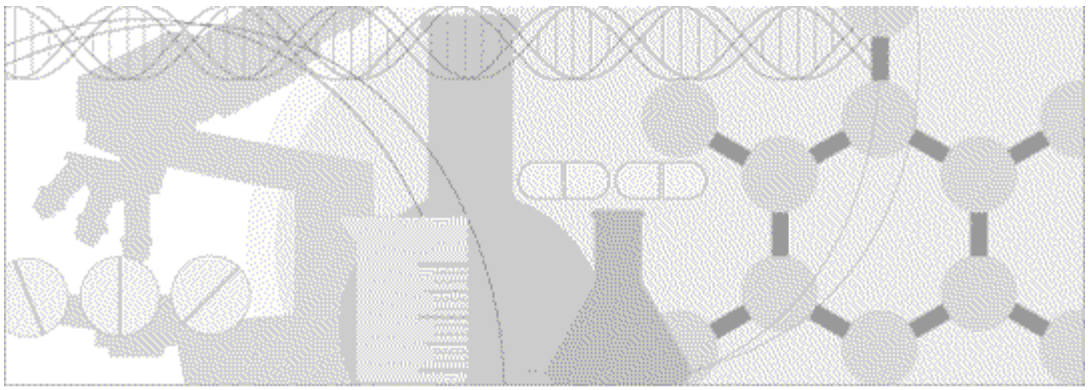
Standard Data Extracts Guide

Oracle® Health Sciences OutcomeLogix 3.2.3



ORACLE

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Overview of this guide

The *Standard Data Extracts Guide* contains information about the standard data extract that is available for the OutcomeLogix application, and includes descriptions of the default views for the extract, naming conventions for the views and the columns in the views, and contact information for requesting a standard data extract.

Audience

This guide is for sponsor and site users of the OutcomeLogix application. These users conduct late-phase, post-marketing, and observational studies through a user interface accessed with an internet browser. Users enter study-specific data into electronic forms. The data is saved in an Oracle database, and is available for data monitoring, reporting, and exporting from the OutcomeLogix application.

OutcomeLogix 3.2.3 documentation

The product documentation is available from the following locations:

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

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

Document	Description	Last updated
Release Notes	The *Release Notes* document describes hardware and software requirements and describes the new features, enhancements, and fixed issues in this release.	3.2.3
Known Issues	The *Known Issues* document provides detailed information about the known issues in this release, along with workarounds, if available.	3.2.3
User Guide	The *User Guide* provides an overview of the OutcomeLogix application including details on how to navigate through the user interface and how to use the application to accomplish typical tasks you perform while running a late-phase, registry, or observational study.	3.2.2
Secure Configuration Guide	The *Secure Configuration Guide* provides an overview of the security features provided with the OutcomeLogix application, including general principles of application security. Throughout the *Secure Configuration Guide* are references to chapters in the OutcomeLogix *User Guide* covering how to configure and use the OutcomeLogix application securely.	3.2.2
Standard Data Extracts Guide	The *Standard Data Extracts Guide* contains information about the standard data extract that is available for the OutcomeLogix application, and includes descriptions of the default views for the extract, naming conventions for the views and the columns in the views, and contact information for requesting a standard data extract.	3.2.3
Third Party Licenses and Notices	This document includes licenses and notices for third party technology that may be included in or distributed with the OutcomeLogix software.	3.2.2

Documentation accessibility

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

If you need assistance

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

Finding OutcomeLogix information and patches on My Oracle Support

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

Creating a My Oracle Support account

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

1 Open a browser to https://support.oracle.com.

2 Click the **Register** link.

3 Follow the instructions on the registration page.

Finding information and articles

1 Sign in to My Oracle Support at https://support.oracle.com.

2 If you know the ID number of the article you need, enter the number in the text box at the top right of any page, and then click the magnifying glass icon or press **Enter**.

3 To search the knowledge base, click the **Knowledge** tab, and then use the options on the page to search by:

- Product name or family.
- Keywords or exact terms.

Finding patches

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

1 Sign in to My Oracle Support at https://support.oracle.com.

2 Click the **Patches & Updates** tab.

3 Enter your search criteria and click **Search**.

4 Click the patch ID number.

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

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

Finding Oracle documentation

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

Finding Oracle Health Sciences documentation

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

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

Finding other Oracle documentation

1 Do one of the following:

- Go to http://www.oracle.com/technology/documentation/index.html.
- Go to http://www.oracle.com, point to the **Support** tab, and then click **Product Documentation**.

2 Scroll to the product you need, and click the link.

Finding prerequisite software for Oracle Health Sciences applications

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

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

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

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

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

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

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

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

CHAPTER 1

Standard data extracts

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About standard data extracts

A standard data extract is a collection of views that is created for an OutcomeLogix study during the OutcomeLogix installation, and whose data is extracted into one of several supported formats.

A standard data extract has the following components:

- **Views**—Database views that are installed as part of the OutcomeLogix installation. There are two types of views:
  - **Clinical views**, which represent the clinical forms in a study and begin with the prefix RD.

    When a standard data extract is created, the RD view definitions are based on the structure outlined in the RD_DATADICTIONARY table, and contain the metadata in the RD_METADATA table, which are installed by default during the OutcomeLogix installation.

    For more information, see *Data extract design* (on page 4).
  - **Operational views**, which begin with the prefix IRV.

    IRV views do not change from study to study. They provide the linking information to tie the operational data to the clinical data.

    For more information, see *About operational views* (on page 18).
- **Extract**—A file that contains data from each of the RD views and IRV views for a study. The extract appears in the structure that is specified in the *RD_DATADICTIONARY* (on page 5) table.

  The extract is processed on internal Oracle servers, provided in the specified format, and made available on demand in the OutcomeLogix Portal or at regularly scheduled intervals on the sFTP server. For more information, see *Requesting a standard data extract* (on page 3).

  Extracts are available in the following formats:
  - Oracle (EXP, data pump)
  - SAS (datasets, transport)
  - ASCII (CSV, XML, pipe-delimited)

  Sponsors can load the extract into a supported application, such as the Microsoft Excel spreadsheet software, to create custom reports and to analyze data.

Requesting a standard data extract

Contact your Oracle representative to request access to a standard data extract on demand. An Oracle representative grants a user access to an up-to-date standard data extract on demand in the OutcomeLogix Portal application.

Additional information about data extracts and how they are delivered is available in the *DOD Extracts Base Specification* document, which you can obtain from your Oracle representative.

Database extract design

When a database extract is created, the view definitions are based on the structure outlined in the RD_DATADICTIONARY table, which is installed by default during the OutcomeLogix installation.

A database extract includes the following tables:

- **RD_DATADICTIONARY**—Describes how RD views are mapped to clinical forms.
- **RD_METADATA**—Stores metadata for the RD views.
- **RD_CODEVALUES**—Describes the code labels for each drop-down list and radio button control in the RD views.
- **RD_COLUMNLABELS**—Used to populate the SAS column labels for the RD views.
- **RD_VIEWMAPPING**—Used to map the RD view name to the form name and form display name.

Note: An extract also includes supporting tables and views, which are used by the Clinical Development Center (CDC) data transfer process.

RD_DATADICTIONARY

The RD_DATADICTIONARY table (Data Dictionary) describes how RD views are mapped to clinical forms. The table contains one row for each control, with additional rows for different control formats (for example, date time items and entered and normalized units).

RD_DATADICTIONARY table	
Column Name	**Description**
RD_VIEWNAME	Name of the RD view, from R_FORM_LAYOUT.FLAYOUT_NAME, prefixed by RD_. For example: RD_DEMOGRAPHICS. RD view names are truncated to 30 characters.
RD_COLUMNNAME	Column name, truncated and appended with the following, where appropriate, so that the column name contains a maximum of 30 characters. • **_DT** - Datetime item. • **_MY** - Month/Year item. • **_TM** - Time item. • **_DTS** - Datetime string. • **_TMS** - Time string. • **_DTR** - Date time as entered, including UNK and NULL. • **_TMR** - Time as entered, including UNK and NULL. • **_C** - Codelist item (coded value). For more information about column naming conventions for RD views, see *About RD views* (on page 14).
RD_RAWCOLUMN	Name of column as it is found in the R_LAYOUT_CONTROL.NAME column. Used to find the matching column in the flat table.
TABLENAME	Table where clinical data exists. Used to populate the RD_VIEW. Formed by the concatenation of the R_FORM_LAYOUT.FLAYOUT name and F_.
COLUMNNAME	Column in R_LAYOUT_CONTROL. Same as RD_RAWCOLUMN.

RD_DATADICTIONARY table	
Column Name	**Description**
COLUMNTYPE	Generated column type: • 0 - NUMBER • 1 - STRING • 2 - DATE • 3 - BOOLEAN • 6 - DATE TIME • 7 - PARTIAL DATE • 8 - TIME • 20 - CODEVALUE
COLUMNORDER	Relative order of the column in the RD view. **Note:** This is always null and is present in the table to support the CDC transfer.
FORMREFNAME	Form layout name. Same as FORMNAME. For example: DEMOGRAPHICS.
SECTIONREF	Used by the CDC transfer. Not used by the standard extracts. This is always null.
ITEMREFNAME	Internal names of controls in OutcomeLogix database. . Same as RD_RAWCOLUMN and RD_COLUMNNAME.
ITEMREFID	Internal identifier of the control. Used by the CDC transfer. It is the corresponding ID from R_LAYOUT_CONTROL. Same as CONTROLID.
CONTROLID	Numeric identifier for the control, from R_LAYOUT_CONTROL.Id. Same as ITEMREFID.
COLUMNDBTYPE	Internal OutcomeLogix data type for the control from the C_CONTROL_DATA_TYPE table, populated from the RD_METADATA table.
FORMNAME	Form display name from R_FORM_LAYOUT.FLAYOUT_NAME. Same as FORMREFNAME. For example: DEMOGRAPHICS.
ITEMQUESTION	Question as it appears on a form in the user interface. If ITEMREFNAME is INITIALS; the ITEMQUESTION is Subject Initials.
CONTROLCAPTION	Control caption from T_LAYOUT_CONTROL.Display_name.

RD_DATADICTIONARY table	
Column Name	**Description**
ITEMORDER	Order of appearance of the item (control) on the form. Item numbers (questions) on an EDC can change between EDC versions.
COLUMNLABEL	Used by the CDC transfer. Not used by the standard extracts. This is always null.
COLUMNDESC	Corresponding item description from R_LAYOUT_CONTROL.Name. Same as RD_RAWCOLUMN.
SASDATASETNAME	Used by the CDC transfer. Not used by the standard extracts. This is always null.
SASFIELDNAME	Used by the CDC transfer. Corresponds to R_LAYOUT_CONTROL.Name. Same as RD_RAWCOLUMN.
SDSDOMAINNAME	Used by the CDC transfer. Not used by the standard extracts. This is always null.
SDSVARNAME	Used by the CDC transfer. Not used by the standard extracts. This is always null.
ITEMSET	Indicates whether an item is part of an itemset. Not used by the standard extracts. This is always null.
CONTROL_TYPE	Text description of control: • OL Image Upload • Partial Date Calendar • OL Calendar Time • Calendar • Text Area • OL Calendar Entry • OL Slider • Label • Clock • Radio Group • Checkbox • Drop-Down
REPEATINGVISIT	Indicates whether the visit is repeating. 0 - Visit is not repeating. 1 - Visit is repeating.

RD_DATADICTIONARY table	
Column Name	**Description**
REPEATINGFORM	Indicates whether the form is repeating. Always set to 0. 0 - Form is not repeating. 1 - Form is repeating.
REPEATINGITEM	Indicates whether the item is repeating. Always set to 0. 0 - Item is not repeating. 1 - Item is repeating.
FORMID	Numeric identifier for the form type, from R_FORM_LAYOUT.Id. FORMID is the OutcomeLogix internal layout ID.
FORMREV	Used by the CDC transfer. Not used by the standard extracts. Always set to 0. Should be maintained by a study patch.
SECTIONID	Not used by the standard extracts. The value for this column is always 1.
LISTVALUENAMEID	Numeric values for the codelist corresponding to the ID in R_LISTVALUENAME and used to populate the RD_CODEVALUES table.
MAX_LENGTH	Maximum length of column data, measured in characters. If maximum length is missing, it means the text area control is missing the MAX_LENGTH (when designed in ELX).
DDS_DATE	The most recent time the row was updated. The last date the RD_DATADICTIONARY was loaded.
ENCRYPTED	Indicates whether or not the column value should be encrypted in the RD_ views.

RD_METADATA

The RD_METADATA table stores metadata for the RD views.

RD_METADATA table	
Column Name	**Description**
FLAYOUT_ID	Numerical identifier for the form layout from the R_FORM_LAYOUT table.
FLAYOUT_NAME	Name of the form layout from the R_FORM_LAYOUT table. This value is prefixed with **RD_** to create the name for each RD view.
CONTROL_LAYOUT_ID	Numerical identifier for the control from the R_LAYOUT_CONTROL table.
CONTROL_NAME	Name of the control. This value is used as the column name for the control in the RD views.
CONTROL_DISPLAYNAME	Display name for the control. This value is localized.
CONTROL_TYPE	Type of control.
DATATYPE	Data type for the control from the C_CONTROL_DATA_TYPE table.
LISTVALUENAMEID	Numerical identifier for the codelist in the column.
MAX_LENGTH	Maximum length for a control with a data type of STRING.

RD_CODEVALUES

The RD_CODEVALUES table describes the code labels for each drop-down list and radio button control in the RD views.

RD_CODEVALUES table	
Column Name	**Description**
RD_VIEWNAME	Name of the RD view, from R_FORM_LAYOUT.FLAYOUT_NAME, prefixed by RD_. For example: RD_DEMOGRAPHICS. RD view names are truncated to 30 characters.
RD_COLUMNNAME	Column name, truncated and appended with the following, where appropriate, so that the column name contains a maximum of 30 characters. **_C** - Codelist item (coded value).
CODE_VALUE	Value for the codes.
CODE_LABEL	Label for the codes, which appears in the user interface.
DDS_DATE	The most recent time the row was updated. Always is the last date the RD_DATADICTIONARY was loaded.

RD_COLUMNLABELS

The RD_COLUMNLABELS table is used to populate the SAS column labels for the RD views.

RD_COLUMNLABELS table	
Column Name	**Description**
RD_VIEWNAME	Name of the RD view, from R_FORM_LAYOUT.FLAYOUT_NAME, prefixed by RD. RD view names are truncated to 30 characters.
RD_COLUMNNAME	Column name, truncated and appended with the following, where appropriate, so that the column name contains a maximum of 30 characters. • **_DT**—Datetime item. • **_MY**—Month/Year item. • **_TM**—Time item. • **_DTS**—Datetime string. • **_TMS**—Time string. • **_DTR**—Date time as entered, including UNK and NULL. • **_TMR**—Time as entered, including UNK and NULL. For more information about column naming conventions for RD views, see *About standard data extracts* (on page 2).
COLUMNDESC	SAS column label.

RD_VIEWMAPPING

The RD_VIEWMAPPING table is used to map the RD view name to the form name and form display name.

RD_VIEWMAPPING table	
Column Name	**Description**
DATASET_NAME	RD view name.
FLAYOUT_NAME	Form name.
DISPLAY_NAME	Form display name.

CHAPTER 2

RD views

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About RD views

RD views are representations of clinical forms in a study. One RD view exists for each unique form name in the R_FORM_LAYOUT table. The following naming conventions are used for each RD view in the OutcomeLogix database.

- **View names**—Names of views consist of the prefix RD_ and form layout name (the value of the FLAYOUT_NAME column in the R_FORM_LAYOUT table). RD view names are truncated to 30 characters.
- **Column names**—Each control on a form has a column in the RD view for the form. The column name for each control (<*variablename*>) corresponds to the DISPLAYNAME value for the control. Column names are truncated and appended with the following suffixes, where appropriate, so that the column name contains a maximum of 30 characters.
  - Date time controls have multiple rows, which break the control into its component parts and present the data in different formats.
    - **_DT**—Date time item.
    - **_MY**—Month/Year item.
    - **_TM**—Time item.
    - **_DTS**—Date time string, in the format YYYY-MM-DD hh:mm:ss. Hours use the 24-hour clock.
    - **_TMS**—Time string, in the format Thh:mm:ss. Hours use the 24-hour clock.
    - **_DTR**—Date time as entered, including UNK and NULL.
    - **_TMR**—Time as entered, including UNK and NULL.
    - The <*variablename*> row contains a valid, complete date time in the format YYYY/MM/DD HH:MM:SS. Hours use the 24-hour clock.
  - Controls with codelists (radio, checkbox, and drop-down list controls) each have two rows:
    - **_C**—Code item.
    - The <*variablename*> row contains the label for that value.

      For example, if the coded value of the FEMALE option of the GENDER codelist is F, the GENDER_C column contains F, and the GENDER column contains FEMALE.

Key columns in RD views

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

Key variable columns in RD views	
Column Name	**Description**
SUBJECTID	Numeric identifier for the subject.
SITE_NUMBER	Display number of the site (IRV-NUMBER from R_SITE_IDENTIFIER). INV number.
SITEID	Internal site identifier. Differs from SITE_NUMBER. You can use SITEID to join with IRV_CUR_SITE.
STUDYVERSIONID	Numeric identifier of the study version. **Note:** The value of this column is always 1.
SUBJECTVISITID	Internal ID for the actual visit.
SUBJECTVISITREV	Revision number of the subject visit. Same as FORMREV. **Note:** The value of this column is always 1.
ARMNAME	Display name of the study arm. Mnemonic arm description.
ARMID	Identifier of the study arm. Can be joined back to IRV_STUDYVERSION_ARMS.
VISITID	ID of the prototype for the visit; an ID for visit type. Can be joined back to IRV_STUDYVERSION_VISITS.
VISITINDEX	Internal ID for the actual visit. Same as SUBJECTVISITID. The value of this column is 1 for a non-repeating visit. A repeating visit will have M_VisitID # (identifier of the instance of the visit).
FORMID	Internal ID for form type. Can be joined back to IRV_STUDYVERSION_FORMS.
FORMREV	Revision number for the form. **Note:** The value of this column is always 1.
FORMDATAID	Unique form identifier for an instance of a form. Can be joined back to IRV_ACTIVATED_FORMS using FORMDATAID.

Key variable columns in RD views	
PARENTFORMDATAID	Internal number that is a unique form identifier. For a log form or repeating section, PARENTFORMDATAID contains the instance ID for the parent container form.
FORMINDEX	For a log form, the FORMINDEX is the instance of that form. For a normal form, the value will always be 1.
DOV	Date of visit. For a log form, the DOV is the first entry date of the flat table. For a normal form, the DOV is the actual date from M_VISIT. Can be blank if there is no Visit Landing page.
SUBJECTINITIALS	Patient initials. Part of standard extract. Is populated if initials are entered in the study design.
SUBJECTNUMBERSTR	Subject number string; the Patient ID in the user interface.
FORMFIRSTDATE	First entry date from the flat table.
FORMLASTDATE	Last date and time when a user entered or updated on the form.
SITEMNEMONIC	Site name displayed in the user interface.
VISITMNEMONIC	Name of the template used to create the visit.
FORMMNEMONIC	Name of the template used to create the form.
VISITORDER	Order of the visit in the study. VISITORDER is the display order of visits within the user interface. To order these rows in the order they appear in the study, select * from <viewname> ORDER BY VISITORDER, VISITINDEX.
SITENAME	Site name displayed in the user interface. Same as SITEMNEMONIC.
SITECOUNTRY	Country in which the site is located.
DDS_DATE	Last time anything related to the form was updated (data, status, and so on).

CHAPTER 3

Operational views

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About operational views

Standard data extracts in the OutcomeLogix application contain study design and operational data, and study metrics. These views do not change from study to study. They provide the linking information to tie the operational data to the clinical data. This information appears in the following views, which are created by default with each OutcomeLogix installation.

IRV_STUDYVERSIONS

This view contains one record for each time the study is revised.

IRV_STUDYVERSIONS	
Column Name (Key indicator)	**Description**
STUDYVERSIONID	Numeric identifier of the study version. **Note:** The value of this column is always 1.
STUDYID	Internal numeric identifier of the study.
STUDYREV	Revision number of the study. Same as STUDYVERSIONID. **Note:** The value of this column is always 1.
REVTIME	Date and time the study version was entered into the database. Changes when the database is updated; for example, when you apply an ELX patch.
STUDYTYPE	Type of study: 0 - System forms 1 - Study forms **Note:** The value of this column is always 1.
STUDYNAME	Name of the study associated with the study version, displayed in the user interface. Same as STUDYVERSION.
TRADEDRUGNAME	Trade name for the drug associated with the study version. **Note:** This column always contains a null value.
SPONSORDRUGNAME	Name that the sponsor uses for the drug associated with the study version.
EDITIONDESCRIPTION	Description of the study version. **Note:** This column contains a null value.
STUDYVERSION	Name of the study associated with the version of the study, shown in the user interface. Same as STUDYNAME.
PROTOCOLDESIGNNOTE	Design note for the protocol for the study version, as provided by the study designer. **Note:** This column contains a null value.

IRV_STUDYVERSIONS	
Column Name (Key indicator)	**Description**
DODVERSION	Version of Data on Demand. **Note:** This column always contains the value 3.1.1.11.
DDS_DATE	Most recent time the data was updated. **Note:** This column contains a null value.

IRV_STUDYVERSION_VISITS

This view contains one row for each visit template defined for the study.

IRV_STUDYVERSION_VISITS	
Column Name (Key indicator)	**Description**
SVVROWID	Oracle ROWID.
STUDYVERSIONID	Numeric identifier of the study version. **Note:** The value of this column is always null.
VISITID	Internal numeric identifier of the visit.
ARMID	Internal identifier of the study arm.
ARMNAME	Name of the study arm displayed in the user interface.
VISITREFNAME	RefName for the visit. Same as VISITNAME.
VISITNAME	Name of the visit; internal identifier of the visit.
DISPLAYNAME	Name of the visit as displayed in the user interface.
VISITTYPE	Numeric value of the type of visit. **Note:** The value of this column is always 1.
VTSUBJECTVISIT	Visit type is CRF: 0 - No 1 - Yes **Note:** The value of this column is always 1.
VTENROLLMENT	Visit type is Enrollment: 0 - No 1 - Yes **Note:** The value for this column is always 0.
VTSCREENING	Visit type is Screening: 0 - No 1 - Yes **Note:** The value for this column is always 0.
VTMONITOR	Visit type is Monitor: 0 - No 1 - Yes **Note:** The value for this column is always 0.

IRV_STUDYVERSION_VISITS	
Column Name (Key indicator)	**Description**
VTSTATUS	Visit type is Status: 0 - No 1 - Yes **Note:** The value for this column is always 0.
VTCOMMONCRF	Visit type is Common CRF: 0 - No 1 - Yes **Note:** The value for this column is always 0.
VTREGDOCS	Visit type is Regulatory Document: 0 - No 1 - Yes **Note:** The value for this column is always 0.
VTVISITREPORT	Visit type is Visit Report: 0 - No 1 - Yes **Note:** The value for this column is always 0.
VTCONFLICT	Visit type is Conflict: 0 - No 1 - Yes **Note:** The value for this column is always 0.
VISITPROPERTIES	Contains the same data as the VISITTYPE column; numeric value of the type of visit. **Note:** The value of this column is always 1.
VISITSREPEATING	Visit is repeating: 0 - No 1 - Yes
VISITDYNAMIC	Visit is dynamic; that is, visit is a log form: 0 - No 1 - Yes
VISITRELATION	Visit type is Relation: 0 - No 1 - Yes **Note:** The value for this column is always 0.

IRV_STUDYVERSION_VISITS	
Column Name (Key indicator)	**Description**
VISITORDER	Order of the visit in the study hierarchy.
STARTHOURSFROMPREVIOUS	Number of hours from the previous visit to when the current visit is scheduled to start. **Note:** This column contains a null value.
STARTHOURSFROMENROLL	Number of hours from enrollment to when the visit is scheduled to start. **Note:** This column contains a null value.
DDS_DATE	Most recent time the data was updated. **Note:** This column contains a null value.

IRV_STUDYVERSION_FORMS

This view contains one row for each form in the study.

IRV_STUDYVERSION_FORMS	
Column Name (Key Indicator)	**Description**
SVFROWID	Oracle ROWID.
STUDYID	Numeric identifier of the study.
STUDYVERSIONID	Numeric identifier of the study version. **Note:** The value of this column is always 1.
ARMID	Internal identifier of the study arm.
ARMNAME	Display name of the study arm.
VISITID	Internal numeric identifier for the visit.
FORMID	Internal numeric identifier for the form.
FORMREV	Revision number for the form.
FORMNAME	Form name.
FORMTYPE	Form type: 0 - Unknown type 1 - Normal form 2 - Repeating form 3 - Visit Landing page
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 **Note:** The value for this column is always 0.
FORMUNIQUEKEY	Each combination of forms having KEYFORM=1. Must be unique within the visit: 0 - No 1 - Yes **Note:** The value of this column is always 1.

IRV_STUDYVERSION_FORMS	
Column Name (Key Indicator)	**Description**
DYNAMICFORM	Form is dynamic: 0 - No 1 - Yes
ALTFORM	Form is an alternate form: 0 - No 1 - Yes **Note:** The value for this column is always 0.
EXPECTINGALTFORM	Form is expecting an alternate form: 0 - No 1 - Yes **Note:** The value for this column is always 0.
ASSOCVISIT	Form is repeating, with one or more instances associated with a one or more visits: 0 - No 1 - Yes **Note:** The value of this column is always 1.
ASSOCVISITID	Numeric identifier for the visit associated with an instance of the repeating form.
FORMINCOMMONVISIT	Form appears in the Common CRF visit: 0 - No 1 - Yes **Note:** The value for this column is always 0.
DDS_DATE	Most recent time the data was updated. **Note:** This column contains a null value.

IRV_CONTROL_REVS

This view contains one row for each control used in the study. Using the CONTROLID, you can join the control to *RD_DATADICTIONARY.CONTROLID* (on page 5) for additional information.

IRV_CONTROL_REVS	
Column Name (Key indicator)	**Description**
MDCONTROLID	Internal numeric identifier for the control metadata.
CONTROLID	Internal numeric identifier for the form.
CURRENTREV	This is the most current revision of the control: 0 - No 1 - Yes **Note:** The value of this column is always 1.
CONTROLNAME	Internal name of the control.
CONTROLTYPE	Text description of control: • OL Image Upload • Partial Date Calendar • OL Calendar Time • Calendar • Text Area • OL Calendar Entry • OL Slider • Label • Clock • Radio Group • Checkbox • Drop-Down
CONTROLLAYOUT	Control layout: 1 - Horizontal 2 - Vertical 3 - No wrapping **Note:** The value of this column is always 1.

IRV_CONTROL_REVS	
Column Name (Key indicator)	**Description**
CONTROLALIGNMENT	Control alignment: 1 - Left 2 - Center 3 - Right 4 - Top 5 - Middle 6 - Bottom **Note:** The value of this column is always 1.
CAPTIONALIGNMENT	Caption alignment with respect to the control: 1 - Left 2 - Center 3 - Right 4 - Top 5 - Middle 6 - Bottom **Note:** The value of this column is always 1.
UNITDISPLAYTYPE	Units display as: 1 - A single element 2 - Radio buttons 3 - Drop-down list **Note:** This column contains a null value.
DDS_DATE	Most recent time the data was updated. **Note:** This column contains a null value.

IRV_CUR_SITE

This view contains the most recent definition of each site.

IRV_CUR_SITE	
Column Name (Key indicator)	**Description**
SITECOUNT	Always 1; indicates that the row represents one site.
SITETYPEID	Numeric identifier of the site type.
SITEID	Numeric identifier of the site.
SITEREV	Revision number of the site.
SITENAME	Name of the site.
SITE_NUMBER	Display number of the site (IRV-NUMBER from R_SITE_IDENTIFIER).
SITEADDRESS1	First line of the site address.
SITECONTACTUSER	User to contact at the site.
SITEDATEFORMAT	The format of the dates displayed for the site, if a format is not specified at the user level: • **DDMONYYYY HH24:MM:SS**—28MAY2011 14:00:00
SITEPOSTALCODE	Site postal code.
COUNTRY	Country where the site is located.
COUNTRYID	Numeric identifier of the country where the site is located.
STATE	State where the site is located.
CITY	City where the site is located.
SITESTUDYINITIATIONDATE	Date the site came online, in the following format: • **MM/DD/YYYY HH:MM:SS**—1/25/1996 8:30:00
DDS_DATE	Most recent time the data was updated.

IRV_CUR_SUBJECT

This view contains the most recent information for each subject.

IRV_CUR_SUBJECT	
Column Name (Key indicator)	**Description**
SUBJECTCOUNT	Always 1; indicates that the row represents one subject.
SUBJECTID	Numeric identifier for the subject.
SUBJECTNUMBERSTR	Subject number, as it appears in the user interface.
USERID	Numeric identifier for the user who last modified the subject information. This column can be used to join to the IRV_CUR_USER.USERID for more information about the modifying user.
SITEID	Internal numeric identifier of the site.
SITEREV	Revision number for the site with which the subject is associated. **Note:** The value of this column is always 1.
STUDYVERSIONID	Numeric identifier of the study version. **Note:** The value of this column is always 1.
SUBJECTDOB	Subject date of birth.
SUBJECTSCREENINGDATE	Subject screening date.
CURSUBJECTSTATUSTIME	Time the subject state was last changed.

IRV_CUR_SUBJECT	
Column Name (Key indicator)	**Description**
SUBJECTSTATETEXT	One of the following values from the C_PERSON_STATE_TYPE table: • Created • Discontinued • Enrolled • Completed • Opt Out • Screen Fail • Pre-Screened • Screening • Randomized • Consented • Lost to follow-up Withdrawn
SUBJECTSTATE	Numeric value for the subject state from the C_PERSON_STATE_TYPE table: • 40001 - Created • 40002 - Discontinued • 40003 - Enrolled • 40004 - Completed • 40005 - Opt Out • 40006 - Screen Fail • 40007 - Pre-Screened • 40008 - Screening • 40009 - Randomized • 40010 - Consented • 40011 - Lost to follow-up • 40012 - Withdrawn
SUBJECTSCREENED	Subject is currently Screened: 0 - No 1 - Yes

IRV_CUR_SUBJECT	
Column Name (Key indicator)	**Description**
SUBJECTSCREENFAIL	Subject is currently Screen Failed: 0 - No 1 - Yes
SUBJECTENROLLED	Subject is currently Enrolled: 0 - No 1 - Yes
SUBJECTINCOMPLETE	Subject is currently Not Complete: 0 - No 1 - Yes
DDS_DATE	Most recent time the data was updated.

IRV_CUR_USER

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

IRV_CUR_USER	
Column Name (Key indicator)	**Description**
USERCOUNT	Always 1; indicates that the row represents one user.
USERTYPEID	Internal numeric identifier for the user type.
USERID	Internal numeric identifier for the user.
USERCREATETIME	Date the user was created.
USERNAME	Account name for the user.
RIGHTSGROUPID	Numeric identifier of the rights group to which the user is currently assigned.
RIGHTSGROUP	Name of the rights group to which the user is currently assigned.
USERACTIVESTATE	User is currently activated: 0 - No 1 - Yes
USERALTPHONENUMBER	Alternate telephone number of the user.
USERCOUNTRY	Country in which the user address is located.
USERDATEFORMAT	Desired date format for viewable OutcomeLogix pages for the user.
USERDESCRIPTION	Description of the user; for example, role of the user in the study.
USERDISPLAYNAME	User name, as displayed in the OutcomeLogix application window.
USEREMAILADDRESS	Email address of the user.
USERFIRSTNAME	Given name of the user.
USERLANGID	Preferred language of the user.
USERLASTNAME	Surname of the user.
USERPOSTALCODE	Postal code of the user address.
USERRESETPASSWORD	If a user must reset a password, set to 1.
USERSTATEPROVINCE	State or province where the user is located. **Note:** This column contains a null value.
USERSUBJECTGUID	Globally Unique Identifier (GUID) of the user identifier. **Note:** This column contains the Oracle ROWID.

IRV_CUR_USER	
Column Name (Key indicator)	**Description**
DDS_DATE	Most recent time the data was updated.

IRV_CUR_QUERY

This view contains the most recent information about each query.

IRV_CUR_QUERY	
Column Name (Key indicator)	**Description**
QUERYCOUNT	Always 1; indicates that the row represents one query.
QUERYID	Internal numeric identifier of the query.
QUERYTIME	Time of the most recent query revision.
QUERYUSERID	Internal numeric identifier of the user who last revised the query.
CONTEXTID	Internal numeric identifier of the item context with which the query is associated.
SUBJECTVISITID	Internal numeric identifier of the subject visit associated with the query.
SUBJECTID	Internal numeric identifier of the subject associated with the query.
STUDYID	Internal numeric identifier of the study associated with the query.
SITEID	Internal numeric identifier of the site associated with the query.
STUDYVERSIONID	Numeric identifier of the study version. **Note:** The value of this column is always 1.
VISITID	Internal numeric identifier for the visit in which the query exists.
VISITINDEX	Identifier of the instance of the visit. 0 - Unstarted, scheduled visit. 1 - