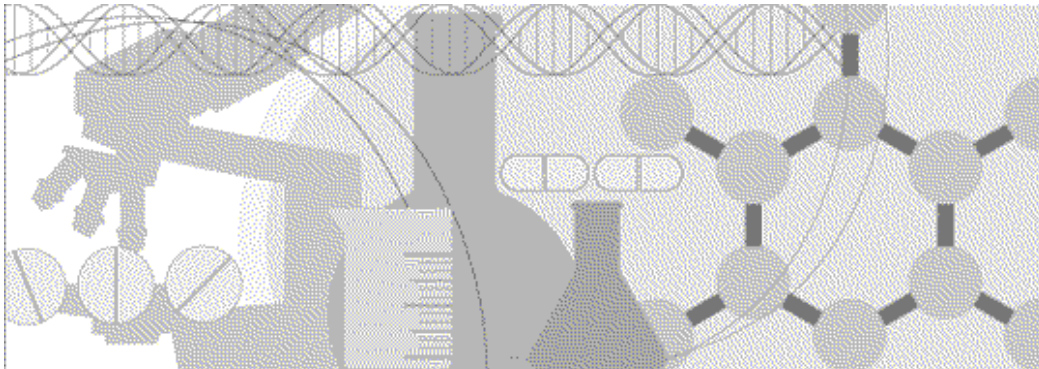


Reporting Database Schema Guide

InForm™ ITM 4.6 SP3



ORACLE®

Copyright © 2008 - 2011, Oracle and/or its affiliates. All rights reserved.

The Programs (which include both the software and documentation) contain proprietary information; they are provided under a license agreement containing restrictions on use and disclosure and are also protected by copyright, patent, and other intellectual and industrial property laws. Reverse engineering, disassembly, or decompilation of the Programs, except to the extent required to obtain interoperability with other independently created software or as specified by law, is prohibited.

The information contained in this document is subject to change without notice. If you find any problems in the documentation, please report them to us in writing. This document is not warranted to be error-free. Except as may be expressly permitted in your license agreement for these Programs, no part of these Programs may be reproduced or transmitted in any form or by any means, electronic or mechanical, for any purpose.

If the Programs are delivered to the United States Government or anyone licensing or using the Programs on behalf of the United States Government, the following notice is applicable:

U.S. GOVERNMENT RIGHTS Programs, software, databases, and related documentation and technical data delivered to U.S. Government customers are "commercial computer software" or "commercial technical data" pursuant to the applicable Federal Acquisition Regulation and agency-specific supplemental regulations. As such, use, duplication, disclosure, modification, and adaptation of the Programs, including documentation and technical data, shall be subject to the licensing restrictions set forth in the applicable Oracle license agreement, and, to the extent applicable, the additional rights set forth in FAR 52.227-19, Commercial Computer Software -- Restricted Rights (June 1987). Oracle USA, Inc., 500 Oracle Parkway, Redwood City, CA 94065.

The Programs are not intended for use in any nuclear, aviation, mass transit, medical, or other inherently dangerous applications. It shall be the licensee's responsibility to take all appropriate fail-safe, backup, redundancy and other measures to ensure the safe use of such applications if the Programs are used for such purposes, and we disclaim liability for any damages caused by such use of the Programs.

The Programs may provide links to Web sites and access to content, products, and services from third parties. Oracle is not responsible for the availability of, or any content provided on, third-party Web sites. You bear all risks associated with the use of such content. If you choose to purchase any products or services from a third party, the relationship is directly between you and the third party. Oracle is not responsible for: (a) the quality of third-party products or services; or (b) fulfilling any of the terms of the agreement with the third party, including delivery of products or services and warranty obligations related to purchased products or services. Oracle is not responsible for any loss or damage of any sort that you may incur from dealing with any third party.

Oracle is a registered trademark of Oracle Corporation and/or its affiliates. Other names may be trademarks of their respective owners.

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

Contents

About this guide	v
Overview of this guide.....	vi
Audience	vi
Related information.....	vii
Documentation.....	vii
Cognos documentation	ix
Training	x
If you need assistance.....	xi
Chapter 1 The InForm reporting database	1
Overview of the reporting database	2
Naming conventions	3
Chapter 2 Operational view descriptions	5
Trial design metadata	6
IRV_STUDYVERSIONS	6
IRV_STUDYVERSION_VISITS	6
IRV_STUDYVERSION_FORMS.....	8
IRV_FORM_REVS.....	10
IRV_SECTION_REVS	11
IRV_ITEM_REVS	12
IRV_ITEMSET_REVS	13
IRV_CONTROL_REVS.....	14
IRV_MD_FORMS_CONTROLS.....	16
IRV_ITEM_CONTROL_NESTING.....	23
IRV_FORM_ASSOC.....	23
Trial objects and administrative data.....	25
IRV_CUR_CONFIG.....	25
IRV_CUR_RULE	28
IRV_CUR_RULEITEM.....	29
IRV_CUR_SITE	30
IRV_CUR_SPONSOR	32
IRV_CUR_SUBJECT	33
IRV_CUR_SUBJECT_DIM.....	36
IRV_SUBJECT_STATE_CHANGES	38
IRV_CUR_SYSTEMVERSION.....	38
IRV_SYSTEMVERSIONS.....	39
IRV_CUR_USER.....	39
IRV_CUR_USERLIST	41
IRV_USERS_SITES	42
IRV_USER_ACTIVESTATE_CHANGES	42
IRM_USER_BLINDED_ITEMS	43
IRV_CUR_COMMENT	43
Trial operational data	46
IRV_SUBJECT_DROPOUT_REASON	46
IRV_SV_SUBJECTVISITS	46
IRV_AF_SUBJECT_FORMS	49
IRV_SV_SUBJECT_FORMS	55

IRV_CRF_STATUS_REPORT.....	62
IRV_FORM_ITEMS	66
IRV_CUR_QUERY	69
IRV_QUERY_STATE_CHANGES.....	73
IRV_USER_HISTORICAL_CHANGES	74
Summary views.....	75
Form summaries	75
Visit Summaries	79
Item Summaries	81
Subject Summaries	89
Identifying keys	93

Chapter 3 Clinical view descriptions 95

Clinical metadata.....	96
CV_DATADictionary	96
Clinical data view generation	99
CM_<FormRefname/Itemset> MVs and CV_<FormRefname/Itemset> Views	99
Clinical data audit information	112
Study versioning.....	112
Alternate forms.....	113
Cognos 8 Business Intelligence models.....	115
Clinical model security.....	116
Auto-generated mappings	117
Structural mappings	117
Naming conventions for mappings.....	117
Built-in columns for views.....	119
Visits	121
Forms.....	122
Sections	125
Itemsets	125
Items	128
Controls.....	130
Examples of auto-generated mappings	155

Appendix A Appendix 159

Mapping Central Designer terms to InForm terms.....	160
---	-----

About this guide

In this preface

Overview of this guide	vi
Related information	vii
If you need assistance	xi

Overview of this guide

The *Reporting Database Schema* Guide describes the InForm reporting database schema.

Audience

This guide is for system and database administrators who are responsible for setting up the InForm software and InForm trials, and producing reports using the Cognos 8 Business Intelligence software.

Related information

Documentation

All documentation is available from the Phase Forward Download Center.

Item	Description
<i>Release Notes</i>	The <i>Release Notes</i> document describes enhancements introduced and problems fixed in the current release, upgrade considerations, release history, and other late-breaking information.
<i>Known Issues</i>	<p>The <i>Known Issues</i> document provides detailed information about the known issues in this release, along with workarounds, if available.</p> <p>Note: The most current list of known issues is available on the Phase Forward Extranet.</p> <p>To sign in to the Extranet, go to www.phaseforward.com and click Customer Login. Enter your email address and password, and navigate to the Known Issues section. Select a product, and then enter your search criteria.</p>
<i>Installation and Configuration</i>	<p>The <i>Installation and Configuration</i> guide describes how to install the software and configure the environment for the InForm application and Cognos 8 Business Intelligence.</p> <p>This document is also available from the Documentation CD.</p>
<i>Setting Up a Trial with InForm Architect and MedML</i>	<p>The <i>Setting Up a Trial with InForm Architect and MedML</i> describes how to design and implement trials in the InForm application using the InForm Architect application.</p> <p>This document is also available from the Documentation CD.</p>
<i>Step by Step for CRCs and CRAs</i>	<p>The <i>Step by Step for CRCs and CRAs Guide</i> describes how to use the InForm application to:</p> <ul style="list-style-type: none"> • Screen and enroll patients. • Enter, update, and monitor clinical data. • Enter and respond to queries. • Run trial management reports and clinical data listings. <p>This document is also available from the Documentation CD and the user interface.</p>

Item	Description
<i>Reporting and Analysis Guide</i>	<p>The <i>Reporting and Analysis Guide</i> provides an overview of the Reporting and Analysis module. It includes a brief overview of the Reporting and Analysis interface, illustrates how to access the Ad Hoc Reporting feature, and describes the study management and clinical data packages available for reporting. It also provides detailed descriptions of each standard report that is included with your installation.</p> <p>This document is also available from the Documentation CD and the user interface.</p>
<i>Utilities Guide</i>	<p>The <i>Utilities Guide</i> provides information about and step-by-step instructions for using the following utilities:</p> <ul style="list-style-type: none"> • PFConsole utility • MedML Installer utility • InForm Data Import utility • InForm Data Export utility • InForm Performance Monitor utility • InForm Report Folder Maintenance utility <p>This document is also available from the Documentation CD.</p>
<i>Reporting Database Schema</i>	<p>The <i>Reporting Database Schema</i> Guide describes the InForm reporting database schema.</p> <p>This document is also available from the Documentation CD.</p>
<i>Portal Administration Guide</i>	<p>The <i>Portal Administration Guide</i> provides step-by-step instructions for setting up the InForm Portal software, and configuring and managing the InForm Portal application.</p> <p>This document is also available from the Documentation CD.</p>
Online Help	<p>The online Help describes how to use and administer the InForm application.</p> <p>This document is available only from the user interface.</p>
InForm Architect online Help	<p>The InForm Architect online Help describes how to design and implement trials in the InForm application using the InForm Architect application.</p> <p>This document is available only from the user interface.</p>
MedML Installer utility online Help	<p>The MedML Installer utility online Help provides information about, and step-by-step instructions for using, the MedML Installer utility, which is used to load XML that defines study components into the InForm database.</p> <p>This guide also provides reference information for the MedML elements and scripting objects that are used to import and export data to and from the InForm application, as well as sample data import XML.</p> <p>This document is available only from the user interface.</p>

Item	Description
InForm Data Export utility online Help	<p>The InForm Data Export utility online Help provides information about and step-by-step instructions for using the InForm Data Export utility, which is used to export data from the InForm application to the following output formats:</p> <ul style="list-style-type: none"> • AutoCode. • Customer-defined database (CDD). • Name value pairs. • Oracle Clinical. <p>This document is available only from the user interface.</p>
InForm Data Import utility online Help	<p>The InForm Data Import utility online Help provides information about and step-by-step instructions for using the InForm Data Import utility, which is used to import data into the InForm application.</p> <p>This document is available only from the user interface.</p>

Cognos documentation

The InForm application includes the Cognos 8 Business Intelligence reporting software, which is licensed from Cognos Corporation and includes a customized version of Cognos Report Studio. Report Studio provides advanced reporting capabilities and requires a separate license from Phase Forward. The Cognos 8 Business Intelligence and Report Studio software is licensed solely for use in connection with the InForm application and data contained in the Reporting and Analysis database. For advanced reporting using Report Studio, custom tables and extensions to the Reporting and Analysis database can be implemented and are covered under the InForm license.

A complete Reporting and Analysis module installation requires you to install both Cognos 8 Business Intelligence software and Sun ONE Directory Server. The following Cognos 8 Business Intelligence manuals are available from the InForm user interface.

Document	Description
Product documentation	
IBM Cognos 8 <i>Architecture and Deployment Guide</i>	Describes the Cognos 8 architecture from the perspectives of structure, communications, workflow, and security. Provides information for planning the Cognos 8 installation and configuration, and for maximizing its performance.
IBM Cognos 8 <i>New Features Guide</i>	Contains information about the new features and supported environments in this release of Cognos 8 Business Intelligence.
IBM Cognos 8 Reporting <i>Readme</i>	Provides late-breaking information about installation issues, limitations, and other known issues.
Installation and Configuration Documentation	

Document	Description
IBM Cognos 8 <i>Installation and Configuration Guide</i>	Contains instructions for installing, upgrading, configuring, and testing Cognos 8 Business Intelligence, changing application servers, and setting up samples.
IBM Cognos 8 BI Reporting <i>Getting Started Installation Guide</i>	Provides information for installing and configuring Cognos 8 on a single server with default settings.
Administration and Portal Documentation	
<i>Using IBM Cognos Series 7 and IBM Cognos BI in the Same Environment</i>	Provides information about using interoperability as part of the recommended migration strategy.
IBM Cognos 8 <i>Administration and Security Guide</i>	Contains step-by-step procedures and background information on Cognos 8 administration.
IBM Cognos Connection <i>User's Guide</i>	Explains how to use Cognos Connection and the Cognos 8 portal to view, edit, schedule, and distribute standard and complex reports.
Modeling Documentation	
Framework Manager <i>User's Guide</i>	Provides information about creating and publishing models using Framework Manager.
IBM Cognos Transformer <i>User's Guide</i>	Provides information about creating and publishing models and cubes using IBM Cognos Transformer.

Training

For information about training offerings, please see the course catalog on our website at <http://www.phaseforward.com/support/training/> or contact Phase Forward Educational Services at training@phaseforward.com.

If you need assistance

If you are a Phase Forward customer with a maintenance agreement, you can contact the Global Support Center for assistance with product issues.

Your maintenance agreement indicates the type of support you are eligible to receive and describes how to contact Phase Forward. Additionally, the Phase Forward website lists the toll-free support number for your product, location, and support level:

<http://www.phaseforward.com/support/>

In the event that our toll-free telephone service is interrupted, please use either of the following methods to contact the Global Support Center:

- Email
customer.support@phaseforward.com
- Telephone

In the US: 781-902-4900

Outside the US: +44 (0) 1628 640794

Phase Forward also provides assistance with User Management, Site Assessment, and Provisioning. Please refer to your Master Services Agreement and individual Statement of Work to determine if you are eligible to use these services.

CHAPTER 1

The InForm reporting database

In this chapter

Overview of the reporting database	2
Naming conventions.....	3

Overview of the reporting database

The InForm application is a data collection and trial management application that uses a secure web browser to provide access to clinical trial data and management of the clinical trial process.

Embedded within the InForm user interface is the Reporting and Analysis module, which is a reporting application that was developed by the Cognos Corporation and that has been customized and integrated into the InForm application by Phase Forward. The Reporting and Analysis module provides a library of configurable reports, predefined reports, and ad hoc reporting and charting tools. Both clinical and operational data are available in real time from a database that can be accessed using the Internet.

This guide describes the InForm reporting database, the views that are used by the Cognos 8 Business Intelligence operational and clinical models, and other views that may be useful when writing SQL directly against the database.

Naming conventions

The reporting database uses the following naming conventions for schema objects:

Prefix	Schema Object Type
CV_	Patient data view (clinical view)
CD_	Clinical data and metadata materialized view for form controls
CM_	Clinical data materialized view for forms and itemsets
IRV_	View
IRV_MD	View of trial design metadata
IRM_	Materialized view
IRT_	Table
IRI_	Index
IRC_	Constraint
PF_	Table replicated from the transaction database

Note: This guide intentionally does not describe the IRM_objects because Phase Forward strongly recommends that you use only the IRV_objects. PF_ tables are described in the InForm Transactional Schema document.

The reporting database is closely tied to the InForm trial database. However, many of the items in the InForm database have different names in the reporting database, as shown in the following table.

Object Type	MedML Type	InForm Database Name	Reporting Database Name
Trial		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

CHAPTER 2

Operational view descriptions

In this chapter

Trial design metadata	6
Trial objects and administrative data.....	25
Trial operational data	46
Summary views	75
Identifying keys.....	93

Trial design metadata

The following views define the trial design metadata.

IRV_STUDYVERSIONS

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

IRV_STUDYVERSIONS	
Column Name (Key indicator)	Column Description
STUDYVERSIONID (PK)	Study version numerical identifier
STUDYID	Study numerical identifier
STUDYREV	Study revision.
REVTIME	Time study version was entered into the database
STUDYNAME	Study name
TRADEDRUGNAME	Trade drug name
GENERICDRUGNAME	Generic drug name
SPONSORDRUGNAME	Sponsor drug name
SPONSORAPPROVALDATE	Sponsor approval date
EDITIONDESCRIPTION	Version description
STUDYVERSION	Study name
PROTOCOLDESIGNNOTE	Design note

IRV_STUDYVERSION_VISITS

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

IRV_STUDYVERSION_VISITS	
Column Name (Key indicator)	Column Description
SVVROWID	Oracle ROWID
STUDYVERSIONID (PK)	Study version numerical identifier
VISITID (PK)	Visit numerical identifier
VISITREV	Visit revision
VISITREFNAME	Visit RefName
VISITNAME	Visit name
VISITMNEMONIC	Visit mnemonic

IRV_STUDYVERSION_VISITS	
Column Name (Key indicator)	Column Description
VISITTYPE	Visit type: 1 - Visit 2 - Enrollment 3 - Screening 4 - Monitor 5 - Status 6 - Common CRF 7 - Regdocs 8 - Visitreports 9 - Conflict 16 - Relation
VTSUBJECTVISIT	Visit type CRF: 0 - no 1 - yes
VTENROLLMENT	Visit type enrollment: 0 - no 1 - yes
VTSCREENING	Visit type screening: 0 - no 1 - yes
VTMONITOR	Visit type monitor: 0 - no 1 - yes
VTSTATUS	Visit type status: 0 - no 1 - yes
VTCOMMONCRF	Visit type common CRF: 0 - no 1 - yes
VTREGDOCS	Visit type reg doc: 0 - no 1 - yes
VTVISITREPORT	Visit type visit report: 0 - no 1 - yes

IRV_STUDYVERSION_VISITS	
Column Name (Key indicator)	Column Description
VICONFLICT	Visit type conflict: 0 - no 1 - yes
VISITPROPERTIES	Visit properties
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 relation: 0 - no 1 - yes
HELPTTEXT	Help text
DESIGNNOTE	Design note
VISITORDER	Visit order
STARTEHOURSFRMPREVIOUS	Start hours from previous visit
STARTEHOURSFROMENROLL	Start hours from enrollment

IRV_STUDYVERSION_FORMS

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

IRV_STUDYVERSION_FORMS	
Column Name (Key Indicator)	Column Description
SVFROWID	Oracle ROWID
STUDYID	Study numerical identifier

IRV_STUDYVERSION_FORMS	
Column Name (Key Indicator)	Column Description
STUDYVERSIONID (PK)	Study version numerical identifier
VISITID (PK)	Visit numerical identifier
VISITREV	Visit revision
FORMID (PK)	Form numerical identifier
FORMREV	Form revision
FORMREFNAME	Form RefName
FORMNAME	Form name
FORMMNEMONIC	Form mnemonic
FORMNOTE	Form note
FORMTYPE	Form type: 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
FORMHELPURL	Form help URL
QUESTIONWIDTH	Question width
CONTROLWIDTH	Control width
REPEATINGFORM	Form can appear multiple times in a visit: 0 - no 1 - yes
COMMONFORM	Form is a common form (in Common CRF visit): 0 - no 1 - yes
FORMDESIGNNOTE	Design note
FORMORDER	Form order

IRV_STUDYVERSION_FORMS	
Column Name (Key Indicator)	Column Description
DYNAMICFORM	Form is dynamic: 0 - no 1 - yes
ALTFORM	Form is expecting an alt form: 0 - no 1 - yes
EXPECTINGALTFORM	Form is an alt form: 0 - no 1 - yes
ALTFORMID	Alt form numerical identifier
ALTFORMREV	Alt form revision
ASSOCVISIT	Form has association: 0 - no 1 - yes
ASSOCVISITID	Associated visit numerical identifier
ASSOCVISITREV	Associated visit revision
FORMINCOMMONVISIT	Form also appears in the Common CRF visit: 0 - no 1 - yes

IRV_FORM_REVS

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

IRV_FORM_REVS	
Column Name (Key indicator)	Column Description
FORMID (PK)	Form numerical identifier
FORMREV (PK)	Form revision
FIRSTREV	This is the first revision of this form: 0 - no 1 - yes

IRV_FORM_REVS	
Column Name (Key indicator)	Column Description
CURRENTREV	This is the most current revision of this form: 0 - no 1 - yes
FORMREFNAME	Form RefName
FORMNAME	Form name
FORMMNEMONIC	Form mnemonic
FORMNOTE	Form note
FORMTYPE	Form type: 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
FORMHELPURL	Form help URL
QUESTIONWIDTH	Question width
CONTROLWIDTH	Control width
REPEATINGFORM	Form can be repeated within the same visit: 0 - no 1 - yes
FORMDESIGNNOTE	Design note

IRV_SECTION_REVS

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

IRV_SECTION_REVS	
Column Name (Key indicator)	Column Description
SECTIONID (PK)	Section numerical identifier
SECTIONREV (PK)	Section revision

IRV_SECTION_REVS	
Column Name (Key indicator)	Column Description
FIRSTREV	This is the first revision of this section: 0 - no 1 - yes
CURRENTREV	This is the most current revision of this section: 0 - no 1 - yes
SECTIONREFNAME	Section RefName
SECTIONHEADER	Section title
SECTIONNOTE	Section note
REPEATINGSECTION	Section contains a repeating itemset: 0 - no 1 - yes
SECTIONDESIGNNOTE	Design note

IRV_ITEM_REVS

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

IRV_ITEM_REVS	
Column Name (Key indicator)	Column Description
ITEMID (PK)	Item numerical identifier
ITEMREV (PK)	Item revision
FIRSTREV	This is the first revision of this item: 0 - no 1 - yes
CURRENTREV	This is the most current revision of this item: 0 - no 1 - yes
ITEMLABEL	Item label
ITEMQUESTION	Item question
CONTROLID	Control numerical identifier
CONTROLREV	Control revision

IRV_ITEM_REVS	
Column Name (Key indicator)	Column Description
CALCULATED	Item is calculated: 0 - no 1 - yes
SDVREQUIRED	Item requires Source Verification: 0 - no 1 - yes
ITEMREQUIRED	Item is required
ITEMREFNAME	Item RefName
DISPLAYOVERRIDE	Item display mode: 1 - Read-only 2 - Editable 3 - Hidden
ITEMHELPURL	Item help URL
ITEMDESIGNNOTE	Design note

IRV_ITEMSET_REVS

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

IRV_ITEMSET_REVS	
Column Name (Key indicator)	Column Description
ITEMSETID (PK)	Itemset numerical identifier
ITEMSETREV (PK)	Itemset revision
ITEMSETREFNAME	Itemset RefName
SDVREQUIRED	Itemset requires source verification: 0 - no 1 - yes
ITEMSETREQUIRED	Itemset is required: 0 - no 1 - yes
DISPLAYOVERRIDE	Item display mode: 1 - Read-only 2 - Editable 3 - Hidden
ITEMSETHelpURL	Item help URL

IRV_ITEMSET_REVS	
Column Name (Key indicator)	Column Description
ITEMSETDESIGNNOTE	Design note

IRV_CONTROL_REVS

This view contains one row for each distinct control installed into the trial (MedML Control).

IRV_CONTROL_REVS	
Column Name (Key indicator)	Column Description
MDCONTROLID (PK)	Metadata control numerical identifier
CONTROLID	Control numerical identifier
CONTROLREV	Control revision
FIRSTREV	This is the first revision of this object: 0 - no 1 - yes
CURRENTREV	This is the most current revision of this object: 0 - no 1 - yes
CONTROLREFNAME	Control RefName
CONTROLNAME	Control name
CONTROLCAPTION	Control caption
CONTROLTABLE	Name of the table containing attributes specific to this type of control.
CONTROLTYPE	Control type: 1 - Simple control 2 - Pulldown control 3 - Listbox control 5 - Text control 6 - Calculated control 7 - Group control 8 - Radio control 9 - Check box group 10 - Date control
CONTROLLAYOUT	Control layout: 1 - Horizontal 2 - Vertical 3 - No wrapping

IRV_CONTROL_REVS	
Column Name (Key indicator)	Column Description
CONTROLCAPTION	Control caption
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 - Pulldown control
CONTROLDESIGNNOTE	Design note

IRV_MD_FORMS_CONTROLS

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

Itemid always refers to the ultimate parent item—the item that comes from PF_SECTIONITEM. Itemid refers to either an item or an itemset.

If (itemset = 0):

- Itemid—itemid (itemtype 0).
- Rootcontrolid—root control for the item.
- I_ and C_ attributes—attribute columns for item and its 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. (If you think of child1-4 as an array, then childid is the controlid located at array index childdepth.)

If (itemset = 1)

- Itemid—itemsetid (itemtype 1).
- I_—attribute columns for the itemset.
- Childitemid/childitemorder—determines which item in the itemset is described by the row.
- CI_ attributes—attributes for the itemset item.
- C_ attributes—attributes of the root control of the itemset item.
- Child controls—described the same as they are for non-itemset items.

IRV_MD_FORMS_CONTROLS	
Column Name (Key indicator)	Column Description
MDFCID	Unique numerical identifier (secondary PK)
FORMID (PK)	Form numerical identifier
FORMREV (PK)	Form revision
FORMREFNAME	Form RefName
FORMNAME	Form name
FORMMNEMONIC	Form mnemonic

IRV_MD_FORMS_CONTROLS	
Column Name (Key indicator)	Column Description
FORMTYPE	Form type: 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
FORMHELPURL	Form help URL
QUESTIONWIDTH	Question width
FORMCONTROLWIDTH	Control width
REPEATINGFORM	Form can be repeated within the same visit: 0 - no 1 - yes
FORMDESIGNNOTE	Form design note
SECTIONID (PK)	Section numerical identifier
SECTIONREV (PK)	Section revision
FORMSECTIONORDER (PK)	Section order within the form
NUMBERSTART	Indicates where to start numbering the items within the Section.
NUMBERTYPE	Identifies the numbering scheme used for items within the section: 0 - Numeric 1 - Alphanumeric
SECTIONREFNAME	Section RefName
SECTIONHEADER	Section title
SECTIONNOTE	Section note
REPEATINGSECTION	Section contains a repeating itemset: 0 - no 1 - yes
SECTIONDESIGNNOTE	Section design note
ITEMID (PK)	Item numerical identifier
ITEMREV (PK)	Item revision

IRV_MD_FORMS_CONTROLS	
Column Name (Key indicator)	Column Description
SECTIONITEMORDER (PK)	Order of item within section
ITEMSET	Item is an itemset: 0 - no 1 - yes
ITEMSETUNIQUEKEY	Each combination of items having KEYITEM=1 must be unique within the itemset: 0 - no 1 - yes
I_ITEMTYPE	Item type: 0 - Item 1 - Itemset
I_ITEMQUESTION	Item question
I_ITEMLABEL	Item label
I_CALCULATED	Item is calculated: 0 - no 1 - yes
I_SDVREQUIRED	Item requires source verification: 0 - no 1 - yes
I_ITEMREQUIRED	Item is required: 0 - no 1 - yes
I_ITEMREFNAME	Item RefName
I_ITEMHELPURL	Item help URL
I_DISPLAYOVERRIDE	Item display mode: 1 - Read-only 2 - Editable 3 - Hidden
I_ITEMDESIGNNOTE	Item design note
CHILDITEMORDER (PK)	Order of child item within itemset
CHILDITEMID (PK)	Child item numerical identifier
CHILDITEMREV (PK)	Child item revision

IRV_MD_FORMS_CONTROLS	
Column Name (Key indicator)	Column Description
KEYITEM	Child item is part of unique key (see ITEMSETUNIQUEKEY): 0 - no 1 - yes
CI_ITEMTYPE	Child item type - always 0
CI_ITEMQUESTION	Child item question
CI_ITEMLABEL	Child item label
CI_CALCULATED	Child item is calculated: 0 - no 1 - yes
CI_SDVREQUIRED	Child item requires source verification: 0 - no 1 - yes
CI_ITEMREQUIRED	Child item is required: 0 - no 1 - yes
CI_ITEMREFNAME	Child item RefName
CI_ITEMHELPURL	Child item help URL
CI_DISPLAYOVERRIDE	Item display mode (overridden by itemset property): 1 - Read-only 2 - Editable 3 - Hidden
CI_ITEMDESIGNNOTE	Child item design note
C_CONTROLID (PK)	Control numerical identifier (root control for nested controls)
C_CONTROLREV (PK)	Control revision
C_CONTROLREFNAME	Control RefName
C_CONTROLNAME	Control name
C_CONTROLTABLE	Name of the table containing attributes specific to this type of control.

IRV_MD_FORMS_CONTROLS	
Column Name (Key indicator)	Column Description
C_CONTROLTYPE	Control type: 1 - Simple control 2 - Pulldown control 3 - Listbox control 5 - Text control 6 - Calculated control 7 - Group control 8 - Radio control 9 - Check box group 10 - Date control
C_CONTROLLAYOUT	Control layout: 1 - Horizontal 2 - Vertical 3 - No wrapping
C_CAPTION	Control caption
C_CONTROLALIGNMENT	Control alignment: 1 - Left 2 - Center 3 - Right 4 - Top 5 - Middle 6 - Bottom
C_CAPTIONALIGNMENT	Caption alignment with respect to the control: 1 - Left 2 - Center 3 - Right 4 - Top 5 - Middle 6 - Bottom
C_HEIGHT	Control height
C_UNITDISPLAYTYPE	Units display as: 1 - A single element 2 - Radio buttons 3 - Pulldown control
C_CONTROLDESIGNNOTE	Control design note
CC_CONTROLID	Child control numerical identifier (for nested control)
CC_CONTROLREV	Child control revision
CHILDDEPTH	Depth of child control
CHILDORDER	Order of child control

IRV_MD_FORMS_CONTROLS	
Column Name (Key indicator)	Column Description
CHILDSELECT	Value to associate with the parent control when this child control is selected. (If blank, InForm 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 this type of control.
CC_CONTROLTYPE	Control type: 1 - Simple control 2 - Pulldown control 3 - Listbox control 5 - Text control 6 - Calculated control 7 - Group control 8 - Radio control 9 - Check box group 10 - Date control
CC_CONTROLLAYOUT	Control layout: 1 - Horizontal 2 - Vertical 3 - No wrapping
CC_CAPTION	Control caption
CC_CONTROLALIGNMENT	Control alignment: 1 - Left 2 - Center 3 - Right 4 - Top 5 - Middle 6 - Bottom
CC_CAPTIONALIGNMENT	Caption alignment with respect to the control: 1 - Left 2 - Center 3 - Right 4 - Top 5 - Middle 6 - Bottom
CC_HEIGHT	Control height

IRV_MD_FORMS_CONTROLS	
Column Name (Key indicator)	Column Description
CC_UNITDISPLAYTYPE	Units display as: 1 - A single element 2 - Radio buttons 3 - Pulldown control
CC_CONTROLDESIGNNOTE	Control design note
CHILD1ID (PK)	First child control numerical identifier
CHILD1REV (PK)	First child control revision
CHILD1ORDER (PK)	First child control order
CHILD1SELECT	First child control value to associate with the parent control when this child control is selected. (If blank, InForm generates a value of the format "!pf!{CONTROLGUID}").
CHILD2ID (PK)	Second child control numerical identifier
CHILD2REV (PK)	Second child control revision
CHILD2ORDER (PK)	Second child control order
CHILD2SELECT	Second child control value to associate with the parent control when this child control is selected. (If blank, InForm generates a value of the format "!pf!{CONTROLGUID}").
CHILD3ID (PK)	Third child control numerical identifier
CHILD3REV (PK)	Third child control revision
CHILD3ORDER (PK)	Third child control order
CHILD3SELECT	Third child control value to associate with the parent control when this child control is selected. (If blank, InForm generates a value of the format "!pf!{CONTROLGUID}").
CHILD4ID (PK)	Fourth child control numerical identifier
CHILD4REV (PK)	Fourth child control revision
CHILD4ORDER (PK)	Fourth child control order
CHILD4SELECT	Fourth child control value to associate with the parent control when this child control is selected. (If blank, InForm generates a value of the format "!pf!{CONTROLGUID}").

IRV_ITEM_CONTROL_NESTING

This view is used for the Audit Trail standard report, which displays audit trail data for a particular item.

IRV_ITEM_CONTROL_NESTING	
Column Name (Key indicator)	Column Description
ITEMID	Numeric identifier for the item whose audit trail is displayed.
ITEMREVISIONNUMBER	Revision number for the item whose audit trail is displayed.
ITEMREFNAME	RefName for the item whose audit trail is displayed.
ITEMQUESTION	Item question for the item whose audit trail is displayed.
CHILDCONTROLID	Numeric identifier for the child control for the item whose audit trail is displayed.
CONTROLID	Numeric identifier for the control on the item whose audit trail is displayed.
CHILDREVISIONNUMBER	Revision number for the child control for the item whose audit trail is displayed.
CONTROLREVISIONNUMBER	Revision number for the control on the item whose audit trail is displayed.
CONTROLREFNAME	RefName for the control on the item whose audit trail is displayed.

IRV_FORM_ASSOC

This view contains data from associated forms.

IRV_FORM_ASSOC	
Column Name (Key indicator)	Column Description
SUBJECTID	Numeric identifier for the subject associated with the forms.
SITEID	Numeric identifier for the site associated with the forms.
VISITID	Numeric identifier for the visit in which the associated forms exist.
VISITINDEX	Instance identifier for the visit in which the associated forms exist.
STATUS	Status of the associated forms.

IRV_FORM_ASSOC	
Column Name (Key indicator)	Column Description
FORMASSOCID	Numeric identifier for the transaction in which the forms were associated.
FORMID	Numeric identifier for one of the associated forms.
FORMINDEX	Instance identifier for one of the associated forms.
ASSOCFORMID	Numeric identifier for one of the associated forms.
ASSOCFORMINDEX	Instance identifier for one of the associated forms.

Trial objects and administrative data

IRV_CUR_CONFIG

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

IRV_CUR_CONFIG	
Column Name (Key indicator)	Column Description
CONFIGID (PK)	Config numerical identifier
ALLOWCPRESIZE	Indicates whether the InForm application permits a user to minimize the navigation panel on the left side of the screen, including the user's 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 system 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 in a configuration that uses InForm Unplugged application for trial synchronization across multiple servers.
DAYSPASSWORDEXPIRATION	Number of days that can pass before the InForm system requires users to change their passwords. The default is 30.
DEFAULTCPMAXIMIZED	Indicates whether or not the Navigation pane in the InForm application window opens maximized. 0 - no 1 - yes (default)
ENABLEFORGOTPASSWORD	Indicates whether to enable the feature that lets users 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 Date of Visit 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) defined as the server(s) on which execution plans run in a configuration that uses InForm Unplugged application for trial synchronization across multiple servers.
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	Indicates whether to enable or disable special navigation modes for a trial. 0 - Disable (default) 1 - Enable
NUMCHARSCRFLLENGTH	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 any execution plans to run.

IRV_CUR_CONFIG	
Column Name (Key indicator)	Column Description
ONENONALPHANUMERICCHARACTER	Indicates whether passwords must include at least one special character. 0 - no (default) 1 - yes
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	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 below an item on a CRF. The default is 80.
RANDOMIZATIONSRC	Name of the randomization source manager (COM object) that 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 <i>Setting Up a Trial with InForm Architect and MedML</i> .
REQUIRECOMMENTFORNA	Indicates whether the InForm application requires a user to enter a comment when entering N/A, Unknown, or Not Done in response to a question on a form. 0 - no (default) 1 - yes
SCREENINGSEQUENCE	Sequence number format for assigning screening numbers. For information about sequence number formats, see the <i>Setting Up a Trial with InForm Architect and MedML</i> .

IRV_CUR_CONFIG	
Column Name (Key indicator)	Column Description
SPONSOREDITFROZEN	Indicates whether sponsors will be able to edit a form after it has been marked as frozen. 0 - no (default) 1 - yes
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 trial. The default is Month_Day_Year.
UNIQUEINTLDOBSWTCH	Study, site or none, 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 is not required 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	Study, site or none, indicates whether the InForm application requires a unique subject ID for a study, a site or not at all: 0 (default) - Patient ID is not required to be unique. 1 - Patient ID must be unique within a site. 2 - Patient ID 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 trial.

IRV_CUR_RULE	
Column Name (Key indicator)	Column Description
RULECOUNT	Always 1, indicates the row represents one rule

IRV_CUR_RULE	
Column Name (Key indicator)	Column Description
RULEID (PK)	Rule numeric identifier
RULEREV	Rule revision
RREVS	Number of times this rule has been revised
MINRREV	First rule revision
MAXRREV	Most recent rule revision
RULEREFNAME	Rule RefName
RULEDESCRIPTION	Rule description
RULEENABLED	Rule enabled - 1 enabled, 0 disabled
EVENTTYPEID	Event type numeric identifier
ETINITIALREVISIONNUMBER	Event type initial revision
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
HELPTXTID	Help text numeric identifier
DESIGNNOTE	Design note
CTMSGTEXT	Message text, Clintrial rules only
CTRULEACTION	Action, Clintrial rules only
CTRULEOPTIONS	Options, Clintrial rules only

IRV_CUR_RULEITEM

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

IRV_CUR_RULEITEM	
Column Name (Key indicator)	Column Description
RULEITEMCOUNT	Always 1, indicates the row represents one ruleitem
RULEITEMID (PK)	Ruleitem numeric identifier

IRV_CUR_RULEITEM	
Column Name (Key indicator)	Column Description
RIREVS	Number of times this ruleitem has been revised
MINRIREV	First ruleitem revision
MAXRIREV	Most recent ruleitem revision
RULEITEMREFNAME	Ruleitem RefName
APPLYEVENT	Rule dependency type: 0 - DEPENDENCY 1 - APPLIED 2 - TRIGGER
ACTIVE	0 - Rule is not run for this item 1 - Rule is run for this item
RULEID	Rule numeric identifier
CHAPTERID	Visit numeric identifier (VISITID)
PAGEID	Form numeric identifier (FORMID)
SECTIONID	Section numeric identifier
ITEMSETID	Itemset numeric identifier
ITEMID	Item numeric identifier
RULESETID	RuleitemId of parent Ruleitem. If blank, this Ruleitem is a key context. Child RULEITEMs are additional dependencies for the rule.
ITEMSETEVENTID	Itemset event numeric identifier
ITEMSETHELPID	Itemset help numeric identifier

IRV_CUR_SITE

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

IRV_CUR_SITE	
Column Name (Key indicator)	Column Description
SITECOUNT	Always 1, indicates the row represents one site
SITETYPEID	Site type numeric identifier
SITEID (PK)	Site numeric identifier
SITEREV	Site revision
SITENAME	Site name
SITEADDRESS1	First line of the site address.

IRV_CUR_SITE	
Column Name (Key indicator)	Column Description
SITEADDRESS2	Second line of the site address.
SITEALTPHONENUMBER	Site alternate telephone number.
SITEBEEPER	Beeper number for the site.
SITECITY	City in which the site address is located.
SITECONTACTUSER	User to contact at the site.
SITECOUNTRY	Country in which the site address is located.
SITEDATEFORMAT	The format of the date as you want it to be displayed for the site, if a format is not specified at the user level.
SITEDAYPHONENUMBER	Day telephone number for the site.
SITEEMAILADDRESS	E-mail 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. The site server is dedicated for specific activities such as randomization, screening and enrollment, and generating subject numbers. Change the site server only at the current site server and synchronize the change to the new site server.
SITESTATEPROVINCE	State or Province in which the site address is located.
SITESTUDYINITIATIONDATE	<p>Date that the site came on line. Users cannot add data for a site before the specified date. Year values must be between 100 and 9999, inclusively. Always enter the full year, even in abbreviated date formats.</p> <p>The following date and time formats are valid:</p> <p>"dd month yyyy" "25 January 1996"</p> <p>"hh:mm:ss" (12-hour clock) "8:30:00"</p> <p>"hh:mm:ss" (24-hour clock) "20:30:00"</p> <p>"month dd, yyyy hh:mm:ss:" "January 25, 1996 8:30:00"</p> <p>"hh:mm:ss mon dd, yyyy" "8:30:00 Jan. 25, 1996"</p> <p>"mm/dd/yyyy hh:mm:ss" "1/25/1996 8:30:00"</p>
SITESTUDYTERMINATIONDATE	Date that the site came off line; for example, date that the last subject was signed off and locked.

IRV_CUR_SITE	
Column Name (Key indicator)	Column Description
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 sponsor information from MedML.

IRV_CUR_SPONSOR	
Column Name (Key indicator)	Column Description
SPONSORID (PK)	Sponsor numeric identifier
SPONSORREVISIONNUMBER	Sponsor revision
SPONSORCONTACTUSERID	User ID for the primary sponsor contact.
SPONSORNAME	Name of the Sponsor.
ADDRESS1	First line of the Sponsor's address.
ADDRESS2	Second line of the Sponsor's address.
CITY	City in which the Sponsor's address is located.
STATE_PROVINCE	State or Province in which the Sponsor's address is located.
ZIPCODE_POSTCODE	Sponsor's Zip or postal code.
COUNTRY	Country in which the Sponsor's address is located.
PHONE	Sponsor's telephone number.
FAX	Sponsor's fax number.
ALTPHONE	Sponsor's alternate telephone number.
EMAILADDRESS	E-mail address used for contacting the Sponsor.
LOGOID	Logon ID for the Sponsor.
THERAPUTICAREA	Therapeutic area of the study.
PROGRAMNAME	Name of the study.
NOTE	Description of the study.

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 the row represents one subject
SUBJECTID (PK)	Subject numeric identifier
SUBJECTREV	Subject revision
SUBJECTNUMBERSTR	Subject number
SUBJHIST	Subject HISTORICALORDER
SUBJTIME	Subject revision timestamp
USERID	User that last modified the subject
TRANSACTIONID	Transaction that last modified the subject
SITEID	Site the user is assigned to
SITEREV	Site revision
STUDYVERSIONID	Study version associated with subject's site
SUBJECTINITIALS	Subject initials
SUBJECTDOB	Subject DOB
SUBJECTDOBVALIDMAP	Indicates valid date components that comprise the DOB. 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's state was last changed
SUBJECTSTATETEXT	Textual description of subject state: Screened Screen Failed Enroll Failed Enrolled Randomized Complete Not Complete

IRV_CUR_SUBJECT	
Column Name (Key indicator)	Column Description
SUBJECTSTATE	Numeric value for subject state: 1 - Screened 2 - Screen Failed 3 - Enroll Failed 4 - Enrolled 5 - Randomized 6 - Complete 7 - Not Complete
SUBJECTSCREENED	Subject is currently screened: 0 - no 1 - yes
SUBJECTEVERSCREENED	Has subject ever been screened: 0 - no 1 - yes
MINSCREEN	First system screening date
MAXSCREEN	Most recent system screening date
SUBJECTSCREENFAIL	Subject is currently screen failed: 0 - no 1 - yes
SUBJECTEVERSCREENFAIL	Has subject ever been screen failed: 0 - no 1 - yes
MINSCREENFAIL	First system screening failure date
MAXSCREENFAIL	Most recent system screening failure date
SUBJECTSCREENFAILTEXT	Screening failure reason
SUBJECTENROLLFAIL	Subject is currently enrollment failed: 0 - no 1 - yes
SUBJECTEVERENROLLFAIL	Has Subject ever been enrollment failed: 0 - no 1 - yes
MINENROLLFAIL	First system enrollment failure date
MAXENROLLFAIL	Most recent system enrollment failure date
SUBJECTENROLLFAILTEXT	Enrollment failure reason

IRV_CUR_SUBJECT	
Column Name (Key indicator)	Column Description
SUBJECTENROLLED	Subject is currently enrolled: 0 - no 1 - yes
SUBJECTEVERENROLLED	Has Subject ever been enrolled: 0 - no 1 - yes
SUBJECTENROLLDATE	First system enrollment date
MAXENROLLED	Most recent system enrollment date
SUBJECTENROLLOVERRIDE TEXT	Enrollment override reason
SUBJECTRANDOMIZED	Subject is currently randomized: 0 - no 1 - yes
SUBJECTEVERRANDOMIZED	Has subject ever been randomized: 0 - no 1 - yes
MINRANDOMIZED	First system randomization date
MAXRANDOMIZED	Most recent system randomization date
SUBJECTCOMPLETED	Subject is currently complete: 0 - no 1 - yes
SUBJECTEVERCOMPLETED	Has subject ever been complete: 0 - no 1 - yes
MINCOMPLETED	First system subject completed date
MAXCOMPLETED	Most recent subject completed date
SUBJECTINCOMPLETE	Subject is currently not complete: 0 - no 1 - yes
SUBJECTEVERINCOMPLETE	Has subject ever been not complete: 0 - no 1 - yes
MINNOTCOMPLETED	First system subject dropout date
MAXNOTCOMPLETED	Most recent subject dropout date

IRV_CUR_SUBJECT	
Column Name (Key indicator)	Column Description
BOOKSIGNED	Date subject CRB signed
BOOKFROZEN	Date subject CRB frozen
BOOKLOCKED	Date subject CRB locked
BOOKSDVREADY	Date subject CRB source verified ready
COUNTBOOKSIGNED	Subject CRB has been signed
COUNTBOOKFROZEN	Subject CRB has been frozen
COUNTBOOKLOCKED	Subject CRB has been locked
COUNTBOOKSDVREADY	Subject CRB has been source verified 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)	Subject numeric identifier
SUBJECTREV	Subject revision
SUBJECTNUMBERSTR	Subject number
SUBJHIST	Subject HISTORICALORDER
SUBJTIME	Subject revision timestamp
USERID	User that last modified the subject
TRANSACTIONID	Transaction that last modified the subject
SITEID	Site the user is assigned to
SITEREV	Site revision
STUDYVERSIONID	Study version associated with subject's site
SUBJECTINITIALS	Subject initials
SUBJECTDOB	Subject DOB
SUBJECTDOBVALIDMAP	Indicates valid date components that comprise the DOB. 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	Clinical subject screening date

IRV_CUR_SUBJECT_DIM	
Column Name (Key indicator)	Column Description
SUBJECTSCREENINGDATEVALID MAP	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's state was last changed
SUBJECTSTATETEXT	Textual description of subject state: Screened Screen Failed Enroll Failed Enrolled Randomized Complete Not Complete
SUBJECTSTATE	Numeric value for subject state: 1 - Screened 2 - Screen Failed 3 - Enroll Failed 4 - Enrolled 5 - Randomized 6 - Complete 7 - Not Complete
MINSCREEN	First system screening date
MAXSCREEN	Most recent system screening date
MINSCREENFAIL	First system screening failure date
MAXSCREENFAIL	Most recent system screening failure date
SUBJECTSCREENFAILTEXT	Screening failure reason
MINENROLLFAIL	First system enrollment failure date
MAXENROLLFAIL	Most recent system enrollment failure date
SUBJECTENROLLFAILTEXT	Enrollment failure reason
SUBJECTENROLLDATE	First system enrollment date
MAXENROLLED	Most recent system enrollment date
SUBJECTENROLLOVERRIDE TEXT	Enrollment override reason
MINRANDOMIZED	First system randomization date
MAXRANDOMIZED	Most recent system randomization date
MINCOMPLETED	First system subject completed date
MAXCOMPLETED	Most recent subject completed date

IRV_CUR_SUBJECT_DIM	
Column Name (Key indicator)	Column Description
MINNOTCOMPLETED	First system subject dropout date
MAXNOTCOMPLETED	Most recent subject dropout date
BOOKSIGNED	Date subject CRB signed
BOOKFROZEN	Date subject CRB frozen
BOOKLOCKED	Date subject CRB locked
BOOKSDVREADY	Date subject CRB source verified ready

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)	Subject numeric identifier
SUBJECTREV (PK)	Subject revision
SUBJECTSTATE	Subject state
SUBJECTSTATETIME	Time of state change
PREVSUBJECTSTATE	Previous subject state
PREVSUBJECTSTATETIME	Time of previous state change (NULL if first revision)
NEXTSUBJECTSTATE	Next subject state
NEXTSUBJECTSTATETIME	Time of next state change (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)	System numeric identifier
SYSTEMREV	System revision
REVTIME	Time system revision was entered into database
SYSTEMNAME	InForm system name
SYSTEMVERSIONID	System version numeric identifier

IRV_CUR_SYSTEMVERSION	
Column Name (Key indicator)	Column Description
SPONSORAPPROVALDATE	Sponsor approval date
VERSIONDESCRIPTION	InForm version description
SYSTEMVERSION	InForm system name

IRV_SYSTEMVERSIONS

This view contains information about all the InForm versions this trial has been run against.

IRV_SYSTEMVERSIONS	
Column Name (Key indicator)	Column Description
SYSTEMID (PK)	System numeric identifier
SYSTEMREV (PK)	System revision
FIRSTSYSTEMVERSION	First system version: 0 - no 1 - yes
CURRENTSYSTEMVERSION	Most recent system version: 0 - no 1 - yes
REVTIME	Time system revision was entered into database
SYSTEMNAME	InForm system name
SYSTEMVERSIONID	System version numeric identifier
SPONSORAPPROVALDATE	Sponsor approval date
VERSIONDESCRIPTION	InForm version description
SYSTEMVERSION	InForm system name

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 the row represents one user
USERTYPEID	User type numeric identifier

IRV_CUR_USER	
Column Name (Key indicator)	Column Description
USERID (PK)	User numeric identifier
USERREV	User revision
USERCREATETIME	Date the user was created
USERACTIVESTATETIME	Most recent date the user was put into the active state
USERDELETESTATETIME	Most recent date the user was put into the deleted state
USERREVTIME	Time of last user revision
USERNAME	Name of the user
RIGHTSGROUPID	Numeric identifier of the rights group the user is currently assigned to
RIGHTSGROUP	Name of the rights group to which the user is currently assigned
USERACTIVESTATE	User currently activated: 0 - no 1 - yes
USERADDRESS1	First line of the user's address.
USERADDRESS2	Second line of the user's address.
USERALTPHONENUMBER	User's alternate telephone number.
USERAUTHTYPE	Determines whether or not the user has authority to reset passwords
USERCITY	City in which the user's address is located.
USERCONFLICT	Used by synchronization to identify sync conflicts
USERCOUNTRY	Country in which the user's address is located.
USERDATEFORMAT	Desired date format for viewable InForm pages for this particular user.
USERDAYPHONENUMBER	User's daytime telephone number.
USERDELETESTATE	Indicates whether the user has been terminated: true or false. Optional. false is the default. Terminated users remain in the database.
USERDESCRIPTION	Description of the user; for example, user's role in the trial.
USERDISPLAYNAME	User name as displayed on the navigation pane in the InForm application. Maximum length is 63 characters; shorter strings are recommended.
USEREMAILADDRESS	User's e-mail address.
USERFAXNUMBER	User's fax number.

IRV_CUR_USER	
Column Name (Key indicator)	Column Description
USERFIRSTNAME	First name of the user
USERHOMESCREENURL	Local or external URL identifying the initial screen that appears when a user logs in to the InForm application. The address must include the http:// prefix and identify the server on which the file is located by name or IP address.
USERIMAGEID	Name of the image file that appears on the navigation panel in the InForm application above the user's name.
USERLANGID	User's preferred language.
USERLASTNAME	Last name of the user
USERPOSTALCODE	User's postal code.
USERRESETPASSWORD	Set to 1 if a user must reset a password
USERSTATEPROVINCE	State or Province where the use is located.
USERSUBJECTGUID	A GUID for the userid
USERTITLE	Title of the user. This title also appears on the navigation pane in the InForm application along with the user's name.
USERTYPE	Type for a user. Type can be: System - User with specialized system capabilities. For example, when the InForm application generates a query automatically, the user name assigned as the query originator is "autoquery." The autoquery user is a system user. Site - User associated with a site. Sponsor - User associated with a sponsor

IRV_CUR_USERLIST

This view contains user-group associations.

IRV_CUR_USERLIST	
Column Name (Key indicator)	Column Description
GROUPID (PK)	Group numeric identifier
GROUPNAME	Group name
GROUPTYPE	Group type
GROUPTYPENAME	Group type UUID
USERID (PK)	User numeric identifier

IRV_USERS_SITES

This view contains user-site associations.

IRV_USERS_SITES	
Column Name	Column Description
USERID (PK)	User numeric identifier
SITEID (PK)	Site numeric identifier
RIGHTSGROUPID	Rights group numeric identifier
USERNAME	User name
RIGHTSGROUP	Rights group name
SITEMNEMONIC	Site mnemonic
SITENAME	Site name
SITECOUNTRY	Site country

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)	User numeric identifier
USERREV (PK)	User revision
FIRSTREV	First user revision: 0 - no 1 - yes
CURRENTREV	Most recent user revision: 0 - no 1 - yes
USERACTIVESTATE	New active state - 1 active, 0 inactive
ENTEREDBY	Numeric identifier of the user making the state change
ENTEREDDATE	Time of state change
ENTEREDREASON	Action that caused the state change

IRM_USER_BLIINDED_ITEMS

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

IRM_USER_BLIINDED_ITEMS	
Column Name (Key indicator)	Column Description
USERNAME (PK)	User account name
ITEMID (PK)	Item numeric identifier
ITEMREV (PK)	Item revision number.
ITEMBLINDED	Blind flag. If value is 1, the item is blinded to this user.

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 the row represents one comment
COMMENTID (PK)	Comment numeric identifier
COMMENTTIME	Time of the most recent comment revision
COMMENTUSERID	Numeric identifier of the user that last revised the comment
COMMENTHIST	HISTORICALORDER of the last comment revision
CONTEXTID	Numeric identifier of the item or form context associated with this comment
SUBJECTVISITID	Subject visit numeric identifier
SUBJECTID	Subject numeric identifier
SITEID	Site numeric identifier
STUDYVERSIONID	Study version numeric identifier
VISITID	Visit numeric identifier
VISITREV	Visit revision
VISITINDEX	Visit instance identifier 0 - expected visit 1 - started, non-repeating visit revisionnumber - repeating visit

IRV_CUR_COMMENT	
Column Name (Key indicator)	Column Description
VISITIDX	Visit instance identifier 1 - Indicates a non-repeating visit, or the first instance of a repeating visit. Greater than 1 - Instance number within a trial for a repeating visit.
FORMID	Form numeric identifier
FORMREV	Form revision
FORMINDEX	Form instance identifier 0 - unstarted form 1 - non-repeating form revisionnumber - repeating form
FORMIDX	Form instance identifier 1 - Indicates a non-repeating form, or the first instance of a repeating form. Greater than 1 - Instance number within a visit for a repeating form.
SECTIONID	Section numeric identifier
SECTIONREV	Section revision
ITEMSETID	Itemset numeric identifier
ITEMSETREV	Itemset revision
ITEMSETINDEX	Itemset instance identifier
ITEMSETIDX	Itemset instance identifier 1 - Indicates the first row in an itemset. Greater than 1 - Row instance number within an itemset.
ITEMID	Item numeric identifier
ITEMREV	Item revision
CREVS	Number of times the comment has been revised
MINCOMMENTREV	First comment revision
MAXCOMMENTREV	Most recent comment revision
COMMENTTYPE	Type of comment: 0 - Form Comment 1 - Item Comment

IRV_CUR_COMMENT	
Column Name (Key indicator)	Column Description
CITEMCOMMENT	Comment is an item comment: 0 - no 1 - yes
CFORMCOMMENT	Comment is a form comment: 0 - no 1 - yes
COMMENTTEXT	Comment text

Trial operational data

IRV_SUBJECT_DROPOUT_REASON

This view contains subject that have dropped out of the study and the reason.

IRV_SUBJECT_DROPOUT_REASON	
Column Name (Key indicator)	Column Description
SUBJECTID (PK)	Subject numeric identifier
DROPOUTREASON	This field contains the reason text depending on usage of the suggested Study Complete 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
CSVROWID	Oracle ROWID - secondary PK
SUBJECTVISITCOUNT	Always 1, indicates the row represents one subject visit
SUBJECTID (PK)	Subject numeric identifier
SUBJECTSTATE	Numeric value for subject state: 1 - Screened 2 - Screen Failed 3 - Enroll Failed 4 - Enrolled 5 - Randomized 6 - Complete 7 - Not Complete
STUDYID	Study numeric identifier
SITEID	Site numeric identifier
STUDYVERSIONID	Study version numeric identifier
VISITID (PK)	Visit numeric identifier
VISITREV	Visit revision

IRV_SV_SUBJECTVISITS	
Column Name (Key indicator)	Column Description
VISITINDEX (PK)	Visit instance identifier 0 - expected visit 1 - started, non-repeating visit revisionnumber - repeating visit
VISITORDINAL	Visit ordinal (0, 1, 2, 3...n ordered by visitindex)
SUBJECTVISITID	Subject visit numeric identifier
SUBJECTVISITREV	Subject visit revision
VISITACTIVATED	Visit is started: 0 - no 1 - yes
VISITINCURSV	Visit is in current study version: 0 - no 1 - yes
VISITORDER	Visit order
STARTHOURSFROMPREVIOUS	Start hours from previous visit
STARTHOURSFROMENROLL	Start hours from enrollment
VISITTYPE	Visit type: 1 - Visit 2 - Enrollment 3 - Screening 4 - Monitor 5 - Status 6 - Common CRF 7 - Regdocs 8 - Visitreports 9 - Conflict 16 - Relation
VTSUBJECTVISIT	Visit type CRF: 0 - no 1 - yes
VTCOMMONCRF	Visit type Common CRF: 0 - no 1 - yes
VISITPROPERTIES	Visit properties
VISITSCHEDULED	Visit is scheduled: 0 - no 1 - yes

IRV_SV_SUBJECTVISITS	
Column Name (Key indicator)	Column Description
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 of first data entry
VISIT_LAST_ENTRY	Date when data was most recently modified for the visit
PROJECTEDSTARTHOURS	Not used
STARTDATETIME	Not used
DOV	DOV as entered
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 that 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
VISITFROZEN	All expected forms in the visit are frozen: 0 - no 1 - yes
VISITSDVCOMPLETE	All expected forms in the visit are Source-Verified complete: 0 - no 1 - yes

IRV_SV_SUBJECTVISITS	
Column Name (Key indicator)	Column Description
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 the row represents one form
AFROWID	Oracle ROWID - secondary PK
SUBJECTID (PK)	Subject numeric identifier
SITEID	Site numeric identifier
STUDYID	Study numeric identifier
STUDYVERSIONID	Study version numeric identifier
VISITID (PK)	Visit numeric identifier
VISITREV	Visit revision
VISITORDER	Visit order
VISITTYPE	Visit type: 1 - Visit 2 - Enrollment 3 - Screening 4 - Monitor 5 - Status 6 - Common CRF 7 - Regdocs 8 - Visitreports 9 - Conflict 16 - Relation

IRV_AF_SUBJECT_FORMS	
Column Name (Key indicator)	Column Description
VISITINDEX (PK)	Visit instance identifier 0 - expected visit 1 - started, non-repeating visit revisionnumber - repeating visit
SUBJECTVISITID	Subject visit numeric identifier
SUBJECTVISITREV	Subject visit revision
FORMID (PK)	Form numeric identifier
FORMREV (PK)	Form revision
FORMINDEX (PK)	Form instance identifier 0 - unstarted form 1 - non-repeating form revisionnumber - repeating form
DOV	DOV as entered
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 of first data entry
VISITDELETED	Visit has been deleted: 0 - no 1 - yes
EXPECTEDSTARTDATE	Visit expected start date (STARTHOURSFROMENROLL + subject enrolled date)
FORMORDER	Form order
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

IRV_AF_SUBJECT_FORMS	
Column Name (Key indicator)	Column Description
ALTFORM	Form is an alt form: 0 - no 1 - yes
EXPECTINGALTFORM	Form is expecting an alt form: 0 - no 1 - yes
ALTFORMID	Alt form numeric identifier
ALTFORMREV	Alt form revision
HASREQUIREDITEMS	Form has one or more required items
HASSDVREQUIREDITEMS	Form has one or more Source-Verified required items
FHREVS	Count of times the form's state has changed
MINFORMHISTORYID	First form history revision
MINFORMHISTORYREV	Most recent form history revision
MAXFORMHISTORYID	First form history numeric identifier
MAXFORMHISTORYREV	Most recent form history numeric identifier
HISTORICALORDER	HISTORICALORDER of current form state revision
USERID	Numeric identifier of the user that last changed the form's state
FORMHISTORYTIME	Time of the most recent form state change
TRANSACTIONID	Numeric identifier of the most recent transaction to change the form's state
REASON	Reason for most recent form state change
STATEHIST	Current form state
ORIGINALSTATE	Previous form state
ACTION	Special 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 started
SDVREADYSTATE	Form is in the Source-Verified ready state: 0 - no 1 - yes

IRV_AF_SUBJECT_FORMS	
Column Name (Key indicator)	Column Description
FMINSDVREADYSTATE	First time the form was placed in the Source-Verified ready state
FMAXSDVREADYSTATE	Most recent time the form was marked SV Ready
SDVPARTIALSTATE	Form is in the partially Sved state: 0 - no 1 - yes
FMINSDVPARTIALSTATE	First time the form was placed in the partially Sved state
FMAXSDVPARTIALSTATE	Most recent time the form was marked SV Partial
SDVCOMPLETESTATE	Form is in the completely Sved state: 0 - no 1 - yes
FMINSDVCOMPLETESTATE	First time the form was placed in the completely Sved state
FMAXSDVCOMPLETESTATE	Most recent time the form was marked SV Complete
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 locked
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 frozen
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 signed
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 marked complete

IRV_AF_SUBJECT_FORMS	
Column Name (Key indicator)	Column Description
HASQUERIESSTATE	Form has queries: 0 - no 1 - yes
FMINHASQUERIESSTATE	First time the form had queries
FMAXHASQUERIESSTATE	Most recent time the form had queries
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 was modified while it 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

IRV_AF_SUBJECT_FORMS	
Column Name (Key indicator)	Column Description
FMINDELETEDDYNAMICFORMS TATE	First time the form was deleted
FMAXDELETEDDYNAMICFORM STATE	Most recent time the 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
INFORMPARTIALURL_CRFVIEW	Partial InForm URL for the form
FDAYSSINCEDOV	Number of days since DOV for the visit containing this form
FDAYSSINCESTART	Count of days since the form was started
FDAYSDOVTOSTART	Count of days from DOV to form started
FDAYSDOVTOCOMPLETE	Count of days from DOV to form complete
FDAYSSSTARTTOCOMPLETE	Count of days from form started to form complete
FDAYSCOMPLETETOFROZEN	Count of days from form complete to form frozen
FDAYSCOMPLETETOSDVREADY	Count of days from form complete to Source-Verified ready
FDAYSCOMPLETETOSDVCOMPL ETE	Count of days from form complete to Source-Verified complete
FDAYSCOMPLETETOSIGNED	Count of days from form complete to signed
FDAYSSIGNTOSDVCOMPLETE	Count of days from form signed to Source-Verified complete
FDAYSSDVREADYTOSDVCOMPL ETE	Count of days from form Source-Verified ready to Source-Verified complete
FDAYSFROZENTOSDVCOMPLET E	Count of days from form frozen to Source-Verified complete
FDAYSSDVCOMPLETEETOSIGN	Count of days from form frozen to Source-Verified complete
FDAYSSIGNTOLOCK	Count of days from form signed to locked
FDAYSCOMPLETETETOLOCK	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 auto queries

IRV_AF_SUBJECT_FORMS	
Column Name (Key indicator)	Column Description
QTYPEMANUAL	Count of manual queries
QTYPECONFLICT	Count of conflict queries
QREISSUED	Count of reissued queries
QCANDIDATE	Count of candidate queries
QOPENED	Count of opened queries
QANSWERED	Count of answered queries
QCLOSED	Count of closed queries
QDELETED	Count of deleted queries
HASANSWEREDQUERY	Form has 1 or more answered queries: 0 - no 1 - yes
ITEMCOMMENTS	Count of item comments
FORMCOMMENTS	Count of form comments
HASITEMCOMMENT	Form has 1 or more item 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 plus 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 the row represents one form
AFROWID	Oracle ROWID - secondary PK
SUBJECTID (PK)	Subject numeric identifier

IRV_SV_SUBJECT_FORMS	
Column Name (Key indicator)	Column Description
SUBJECTSTATE	Numeric value for subject state: 1 - Screened 2 - Screen Failed 3 - Enroll Failed 4 - Enrolled 5 - Randomized 6 - Complete 7 - Not Complete
SITEID	Site numeric identifier
STUDYID	Study numeric identifier
STUDYVERSIONID	Study version numeric identifier
VISITID (PK)	Visit numeric identifier
VISITREV	Visit revision
VISITINDEX (PK)	Visit instance identifier 0 - expected visit 1 - started, non-repeating visit revisionnumber - repeating visit
SUBJECTVISITID	Subject visit numeric identifier
SUBJECTVISITREV	Subject visit revision
FORMID (PK)	Form numeric identifier
FORMREV (PK)	Form revision
FORMINDEX (PK)	Form instance identifier 0 - unstarted form 1 - non-repeating form revisionnumber - repeating form
INFORMACTIVATIONTIME	Date and time the form was activated
DOV	DOV as entered
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 of first data entry
VISITDELETED	Visit has been deleted: 0 - no 1 - yes

IRV_SV_SUBJECT_FORMS	
Column Name (Key indicator)	Column Description
EXPECTEDSTARTDATE	Visit expected start date (STARTHOURSFROMENROLL + subject enrolled date)
FORMORDER	Form order
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 alt form: 0 - no 1 - yes
EXPECTINGALTFORM	Form is expecting an alt form: 0 - no 1 - yes
ALTFORMID	Alt form numeric identifier
ALTFORMREV	Alt form revision
ALTFORM	Form is an alt form: 0 - no 1 - yes
HASREQUIREDITEMS	Form has one or more required items
HASDVREQUIREDITEMS	Form has one or more Source-Verified required items
EXPECTEDFORM	Form is expected: 0 - no 1 - yes
FHREVS	Count of times the form's state has changed
MINFORMHISTORYID	First form history revision
MINFORMHISTORYREV	Most recent form history revision
MAXFORMHISTORYID	First form history numeric identifier
MAXFORMHISTORYREV	Most recent form history numeric identifier

