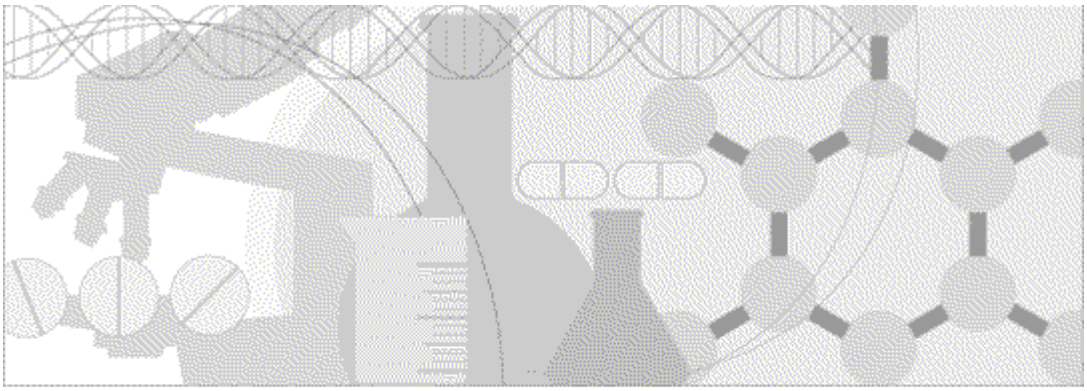
Reporting Database Schema Guide

Oracle® Health Sciences InForm 6.0.1



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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
Release Notes	The *Release Notes* document describes enhancements introduced and problems fixed in the current release, upgrade considerations, release history, and other late-breaking information.
Known Issues	The *Known Issues* document provides detailed information about the known issues in this release, along with workarounds, if available.
Upgrade and Migration Guide	The *Upgrade and Migration Guide* 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.
Secure Configuration Guide	The *Secure Configuration Guide* 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.
Installation Guide	The *Installation Guide* describes how to install the software and configure the environment for the InForm application and Cognos software.
Study and Reporting Setup Guide	The *Study and Reporting Setup Guide* 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.
User Guide	The *User Guide* provides an overview of the InForm application including details on multilingual studies, how to navigate through the user interface, and how to use the application to accomplish typical tasks you perform while running a clinical study.
Reporting and Analysis Guide	The *Reporting and Analysis Guide* 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
Reporting Database Schema Guide	The *Reporting Database Schema Guide* describes the Reporting and Analysis database schema, and provides information on creating Reporting Database Extracts (RDEs).
Portal Administration Guide	The *Portal Administration Guide* provides step-by-step instructions for setting up the InForm Portal software, and configuring and managing the InForm Portal application.
Utilities Guide	The *Utilities Guide* provides information about and step-by-step instructions for using the following utilities: • PFConsole utility • MedML Installer utility • InForm Data Import utility • InForm Data Export utility • InForm Performance Monitor utility • InForm Report Folder Maintenance utility 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.
MedML Installer utility online Help	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. 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. This document is also available from the user interface.
InForm Data Export utility online Help	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: • Customer-defined database (CDD) • Name value pairs This document is also available from the user interface.
InForm Data Import utility online Help	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. This document is also available from the user interface.
Clinical Data API Guide	The *Clinical Data API Guide* provides information about submitting data to the InForm application in InForm ODM format.

Document	Description
Third Party Licenses and Notices	The *Third Party Licenses and Notices* document includes third party technology that may be included in or distributed with this product.

Documentation accessibility

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

If you need assistance

Oracle customers have access to support through My Oracle Support. For information, visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=info, or if you are hearing impaired, visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs.

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 PFAdmin 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
HELPTEXT	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.
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.

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
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
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.

IRV_SECTION_REVS	
Column Name (Key indicator)	Column Description
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
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.

IRV_ITEM_REVS	
Column Name (Key indicator)	Column Description
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

IRV_ITEMSET_REVS	
Column Name (Key indicator)	Column Description
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.

IRV_CONTROL_REVS	
Column Name (Key indicator)	Column Description
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
CAPTIONALIGNMENT	Caption alignment with respect to the control: 1 - Left 2 - Center 3 - Right 4 - Top 5 - Middle 6 - Bottom
HEIGHT	Control height.
UNITDISPLAYTYPE	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	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.
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.
MODIFIEDDATETIME	Date and time when the reported form was most recently started or modified; that is, when a user entered or modified data on the form or triggered a rule that entered or modified data on the form. When the review schema is recreated, this column displays the date and time when the review schema was recreated.
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.

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
NUMCHARSCRFLENGTH	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.
RANDSIMPLECENTRAL	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 *Study and Reporting Setup Guide*.
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 *Study and Reporting Setup Guide*.
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: • **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: • Screened • Screening Failure • Enrollment Failure • Enrolled • Randomized • Completed • Dropped Out
SUBJECTSTATE	Numeric value for the subject state: 1 - Screened 2 - Screening Failure 3 - Enrollment Failure 4 - Enrolled 5 - Randomized 6 - Completed 7 - Dropped Out
SUBJECTSCREENED	Subject is currently Screened: 0 - No 1 - Yes
SUBJECTEVERSCREENED	Subject has ever been screened: 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: 0 - No 1 - Yes
SUBJECTEVERSCREENFAIL	Subject has ever failed screening: 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.
SUBJECTRAMDOMIZED	Subject is currently Randomized: 0 - No 1 - Yes
SUBJECTEVERRAMDOMIZED	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: • Screened • Screening Failure • Enrollment Failure • Enrolled • Randomized • Completed • Dropped Out
SUBJECTSTATE	Numeric value for the subject state: 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.

IRV_CUR_SYSTEMVERSION	
Column Name (Key indicator)	Column Description
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.
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.
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.

IRV_CUR_USER	
Column Name (Key indicator)	Column Description
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_CHANGES	
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

IRV_USER_ACTIVESTATE_CHANGES	
Column Name (Key indicator)	Column Description
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_BLINDED_ITEMS

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

RT_USER_BLINDED_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
CREATEDDATETIME	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. 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 item by entering data on the item or triggering a rule that entered data on 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 on the item or triggered a rule that entered data on the item. When the review schema is recreated, this column displays the date and time when the review schema was recreated.

RT_USER_BLINDED_ITEMS	
Column Name (Key indicator)	Column Description
MODIFIEDBYUSERID	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. When the review schema is recreated, this column displays the system user ID.

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.
HASSDVREQUIREDITEMS	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
FMINDELETEDDYNAMICFORMSTATE	First time the dynamic form was deleted.
FMAXDELETEDDYNAMICFORMSTATE	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.
FDAYSSTARTTOCOMPLETE	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.

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.
FMAXHASCOMMENTSSTATE	Most recent time the form had associated comments.

IRV_SV_SUBJECT_FORMS	
Column Name (Key indicator)	Column Description
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.
FDAYSSTARTTOCOMPLETE	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
SUBJECTRAMDOMIZED	Subject is currently Randomized: 0 - No 1 - Yes
SUBJECTEVERRAMDOMIZED	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
HASSDVREQUIREDITEMS	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

IRV_CRF_STATUS_REPORT	
Column Name (Key indicator)	Column Description
MISSINGITEMSSTATE	Form is missing required items: 0 - No 1 - Yes
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.

IRV_CRF_STATUS_REPORT	
Column Name (Key indicator)	Column Description
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.

IRV_FORM_ITEMS	
Column Name (Key indicator)	Column Description
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.
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.

IRV_FORM_ITEMS	
Column Name (Key indicator)	Column Description
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
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.

IRV_FORM_ITEMS	
Column Name (Key indicator)	Column Description
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.
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 Open 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.
FIRSTSTATETRANSACTIONID	Numeric identifier for the first state transaction for the form instance.
LASTSTATETRANSACTIONID	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.
FIRSTSTATETRANSACTIONID	First item state transaction for the study version.
LASTSTATETRANSACTIONID	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.
FIRSTSTATETRANSACTIONID	First item state transaction for the subject.
LASTSTATETRANSACTIONID	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
LASTSTATETRANSACTIONID	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.
SUBJECTSRAMDOMIZED	Number of subjects currently in the Randomized state for the site.
SUBJECTSEVERRAMDOMIZED	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.
SUBJECTSRAMDOMIZED	Number of subjects currently in the Randomized state for the study.
SUBJECTSEVERRAMDOMIZED	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.
SUBJECTSRAMDOMIZED	Number of subjects currently in the Randomized state for the study version.
SUBJECTSEVERRAMDOMIZED	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
TABLENAME	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
COLUMNVALUEREFNAME	• 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.
COLUMNFLOATPRECISION	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: • 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.
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.

RT_MD_DATADICTIONARY	
Column Name	Column Description
TXT_PRECISION	Precision associated with a text box with a data type of FLOAT. 0 - Control can have any precision. *n* - 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_DATADICTIONARY, and is used to create the Cognos labels that appear in the Reporting and Analysis module.

RT_CV_MODELDICTIONARY	
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	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
COLUMNDBTYPE	Generated DB column type: 1 - String 2 - Integer 3 - Float 4 - Datetime
COLUMNVALUEREFNAME	• 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. *n* - 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: • 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.
UNITREVISIONNUMBER	Internal revision number for the unit.
CLASSIFICATION	Type specified in the MedML, such as volume or length.
UNITREFNAME	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.

RT_CONTROLDATA	
Column name (Key indicator)	Column description
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.
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

RT_CONTROLDATA	
Column name (Key indicator)	Column description
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. • **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.
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).

RT_CONTROLDATA	
Column name (Key indicator)	Column description
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
FMINDELETEDDYNAMICFORMSTATE	First time the dynamic form was deleted.
FMAXDELETEDDYNAMICFORMSTATE	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.
MODIFIEDDATETIME	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.
CREATEDDATETIME	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.
DATATIME	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
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

RT_ITEMSTATE	
Column name (Key indicator)	Column description
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.
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.

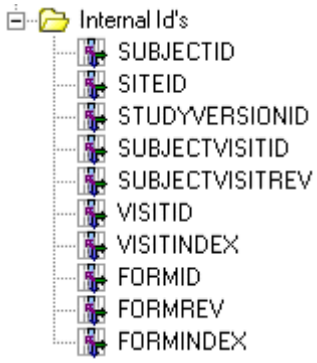
Key columns			
View column name	View column type	Report element name	Element folder
SUBJECTID	NUMBER	SUBJECTID	Internal IDs
SITEID	NUMBER	SITEID	Internal IDs
STUDYVERSIONID	NUMBER	STUDYVERSIONID	Internal IDs
SUBJECTVISITID	NUMBER	SUBJECTVISITID	Internal IDs
SUBJECTVISITREV	FLOAT	SUBJECTVISITREV	Internal 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.

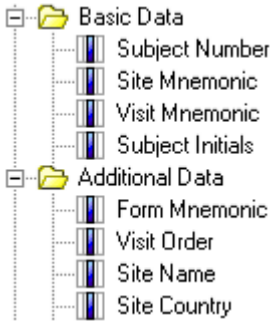
Metric columns			
View column name	View column type	Report element name	Element folder
SITEMNEMONIC	VARCHAR2	Site Mnemonic	Basic Data
VISITMNEMONIC	VARCHAR2	Visit Mnemonic	Basic Data
FORMNEMONIC	VARCHAR2	Form Mnemonic	Additional Data
SUBJECTINITIALS	VARCHAR2	Subject Initials	Basic Data
SITENAME	VARCHAR2	Site Name	Additional Data
COUNTRY	VARCHAR2	Country	Additional Data
VISITORDER	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)
VISITORDER	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		
MODIFIEDDATETIME	Date and time when the reported form was most recently started or modified; that is, when a user entered or modified data on the form or triggered a rule that entered or modified data on the form. When the review schema is recreated, this column displays the date and time when the review schema was recreated.	Basic Data

Visits

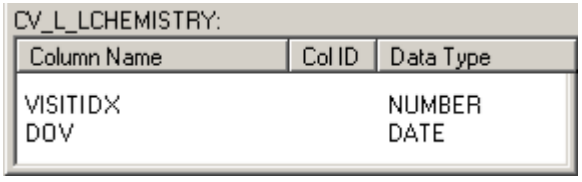
If a form is part of a repeating visit, the generated clinical view and clinical report topic include two additional columns and items.

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

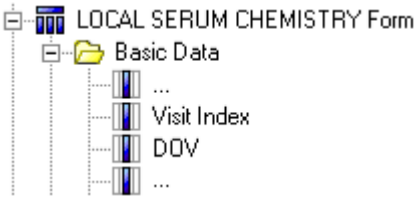
Visits				
View column name	View column type	Element name	Element folder	Content
VISITIDX	NUMBER	Visit Index	Basic Data	Ordinal number of the visit instance starting from 1.
DOV	DATE	DOV	Basic Data	Visit instance date of visit.

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

Database view



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 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.

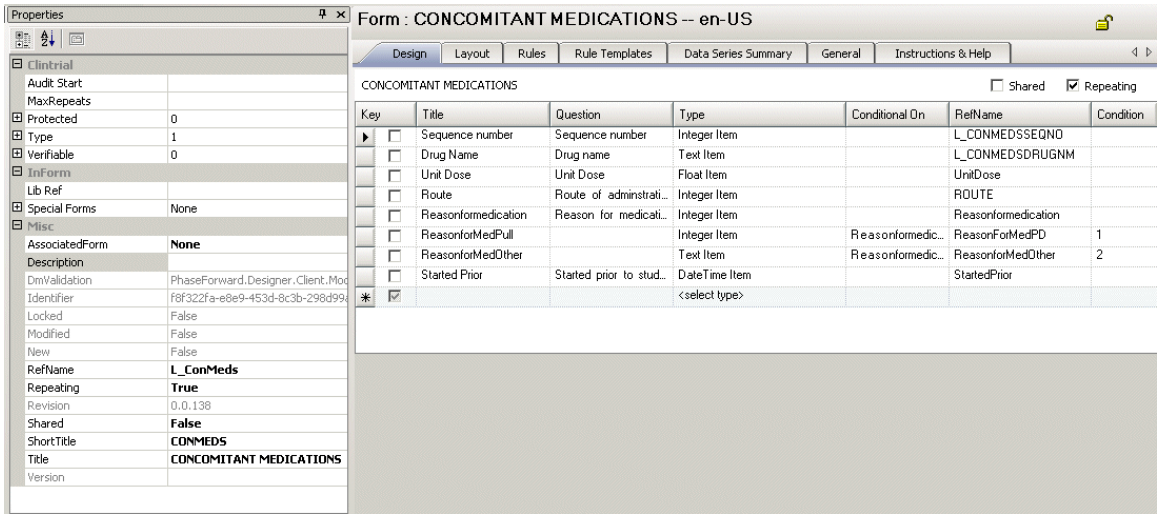
Forms		
View name	Report element name	Report topic description
CV_<*FormRefName*>	<*FormTitle*> Form	<*FormTitle*> Form - <*FormDesignNote*> or <*FormTitle*> - <*FormMnemonic*> if FormDesignNote is empty.

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

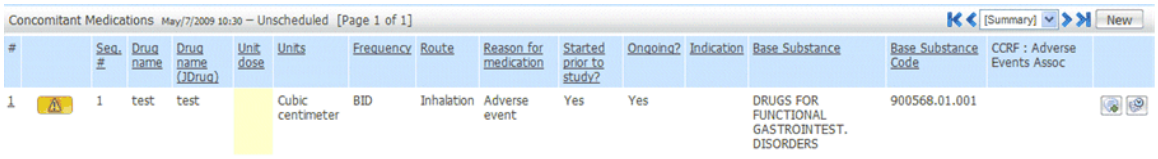
Repeating forms				
View column name	View column type	Report element name	Report element folder	Content
FORMIDX	NUMBER	Form Index	Basic Data	Ordinal number of the Form instance starting from 1.
DELETEDFORM	VARCHAR(1)	Deleted Form	Basic Data	'Y': if instance of the Form is deleted or 'N' if it is not.

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

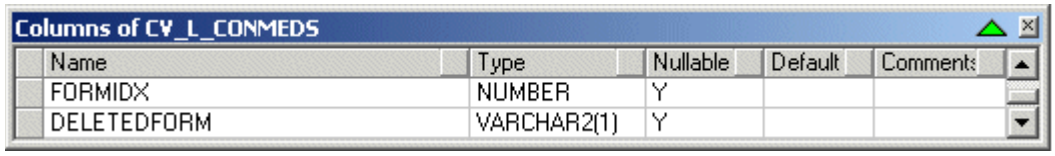
Central Designer Properties Browser view



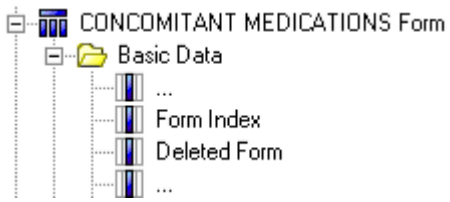
Display in the InForm application



Database view



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.

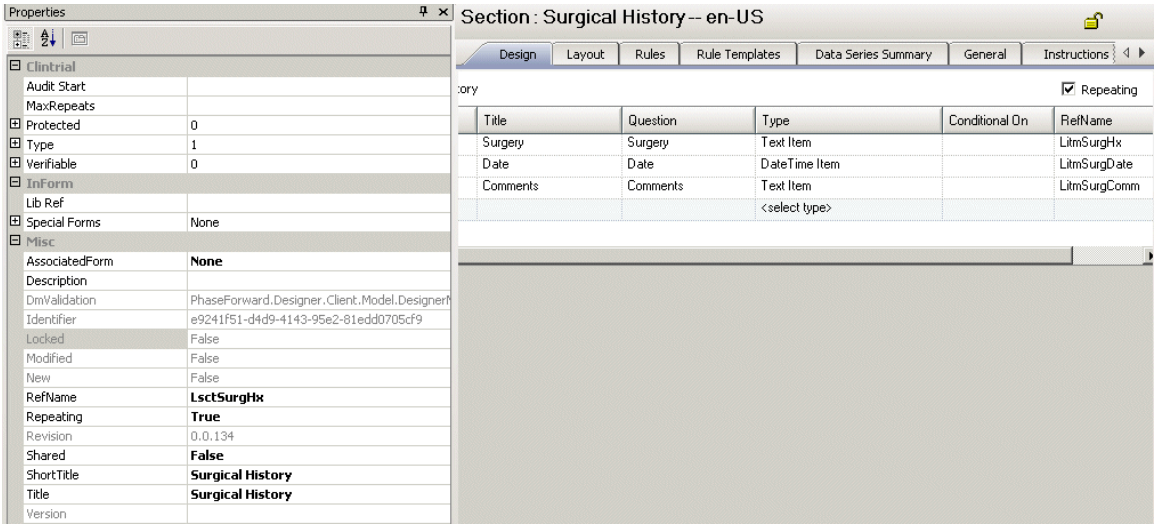
Itemsets		
View name	Report element name	Report topic description
CV_<*FormRefName*>_ <*ItemsetRefName*>	<*FormTitle*> - <*SectionTitle*> Itemset	<*FormTitle*> - <*SectionTitle*> Itemset <*FormDesignNote*> or <*FormTitle*> - <*SectionTitle*> Itemset <*FormMnemonic*> if FormDesignNote is empty.

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.

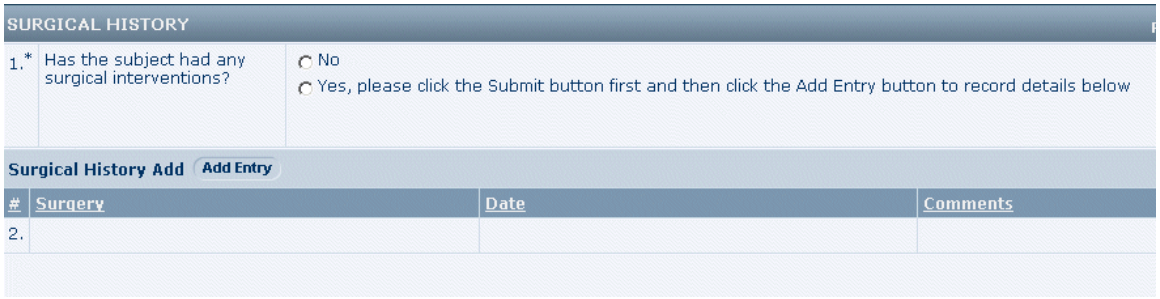
Central Designer Properties Browser view



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>
```

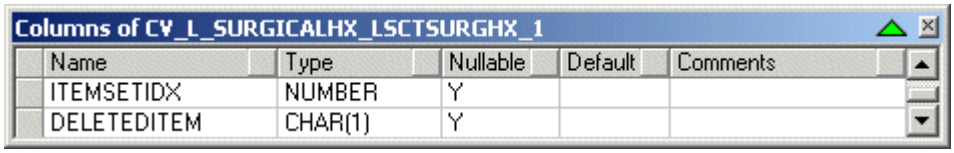
Display in the InForm application



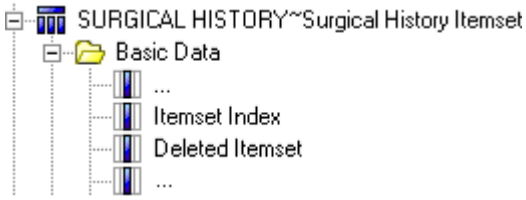
Cognos model

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



Cognos model



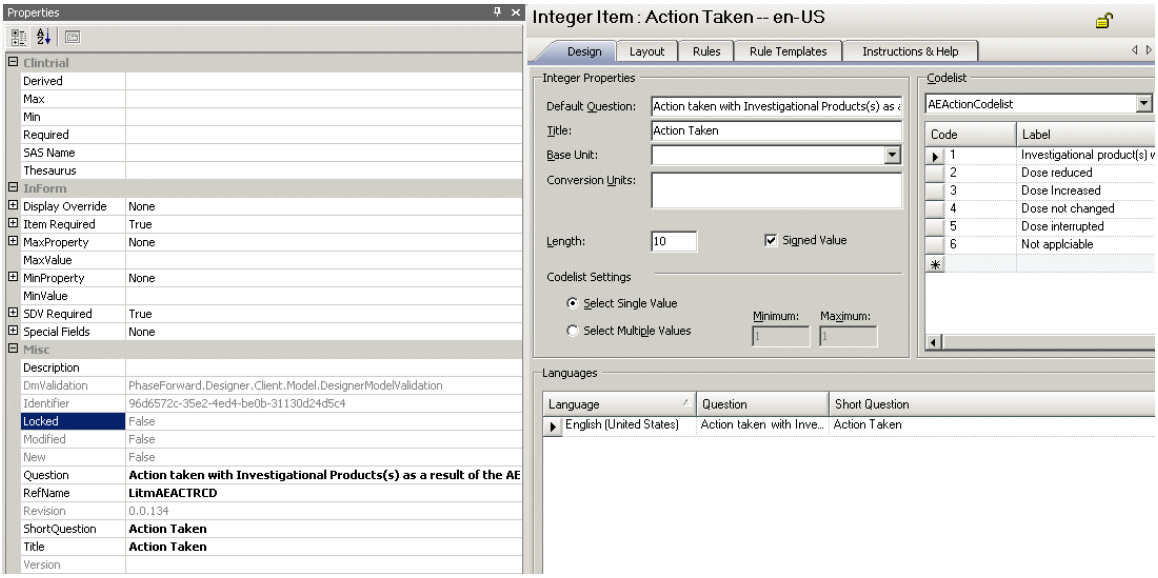
Items

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.

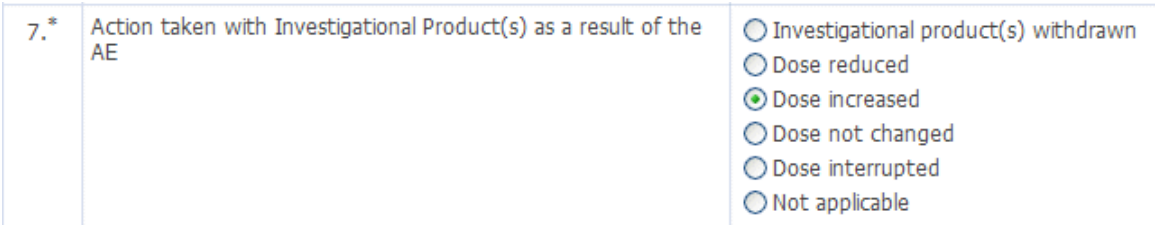
Central Designer Properties Browser view



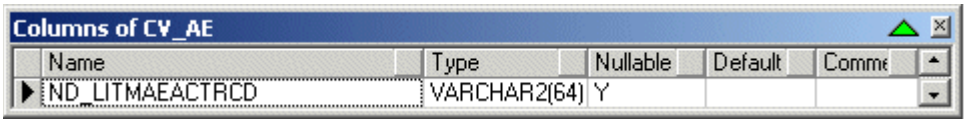
MedML definition

```
<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



Database view



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.

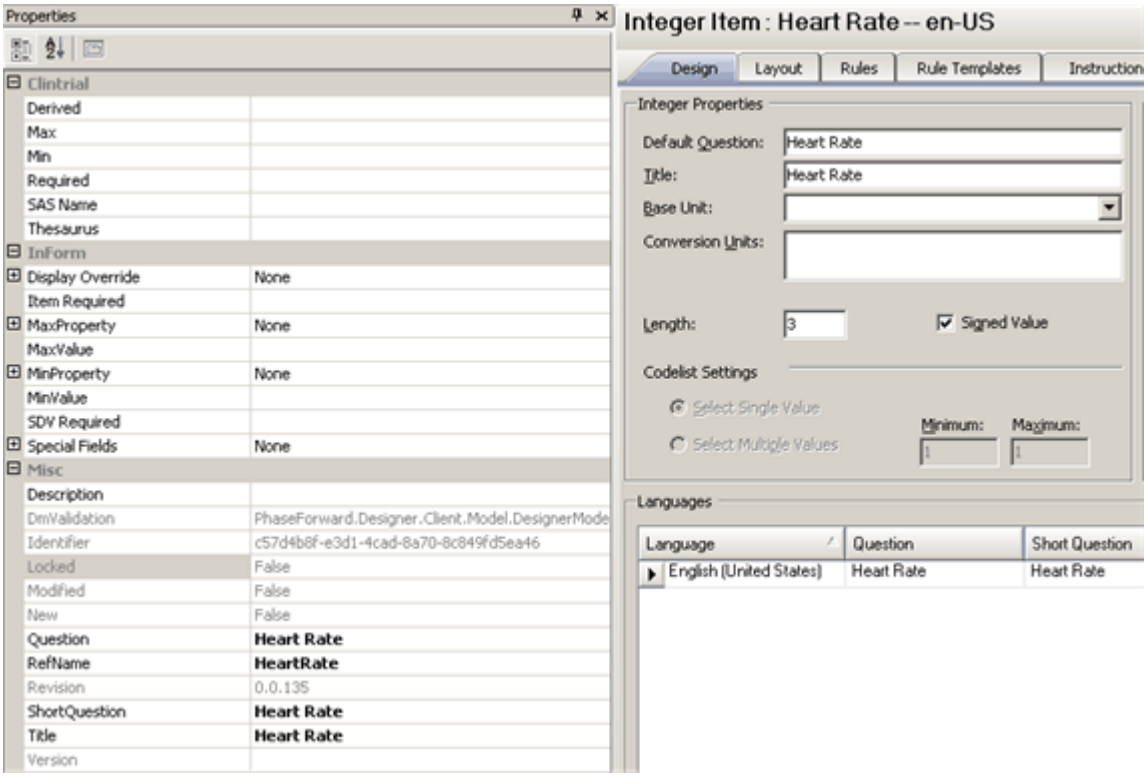
Text controls			
View column name	View column type	Report element name	Report element folder
<CoreColumnName>— (Generally <*ItemRefName*>_ <*ControlRefName*>)	**VARCHAR2(N)**—If the control datatype is CHARACTER and its MAXLENGTH value is 255 or less. N is equal to the MAXLENGTH value. **CLOB**—If the 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*>	VARCHAR2	Unit Code ~ <*CoreItemName*>	Additional Data	Coded value of selected unit, which represents **UNITREFNAME** attribute.
U_<*CoreColumnName*>	VARCHAR2	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

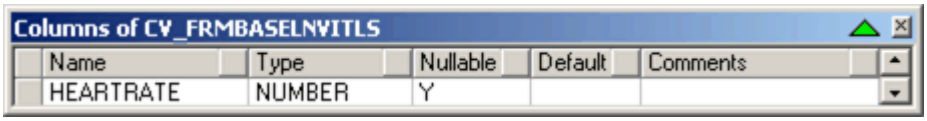


MedML definition

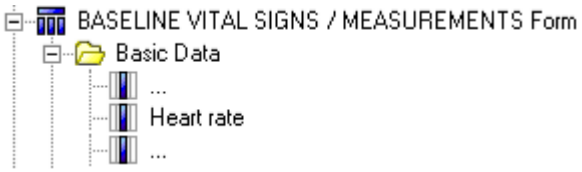
```
<TEXTCONTROL REFNAME="HeartRate"
    LANGUAGE="English"
    NAME="HeartRate"
    CAPTION="bpm"
    ALIGN="LEFT"
    CAPTIONALIGN="RIGHT"
    UNITDISPLAYTYPE="ELEMENT"
    HEIGHT="1"
    LENGTH="3"
    MAXLENGTH="3"
    DATATYPE="INTEGER"
    MINVALUE="0"
    MAXVALUE="0"
    MINPROPERTY="NOTSPECIFIED"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

Database view

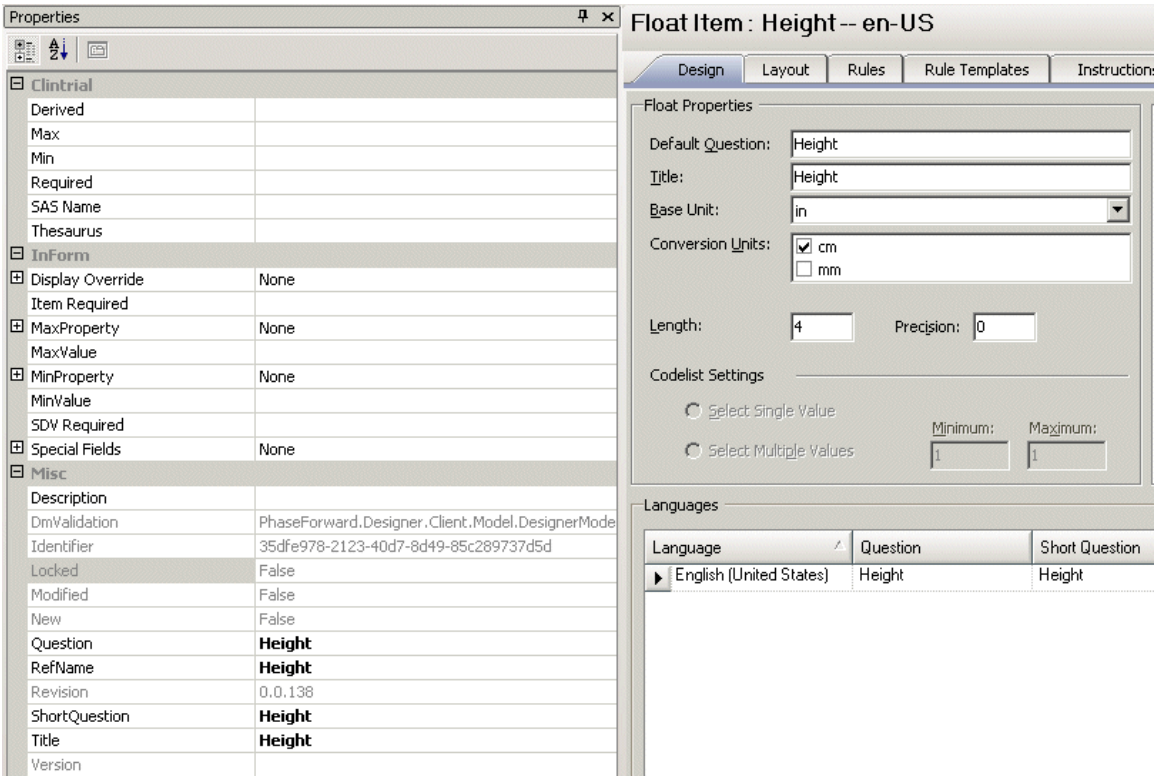


Cognos model



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

Central Designer Properties Browser view



MedML definition

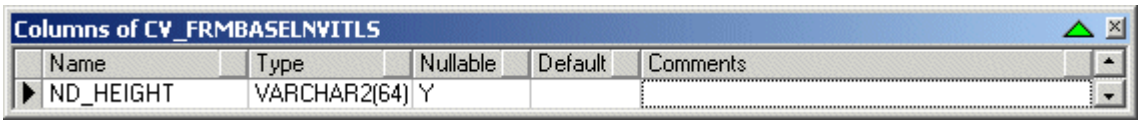
Design | MedML

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

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

<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>
```

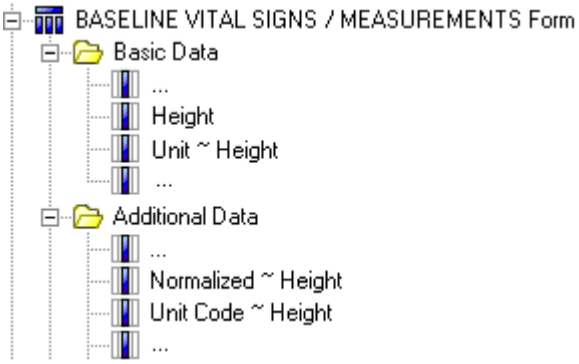
Display in the InForm application

5.*	Height	65.0	○ cm ◉ in

Database view



Cognos model



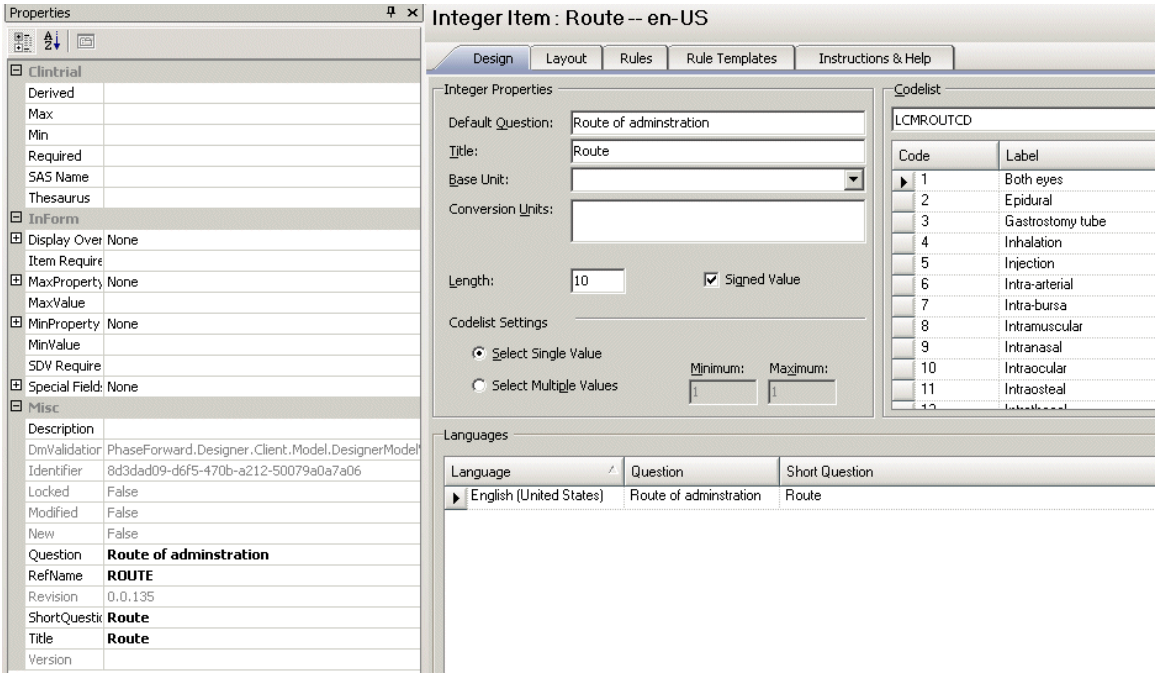
Drop-down lists

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
C_<*CORECOLUMNNAME*>	FLOAT, NUMBER or VARCHAR2 (depends on the type of the child elements.)	Code ~ <*COREITEMNAME*>	Additional Data	ELEMENTVALUE
<*COREITEMNNAME*>	VARCHAR2	<*COREITEMNAME*>	Basic Data	ELEMENTLABEL

The following examples illustrate mapping a drop-down list.

Central Designer Properties Browser view



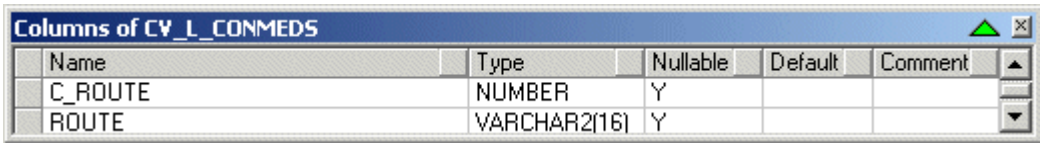
MedML definition

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 adminstration"
        LABEL="Route"
        CALCULATED="false"
        ITEMREQUIRED="true"
        SDVREQUIRED="true">

        <CONTROLREF REFNAME="ROUTE"/>

    </ITEM>
```

Display in the InForm application

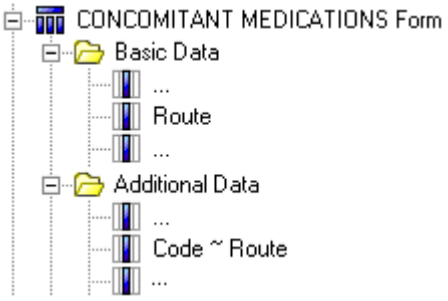
Database view



Columns of CV_L_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*>	DATE	Date ~ <*COREITEMNAME*>	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*>	DATE	Month Yr ~ <*COREITEMNAME*>	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.

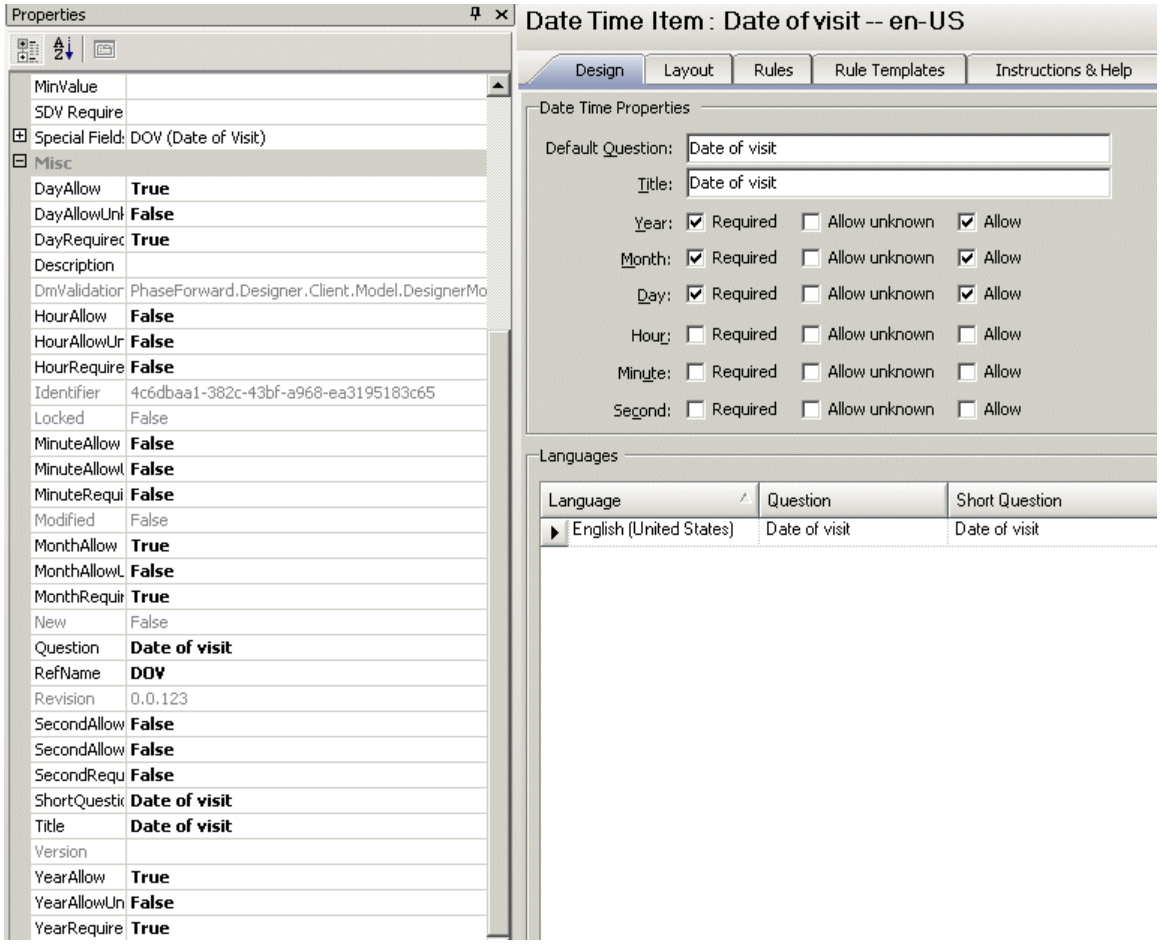
Date controls				
View column name	View column type	Report element name	Report element folder	Content
DTS_<*CORECOLUMNNAME*>	VARCHAR2	YYYY/MM/DD ~ <*COREITEMNAME*>	Basic Data	This column is generated only if the Year, Month and Day **DISPLAY** attributes are all set to TRUE and one or all of these components' **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	This column is generated only if the control Month **DISPLAY** attribute is set to TRUE. 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.

The following examples illustrate mapping a datetime control.

Central Designer Properties Browser view



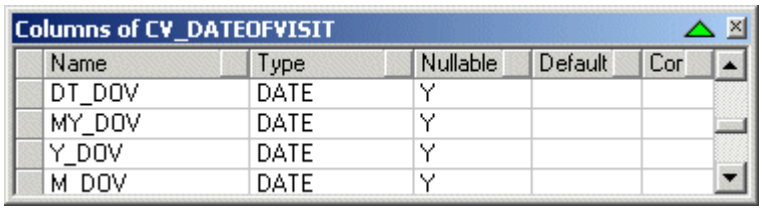
MedML definition

Design | MedML

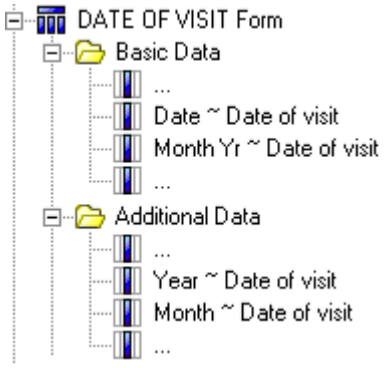
```
<DATETIMECONTROL REFNAME="DOV"
    UUID="BD991BC0-B0A4-11D2-80E3-00A0C9AF7674"
    LANGUAGE="English"
    ALIGN="LEFT"
    CAPTIONALIGN="LEFT"
    STARTYEAR="2007"
    ENDYEAR="2015"
    DISPLAYMONTH="true"
    DISPLAYDAY="true"
    DISPLAYYEAR="true"
    DISPLAYHOUR="false"
    DISPLAYMINUTE="false"
    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

Database view



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.

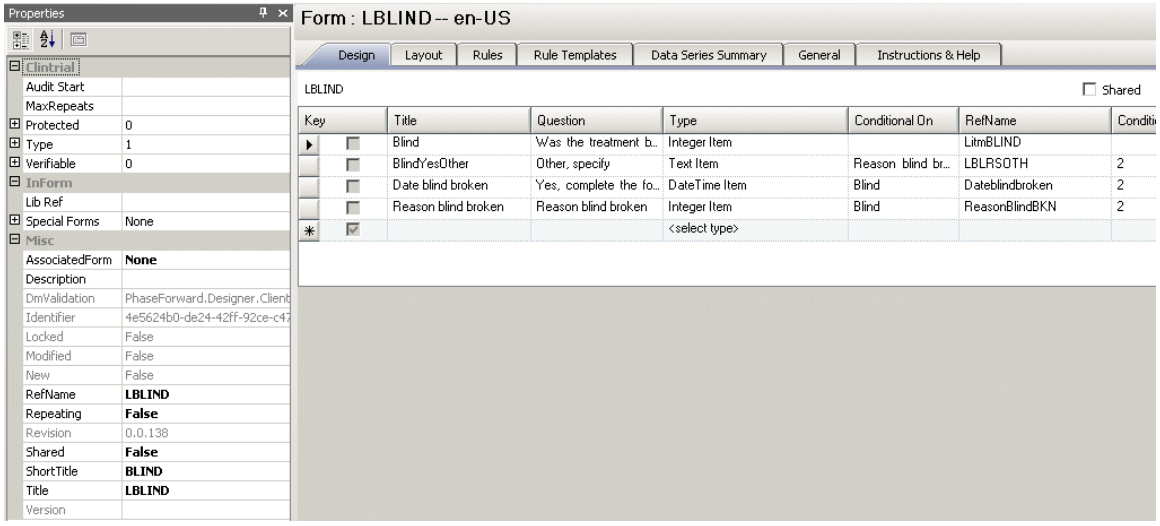
In addition to these two columns, the children associated with a radio control have their own column mappings, with the exception of simple controls, which do not map to columns.

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.

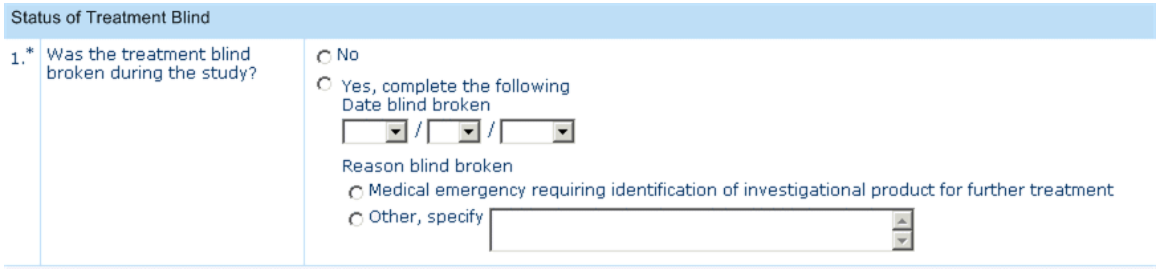
Central Designer Properties Browser view



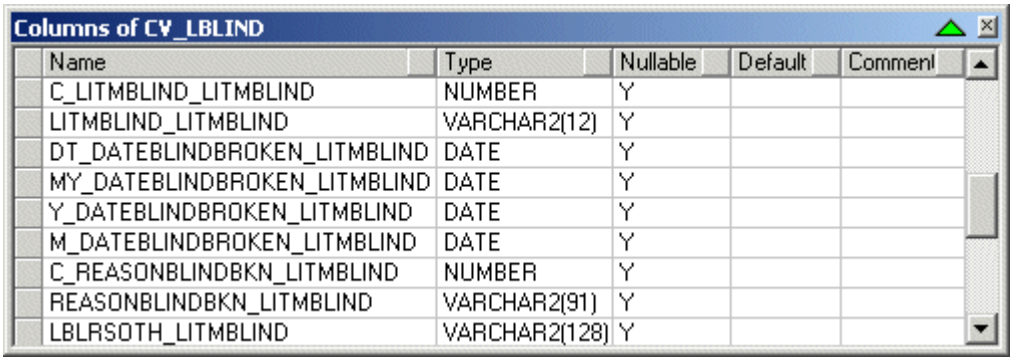
MedML definition

```
    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



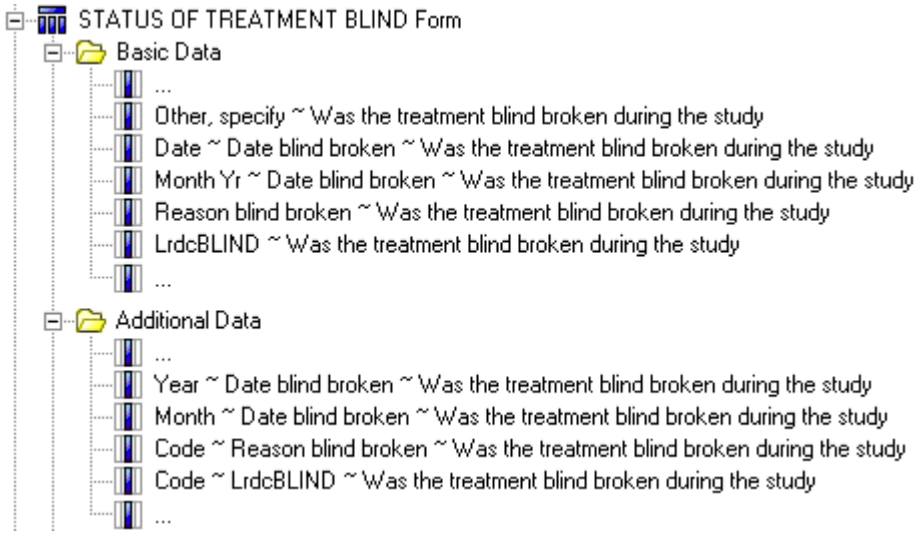
Database view



Columns of CV_LBLIND

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



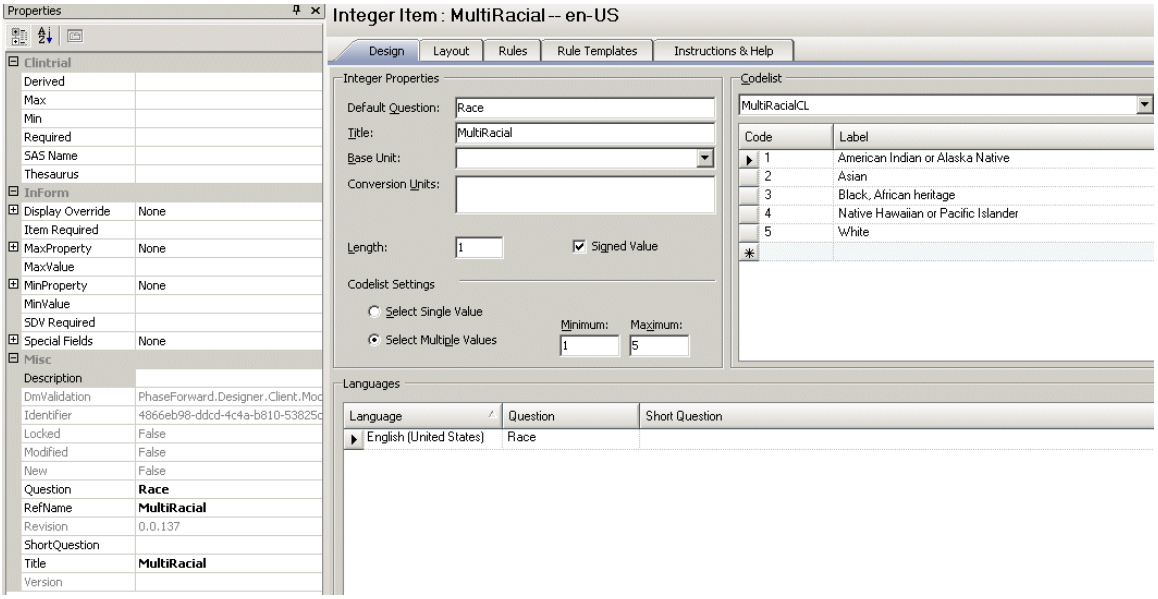
Checkbox controls

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.

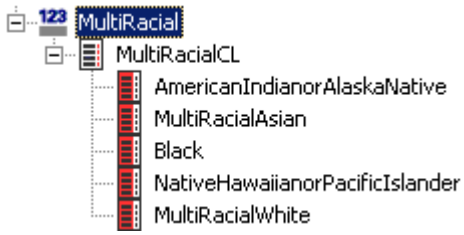
Checkbox controls				
View column name	View column type	Report element name	Report element folder	Content
C_<*CORECOLUMNNAME*>	FLOAT, NUMBER or VARCHAR2 if the child is a simple control, otherwise VARCHAR2.	Code ~ <*COREITEMNAME*>	Additional Data	ELEMENTVALUE if a child control is a simple control, CONTROLSELECTIONVALUE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



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

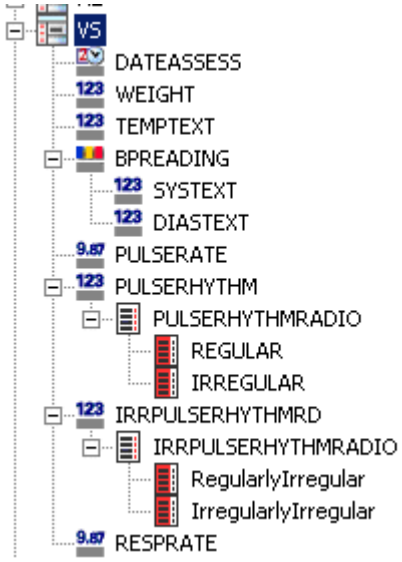
3.*	Race	White, not of Hispanic origin Black, not of Hispanic origin Hispanic Asian or Pacific Islander American Indian or Alaskan Native Other or Unknown

Group controls

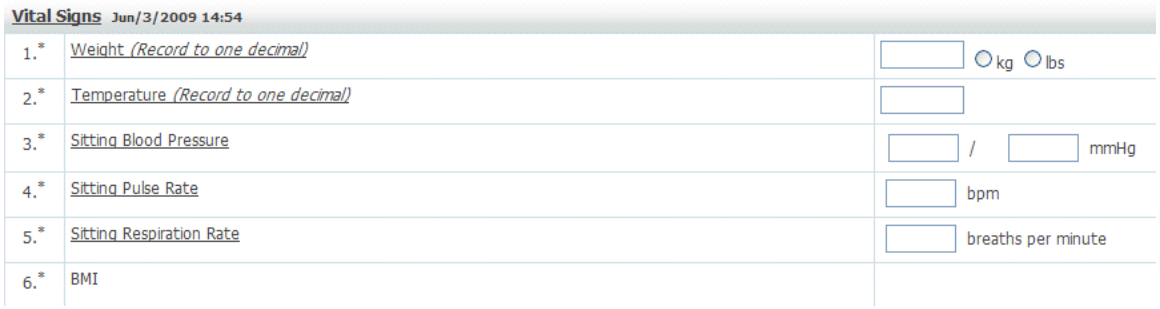
Group controls do not map into generated clinical view columns, but group control children are mapped.

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 *(Record to one decimal)*	kg lbs
2.*	Temperature *(Record to one decimal)*	
3.*	Sitting Blood Pressure	/ mmHg
4.*	Sitting Pulse Rate	bpm
5.*	Sitting Respiration Rate	breaths per minute
6.*	BMI	

Clinical view schema

Columns of CV_VS

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_DATADICTIONARY**—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_DATADICTIONARY and RT_MD_VIEWDICTIONARY tables. This view also contains unit information from the RD_GCV_V_UNITLIST table.

RD_DATADICTIONARY

The RD_DATADICTIONARY 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_DATADICTIONARY table contains language-dependent data.

RD_DATADICTIONARY	
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 6.0.1 release, names of truncated RD views may change.

RD_DATADICTIONARY	
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.
TABLENAME	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_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 32 - COLTYPE_SUBJECTNUMBERSTR 33 - COLTYPE_FORMFIRSTDATE 34 - COLTYPE_FORMLASTDATE

RD_DATADICTIONARY	
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
COLUMNVALUEREFNAME	• 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.
COLUMNFLOATPRECISION	Column precision. Used only for Float text controls and is NULL for all other columns. 0 - Unlimited precision. *n* - 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_DATADICTIONARY	
COLUMNFOLDER	Report topic folder. Only one of the three predefined folders is allowed: • 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: 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. 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. *n* - 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_DATADICTIONARY	
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_DATADICTIONARY 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_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 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_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 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. *n* - 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: • **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: • **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,
   COLUMNTYPE,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,
   COLUMNTYPE,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

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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	The following codelist specifications determine how codelist items deploy to the InForm application: • **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: ▪ 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	• Table column in CDD mapping definition. • Panel item in CIS mapping definition.	

Central Designer study component	Corresponding InForm study component	Notes
Data set	• Table in CDD mapping definition. • Panel in CIS mapping definition.	The data dimensions of a data set form the key for each row of a CDD table. Data values defined as custom dimensions form pivot columns around which the data in the table is organized.
Description	No corresponding component	Study object descriptions are visible only in a Central Designer annotated study book.
Form	Form	• 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	• 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	Item deployment considerations: • The Central Designer application includes the following custom properties for InForm deployment: ▪ **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	• 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	• 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	• 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	The study version (VERSIONDESCRIPTION attribute in InForm MedML) is a concatenation of: • The Title property of the study object. • The revision number of the validation baseline used to create the deployment package. • An abbreviation for the locale, if the deployment package is created for multiple locales.
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	A special InForm visit that must be included in the Central Designer study design. • The enrollment form must belong to the enrollment visit. • The enrollment visit must be a standalone visit in the study workflow. • The enrollment visit must be the second visit in the workflow after the screening visit.
	Regulatory report and visit report visits	The deployment process creates regulatory report and visit report visits.
	Repeating visit	A study event defined as repeating in the Central Designer application deploys as a repeating visit in the InForm application.
	Screening visit	A special InForm visit that must be included in the Central Designer study design. • The screening form must belong to the screening visit. • The screening visit must be a standalone visit in the workflow. The screening visit must be the first visit in the workflow and the enrollment visit must be second.

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.