | Query text associated with first reissue. |
| LASTREISSUEDTEXT | Query text associated with most recent reissue. |
| QCOUNTCANDIDATE | Count of times the query was in the Candidate state. |
| QMINCANDIDATE | First time the query was assigned the Candidate state. |
| QMAXCANDIDATE | Most recent time the query was assigned the Candidate state. |
| FIRSTCANDIDATETEXT | Query text when the query was first assigned the Candidate state. |
| LASTCANDIDATETEXT | Query text when the query was most recently assigned the Candidate state. |
| QCOUNTOPENED | Count of times the query was in the Opened state. |
| QMINOPENED | First time the query was assigned the Opened state. |
| QMAXOPENED | Most recent time the query was assigned the Opened state. |
| FIRSTOPENEDTEXT | Query text when the query was first assigned the Opened state. |
| LASTOPENEDTEXT | Query text when the query was most recently assigned the Opened state. |
| QCOUNTANSWERED | Count of times the query was in the Answered state. |
| QMINANSWERED | First time the query was assigned the Answered state. |
| QMAXANSWERED | Most recent time the query was assigned the Answered state. |
| FIRSTANSWEREDTEXT | Query text when the query was first assigned the Answered state. |
| LASTANSWEREDTEXT | Query text when the query was most recently assigned the Answered state. |
| QCOUNTCLOSED | Count of times the query was in the Closed state. |
| QMINCLOSED | First time the query was assigned the Closed state. |
| QMAXCLOSED | Most recent time the query was assigned the Closed state. |
| FIRSTCLOSEDTEXT | Query text when the query was first assigned the Closed state. |
| LASTCLOSEDTEXT | Query text when the query was most recently assigned the Closed state. |
| QCOUNTDELETED | Count of times the query was in the Deleted state. |

| IRV_CUR_QUERY | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| QMINDELETED | First time the query was assigned the Deleted state. |
| QMAXDELETED | Most recent time the query was assigned the Deleted state. |
| FIRSTDELETEDTEXT | Query text when the query was first assigned the Deleted state. |
| LASTDELETEDTEXT | Query text when the query was first assigned the Deleted state. |

IRV_QUERY_STATE_CHANGES

This view contains a history of state changes for each query.

| IRV_QUERY_STATE_CHANGES | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| QUERYID (PK) | Numeric identifier for the query. |
| QUERYREV (PK) | Revision number for the query. |
| QUERYSTATE | Query state: 0 - Candidate 1 - Opened 2 - Answered 3 - Closed 4 - Deleted |
| QUERYSTATETIME | Time the query was changed to the state. |
| QUERYUSERID | Numeric identifier of user who made the state change. |
| QUERYTEXT | Text associated with the state change. |
| QSTATEORDER | Query change ordinal 1..n (ordered by QUERYREV). |
| PREVQUERYSTATE | Previous query state (NULL if first revision). |
| PREVQUERYSTATETIME | Time the state was previously changed (NULL if first revision). |
| PREVQUERYUSERID | User who made the previous state change (NULL if first revision). |
| PREVQUERYTEXT | Previous query text (NULL if first revision). |
| NEXTQUERYSTATE | Next query state (NULL if current revision). |
| NEXTQUERYSTATETIME | Time the query was changed to the next state (NULL if current revision). |
| NEXTQUERYUSERID | User who made the next state change (NULL if current revision). |

IRV_QUERY_STATE_CHANGES

Column Name (Key indicator)

Column Description

NEXTQUERYTEXT

Next query text (NULL if current revision).

Summary views

Form summaries

IRV_AF_ROLLUP_SITES

This view contains form states summarized to the site level.

| IRV_AF_ROLLUP_SITES | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| SITE | Always 1; indicates that the row represents one site. |
| SITEID (PK) | Numeric identifier for the site. |
| FORMSSTARTED | Number of forms associated with the site that are in the Started state. |
| FORMSSDVREADY | Number of forms associated with the site that are in the SV Ready state. |
| FORMSSDVPARTIAL | Number of forms associated with the site that are selected for source verification, and are in the Not Complete state. |
| FORMSSDVCOMPLETE | Number of forms associated with the site that are selected for source verification, and are in the Verified state. |
| FORMSLOCKED | Number of forms associated with the site that are in the Locked state. |
| FORMSFROZEN | Number of forms associated with the site that are in the Frozen state. |
| FORMSSIGNED | Number of forms associated with the site that are in the Signed state. |
| FORMSCOMPLETE | Number of forms associated with the site that are in the Complete state. |
| FORMSHAVEQUERIES | Number of forms associated with the site that have queries. |
| FORMSHAVECOMMENTS | Number of forms associated with the site that have comments. |
| FORMSHAVEDATA | Number of forms associated with the site that have data. |
| FORMSMISSINGITEMS | Number of forms associated with the site that are missing required items. |
| FORMSNOTDONE | Number of forms associated with the site that are not done. |
| FORMSDELETED | Number of forms associated with the site that have been removed. |

| IRV_AF_ROLLUP_SITES | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| FORMSDELETEDDYNAMICFORM | Number of dynamic forms associated with the site that have been removed. |
| FORMSBOOKSIGN | Number of forms associated with the site that represent a CRB signature form. |

IRV_AF_ROLLUP_STUDY

This view contains form states summarized to the study level.

| IRV_AF_ROLLUP_STUDY | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| STUDY | Always 1; indicates that the row represents one study. |
| STUDYID (PK) | Numerical identifier for the study. |
| FORMSSTARTED | Number of forms associated with the study that are in the Started state. |
| FORMSSDVREADY | Number of forms associated with the study that are in the SV Ready state. |
| FORMSSDVPARTIAL | Number of forms associated with the study that are selected for source verification, and are in the Not Complete state. |
| FORMSSDVCOMPLETE | Number of forms associated with the study that are selected for source verification, and are in the Verified state. |
| FORMSLOCKED | Number of forms associated with the study that are in the Locked state. |
| FORMSFROZEN | Number of forms associated with the study that are in the Frozen state. |
| FORMSSIGNED | Number of forms associated with the study that are in the Signed state. |
| FORMSCOMPLETE | Number of forms associated with the study that are in the Complete state. |
| FORMSHAVEQUERIES | Number of forms associated with the study that have queries. |
| FORMSHAVECOMMENTS | Number of forms associated with the study that have comments. |
| FORMSHAVEDATA | Number of forms associated with the study that have data. |
| FORMSMISSINGITEMS | Number of forms associated with the study that are missing required items. |

| IRV_AF_ROLLUP_STUDY | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| FORMSNOTDONE | Number of forms associated with the study that are not done. |
| FORMSDELETED | Number of forms associated with the study that have been removed. |
| FORMSDELETEDDYNAMICFORM | Number of dynamic forms associated with the study that have been removed. |
| FORMSBOOKSIGN | Number of forms associated with the study that represent a CRB signature form. |

IRV_AF_ROLLUP_STUDYVERSIONS

This view contains form states summarized to the study version level.

| IRV_AF_ROLLUP_STUDYVERSIONS | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| STUDYVERSION | Always 1; indicates that the row represents one study version. |
| STUDYVERSIONID (PK) | Numeric identifier for the study version. |
| FORMSSTARTED | Number of forms associated with the study version that are in the Started state. |
| FORMSSDVREADY | Number of forms associated with the study version that are in the SV Ready state. |
| FORMSSDVPARTIAL | Number of forms associated with the study version that are selected for source verification, and are in the Not Complete state. |
| FORMSSDVCOMPLETE | Number of forms associated with the study version that are selected for source verification, and are in the Verified state. |
| FORMSLOCKED | Number of forms associated with the study version that are in the Locked state. |
| FORMSFROZEN | Number of forms associated with the study version that are in the Frozen state. |
| FORMSSIGNED | Number of forms associated with the study version that are in the Signed state. |
| FORMSCOMPLETE | Number of forms associated with the study version that are in the Complete state. |
| FORMSHAVEQUERIES | Number of forms associated with the study version that have queries. |

| IRV_AF_ROLLUP_STUDYVERSIONS | |
|------------------------------------|--|
| Column Name (Key indicator) | Column Description |
| FORMSHAVECOMMENTS | Number of forms associated with the study version that have comments. |
| FORMSHAVEDATA | Number of forms associated with the study version that have data. |
| FORMSMISSINGITEMS | Number of forms associated with the study version that are missing required items. |
| FORMSNOTDONE | Number of forms associated with the study version that are not done. |
| FORMSDELETED | Number of forms associated with the study version that have been removed. |
| FORMSDELETEDDYNAMICFORM | Number of dynamic forms associated with the study version that have been removed. |
| FORMSBOOKSIGN | Number of forms associated with the study version that represent a CRB signature form. |

IRV_AF_ROLLUP_SUBJECTS

This view contains form states summarized to the subject level.

| IRV_AF_ROLLUP_SUBJECTS | |
|------------------------------------|---|
| Column Name (Key indicator) | Column Description |
| SUBJECT | Always 1; indicates that the row represents one subject. |
| SUBJECTID (PK) | Numeric identifier for the subject numerical identifier |
| FORMSSTARTED | Number of forms associated with the subject that are in the Started state. |
| FORMSSDVREADY | Number of forms associated with the subject that are in the SV Ready state. |
| FORMSSDVPARTIAL | Number of forms associated with the subject that are selected for source verification, and are in the Not Complete state. |
| FORMSSDVCOMPLETE | Number of forms associated with the subject that are selected for source verification, and are in the Verified state. |
| FORMSLOCKED | Number of forms associated with the subject that are in the Locked state. |
| FORMSFROZEN | Number of forms associated with the subject that are in the Frozen state. |

| IRV_AF_ROLLUP_SUBJECTS | |
|------------------------------------|--|
| Column Name (Key indicator) | Column Description |
| FORMSSIGNED | Number of forms associated with the subject that are in the Signed state. |
| FORMSCOMPLETE | Number of forms associated with the subject that are in the Complete state. |
| FORMSHAVEQUERIES | Number of forms associated with the subject that have queries. |
| FORMSHAVECOMMENTS | Number of forms associated with the subject that have comments. |
| FORMSHAVEDATA | Number of forms associated with the subject that have data. |
| FORMSMISSINGITEMS | Number of forms associated with the subject that are missing required items. |
| FORMSNOTDONE | Number of forms associated with the subject that are not done. |
| FORMSDELETED | Number of forms associated with the subject that have been removed. |
| FORMSDELETEDDYNAMICFORM | Number of dynamic forms associated with the subject that have been removed. |
| FORMSBOOKSIGN | Number of forms associated with the subject that represent a CRB signature form. |

IRV_AF_ROLLUP_VISITS

This view contains form states summarized to the subject visit level.

| IRV_AF_ROLLUP_VISITS | |
|------------------------------------|---|
| Column Name (Key indicator) | Column Description |
| SUBJECTVISIT | Always 1; indicates that the row represents one subject visit. |
| CSVROWID (PK) | Unique identifier for the subject visit (Oracle ROWID). |
| FORMSSTARTED | Number of forms associated with the subject visit that are in the Started state. |
| FORMSSDVREADY | Number of forms associated with the subject visit that are in the SV Ready state. |
| FORMSSDVPARTIAL | Number of forms associated with the subject visit that are selected for source verification, and are in the Not Complete state. |

| IRV_AF_ROLLUP_VISITS | |
|------------------------------------|---|
| Column Name (Key indicator) | Column Description |
| FORMSSDVCOMPLETE | Number of forms associated with the subject visit that are selected for source verification, and are in the Verified state. |
| FORMSLOCKED | Number of forms associated with the subject visit that are in the Locked state. |
| FORMSFROZEN | Number of forms associated with the subject visit that are in the Frozen state. |
| FORMSSIGNED | Number of forms associated with the subject visit that are in the Signed state. |
| FORMSCOMPLETE | Number of forms associated with the subject visit that are in the Complete state. |
| FORMSHAVEQUERIES | Number of forms associated with the subject visit that have queries. |
| FORMSHAVECOMMENTS | Number of forms associated with the subject visit that have comments. |
| FORMSHAVEDATA | Number of forms associated with the subject visit that have data. |
| FORMSMISSINGITEMS | Number of forms associated with the subject visit that are missing required items. |
| FORMSNOTDONE | Number of forms associated with the subject visit that are not done. |
| FORMSDELETED | Number of forms associated with the subject visit that have been removed. |
| FORMSDELETEDDYNAMICFORM | Number of dynamic forms associated with the subject visit that have been removed. |
| FORMSBOOKSIGN | Number of forms associated with the subject visit that represent a CRB signature form. |

Visit summaries

IRV_CSV_ROLLUP_SITES

This view contains visit detail summarized at the site level.

| IRV_CSV_ROLLUP_SITES | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| SITE | Always 1; indicates that the row represents one site. |
| SITEID (PK) | Numeric identifier for the site. |
| SITEVISITS | Count of visits for the site. |
| SITE_FIRST_ENTRY | First time data was entered for the site. |
| SITE_LAST_ENTRY | Date when data was most recently modified for the site. |
| FIRSTDOV | First date of visit for the site. |
| LASTDOV | Most recent date of visit for the site. |
| VISITSDELETED | Count of deleted visits for the site. |

IRV_CSV_ROLLUP_STUDY

This view contains visit detail summarized at the study level.

| IRV_CSV_ROLLUP_STUDY | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| STUDY | Always 1; indicates that the row represents one study. |
| STUDYID (PK) | Numeric identifier for the study. |
| SVVISITS | Count of visits for the study. |
| STUDY_FIRST_ENTRY | First time data was entered for the study. |
| STUDY_LAST_ENTRY | Date when data was most recently modified for the study. |
| FIRSTDOV | First date of visit for the study. |
| LASTDOV | Most recent date of visit for the study. |
| VISITSDELETED | Count of deleted visits for the study. |

IRV_CSV_ROLLUP_STUDYVERSIONS

This view contains visit detail summarized at the study version level.

| IRV_CSV_ROLLUP_STUDYVERSIONS | |
|------------------------------|--|
| Column Name (Key indicator) | Column Description |
| STUDYVERSION | Always 1; indicates that the row represents one study version. |
| STUDYVERSIONID (PK) | Numeric identifier for the study version. |
| SVVISITS | Count of visits for the study version. |
| SV_FIRST_ENTRY | First time data was entered for the study version. |
| SV_LAST_ENTRY | Date when data was most recently modified for the study version. |
| FIRSTDOV | First date of visit for the study version. |
| LASTDOV | Most recent date of visit for the study version. |
| VISITSDELETED | Count of deleted visits for the study version. |

IRV_CSV_ROLLUP_SUBJECTS

This view contains visit detail summarized at the subject level.

| IRV_CSV_ROLLUP_SUBJECTS | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| SUBJECT | Always 1; indicates that the row represents one subject. |
| SUBJECTID (PK) | Numeric identifier for the subject. |
| SUBJECTVISITS | Count of visits with which the subject is associated. |
| SUBJECT_FIRST_ENTRY | First time data was entered for the subject. |
| SUBJECT_LAST_ENTRY | Date when data was most recently modified for the subject. |
| FIRSTDOV | First date of visit for the subject. |
| LASTDOV | Most recent date of visit for the subject. |
| VISITSDELETED | Count of deleted visits for the subject. |

Item summaries

IRV_IC_ROLLUP_FORMS

This view contains item detail summarized at the form instance level.

| IRV_IC_ROLLUP_FORMS | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| SUBJECTFORM | Always 1; indicates that the row represents one form instance. |
| SUBJECTID | Numeric identifier for the subject for whom the form instance exists. |
| VISITID | Numeric identifier for the visit in which the form instance exists. |
| VISITINDEX | Identifier for the visit instance associated with the form: 0 - expected visit 1 - started, non-repeating visit <revisionnumber> - repeating visit |
| FORMID | Numeric identifier for the form instance. |
| FORMINDEX | Identifier for the form instance: 0 - expected form 1 - started, non-repeating form <revisionnumber> - repeating form |
| FORMREV | Revision number for the form. |
| SITEID | Numeric identifier for the site with which the form instance is associated. |
| STUDYID | Numeric identifier for the study with which the form instance is associated. |
| STUDYVERSIONID | Numeric identifier for the study version with which the form instance is associated. |
| ITEMS | Count of items on the form instance. |
| SECTIONITEMS | Count of items in each section on the form instance. |
| ITEMSETITEMS | Count of items in itemsets on the form instance. |
| FIRSTSDVTIME | First time the form instance was source verified. |
| LASTSDVTIME | Most recent time the form instance was source verified. |
| FIRSTDATATIME | First time data was entered for the form instance. |
| LASTDATATIME | Most recent time data was entered for the form instance. |
| FIRSTDATATRANSACTIONID | Numeric identifier for the first data transaction for the form instance. |

| IRV_IC_ROLLUP_FORMS | |
|------------------------------------|---|
| Column Name (Key indicator) | Column Description |
| LASTDATATRANSACTIONID | Numeric identifier for the most recent data transaction for the form instance. |
| FIRSTSTATETIME | First date and time the item state changed for the form instance. |
| LASTSTATETIME | Most recent date and time the item state changed for the form instance. |
| FIRSTSTATE TRANSACTIONID | Numeric identifier for the first state transaction for the form instance. |
| LASTSTATE TRANSACTIONID | Numeric identifier for the most recent state transaction for the form instance. |
| ITEMSDELETED | Count of deleted items on the form instance. |
| ITEMSSDVED | Count of Source Verified items on the form instance. |
| ITEMSWITHDATA | Count of items on the form instance that have data. |
| CONTROLS | Count of controls on the form instance. |
| CONTROLSWITHDATA | Count of controls with data on the form instance. |
| QUERIES | Count of queries associated with the form instance. |
| QTYPEAUTO | Count of autoqueries associated with the form instance. |
| QTYPEMANUAL | Count of manual queries associated with the form instance. |
| QTYPECONFLICT | Count of conflict queries associated with the form instance. |
| QREISSUED | Count of reissued queries associated with the form instance. |
| QCANDIDATE | Count of candidate queries associated with the form instance. |
| QOPENED | Count of opened queries associated with the form instance. |
| QANSWERED | Count of answered queries associated with the form instance. |
| QCLOSED | Count of closed queries associated with the form instance. |
| QDELETED | Count of deleted queries associated with the form instance. |
| ITEMCOMMENTS | Count of item comments associated with the form instance. |
| FORMCOMMENTS | Count of form comments associated with the form instance. |

IRV_IC_ROLLUP_SITES

This view contains item detail summarized at the site level.

| IRV_IC_ROLLUP_SITES | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| SITE | Always 1; indicates that the row represents one site. |
| SITEID (PK) | Numeric identifier for the site. |
| SUBJECTVISITS | Count of subject visits for the site. |
| SUBJECTFORMS | Count of forms for the site. |
| ITEMS | Count of items for the site. |
| SECTIONITEMS | Count of items in each section for the site. |
| ITEMSETITEMS | Count of items in itemsets for the site. |
| FIRSTSDVTIME | Earliest time an item associated with the site was source verified. |
| LASTSDVTIME | Most recent time an item associated with the site was source verified. |
| FIRSTDATATIME | Earliest time an item associated with the site had data. |
| LASTDATATIME | Most recent time an item associated with the site had data. |
| FIRSTDATATRANSACTIONID | Earliest data transaction for the site. |
| LASTDATATRANSACTIONID | Most recent data transaction for the site. |
| FIRSTSTATETIME | First date and time the item state changed for the site. |
| LASTSTATETIME | Most recent date and time the item state changed for the site. |
| FIRSTSTATETRANSACTIONID | Earliest item state transaction for the site. |
| LASTSTATETRANSACTIONID | Most recent item state transaction for the site. |
| ITEMSDELETED | Count of deleted items for the site. |
| ITEMSSDVED | Count of source verified items for the site. |
| ITEMSWITHDATA | Count of items that have data for the site. |
| CONTROLS | Count of controls for the site. |
| CONTROLSWITHDATA | Count of controls with data for the site. |
| QUERIES | Count of queries for the site. |
| QTYPEAUTO | Count of autoqueries for the site. |
| QTYPEMANUAL | Count of manual queries for the site. |
| QTYPECONFLICT | Count of conflict queries for the site. |
| QREISSUED | Count of reissued queries for the site. |

| IRV_IC_ROLLUP_SITES | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| QCANDIDATE | Count of candidate queries for the site. |
| QOPENED | Count of opened queries for the site. |
| QANSWERED | Count of answered queries for the site. |
| QCLOSED | Count of closed queries for the site. |
| QDELETED | Count of deleted queries for the site. |
| ITEMCOMMENTS | Count of item comments for the site. |
| FORMCOMMENTS | Count of form comments for the site. |

IRV_IC_ROLLUP_STUDY

This view contains item detail summarized at the study level.

| IRV_IC_ROLLUP_STUDY | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| STUDY | Always 1; indicates that the row represents one study. |
| STUDYID (PK) | Numeric identifier for the study. |
| SUBJECTVISITS | Count of subject visits for the study. |
| SUBJECTFORMS | Count of forms for the study. |
| ITEMS | Count of items for the study. |
| SECTIONITEMS | Count of items in each section for the study. |
| ITEMSETITEMS | Count of items in itemsets for the study. |
| FIRSTSDVTIME | First time an item associated with the study was source verified. |
| LASTSDVTIME | Most recent time an item associated with the study was source verified. |
| FIRSTDATATIME | First time an item associated with the study had data. |
| LASTDATATIME | Most recent time an item associated with the study had data. |
| FIRSTDATATRANSACTIONID | First data transaction for the study. |
| LASTDATATRANSACTIONID | Most recent data transaction for the study. |
| FIRSTSTATETIME | First date and time the item state changed for the site. |
| LASTSTATETIME | Most recent date and time the item state changed for the site. |
| FIRSTSTATETRANSACTIONID | First item state transaction for the study. |

| IRV_IC_ROLLUP_STUDY | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| LASTSTATETRANSACTIONID | Most recent item state transaction for the study. |
| ITEMSDELETED | Count of deleted items for the study. |
| ITEMSSDVED | Count of source verified items for the study. |
| ITEMSWITHDATA | Count of items that have data for the study. |
| CONTROLS | Count of controls for the study. |
| CONTROLSWITHDATA | Count of controls with data for the study. |
| QUERIES | Count of queries for the study. |
| QTYPEAUTO | Count of autoqueries for the study. |
| QTYPEMANUAL | Count of manual queries for the study. |
| QTYPECONFLICT | Count of conflict queries for the study. |
| QREISSUED | Count of reissued queries for the study. |
| QCANDIDATE | Count of candidate queries for the study. |
| QOPENED | Count of opened queries for the study. |
| QANSWERED | Count of answered queries for the study. |
| QCLOSED | Count of closed queries for the study. |
| QDELETED | Count of deleted queries for the study. |
| ITEMCOMMENTS | Count of item comments for the study. |
| FORMCOMMENTS | Count of form comments for the study. |

IRV_IC_ROLLUP_STUDYVERSIONS

This view contains item detail summarized at the study version level.

| IRV_IC_ROLLUP_STUDYVERSIONS | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| STUDYVERSION | Always 1; indicates that the row represents one study version. |
| STUDYVERSIONID (PK) | Numeric identifier for the study version. |
| SUBJECTVISITS | Count of subject visits for the study version. |
| SUBJECTFORMS | Count of forms for the study version. |
| ITEMS | Count of items for the study version. |
| SECTIONITEMS | Count of items in each section for the study version. |
| ITEMSETITEMS | Count of items in itemsets for the study version. |

| IRV_IC_ROLLUP_STUDYVERSIONS | |
|------------------------------------|---|
| Column Name (Key indicator) | Column Description |
| FIRSTSDVTIME | First time an item associated with the study version was source verified. |
| LASTSDVTIME | Most recent time an item associated with the study version was source verified. |
| FIRSTDATATIME | First time an item associated with the study version had data. |
| LASTDATATIME | Most recent time an item associated with the study version had data. |
| FIRSTDATATRANSACTIONID | First data transaction for the study version. |
| LASTDATATRANSACTIONID | Most recent data transaction for the study version. |
| FIRSTSTATETIME | First date and time the item state changed for the study version. |
| LASTSTATETIME | Most recent date and time the item state changed for the study version. |
| FIRSTSTATE TRANSACTIONID | First item state transaction for the study version. |
| LASTSTATE TRANSACTIONID | Most recent item state transaction for the study version. |
| ITEMSDELETED | Count of deleted items for the study version. |
| ITEMSSDVED | Count of source verified items for the study version. |
| ITEMSWITHDATA | Count of items that have data for the study version. |
| CONTROLS | Count of controls for the study version. |
| CONTROLSWITHDATA | Count of controls with data for the study version. |
| QUERIES | Count of queries for the study version. |
| QTYPEAUTO | Count of autoqueries for the study version. |
| QTYPEMANUAL | Count of manual queries for the study version. |
| QTYPECONFLICT | Count of conflict queries for the study version. |
| QREISSUED | Count of reissued queries for the study version. |
| QCANDIDATE | Count of candidate queries for the study version. |
| QOPENED | Count of opened queries for the study version. |
| QANSWERED | Count of answered queries for the study version. |
| QCLOSED | Count of closed queries for the study version. |
| QDELETED | Count of deleted queries for the study version. |
| ITEMCOMMENTS | Count of item comments for the study version. |
| FORMCOMMENTS | Count of form comments for the study version. |

IRV_IC_ROLLUP_SUBJECTS

This view contains item detail summarized at the subject level.

| IRV_IC_ROLLUP_SUBJECTS | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| SUBJECT | Always 1; indicates that the row represents one subject. |
| SUBJECTID (PK) | Numeric identifier for the subject. |
| SUBJECTVISITS | Count of visits for the subject. |
| SUBJECTFORMS | Count of forms for the subject. |
| ITEMS | Count of items for the subject. |
| SECTIONITEMS | Count of items in each section for the subject. |
| ITEMSETITEMS | Count of items in itemsets for the subject. |
| FIRSTSDVTIME | First time an item associated with the subject was source verified. |
| LASTSDVTIME | Most recent time an item associated with the subject was source verified. |
| FIRSTDATATIME | First time an item associated with the subject had data. |
| LASTDATATIME | Most recent time an item associated with the subject had data. |
| FIRSTDATATRANSACTIONID | First data transaction for the subject. |
| LASTDATATRANSACTIONID | Most recent data transaction for the subject. |
| FIRSTSTATETIME | First date and time the item state changed for the subject. |
| LASTSTATETIME | Most recent date and time the item state changed for the subject. |
| FIRSTSTATE TRANSACTIONID | First item state transaction for the subject. |
| LASTSTATE TRANSACTIONID | Most recent item state transaction for the subject. |
| ITEMSDELETED | Count of deleted items for the subject. |
| ITEMSSDVED | Count of source verified items for the subject. |
| ITEMSWITHDATA | Count of items that have data for the subject. |
| CONTROLS | Count of controls for the subject. |
| CONTROLSWITHDATA | Count of controls with data for the subject. |
| QUERIES | Count of queries for the subject. |
| QTYPEAUTO | Count of autoqueries for the subject. |
| QTYPEMANUAL | Count of manual queries for the subject. |
| QTYPECONFLICT | Count of conflict queries for the subject. |

| IRV_IC_ROLLUP_SUBJECTS | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| QREISSUED | Count of reissued queries for the subject. |
| QCANDIDATE | Count of candidate queries for the subject. |
| QOPENED | Count of opened queries for the subject. |
| QANSWERED | Count of answered queries for the subject. |
| QCLOSED | Count of closed queries for the subject. |
| QDELETED | Count of deleted queries for the subject. |
| ITEMCOMMENTS | Count of item comments for the subject. |
| FORMCOMMENTS | Count of form comments for the subject. |

IRV_IC_ROLLUP_VISITS

This view contains item detail summarized at the visit level.

| IRV_IC_ROLLUP_VISITS | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| SUBJECTVISIT | Always 1; indicates that the row represents one visit. |
| SUBJECTVISITID | Numeric identifier for the subject visit instance. |
| SUBJECTFORMS | Count of forms for the visit. |
| ITEMS | Count of items for the visit. |
| SECTIONITEMS | Count of items in each section for the visit. |
| ITEMSETITEMS | Count of items in itemsets for the visit. |
| FIRSTSDVTIME | First time an item associated with the visit was source verified. |
| LASTSDVTIME | Most recent time an item associated with the visit was source verified. |
| FIRSTDATATIME | First time an item associated with the visit had data. |
| LASTDATATIME | Most recent time an item associated with the visit had data. |
| FIRSTDATATRANSACTIONID | First data transaction for the visit. |
| LASTDATATRANSACTIONID | Most recent data transaction for the visit. |
| FIRSTSTATETIME | First date and time the item state changed for the visit. |
| LASTSTATETIME | Most recent date and time the item state changed for the visit. |
| FIRSTSTATETRANSACTIONID | First item state transaction for the visit. |

| IRV_IC_ROLLUP_VISITS | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| LASTSTATE TRANSACTIONID | Most recent item state transaction for the visit. |
| ITEMSDELETED | Count of deleted items for the visit. |
| ITEMSSDVED | Count of source verified items for the visit. |
| ITEMSWITHDATA | Count of items that have data for the visit. |
| CONTROLS | Count of controls for the visit. |
| CONTROLSWITHDATA | Count of controls with data for the visit. |
| QUERIES | Count of queries for the visit. |
| QTYPEAUTO | Count of autoqueries for the visit. |
| QTYPEMANUAL | Count of manual queries for the visit. |
| QTYPECONFLICT | Count of conflict queries for the visit. |
| QREISSUED | Count of reissued queries for the visit. |
| QCANDIDATE | Count of candidate queries for the visit. |
| QOPENED | Count of opened queries for the visit. |
| QANSWERED | Count of answered queries for the visit. |
| QCLOSED | Count of closed queries for the visit. |
| QDELETED | Count of deleted queries for the visit. |
| ITEMCOMMENTS | Count of item comments for the visit. |
| FORMCOMMENTS | Count of form comments for the visit. |

Subject summaries

IRV_SUBJ_ROLLUP_SITES

This view contains subject detail summarized at the site level.

| IRV_SUBJ_ROLLUP_SITES | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| SITE | Always 1; indicates that the row represents one site. |
| SITEID (PK) | Numeric identifier for the site. |
| SUBJECTS | Number of subjects for the site. |
| SUBJECTSSCREENED | Number of subjects currently in the Screened state for the site. |
| SUBJECTSEVERSCREENED | Number of subjects who have ever been screened for the site. |

| IRV_SUBJ_ROLLUP_SITES | |
|------------------------------------|---|
| Column Name (Key indicator) | Column Description |
| SUBJECTSSCREENFAIL | Number of subjects currently in the Screen Failed state for the site. |
| SUBJECTSEVERSCREENFAIL | Number of subjects who have ever failed screening for the site. |
| SUBJECTSENROLLFAIL | Number of subjects currently in the Enroll Failed state for the site. |
| SUBJECTSEVERENROLLFAIL | Number of subjects who have ever failed enrollment for the site. |
| SUBJECTSENROLLED | Number of subjects currently in the Enrolled state for the site. |
| SUBJECTSEVERENROLLED | Number of subjects who have ever been enrolled for the site. |
| SUBJECTSRANDOMIZED | Number of subjects currently in the Randomized state for the site. |
| SUBJECTSEVERRANDOMIZED | Number of subjects who have ever been randomized for the site. |
| SUBJECTSCOMPLETED | Number of subjects currently in the Complete state for the site. |
| SUBJECTSEVERCOMPLETED | Number of subjects who have ever been complete for the site. |
| SUBJECTSINCOMPLETE | Number of subjects currently in the Dropped Out state for the site. |
| SUBJECTSEVERINCOMPLETE | Number of subjects who have ever been dropped out for the site. |
| COUNTBOOKSIGNED | Number of signed case books for the site. |
| COUNTBOOKFROZEN | Number of frozen case books for the site. |
| COUNTBOOKLOCKED | Number of locked case books for the site. |
| COUNTBOOKSDVREADY | Number of SV Ready case books for the site. |
| FIRSTBOOKSIGNED | Date of first signed case book for the site. |
| LASTBOOKSIGNED | Date of most recent signed case book for the site. |
| FIRSTBOOKFROZEN | Date of first frozen case book for the site. |
| LASTBOOKFROZEN | Date of most recent frozen case book for the site. |
| FIRSTBOOKLOCKED | Date of first locked case book for the site. |
| LASTBOOKLOCKED | Date of most recent locked case book for the site. |
| FIRSTBOOKSDVREADY | Date of first SV Ready case book for the site. |
| LASTBOOKSDVREADY | Date of most recent SV Ready case book for the site. |

IRV_SUBJ_ROLLUP_STUDY

This view contains subject detail summarized at the study level.

| IRV_SUBJ_ROLLUP_STUDY | |
|-----------------------------|--|
| Column Name (Key indicator) | Column Description |
| STUDY | Always 1; indicates that the row represents one study. |
| STUDYID (PK) | Numeric identifier for the study. |
| SUBJECTS | Number of subjects in the study. |
| SUBJECTSSCREENED | Number of subjects currently in the Screened state for the study. |
| SUBJECTSEVERSCREENED | Number of subjects who have ever been screened for the study. |
| SUBJECTSSCREENFAIL | Number of subjects currently in the Screen Failed state for the study. |
| SUBJECTSEVERSCREENFAIL | Number of subjects who have ever been screen failed for the study. |
| SUBJECTSENROLLFAIL | Number of subjects currently in the Enroll Failed state for the study. |
| SUBJECTSEVERENROLLFAIL | Number of subjects who have ever failed enrollment for the study. |
| SUBJECTSENROLLED | Number of subjects currently in the Enrolled state for the study. |
| SUBJECTSEVERENROLLED | Number of subjects who have ever been enrolled for the study. |
| SUBJECTSRANDOMIZED | Number of subjects currently in the Randomized state for the study. |
| SUBJECTSEVERRANDOMIZED | Number of subjects who have ever been randomized for the study. |
| SUBJECTSCOMPLETED | Number of subjects currently in the Completed state for the study. |
| SUBJECTSEVERCOMPLETED | Number of subjects who have ever completed the study. |
| SUBJECTSINCOMPLETE | Number of subjects currently in the Dropped Out state for the study. |
| SUBJECTSEVERINCOMPLETE | Number of subjects who have ever dropped out of the study. |
| COUNTBOOKSIGNED | Number of signed case books for the study. |
| COUNTBOOKFROZEN | Number of frozen case books for the study. |
| COUNTBOOKLOCKED | Number of locked case books for the study. |

| IRV_SUBJ_ROLLUP_STUDY | |
|-----------------------------|---|
| Column Name (Key indicator) | Column Description |
| COUNTBOOKSDVREADY | Number of SV Ready case books for the study. |
| FIRSTBOOKSIGNED | Date of first signed case book for the study. |
| LASTBOOKSIGNED | Date of most recent signed case book for the study. |
| FIRSTBOOKFROZEN | Date of first frozen case book for the study. |
| LASTBOOKFROZEN | Date of most recent frozen case book for the study. |
| FIRSTBOOKLOCKED | Date of first locked case book for the study. |
| LASTBOOKLOCKED | Date of most recent locked case book for the study. |
| FIRSTBOOKSDVREADY | Date of first SV Ready case book for the study. |
| LASTBOOKSDVREADY | Date of most recent SV Ready case book for the study. |

IRV_SUBJ_ROLLUP_STUDYVERSIONS

This view contains subject detail summarized at the study version level.

| IRV_SUBJ_ROLLUP_STUDYVERSIONS | |
|-------------------------------|--|
| Column Name (Key indicator) | Column Description |
| STUDYVERSION | Always 1; indicates that the row represents one study version. |
| STUDYVERSIONID (PK) | Numeric identifier for the study version. |
| SUBJECTS | Number of subjects for the study version. |
| SUBJECTSSCREENED | Number of subjects currently in the Screened state for the study version. |
| SUBJECTSEVERSCREENED | Number of subjects that have ever been screened for the study version. |
| SUBJECTSSCREENFAIL | Number of subjects currently in the Screen Failed state for the study version. |
| SUBJECTSEVERSCREENFAIL | Number of subjects that have ever failed screening for the study version. |
| SUBJECTSENROLLFAIL | Number of subjects currently in the Enroll Failed state for the study version. |
| SUBJECTSEVERENROLLFAIL | Number of subjects that have ever failed enrollment for the study version. |
| SUBJECTSENROLLED | Number of subjects currently in the Enrolled state for the study version. |

| IRV_SUBJ_ROLLUP_STUDYVERSIONS | |
|--------------------------------------|--|
| Column Name (Key indicator) | Column Description |
| SUBJECTSEVERENROLLED | Number of subjects that have ever been enrolled for the study version. |
| SUBJECTSRANDOMIZED | Number of subjects currently in the Randomized state for the study version. |
| SUBJECTSEVERRANDOMIZED | Number of subjects that have ever been randomized for the study version. |
| SUBJECTSCOMPLETED | Number of subjects currently in the Completed state for the study version. |
| SUBJECTSEVERCOMPLETED | Number of subjects that have ever been completed for the study version. |
| SUBJECTSINCOMPLETE | Number of subjects currently in the Dropped Out state for the study version. |
| SUBJECTSEVERINCOMPLETE | Number of subjects that have ever been dropped out for the study version. |
| COUNTBOOKSIGNED | Number of signed case books for the study version. |
| COUNTBOOKFROZEN | Number of frozen case books for the study version. |
| COUNTBOOKLOCKED | Number of locked case books for the study version. |
| COUNTBOOKSDVREADY | Number of SV Ready case books for the study version. |
| FIRSTBOOKSIGNED | Date of first signed case book for the study version. |
| LASTBOOKSIGNED | Date of most recent signed case book for the study version. |
| FIRSTBOOKFROZEN | Date of first frozen case book for the study version. |
| LASTBOOKFROZEN | Date of most recent frozen case book for the study version. |
| FIRSTBOOKLOCKED | Date of first locked case book for the study version. |
| LASTBOOKLOCKED | Date of most recent locked case book for the study version. |
| FIRSTBOOKSDVREADY | Date of first SV Ready case book for the study version. |
| LASTBOOKSDVREADY | Date of most recent SV Ready case book for the study version. |

Identifying keys

The following table describes the identifying keys in the InForm database and their corresponding names in the Reporting and Analysis database.

| Object type | InForm key name | Reporting and Analysis key name | Originating view |
|-------------------|------------------|---------------------------------|----------------------|
| Sponsor | SponsorID | SponsorID | IRV_CUR_SPONSOR |
| Study | VolumeID | StudyID | IRV_STUDYVERSIONS |
| Study version | VolumeEditionID | StudyVersionID | IRV_STUDYVERSIONS |
| Site | SiteID | SiteID | IRV_CUR_SITE |
| User | UserID | UserID | IRV_CUR_USER |
| Visit | ChapterID | VisitID | IRV_VISIT_REVS |
| Visit instance | ChapterIndex | VisitIndex | IRV_SV_SUBJECTVISIT |
| Form | PageID | FormID | IRV_FORM_REVS |
| Form instance | PageIndex | FormIndex | IRV_AF_SUBJECT_FORMS |
| Section | SectionID | SectionID | IRV_SECTION_REVS |
| Item | ItemID | ItemID | IRV_ITEM_REVS |
| Itemset | ItemsetID | ItemsetID | IRV_ITEMSET_REVS |
| Itemset instance | SetItemOrder | ItemsetIndex | IRV_FORM_ITEMS |
| Control | ControlID | ControlID | IRV_CONTROL_REVS |
| Subject | PatientID | SubjectID | IRV_CUR_SUBJECT |
| Subject visit | SubjectChapterID | SubjectVisitID | IRV_SV_SUBJECTVISIT |
| Subject form item | ContextID | ContextID | IRV_FORM_ITEMS |
| Query | QueryID | QueryID | IRV_CUR_QUERY |
| Comment | CommentID | CommentID | IRV_CUR_COMMENT |
| Rule | RuleID | RuleID | IRV_CUR_RULE |
| Rule item | RuleItemID | RuleItemID | IRV_CUR_RULEITEM |

CHAPTER 3

Clinical view descriptions

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Clinical metadata

RT_MD_DATADictionary

The controls for a form are mapped into zero or more columns in the RT_MD_DATADictionary table. A column can contain either an arbitrary value or a list of predefined values (Checkbox, Pulldown, Units, and so on). For an arbitrary value, a column is represented by a single row in the RT_MD_DATADictionary table, and for a list of predefined values, a column is represented by multiple rows that correspond to all potential values of the column.

The RT_MD_DATADictionary table contains information about each form, section, item, itemset, and control that exists in each study version for a study, and is essential for the generated clinical table customization process.

Note: This table contains language-dependent data.

| RT_MD_DATADictionary | |
|----------------------|--|
| Column Name | Column Description |
| TABLERNAME | Clinical table name. |
| COLUMNNAME | Clinical column name. (The logic used to build this column name is described in the clinical table description.) |

| RT_MD_DATADICTIONARY | |
|----------------------|---|
| Column Name | Column Description |
| COLUMNTYPE | Generated column type: 1 - COLTYPE_TEXTFLOAT 2 - COLTYPE_TEXTNUM 3 - COLTYPE_TEXTSTR 4 - COLTYPE_TEXTBLOB 5 - COLTYPE_DATE 6 - COLTYPE_MONTHYEAR 7 - COLTYPE_DATESTR 8 - COLTYPE_TIME_HM 9 - COLTYPE_TIME_HMS 10 - COLTYPE_TIMESTR 11 - COLTYPE_YEAR 12 - COLTYPE_MONTH 13 - COLTYPE_UNITNORMALIZED 14 - COLTYPE_UNITCODE 15 - COLTYPE_UNITLABEL 16 - COLTYPE_CHILDSELCODE 17 - COLTYPE_CHILDSELLABEL 18 - COLTYPE_VISITINDEX 19 - COLTYPE_FORMINDEX 20 - COLTYPE_ITEMINDEX 21 - COLTYPE_DOV 22 - COLTYPE_DELETEDFORM 23 - COLTYPE_DELETEDITEM 24 - COLTYPE_ITEMNOTDONEREASON 25 - COLTYPE_FORMMNEMONIC 26 - COLTYPE_VISITMNEMONIC 27 - COLTYPE_VISITORDER 28 - COLTYPE_SUBJECTINITIALS 29 - COLTYPE_SITENAME 30 - COLTYPE_SITEMNEMONIC 31 - COLTYPE_SITECOUNTRY |
| COLUMNORDER | Order of the column in the view. |
| FORMREFNAME | Form RefName. |
| SECTIONREFNAME | Section RefName. |
| ITEMREFNAME | Item RefName. |
| CHILDITEMREFNAME | Childitem RefName (for Itemsets). |
| CTL0REFNAME | Top level control RefName. |
| CTL1REFNAME | Second level control RefName. |
| CTL2REFNAME | Third level control RefName. |
| CTL3REFNAME | Fourth level control RefName. |
| CTL4REFNAME | Fifth level control RefName. |

| RT_MD_DATADICTIONARY | |
|--------------------------|--|
| Column Name | Column Description |
| RAWCOLUMNNAME | Generated name (typically item RefName + control RefName). |
| COLUMNDBTYPE | Generated DB column type: 1 - String 2 - Integer 3 - Float 4 - Datetime |
| COLUMNVALUEREFN AME | <ul style="list-style-type: none"> • If the column uses a list of pre-defined values, the value RefName. • For Units, the unit RefName. • For a radio or checkbox control, the child control RefName. • For a drop-down list, the element RefName. |
| COLUMNFLOATPRECISI ON | Column precision. Used only for Float text controls and is NULL for all other columns. |
| FORMNAME | Form name. |
| SECTIONHEADER | Section header. |
| ITEMQUESTION | Item question. |
| CONTROLCAPTION | Control caption. |
| SECTIONORDER | Order of the section on the form. |
| ITEMORDER | Order of the item within a section on the form. |
| CHILDITEMORDER | Child item order (for items within itemsets only). |
| VIEWLABEL | Report topic name. |
| VIEWDESC | Report topic description, from the form description. |
| COLUMNFOLDER | Report topic folder. Can have English or Japanese folder names. Only one of the three predefined folders is allowed: <ul style="list-style-type: none"> • Basic Data • Additional Data • Incomplete Data Reasons |
| COLUMNENABLE | If value is zero, this column is suppressed from the clinical table and clinical report topic. |
| COLUMNLABEL | Corresponding Cognos model report element name. |
| COLUMNDESC | Corresponding Cognos model report element description. |
| COLUMNVALUE | Column value. One of the set of values pertain to the clinical view column/clinical report element. |
| SASDATASETNAME | Null value. Reserved for future use. |

| RT_MD_DATADICTIONARY | |
|----------------------|--|
| Column Name | Column Description |
| SASFIELDNAME | |
| SDSDOMAIN | |
| SDSVARNAME | |
| FORMTYPE | Type of form. |
| ITEMSET | Indicates whether an item is part of an itemset. 0 - The item is not part of an itemset. 1 - The item is part of an itemset. |
| CONTROLTYPE | Control type: 1 - ELEMENTTYPE 2 - PULLDOWNTYPE 5 - TEXTBOXTYPE 6 - CALCULATIONTYPE 7 - CONTROLGROUPTYPE 8 - RADIOGROUPTYPE 9 - CHECKBOXGROUPTYPE 10 - DATETIMETYPE |
| CH0TYPE | Control type of the top-level control. |
| CH1TYPE | Control type of the second level control. |
| CH2TYPE | Control type of the third level control. |
| CH3TYPE | Control type of the fourth level control. |
| CH4TYPE | Control type of the fifth level control. |
| REPEATINGVISIT | Indicates whether the visit is repeating. 0 - Visit is not repeating. 1 - Visit is repeating. |
| REPEATINGFORM | Indicates whether the form is repeating. 0 - Form is not repeating. 1 - Form is repeating. |
| REPEATINGITEM | Indicates whether the item is repeating. 0 - Item is not repeating. 1 - Item is repeating. |
| FORMID | DBUID for the form. |
| FORMREV | Revision number for the form. |

| RT_MD_DATADICTIONARY | |
|-----------------------------|---|
| Column Name | Column Description |
| SECTIONID | DBUID for the section |
| ITEMID | DBUID for the item. |
| CHILDITEMID | DBUID for the child item in an itemset. |
| CONTROLID | DBUID for the control. |
| CONTROLREV | Revision number for the control. |
| CONTROLREFNAME | Control RefName. |
| CID0 | DBUID for the top-level nested control. |
| CID1 | DBUID for the second level nested control. |
| CID2 | DBUID for the third level nested control. |
| CID3 | DBUID for the fourth level nested control. |
| CID4 | DBUID for the fifth level nested control. |
| SECORD | Order of the section on the form. |
| ITEMORD | Order of the item in the section. |
| CHILDITEMORD | Order of the child item in the itemset. |
| CONTROLDEPTH | Depth of nesting for the control. |
| CH1ORD | Order of the first level child item. |
| CH2ORD | Order of the second level child item. |
| CH3ORD | Order of the third level child item. |
| CH4ORD | Order of the fourth level child item. |
| FORMMNEMONIC | Mnemonic for the form. |
| FORMNOTE | Form note. |
| FORMDESIGNNOTE | Form design note |
| ITEMLABEL | Item label. |
| SINGLECHILDCONTROL | Indicates whether the control has a single child. 0 - Control has no children. 1 - Control has one child. |
| CONTROLNAME | Name of the control. |
| CONTROLDESIGNNOTE | Design note for the control. |
| THESAMECONTROLCO UNT | Number of times the control exists in the study design. |
| TXT_MAXLENGTH | Maximum length for a text field. |
| TXT_DATATYPE | Data type of the object. |

| RT_MD_DATADICTINARY | |
|---------------------|--|
| Column Name | Column Description |
| TXT_PRECISION | Precision associated with a text box with a data type of FLOAT. 0 - Control can have any precision. <i>n</i> - Number of decimal places in precision. |
| DATE_DISPLAYMASK | Mask for date components to display. 1 - Year information is displayed. 2 - Month information is displayed. 4 - Day information is displayed. |
| DATE_REQUIREDMASK | Mask for date components that are required. 1 - Year information is required. 2 - Month information is required. 4 - Day information is required. |
| DATE_UNKNOWNMASK | Mask for date components that are not required. 1 - Year information is not required. 2 - Month information is not required. 4 - Day information is not required. |

RT_CV_MODELDICTIONARY

The RT_CV_MODELDICTIONARY is created from the RT_MD_DATADICTINARY, and is used to create the Cognos labels that appear in the Reporting and Analysis module.

| RT_CV_MODELDICTIONAR Y | |
|---------------------------|------------------------------------|
| Column Name | Column Description |
| FORMREFNAME | Form RefName. |
| SECTIONREFNAME | Section RefName. |
| ITEMREFNAME | Item RefName. |
| CHILDITEMREFNAME | Child item RefName (for itemsets). |
| CTL0REFNAME | Top level control RefName. |
| CTL1REFNAME | Second level control RefName. |
| CTL2REFNAME | Third level control RefName. |
| CTL3REFNAME | Fourth level control RefName. |
| CTL4REFNAME | Fifth level control RefName. |
| RAWCOLUMNNAME | Untruncated column name. |

| RT_CV_MODELDICTIONARY | |
|------------------------|--|
| Column Name | Column Description |
| COLUMNTYPE | <p>Generated column type:</p> <ul style="list-style-type: none"> 1 - COLTYPE_TEXTFLOAT 2 - COLTYPE_TEXTNUM 3 - COLTYPE_TEXTSTR 4 - COLTYPE_TEXTBLOB 5 - COLTYPE_DATE 6 - COLTYPE_MONTHYEAR 7 - COLTYPE_DATESTR 8 - COLTYPE_TIME_HM 9 - COLTYPE_TIME_HMS 10 - COLTYPE_TIMESTR 11 - COLTYPE_YEAR 12 - COLTYPE_MONTH 13 - COLTYPE_UNITNORMALIZED 14 - COLTYPE_UNITCODE 15 - COLTYPE_UNITLABEL 16 - COLTYPE_CHILDSELCODE 17 - COLTYPE_CHILDELLABEL 18 - COLTYPE_VISITINDEX 19 - COLTYPE_FORMINDEX 20 - COLTYPE_ITEMINDEX 21 - COLTYPE_DOV 22 - COLTYPE_DELETEDFORM 23 - COLTYPE_DELETEDITEM 24 - COLTYPE_ITEMNOTDONEREASON 25 - COLTYPE_FORMMNEMONIC 26 - COLTYPE_VISITMNEMONIC 27 - COLTYPE_VISITORDER 28 - COLTYPE_SUBJECTINITIALS 29 - COLTYPE_SITENAME 30 - COLTYPE_SITEMNEMONIC 31 - COLTYPE_SITECOUNTRY |
| COLUMNDBTYPE | <p>Generated DB column type:</p> <ul style="list-style-type: none"> 1 - String 2 - Integer 3 - Float 4 - Datetime |
| COLUMNVALUEREFNAM E | <ul style="list-style-type: none"> • If the column uses a list of pre-defined values, the value RefName. • For Units, the unit RefName. • For a radio or checkbox control, the child control RefName. • For a drop-down list, the element RefName. |

| RT_CV_MODELDICTIONARY | |
|-----------------------|---|
| Column Name | Column Description |
| COLUMNFLOATPRECISION | Column precision. Used only for Float text controls and is NULL for all other columns. 0 - Unlimited precision. <i>n</i> - Number of decimal places for the precision. |
| FORMNAME | Form name. |
| SECTIONHEADER | Section header. |
| ITEMQUESTION | Item question. |
| CONTROLCAPTION | Control caption. |
| SECTIONORDER | Order of the section on the form. |
| ITEMORDER | Order of the item within a section on the form. |
| CHILDITEMORDER | Order of the child item in the itemset. |
| VIEWNAME | Name of the view. |
| VIEWLABEL | Report topic name. |
| VIEWDESC | Report topic description, from the form description. |
| COLUMNFOLDER | Report topic folder. Can have English or Japanese folder names. Only one of the three predefined folders is allowed: <ul style="list-style-type: none"> • Basic Data • Additional Data • Incomplete Data Reasons |
| COLUMNENABLE | If value is zero, this column is suppressed from the clinical table and clinical report topic. |
| COLUMNNAME | Column name. |
| COLUMNLABEL | Corresponding Cognos model report topic item name. |
| COLUMNDESC | Corresponding Cognos model report topic item description. |
| COLUMNVALUE | Column value. One of the set of values pertain to the clinical view column/clinical report topic item. |
| SASDATASETNAME | Null value. Reserved for future use. |
| SASFIELDNAME | |
| SDSDOMAIN | |
| SDSVARNAME | |
| ITEMID | Numeric identifier for the item. |

Clinical data table generation

CT_<FormRefname/Itemset> and CV_<FormRefname/Itemset> tables

A CT_<FormRefName/Itemset> table exists for each form and each itemset. Each form/itemset data instance row contains the context, code/selection values, and external clinical data values. The structure is form design dependent.

RD_<FormRefName/Itemset> objects correspond to CT_ objects but also add additional dimensional context such as Site Name, Country, Visit and Form mnemonics, and so on. The structure is form design dependent.

The following tables are used to build the clinical tables that are generated for each form and itemset.

RT_ELEMENTLABELS

The following view has a row for each internal value for radio button, checkbox control, and drop-down list selections and the corresponding external label.

| RT_ELEMENTLABELS | |
|-----------------------------|---|
| Column name (Key indicator) | Column description |
| FORMID | Numeric identifier for the form on which the control exists. |
| FORMREV | Revision number for the form on which the control exists. |
| CONTROLID | Numeric identifier for the control. |
| ELEMENTVALUE (PK) | Element value for the control in string format. |
| ELEMENTLABEL | Label string for the control. |
| CREATEDBYUSERID | User ID of the user who started the control by entering data in the control or triggering a rule that entered data in the control. When the review schema is recreated, this column displays the system user ID. |
| CREATEDBYDATETIME | Date and time when the control was started; that is, when a user entered data in the control or triggered a rule that entered data in the control. When the review schema is recreated, this column displays the date and time when the review schema was recreated. |
| MODIFIEDBYUSERID | User ID of the user who most recently modified the control by entering data in the control or triggering a rule that entered data in the control. When the review schema is recreated, this column displays the system user ID. |

| RT_ELEMENTLABELS | |
|-----------------------------|--|
| Column name (Key indicator) | Column description |
| MODIFIEDBYDATETIME | Date and time when the control was most recently modified; that is, when a user most recently entered data in the control or triggered a rule that entered data in the control. When the review schema is recreated, this column displays the date and time when the review schema was recreated. |

RT_UNITS

This view has a row for each unit identifier and the corresponding unit symbol.

| RT_UNITS | |
|-------------------------------|---|
| Column name (Key indicator) | Column description |
| CONTROLID (PK) | Numeric identifier for the control associated with the unit identifier and corresponding unit symbol. |
| CONTROLREVISIONNUMBER | Revision number for the control associated with the unit identifier and corresponding unit symbol. |
| UNITID (PK) | Internal identifier for the unit and the corresponding unit symbol. |
| UNTREVISIONNUMBER | Internal revision number for the unit. |
| CLASSIFICATION | Type specified in the MedML, such as volume or length. |
| UNTREFNAME | RefName for the unit. |
| UNITSYMBOL | Symbol string for the unit. |
| BASEUNITID | Unit identifier of the base unit definition. If this equal to the UnitID, this is the base unit. |
| BASEUNITREVISIONNUMBER | Revision number for the base unit. |
| CONVERTTOBASEID | Associated rule identifier that will convert from this unit to the base unit; the value is NULL if this is the base unit. |
| CONVERTTOBASEREVISIONNUMBER | ConvertToBase revision number. |
| CONVERTFROMBASEID | Associated rule identifier that will convert from the base unit to this unit; the value is NULL if this is the base unit. |
| CONVERTFROMBASEREVISIONNUMBER | ConvertFromBase revision number. |

| RT_UNITS | |
|------------------------------------|---|
| Column name (Key indicator) | Column description |
| DESIGNNOTE | Design note for the unit, as provided by the study designer. |
| CREATEDBYUSERID | User ID of the user who started the unit control by entering data or triggering a rule that entered data in the unit control. When the review schema is recreated, this column displays the system user ID. |
| CREATEDBYDATETIME | Date and time when the unit control was started; that is, when a user entered data in the unit control or triggered a rule that entered data in the unit control. When the review schema is recreated, this column displays the date and time when the review schema was recreated. |
| MODIFIEDBYUSERID | User ID of the user who most recently modified the unit control by entering data in the unit control or triggering a rule that entered data in the unit control. When the review schema is recreated, this column displays the system user ID. |
| MODIFIEDBYDATETIME | Date and time when the unit control was most recently modified; that is, when a user most recently entered data in the unit control or triggered a rule that entered data in the unit control. When the review schema is recreated, this column displays the date and time when the review schema was recreated. |

RT_CONTROLDATA

This view contains a reference to the current version of each control that has or has had a value (was cleared).

| RT_CONTROLDATA | |
|-----------------------------|--|
| Column name (Key indicator) | Column description |
| CONTROLVALUEID (PK) | Unique identifier for this control value. |
| VALUEORDER (PK) | Revision of this value record. |
| CONTEXTID | Foreign key to PF_ITEMDATA to PF_ITEMCONTEXT. Identifier of the Item context. |
| AUDITORDER | FK to PF_ITEMDATA. Revision number of this row; timestamp matching transaction revision. |
| CONTROLID | Identifier of the control metadata identifier. |
| PARENTCONTROLVALUEID | Identifier of the Parent Control Value (refers to this table). If NULL, this is the top level control. |
| PARENTVALUEORDER | Corresponding revision to the ParentControlValueID. |
| SUBJECTID | Numeric identifier for the subject associated with the current version of the control. |
| SUBJECTTYPE | Describes the form type. Subject forms are CRFs and Enrollment forms; Site type is for Reg Docs and Visit Reports: 1 - Subject 2 - Site |
| VISITID | Numeric identifier for the visit associated with the current version of the control. |
| VISITINDEX | Identifier for the visit instance on which the control exists: 0 - expected visit 1 - started, non-repeating visit <revisionnumber> - repeating visit |
| FORMID | Numeric identifier for the form associated with the current version of the control. |
| FORMREV | Numeric identifier for the form revision associated with the current version of the control. |
| FORMINDEX | Identifier for the form instance on which the control exists: 0 - unstarted form 1 - non-repeating form <revisionnumber> - repeating form |
| SECTIONID | Numeric identifier for the section associated with the current version of the control. |

| RT_CONTROLDATA | |
|-----------------------------|--|
| Column name (Key indicator) | Column description |
| ITEMSETID | Numeric identifier for the itemset associated with the current version of the control. |
| ITEMSETINDEX | Numeric identifier for the itemset instance associated with the current version of the control. |
| ITEMID | Numeric identifier for the item associated with the current version of the control. |
| ITEMDELETED | Item on which the control exists has been deleted: 0 - No 1 - Yes |
| ITEMSDVED | Item on which the control exists has been source verified: 0 - No 1 - Yes |
| IMPUTEDDATETIME | InForm-provided data, entered when user-entered dates are partial or invalid. <ul style="list-style-type: none"> • Month—January • Day—1 • Time—12:00 a.m. |
| CONTROLHASDATA | Control has data: 0 - No 1 - Yes |
| DATATYPE | Type of data for the control: -1 - INVALID 0 - NULL 1 - LONG 2 - DOUBLE 3 - STRING 4 - TEXT 5 - DATETIME |
| NUMVALUE | Value if the datatype is 1 (LONG). |
| FLOATVALUE | Value if the datatype is 2 (DOUBLE). |
| STRVALUE | Value if the datatype is 3 (STRING). |
| BLOBVALUE | Value if the datatype is 4 (TEXT) |
| NORMALIZEDVALUE | Normalized value for the control. |

| RT_CONTROLDATA | |
|------------------------------------|--|
| Column name (Key indicator) | Column description |
| NORMALIZEDUNITID | Numeric identifier for the normalized unit associated with the control. |
| UNITID | Numeric identifier for the unit associated with the control. |
| PFDATETIME | Value if the datatype is 5 (DATETIME), and the value is a complete valid date. |
| MONTH | Month value entered for the control if the datatype is 5 (DATETIME). |
| DAY | Day value entered for the control if the datatype is 5 (DATETIME). |
| YEAR | Year value entered for the control if the datatype is 5 (DATETIME). |
| HOUR | Hour value entered for the control if the datatype is 5 (DATETIME). |
| MINUTE | Minute value entered for the control if the datatype is 5 (DATETIME). |
| SECOND | Second value entered for the control if the datatype is 5 (DATETIME). |
| FD_ITEMSETID | For internal Oracle use only. |
| FD_SECTIONID | For internal Oracle use only. |
| CREATEDATETIME | Date and time when the control was started; that is, when a user entered data in the control or triggered a rule that entered data in the control. When the review schema is recreated, this column displays the date and time when the review schema was recreated. |
| CREATEDBYUSERID | User ID of the user who started the control by entering data in the control or triggering a rule that entered data in the control. When the review schema is recreated, this column displays the system user ID. |
| MODIFIEDDATETIME | Date and time when the control was most recently modified; that is, when a user most recently entered data in the control or triggered a rule that entered data in the control. When the review schema is recreated, this column displays the date and time when the review schema was recreated. |
| MODIFIEDBYUSERID | User ID of the user who most recently modified the control by entering data in the control or triggering a rule that entered data in the control. When the review schema is recreated, this column displays the system user ID. |

RT_ACTIVATED_FORMS

This view contains information about forms that are in visits that have been started or activated in the InForm application. Each row in this view corresponds to one row in the InForm table PF_SUBJECTVECHAPTERPAGE.

| RT_ACTIVATED_FORMS | |
|-----------------------------|---|
| Column name (Key indicator) | Column description |
| SUBJECTVISITID (PK) | Numeric identifier for the activated subject visit associated with the form. |
| SUBJECTID | Numeric identifier for the subject associated with the form. |
| SITEID | Numeric identifier for the site associated with the form. |
| VISITID | Numeric identifier for the visit in which the form exists. |
| VISITINDEX | Identifier for the visit instance associated with the form: 0 - expected visit 1 - started, non-repeating visit <revisionnumber> - repeating visit |
| FORMID | Numeric identifier for the form. |
| FORMREV | Revision number for the form. |
| FORMINDEX | Identifier for the form instance: 0 - unstarted form 1 - non-repeating form <revisionnumber> - repeating form |
| DOV | Date of visit, as entered in the InForm user interface. |
| VISITDELETED | Visit associated with the form has been deleted: 0 - No 1 - Yes |
| INFORMACTIVATIONTIME | Date when the visit with which the form is associated was activated. |

| RT_ACTIVATED_FORMS | |
|------------------------------------|--|
| Column name (Key indicator) | Column description |
| FORMTYPE | Form type: 1 - CRF 3 - Enrollment 4 - Custom 5 - Custom study 6 - Custom Admin 7 - Custom Rules 8 - Custom Auth 101 - Monitor Regdoc 102 - Monitor Visit Report |
| AFSOURCE | Reserved for internal Oracle use. |
| HISTORICALORDER | Sequential numeric identifier that corresponds to the current form state revision transaction. |
| USERID | Numeric identifier of the user who last changed the form state. |
| PFTIMESTAMP | Reserved for internal Oracle use. |
| TRANSACTIONID | Numeric identifier for the transaction in which the form was activated. |
| REASON | Reason for modifying the form. |
| ACTION | Action performed on the form. |

| RT_ACTIVATED_FORMS | |
|------------------------------------|---|
| Column name (Key indicator) | Column description |
| STATEHIST | States in which the form has existed: 00000001—Started 00000002—Has queries 00000004—Has missing items 00000008—SV Ready 00000010—Frozen 00000020—Locked 00000040—Signed 00000080—Verified 00000100—Not Complete 00000200—Not Done 00000400—Has comments 00000800—Has data 00001000—Deleted dynamic form 00002000—Deleted 00004000—Answered 00008000—Not selected for source verification |
| ORIGINALSTATE | First state in which the form existed. |
| FORMHISTORYID | Numeric identifier for the most recent state in which the form exists. This column is a foreign key for the PF_SVECPSTATEHISTORY table. |
| FORMHISTORYREV | Revision number for the most recent revision for the form. This column is a foreign key for the PF_SVECPSTATEHISTORY table. |
| CURFORMHISTORYID | Numeric identifier for the most recent state in which the form exists. This column is a foreign key for the PF_SVECPSTATEHISTORY table. |
| CURFORMHISTORYREV | Revision number for the most recent revision for the form. This column is a foreign key for the PF_SVECPSTATEHISTORY table. |

| RT_ACTIVATED_FORMS | |
|------------------------------------|--|
| Column name (Key indicator) | Column description |
| STARTEDSTATE | Form is in the Started state: 0 - No 1 - Yes |
| FMINSTARTEDSTATE | First time the form was placed in the Started state. |
| FMAXSTARTEDSTATE | Most recent time the form was placed in the Started state. |
| SDVREADYSTATE | Form is in the SV Ready state: 0 - No 1 - Yes |
| FMINSDVREADYSTATE | First time the form was placed in the SV Ready state. |
| FMAXSDVREADYSTATE | Most recent time the form was placed in the SV Ready state. |
| SDVPARTIALSTATE | Form is selected for source verification, and is in the Not Complete state: 0 - No 1 - Yes |
| FMINSDVPARTIALSTATE | First time the form was placed in the Not Complete state. |
| FMAXSDVPARTIALSTATE | Most recent time the form was placed in the Not Complete state. |
| SDVCOMPLETESTATE | Form is selected for source verification, and is in the Verified state: 0 - No 1 - Yes |
| FMINSDVCOMPLETESTATE | First time the form was placed in the Verified state. |
| FMAXSDVCOMPLETESTATE | Most recent time the form was placed in the Verified state. |
| SDVSELECTEDSTATE | Form is selected for source verification: 0 - No 1 - Yes |
| FMINSDVSELECTEDSTATE | First time the form was selected for source verification. |
| FMAXSDVSELECTEDSTATE | Most recent time the form was selected for source verification. |
| LOCKEDSTATE | Form is in the Locked state: 0 - No 1 - Yes |

| RT_ACTIVATED_FORMS | |
|------------------------------------|---|
| Column name (Key indicator) | Column description |
| FMINLOCKEDSTATE | First time the form was placed in the Locked state. |
| FMAXLOCKEDSTATE | Most recent time the form was placed in the Locked state. |
| FROZENSTATE | Form is in the Frozen state: 0 - No 1 - Yes |
| FMINFROZENSTATE | First time the form was placed in the Frozen state. |
| FMAXFROZENSTATE | Most recent time the form was placed in the Frozen state. |
| SIGNEDSTATE | Form is in the Signed state: 0 - No 1 - Yes |
| FMINSIGNEDSTATE | First time the form was placed in the Signed state. |
| FMAXSIGNEDSTATE | Most recent time the form was placed in the Signed state. |
| COMPLETESTATE | Form is in the Complete state: 0 - No 1 - Yes |
| FMINCOMPLETESTATE | First time the form was placed in the Complete state. |
| FMAXCOMPLETESTATE | Most recent time the form was placed in the Complete state. |
| HASQUERIESSTATE | Form has associated queries: 0 - No 1 - Yes |
| FMINHASQUERIESSTATE | First time the form had associated queries. |
| FMAXHASQUERIESSTATE | Most recent time the form had associated queries. |
| HASCOMMENTSSTATE | Form has associated comments: 0 - No 1 - Yes |
| FMINHASCOMMENTSSTATE | First time the form had associated comments. |
| FMAXHASCOMMENTSSTATE | Most recent time the form had associated comments. |
| HASDATASTATE | Form has data: 0 - No 1 - Yes |
| FMINHASDATASTATE | First time the form had data. |

| RT_ACTIVATED_FORMS | |
|------------------------------------|--|
| Column name (Key indicator) | Column description |
| FMAXHASDATASTATE | Most recent time the form had data. |
| MISSINGITEMSSTATE | Form is missing required items: 0 - No 1 - Yes |
| FMINMISSINGITEMSSTATE | First time the form was considered to have missing items. |
| FMAXMISSINGITEMSSTATE | Most recent time the form was considered to have missing items. |
| NOTDONESTATE | Form has been marked Not Done: 0 - No 1 - Yes |
| FMINNOTDONESTATE | First time the form was marked Not Done. |
| FMAXNOTDONESTATE | Most recent time the form was marked Not Done. |
| DELETEDSTATE | Form has been deleted: 0 - No 1 - Yes |
| FMINDELETEDSTATE | First time the form was deleted. |
| FMAXDELETEDSTATE | Most recent time the form was deleted. |
| DELETEDDYNAMICFORMSTATE | Form is a dynamic form that has been deleted: 0 - No 1 - Yes |
| FMINDELETEDDYNAMICFORMS TATE | First time the dynamic form was deleted. |
| FMAXDELETEDDYNAMICFORMS TATE | Most recent time the dynamic form was deleted. |
| BOOKSIGN | Form represents a CRB signature: 0 - No 1 - Yes |
| FMINBOOKSIGN | First time this form was a CRB signature. |
| FMAXBOOKSIGN | Most recent time this form was a CRB signature. |
| COUNTOPENQUERIES | Count of open queries on the form. |
| COUNTANSWEREDQUERIES | Count of answered queries on the form. |
| COUNTCANDIDATEQUERIES | Count of candidate queries on the form. |
| INFORMPARTIALURL_CRFVIEW | Partial InForm URL for the form. |

| RT_ACTIVATED_FORMS | |
|------------------------------------|---|
| Column name (Key indicator) | Column description |
| REVIEWSTATE1 | Custom review state and stage in which the form exists, if custom review states are defined for the study. 0 - Custom review stage 1 1 - Custom review stage 2 2 - Custom review stage 3 |
| REVIEWSTATE2 | Custom review state and stage in which the form exists, if custom review states are defined for the study. 0 - Custom review stage 1 1 - Custom review stage 2 2 - Custom review stage 3 |
| REVIEWSTATE3 | Custom review state and stage in which the form exists, if custom review states are defined for the study. 0 - Custom review stage 1 1 - Custom review stage 2 2 - Custom review stage 3 |
| REVIEWSTATE4 | Custom review state and stage in which the form exists, if custom review states are defined for the study. 0 - Custom review stage 1 1 - Custom review stage 2 2 - Custom review stage 3 |
| REVIEWSTATE5 | Custom review state and stage in which the form exists, if custom review states are defined for the study. 0 - Custom review stage 1 1 - Custom review stage 2 2 - Custom review stage 3 |
| REVIEWSTATE1DATECHANGED | Date on which the custom review state changed for the form, if custom review states are defined for the study. |
| REVIEWSTATE2DATECHANGED | Date on which the custom review state changed for the form, if custom review states are defined for the study. |
| REVIEWSTATE3DATECHANGED | Date on which the custom review state changed for the form, if custom review states are defined for the study. |
| REVIEWSTATE4DATECHANGED | Date on which the custom review state changed for the form, if custom review states are defined for the study. |
| REVIEWSTATE5DATECHANGED | Date on which the custom review state changed for the form, if custom review states are defined for the study. |

| RT_ACTIVATED_FORMS | |
|------------------------------------|--|
| Column name (Key indicator) | Column description |
| DATEDATACHANGED | The date and time (GMT) when the data on the form was last modified. |
| ITEMSMARKEDINCOMPLETE | Indicates whether the form contains incomplete items: 0 - No items on the form are marked incomplete. 1 - The form contains items marked incomplete. |
| CREATEDATETIME | Date and time when the 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. |
| CREATEDBYUSERID | User ID of the user who started the form by entering data or triggering a rule that entered data on the form. When the review schema is recreated, this column displays the system user ID. |
| MODIFIEDDATE'TIME | Date and time when the form was most recently started or modified; that is, when a user most recently 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. |
| 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. |

RT_NOTDONE_CONTROL

This view contains metadata that defines the possible values for the Not Done control (by default: Not Done, Unknown, Not Applicable).

| RT_NOTDONE_CONTROL | |
|-----------------------------|---|
| Column name (Key indicator) | Column description |
| NCCONTROLID | Identifier for the Not Done control. |
| NDVALUE | Element name for the Not Done control. |
| NDLABEL | Label value for the Not Done control. |
| CREATEDATETIME | Date and time when the Not Done control was started; that is, when a user entered data in the control or triggered a rule that entered data in the control. When the review schema is recreated, this column displays the date and time when the review schema was recreated. |
| CREATEDBYUSERID | User ID of the user who started the Not Done control by entering data in the control or triggering a rule that entered data in the control. When the review schema is recreated, this column displays the system user ID. |
| MODIFIEDDATE | Date and time when the Not Done control was most recently modified; that is, when a user most recently entered data in the control or triggered a rule that entered data in the control. When the review schema is recreated, this column displays the date and time when the review schema was recreated. |
| MODIFIEDBYUSERID | User ID of the user who most recently modified the Not Done control by entering data in the control or triggering a rule that entered data in the control. When the review schema is recreated, this column displays the system user ID. |

Note: To accommodate international studies, the length of the Not Done control is set to varchar2(64), which accepts 64 multi-byte international characters, rather than 64 bytes of data.

RT_ITEMSTATE

This view contains information about items and itemsets on started forms.

| RT_ITEMSTATE | |
|-----------------------------|--|
| Column name (Key indicator) | Column description |
| CONTEXTID | Numeric identifier for the item context. |
| ITEM | Always 1; indicates that the row represents one item or itemset. |
| SECTIONITEM | Item is in a section. 0 - No 1 - Yes |
| ITEMSETITEM | Item is in an itemset. 0 - No 1 - Yes |
| SITEID | Numeric identifier for the site with which the item is associated. |
| SUBJECTID | Numeric identifier for the subject with which the item is associated. |
| SUBJECTVISITID | Numeric identifier for the subject visit with which the item is associated. |
| VISITID | Numeric identifier for the visit with which the item is associated. |
| VISITINDEX | Instance identifier for the started or activated visit in which the item exists: 0 - expected visit 1 - started, non-repeating visit <revisionnumber> - repeating visit |
| FORMID | Numeric identifier for the form on which the item exists. |
| FORMINDEX | Instance identifier for the started or activated form in which the item exists: 0 - expected form 1 - started, non-repeating form <revisionnumber> - repeating form |
| FORMREV | Revision number for the activated form on which the item exists. |
| SECTIONID | Numeric identifier for the section in which the item exists on an activated form. |
| SECTIONREV | Revision number for the section in which the item exists on an activated form. |

| RT_ITEMSTATE | |
|------------------------------------|--|
| Column name (Key indicator) | Column description |
| SECTIONORDER | Order of the section in which the item exists on an activated form. |
| SECTIONITEMORDER | Item order within the section in which the item exists on an activated form. |
| ITEMSETID | Numeric identifier for the itemset in which the item exists. |
| ITEMSETREV | Revision number for the itemset in which the item exists. |
| ITEMSETINDEX | Itemset instance identifier for the itemset in which the item exists on an activated form. |
| ITEMSETITEMORDER | Item order within itemset in which the item exists on an activated form. |
| ITEMID | Numeric identifier for the item. |
| ITEMREV | Revision number for the item. |
| MAXAUDITORDER | Most recent item data change revision. |
| ITEMSDVED | Item has been source verified: 0 - No 1 - Yes |
| ITEMDELETED | Item has been deleted: 0 - No 1 - Yes |
| MINCONTEXTREV | First item state change revision. |
| MAXCONTEXTREV | Most recent item state change revision. |
| DATATRANSACTIONID | Transaction numeric identifier associated with the most recent item data change. |
| DATAUSERID | Numeric identifier of the user that made the most recent item data change. |
| DATETIME | Time of the most recent item data change. |
| DATAREASON | Reason for the most recent item data change. |
| SDVTIME | Most recent time the item was source verified. |
| ITEMHASDATA | Indicates whether the item contains data. |
| CONTROLS | Count of controls in the item. |
| CONTROLSWITHDATA | Count of controls in the item that contain data. |
| STATETRANSACTIONID | Transaction numeric identifier associated with the most recent item state change. |
| STATEUSERID | Numeric identifier of the user who made the most recent item state change. |

| RT_ITEMSTATE | |
|------------------------------------|--|
| Column name (Key indicator) | Column description |
| STATETIME | Time of the most recent item state change. |
| STATEREASON | Reason for the most recent item state change. |
| QUERIES | Count of queries against the item. |
| QTYPEAUTO | Count of autoqueries against the item. |
| QTYPEMANUAL | Count of manual queries against the item. |
| QTYPECONFLICT | Count of conflict queries against the item. |
| QCANDIDATE | Count of candidate queries against the item. |
| QOPENED | Count of open queries against the item. |
| QANSWERED | Count of answered queries against the item. |
| QCLOSED | Count of closed queries against the item. |
| QDELETED | Count of deleted queries against the item. |
| ITEMCOMMENTS | Count of comments associated with the item or itemset. |
| ITEMMARKEDINCOMPLETE | Item is marked incomplete: 0 - No 1 - Yes |
| BLANK | The item exists in a Repeating Data itemset, and is blank in the itemset. 0 - No 1 - Yes |
| PREDEFINED | The item exists in a Repeating Data itemset, and is predefined in the itemset. 0 - No 1 - Yes |
| ITEMSDVOVERRIDE | Critical setting for the item is overridden: 0 - No 1 - Yes |
| ITEMSDVSELECTED | Item is selected for source verification: 0 - No 1 - Yes |
| CREATEDDATETIME | Date and time when the item was started; that is, when a user entered data in the item or triggered a rule that entered data in the item. When the review schema is recreated, this column displays the date and time when the review schema was recreated. |

| RT_ITEMSTATE | |
|-----------------------------|---|
| Column name (Key indicator) | Column description |
| CREATEDBYUSERID | User ID of the user who started the item by entering data or triggering a rule that entered data in the item. When the review schema is recreated, this column displays the system user ID. |
| MODIFIEDDATETIME | Date and time when the item was most recently modified; that is, when a user most recently entered data in the item or triggered a rule that entered data in the item. When the review schema is recreated, this column displays the date and time when the review schema was recreated. |
| MODIFIEDBYUSERID | User ID of the user who most recently started the item by entering data or triggering a rule that entered data in the item. When the review schema is recreated, this column displays the system user ID. |

Clinical data audit information

The InForm application tracks all subject data modifications to comply with the auditing required by regulatory authorities. Auditing captures who, when, and why data has been changed. Generated clinical views contain only current values.

Study versioning

A study version is a named collection of visits and forms with particular characteristics including order, repetition, and so forth. These specific properties determine which visits and CRFs display in the navigation tools in the user interface for the study. The InForm application allows concurrent use of multiple study versions. A single site can be assigned to only one of the installed study versions at a time, but during the life cycle of a study a site can use multiple versions.

Note: The study version must be updated if study protocol modifications are made.

Clinical view mapping is based on the concept of mapping all controls on a single CRF to a single clinical view. If a CRF has multiple modifications, the clinical view that is generated is based on the latest version of the CRF and on all previous versions of the CRF.

Because the generated clinical views are based on all versions of a CRF, if a particular version does not contain some items which were added to the form later or removed earlier, the columns that represent those items and controls have NULL values.

Alternate forms

The InForm server uses the current study version for a site to determine which form version needs to be displayed for a site user. In addition to the study version, you must consider whether this form was already submitted for the current subject. If the form has been submitted, the InForm application uses the form version that existed at the time of submission (which is defined by the site's study version at submission time). An alternate form can be used as a delta between form versions, and displays only for subjects with data submitted through an earlier form version.

The clinical model generates a single view for all versions of the form used in the study and generates an additional view for the alternate form.

Cognos models

The study reporting set up process generates a Cognos Model and a Clinical Package. Report topics, known in the Cognos model as query subjects, correlate directly with the generated clinical views on which they are based. Report elements, known in the Cognos model as query subject items, are directly correlated to clinical view columns. Each report element is formatted based on the type of the control it represents. For example, a report element representing a month control displays only month data, even though the clinical view column for this control has the full date format.

A clinical package groups report topics into four sub-folders: Basic Data, Additional Data, Incomplete Data Reasons and Internal IDs.

For more information, see the *Reporting and Analysis Guide* and the *Study and Reporting Setup Guide*.

Data model security

Display override settings and site associations determine the clinical data that is available from the clinical model for use in reports. For example:

- If an item is not visible to you in the InForm application, when you create a report that contains the item, data does not appear in the cells in the column that corresponds to the item.
- You can see and create reports using only information for the sites in the study to which you have access.

The clinical model also contains relationships to the operational report topics. These relationships allow you to create reports in the Ad Hoc Reporting workspace by dragging and dropping clinical and operational report elements onto the report palette. This operation is conceptually similar to creating a SQL join directly between a clinical view and an operational view.

Auto-generated mappings

Structural mappings

Auto-generated structural mappings consist of a single CRF control mapped to zero or more multiple clinical view columns.

| Control type | Number of clinical view columns generated |
|---|---|
| Simple and group controls | 0 |
| String, text, numeric, and float controls without units | 1 |
| Radio controls and drop-down lists | 2 |
| Numeric or float text controls with units | 4 |
| Date control | Up to 7 |
| Checkbox control with N children | 2xN |

Note: Group control children (radio, checkbox, group controls) are mapped recursively.

Naming conventions for mappings

Auto-generated mappings have default names that must meet constraints for uniqueness and maximum length. If you customize automatically-generated names, the customized names must still comply with these constraints.

- **Uniqueness**—Default mappings include an algorithm to provide uniqueness. Uniqueness is required only within a certain scope; for example column name within a view, view name within a Reporting and Analysis database.

The uniqueness algorithm adds a numeric suffix to items that have the same name.

Note: The resulting name may be subject to the max length limitation.

- **Max length**—The Oracle database has a thirty character limitation for any name. If the auto-generated Oracle database name (view or column) exceeds 30 characters, it is shortened according to the following algorithm:
 - Remove all characters after the 26th character.
 - Append an underscore (`_`), and if this is the first iteration, add '1', otherwise increment it.
 - Test for uniqueness. If the column or view name exceeds 30 characters as a result of adding a suffix to resolve uniqueness, the algorithm is applied.

Built-in columns for views

Built-in clinical view columns and clinical report topics do not depend on properties of the forms, sections, itemsets, items, or controls. The two types of built-in columns and items are key columns and metric columns.

Key columns

Key columns are not customizable and should only be used by advanced users. These columns serve as a key to the Reporting and Analysis operational tables and views, and include the following.

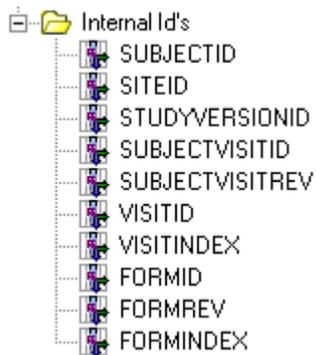
| Key columns | | | |
|------------------|------------------|---------------------|----------------|
| View column name | View column type | Report element name | Element folder |
| SUBJECTID | NUMBER | SUBJECTID | Internal IDs |
| SITEID | NUMBER | SITEID | Internal IDs |
| STUDYVERSIONID | NUMBER | STUDYVERSIONID | Internal IDs |
| SUBJECTVISITID | NUMBER | SUBJECTVISITID | Internal IDs |
| SUBJECTVISITREV | FLOAT | SUBJECTVISITREV | Internal IDs |
| VISITID | NUMBER | VISITID | Internal IDs |
| VISITINDEX | FLOAT | VISITINDEX | Internal IDs |
| FORMID | NUMBER | FORMID | Internal IDs |
| FORMINDEX | FLOAT | FORMINDEX | Internal IDs |
| FORMREV | FLOAT | FORMREV | Internal IDs |

The following examples illustrate generated key columns and items.

Database view

| Column Name | Col ID | Data Type |
|-----------------|--------|-----------|
| SUBJECTID | 1 | NUMBER |
| SITEID | 2 | NUMBER |
| STUDYVERSIONID | 3 | NUMBER |
| SUBJECTVISITID | 4 | NUMBER |
| SUBJECTVISITREV | 5 | FLOAT |
| VISITID | 6 | NUMBER |
| VISITINDEX | 7 | FLOAT |
| FORMID | 8 | NUMBER |
| FORMREV | 9 | FLOAT |
| FORMINDEX | 10 | FLOAT |

Cognos model



Metric columns

Metric columns do not result from control mapping generation. These columns represent information that can also be found in the operational views.

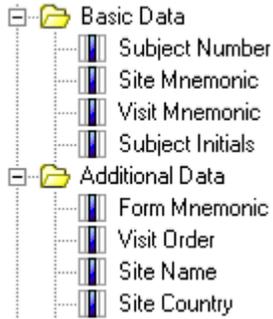
| Metric columns | | | |
|------------------|------------------|---------------------|-----------------|
| View column name | View column type | Report element name | Element folder |
| SITEMNEMONIC | VARCHAR2 | Site Mnemonic | Basic Data |
| VISITMNEMONIC | VARCHAR2 | Visit Mnemonic | Basic Data |
| FORMNEMONIC | VARCHAR2 | Form Mnemonic | Additional Data |
| SUBJECTINITIALS | VARCHAR2 | Subject Initials | Basic Data |
| SITENAME | VARCHAR2 | Site Name | Additional Data |
| COUNTRY | VARCHAR2 | Country | Additional Data |
| VISITORORDER | NUMBER | Visit Order | Additional Data |

The following examples illustrate generated metrical columns and items.

Database view

| Column Name | Col ID | Data Type |
|-----------------|--------|-----------------|
| SITEMNEMONIC | 46 | VARCHAR2 (255) |
| VISITMNEMONIC | 47 | VARCHAR2 (2000) |
| SUBJECTINITIALS | 48 | CHAR (3) |
| FORMMNEMONIC | 49 | VARCHAR2 (2000) |
| VISITORORDER | 50 | NUMBER |
| SITENAME | 51 | VARCHAR2 (255) |
| SITECOUNTRY | 52 | VARCHAR2 (255) |

Cognos model



Additional columns

The following columns appear in each CV view for a form. Each column is updated when data on the form is added or modified. In addition, each column is updated when the review schema is recreated.

Note: These columns are not updated when you perform tasks such as adding a comment, working with a query, making changes to source verification status, and so on.

Additional columns

| Column | Description | Element 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 |
| CREATEDDATETIME | 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 |

Additional columns

| | | |
|----------------------|--|------------|
| MODIFIEDDATE TIME | 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. | Basic Data |
| | When the review schema is recreated, this column displays the date and time when the review schema was recreated. | |

Visits

If a form is part of a repeating visit, the generated clinical view and clinical report topic include two additional columns and items.

Note: A non-repeating visit has no effect on clinical view and clinical report topic generation.

Visits

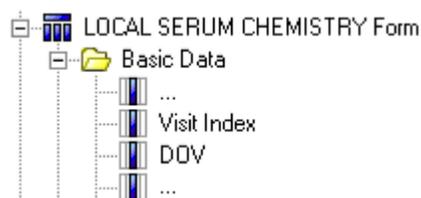
| View column name | View column type | Element name | Element folder | Content |
|------------------|------------------|--------------|----------------|---|
| VISITIDX | NUMBER | Visit Index | Basic Data | Ordinal number of the visit instance starting from 1. |
| DOV | DATE | DOV | Basic Data | Visit instance date of visit. |

The following example shows the columns and items generated as a result of mapping a form in a repeating visit.

Database view

| CV_L_LCHEMISTRY: | | |
|------------------|--------|-----------|
| Column Name | Col ID | Data Type |
| VISITIDX | | NUMBER |
| DOV | | DATE |

Cognos model



Forms

Each form is mapped into a separate clinical view. All form controls, with the exception of controls in repeating sections (itemsets) are mapped to columns in that clinical view. Similarly, a form is mapped into a separate Cognos 10 Business Intelligence clinical report topic based on the underlying clinical view. All form controls, with the exception of controls in repeating sections (itemsets), are mapped to items for that clinical report topic based on the columns in the clinical view.

| Forms | | |
|------------------|---------------------|--|
| View name | Report element name | Report topic description |
| CV_<FormRefName> | <FormTitle> Form | <FormTitle> Form - <FormDesignNote> or <FormTitle> - <FormMnemonic> if FormDesignNote is empty. |

For a repeating form, the following columns and items are added to the clinical view and clinical report topic.

| Repeating forms | | | | |
|------------------|------------------|---------------------|-----------------------|--|
| View column name | View column type | Report element name | Report element folder | Content |
| FORMIDX | NUMBER | Form Index | Basic Data | Ordinal number of the Form instance starting from 1. |
| DELETEDFORM | VARCHAR(1) | Deleted Form | Basic Data | 'Y': if instance of the Form is deleted or 'N' if it is not. |

The following examples show form index and deleted form clinical view columns and clinical report topics generated for a repeating form.

Central Designer Properties Browser view

| Key | Title | Question | Type | Conditional On | RefName | Condition |
|-------------------------------------|---------------------|--------------------------|----------------|-------------------|---------------------|-----------|
| <input type="checkbox"/> | Sequence number | Sequence number | Integer Item | | L_CONMEDSSEQNO | |
| <input type="checkbox"/> | Drug Name | Drug name | Text Item | | L_CONMEDSDRUGNM | |
| <input type="checkbox"/> | Unit Dose | Unit Dose | Float Item | | UnitDose | |
| <input type="checkbox"/> | Route | Route of administrati... | Integer Item | | ROUTE | |
| <input type="checkbox"/> | Reasonformedication | Reason for medicati... | Integer Item | | Reasonformedication | |
| <input type="checkbox"/> | ReasonforMedPull | | Integer Item | Reasonformedic... | ReasonForMedPD | 1 |
| <input type="checkbox"/> | ReasonforMedOther | | Text Item | Reasonformedic... | ReasonforMedOther | 2 |
| <input type="checkbox"/> | Started Prior | Started prior to stud... | Date Time Item | | StartedPrior | |
| <input checked="" type="checkbox"/> | | | <select type> | | | |

Display in the InForm application

| # | Seq. # | Drug name | Drug name (JDrug) | Unit dose | Units | Frequency | Route | Reason for medication | Started prior to study? | Ongoing? | Indication | Base Substance | Base Substance Code | CCRF : Adverse Events Assoc |
|---|--------|-----------|-------------------|-----------|------------------|-----------|------------|-----------------------|-------------------------|----------|------------|--|---------------------|-----------------------------|
| 1 | 1 | test | test | | Cubic centimeter | BID | Inhalation | Adverse event | Yes | Yes | | DRUGS FOR FUNCTIONAL GASTROINTEST. DISORDERS | 900568.01.001 | |

Database view

| Name | Type | Nullable | Default | Comment: |
|-------------|-------------|----------|---------|----------|
| FORMIDX | NUMBER | Y | | |
| DELETEDFORM | VARCHAR2(1) | Y | | |

Cognos model



Sections

A single child item in a repeating section is considered an itemset and is mapped to a separate clinical view. For more information, see *Itemsets* (on page 144).

Note: A section has no effect on clinical view generation.

Itemsets

Each itemset is mapped to a separate clinical view. Each itemset control is mapped to a column in that clinical view. Similarly, an itemset is mapped into a separate clinical report topic, which is based on the underlying clinical view. All the controls for the itemset are mapped to items for that clinical report topic, which are based on the clinical view columns. If a form contains more than one itemset, each itemset is mapped to a separate clinical view. If the same itemset is used in different sections of the same or different forms, the itemset is still mapped to separate clinical views.

| Itemsets | | |
|-----------------------------------|--------------------------------------|--|
| View name | Report element name | Report topic description |
| CV_<FormRefName>_<ItemsetRefName> | <FormTitle> - <SectionTitle> Itemset | <FormTitle> - <SectionTitle> Itemset <FormDesignNote> |
| | | or <FormTitle> - <SectionTitle> Itemset <FormMnemonic> if FormDesignNote is empty. |

The following columns and items are added to the generated clinical view and clinical report topic.

| Itemsets | | | | |
|------------------|------------------|---------------------|-----------------------|--|
| View column name | View column type | Report element name | Report element folder | Content |
| ITEMSETIDX | NUMBER | Itemset Index | Basic Data | Ordinal number of the itemset instance, starting from 1. |
| DELETEDITEMSET | VARCHAR2(1) | Delete Itemset | Basic Data | 'Y' if the instance of the itemset is deleted or 'N' if it is not. Note: You cannot delete or undelete a Repeating Data itemset. |

The following examples illustrate default form mapping for the Surgical History repeating section of the Surgical History form.

Central Designer Properties Browser view

The screenshot shows the Central Designer Properties Browser for the 'Surgical History' repeating section. The left pane displays the 'Misc' properties, and the right pane shows the 'Data Series Summary' table.

| Title | Question | Type | Conditional On | RefName |
|----------|----------|---------------|----------------|--------------|
| Surgery | Surgery | Text Item | | LitmSurgHx |
| Date | Date | DateTime Item | | LitmSurgDate |
| Comments | Comments | Text Item | | LitmSurgComm |
| | | <select type> | | |

The 'Misc' properties on the left include:

- AssociatedForm: None
- Description:
- DmValidation: PhaseForward.Designer.Client.Model.Designerf
- Identifier: e9241f51-d4d9-4143-95e2-81edd0705cf9
- Locked: False
- Modified: False
- New: False
- RefName: **LsctSurgHx**
- Repeating: **True**
- Revision: 0.0.134
- Shared: **False**
- ShortTitle: **Surgical History**
- Title: **Surgical History**
- Version:

MedML definition

```
<ITEMSET REFNAME="LsctSurgHx"
  ITEMREQUIRED="true"
  SDVREQUIRED="true" >
  <ITEMREF REFNAME="LitmSurgHx"
    ORDER="1" />
  <ITEMREF REFNAME="LitmSurgDate"
    ORDER="2" />
  <ITEMREF REFNAME="LitmSurgComm"
    ORDER="3" />
</ITEMSET>

<SECTION REFNAME="LsctSurgHx"
  LANGUAGE="English"
  TITLE="Surgical History Add"
  REPEATING="true" >
  <ITEMREF REFNAME="LsctSurgHx" />
</SECTION>
```

Display in the InForm application

SURGICAL HISTORY

1.* Has the subject had any surgical interventions? No
 Yes, please click the Submit button first and then click the Add Entry button to record details below

Surgical History Add

| # | Surgery | Date | Comments |
|----|---------|------|----------|
| 2. | | | |

Cognos model

SURGICAL HISTORY~Surgical History Itemset

| Properties | | Languages |
|---------------------|--|-----------|
| Name | SURGICAL HISTORY~Surgical History Itemset | |
| Description | SURGICAL HISTORY~Surgical History Itemset SURGHX | |
| Last Changed | 2005-01-18T12:52:35 | |
| Screen Tip | SURGICAL HISTORY~Surgical History Itemset SURGHX | |

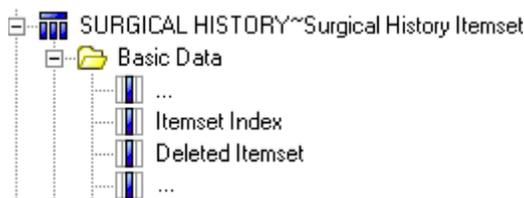
The following examples illustrate itemset index and deleted itemset clinical view columns and clinical report topics generated for the Surgical History repeating section.

Database view

Columns of CY_L_SURGICALHX_LSCTSURGHX_1

| Name | Type | Nullable | Default | Comments |
|-------------|---------|----------|---------|----------|
| ITEMSETIDX | NUMBER | Y | | |
| DELETEDITEM | CHAR(1) | Y | | |

Cognos model



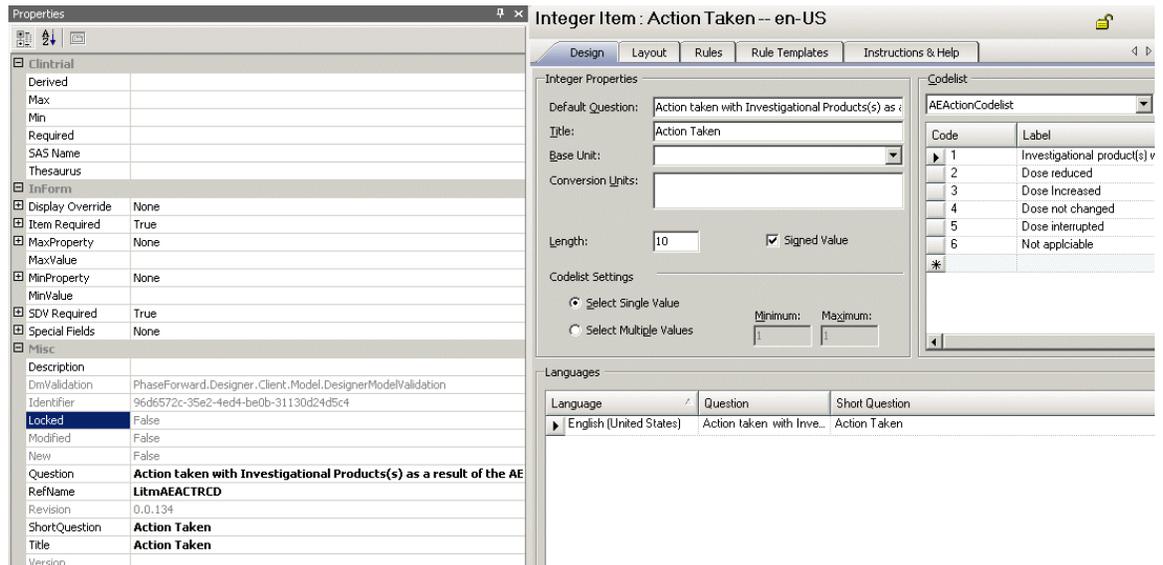
Items

Item controls are mapped to one or more clinical view columns and clinical report topics. The item is mapped to a single column for items that contain Incomplete Item Reasons entered in a CRF or item comment form. Reasons are study-dependent (for example, Not Done, Not Applicable, or Unknown).

| Items | | | | |
|------------------|------------------|---|-------------------------|---|
| View column name | View column type | Report element name | Report element folder | Content |
| ND_<ItemRefName> | VARCHAR2(64) | Not Done ~ <ItemLabel>. ItemLabel is also known as Short Question in the Central Designer application. If ItemLabel is empty or has default value similar to ITEM1, then the ITEMQUESTION attribute is used. | Incomplete Data Reasons | Not Done reason entered via Comment Form (for example, Not Applicable). Reason text length, but not more than 64. |

The following examples illustrate default form mapping for items with the NOT empty (or NOT default) ItemLabel. ItemLabel is also known as Short Question in the Central Designer application.

Central Designer Properties Browser view



MedML definition

```

<ITEM REFNAME="LitmAEACTRCD"
  LANGUAGE="English"
  QUESTION="Action taken with Investigational Products(s) as a result of the AE"
  LABEL="Action Taken"
  CALCULATED="false"
  ITEMREQUIRED="true"
  SDVREQUIRED="true">

  <CONTROLREF REFNAME="LitmAEACTRCD" />
</ITEM>

<SECTION REFNAME="AE"
  LANGUAGE="English"
  REPEATING="false"
  DESIGNNOTE="dynamically created section for items without section">

  <ITEMREF REFNAME="LitmAEACTRCD" />
</SECTION>

```

Display in the InForm application

| | | |
|-----|--|---|
| 7.* | Action taken with Investigational Product(s) as a result of the AE | <input type="radio"/> Investigational product(s) withdrawn <input type="radio"/> Dose reduced <input checked="" type="radio"/> Dose increased <input type="radio"/> Dose not changed <input type="radio"/> Dose interrupted <input type="radio"/> Not applicable |
|-----|--|---|

Database view

| Name | Type | Nullable | Default | Comm |
|-----------------|--------------|----------|---------|------|
| ND_LITMAEACTRCD | VARCHAR2(64) | Y | | |

Cognos model



Controls

Although control types are mapped to the clinical view columns and clinical report topics differently, they have similar naming constraints.

A control is mapped to zero or more clinical view columns and related clinical report topics. If a control is mapped to more than one column, all column and item names have the same beginning or root. To differentiate multiple columns generated for a single control, a special naming component is added as a suffix or prefix. The naming component depends on the type of the mapped control and the nature of the columns.

The clinical view column name is a result of the following algorithm:

```

/* Get column base name */
IF control's type is CHECKBOX THEN
columnName := CONTROLREFNAME _CHILDCONTROLREFNAME
ELSE
columnName := CONTROLREFNAME
END IF

/* Add or replace with Item REFNAME */
IF control is the only control of the item THEN
columnName := ITEMREFNAME
ELSE
columnName := columnName_ITEMREFNAME
END IF

/* Append column prefix (column prefixes are described in the following
sections) */
IF control is mapped to more than one column THEN
columnName := <COLUMNSUFFIX>_columnName
END IF

```

The clinical report element name is a result of the following algorithm:

```

/* Get Query Subject Item base name */
IF Item Label (Itemset Header) is NOT empty or NOT default (e.g. ITEM1_I)
THEN
itemName := ITEMLABEL
ELSE
itemName := ITEMQUESTION
END IF

/* Add control if the item has more than one control */
IF control is NOT the only control of the item THEN
/* Get Control name */
IF control's Caption exists THEN
controlName := CONTROLCAPTION
ELSE
controlName := CONTROLREFNAME
END IF

/* Append child control name for Checkbox control*/
IF control's type is CHECKBOX THEN
IF child control's type is Simple control THEN
controlName := controlName ~ CHILDCONTROLELEMENTLABEL
ELSE IF child control has Caption THEN
controlName := controlName ~ CHILDCONTROLCAPTION
ELSE
controlName := controlName ~ CHILDCONTROLREFNAME
END IF
END IF

itemName := controlName ~ itemName
END IF

/* Append column prefix (column prefix is described in the following
sections) */

```

```
IF control is mapped to more than one column THEN
  itemName := COLUMNPREFIX ~ itemName
END IF
```

The corresponding Cognos report element description is the same as the report element name. The following naming convention is used when clinical view names and column names are created.

- Generated names are capitalized.
- Special characters ~ ! @ # \$ % ^ & * () + - = { } [] \ | ; : ' " , < . > / ? ` ' and spaces are replaced by underscores (_).

The InForm application does the following during the generation of report topic names and element names.

- Trims leading and trailing white spaces.
- Removes trailing question marks and colons in columns.
- Removes angle brackets and text between them.
- Removes other HTML artifacts including ' ';

Simple controls

Simple controls do not map to the clinical view column or clinical report element. Control attributes affect the content of the column that results from mapping a parent control.

Text controls

A text control is always mapped to at least one column.

| Text controls | | | |
|--|---|---|-----------------------|
| View column name | View column type | Report element name | Report element folder |
| <CoreColumnName>— (Generally <ItemRefName>_ <ControlRefName>) | VARCHAR2(N) —If the control datatype is CHARACTER and its MAXLENGTH value is 255 or less. N is equal to the MAXLENGTH value. CLOB —If the control datatype is CHARACTER and its MAXLENGTH value is more than 255. Only the first 32000 characters of entered text are mapped. NUMBER —If the control datatype is INTEGER. FLOAT —If the control datatype is FLOAT. | <CoreItemName>— A name generated according to control mapping logic, generally the item question or item label prefixed by the control caption or control RefName. | Basic Data |

If the data type of a text control is NUMERIC or FLOAT and has assigned units, the text control is mapped to three additional columns if there is more than one associated unit. A single unit may be

read-only and cannot be selected.

| Text controls | | | | |
|---------------------|------------------|-----------------------------|-----------------------|--|
| View column name | View column type | Report element name | Report element folder | Content |
| N_<CoreColumnName> | NUMBER | Normalized ~ <CoreItemName> | Additional Data | Normalized value generated by associated unit rule from entered data. |
| UC_<CoreColumnName> | VARCHAR 2 | Unit Code ~ <CoreItemName> | Additional Data | Coded value of selected unit, which represents UNITREFNAME attribute. |
| U_<CoreColumnName> | VARCHAR 2 | Unit ~ <CoreItemName> | Basic Data | Value of selected unit, which represents UNITSYMBOL attribute. |

The following examples illustrate mapping a character text control.

Central Designer Properties Browser view

The screenshot displays the 'Properties' browser for an 'Integer Item: Heart Rate -- en-US'. The left pane shows a tree view with categories like 'Clinical', 'InForm', and 'Misc'. The right pane shows the configuration for the 'Integer Properties' of this item.

Integer Properties:

- Default Question: Heart Rate
- Title: Heart Rate
- Base Unit: (dropdown menu)
- Conversion Units: (text field)
- Length: 3
- Signed Value
- Codelist Settings:
 - Select Single Value
 - Select Multiple Values
 - Minimum: 1
 - Maximum: 1
- Languages:

| Language | Question | Short Question |
|-------------------------|------------|----------------|
| English (United States) | Heart Rate | Heart Rate |

Misc Properties:

- Description: PhaseForward.Designer.Client.Model.DesignerMode
- Identifier: c57d4b8f-e3d1-4cad-8a70-8c849fd5ea46
- Locked: False
- Modified: False
- New: False
- Question: **Heart Rate**
- RefName: **HeartRate**
- Revision: 0.0.135
- ShortQuestion: **Heart Rate**
- Title: **Heart Rate**
- Version: (empty)

MedML definition

```

<TEXTCONTROL REFNAME="HeartRate"
  LANGUAGE="English"
  NAME="HeartRate"
  CAPTION="bpm"
  ALIGN="LEFT"
  CAPTIONALIGN="RIGHT"
  UNITDISPLAYTYPE="ELEMENT"
  HEIGHT="1"
  LENGTH="3"
  MAXLENGTH="3"
  DATATYPE="INTEGER"
  MINVALUE="0"
  MAXVALUE="0"
  MINPROPERTY="NOTSPECIFIED"
  MAXPROPERTY="NOTSPECIFIED"/>

<ITEM REFNAME="HeartRate"
  LANGUAGE="English"
  QUESTION="Heart Rate"
  LABEL="Heart Rate"
  CALCULATED="false"
  ITEMREQUIRED="true"
  SDVREQUIRED="true">

  <CONTROLREF REFNAME="HeartRate"/>

</ITEM>

```

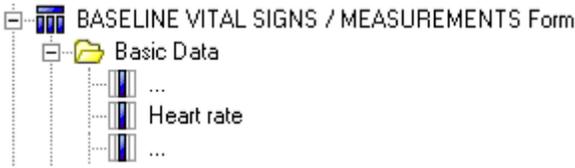
Display in the InForm application

2.* Heart Rate bpm

Database view

| Columns of CV_FRMBASELNVITLS | | | | | |
|------------------------------|--------|----------|---------|----------|--|
| Name | Type | Nullable | Default | Comments | |
| HEARTRATE | NUMBER | Y | | | |

Cognos model



The following examples illustrate mapping a text control with associated units.

Central Designer Properties Browser view

| Description | |
|---------------|---|
| DmValidation | PhaseForward.Designer.Client.Model.DesignerMode |
| Identifier | 35dfe978-2123-40d7-8d49-85c289737d5d |
| Locked | False |
| Modified | False |
| New | False |
| Question | Height |
| RefName | Height |
| Revision | 0.0.138 |
| ShortQuestion | Height |
| Title | Height |
| Version | |

| Language | Question | Short Question |
|-------------------------|----------|----------------|
| English (United States) | Height | Height |

MedML definition

```

CLASSIFICATION="Length"
BASEREFNAME="Heightin"/>

<UNIT REFNAME="Heightcm"
LANGUAGE="English"
SYMBOL="cm"
CLASSIFICATION="Length"
BASEREFNAME="Heightin"
CONVERSIONTOBASE="Heightcm"/>

<TEXTCONTROL REFNAME="Height"
LANGUAGE="English"
NAME="Height"
ALIGN="LEFT"
CAPTIONALIGN="LEFT"
UNITDISPLAYTYPE="RADIO"
HEIGHT="1"
LENGTH="7"
MAXLENGTH="4"
DATATYPE="FLOAT"
PRECISION="0"
MINVALUE="0"
MAXVALUE="0"
MINPROPERTY="NOTSPECIFIED"
MAXPROPERTY="NOTSPECIFIED" >

  <UNITREF REFNAME="Heightcm"/>

  <UNITREF REFNAME="Heightin"/>

</TEXTCONTROL >

<ITEM REFNAME="Height"
LANGUAGE="English"
QUESTION="Height"
LABEL="Height"
CALCULATED="false"
ITEMREQUIRED="true"
SDVREQUIRED="true" >

  <CONTROLREF REFNAME="Height"/>

</ITEM >

```

Display in the InForm application

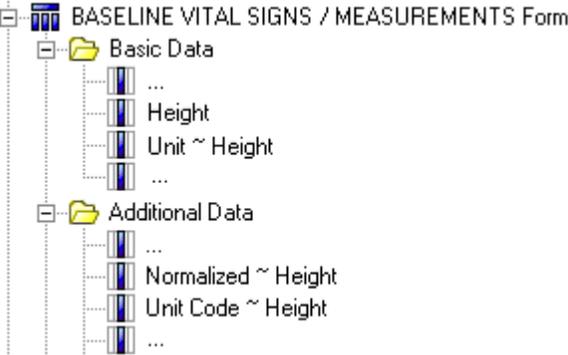
| | | | | |
|-----|---------------|------|--------------------------|-------------------------------------|
| 5.* | <u>Height</u> | 65.0 | <input type="radio"/> cm | <input checked="" type="radio"/> in |
|-----|---------------|------|--------------------------|-------------------------------------|

Database view



| Name | Type | Nullable | Default | Comments |
|-----------|--------------|----------|---------|----------|
| ND_HEIGHT | VARCHAR2(64) | Y | | |

Cognos model



Drop-down lists

Drop-down lists are mapped to two clinical view columns.

| Drop-down lists | | | | |
|--------------------|--|-----------------------|-----------------------|-----------------|
| View column name | View column type | Report element name | Report element folder | Content element |
| C_<CORECOLUMNNAME> | FLOAT, NUMBER or VARCHAR2 (depends on the type of the child elements.) | Code ~ <COREITEMNAME> | Additional Data | ELEMENTVALUE |
| <COREITEMNAME> | VARCHAR2 | <COREITEMNAME> | Basic Data | ELEMENTLABEL |

The following examples illustrate mapping a drop-down list.

Central Designer Properties Browser view

The screenshot displays the 'Integer Item : Route -- en-US' configuration window. On the left, a 'Properties' browser shows a tree view with categories like 'Clinical', 'InForm', and 'Misc'. The 'Misc' category is expanded, showing fields such as 'Description', 'Identifier', 'Locked', 'Modified', 'New', 'Question', 'RefName', 'Revision', 'ShortQuestion', 'Title', and 'Version'. The 'Question' field is set to 'Route of administration' and 'RefName' is 'ROUTE'. The main configuration area has tabs for 'Design', 'Layout', 'Rules', 'Rule Templates', and 'Instructions & Help'. The 'Design' tab is active, showing 'Integer Properties' with fields for 'Default Question' (Route of administration), 'Title' (Route), 'Base Unit', 'Conversion Units', 'Length' (10), and 'Signed Value' (checked). Below this are 'Codelist Settings' with radio buttons for 'Select Single Value' and 'Select Multiple Values', and 'Minimum' and 'Maximum' value fields. To the right, the 'Codelist' section shows a table with columns 'Code' and 'Label'. The table contains 12 entries, with 'Both eyes' (Code 1) selected. At the bottom, the 'Languages' section shows a table with columns 'Language', 'Question', and 'Short Question'. The entry for 'English (United States)' shows 'Route of administration' for the question and 'Route' for the short question.

MedML definition

```

Design MedML
<ELEMENTREF REFNAME="Intravenous_en-US"
  ORDER="14"/>
<ELEMENTREF REFNAME="Nasal_en-US"
  ORDER="15"/>
<ELEMENTREF REFNAME="Oral_en-US"
  ORDER="16"/>
<ELEMENTREF REFNAME="Rectal_en-US"
  ORDER="17"/>
<ELEMENTREF REFNAME="Subcutaneous_en-US"
  ORDER="18"/>
<ELEMENTREF REFNAME="Sublingual_en-US"
  ORDER="19"/>
<ELEMENTREF REFNAME="Topical_en-US"
  ORDER="20"/>
<ELEMENTREF REFNAME="Transdermal_en-US"
  ORDER="21"/>
<ELEMENTREF REFNAME="Unknown_en-US"
  ORDER="22"/>
<ELEMENTREF REFNAME="Vaginal_en-US"
  ORDER="23"/>
</PULLDOWNCONTROL>
<ITEM REFNAME="ROUTE"
  LANGUAGE="English"
  QUESTION="Route of administration"
  LABEL="Route"
  CALCULATED="false"
  ITEMREQUIRED="true"
  SDVREQUIRED="true">
  <CONTROLREF REFNAME="ROUTE"/>
</ITEM>

```

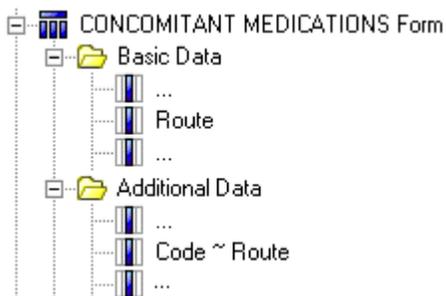
Display in the InForm application

| | | |
|----|-------|-----------------|
| 7. | Route | Both eyes |
| | | Both eyes |
| | | Epidural |
| | | Gastronomy tube |
| | | Inhalation |
| | | Injection |
| | | Intra-arterial |
| | | Intra-bursa |
| | | Intramuscular |
| | | Intranasal |
| | | Intraocular |
| | | Intraosteal |
| | | Intrathecal |
| | | Intrauterine |
| | | Intraceneous |
| | | Nasal |
| | | Oral |
| | | Rectal |
| | | Subcutaneous |
| | | Sublingual |
| | | Topical |
| | | Transdermal |
| | | Unknown |
| | | Vaginal |

Database view

| Columns of CV_I_CONMEDS | | | | | |
|-------------------------|--------------|----------|---------|---------|--|
| Name | Type | Nullable | Default | Comment | |
| C_ROUTE | NUMBER | Y | | | |
| ROUTE | VARCHAR2(16) | Y | | | |

Cognos model



Calculated controls

Calculated controls are mapped using the same logic used for CHARACTER text controls with the **MAXLENGTH** attribute set to 255.

Date controls

Date controls can be mapped to up to seven columns depending on the date control attribute values.

| Date controls | | | | |
|---------------------------|------------------|-------------------------------------|-----------------------|---|
| View column name | View column type | Report element name | Report element folder | Content |
| DT_<CORECOLUMNNAME> E> | DATE | Date ~ <COREITEMNAME> ME> | Basic Data | Date without time component. This column is generated only if the Year, Month, and Day DISPLAY attributes are all set to TRUE. This column will be populated if a user selects a value other than Empty or Unknown for all three Year, Month and Day components. |
| MY_<CORECOLUMNNAME> E> | DATE | Month Yr ~ <COREITEMNAME> ME> | Basic Data | Date without day and time components. This column is generated only if the Year and Month DISPLAY attributes are set to TRUE . This column will be populated if a user selects a value other than Empty or Unknown for all Year and Month components. |

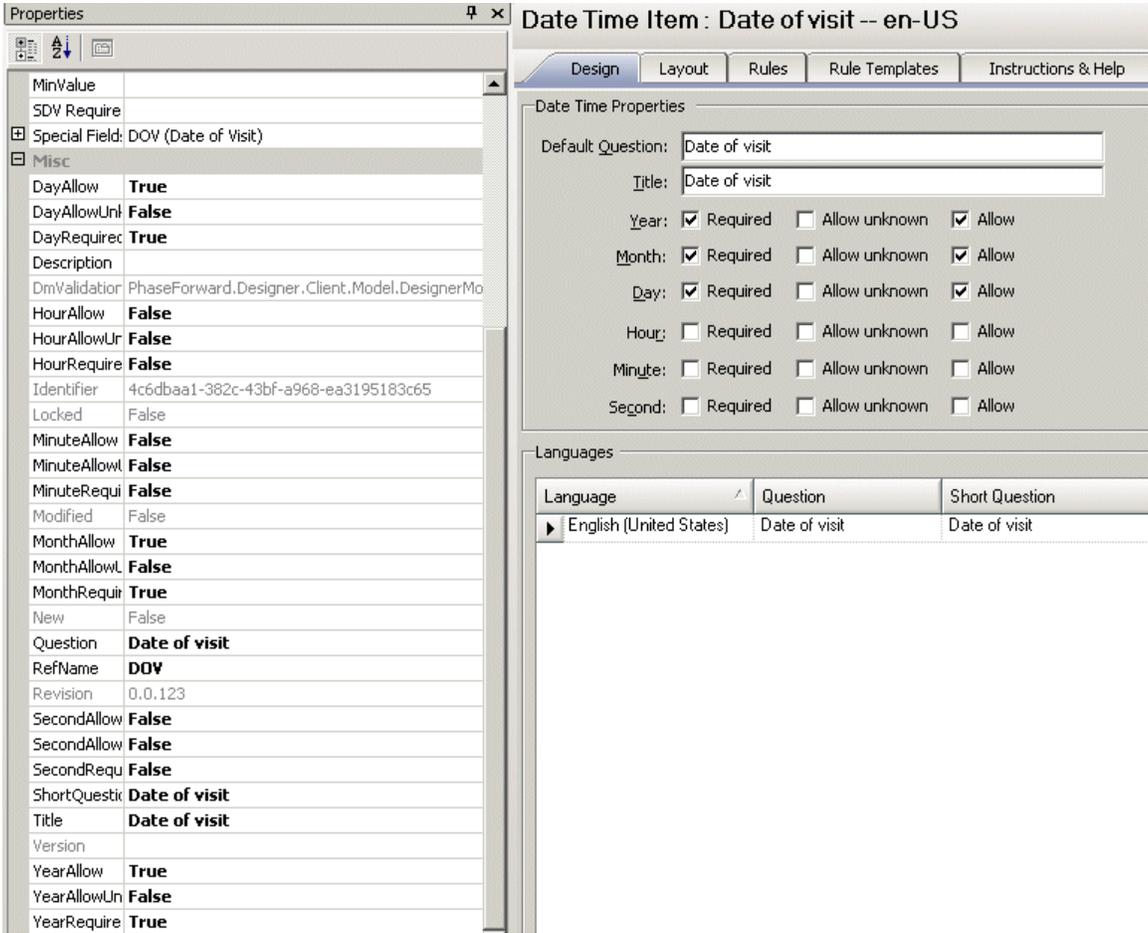
| Date controls | | | | |
|----------------------|------------------|----------------------------|-----------------------|--|
| View column name | View column type | Report element name | Report element folder | Content |
| DTS_<CORECOLUMNNAME> | VARCHAR2 | YYYY/MM/DD ~<COREITEMNAME> | Basic Data | This column is generated only if the Year, Month and Day DISPLAY attributes are all set to TRUE and one or all of these components' REQUIRED attributes is set to FALSE, or the UNKNOWN attribute is set to TRUE. Date components are populated with entered numbers, or with NULL if you do not select a value, or with UNK if you select Unknown. |
| TM_<CORECOLUMNNAME> | DATE | Time ~<COREITEMNAME> | Basic Data | This column is generated only if the Hour and Minute DISPLAY attributes are all set to TRUE . This column will be populated if a user selects a value other than Empty or Unknown for all Hour and Minute components. Seconds component values are used if selected by the user. |

| Date controls | | | | |
|----------------------|------------------|----------------------------|-----------------------|--|
| View column name | View column type | Report element name | Report element folder | Content |
| TMS_<CORECOLUMNNAME> | VARCHAR2 | HH24:MM:SS ~<COREITEMNAME> | Basic Data | This column is generated only if the Hour and Minute DISPLAY attributes are all set to TRUE and one of these components' REQUIRED attribute is set to FALSE or the UNKNOWN attribute is set to TRUE. As with Date Strings, these column values use the format HH24:MM:SS (or HH24:MM if no seconds are displayed). This column is populated with values for HH, MM, and SS if selected, NULL if you do not make a selection, or UNK if you select Unknown. |
| Y_<CORECOLUMNNAME> | DATE | Year ~<COREITEMNAME> | Additional Data | This column is generated only if the Year DISPLAY attribute is set to TRUE. This column will be populated if a user selects a value other than Empty or Unknown for Year components. Month and Day components are ignored. |

| Date controls | | | | |
|--------------------|------------------|-----------------------|-----------------------|--|
| View column name | View column type | Report element name | Report element folder | Content |
| M_<CORECOLUMNNAME> | DATE | Month ~<COREITEMNAME> | Additional Data | <p>This column is generated only if the control Month DISPLAY attribute is set to TRUE.</p> <p>This column will be populated if a user selects a value other than Empty or Unknown for Month components. Year and Day components are ignored.</p> |

The following examples illustrate mapping a datetime control.

Central Designer Properties Browser view



MedML definition

```

Design MedML
<DATETIMECONTROL REFNAME="DOV"
  UUID="BD991BC0-B0A4-11D2-80E3-00A0C9AF7674"
  LANGUAGE="English"
  ALIGN="LEFT"
  CAPTIONALIGN="LEFT"
  STARTYEAR="2007"
  ENDEYEAR="2015"
  DISPLAYMONTH="true"
  DISPLAYDAY="true"
  DISPLAYYEAR="true"
  DISPLAYHOUR="false"
  DISPLAYMINUTE="false"
  DISPLAYSECOND="false"
  REQUIREMONTH="true"
  REQUIREDAY="true"
  REQUIREYEAR="true"
  REQUIREHOUR="false"
  REQUIREMINUTE="false"
  REQUIRESECOND="false"
  UNKNOWNMONTH="false"
  UNKNOWNDAY="false"
  UNKNOWNYEAR="false"
  UNKNOWNHOUR="false"
  UNKNOWNMINUTE="false"
  UNKNOWNSECOND="false"
  CHECKCONSISTENT="true"
  TEXTFORMAT="false"/>

<ITEM REFNAME="DOV"
  UUID="BD991BBF-B0A4-11D2-80E3-00A0C9AF7674"
  LANGUAGE="English"
  QUESTION="Date of visit"
  LABEL="Date of visit"
  CALCULATED="false"
  ITEMREQUIRED="true"
  SDVREQUIRED="true">

  <CONTROLREF REFNAME="DOV"/>

</ITEM>

```

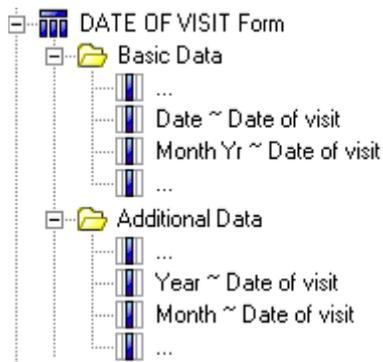
Display in InForm

| | | | | | | |
|-----|------------------------|-----|---|----|---|---------------|
| 1.* | Date and Time of Visit | Jun | / | 1 | / | 2009 |
| | | 15 | : | 07 | | 24-hour clock |

Database view

| Name | Type | Nullable | Default | Cor |
|--------|------|----------|---------|-----|
| DT_DOV | DATE | Y | | |
| MY_DOV | DATE | Y | | |
| Y_DOV | DATE | Y | | |
| M DOV | DATE | Y | | |

Cognos model



Radio controls

Radio controls are mapped to two clinical view columns.

| Radio controls | | | | |
|--------------------|--|-----------------------|-----------------------|--|
| View column name | View column type | Report element name | Report element folder | Content |
| C_<CORECOLUMNNAME> | FLOAT, NUMBER or VARCHAR2 if all children are simple controls, otherwise VARCHAR2 | Code ~ <COREITEMNAME> | Additional Data | ELEMENTVALUE if a child control is a simple control, CONTROLSELECTIONVALUE if a control has a selection value, otherwise CONTROLREFNAME. |

| Radio controls | | | | |
|------------------|------------------|---------------------|-----------------------|--|
| View column name | View column type | Report element name | Report element folder | Content |
| <COREITEMNNAME> | VARCHAR2 | <COREITEMNAME> | Basic Data | ELEMENTLABEL if a child control is a simple control, CONTROLCAPTION if it has a caption, otherwise CONTROLREFNAME. |

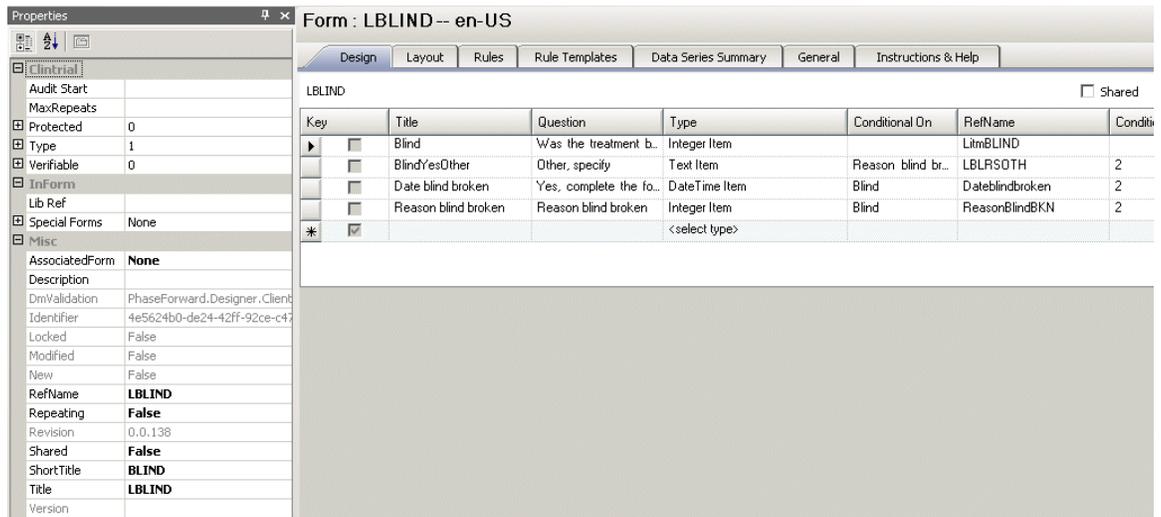
In addition to these two columns, the children associated with a radio control have their own column mappings, with the exception of simple controls, which do not map to columns.

Clinical view column names and report element names for radio controls use the following unique naming convention:

- Clinical view column name: **columnName_ITEMREFNAME**
- Query Subject Item name: **controlName ~ itemName**

The following examples illustrate mapping a radio control.

Central Designer Properties Browser view



MedML definition

```

NAME="ReasonBlindBKN"
CAPTION="Reason blind broken"
LAYOUT="VERTICAL"
ALIGN="LEFT"
CAPTIONALIGN="TOP">

<CONTROLREF REFNAME="Medical"
ORDER="1"/>

<CONTROLREF REFNAME="LBLRSOTH"
ORDER="2"
SELECTIONVALUE="2"/>

</RADIOCONTROL>

<GROUPCONTROL REFNAME="GC_LitmBLIND"
LANGUAGE="English"
NAME="GC_LitmBLIND"
LAYOUT="VERTICAL"
ALIGN="LEFT"
CAPTIONALIGN="LEFT">

<CONTROLREF REFNAME="Dateblindbroken"
ORDER="1"/>

<CONTROLREF REFNAME="ReasonBlindBKN"
ORDER="2"/>

</GROUPCONTROL>

<RADIOCONTROL REFNAME="LitmBLIND"
LANGUAGE="English"
NAME="LitmBLIND"
LAYOUT="VERTICAL"
ALIGN="LEFT"
CAPTIONALIGN="LEFT">

<CONTROLREF REFNAME="BLINDCLNo"
ORDER="1"/>

<CONTROLREF REFNAME="GC_LitmBLIND"
ORDER="2"
SELECTIONVALUE="2"/>

</RADIOCONTROL>

<ITEM REFNAME="LitmBLIND"
LANGUAGE="English"
QUESTION="Was the treatment blind broken during the study?"
LABEL="Was the treatment blind broken during the study?"
CALCULATED="false"
ITEMREQUIRED="true"
SDVREQUIRED="true">

<CONTROLREF REFNAME="LitmBLIND"/>

</ITEM>

```

Display in the InForm application

Status of Treatment Blind

1.* Was the treatment blind broken during the study?

No

Yes, complete the following

Date blind broken

/ /

Reason blind broken

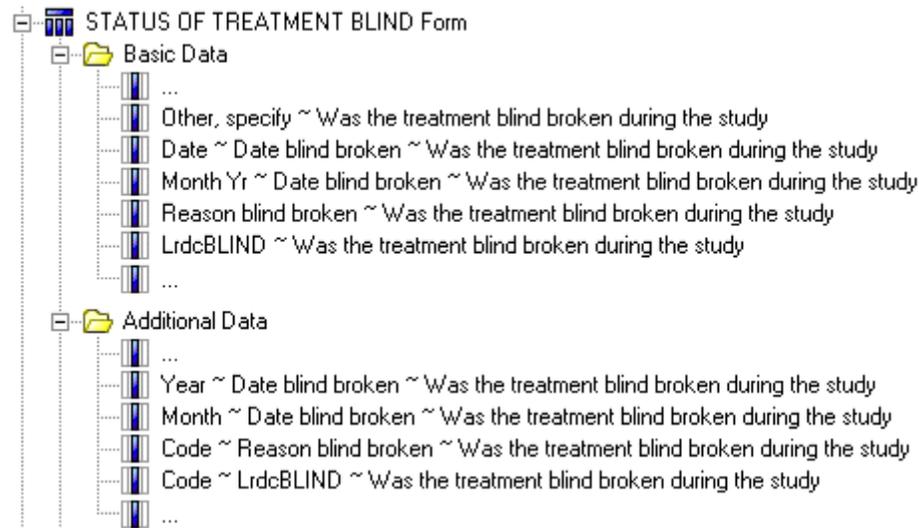
Medical emergency requiring identification of investigational product for further treatment

Other, specify

Database view

| Name | Type | Nullable | Default | Comment |
|------------------------------|---------------|----------|---------|---------|
| C_LITMBLIND_LITMBLIND | NUMBER | Y | | |
| LITMBLIND_LITMBLIND | VARCHAR2(12) | Y | | |
| DT_DATEBLINDBROKEN_LITMBLIND | DATE | Y | | |
| MY_DATEBLINDBROKEN_LITMBLIND | DATE | Y | | |
| Y_DATEBLINDBROKEN_LITMBLIND | DATE | Y | | |
| M_DATEBLINDBROKEN_LITMBLIND | DATE | Y | | |
| C_REASONBLINDBKN_LITMBLIND | NUMBER | Y | | |
| REASONBLINDBKN_LITMBLIND | VARCHAR2(91) | Y | | |
| LBLRSOTH_LITMBLIND | VARCHAR2(128) | Y | | |

Cognos model



Checkbox controls

Checkbox controls are mapped to 2xN clinical view columns, where N is the number of checkboxes (children). Each checkbox is mapped to two individual columns.

| Checkbox controls | | | | |
|--------------------|--|-----------------------|-----------------------|--|
| View column name | View column type | Report element name | Report element folder | Content |
| C_<CORECOLUMNNAME> | FLOAT, NUMBER or VARCHAR2 if the child is a simple control, otherwise VARCHAR2 | Code ~ <COREITEMNAME> | Additional Data | ELEMENTVALUE if a child control is a simple control, CONTROLSELECTIONVALUE if the control has a selection value, otherwise CONTROLREFNAME. |
| <COREITEMNAME> | VARCHAR2 | <COREITEMNAME> | Basic Data | ELEMENTLABEL if a child control is a simple control, CONTROLCAPTION, otherwise CONTROLREFNAME. |

The following examples illustrate mapping a checkbox control.

Central Designer Properties Browser view

The screenshot displays the 'Integer Item : MultiRacial -- en-US' configuration window. The 'Integer Properties' section includes:

- Default Question: Race
- Title: MultiRacial
- Base Unit: (empty)
- Conversion Units: (empty)
- Length: 1
- Signed Value

The 'Codelist Settings' section shows:

- Select Single Value
- Select Multiple Values
- Minimum: 1
- Maximum: 5

The 'Codelist' table is as follows:

| Code | Label |
|------|-------------------------------------|
| 1 | American Indian or Alaska Native |
| 2 | Asian |
| 3 | Black, African heritage |
| 4 | Native Hawaiian or Pacific Islander |
| 5 | White |

The 'Languages' section shows:

| Language | Question | Short Question |
|-------------------------|----------|----------------|
| English (United States) | Race | |

Central Designer Project Explorer view



MedML definition

```

<CHECKBOXCONTROL REFNAME="MultiRacial"
  LANGUAGE="English"
  NAME="MultiRacial"
  LAYOUT="VERTICAL"
  ALIGN="LEFT"
  CAPTIONALIGN="LEFT" >

  <CONTROLREF REFNAME="AmericanIndianorAlaskaNative"
    ORDER="1"/>

  <CONTROLREF REFNAME="MultiRacialAsian"
    ORDER="2"/>

  <CONTROLREF REFNAME="Black"
    ORDER="3"/>

  <CONTROLREF REFNAME="NativeHawaiianorPacificIslander"
    ORDER="4"/>

  <CONTROLREF REFNAME="MultiRacialWhite"
    ORDER="5"/>

</CHECKBOXCONTROL>

<ITEM REFNAME="MultiRacial"
  LANGUAGE="English"
  QUESTION="Race"
  LABEL="Race"
  CALCULATED="false"
  ITEMREQUIRED="true"
  SDVREQUIRED="true" >

  <CONTROLREF REFNAME="MultiRacial"/>

</ITEM>

```

Display in the InForm application

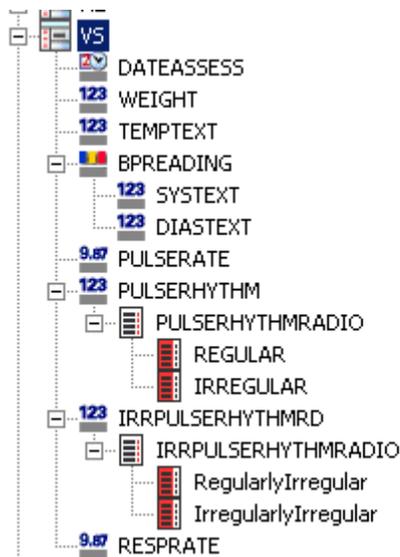
| | | |
|-----|------|---|
| 3.* | Race | <input checked="" type="radio"/> White, not of Hispanic origin <input type="radio"/> Black, not of Hispanic origin <input type="radio"/> Hispanic <input type="radio"/> Asian or Pacific Islander <input type="radio"/> American Indian or Alaskan Native <input type="radio"/> Other or Unknown |
|-----|------|---|

Group controls

Group controls do not map into generated clinical view columns, but group control children are mapped.

Examples of auto-generated mappings

Form definition in the Central Designer Project Explorer



Display in the InForm application

Vital Signs Jun/3/2009 14:54

| | | |
|-----|--|---|
| 1.* | Weight <i>(Record to one decimal)</i> | <input type="text"/> <input type="radio"/> kg <input type="radio"/> lbs |
| 2.* | Temperature <i>(Record to one decimal)</i> | <input type="text"/> |
| 3.* | Sitting Blood Pressure | <input type="text"/> / <input type="text"/> mmHg |
| 4.* | Sitting Pulse Rate | <input type="text"/> bpm |
| 5.* | Sitting Respiration Rate | <input type="text"/> breaths per minute |
| 6.* | BMI | |

Clinical view schema

| Name | Type | Nullable | Default | Comments |
|--------------------------------|--------------|----------|---------|----------|
| DT_DATEASSESS | DATE | Y | | |
| MY_DATEASSESS | DATE | Y | | |
| Y_DATEASSESS | DATE | Y | | |
| M_DATEASSESS | DATE | Y | | |
| ND_DATEASSESS | VARCHAR2(64) | Y | | |
| WEIGHT | NUMBER | Y | | |
| N_WEIGHT | NUMBER | Y | | |
| UC_WEIGHT | VARCHAR2(14) | Y | | |
| U_WEIGHT | VARCHAR2(3) | Y | | |
| ND_WEIGHT | VARCHAR2(64) | Y | | |
| TEMPTEXT | NUMBER | Y | | |
| N_TEMPTEXT | NUMBER | Y | | |
| UC_TEMPTEXT | VARCHAR2(14) | Y | | |
| U_TEMPTEXT | CHAR(1) | Y | | |
| ND_TEMPTEXT | VARCHAR2(64) | Y | | |
| SYSTEXT_BPREADING | NUMBER | Y | | |
| DIASTEXT_BPREADING | NUMBER | Y | | |
| ND_BPREADING | VARCHAR2(64) | Y | | |
| PULSERATE | NUMBER | Y | | |
| ND_PULSERATE | VARCHAR2(64) | Y | | |
| C_PULSERHYTHM_PULSERHYTHM | NUMBER | Y | | |
| PULSERHYTHM_PULSERHYTHM | VARCHAR2(20) | Y | | |
| C_IRRPULSERHYTHMRD_PULSERHYTHM | NUMBER | Y | | |
| IRRPULSERHYTHMRD_PULSERHYTHM | VARCHAR2(21) | Y | | |
| ND_PULSERHYTHM | VARCHAR2(64) | Y | | |
| RESPRATE | NUMBER | Y | | |
| ND_RESPRATE | VARCHAR2(64) | Y | | |

CHAPTER 4

Reporting Data Extracts (RDEs)

In this chapter

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RDE design

When an RDE is created, the view definitions are based on the structure outlined in the Data Dictionary, which is a table that is installed by default during the Reporting and Analysis installation. Sponsors can customize the Data Dictionary to modify the RD view structure.

An RDE includes two tables that store metadata:

- **RD_DATADITIONARY**—Stores metadata for RD views that map to clinical forms.
- **RT_MD_VIEWDICTIONARY**—Stores metadata for RD views that map to CT_ tables.

An RDE also includes the following view:

- **RD_VIEWDICTIONARY**—Join of the RD_DATADITIONARY and RT_MD_VIEWDICTIONARY tables. This view also contains unit information from the RD_GCV_V_UNITLIST table.

RD_DATADITIONARY

The RD_DATADITIONARY table (Data Dictionary) describes how RD views are mapped to clinical forms, is built from the RT_CV_MODELDICTIONARY table, and contains metadata for each control in a study, or a description of the control.

Note: The RD_DATADITIONARY table contains language-dependent data.

RD_DATADITIONARY

Column Name

Column Description

RD_VIEWNAME

Name of the RD view:

- If the form does not contain any itemsets, RD_<FormRefName>.
- If the form contains one or more itemsets, RD_<FormRefName_ItemsetRefName>.
- If the form contains one or more itemsets, and the itemsets do not have RefNames, RD_<FormRefName>_<Count>.

RD view names are truncated to 30 characters. If duplicate RD view names exist, each view is assigned the name that corresponds to the value in the TABLENAME column in the view, prefixed with RD_. If the value in the TABLENAME column includes a prefix, the prefix is removed, and replaced with RD_.

For example, if two views named RD_AdverseEvent exist, one might be named RD_AE, and the other might be named RD_AdverseEvent.

Note: When you migrate to the InForm 6.1 release, names of truncated RD views may change.

RD_DATADITIONARY

RD_COLUMNNAME Column name, truncated and appended with the following, where appropriate, so that the column name contains a maximum of 30 characters.

- **_DTS**—Datetime string in ISO format.
- **_TMS**—Time string in ISO format.
- **_DTR**—Date time as entered, including UNK and NUL.
- **_TMR**—Time as entered, including UNK and NUL.
- **_N**—Normalized item.
- **_NU**—Normalized unit.
- **_U**—Unit item.
- **_C**—Code item.
- **_ND**—Not done item.

For more information about column naming conventions for RD views, see *Column naming conventions for RD views* (on page 188).

| | |
|--------------|--|
| RD_RAWCOLUMN | Untruncated RD column name. |
| TABLERNAME | Clinical table name. |
| COLUMNNAME | Clinical column name. The logic used to build this column name is described in the clinical table description. |

RD_DATADICTIONARY

| | |
|------------|--------------------------------|
| COLUMNTYPE | Generated column type: |
| | 1 - COLTYPE_TEXTFLOAT |
| | 2 - COLTYPE_TEXTNUM |
| | 3 - COLTYPE_TEXTSTR |
| | 4 - COLTYPE_TEXTBLOB |
| | 5 - COLTYPE_DATE |
| | 6 - COLTYPE_MONTHYEAR |
| | 7 - COLTYPE_DATESTR |
| | 8 - COLTYPE_TIME_HM |
| | 9 - COLTYPE_TIME_HMS |
| | 10 - COLTYPE_TIMESTR |
| | 11 - COLTYPE_YEAR |
| | 12 - COLTYPE_MONTH |
| | 13 - COLTYPE_UNITNORMALIZED |
| | 14 - COLTYPE_UNITCODE |
| | 15 - COLTYPE_UNITLABEL |
| | 16 - COLTYPE_CHILDSELCODE |
| | 17 - COLTYPE_CHILDELLABEL |
| | 18 - COLTYPE_VISITINDEX |
| | 19 - COLTYPE_FORMINDEX |
| | 20 - COLTYPE_ITEMINDEX |
| | 21 - COLTYPE_DOV |
| | 22 - COLTYPE_DELETEDFORM |
| | 23 - COLTYPE_DELETEDITEM |
| | 24 - COLTYPE_ITEMNOTDONEREASON |
| | 25 - COLTYPE_FORMMNEMONIC |
| | 26 - COLTYPE_VISITMNEMONIC |
| | 27 - COLTYPE_VISITORDER |
| | 28 - COLTYPE_SUBJECTINITIALS |
| | 29 - COLTYPE_SITENAME |
| | 30 - COLTYPE_SITEMNEMONIC |
| | 31 - COLTYPE_SITECOUNTRY |
| | 32 - COLTYPE_SUBJECTNUMBERSTR |
| | 33 - COLTYPE_FORMFIRSTDATE |
| | 34 - COLTYPE_FORMLASTDATE |

| RD_DATADITIONARY | |
|--------------------------|--|
| COLUMNORDER | Relative order of the column in the RD view. |
| FORMREFNAME | Form RefName. |
| SECTIONREFNAME | Section RefName. |
| ITEMREFNAME | Item RefName. |
| CHILDITEMREFNAME | Child item RefName (for itemsets). |
| CTL0REFNAME | Top-level control RefName. |
| CTL1REFNAME | Second-level control RefName. |
| CTL2REFNAME | Third-level control RefName. |
| CTL3REFNAME | Fourth-level control RefName. |
| CTL4REFNAME | Fifth-level control RefName. |
| RAWCOLUMNNAME | Untruncated column name. |
| COLUMNDBTYPE | Generated DB column type: 1 - String 2 - Integer 3 - Float 4 - Datetime |
| COLUMNVALUEREFN AME | <ul style="list-style-type: none"> • If the column uses a list of pre-defined values, the value RefName. • For Units, the unit RefName. • For a radio or checkbox control, the child control RefName. • For a drop-down list, the element RefName. |
| COLUMNFLOATPRECISI ON | Column precision. Used only for Float text controls and is NULL for all other columns. 0 - Unlimited precision. <i>n</i> - Number of decimal places for the precision. |
| FORMNAME | Form name. |
| SECTIONHEADER | Section header. |
| ITEMQUESTION | Item question. |
| CONTROLCAPTION | Control caption. |
| SECTIONORDER | Order of the section on the form. |
| ITEMORDER | Order of the item within a section on the form. |
| CHILDITEMORDER | Order of the child item in the itemset. |
| VIEWLABEL | Report topic name. |
| VIEWDESC | Report topic description, from the form description. |

RD_DATADITIONARY

| | |
|----------------|---|
| COLUMNFOLDER | Report topic folder. Only one of the three predefined folders is allowed: <ul style="list-style-type: none"> • Basic Data • Additional Data • Incomplete Data Reasons |
| COLUMNENABLE | If value is zero, this column is suppressed from the clinical table and clinical query subject. |
| COLUMNLABEL | Corresponding Cognos model report topic item name. |
| COLUMNDESC | Corresponding Cognos model report topic item description. |
| COLUMNVALUE | Column value. One of the set of values pertain to the clinical view column/clinical report topic item. |
| SASDATASETNAME | Null value. Reserved for future use. |
| SASFIELDNAME | |
| SDSDOMAIN | |
| SDSVARNAME | |
| FORMTYPE | Form type: <ul style="list-style-type: none"> 1 - CRF 3 - Enrollment 4 - Custom 5 - Custom study 6 - Custom Admin 7 - Custom Rules 8 - Custom Auth 101 - Monitor Regdoc 102 - Monitor Visit Report |
| ITEMSET | Indicates whether an item is part of an itemset. <ul style="list-style-type: none"> 0 - The item is not part of an itemset. 1 - The item is part of an itemset. |

RD_DATADICTIONARY

| | |
|----------------|--|
| CONTROLTYPE | Control type: 1 - ELEMENTTYPE 2 - PULLDOWNTYPE 5 - TEXTBOXTYPE 6 - CALCULATIONTYPE 7 - CONTROLGROUPTYPE 8 - RADIOGROUPTYPE 9 - CHECKBOXGROUPTYPE 10 - DATETIMETYPE |
| CH0TYPE | Control type of the top-level control. |
| CH1TYPE | Control type of the second-level control. |
| CH2TYPE | Control type of the third-level control. |
| CH3TYPE | Control type of the fourth-level control. |
| CH4TYPE | Control type of the fifth-level control. |
| REPEATINGVISIT | Indicates whether the visit is repeating. 0 - Visit is not repeating. 1 - Visit is repeating. |
| REPEATINGFORM | Indicates whether the form is repeating. 0 - Form is not repeating. 1 - Form is repeating. |
| REPEATINGITEM | Indicates whether the item is repeating. 0 - Item is not repeating. 1 - Item is repeating. |
| FORMID | DBUID for the form. |
| FORMREV | Revision number for the form. |
| SECTIONID | DBUID for the section. |
| ITEMID | DBUID for the item. |
| CHILDITEMID | DBUID for the child item in an itemset. |
| CONTROLID | DBUID for the control. |
| CONTROLREV | Revision number for the control. |
| CONTROLREFNAME | Control RefName. |
| CID0 | DBUID for the top-level nested control. |
| CID1 | DBUID for the second-level nested control. |

| RD_DATADICTIONARY | |
|---------------------|---|
| CID2 | DBUID for the third-level nested control. |
| CID3 | DBUID for the fourth-level nested control. |
| CID4 | DBUID for the fifth-level nested control. |
| SECORD | Order of the section on the form. |
| ITEMORD | Order of the item in the section. |
| CHILDITEMORD | Order of the child item in the itemset. |
| CONTROLDEPTH | Depth of nesting for the control. |
| CH1ORD | Order of the first-level child item. |
| CH2ORD | Order of the second-level child item. |
| CH3ORD | Order of the third-level child item. |
| CH4ORD | Order of the fourth-level child item. |
| FORMMNEMONIC | Mnemonic for the form. |
| FORMNOTE | Form note. |
| FORMDESIGNNOTE | Form design note. |
| ITEMLABEL | Item label. |
| SINGLECHILDCONTROL | Indicates whether the control has a single child. 0 - Control has no children. 1 - Control has one child. |
| CONTROLNAME | Name of the control. |
| CONTROLDESIGNNOTE | Design note for the control. |
| THESAMECONTROLCOUNT | Number of times the control exists in the study design. |
| TXT_MAXLENGTH | Maximum length for a text field. |
| TXT_DATATYPE | Data type of the object. |
| TXT_PRECISION | Precision associated with a text box with a data type of FLOAT. 0 - Control can have any precision. <i>n</i> - Number of decimal places in precision. |
| DATE_DISPLAYMASK | Mask for date components to display. 1 - Year information is displayed. 2 - Month information is displayed. 4 - Day information is displayed. |

RD_DATADITIONARY

| | |
|-------------------|---|
| DATE_REQUIREDMASK | Mask for date components that are required. |
|-------------------|---|

1 - Year information is required.

2 - Month information is required.

4 - Day information is required.

| | |
|------------------|---|
| DATE_UNKNOWNMASK | Mask for date components that are not required. |
|------------------|---|

1 - Year information is not required.

2 - Month information is not required.

4 - Day information is not required.

| | |
|--------|-----------------|
| HEIGHT | Control height. |
|--------|-----------------|

RT_MD_VIEWDICTIONARY

Each row in the RT_MD_VIEWDICTIONARY table represents a column in the CV, DV, or RD views and has instructions on how this view is built.

Each row in the RD_DATADITIONARY table has a corresponding row in the RT_MD_VIEWDICTIONARY table, and each of these rows has a VIEWTYPE of RD.

RT_MD_VIEWDICTIONARY**Column Name****Column Description**

VIEWTYPE

Type of view.

- **CV**—Clinical view.
- **DV**—Data Viewer view.
- **RD**—RDE view.
- **DI**—Clinical view with date and state data for items and itemsets.

VIEWNAME

Name for the view.

SECTIONORDER

Order of the section in the view.

LANGUAGEID

ID for the locale.

ITEMORDER

Order of the item.

EXPRESSION

SQL expression that is used to obtain data for this column.

RT_MD_VIEWDICTIONARY

| | |
|------------|--------------------------------|
| COLUMNTYPE | Generated column type: |
| | 1 - COLTYPE_TEXTFLOAT |
| | 2 - COLTYPE_TEXTNUM |
| | 3 - COLTYPE_TEXTSTR |
| | 4 - COLTYPE_TEXTBLOB |
| | 5 - COLTYPE_DATE |
| | 6 - COLTYPE_MONTHYEAR |
| | 7 - COLTYPE_DATESTR |
| | 8 - COLTYPE_TIME_HM |
| | 9 - COLTYPE_TIME_HMS |
| | 10 - COLTYPE_TIMESTR |
| | 11 - COLTYPE_YEAR |
| | 12 - COLTYPE_MONTH |
| | 13 - COLTYPE_UNITNORMALIZED |
| | 14 - COLTYPE_UNITCODE |
| | 15 - COLTYPE_UNITLABEL |
| | 16 - COLTYPE_CHILDSELCODE |
| | 17 - COLTYPE_CHILDELLABEL |
| | 18 - COLTYPE_VISITINDEX |
| | 19 - COLTYPE_FORMINDEX |
| | 20 - COLTYPE_ITEMINDEX |
| | 21 - COLTYPE_DOV |
| | 22 - COLTYPE_DELETEDFORM |
| | 23 - COLTYPE_DELETEDITEM |
| | 24 - COLTYPE_ITEMNOTDONEREASON |
| | 25 - COLTYPE_FORMMNEMONIC |
| | 26 - COLTYPE_VISITMNEMONIC |
| | 27 - COLTYPE_VISITORDER |
| | 28 - COLTYPE_SUBJECTINITIALS |
| | 29 - COLTYPE_SITENAME |
| | 30 - COLTYPE_SITEMNEMONIC |
| | 31 - COLTYPE_SITECOUNTRY |
| | 32 - COLTYPE_SUBJECTNUMBERSTR |
| | 33 - COLTYPE_FORMFIRSTDATE |
| | 34 - COLTYPE_FORMLASTDATE |

RT_MD_VIEWDICTIONARY

| | |
|----------------|--|
| COLUMNORDER | Relative order of the column in the RD view. |
| COLUMNNAME | Column name. |
| CLAUSE | Indicates how to gather data to insert into this table (SELECT or FROM). |
| CHILDITEMORDER | Order of the child item in the itemset. |

RD_VIEWDICTIONARY

The RD_VIEWDICTIONARY view is created from the join of the RT_MD_VIEWDICTIONARY table and the RD_DATADICTIONARY table. It also contains unit information from the RD_GCV_V_UNITLIST table.

RD_VIEWDICTIONARY

| Column Name | Column Description |
|-------------|--|
| VIEWNAME | Name for the RD view. |
| COLUMNNAME | Column name. |
| VIEWTYPE | Type of view. Always RD. |
| LANGUAGEID | ID for the locale. |
| CLAUSE | Indicates how to gather data to insert into this table (SELECT or FROM). |

RD_VIEWDICTIONARY

| | |
|------------|--------------------------------|
| COLUMNTYPE | Generated column type: |
| | 1 - COLTYPE_TEXTFLOAT |
| | 2 - COLTYPE_TEXTNUM |
| | 3 - COLTYPE_TEXTSTR |
| | 4 - COLTYPE_TEXTBLOB |
| | 5 - COLTYPE_DATE |
| | 6 - COLTYPE_MONTHYEAR |
| | 7 - COLTYPE_DATESTR |
| | 8 - COLTYPE_TIME_HM |
| | 9 - COLTYPE_TIME_HMS |
| | 10 - COLTYPE_TIMESTR |
| | 11 - COLTYPE_YEAR |
| | 12 - COLTYPE_MONTH |
| | 13 - COLTYPE_UNITNORMALIZED |
| | 14 - COLTYPE_UNITCODE |
| | 15 - COLTYPE_UNITLABEL |
| | 16 - COLTYPE_CHILDSELCODE |
| | 17 - COLTYPE_CHILDSSELLABEL |
| | 18 - COLTYPE_VISITINDEX |
| | 19 - COLTYPE_FORMINDEX |
| | 20 - COLTYPE_ITEMINDEX |
| | 21 - COLTYPE_DOV |
| | 22 - COLTYPE_DELETEDFORM |
| | 23 - COLTYPE_DELETEDITEM |
| | 24 - COLTYPE_ITEMNOTDONEREASON |
| | 25 - COLTYPE_FORMMNEMONIC |
| | 26 - COLTYPE_VISITMNEMONIC |
| | 27 - COLTYPE_VISITORDER |
| | 28 - COLTYPE_SUBJECTINITIALS |
| | 29 - COLTYPE_SITENAME |
| | 30 - COLTYPE_SITEMNEMONIC |
| | 31 - COLTYPE_SITECOUNTRY |
| | 32 - COLTYPE_SUBJECTNUMBERSTR |
| | 33 - COLTYPE_FORMFIRSTDATE |
| | 34 - COLTYPE_FORMLASTDATE |

| RD_VIEWDICTIONARY | |
|-------------------|---|
| SECTIONORDER | Order of the section in the view. |
| ITEMORDER | Order of the item. |
| CHILDITEMORDER | Child item order (for items within itemsets only). |
| COLUMNORDER | Relative order of the column in the RD view. |
| EXPRESSION | SQL expression that is used to obtain data for this column. |
| TABlename | Table name. |
| TAB_COLUMN | Table column. |
| COLUMNDBTYPE | Generated DB column type: 1 - String 2 - Integer 3 - Float 4 - Datetime |
| TXT_PRECISION | Precision associated with a text box with a data type of FLOAT. 0 - Control can have any precision. <i>n</i> - Number of decimal places in precision. |
| TXT_MAXLENGTH | Maximum length for a text field. |
| RD_TIME_STR | Reserved for internal use. |
| CV_PREFIX | Reserved for internal use. |
| HEIGHT | Control height. |
| UNITLEN | Length of the unit control. |
| UNITSYMBOL | Symbol string for the unit control. |
| BASEUNIT | Base unit for the control. |

About RD views

An RD view is a representation of the clinical forms in a study. The views begin with the prefix RD, are installed as part of the Reporting and Analysis installation, and contain clinical data for the study. Each CV clinical view in the Reporting schema has a corresponding RD view. The views are updated as needed due to study revisions.

Columns in RD views

Each RD view contains columns for some or all of the following key variables.

| Column Name | Column Description |
|------------------|---|
| SUBJECTID | Subject numeric identifier. |
| SITEID | Site numeric identifier. |
| SUBJECTVISITID | Subject visit numeric identifier. |
| VISITID | Visit numeric identifier. Note: For common forms, the VISITID is the numeric identifier for the common visit. |
| VISITINDEX | Visit instance identifier. 0 - Expected visit. 1 - Started, non-repeating visit. <revision number> - Repeating visit |
| FORMID | Form numeric identifier. |
| FORMREV | Revision number for the form. |
| FORMINDEX | Form instance identifier. 0 - Unstarted form. 1 - Non-repeating form. <revision number> - Repeating form. |
| SUBJECTINITIALS | Subject initials. |
| SUBJECTNUMBERSTR | Subject number. |
| FIRSTDATETIME | Date and time when data was first entered for an item on the form. |
| LASTDATETIME | Date and time when data was most recently entered for an item on the form. |
| SITEMNEMONIC | Site mnemonic. |
| VISITMNEMONIC | Visit mnemonic. |
| FORMMNEMONIC | Form mnemonic. |
| VISITORDER | Order of the visit in the study. |

| Column Name | Column Description |
|-----------------|--|
| SITENAME | Site name. |
| SITECOUNTRY | Country in which the site exists. |
| FORMCOMMENTTEXT | Comment text for a form- or item-level comment on the form. |
| FORMIDX | Ordinal number for the form sequence in the visit. Note: Contains data for repeating forms only. |
| DELETEDFORM | Indicates whether the form instance is deleted. Y - The form is deleted. N - The form is not deleted. Note: Contains data for repeating forms only. |
| ITEMSETID | Numeric identifier for the itemset. Note: Contains data only for forms that contain itemsets. |
| ITEMSETINDEX | Numeric identifier for the itemset instance. Note: Contains data only for forms that contain itemsets. |
| ITEMSETIDX | Ordinal number for the itemset row sequence in the itemset. Note: Contains data only for forms that contain itemsets. |
| DELETEDITEM | Indicates whether the itemset row is deleted. Y - The itemset row is deleted. N - The itemset row is not deleted. Note: Contains data only for forms that contain itemsets. |
| VISITIDX | Ordinal number for the visit sequence in the study. Note: Contains data only for forms that exist in a repeating visit. |
| CD_COUNT | Count of data items processed for the form instance. |
| CREATEDBYUSERID | User ID of the user who started the study object by entering data for the study object in the RD view or triggering a rule that entered data for the study object. When the review schema is recreated, this column displays the system user ID. |
| CREATEDDATETIME | Date and time when the study object in the RD view was started; that is, when a user entered data on the study object or triggered a rule that entered data for the study object. When the review schema is recreated, this column displays the date and time when the review schema was recreated. |

| Column Name | Column Description |
|------------------|---|
| MODIFIEDBYUSERID | User ID of the user who most recently modified the study object by entering data for the study object in the RD view or triggering a rule that entered data for the study object. When the review schema is recreated, this column displays the system user ID. |
| MODIFIEDDATETIME | Date and time when the study object in the RD view was most recently modified; that is, when a user most recently entered data on the study object or triggered a rule that entered data for the study object. When the review schema is recreated, this column displays the date and time when the review schema was recreated. |
| DOV | Date of visit. If the form on which the RD view is based is not the DOV form, a column for the date of the visit is created. |

Column naming conventions for RD views

Columns that correspond to study-specific metadata such as itemset names, control names, and so forth, are created based on the following naming conventions, and must follow the following rules.

- Each column name is truncated to 30 characters, including any text that is automatically appended to the column name.

For example, if the RefName for a control with units exceeds 30 characters, the column name for the normalized unit symbol for the control would contain the first 27 characters of the RefName, followed by _NU, resulting in a column name with a total length of 30 characters.
- Column names must be unique within each view.
 - If a column name for a control conflicts with the column name for a key variable, the control column name is appended with a number to ensure uniqueness.

For example, if a form contains a date control called DOV, it is renamed DOV2 so as not to conflict with the key variable DOV column.
 - If a column name for a control conflicts with a column name for another control, each control is assigned a column name that corresponds to the COLUMNNAME value from the CV view for the form on which the control exists. If the COLUMNNAME value in the CV view includes a prefix, the prefix is stripped for the RD view.

| Naming convention | Description |
|----------------------------------|--|
| Simple and group controls | |
| <controlrefname> | Text or numeric value for the control or entered control data. |
| <controlrefname>_N | Normalized value for the control data. |
| <controlrefname>_U | Entered unit symbol for the control. |
| <controlrefname>_NU | Normalized unit symbol entered for the control. |

| Naming convention | Description |
|---------------------------------------|---|
| Radio and pulldown controls | |
| <controlrefname> | Label value for the control. |
| <controlrefname>_C | Coded value for the control. |
| Date/time controls | |
| <controlrefname> | Valid complete date/time. If the control is empty, or if a user entered UNK for the control, this column is populated with NULL . |
| <controlrefname>_DTS | ISO-compliant date/time string in YYYY-MM-DDThh:mm:ss format, where: <ul style="list-style-type: none"> • YYYY—Four-digit year. • MM—Two-digit month (01 through 12). • DD—Two-digit day (01 through 31). • T—Time designator. • hh—Two-digit hour, in 24-hour format (01 through 23). • mm—Two-digit minute (00 through 59). • ss—Two-digit second (00 through 59). |
| <controlrefname>_DTR | Raw date/time string. This column includes UNK for unknown date/time data, and only appears in the RD view if the date/time control contains fields that are not required, and for which a user can enter UNK. |
| <controlrefname>_TMS | ISO-compliant time string in Thh:mm:ss format, where: <ul style="list-style-type: none"> • T—Time designator. • hh—Two-digit hour, in 24-hour format (01 through 23). • mm—Two-digit minute (00 through 59). • ss—Two-digit second (00 through 59). |
| <controlrefname>_TMR | Raw time string. This column includes UNK for unknown time data, and only appears in the RD view if the time control contains fields that are not required, and for which a user can enter UNK. |
| Checkbox controls | |
| <itemrefname>_<childcontrolrefname> | Label value for the control and child control. |
| <itemrefname>_<childcontrolrefname>_C | Coded value for the control and child control. |
| Items | |
| <itemrefname>_ND | Incomplete item reason. For example, Not Done, Not Applicable, Unknown. |

| Naming convention | Description |
|-------------------|---|
| Itemsets | |
| IB_<controlname> | Control name of the blank item in a Repeating Data itemset. |

Creating a custom RDE

The Reporting and Analysis installation includes logic that allows sponsor users to create scripts that can change the content of the RT_MD_VIEWDICTIONARY and RD_DATADICTIONARY tables to modify the default RDE before data is extracted. You can modify the structure of the RD views, and you can create or drop views based on the data that appears in existing views.

Perform the following steps to customize RDE views:

- 1 Create a customization SQL file with SQL statements to insert, delete, and update the RT_MD_VIEWDICTIONARY and RD_DATADICTIONARY tables.
For more information, see *Creating a customization script* (on page 191).
- 2 Run the RD_VIEWS_GEN.GenerateRDViews stored procedure to propagate your changes to the RD views.
For more information, see *Running the customization script* (on page 191).

Hosted customers who want custom RDEs must provide Oracle with a customized SQL script to create the extract. For more information, see *Posting the customized script—Hosted customers only* (on page 193).

Creating a customization script

- 1 Before you make any customizations, inspect the content of the RT_MD_VIEWDICTIONARY table, using the following SQL:

```
SELECT * FROM RT_MD_VIEWDICTIONARY WHERE VIEWTYPE='RD' ORDER BY VIEWNAME
```

- 2 Create a SQL file with a text editor, such as Notepad.
- 3 Add SQL statements to customize the RD views.

Note: Remember to commit at the end.

- 4 Save the file to your local directory. You can assign the file any name. For example, MyCustomizeRDE.sql.

Running the customization script

- 1 Open a Command Prompt window.
- 2 Navigate to the directory where you saved the customization script.
- 3 Log in to SQL Plus as the study database user.
- 4 Run the customization SQL file. For example, @MyCustomizeRDE.sql.
- 5 At SQL Plus, run the following command:

```
exec RD_VIEWS_GEN.GenerateRDViews;
```

Example: Drop a view

To remove the RD_MEDHIST view from the RDE:

```
Drop view RD_MEDHIST;
delete from RT_MD_VIEWDICTIONARY where viewname='RD_MEDHIST';
delete from RD_DATADICTIONARY where rd_viewname='RD_MEDHIST';
commit;
```

Example: Drop a column from an existing view

To remove the SUBJECTINITIALS column from the RD_MEDHIST view:

```
delete from RT_MD_VIEWDICTIONARY where viewname='RD_MEDHIST' and
columnname='SUBJECTINITIALS';
delete from RD_DATADICTIONARY where rd_viewname='RD_MEDHIST' and
rd_columnname='SUBJECTINITIALS';
commit;
```

Example: Change a column name

To change the name of the SUBJECTINITIALS column to SUB_INIT in the RD_MEDHIST view:

```
update RT_MD_VIEWDICTIONARY set columnname='SUB_INIT' where
viewname='RD_MEDHIST' and columnname='SUBJECTINITIALS';
update RD_DATADICTIONARY set rd_columnname='SUB_INIT' where
rd_viewname='RD_MEDHIST' and rd_columnname='SUBJECTINITIALS';
commit;
```

Example: Change a view name

To change the name of the RD_MEDHIST view to RD_MEDICAL_H:

```
update RT_MD_VIEWDICTIONARY set viewname='RD_MEDICAL_H' where
viewname='RD_MEDHIST';
update RD_DATADICTIONARY set rd_viewname='RD_MEDICAL_H' where
rd_viewname='RD_MEDHIST';
commit;
```

Example: Add a where clause to a view

You can insert a new FROM clause to the RT_MD_VIEWDICTIONARY table to add an additional where clause to a view. To add the where clause CT.MHTERM12_ITMMEDHISTALLER != 'abc' to the RD_MEDHIST view:

```
insert into RT_MD_VIEWDICTIONARY
(VIEWNAME, COLUMNNAME, VIEWTYPE, LANGUAGEID, CLAUSE,
COLUMNNTYPE, SECTIONORDER, ITEMORDER, CHILDITEMORDER,
COLUMNORDER, EXPRESSION)
values ('RD_MEDHIST',
'AND5', -- increase the existing count by 1 to create a unique
--column name
'RD', -- has to be RD view type
2,
'FROM', -- has to be a FROM clause
0,
0,
7, -- increase the max count by 1
0,
7, -- increase the max count by 1
' AND CT.MHTERM12_ITMMEDHISTALLER != 'abc'' -- leave space
--before AND. escape the single quote
);

commit;
```

Example: Add a column to a view

You can insert a SELECT clause to the RT_MD_VIEWDICTIONARY table to add an additional column. To add the column TEST_COL, which gets data from the RT_ACTIVATED_FORMS table, to the RD_MEDHIST view:

```
insert into RT_MD_VIEWDICTIONARY
(VIEWNAME, COLUMNNAME, VIEWTYPE, LANGUAGEID, CLAUSE,
COLUMNNTYPE, SECTIONORDER, ITEMORDER, CHILDITEMORDER,
COLUMNORDER, EXPRESSION)
values ('RD_MEDHIST',
'TEST_COL', -- a unique column name
'RD', -- has to be RD view type
2,
'SELECT', -- has to be a SELECT clause
3, -- string type
999,
25, -- increase the max count by 1
25, -- increase the max count by 1
160, -- increase the max count by 1
'AF.REASON' -- get the REASON column from the base table
);

commit;
```

Posting the customized script—Hosted customers only

Before you request an extract, you must post the customization script to a location where an Oracle representative can access it. Contact your Oracle contact for more information about where to post the file.

Requesting the extract—Hosted customers only

Note: To request a default RDE, contact your Oracle contact for an extract of the RD views that are included by default with each Reporting and Analysis installation.

Self-hosting customers must create and run a script to extract data.

- 1 Post the customization script in the location specified by your Oracle contact.
For more information, see *Posting the customized script—Hosted customers only* (on page 193).
- 2 Contact your Oracle contact to request access to the RDE extract in one or both of the following ways:
 - **On demand**—An Oracle representative installs a tab in the InForm Portal from which you can access an up-to-date RDE on demand. You are notified by email when a new extract is available.

Note: An extract is available for 24 hours after posting. You can request a maximum of 10 RDEs from the InForm Portal application per study per day.

- **Regularly-scheduled**—An Oracle representative creates an up-to-date RDE on either a weekly or monthly schedule, based on your preference. You are notified by email when a new extract is available, and you can access the up-to-date RDE on the sFTP server.

APPENDIX A

Appendix

In this appendix

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| Mapping Central Designer terms to InForm terms | 196 |
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Mapping Central Designer terms to InForm terms

When you deploy a study created in the Central Designer application to the InForm application, the Central Designer study components and workflow are translated to InForm study components. The conversion to InForm study components is based on both the data definition of each study component and the layout specified for each form or item in the Central Designer application.

| Central Designer study component | Corresponding InForm study component | Notes |
|----------------------------------|--|---|
| Codelist | Radio, checkbox, or pulldown control | <p>The following codelist specifications determine how codelist items deploy to the InForm application:</p> <ul style="list-style-type: none"> • Single selection—Deploys as a radio or pulldown control. • Multiple selection—Deploys as a checkbox control. • The Layout section of the Central Designer Options dialog box (available from the Tools > Options menu) specifies the following defaults: <ul style="list-style-type: none"> ▪ Automatic formatting of codelist-based controls based on the number of codelist items. ▪ Default control sizes. • The layout specification in the Central Designer application determines whether a radio control is displayed vertically or horizontally. You can also use the layout specification to indicate whether a codelist is single selection, single selection with user, or multiple selection, and whether codelist items in a single-selection codelist deploy as a radio control or a pulldown control. |
| Codelist item | Simple control | |
| Collaboration note | No corresponding component | This type of study object is not deployed to the InForm application. |
| Data series | <ul style="list-style-type: none"> • Table column in CDD mapping definition. • Panel item in CIS mapping definition. | |

| Central Designer study component | Corresponding InForm study component | Notes |
|----------------------------------|--|---|
| Data set | <ul style="list-style-type: none"> Table in CDD mapping definition. Panel in CIS mapping definition. | The data dimensions of a data set form the key for each row of a CDD table. Data values defined as custom dimensions form pivot columns around which the data in the table is organized. |
| Description | No corresponding component | Study object descriptions are visible only in a Central Designer annotated study book. |
| Form | Form | <ul style="list-style-type: none"> In the Central Designer application, a form note is specified in the layout definition. The Short Title specified in the Central Designer application deploys as the form mnemonic in the InForm application. The form RefName is used in Reporting and Analysis and in CDD table columns for which no data series alias exists. |
| | Alternate form | <ul style="list-style-type: none"> In the InForm application, an alternate form is used to collect new or changed information for those subjects who have started the original version of the form. A form containing new or changed items in a subsequent, incremental deployment deploys as an alternate form for those subjects who have started the original version of the form. Alternate forms are not created when you install an incremental deployment package that contains additions to repeating forms or itemsets. |
| | Associated forms | Two forms defined as repeating and linked with the AssociatedForm property in the Central Designer application deploy as associated forms in the InForm application. |
| | Common form | A form defined as a common form deploys as a common form. |
| | Date of Visit form | If you do not include a special Date of Visit item in the study, a default Date of Visit form is deployed to the InForm application. |
| | Dynamic form | A form for which the precondition is the outcome of a workflow rule or global condition deploys as a dynamic form in the InForm application. |
| | Enrollment form | If you do not include a special Enrollment form in the study, a default Enrollment form is deployed to the InForm application. |

| Central Designer study component | Corresponding InForm study component | Notes |
|----------------------------------|--|---|
| | Regulatory report forms and visit report forms | You can create regulatory report and visit report forms in the NonClinical container in the Project Explorer. If you do not create the forms, default versions are generated and deployed. |
| | Repeating form | A form defined as repeating in the Central Designer application deploys as a repeating form in the InForm application. |
| | Screening form | If you do not include a special Screening form, a default Screening form is deployed to the InForm application. |
| Global condition | Rule | The deployment process treats a global condition as a rule and creates rule attachments, arguments, and dependencies in the InForm application as necessary based on the items referenced in the global condition definition. |
| Help text | CRF Help | Instructions and Help defined for forms or items in the Central Designer application deploy as CRF Help in the InForm application. Instructions and Help defined for other study objects (for example, study events) in the Central Designer application do not deploy to the InForm application. |

| Central Designer study component | Corresponding InForm study component | Notes |
|----------------------------------|--------------------------------------|---|
| Item | Item | <p>Item deployment considerations:</p> <ul style="list-style-type: none"> • The Central Designer application includes the following custom properties for InForm deployment: <ul style="list-style-type: none"> ▪ Collapsible (for items)—Defaults to False in the InForm application. Collapsed items in the Central Designer application become dynamic controls in the InForm application. ▪ Display Override (for items)—Defaults to False in the InForm application. ▪ Required (for items)—Defaults to True in the InForm application. ▪ SDV Critical (for forms and items)—Defaults to False in the InForm application. ▪ SDV Required (for items)—Defaults to True in the InForm application. ▪ Special Fields (for items)—Identifies items that have a special meaning in the InForm application, including special Date of Visit and Randomization items and items that appear on special forms. • Layout specifications determine how controls appear in the InForm application. For date time items, layout specifications include the specification of year ranges. |
| | Date/time control | Date time items in the Central Designer application become date/time controls in the InForm application. |
| | Group control | A compound item defined with child items in the Central Designer application deploys in the InForm application as a group control consisting of the child items. |
| | Nested control | An item in the Central Designer application that is conditional on another item deploys in the InForm application as a nested control within the item on which it is conditional. |
| | Text control | Text, integer, and float items in the Central Designer application become the appropriate text controls in the InForm application. |

| Central Designer study component | Corresponding InForm study component | Notes |
|----------------------------------|--------------------------------------|---|
| | Unit | <ul style="list-style-type: none"> • A base unit or a base unit and a single conversion unit specified in an integer, float, or yes no item definition in the Central Designer application deploy as units in the InForm application. • If more than one conversion unit is selected in the item definition, the conversion units deploy in the InForm application as a radio or pulldown control, depending on the layout option selected. |
| Library | No corresponding component | This type of study object is not deployed to the InForm application. |
| Library project | No corresponding component | This type of study object is not deployed to the InForm application. |
| Mapping | CDD or CIS mapping definition object | |
| Rule | Rule | The deployment process creates rule attachments, arguments, and dependencies in the InForm application as necessary based on the items referenced in the rule definition. |
| Section | Section | <ul style="list-style-type: none"> • In the Central Designer application, a section note is specified in the layout definition. • If you do not create a section for a form in the Central Designer application, a section with the same title as the form is automatically generated when the study is deployed to the InForm application. |
| | Itemset | The items in a section defined as repeating in the Central Designer application are grouped into an itemset in the InForm application. |
| | Repeating Data itemset | The items in a section defined as fixed and repeating in the Central Designer application are grouped into a Repeating Data itemset in the InForm application. |
| Short Question | Itemset column header | <ul style="list-style-type: none"> • If a Short Question is specified, the value is used for the column header that appears in the itemset. • If a Short Question is not specified, the value of the Default Question is used. |

| Central Designer study component | Corresponding InForm study component | Notes |
|----------------------------------|---|---|
| Study | Study | <p>The study version (VERSIONDESCRIPTION attribute in InForm MedML) is a concatenation of:</p> <ul style="list-style-type: none"> • The Title property of the study object. • The revision number of the validation baseline used to create the deployment package. • An abbreviation for the locale, if the deployment package is created for multiple locales. |
| Study element | No corresponding component | This type of study object is not deployed to the InForm application. |
| Study event | Visit | The Short Title of a study event is used as the visit mnemonic in the InForm application. |
| | Dynamic visit | A study event for which the precondition is the outcome of a workflow rule or global condition deploys as a dynamic visit in the InForm application. |
| | Enrollment visit | <p>A special InForm visit that must be included in the Central Designer study design.</p> <ul style="list-style-type: none"> • The enrollment form must belong to the enrollment visit. • The enrollment visit must be a standalone visit in the study workflow. • The enrollment visit must be the second visit in the workflow after the screening visit. |
| | Regulatory report and visit report visits | The deployment process creates regulatory report and visit report visits. |
| | Repeating visit | A study event defined as repeating in the Central Designer application deploys as a repeating visit in the InForm application. |
| | Screening visit | <p>A special InForm visit that must be included in the Central Designer study design.</p> <ul style="list-style-type: none"> • The screening form must belong to the screening visit. • The screening visit must be a standalone visit in the workflow. <p>The screening visit must be the first visit in the workflow and the enrollment visit must be second.</p> |

| Central Designer study component | Corresponding InForm study component | Notes |
|----------------------------------|--------------------------------------|--|
| Study project | No corresponding component | This type of study object is not deployed to the InForm application. |
| Task | No corresponding component | This type of study object is not deployed to the InForm application. |
| Template | No corresponding component | This type of study object is not deployed to the InForm application. |
| Type | No corresponding component | This type of study object is not deployed to the InForm application. |
| No corresponding component | Calculated control | You cannot create calculated controls in the Central Designer application. You can create a read-only control that serves the same purpose as a calculated control in that it uses a rule to fill in data. |

Note: Components in MedML are named based on the RefNames of study objects in the Central Designer application, with the following two exceptions:

- PFElements. The RefName from the codelist item is concatenated with an underscore and a 40-character identifier that the application creates using the RefName, code, and translations of the codelist label. If you modify the RefName, code, or codelist label, the application creates a new PFElement.
- Group controls are prefaced with "GC_" only when multiple items are conditional on the same item.