IRV_SV_SUBJECT_FORMS	
Column Name (Key indicator)	Column Description
HISTORICALORDER	HISTORICALORDER of current form state revision
USERID	Numeric identifier of the user that last changed the form's state
FORMHISTORYTIME	Time of the most recent form state change
TRANSACTIONID	Numeric identifier of the most recent transaction to change the form's state
REASON	Reason for most recent form-state change
STATEHIST	Current form state
ORIGINALSTATE	Previous form state
ACTION	Special 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 started
SDVREADYSTATE	Form is in the Source Verified (SV)-ready state: 0 - no 1 - yes
FMINSDVREADYSTATE	First time the form was placed in the Source-Verified-ready state
FMAXSDVREADYSTATE	Most recent time the form was marked SV Ready
SDVPARTIALSTATE	Form is in a partial Source-Verified state: 0 - no 1 - yes
FMINSDVPARTIALSTATE	First time the form was placed in the partial Source-Verified state
FMAXSDVPARTIALSTATE	Most recent time the form was marked SV Partial
SDVCOMPLETESTATE	Form is in the completed Source Verified state: 0 - no 1 - yes
FMINSDVCOMPLETESTATE	First time the form was placed in the complete Source Verified state
FMAXSDVCOMPLETESTATE	Most recent time the form was marked SV Complete

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 locked
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 frozen
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 signed
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 marked complete
HASQUERIESSTATE	Form has queries: 0 - no 1 - yes
FMINHASQUERIESSTATE	First time the form had queries
FMAXHASQUERIESSTATE	Most recent time the form had queries
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

IRV_SV_SUBJECT_FORMS	
Column Name (Key indicator)	Column Description
FMAXHASDATASTATE	Most recent time the form was modified while it 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 form was deleted
FMAXDELETEDDYNAMICFORMSTATE	Most recent time the 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
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

IRV_SV_SUBJECT_FORMS	
Column Name (Key indicator)	Column Description
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
FDAYSCOMPLETEFROZEN	Count of days from form complete to form frozen
FDAYSCOMPLETEOSDVREADY	Count of days from form complete to Source-Verified ready
FDAYSCOMPLETEOSDVCOMPLETE	Count of days from form complete to Source-Verified complete
FDAYSCOMPLETEOSIGNED	Count of days from form complete to signed
FDAYSSIGNTOOSDVCOMPLETE	Count of days from form signed to Source-Verified complete
FDAYSSDVREADYTOOSDVCOMPLETE	Count of days from form Source-Verified ready to Source-Verified complete
FDAYSFROZENTOSDVCOMPLETE	Count of days from form frozen to Source-Verified complete
FDAYSSDVCOMPLETEOSIGN	Count of days from form frozen to Source-Verified complete
FDAYSSIGNTOLOCK	Count of days from form signed to locked
FDAYSCOMPLETEOLOCK	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 auto queries
QTYPEMANUAL	Count of manual queries
QTYPECONFLICT	Count of conflict queries
QREISSUED	Count of reissued queries
QCANDIDATE	Count of candidate queries
QOPENED	Count of opened queries
QANSWERED	Count of answered queries
QCLOSED	Count of closed queries
QDELETED	Count of deleted queries
HASANSWEREDQUERY	Form has 1 or more answered queries: 0 - no 1 - yes
ITEMCOMMENTS	Count of item comments

IRV_SV_SUBJECT_FORMS	
Column Name (Key indicator)	Column Description
FORMCOMMENTS	Count of form comments
HASITEMCOMMENT	Form has 1 or more item comments: 0 - no 1 - yes

IRV_CRF_STATUS_REPORT

This view contains information about forms. It contains a subset of the data for all of the forms from IRV_SV_SUBJECT_FORMS with labels such as Site Name, Visit Name already 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
AFROWID	Oracle ROWID - secondary PK
STUDYID	Study numeric identifier
STUDYVERSIONID	Study version numeric identifier
SUBJECTID (PK)	Subject numeric identifier
SITEID	Site numeric identifier
VISITID (PK)	Visit numeric identifier
VISITREV	Visit revision
VISITINDEX (PK)	Visit instance identifier 0 - expected visit 1 - started, non-repeating visit revisionnumber - repeating visit
FORMID (PK)	Form numeric identifier
FORMREV (PK)	Form revision
FORMINDEX (PK)	Form instance identifier 0 - unstarted form 1 - non-repeating form revisionnumber - repeating form
INFORMACTIVATIONTIME	Date and time the form was activated
SITENAME	Site name
SITEMNEMONIC	Site mnemonic

IRV_CRF_STATUS_REPORT	
Column Name (Key indicator)	Column Description
SITECOUNTRY	Site country
SUBJECTNUMBERSTR	Subject number
SUBJECTSTATE	Subject state
SUBJECTENROLLED	Subject is currently enrolled: 0 - no 1 - yes
SUBJECTEVERENROLLED	Has subject ever been enrolled: 0 - no 1 - yes
SUBJECTRAMDOMIZED	Subject is currently randomized: 0 - no 1 - yes
SUBJECTEVERRAMDOMIZED	Has subject ever been randomized: 0 - no 1 - yes
SUBJECTCOMPLETED	Subject is currently complete: 0 - no 1 - yes
SUBJECTEVERCOMPLETED	Has subject ever been complete: 0 - no 1 - yes
SUBJECTINCOMPLETE	Subject is currently not complete: 0 - no 1 - yes
SUBJECTEVERINCOMPLETE	Has subject ever been not complete: 0 - no 1 - yes
VISITREFNAME	Visit RefName
VISITNAME	Visit name
VISITMNEMONIC	Visit mnemonic
VISITDELETED	Visit has been deleted: 0 - no 1 - yes

IRV_CRF_STATUS_REPORT	
Column Name (Key indicator)	Column Description
EXPECTEDSTARTDATE	Visit expected start date (STARTHOURSFROMENROLL + subject enrolled date)
VISIT_FIRST_ENTRY	Date of first data entry
DOV	DOV as entered
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	Form RefName
FORMNAME	Form name
FORMMNEMONIC	Form mnemonic
FORMORDER	Form order
ACTUALFORM	Form actually exists within the InForm application: 0 - no 1 - yes
EXPECTEDFORM	Form is expected: 0 - no 1 - yes
HASREQUIREDITEMS	Form has required items: 0 - no 1 - yes
HASDVREQUIREDITEMS	Form has Source-Verify required items: 0 - no 1 - yes
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 Source-Verified ready state: 0 - no 1 - yes

IRV_CRF_STATUS_REPORT	
Column Name (Key indicator)	Column Description
SDVPARTIALSTATE	Form is in the Source-Verified partial state: 0 - no 1 - yes
SDVCOMPLETESTATE	Form is in the Source-Verified complete 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 completed state: 0 - no 1 - yes
HASDATASTATE	Form has data: 0 - no 1 - yes
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

IRV_CRF_STATUS_REPORT	
Column Name (Key indicator)	Column Description
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 auto queries
QTYPEMANUAL	Count of manual queries
QTYPECONFLICT	Count of conflict queries
QREISSUED	Count of reissued queries
QCANDIDATE	Count of candidate queries
QOPENED	Count of opened queries
QANSWERED	Count of answered queries
QCLOSED	Count of closed queries
QDELETED	Count of deleted queries
COMMENTCOUNT	Count of comments
CITEMCOMMENT	Count of item comments
CFORMCOMMENT	Count of form comments

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 the row represents one item on a form
CSVROWID	Oracle ROWID denoting visit
AFROWID	Oracle ROWID denoting form
CONTEXTID (PK)	Item numeric identifier
SUBJECTID	Subject numeric identifier
STUDYID	Study numeric identifier

IRV_FORM_ITEMS	
Column Name (Key indicator)	Column Description
STUDYVERSIONID	Study version numeric identifier
SITEID	Site numeric identifier
SUBJECTVISITID	Subject visit numeric identifier
VISITID	Visit numeric identifier
VISITREV	Visit revision
VISITINDEX	Visit instance identifier 0 - expected visit 1 - started, non-repeating visit revisionnumber - repeating visit
FORMID	Form numeric identifier
FORMREV	Form revision
FORMINDEX	Form instance identifier 0 - unstarted form 1 - non-repeating form revisionnumber - repeating form
SECTIONID	Section numeric identifier
SECTIONREV	Section revision
FORMSECTIONORDER	Section order
ITEMSETID	Itemset numeric identifier
ITEMSETREV	Itemset revision
ITEMSETINDEX	Itemset instance identifier
ITEMID	Item numeric identifier
ITEMREV	Item revision
SECTIONITEMORDER	Item/itemset order within the section
ITEMSETITEMORDER	Item order within itemset
INFORMPARTIALURL_CRFVIEW	Partial InForm URL for the form
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 has changed state

IRV_FORM_ITEMS	
Column Name (Key indicator)	Column Description
MINCONTEXTREV	First item state change revision
MAXCONTEXTREV	Most recent item state change revision
STATEUSERID	Numeric identifier of the user that made the most recent item state change
STATETIME	Time of the most recent item state change
STATETRANSACTIONID	Transaction numeric identifier associated with the most recent item state change
STATEREASON	Reason for the most recent item state change
ITEMDELETED	Item has been deleted: 0 - no 1 - yes
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's data has changed
MINAUDITORDER	First item data change revision
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 data had data
ITEMHASQUERIES	Item has queries: 0 - no 1 - yes
QUERIES	Count of queries against the item
QTYPEAUTO	Count of auto queries
QTYPEMANUAL	Count of manual queries
QTYPECONFLICT	Count of conflict queries
QREISSUED	Count of reissued queries

IRV_FORM_ITEMS	
Column Name (Key indicator)	Column Description
QCANDIDATE	Count of candidate queries
QOPENED	Count of opened queries
QANSWERED	Count of answered queries
QCLOSED	Count of closed queries
QDELETED	Count of deleted queries
ITEMHASCOMMENTS	Item has comments: 0 - no 1 - yes
ITEMCOMMENTS	Count of comments
CONTROLS	Count of controls in the item
CONTROLSWITHDATA	Count of controls with 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

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 the row represents one query
QUERYID (PK)	Query numeric identifier
QUERYTIME	Time of most recent query revision
QUERYUSERID	Numeric identifier of the user that last revised the query
QUERYHIST	HISTORICALORDER of the last query revision
CONTEXTID	Numeric identifier of the item context associated with this query
SUBJECTVISITID	Subject visit numeric identifier

IRV_CUR_QUERY	
Column Name (Key indicator)	Column Description
SUBJECTID	Subject numeric identifier
STUDYID	Study numeric identifier
SITEID	Site numeric identifier
STUDYVERSIONID	Study version numeric identifier
VISITID	Visit numeric identifier
VISITREV	Visit revision
VISITINDEX	Visit instance identifier 0 - expected visit 1 - started, non-repeating visit revisionnumber - repeating visit
FORMID	Form numeric identifier
FORMREV	Form revision
FORMINDEX	Form instance identifier 0 - unstarted form 1 - non-repeating form revisionnumber - repeating form
SECTIONID	Section numeric identifier
SECTIONREV	Section revision
ITEMSETID	Itemset numeric identifier
ITEMSETREV	Itemset revision
ITEMSETINDEX	Itemset instance identifier
ITEMID	Item numeric identifier
ITEMREV	Item revision
QREVS	Number of times the query has been revised
MINQUERYREV	First query revision
MAXQUERYREV	Most recent query revision
QUERYTYPE	Query type: 0 - Auto 1 - Manual 2 - Conflict
QTYPEAUTO	Query type is auto: 0 - no 1 - yes

IRV_CUR_QUERY	
Column Name (Key indicator)	Column Description
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
QREISSUED	Query is reissued: 0 - no 1 - yes
QCANDIDATE	Query state is candidate: 0 - no 1 - yes
QOPENED	Query state is opened: 0 - no 1 - yes
QANSWERED	Query state is answered- 1 yes, 0 no
QCLOSED	Query state is closed: 0 - no 1 - yes
QDELETED	Query state is deleted: 0 - no 1 - yes
QUERYGROUP	Numeric identifier of associated query group
QUERYDATA	Current query text
RULEITEMID	Numeric identifier of the ruleitem that generated this query
RULEID	Numeric identifier of the rule that generated this query
CONFLICTSTATE	Contains an explanation of a query that is in conflict
INFORMPARTIALURL_QUERY	Partial InForm URL for the form

IRV_CUR_QUERY	
Column Name (Key indicator)	Column Description
QORIGUSER	Numeric identifier of the user that 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 open to answered
QDAYSANSWERTOCLOSE	Number of days from answered to closed
QDAYSOPENTOCLOSE	Number of days from opened to closed
QCOUNTREISSUED	Count of times the query was reissued
QMINREISSUED	Time of first reissue
QMAXREISSUED	Time of most recent reissue
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	Time of first candidate state
QMAXCANDIDATE	Time of most recent candidate state
FIRSTCANDIDATETEXT	Query text associated with first candidate state
LASTCANDIDATETEXT	Query text associated with most recent candidate state
QCOUNTOPENED	Count of times the query was in the opened state
QMINOPENED	Time of first opened state
QMAXOPENED	Time of most recent opened state
FIRSTOPENEDTEXT	Query text associated with first opened state
LASTOPENEDTEXT	Query text associated with most recent opened state
QCOUNTANSWERED	Count of times the query was in the answered state
QMINANSWERED	Time of first answered state
QMAXANSWERED	Time of most recent answered state
FIRSTANSWEREDTEXT	Query text associated with first answered state
LASTANSWEREDTEXT	Query text associated with most recent answered state
QCOUNTCLOSED	Count of times the query was in the closed state
QMINCLOSED	Time of first closed state
QMAXCLOSED	Time of most recent closed state
FIRSTCLOSEDTEXT	Query text associated with first closed state
LASTCLOSEDTEXT	Query text associated with most recent closed state

IRV_CUR_QUERY	
Column Name (Key indicator)	Column Description
QCOUNTDELETED	Count of times the query was in the deleted state
QMINDELETED	Time of first deleted state
QMAXDELETED	Time of most recent deleted state
FIRSTDELETEDTEXT	Query text associated with first deleted state
LASTDELETEDTEXT	Query text associated with most recent 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)	Query numeric identifier
QUERYREV (PK)	Query revision
QUERYSTATE	Query state: 0 - Candidate 1 - Opened 2 - Answered 3 - Closed 4 - Deleted
QUERYSTATETIME	Time of state change
QUERYUSERID	Numeric identifier of user that made the change
QUERYTEXT	Text associated with the change
QSTATEORDER	Query change ordinal 1..n (ordered by QUERYREV)
PREVQUERYSTATE	Previous query state (NULL if first revision)
PREVQUERYSTATETIME	Previous state time (NULL if first revision)
PREVQUERYUSERID	Previous state user (NULL if first revision)
PREVQUERYTEXT	Previous query text (NULL if first revision)
NEXTQUERYSTATE	Next query state (NULL if current revision)
NEXTQUERYSTATETIME	Next state time (NULL if current revision)
NEXTQUERYUSERID	Next query user (NULL if current revision)
NEXTQUERYTEXT	Next query text (NULL if current revision)

IRV_USER_HISTORICAL_CHANGES

This view contains status and group membership data for a user.

IRV_USER_HISTORICAL_CHANGES	
Column Name (Key indicator)	Column Description
USERID	Numerical identifier for the user whose data is displayed.
CHANGETYPE	Type of change for the user.
CHANGETYPEDESCRIPTION	Description of the type of change for the user.
ENTEREDDATE	Date and time at which the user status or group membership changed.
ENTEREDUSERID	Numerical identifier for the user who made the status or group membership change.
ENTEREDUSERNAME	User name of the user who made the status or group membership change.
ENTEREDREASON	Reason for change entered for the status or group membership change.
GROUPID	Numerical identifier of the group whose membership information changed.
GROUPNAME	Name of the group whose membership information changed.
GROUPTYPE	Type of the group whose membership information changed.
HISTORICALORDER	Sequential numeric identifier that corresponds to the current status or group membership transaction.

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 the row represents one site
SITEID (PK)	Site numeric identifier
FORMSSTARTED	Number of forms in the started state
FORMSSDVREADY	Number of forms in the source-verify ready state
FORMSSDVPARTIAL	Number of forms in the source-verify partial state
FORMSSDVCOMPLETE	Number of forms in the source-verify complete state
FORMSLOCKED	Number of forms in the locked state
FORMSFROZEN	Number of forms in the frozen state
FORMSSIGNED	Number of forms in the signed state
FORMSCOMPLETE	Number of forms in the complete state
FORMSHAVEQUERIES	Number of forms that have queries
FORMSHAVECOMMENTS	Number of forms that have comments
FORMSHAVEDATA	Number of forms that have data
FORMSMISSINGITEMS	Number of forms that are missing required items
FORMSNOTDONE	Number of forms that are 'not done'
FORMSDELETED	Number of forms that have been removed
FORMSDELETEDDYNAMICFORM	Number of dynamic forms that have been removed
FORMSBOOKSIGN	Number of forms that represent a CRB signing

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 the row represents one study
STUDYID (PK)	Study numerical identifier
FORMSSTARTED	Number of forms in the started state
FORMSSDVREADY	Number of forms in the Source-Verify ready state
FORMSSDVPARTIAL	Number of forms in the Source-Verify partial state
FORMSSDVCOMPLETE	Number of forms in the Source-Verify complete state
FORMSLOCKED	Number of forms in the locked state
FORMSFROZEN	Number of forms in the frozen state
FORMSSIGNED	Number of forms in the signed state
FORMSCOMPLETE	Number of forms in the complete state
FORMSHAVEQUERIES	Number of forms that have queries
FORMSHAVECOMMENTS	Number of forms that have comments
FORMSHAVEDATA	Number of forms that have data
FORMSMISSINGITEMS	Number of forms that are missing required items
FORMSNOTDONE	Number of forms that are 'not done'
FORMSDELETED	Number of forms that have been removed
FORMSDELETEDDYNAMICFOR M	Number of dynamic forms that have been removed
FORMSBOOKSIGN	Number of forms that represent a CRB signing

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 the row represents one study version
STUDYVERSIONID (PK)	Study version numerical identifier
FORMSSTARTED	Number of forms in the started state
FORMSSDVREADY	Number of forms in the Source-Verify ready state

IRV_AF_ROLLUP_STUDYVERSIONS	
Column Name (Key indicator)	Column Description
FORMSSDVPARTIAL	Number of forms in the Source-Verify partial state
FORMSSDVCOMPLETE	Number of forms in the Source-Verified complete state
FORMSLOCKED	Number of forms in the locked state
FORMSFROZEN	Number of forms in the frozen state
FORMSSIGNED	Number of forms in the signed state
FORMSCOMPLETE	Number of forms in the complete state
FORMSHAVEQUERIES	Number of forms that have queries
FORMSHAVECOMMENTS	Number of forms that have comments
FORMSHAVEDATA	Number of forms that have data
FORMSMISSINGITEMS	Number of forms that are missing required items
FORMSNOTDONE	Number of forms that are 'not done'
FORMSDELETED	Number of forms that have been removed
FORMSDELETEDDYNAMICFORM	Number of dynamic forms that have been removed
FORMSBOOKSIGN	Number of forms that represent a CRB signing

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 the row represents one subject
SUBJECTID (PK)	Subject numerical identifier
FORMSSTARTED	Number of forms in the started state
FORMSSDVREADY	Number of forms in the source-verify ready state
FORMSSDVPARTIAL	Number of forms in the source-verify partial state
FORMSSDVCOMPLETE	Number of forms in the source-verify complete state
FORMSLOCKED	Number of forms in the locked state
FORMSFROZEN	Number of forms in the frozen state
FORMSSIGNED	Number of forms in the signed state
FORMSCOMPLETE	Number of forms in the complete state
FORMSHAVEQUERIES	Number of forms that have queries

IRV_AF_ROLLUP_SUBJECTS	
Column Name (Key indicator)	Column Description
FORMSHAVECOMMENTS	Number of forms that have comments
FORMSHAVEDATA	Number of forms that have data
FORMSMISSINGITEMS	Number of forms that are missing required items
FORMSNOTDONE	Number of forms that are 'not done'
FORMSDELETED	Number of forms that have been removed
FORMSDELETEDDYNAMICFORM	Number of dynamic forms that have been removed
FORMSBOOKSIGN	Number of forms that represent a CRB signing

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 the row represents one subject visit
CSVROWID (PK)	Subject visit unique identifier (Oracle ROWID)
FORMSSTARTED	Number of forms in the started state
FORMSSDVREADY	Number of forms in the source-verify ready state
FORMSSDVPARTIAL	Number of forms in the source-verify partial state
FORMSSDVCOMPLETE	Number of forms in the source-verify complete state
FORMSLOCKED	Number of forms in the locked state
FORMSFROZEN	Number of forms in the frozen state
FORMSSIGNED	Number of forms in the signed state
FORMSCOMPLETE	Number of forms in the complete state
FORMSHAVEQUERIES	Number of forms that have queries
FORMSHAVECOMMENTS	Number of forms that have comments
FORMSHAVEDATA	Number of forms that have data
FORMSMISSINGITEMS	Number of forms that are missing required items
FORMSNOTDONE	Number of forms that are 'not done'
FORMSDELETED	Number of forms that have been removed
FORMSDELETEDDYNAMICFORM	Number of dynamic forms that have been removed
FORMSBOOKSIGN	Number of forms that represent a CRB signing

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 the row represents one site
SITEID (PK)	Site numerical identifier
SITEVISITS	Count of visits
SITE_FIRST_ENTRY	Earliest data entry
SITE_LAST_ENTRY	Date when data was most recently modified for the site
FIRSTDOV	Earliest DOV
LASTDOV	Most recent DOV
VISITSDELETED	Count of deleted visits

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 the row represents one study
STUDYID (PK)	Study numerical identifier
SVVISITS	Count of visits
STUDY_FIRST_ENTRY	Earliest data entry
STUDY_LAST_ENTRY	Date when data was most recently modified for the study
FIRSTDOV	Earliest DOV
LASTDOV	Most recent DOV
VISITSDELETED	Count of deleted visits

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 the row represents one study version
STUDYVERSIONID (PK)	Study version numerical identifier
SVVISITS	Count of visits
SV_FIRST_ENTRY	Earliest data entry
SV_LAST_ENTRY	Date when data was most recently modified for the study version
FIRSTDOV	Earliest DOV
LASTDOV	Most recent DOV
VISITSDELETED	Count of deleted visits

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 the row represents one subject
SUBJECTID (PK)	Subject numerical identifier
SUBJECTVISITS	Count of visits
SUBJECT_FIRST_ENTRY	Earliest data entry
SUBJECT_LAST_ENTRY	Date when data was most recently modified for the subject
FIRSTDOV	Earliest DOV
LASTDOV	Most recent DOV
VISITSDELETED	Count of deleted visits

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 the row represents one form
CSVROWID	Oracle ROWID for the row in IRV_SV_SUBJECTVISITS that represents the visit this form is associated with
AFROWID (PK)	Oracle ROWID for the row in IRV_AF_SUBJECT_FORMS that represents this form
ITEMS	Count of items
SECTIONITEMS	Count of items in sections
ITEMSETITEMS	Count of items in itemsets
FIRSTSDVTIME	Earliest item Source-Verify time
LASTSDVTIME	Most recent item Source-Verify time
FIRSTDATATIME	Earliest item data time
LASTDATATIME	Most recent item data time
FIRSTDATATRANSACTIONID	Earliest data transaction
LASTDATATRANSACTIONID	Most recent data transaction
FIRSTSTATETIME	Earliest item state time
LASTSTATETIME	Most recent item state time
FIRSTSTATETRANSACTIONID	Earliest item state transaction
LASTSTATETRANSACTIONID	Most recent item state transaction
ITEMSDELETED	Count of deleted items
ITEMSSDVED	Count of Source-Verify items
ITEMSWITHDATA	Count of items that have data
CONTROLS	Count of controls
CONTROLWITHDATA	Count of controls with data
QUERIES	Count of queries
QTYPEAUTO	Count of auto queries
QTYPEMANUAL	Count of manual queries
QTYPECONFLICT	Count of conflict queries

IRV_IC_ROLLUP_FORMS	
Column Name (Key indicator)	Column Description
QREISSUED	Count of reissued queries
QCANDIDATE	Count of candidate queries
QOPENED	Count of opened queries
QANSWERED	Count of answered queries
QCLOSED	Count of closed queries
QDELETED	Count of deleted queries
ITEMCOMMENTS	Count of item comments
FORMCOMMENTS	Count of form comments

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 the row represents one site
SITEID (PK)	Site numerical identifier
SUBJECTVISITS	Count of visits
SUBJECTFORMS	Count of forms
ITEMS	Count of items
SECTIONITEMS	Count of items in sections
ITEMSETITEMS	Count of items in itemsets
FIRSTSDVTIME	Earliest item Source Verified time
LASTSDVTIME	Most recent item Source Verified time
FIRSTDATATIME	Earliest item data time
LASTDATATIME	Most recent item data time
FIRSTDATATRANSACTIONID	Earliest data transaction
LASTDATATRANSACTIONID	Most recent data transaction
FIRSTSTATETIME	Earliest item state time
LASTSTATETIME	Most recent item state time
FIRSTSTATESTRANSACTIONID	Earliest item state transaction
LASTSTATESTRANSACTIONID	Most recent item state transaction

IRV_IC_ROLLUP_SITES	
Column Name (Key indicator)	Column Description
ITEMSDELETED	Count of deleted items
ITEMSSDVED	Count of Source Verified items
ITEMSWITHDATA	Count of items that have data
CONTROLS	Count of controls
CONTROLSWITHDATA	Count of controls with data
QUERIES	Count of queries
QTYPEAUTO	Count of auto queries
QTYPEMANUAL	Count of manual queries
QTYPECONFLICT	Count of conflict queries
QREISSUED	Count of reissued queries
QCANDIDATE	Count of candidate queries
QOPENED	Count of opened queries
QANSWERED	Count of answered queries
QCLOSED	Count of closed queries
QDELETED	Count of deleted queries
ITEMCOMMENTS	Count of item comments
FORMCOMMENTS	Count of form comments

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 the row represents one study
STUDYID (PK)	Study numerical identifier
SUBJECTVISITS	Count of visits
SUBJECTFORMS	Count of forms
ITEMS	Count of items
SECTIONITEMS	Count of items in sections
ITEMSETITEMS	Count of items in itemsets
FIRSTSDVTIME	Earliest item Source-Verify time

IRV_IC_ROLLUP_STUDY	
Column Name (Key indicator)	Column Description
LASTSDVTIME	Most recent item Source-Verify time
FIRSTDATATIME	Earliest item data time
LASTDATATIME	Most recent item data time
FIRSTDATATRANSACTIONID	Earliest data transaction
LASTDATATRANSACTIONID	Most recent data transaction
FIRSTSTATETIME	Earliest item state time
LASTSTATETIME	Most recent item state time
FIRSTSTATESTRANSACTIONID	Earliest item state transaction
LASTSTATESTRANSACTIONID	Most recent item state transaction
ITEMSDELETED	Count of deleted items
ITEMSSDVED	Count of Source-Verified items
ITEMSWITHDATA	Count of items that have data
CONTROLS	Count of controls
CONTROLWITHDATA	Count of controls with data
QUERIES	Count of queries
QTYPEAUTO	Count of auto queries
QTYPEMANUAL	Count of manual queries
QTYPECONFLICT	Count of conflict queries
QREISSUED	Count of reissued queries
QCANDIDATE	Count of candidate queries
QOPENED	Count of opened queries
QANSWERED	Count of answered queries
QCLOSED	Count of closed queries
QDELETED	Count of deleted queries
ITEMCOMMENTS	Count of item comments
FORMCOMMENTS	Count of form comments

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 the row represents one study version
STUDYVERSIONID (PK)	Study version numerical identifier
SUBJECTVISITS	Count of visits
SUBJECTFORMS	Count of forms
ITEMS	Count of items
SECTIONITEMS	Count of items in sections
ITEMSETITEMS	Count of items in itemsets
FIRSTSDVTIME	Earliest item Source Verified time
LASTSDVTIME	Most recent item Source Verified time
FIRSTDATATIME	Earliest item data time
LASTDATATIME	Most recent item data time
FIRSTDATATRANSACTIONID	Earliest data transaction
LASTDATATRANSACTIONID	Most recent data transaction
FIRSTSTATETIME	Earliest item state time
LASTSTATETIME	Most recent item state time
FIRSTSTATETRANSACTIONID	Earliest item state transaction
LASTSTATETRANSACTIONID	Most recent item state transaction
ITEMSDELETED	Count of deleted items
ITEMSSDVED	Count of Source Verified items
ITEMSWITHDATA	Count of items that have data
CONTROLS	Count of controls
CONTROLSWITHDATA	Count of controls with data
QUERIES	Count of queries
QTYPEAUTO	Count of auto queries
QTYPEMANUAL	Count of manual queries
QTYPECONFLICT	Count of conflict queries
QREISSUED	Count of reissued queries
QCANDIDATE	Count of candidate queries

IRV_IC_ROLLUP_STUDYVERSIONS	
Column Name (Key indicator)	Column Description
QOPENED	Count of opened queries
QANSWERED	Count of answered queries
QCLOSED	Count of closed queries
QDELETED	Count of deleted queries
ITEMCOMMENTS	Count of item comments
FORMCOMMENTS	Count of form comments

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 the row represents one subject
SUBJECTID (PK)	Subject numerical identifier
SUBJECTVISITS	Count of visits
SUBJECTFORMS	Count of forms
ITEMS	Count of items
SECTIONITEMS	Count of items in sections
ITEMSETITEMS	Count of items in itemsets
FIRSTSDVTIME	Earliest item Source Verified time
LASTSDVTIME	Most recent item Source Verified time
FIRSTDATATIME	Earliest item data time
LASTDATATIME	Most recent item data time
FIRSTDATATRANSACTIONID	Earliest data transaction
LASTDATATRANSACTIONID	Most recent data transaction
FIRSTSTATETIME	Earliest item state time
LASTSTATETIME	Most recent item state time
FIRSTSTATETRANSACTIONID	Earliest item state transaction
LASTSTATETRANSACTIONID	Most recent item state transaction
ITEMSDELETED	Count of deleted items
ITEMSSDVED	Count of Source Verified items

IRV_IC_ROLLUP_SUBJECTS	
Column Name (Key indicator)	Column Description
ITEMSWITHDATA	Count of items that have data
CONTROLS	Count of controls
CONTROLSWITHDATA	Count of controls with data
QUERIES	Count of queries
QTYPEAUTO	Count of auto queries
QTYPEMANUAL	Count of manual queries
QTYPECONFLICT	Count of conflict queries
QREISSUED	Count of reissued queries
QCANDIDATE	Count of candidate queries
QOPENED	Count of opened queries
QANSWERED	Count of answered queries
QCLOSED	Count of closed queries
QDELETED	Count of deleted queries
ITEMCOMMENTS	Count of item comments
FORMCOMMENTS	Count of form comments

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 the row represents one visit
CSVROWID (PK)	Oracle ROWID for the row in IRV_SV_SUBJECTVISITS that represents the visit
SUBJECTFORMS	Count of forms
ITEMS	Count of items
SECTIONITEMS	Count of items in sections
ITEMSETITEMS	Count of items in itemsets
FIRSTSDVTIME	Earliest item Source Verified time
LASTSDVTIME	Most recent item Source Verified time
FIRSTDATATIME	Earliest item data time
LASTDATATIME	Most recent item data time

IRV_IC_ROLLUP_VISITS	
Column Name (Key indicator)	Column Description
FIRSTDATATRANSACTIONID	Earliest data transaction
LASTDATATRANSACTIONID	Most recent data transaction
FIRSTSTATETIME	Earliest item state time
LASTSTATETIME	Most recent item state time
FIRSTSTATESTRANSACTIONID	Earliest item state transaction
LASTSTATESTRANSACTIONID	Most recent item state transaction
ITEMSDELETED	Count of deleted items
ITEMSSDVED	Count of Source Verified items
ITEMSWITHDATA	Count of items that have data
CONTROLS	Count of controls
CONTROLSWITHDATA	Count of controls with data
QUERIES	Count of queries
QTYPEAUTO	Count of auto queries
QTYPEMANUAL	Count of manual queries
QTYPECONFLICT	Count of conflict queries
QREISSUED	Count of reissued queries
QCANDIDATE	Count of candidate queries
QOPENED	Count of opened queries
QANSWERED	Count of answered queries
QCLOSED	Count of closed queries
QDELETED	Count of deleted queries
ITEMCOMMENTS	Count of item comments
FORMCOMMENTS	Count of form comments

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 the row represents one site
SITEID (PK)	Site numerical identifier
SUBJECTS	Number of subjects
SUBJECTSSCREENED	Number of subjects currently in the 'Screened' state
SUBJECTSEVERSCREENED	Number of subjects that have ever been 'Screened'
SUBJECTSSCREENFAIL	Number of subjects currently in the 'Screen Failed' state
SUBJECTSEVERSCREENFAIL	Number of subjects that have ever been 'Screen Failed'
SUBJECTSENROLLFAIL	Number of subjects currently in the 'Enroll Failed' state
SUBJECTSEVERENROLLFAIL	Number of subjects that have ever been 'Enroll Failed'
SUBJECTSENROLLED	Number of subjects currently in the 'Enrolled' state
SUBJECTSEVERENROLLED	Number of subjects that have ever been 'Enrolled'
SUBJECTSRANDOMIZED	Number of subjects currently in the 'Randomized' state
SUBJECTSEVERRANDOMIZED	Number of subjects that have ever been 'Randomized'
SUBJECTSCOMPLETED	Number of subjects currently in the 'Completed' state
SUBJECTSEVERCOMPLETED	Number of subjects that have ever been 'Completed'
SUBJECTSINCOMPLETE	Number of subjects currently in the 'Dropped Out' state
SUBJECTSEVERINCOMPLETE	Number of subjects that have ever been 'Dropped Out'
COUNTBOOKSIGNED	Number of subject case books signed
COUNTBOOKFROZEN	Number of subject case books frozen
COUNTBOOKLOCKED	Number of subject case books locked
COUNTBOOKSDVREADY	Number of subject case books Source-Verified ready
FIRSTBOOKSIGNED	Date of first case book signed
LASTBOOKSIGNED	Date of most recent case book signed
FIRSTBOOKFROZEN	Date of first case book frozen
LASTBOOKFROZEN	Date of most recent case book frozen
FIRSTBOOKLOCKED	Date of first case book locked

IRV_SUBJ_ROLLUP_SITES	
Column Name (Key indicator)	Column Description
LASTBOOKLOCKED	Date of most recent case book locked
FIRSTBOOKSDVREADY	Date of first case book Source-Verified ready
LASTBOOKSDVREADY	Date of most recent case book Source-Verified ready

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 the row represents one study
STUDYID (PK)	Study numerical identifier
SUBJECTS	Number of subjects
SUBJECTSSCREENED	Number of subjects currently in the 'Screened' state
SUBJECTSEVERSCREENED	Number of subjects that have ever been 'Screened'
SUBJECTSSCREENFAIL	Number of subjects currently in the 'Screen Failed' state
SUBJECTSEVERSCREENFAIL	Number of subjects that have ever been 'Screen Failed'
SUBJECTSENROLLFAIL	Number of subjects currently in the 'Enroll Failed' state
SUBJECTSEVERENROLLFAIL	Number of subjects that have ever been 'Enroll Failed'
SUBJECTSENROLLED	Number of subjects currently in the 'Enrolled' state
SUBJECTSEVERENROLLED	Number of subjects that have ever been 'Enrolled'
SUBJECTSRANDOMIZED	Number of subjects currently in the 'Randomized' state
SUBJECTSEVERRANDOMIZED	Number of subjects that have ever been 'Randomized'
SUBJECTSCOMPLETED	Number of subjects currently in the 'Completed' state
SUBJECTSEVERCOMPLETED	Number of subjects that have ever been 'Completed'
SUBJECTSINCOMPLETE	Number of subjects currently in the 'Dropped Out' state
SUBJECTSEVERINCOMPLETE	Number of subjects that have ever been 'Dropped Out'
COUNTBOOKSIGNED	Number of subject case books signed
COUNTBOOKFROZEN	Number of subject case books frozen
COUNTBOOKLOCKED	Number of subject case books locked
COUNTBOOKSDVREADY	Number of subject case books Source-Verified ready
FIRSTBOOKSIGNED	Date of first case book signed

IRV_SUBJ_ROLLUP_STUDY	
Column Name (Key indicator)	Column Description
LASTBOOKSIGNED	Date of most recent case book signed
FIRSTBOOKFROZEN	Date of first case book frozen
LASTBOOKFROZEN	Date of most recent case book frozen
FIRSTBOOKLOCKED	Date of first case book locked
LASTBOOKLOCKED	Date of most recent case book locked
FIRSTBOOKSDVREADY	Date of first case book Source-Verified ready
LASTBOOKSDVREADY	Date of most recent case book Source-Verified ready

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 the row represents one study version
STUDYVERSIONID (PK)	Study version numerical identifier
SUBJECTS	Number of subjects
SUBJECTSSCREENED	Number of subjects currently in the 'Screened' state
SUBJECTSEVERSCREENED	Number of subjects that have ever been 'Screened'
SUBJECTSSCREENFAIL	Number of subjects currently in the 'Screen Failed' state
SUBJECTSEVERSCREENFAIL	Number of subjects that have ever been 'Screen Failed'
SUBJECTSENROLLFAIL	Number of subjects currently in the 'Enroll Failed' state
SUBJECTSEVERENROLLFAIL	Number of subjects that have ever been 'Enroll Failed'
SUBJECTSENROLLED	Number of subjects currently in the 'Enrolled' state
SUBJECTSEVERENROLLED	Number of subjects that have ever been 'Enrolled'
SUBJECTSRANDOMIZED	Number of subjects currently in the 'Randomized' state
SUBJECTSEVERRANDOMIZED	Number of subjects that have ever been 'Randomized'
SUBJECTSCOMPLETED	Number of subjects currently in the 'Completed' state
SUBJECTSEVERCOMPLETED	Number of subjects that have ever been 'Completed'
SUBJECTSINCOMPLETE	Number of subjects currently in the 'Dropped Out' state
SUBJECTSEVERINCOMPLETE	Number of subjects that have ever been 'Dropped Out'
COUNTBOOKSIGNED	Number of subject case books signed

IRV_SUBJ_ROLLUP_STUDYVERSIONS	
Column Name (Key indicator)	Column Description
COUNTBOOKFROZEN	Number of subject case books frozen
COUNTBOOKLOCKED	Number of subject case books locked
COUNTBOOKSDVREADY	Number of subject case books Source-Verified ready
FIRSTBOOKSIGNED	Date of first case book signed
LASTBOOKSIGNED	Date of most recent case book signed
FIRSTBOOKFROZEN	Date of first case book frozen
LASTBOOKFROZEN	Date of most recent case book frozen
FIRSTBOOKLOCKED	Date of first case book locked
LASTBOOKLOCKED	Date of most recent case book locked
FIRSTBOOKSDVREADY	Date of first case book Source-Verified ready
LASTBOOKSDVREADY	Date of most recent case book Source-Verified ready

Identifying keys

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

Object Type	InForm Key Name	Reporting Key Name	Originating View
Sponsor	SponsorID	SponsorID	IRV_CUR_SPONSOR
Trial	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	IRF_AF_SUBJECT_FOR MS
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

In this chapter

Clinical metadata.....	96
Clinical data view generation	99
Clinical data audit information	112
Cognos 8 Business Intelligence models.....	115
Auto-generated mappings	117

Clinical metadata

CV_DATADictionary

The controls for a CRF are mapped into zero, one, or more than one column of a Clinical View. A Clinical View column can contain either an arbitrary value or a list of predefined values (Radiobox, Pulldown, Units, and so on). In the first case, a column is represented by a single row in the CV_DATADictionary tables, and in the second case, a column is represented by multiple rows which correspond to all potential values of the column.

This table is essential for the generated Clinical View customization process. The following table lists the Column Name, provides a description of the column value in the Column Description column, and identifies the Usage Indicator as (PK) for key columns, (INF) for information columns, and CUST for columns that can be customized.

CV_DATADictionary		
Column Name	Usage Indicator	Column Description
FORMREFNAME	PK	Form REFNAME
SECTIONREFNAME	PK	Section REFNAME
ITEMREFNAME	PK	Item REFNAME
CHILDITEMREFNAME	PK	Childitem REFNAME (for Itemsets)
CTL0REFNAME	PK	Top level Control REFNAME
CTL1REFNAME	PK	Second level Control REFNAME
CTL2REFNAME	PK	Third level Control REFNAME
CTL3REFNAME	PK	Fourth level Control REFNAME
CTL4REFNAME	PK	Fifth level Control REFNAME
RAWCOLUMNNAME	PK	Generated name (typically Item REFNAME+Control REFNAME)

CV_DATADICTIONARY		
Column Name	Usage Indicator	Column Description
COLUMNTYPE	PK	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	INF	Generated DB column type 1 - string 2 - Integer 3 - float 4 - datetime
COLUMNVALUEREFN AME	PK	If column has a list of values, this is its value REFNAME. For Units it uses Unit's REFNAME, for Radio/Checkbox control it uses child control REFNAME, for Pulldown control it uses element REFNAME

CV_DATADICTIONARY		
Column Name	Usage Indicator	Column Description
COLUMNFLOATPRECISION	INF	Column precision. Used only for Float TEXT controls and is NULL for all other columns
FORMNAME	INF	Form Name
SECTIONHEADER	INF	Section Header
ITEMQUESTION	INF	Item Question
CONTROLCAPTION	INF	Control Caption
SECTIONORDER	INF	Section order (within a Form)
ITEMORDER	INF	Item Order (within a Section)
CHILDITEMORDER	INF	Childitem Order (for Itemsets only; for item within Itemset)
VIEWNAME	CUST	Clinical View Name
VIEWLABEL	CUST	Correspondent Cognos model Query subject name
VIEWDESC	CUST	Correspondent Cognos model Query subject description
COLUMNFOLDER	CUST	Query subject Folder. Only one of the 3 predefined Folders allowed: Basic Data Additional Data Incomplete Data Reasons
COLUMNENABLE	CUST	If value is 0 this column suppressed from Clinical View and Clinical Query Subject
COLUMNNAME	CUST	Clinical Column Name (The logic used to build this columnname is described in the clinical views description.)
COLUMNLABEL	CUST	Correspondent Cognos model Query subject item name
COLUMNDESC	CUST	Correspondent Cognos model Query subject item description
COLUMNVALUE	CUST	Column Value. It is one of the set of values pertain to the Clinical View column/Clinical Query Subject item
SASDATASETNAME	NA	Null value. Placeholder for a future feature.
SASFIELDNAME		
SDSDOMAIN		
SDSVARNAME		

Clinical data view generation

CM_<FormRefname/Itemset> MVs and CV_<FormRefname/Itemset>

Views

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

CV_<FormRefname/Itemset> objects are views of CM_ 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 and views are used to build the clinical views that are generated for each form and itemset.

CD_FORMDATA and CD_<FormRefName/Itemset> MVs

CD_FORMDATA contains the control metadata and data values for every form and itemset. CD_FORMDATA has a row for each control of an activated form with columns for context, control data, and translated metadata. CD_<FormRefname/Itemset> Mview has the same structure of CD_FORMDATA but only contains data for that form or itemset.

CD_FORMDATA and CD_<FormRefName/Itemset> MVs	
Column Name (Key indicator)	Column Description
AFROWID	IRM_ACTIVATED_FORMS Oracle ROWID.
CDROWID	IRM_ACTIVATED_FORMS Oracle ROWID.
CCDROWID	PF_CONTROLDATA2 Oracle ROWID.
NDROWID	IRM_NOTDONE_CONTROL Oracle ROWID.
CDBROWID	PF_CONTROLDATA_LONGRAW Oracle ROWID.
CDPROWID	IRT_MD_GROUP_CONTROLS Oracle ROWID.
ELROWID	IRT_ELEMENTLABELS Oracle ROWID.
U1ROWID	IRM_UNITS Oracle ROWID.
U2ROWID	IRM_UNITS2 Oracle ROWID.
SUBJECTID	Subject numeric identifier
SITEID	Site numeric identifier
STUDYVERSIONID	Study version numeric identifier
SUBJECTVISITID	Subject visit numeric identifier
SUBJECTVISITREV	Subject visit revision

CD_FORMDATA and CD_<FormRefName/Itemset> MVs	
Column Name (Key indicator)	Column Description
VISITID	Visit numeric identifier
VISITINDEX	Visit instance identifier 0 - expected visit 1 - started, non-repeating visit revisionnumber - repeating visit
FORMID (IDX)	Form numeric identifier
FORMREV	Form revision.
FORMINDEX	Form instance identifier 0 - unstarted form 1 - non-repeating form revisionnumber - repeating form
CONTROLVALUEID	Unique ID for this control value
VALUEORDER	Revision of this value record
CONTEXTID	Foreign Key to PF_ITEMDATA to PF_ITEMCONTEXT. Identifier of the Item context
AUDITORDER	FK to PF_ITEMDATA. Revision number of this row; timestamp matching transaction revision
CONTROLID	Identifier of the control meta data ID
PARENTCONTROLVALUEID	ID of the Parent Control Value (refers to this table) if this is null then this is the top level control
PARENTVALUEORDER	Corresponding revision to the ParentControlValueID
SUBJECTTYPE	Describes the form type. Patient forms are CRFs and Enrollment forms; Site type is for Reg Docs and Visit Reports: 1=Patient 2=Site
SECTIONID (IDX)	Section numeric identifier
ITEMSETID	Itemset numeric identifier
ITEMSETINDEX (IDX)	Itemset instance identifier
ITEMID	Item numeric identifier
ITEMDELETED	Item has been deleted: 0 - no 1 - yes

CD_FORMDATA and CD_<FormRefName/Itemset> MVs	
Column Name (Key indicator)	Column Description
ITEMSDVED	Item has been Source Verified: 0 - no 1 - yes
CONTROLHASDATA	Control has data: 0 - no 1 - yes
DELETEDSTATE	Item has been deleted: 0 - no 1 - yes
DATATYPE	Designates which data type is stored: -1 - INVALID 0 - NULL 1 - LONG 2 - DOUBLE 3 - STRING 4 - TEXT 5 - DATETIME 99 - DBUID
NUMVALUE	Value if DATATYPE is LONG
FLOATVALUE	Value if DATATYPE is DOUBLE
STRVALUE	Value if DATATYPE is STRING
PFDATETIME	Value if DATATYPE is DATETIME
MONTH	Month numeric value if DATATYPE is DATETIME
DAY	Day numeric value if DATATYPE is DATETIME
YEAR	Year numeric value if DATATYPE is DATETIME
HOUR	Hour numeric value if DATATYPE is DATETIME
MINUTE	Minute numeric value if DATATYPE is DATETIME
SECOND	Second numeric value if DATATYPE is DATETIME
NDCONTROLID	Not Done Control numeric ID
NDVALUE	The Not Done element name
NDLABEL	The Not Done label value
BLOBVALUELEN	Length of value if DATATYPE is TEXT
BLOBVALUESTR	Value if DATATYPE is TEXT
ELEMENTVALUE	Element value in string format.

CD_FORMDATA and CD_<FormRefName/Itemset> MVs	
Column Name (Key indicator)	Column Description
ELEMENTLABEL	Label string.
UNITID	Unit internal identifier.
UNITSYMBOL	Unit symbol string.
NORMALIZEDVALUE	Normalized unit value.
NORMALIZEDUNITID	Normalized unit internal identifier.
NORMUNITSYMBOL	Normalized unit symbol.
CID0	Root control ID
CID1	Next control ID
CID2	Next control ID
CID3	Next control ID
CID4	Next control ID

IRT_MD_GROUP_CONTROLS

This table contains information about the parent/child control relationship for each control.

IRT_MD_GROUP_CONTROLS	
Column Name (Key indicator)	Column Description
FORMID (PK)	Form numeric identifier
SECTIONID (PK)	Section numeric identifier
ITEMID (PK)	Item numeric identifier
CONTROLID (PK)	Control numeric ID
CID0	Root control ID
CID1	Next control ID
CID2	Next control ID
CID3	Next control ID
CID4	Next control ID

IRT_ELEMENTLABELS

The following table has a row for each internal value for radio button, check box and pulldown control selections and the corresponding external label.

IRT_ELEMENTLABELS	
Column Name (Key indicator)	Column Description
CONTROLID (PK)	Control numeric ID
ELEMENTVALUE (PK)	Element value in string format.
ELEMENTLABEL	Label string.

IRM_UNITS

The MView has a row for each unitid and the corresponding unit symbol.

Note: IRM_UNITS2 is a duplicate of IRM_UNITS and is needed to work around restrictions in fast refreshable MVs.

IRM_UNITS	
Column Name (Key indicator)	Column Description
CUROWID	PF_CONTROLUNIT Oracle ROWID.
UROWID	PF_UNIT Oracle ROWID.
USROWID	PF_RESOURCEDATA2 Oracle ROWID.
RDROWID	IRM_DIM_RESOURCEDATA Oracle ROWID.
DUROWID	IRM_DIM_UNITS Oracle ROWID.
CONTROLID (PK)	Control numeric ID
CONTROLREVISIONNUMBER	Control revision number.
UNITID (PK)	Unit internal identifier.
UNITREVISIONNUMBER	Unit internal revision number.
CLASSIFICATION	Type specified in the MedML such as volume or length.
UNITREFNAME	Unit refname.
UNITSYMBOL	Unit symbol string.
BASEUNITID	Unit ID of the base unit definition. If this equal to the UnitID then this is the base unit
BASEUNITREVISIONNUMBER	Base Unit revision number.

IRM_UNITS	
Column Name (Key indicator)	Column Description
CONVERTTOBASEID	Associated rule ID that will convert from this unit to the base unit; NULL if this is the base unit.
CONVERTTOBASEREVISIONNUMBER	ConvertTOBase revision number.
CONVERTFROMBASEID	Associated rule ID that will convert from the base unit to this unit; NULL if this is the base unit.
CONVERTFROMBASEREVISIONNUMBER	ConvertFromBase revision number.
DESIGNNOTE	Design note comment.

IRM_CUR_CONTROLDATA

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

IRM_CUR_CONTROLDATA	
Column Name (Key indicator)	Column Description
CDROWID	Oracle ROWID denoting PF_CONTROLDATA2 unique row ID
IDROWID	Oracle ROWID denoting IRM_DIM_ITEMDATA unique row ID
ICROWID	Oracle ROWID denoting PF_ITEMCONTEXT unique row ID
CONTROLVALUEID (PK)	Unique ID for this control value
VALUEORDER (PK)	Revision of this value record
CONTEXTID	Foreign Key to PF_ITEMDATA to PF_ITEMCONTEXT. Identifier of the Item context
AUDITORDER	FK to PF_ITEMDATA. Revision number of this row; timestamp matching transaction revision
CONTROLID	Identifier of the control meta data ID
PARENTCONTROLVALUEID	ID of the Parent Control Value (refers to this table) if this is null then this is the top level control
PARENTVALUEORDER	Corresponding revision to the ParentControlValueID
SUBJECTID	Subject numeric identifier

IRM_CUR_CONTROLDATA	
Column Name (Key indicator)	Column Description
SUBJECTTYPE	Describes the form type. Patient forms are CRFs and Enrollment forms; Site type is for Reg Docs and Visit Reports: 1=Patient 2=Site
VISITID	Visit numeric identifier
VISITINDEX	Visit instance identifier 0 - expected visit 1 - started, non-repeating visit revisionnumber - repeating visit
FORMID	Form numeric identifier
FORMREV	Form revision
FORMINDEX	Form instance identifier 0 - unstarted form 1 - non-repeating form revisionnumber - repeating form
SECTIONID	Section numeric identifier
ITEMSETID	Itemset numeric identifier
ITEMSETINDEX	Itemset instance identifier
ITEMID	Item numeric identifier
ITEMDELETED	Item has been deleted: 0 - no 1 - yes
ITEMSDVED	Item has been Source Verified: 0 - no 1 - yes
CONTROLHASDATA	Control has data: 0 - no 1 - yes

IRM_ACTIVATED_FORMS

The following materialized 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.

IRM_ACTIVATED_FORMS	
Column Name (Key indicator)	Column Description
SVECPROWID	Oracle ROWID from PF_SUBJECTVECHAPTERPAGE - surrogate PK
FROWID	Oracle ROWID from IRM_FORM_REVS
CSVROWID	Oracle ROWID from IRM_CUR_SUBJECTVISIT
SFROWID	Oracle ROWID from IRM_STARTED_FORMS
FHROWID	Oracle ROWID from IRM_FORMHISTORY_REVS
FTROWID	Oracle ROWID from IRM_FORM_TIMES
SUBJECTVISITID (PK)	Subject visit numeric identifier
SUBJECTVISITREV	Subject visit revision
SUBJECTID	Subject numeric identifier
STUDYID	Study numeric identifier
SITEID	Site numeric identifier
STUDYVERSIONID	Study version numeric identifier
VISITID	Visit numeric identifier
VISITINDEX	Visit instance identifier 0 - expected visit 1 - started, non-repeating visit revisionnumber - repeating visit
DOV	DOV as entered
VISITDELETED	Visit has been deleted: 0 - no 1 - yes
FORMID (PK)	Form numeric identifier
FORMREV (PK)	Form revision
FORMINDEX (PK)	Form instance identifier 0 - unstarted form 1 - non-repeating form revisionnumber - repeating form
INFORMACTIVATIONTIME	Date when the form's visit was activated

IRM_ACTIVATED_FORMS	
Column Name (Key indicator)	Column Description
FORMTYPE	Form type: 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
FHREVS	Count of times the form's state has changed
MINFORMHISTORYID	First form history revision
MINFORMHISTORYREV	Most recent form history revision
MAXFORMHISTORYID	First form history numeric identifier
MAXFORMHISTORYREV	Most recent form history numeric identifier
HISTORICALORDER	HISTORICALORDER of current form state revision
USERID	Numeric identifier of the user that last changed the form's state
FORMHISTORYTIME	Time of the most recent form state change
TRANSACTIONID	Numeric identifier of the most recent transaction to change the form's state
REASON	Reason for most recent form state change
STATEHIST	Current form state
ORIGINALSTATE	Previous form state
ACTION	Special 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 started
SDVREADYSTATE	Form is in the source-verified ready state: 0 - no 1 - yes
FMINSDVREADYSTATE	First time the form was placed in the Source-Verified ready state

IRM_ACTIVATED_FORMS	
Column Name (Key indicator)	Column Description
FMAXSDVREADYSTATE	Most recent time the form was marked SV Ready
SDVPARTIALSTATE	Form is in the partially SVed state: 0 - no 1 - yes
FMINSDVPARTIALSTATE	First time the form was placed in the partially SVed state
FMAXSDVPARTIALSTATE	Most recent time the form was marked SV Partial
SDVCOMPLETESTATE	Form is in the completely SVed state: 0 - no 1 - yes
FMINSDVCOMPLETESTATE	First time the form was placed in the SV Complete
FMAXSDVCOMPLETESTATE	Most recent time the form was marked SV Complete
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 locked
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 marked frozen
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 signed
COMPLETESTATE	Form is in the complete state: 0 - no 1 - yes
FMINCOMPLETESTATE	First time the form was placed in the complete state

IRM_ACTIVATED_FORMS	
Column Name (Key indicator)	Column Description
FMAXCOMPLETESTATE	Most recent time the form was marked complete
HASQUERIESSTATE	Form has queries: 0 - no 1 - yes
FMINHASQUERIESSTATE	First time the form had queries
FMAXHASQUERIESSTATE	Most recent time the form had queries
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 was modified while it 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

IRM_ACTIVATED_FORMS	
Column Name (Key indicator)	Column Description
DELETEDDYNAMICFORMSTATE	Form is a dynamic form that has been deleted: 0 - no 1 - yes
FMINDELETEDDYNAMICFORMS TATE	First time the form was deleted
FMAXDELETEDDYNAMICFORMS TATE	Most recent time the 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
INFORMPARTIALURL_CRFVIEW	Partial InForm URL for the form

IRM_NOTDONE_CONTROL

The following materialized view is metadata that defines the possible values for the Not Done control (by default: Not Done, Unknown, Not Applicable).

IRM_NOTDONE_CONTROL	
Column Name (Key indicator)	Column Description
GCROWID	Oracle ROWID
ECROWID	Oracle ROWID
ELROWID	Oracle ROWID
RROWID	Oracle ROWID
EMROWID	Oracle ROWID
NCCONTROLID	The Not Done control ID
NDVALUE	The Not Done element name
NDLABEL	The Not Done label value

PF_CONTROLDATA2 and PF_CONTROLDATA_LONGRAW

The tables in this section are replicated directly from the InForm transaction database. These tables contain the current and historical clinical values for all items.

For more information, see the InForm Core DB Schema document.

IRV_CUR_ROOT_CHILD_CTRLDATA_R

The following view indicates the control order for items that contain the same control reused multiple times. It is programmatically added to the CV_view definition if the form contains an item with this scenario.

IRV_CUR_ROOT_CHILD_CTRLDATA_R	
Column Name (Key indicator)	Column Description
CONTEXTID	Foreign Key to PF_ITEMDATA to PF_ITEMCONTEXT. Identifier of the Item context
FORMID	Form numeric identifier
CVID0	Root control ID
CVID0_ORDER	Root control ID order
CID0	Root control value ID
CVID1	Next control ID
CVID1_ORDER	Next control ID order
CID1	Next control value ID
CVID2	Next control ID
CVID2_ORDER	Next control ID order
CID2	Next control value ID
CVID3	Next control ID
CVID3_ORDER	Next control ID order
CID3	Next control value ID
CVID4	Next control ID
CVID4_ORDER	Next control ID order
CID4	Next control value 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 designer can use existing and previously defined visits and CRFs to set up an arbitrary collection of visits and CRFs with certain properties, including a list of visits, a list of forms in a visit, the order and repetition of the forms and whether the forms are required. This named collection constitutes a study version and determines which visits display in the visit bar and which CRFs display using the form tabs. 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 trial a site can use multiple versions.

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, then the columns which 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, then instead of using the form version from the current study version for the site, 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 alternative 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 Reporting Model generates a single view for all versions of the form used in the study and generates an additional view for the alternative form.

Version 1

VitalSigns		
Blood pressure		
1.*	Blood Pressure: Lying down	<input type="text" value="60"/> / <input type="text" value="180"/> mmHg
2.*	Blood Pressure: Seated	<input type="text" value="60"/> / <input type="text" value="119"/> mmHg
3.*	Blood Pressure: Standing	<input type="text" value="72"/> / <input type="text" value="127"/> mmHg

Version 2

VitalSigns		
Blood pressure		
1.*	Blood Pressure: Lying down	<input type="text" value="60"/> / <input type="text" value="180"/> mmHg
2.*	Blood Pressure: Seated	<input type="text" value="60"/> / <input type="text" value="119"/> mmHg
3.*	Blood Pressure: Standing	<input type="text" value="72"/> / <input type="text" value="127"/> mmHg
4.*	Blood Pressure: Running	<input type="text" value="79"/> / <input type="text" value="160"/> mmHg

Alternate form

Alt Vital signs		
1.*	Blood pressure: Running	<input type="text" value="120"/> / <input type="text" value="156"/> mmHg

For both versions of the form

LAYDN_BPSYS	LAYDN_BPDIAS	SEAT_BPSYS	SEAT_BPDIAS	STAND_BPSYS	STAND_BPDIAS	RUN_BPSYS	RUN_BPDIAS
60	110	66	119	72	127	79	160

For the alternate form

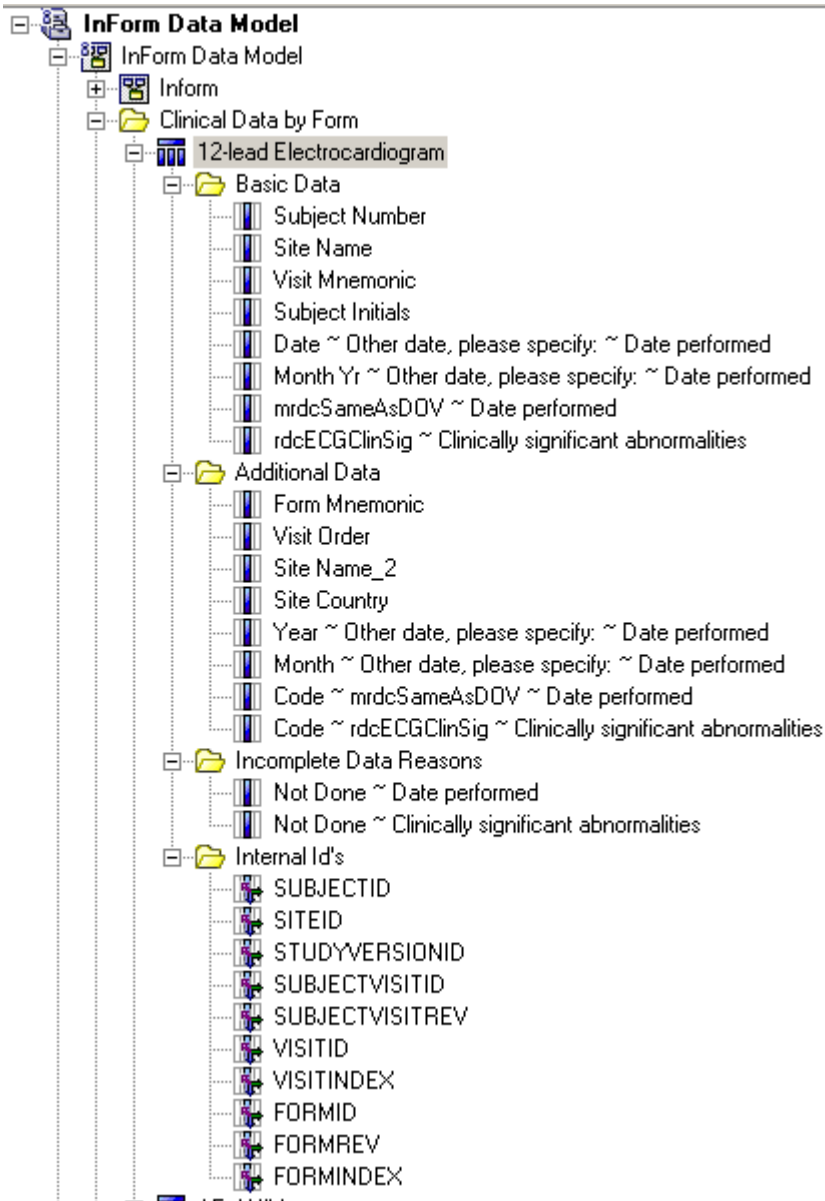
RUN_BPSYS	RUN_BPDIAS
79	160

Cognos 8 Business Intelligence models

The trial reporting set up process generates a Cognos 8 Business Intelligence 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.

A clinical model, or 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 documentation.



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 even though the clinical view

column for this control has the full date format.

Clinical model security

The clinical model transparently maintains InForm security:

- If some of the items in a trial are blinded for the current user, the user is not able to see these items in the clinical model.
- A user can see only those sites which that user is allowed to see in the trial.

The clinical model also contains relationships to the operational report topics. Relationships allow users to create reports or ad hoc queries by dragging and dropping report elements from two different report topics. This operation is conceptually similar to the SQL join operation which you would do directly between a clinical view and an operational area view. Cognos 8 Business Intelligence generates and executes SQL similar to the SQL created manually by a user working on the lower level.

Auto-generated mappings

This section describes the logic used to generate the database views (CM_materialized views and CV_views) and Cognos models based on specific eCRF design.

Structural mappings

Auto-generated structural mappings consist of a single CRF control mapped to zero, one, or 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 and pulldown controls	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 control) are mapped recursively.

Naming conventions for mappings

Auto-generated mappings have default names that must meet constraints for uniqueness and maximum length. You can customize automatically-generated names using the RefreshRepClin.bat command, but the customized names must still comply with the uniqueness and max length constraints.

- **Uniqueness**—Default mapping includes an algorithm to provide uniqueness. Uniqueness is required only within a certain scope: column name within a view, view name within a reporting database, and so on.

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**—Oracle has a thirty character limitation for any name. If the auto-generated Oracle 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 Oracle name (column or view name) exceeds 30 character as result of adding a suffix to resolve uniqueness, the algorithm above is applied.

Examples of uniqueness and max length conversion

No violation of uniqueness or max length

										1	1	1	1	1	1	1	1	1	1	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3	
1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6
V	E	R	Y	L	O	N	G	I	T	E	M	R	E	F	N	A	M	E	P	R	E	F	I	X	_	D	O	B							

Max length limitation exceeded

Before conversion

										1	1	1	1	1	1	1	1	1	1	2	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3
1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6
V	E	R	Y	L	O	N	G	I	T	E	M	R	E	F	N	A	M	E	P	R	E	F	I	X	_	I	N	I	T	I	A	L	S		

After conversion

										1	1	1	1	1	1	1	1	1	2	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3	
1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6
V	E	R	Y	L	O	N	G	I	T	E	M	R	E	F	N	A	M	E	P	R	E	F	I	X	_	_	1								

Uniqueness limitation violated

Before conversion

										1	1	1	1	1	1	1	1	1	2	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3	
1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6
S	H	O	R	T	I	T	E	M	R	E	F	N	A	M	E	_	D	O	B																

After conversion

										1	1	1	1	1	1	1	1	1	2	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3	
1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6
S	H	O	R	T	I	T	E	M	R	E	F	N	A	M	E	_	D	O	B	_	1														

Uniqueness and max length limitation are violated

Original

										1	1	1	1	1	1	1	1	1	2	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3	
1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6
S	H	O	R	T	I	T	E	M	R	E	F	N	A	M	E	_	P	A	T	I	E	N	T	W	E	I	G	H	T						

After uniqueness conversion

										1	1	1	1	1	1	1	1	1	1	1	1	2	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3
1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6		
SHORTITEMREFNAME_PATIENTWEIGHT_1																																					

After max length conversion

										1	1	1	1	1	1	1	1	1	1	1	2	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3
1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	
SHORTITEMREFNAME_PATIENTWE_1																																				

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 metrical columns.

Key columns

Key columns are not customizable and should only be used by advanced users. These columns serve as a key to the Report Operational Tables/Views and include the following.

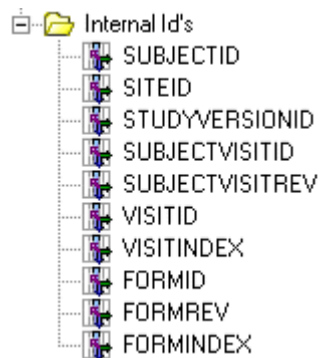
Key columns			
View Column Name	View Column Type	Report Element Name	Report Element Folder
SUBJECTID	NUMBER	SUBJECTID	Internal IDs
SITEID	NUMBER	SITEID	Internal IDs
STUDYVERSIONID	NUMBER	STUDYVERSIONID	Internal IDs
SUBJECTVISITID	NUMBER	SUBJECTVISITID	Internal IDs
SUBJECTVISITREV	FLOAT	SUBJECTVISITREV	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 8 Business Intelligence model



Metrical columns

Metrical columns do not result from control mapping generation. These columns represent information that can also be found in the operational views, but are generated mostly for usability and performance.

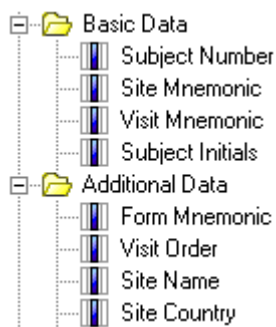
Metrical columns			
View Column Name	View Column Type	Report Element Name	Report Element Folder
SITEMNEMONIC	VARCHAR2	Site Mnemonic	Basic Data
VISITMNEMONIC	VARCHAR2	Visit Mnemonic	Basic Data
FORMNEMONIC	VARCHAR2	Form Mnemonic	Additional Data
SUBJECTINITIALS	VARCHAR2	Subject Initials	Basic Data
SITENAME	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)
VISITORORDER	50	NUMBER
SITENAME	51	VARCHAR2 (255)
SITECOUNTRY	52	VARCHAR2 (255)

Cognos 8 Business Intelligence model



Visits

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

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

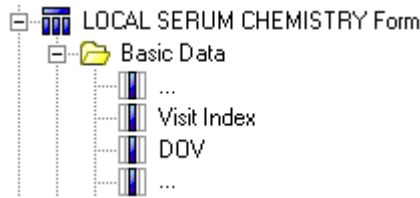
Visits				
View Column Name	View Column Type	Report Element Name	Report Element Folder	Content
VISITIDX	NUMBER	Visit Index	Basic Data	Ordinal number of the Visit instance starting from 1.
DOV	DATE	DOV	Basic Data	Visit instance Date of Visit.

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

Database view

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

Cognos 8 Business Intelligence 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 8 Business Intelligence clinical report topic based on the underlying clinical view. All form controls, with the exception of controls in repeating sections (itemsets), are mapped to items for that clinical report topic based on the columns in the clinical view.

Forms		
View Name	Report Element Name	Report Topic Description
CV_<FormRefName>	<FormTitle> Form	<FormTitle> Form - <FormDesignNote> or <FormTitle> - <FormMnemonic> if FormDesignNote is empty.

For a repeating form, the following two 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.

Repeating forms				
View Column Name	View Column Type	Report Element Name	Report Element Folder	Content
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

The screenshot shows the 'Properties' browser on the left and the 'Form : CONCOMITANT MEDICATIONS -- en-US' design view on the right. The 'Properties' browser shows various form attributes, including 'Repeating' set to 'True'. The design view shows a table of form items with columns for Key, Title, Question, Type, Conditional On, RefName, and Condition.

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

InForm Architect Properties window view

Property	Value
RefName	L_ConMeds
Form Type	CRF
UUID	
Title	CONCOMITANT MEDICATIONS
Mnemonic	CONMEDS
Note	
Question Width	24
Control Width	76
Common Form	True
Repeating Form	True
Design Note	
Unique Key	False

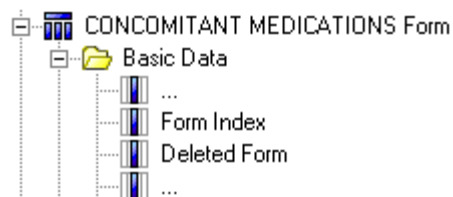
Display in InForm

CONCOMITANT MEDICATIONS	
1.	Sequence number
2.*	Drug name (Trade Name preferred) <input type="text"/>
3.*	Unit Dose <input type="text"/>

Database view

Name	Type	Nullable	Default	Comments
FORMIDX	NUMBER	Y		
DELETEDFORM	VARCHAR2(1)	Y		

Cognos 8 Business Intelligence model



Sections

A section has no effect on clinical view generation. A repeating section has an indirect effect. A single child item in a repeating section is an itemset and is mapped to a separate clinical view.

Itemsets

An itemset is mapped to a separate clinical view. All of the itemset controls are mapped to columns of that clinical view. Similarly, an itemset is mapped into a separate Cognos 8 Business Intelligence's clinical report topic, which is based on the underlying clinical view. All of its controls are mapped to items of 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 instance of the Itemset is deleted or 'N' if it is not.

The following examples illustrate default form mapping for the SURGICAL HISTORY repeating section of the SURGICAL HISTORY form.

Central Designer Properties Browser view

The screenshot shows the Central Designer Properties Browser for the 'Section: Surgical History -- en-US'. The left pane shows a tree view with 'Misc' expanded, listing various properties. The right pane shows a table of items for the repeating section.

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

InForm Architect Properties window view

The screenshot shows the InForm Architect Properties window for the 'Itemset: LsctSurgHx'. It displays a table of properties and their values.

Property	Value
RefName	LsctSurgHx
UUID	
Item Required	True
SV Required	True
Display Override	
Design Note	
Unique Key	False

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 InForm


SURGICAL HISTORY

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

Surgical History Add [Add Entry](#)

#	Surgery	Date	Comments
2.			

Cognos 8 Business Intelligence model

 SURGICAL HISTORY~Surgical History Itemset

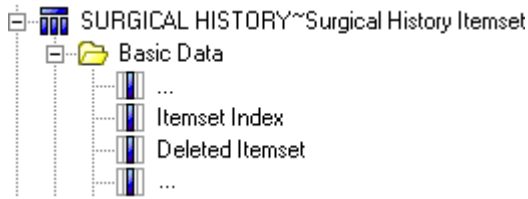
Properties		Languages
Name	SURGICAL HISTORY~Surgical History Itemset	
Description	SURGICAL HISTORY~Surgical History Itemset SURGHX	
Last Change	2005-01-18T12:52:35	
Screen Tip	SURGICAL HISTORY~Surgical History Itemset SURGHX	

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

Database view

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

Cognos 8 Business Intelligence 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 and item that contain Incomplete Item Reasons entered in a CRF or item comment form. Reasons are trial 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 Itemset Column Header in the InForm Architect software and Short Question in the Central Designer software. If ItemLabel is empty or has default value similar to ITEM1, then ItemQuestion attribute is used instead.	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 Itemset Column Header in the InForm Architect software and Short Question in the Central Designer software.

Central Designer Properties Browser view

The screenshot shows the 'Properties' window for an 'Integer Item: Action Taken -- en-US'. The window is divided into several panes:

- Properties:** A tree view showing the item's hierarchy: Clintrial > InForm > Integer Item: Action Taken -- en-US.
- Integer Properties:**
 - Default Question: Action taken with Investigational Products(s) as a result of the AE
 - Title: Action Taken
 - Base Unit: (empty)
 - Conversion Units: (empty)
 - Length: 10
 - Signed Value
 - CodeList Settings:
 - Select Single Value
 - Select Multiple Values
 - Minimum: (empty)
 - Maximum: (empty)
- CodeList:** A table showing the mapping between codes and labels:

Code	Label
1	Investigational product(s) v
2	Dose reduced
3	Dose Increased
4	Dose not changed
5	Dose interrupted
6	Not applicable
- Languages:** A table showing the item's translation:

Language	Question	Short Question
English (United States)	Action taken with Inve...	Action Taken

InForm Architect Properties window view

Item: LitmAEACTRCD	
Property	Value
RefName	LitmAEACTRCD
LUUID	
Question	Action taken with Investigational Products(s) as a result of the AE
Itemset Column Header	Action Taken
Calculated	False
Item Required	True
SV Required	True
Display Override	
Design Note	

MedML defintion

```

<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>

```

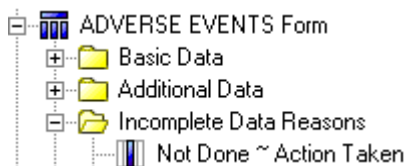
Display in InForm

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

Database view

Name	Type	Nullable	Default	Comm
ND_LITMAEACTRCD	VARCHAR2(64)	Y		

Cognos 8 Business Intelligence 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 0, 1 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 pseudo-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 pseudo-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 then 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 8 Business Intelligence report element description is the same as the report element name. A special process of normalization is used during generation of clinical view names and column names.

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

underscores ('_').

A special process of normalization is used during the generation of report topic names and element names.

- Trim leading and trailing white spaces.
- Remove trailing question mark '?' and column '!'
- Remove angle brackets and text between them.
- Remove 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>)	<p>VARCHAR2(N)—If the control datatype is CHARACTER and its MAXLENGTH is 255 or less. N is equal to the MAXLENGTH value.</p> <p>CLOB—If the control datatype is CHARACTER and the MAXLENGTH is more than 255. Only first 32000 characters of entered text are mapped.</p> <p>NUMBER—If the control datatype is INTEGER.</p> <p>FLOAT—If the control datatype is FLOAT.</p>	<CoreItemName>— A name generated according to control mapping logic, generally ItemQuestion or ItemLabel prefixed by ControlCaption or ControlRefName.	Basic Data

If the data type of a text control is numeric or float and has assigned units, then the text control is mapped to three additional columns if there is more than one associated unit. A single unit is sometimes used for UI purposes only and cannot be selected.

Text controls				
View Column Name	View Column Type	Report Element Name	Report Element Folder	Content
N_<CoreColumnName>	NUMBER	Normalized ~ <CoreItemName >	Additional Data	Normalized value generated by associated unit rule from entered data
UC_<CoreColumnName >	VARCHAR 2	Unit Code ~ <CoreItemName >	Additional Data	Coded value of selected unit, which represents UnitRefName attribute.
U_<CoreColumnName >	VARCHAR 2	Unit ~ <CoreItemName >	Basic Data	Value of selected unit, which represents UnitSymbol attribute.

The following examples illustrate mapping a character text control.

Central Designer Properties Browser view

The screenshot displays the Central Designer Properties Browser for an Integer Item named "Heart Rate -- en-US".

Properties Browser (Left Pane):

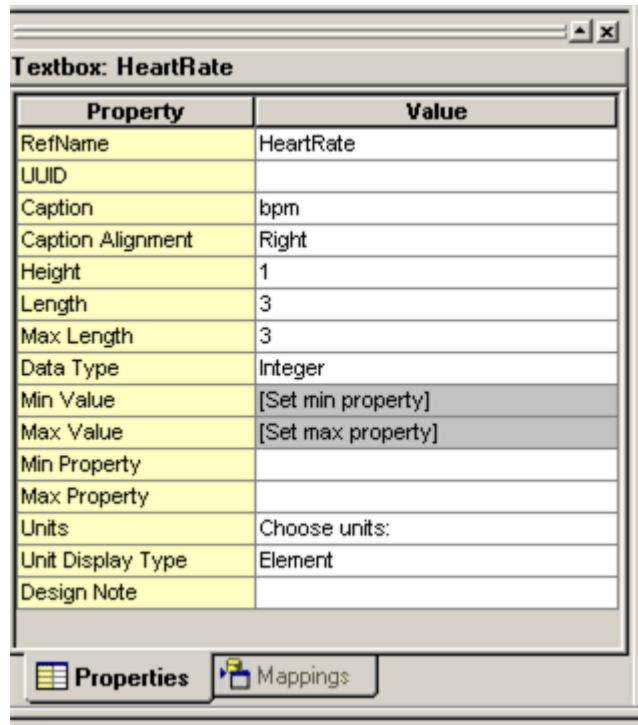
- Clintrial**
 - Derived
 - Max
 - Min
 - Required
 - SAS Name
 - Thesaurus
- InForm**
 - Display Override: None
 - Item Required
 - MaxProperty: None
 - MaxValue
 - MinProperty: None
 - MinValue
 - SDV Required
 - Special Fields: None
- Misc**
 - Description
 - DmValidation: PhaseForward.Designer.Client.Model.DesignerMode
 - Identifier: c57d4b8f-e3d1-4cad-8a70-8c849fd5ea16
 - Locked: False
 - Modified: False
 - New: False
 - Question: **Heart Rate**
 - RefName: **HeartRate**
 - Revision: 0.0.135
 - ShortQuestion: **Heart Rate**
 - Title: **Heart Rate**
 - Version

Integer Properties (Right Pane):

- Integer Properties**
 - Default Question: Heart Rate
 - Title: Heart Rate
 - Base Unit: [Dropdown]
 - Conversion Units: [Text]
 - Length: 3
 - Signed Value
 - Codelist Settings:
 - Select Single Value
 - Select Multiple Values
 - Minimum: [Text]
 - Maximum: [Text]
- Languages**

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

InForm Architect Properties window view



Property	Value
RefName	HeartRate
UUID	
Caption	bpm
Caption Alignment	Right
Height	1
Length	3
Max Length	3
Data Type	Integer
Min Value	[Set min property]
Max Value	[Set max property]
Min Property	
Max Property	
Units	Choose units:
Unit Display Type	Element
Design Note	

Properties Mappings

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>

```

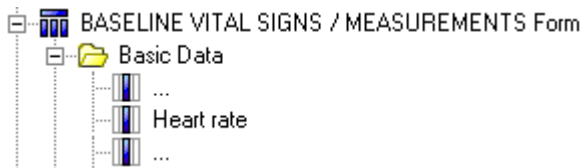
Display in InForm



Database view

Columns of CY_FRMBASELNVITLS					
Name	Type	Nullable	Default	Comments	
HEARTRATE	NUMBER	Y			

Cognos 8 Business Intelligence model



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

Central Designer Properties Browser view

Properties

Clintrial	
Derived	
Max	
Min	
Required	
SAS Name	
Thesaurus	
InForm	
Display Override	None
Item Required	
MaxProperty	None
MaxValue	
MinProperty	None
MinValue	
SDW Required	
Special Fields	None
Misc	
Description	
DmValidation	PhaseForward.Designer.Client.Model.DesignerMode
Identifier	35dfe978-2123-40d7-8d49-85c289737d5d
Locked	False
Modified	False
New	False
Question	Height
RefName	Height
Revision	0.0.138
ShortQuestion	Height
Title	Height
Version	

Float Item : Height-- en-US

Design | Layout | Rules | Rule Templates | Instructions

Float Properties

Default Question: Height

Title: Height

Base Unit: in

Conversion Units: cm mm

Length: 4 Precision: 0

Codelist Settings

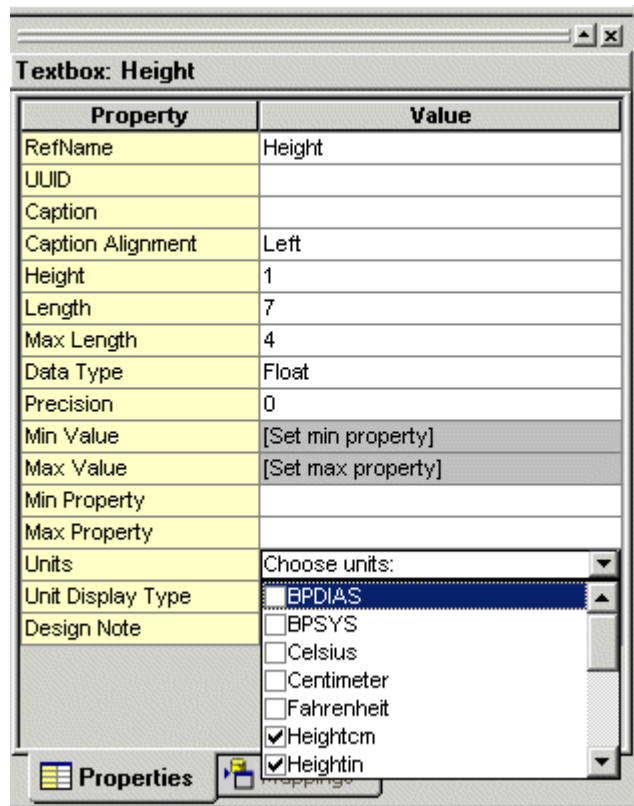
Select Single Value Minimum: Maximum:

Select Multiple Values 1 1

Languages

Language	Question	Short Question
English (United States)	Height	Height

InForm Architect Properties window view



MedML definition

```

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>

```

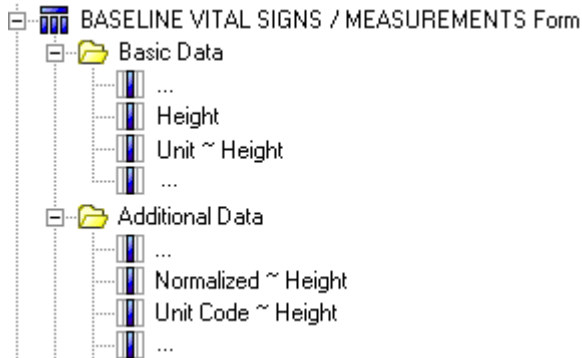
Display in InForm

1.*	Height	<input type="text"/>	<input type="radio"/> in	<input type="radio"/> cm
-----	--------	----------------------	--------------------------	--------------------------

Database view

Columns of CV_FRMBASELVITLS				
Name	Type	Nullable	Default	Comments
ND_HEIGHT	VARCHAR2(64)	Y		

Cognos 8 Business Intelligence model



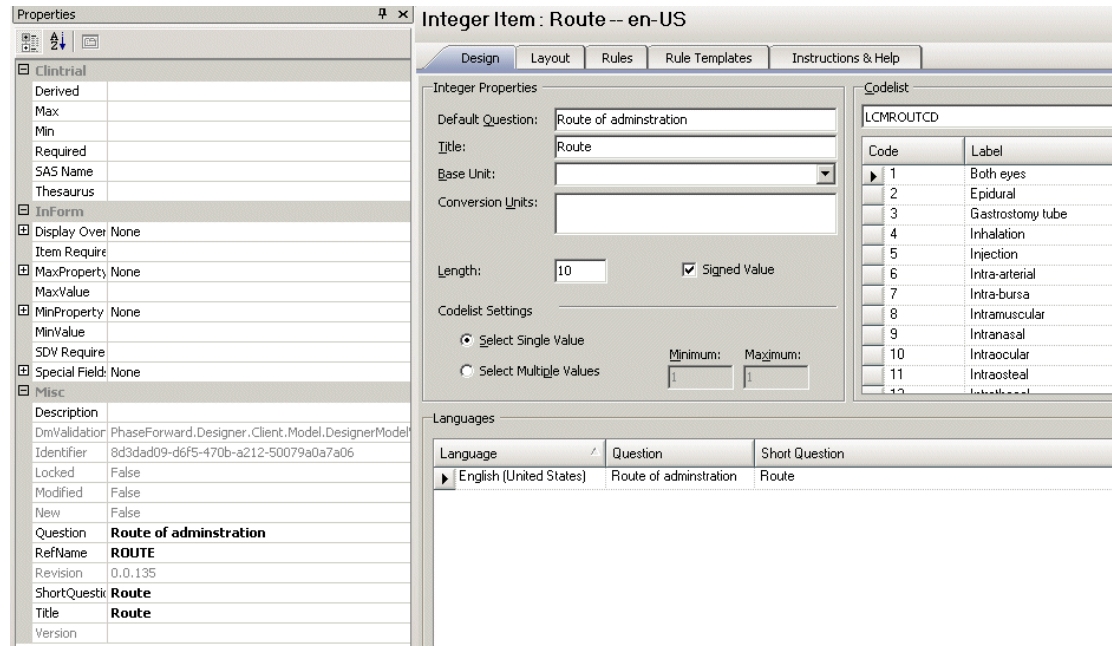
Pulldown controls

Pulldown controls are mapped to two clinical view columns.

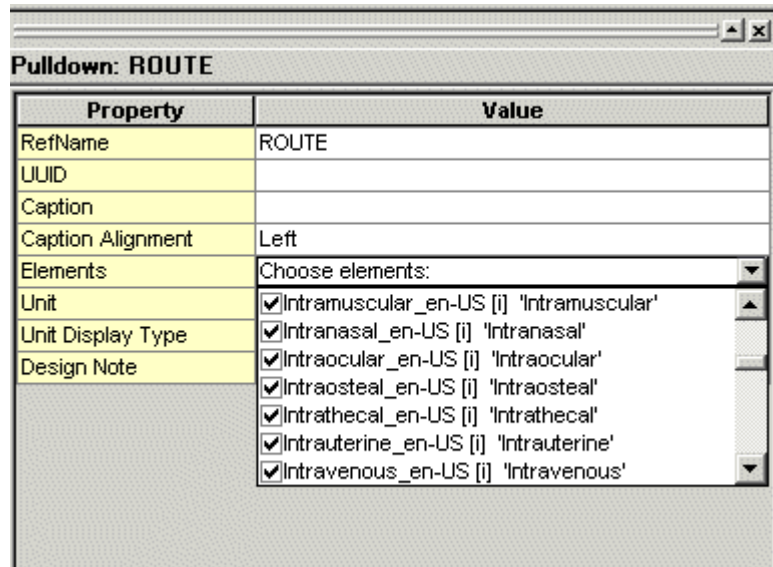
Pulldown controls				
View Column Name	View Column Type	Report Element Name	Report Element Folder	Content
C_<CORECOLUMNNAME>	FLOAT, NUMBER or VARCHAR2 (depends on the type of the child elements.)	Code ~ <COREITEMNAME>	Additional Data	ELEMENTVALUE
<COREITEMNAME>	VARCHAR2	<COREITEMNAME>	Basic Data	ELEMENTLABEL

The following examples illustrate mapping a pulldown control.

Central Designer Properties Browser view



InForm Architect Properties window 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 administration"
  LABEL="Route"
  CALCULATED="false"
  ITEMREQUIRED="true"
  SDVREQUIRED="true">
  <CONTROLREF REFNAME="ROUTE"/>
</ITEM>

```

Display in InForm

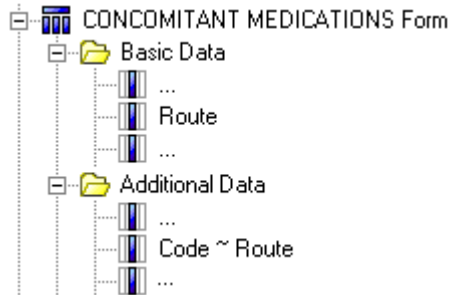
4.*	Route of administration	<input type="text"/>
5.*	Reason for medication	<input type="text"/>
6.*	Started prior to study? Hr:Min (00:00-23:59)	<input type="text"/>

Both eyes
Epidural
Gastrostomy tube
Inhalation
Injection
Intra-arterial
Intra-bursa
Intramuscular
Intranasal
Intraocular

Database view

Name	Type	Nullable	Default	Comment
C_ROUTE	NUMBER	Y		
ROUTE	VARCHAR2(16)	Y		

Cognos 8 Business Intelligence 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 have not-NULL values only if a user selected not Empty and not Unknown values for all three Year, Month and Day components.

Date controls				
View Column Name	View Column Type	Report Element Name	Report Element Folder	Content
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 all set to TRUE. This column will have not-NULL values only if a user selected not Empty and not Unknown values for all Year and Month components.
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 attribute is set to FALSE or the UNKNOWN attribute is set to TRUE. Date components are substituted by entered numbers, by 'NUL' if Empty selection is made, or by 'UNK' if Unknown entry is selected.

Date controls				
View Column Name	View Column Type	Report Element Name	Report Element Folder	Content
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 have not-NULL values only if a user selected not Empty and not Unknown values for all Hour and Minute components. Seconds component values are used if selected by the user.
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 String, these column values use the format "HH24:MM:SS" (or HH24:MM if no seconds are displayed). HH, MM, and SS are substituted if selected by the user, or 'NULL' if Empty selection is made, or 'UNK' if Unknown entry is selected.

Date controls				
View Column Name	View Column Type	Report Element Name	Report Element Folder	Content
Y_<CORECOLUMNNAME >	DATE	Year ~ <COREITEMNAME>	Additional Data	<p>This column is generated only if the Year DISPLAY attribute is set to TRUE.</p> <p>This column will have not-NULL values only if a user selected not Empty and not Unknown values for Year components. Month and Day components are ignored.</p>
M_<CORECOLUMNNAME >	DATE	Month ~ <COREITEMNAME>	Additional Data	<p>This column is generated only if the control Month DISPLAY attribute is set to TRUE.</p> <p>This column will have not-NULL values only if a user selected not Empty and not Unknown values for Month components. Year and Day components are ignored.</p>

The following examples illustrate mapping a date time control.

Central Designer Properties Browser view

The screenshot displays the Central Designer Properties Browser view for a Date Time Item: Date of visit -- en-US. The interface is divided into two main panes.

Properties Browser (Left Pane): This pane lists various properties for the item. Key properties include:

- MinValue: (empty)
- SDV Require: (empty)
- Special Field: DOV (Date of Visit)
- Misc: (expanded)
- DayAllow: **True**
- DayAllowUnl: **False**
- DayRequire: **True**
- Description: (empty)
- DmValidator: PhaseForward.Designer.Client.Model.DesignerMo
- HourAllow: **False**
- HourAllowUnl: **False**
- HourRequire: **False**
- Identifier: 4c6dbaa1-382c-43bf-a968-ea3195183c65
- Locked: False
- MinuteAllow: **False**
- MinuteAllowL: **False**
- MinuteRequire: **False**
- Modified: False
- MonthAllow: **True**
- MonthAllowL: **False**
- MonthRequire: **True**
- New: False
- Question: **Date of visit**
- RefName: **DOV**
- Revision: 0.0.123
- SecondAllow: **False**
- SecondAllowL: **False**
- SecondRequire: **False**
- ShortQuestio: **Date of visit**
- Title: **Date of visit**
- Version: (empty)
- YearAllow: **True**
- YearAllowUnl: **False**
- YearRequire: **True**

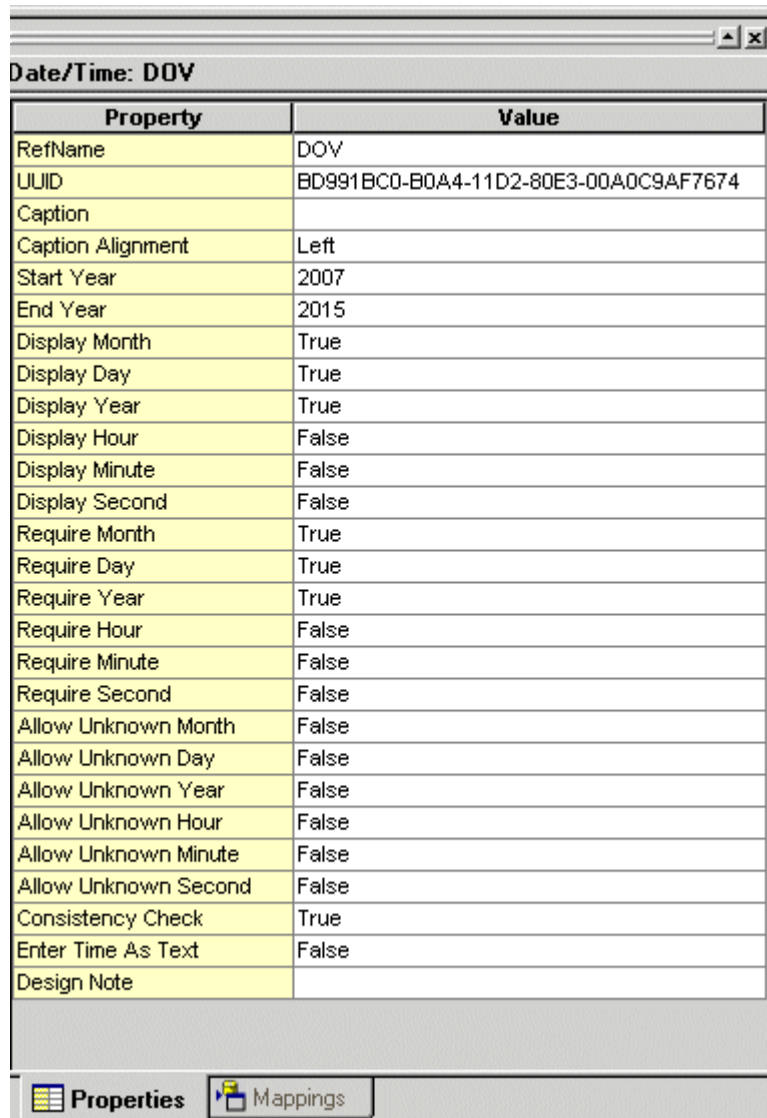
Date Time Properties (Right Pane): This pane provides configuration options for the date time item. It includes a Default Question field (Date of visit) and a Title field (Date of visit). Below these are checkboxes for Required, Allow unknown, and Allow for each time unit:

- Year: Required, Allow unknown, Allow
- Month: Required, Allow unknown, Allow
- Day: Required, Allow unknown, Allow
- Hour: Required, Allow unknown, Allow
- Minute: Required, Allow unknown, Allow
- Second: Required, Allow unknown, Allow

Languages (Bottom Right Table): This table shows the mapping of the question and short question for different languages.

Language	Question	Short Question
English (United States)	Date of visit	Date of visit

InForm Architect Properties window view



Date/Time: DOV

Property	Value
RefName	DOV
UUID	BD991BC0-B0A4-11D2-80E3-00A0C9AF7674
Caption	
Caption Alignment	Left
Start Year	2007
End Year	2015
Display Month	True
Display Day	True
Display Year	True
Display Hour	False
Display Minute	False
Display Second	False
Require Month	True
Require Day	True
Require Year	True
Require Hour	False
Require Minute	False
Require Second	False
Allow Unknown Month	False
Allow Unknown Day	False
Allow Unknown Year	False
Allow Unknown Hour	False
Allow Unknown Minute	False
Allow Unknown Second	False
Consistency Check	True
Enter Time As Text	False
Design Note	

Properties Mappings

MedML definition

```

Design MedML
<DATETIMECONTROL REFNAME="DOV"
  UUID="BD991BC0-B0A4-11D2-80E3-00A0C9AF7674"
  LANGUAGE="English"
  ALIGN="LEFT"
  CAPTIONALIGN="LEFT"
  STARTYEAR="2007"
  ENDEAR="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>

```

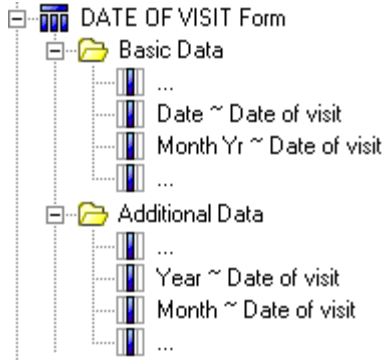
Display in InForm

DATE OF VISIT	
1.* Date of visit	<input type="text"/> / <input type="text"/> / <input type="text"/>

Database view

Name	Type	Nullable	Default	Cor
DT_DOV	DATE	Y		
MY_DOV	DATE	Y		
Y_DOV	DATE	Y		
M_DOV	DATE	Y		

Cognos 8 Business Intelligence 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	<COREITEMNAM E>	Basic Data	ELEMENTLABEL if a child control is a simple control, CONTROLCAPTION if it has one, otherwise CONTROLREFNAME.

The following examples illustrate mapping a radio control.

Central Designer Properties Browser view

The screenshot shows the 'Form : LBLIND -- en-US' window. On the left is the 'Properties' browser for the 'LitmBLIND' control, showing various attributes like 'Type', 'Verifiable', and 'Special Forms'. On the right is a table listing the radio control items:

Key	Title	Question	Type	Conditional On	RefName	Condit
<input type="checkbox"/>	Blind	Was the treatment b...	Integer Item		LitmBLIND	
<input type="checkbox"/>	BlindYesOther	Other, specify	Text Item	Reason blind br...	LBLRS0TH	2
<input type="checkbox"/>	Date blind broken	Yes, complete the fo...	DateTime Item	Blind	Dateblindbroken	2
<input type="checkbox"/>	Reason blind broken	Reason blind broken	Integer Item	Blind	ReasonBlindBKN	2
<input checked="" type="checkbox"/>	*		<select type>			

InForm Architect Properties window view

The screenshot shows the 'Radio Group: LitmBLIND' window with a table of properties and values:

Property	Value
RefName	LitmBLIND
UUID	
Layout	Vertical
Caption	
Caption Alignment	Left
Design Note	

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 InForm

STATUS OF TREATMENT BLIND

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

No

Yes, complete the following

Date blind broken

/ /

Reason blind broken

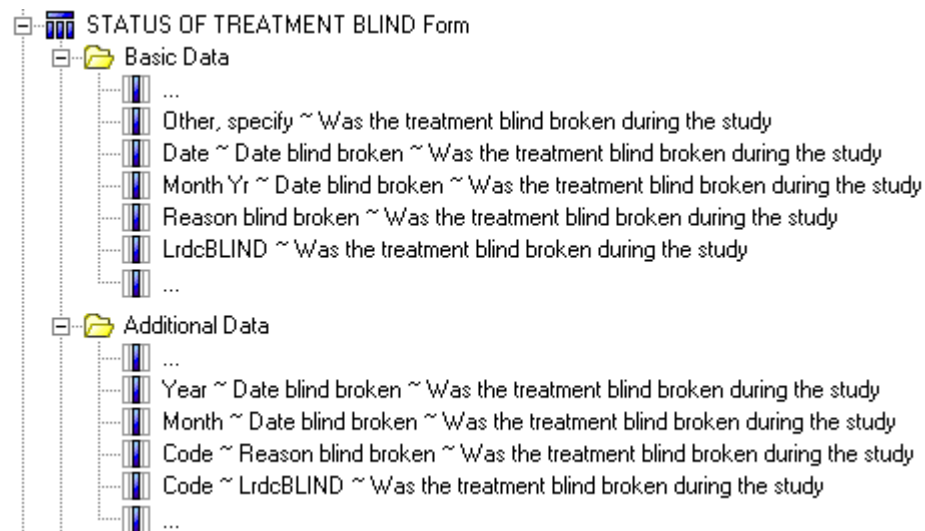
Medical emergency requiring identification of investigational product for further treatment

Other, specify

Database view

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

Cognos 8 Business Intelligence 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 CONTROLREFERENCE.
<COREITEMNAME>	VARCHAR2	<COREITEMNAME>	Basic Data	ELEMENTLABEL if a child control is a simple control, CONTROLCAPTION, otherwise CONTROLREFERENCE.

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

The following examples illustrate mapping a radio control.

Central Designer Properties Browser view

The screenshot shows the 'Integer Item: MultiRacial -- en-US' window. The 'Design' tab is selected, displaying the 'Integer Properties' section with fields for 'Default Question' (Race), 'Title' (MultiRacial), 'Base Unit', and 'Conversion Units'. The 'Length' is set to 1 and 'Signed Value' is checked. The 'Codelist Settings' section has 'Select Multiple Values' selected, with 'Minimum' set to 1 and 'Maximum' set to 5. The 'Codelist' table is visible, listing five categories with their corresponding codes.

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

The 'Languages' section at the bottom shows a table with columns for Language, Question, and Short Question. The entry for 'English (United States)' has the question 'Race'.

Language	Question	Short Question
English (United States)	Race	

Central Designer Project Explorer view



InForm Architect Properties window view

The screenshot shows the 'Checkbox Group: MultiRacial' properties window. It contains a table with the following data:

Property	Value
RefName	MultiRacial
UUID	
Layout	Vertical
Caption	
Caption Alignment	Left
Design Note	

InForm Architect Trial Objects window 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 InForm

4.*	Race	<input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black, African heritage <input type="checkbox"/> Native Hawaiian or Pacific Islander <input type="checkbox"/> White
-----	------	---

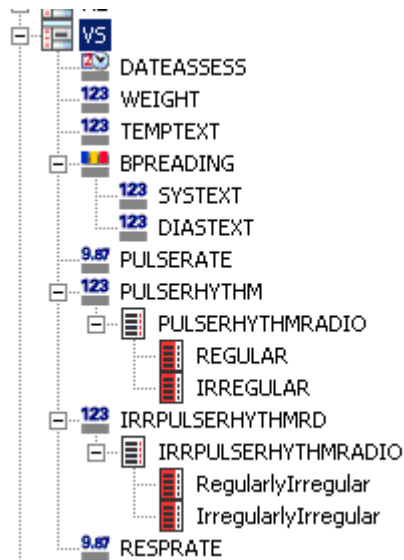
Group controls

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

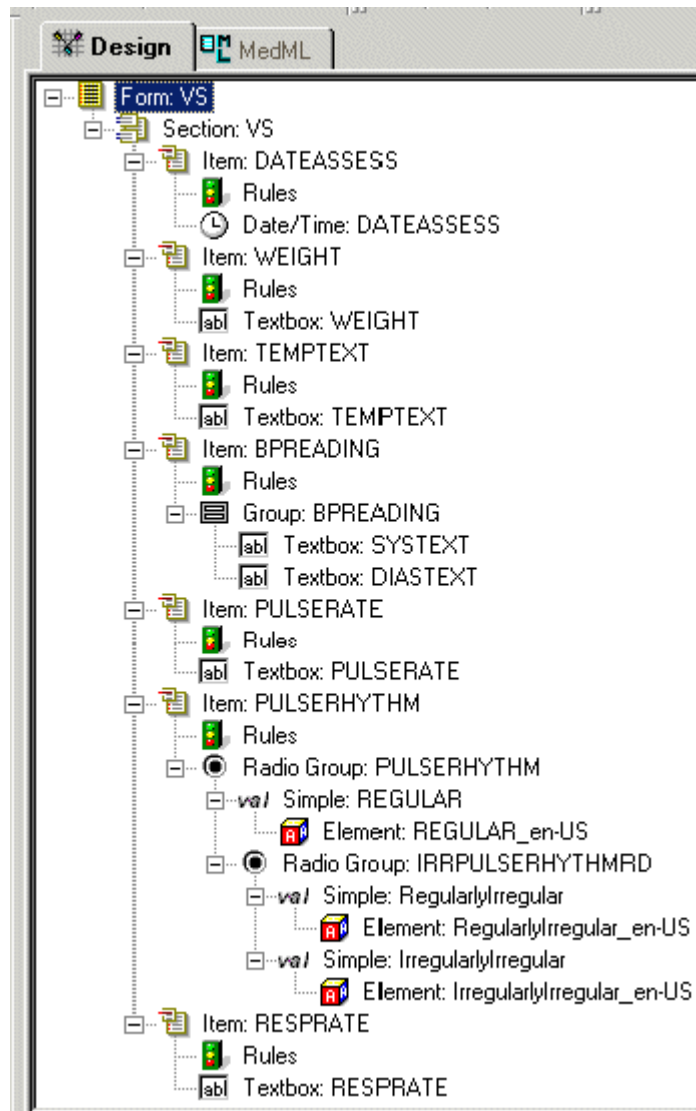
Examples of auto-generated mappings

Form definition

Form definition in the Central Designer Project Explorer



Form definition in the InForm Architect Trial Objects window



Form rendering

Display in InForm

Vital Signs		
1.*	Date of assessment	<input type="text"/> / <input type="text"/> / <input type="text"/>
2.*	Weight	<input type="text"/> <input type="radio"/> lbs <input type="radio"/> kg
3.*	Temperature	<input type="text"/> <input type="radio"/> C <input type="radio"/> F
4.*	Blood Pressure	<input type="text"/> <input type="text"/>
5.*	Pulse Rate	<input type="text"/> bpm
6.*	Pulse Rhythm	<input type="radio"/> Regular <input type="radio"/> Irregular (specify): <input type="radio"/> Regularly Irregular <input type="radio"/> Irregularly Irregular
7.*	Respiratory Rate	<input type="text"/> breaths per minute

Clinical view schema

Columns of CV_V5					
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			

APPENDIX A

Appendix

In this appendix

Mapping Central Designer terms to InForm terms.....	160
---	-----

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 the both the data definition of each study component and the layout specified for each form or item in the Central Designer application:

The following table describes the correspondences between Central Designer and InForm study components and their properties.

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

Central Designer study component	Corresponding InForm study component	Notes
Data series	<ul style="list-style-type: none"> Table column in CDD mapping definition. Panel item in CIS mapping definition. 	
Data set	<ul style="list-style-type: none"> Table in CDD mapping definition. Panel in CIS mapping definition. 	The data dimensions of a data set form the key for each row of a CDD table. Data values defined as custom dimensions form pivot columns around which the data in the table is organized.
Description	No corresponding component	Study object descriptions are visible only in a Central Designer annotated study book.
Form	Form	<ul style="list-style-type: none"> In the Central Designer software, a form note is specified in the layout definition. The Short Title specified in the Central Designer software deploys as the form mnemonic in the InForm application. The form RefName is used in the Reporting and Analysis module and in CDD table columns for which no data series alias exists.
	Alternate form	<ul style="list-style-type: none"> In the InForm application, an alternate form is used to collect new or changed information for those subjects who have started the original version of the form. A form containing new or changed items in a subsequent, incremental deployment deploys as an alternate form for those subjects who have started the original version of the form.
	Associated forms	Two forms defined as repeating and linked with the AssociatedForm property in the Central Designer software deploy as associated forms in the InForm application.
	Common form	A form defined as Shared in the Central Designer software deploys as a common form in the InForm application.
	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.

Central Designer study component	Corresponding InForm study component	Notes
	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.
	RegDocs and Visit Report forms	The Central Designer software does not support creation of RegDocs and Visit Report forms. The deployment process creates placeholders to indicate that this has not yet been implemented.
	Repeating form	A form defined as repeating in the Central Designer software deploys as a repeating form in the InForm application.
	Screening form	If you do not include a special Screening form, the 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 software deploy as CRF Help in the InForm application. Instructions and Help defined for other study objects (for example, study events) in the Central Designer software do not deploy to the InForm application.

Central Designer study component	Corresponding InForm study component	Notes
Item	Item	<p>Item deployment considerations:</p> <ul style="list-style-type: none"> • The Central Designer software includes the following custom properties for InForm application deployment: <ul style="list-style-type: none"> ▪ Optional (for Central Designer study events, InForm visits)—Defaults to False 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 Required (for items)—Defaults to True in the InForm application. ▪ Special Forms (for forms)—Identifies custom Screening, Enrollment, Patient Identification, and Study Completion forms. ▪ 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 software become date/time controls in the InForm application.
Group control		A compound item defined with child items in the Central Designer software deploys in the InForm application as a group control consisting of the child items.
Nested control		An item in the Central Designer software that is conditional on another item deploys in the InForm application as a nested control within the item on which it is conditional.

Central Designer study component	Corresponding InForm study component	Notes
	Text control	Text, integer, and float items in the Central Designer software become the appropriate text controls in the InForm application.
	Unit	<ul style="list-style-type: none"> • A base unit or a base unit and a single conversion unit specified in an integer, float, or yes no item definition in the Central Designer software 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.
Logical schema	CDD or CIS mapping definition object	
Rule	Rule	The deployment process creates rule attachments, arguments, and dependencies in the InForm application as necessary based on the items referenced in the rule definition.
Section	Section	<ul style="list-style-type: none"> • In the Central Designer software, a section note is specified in the layout definition. • If you do not create a section for a form in the Central Designer software, 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 software are grouped into an itemset in the InForm application.
Short Question	Itemset column header	<ul style="list-style-type: none"> • If a Short Question is specified, the value is used for the column header that appears in the itemset. • If a Short Question is not specified, the value of the Default Question is used.

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

Central Designer study component	Corresponding InForm study component	Notes
	Screening visit	<p>A special InForm visit that must be included in the Central Designer study design.</p> <ul style="list-style-type: none"> ▪ The screening form must belong to the screening visit. ▪ The screening visit must be a standalone visit in the workflow. <p>The screening visit must be the first visit in the workflow and the enrollment visit must be second.</p>
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 software. 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 software, with the following two exceptions:

- PFElements. The RefName from the codelist item is concatenated with an underscore and a locale (such as en-US). Concatenation is done because PFElements are not versioned in the InForm application and each must have a unique name.
- Group controls are prefaced with "GC_" only when multiple items are conditional on the same item.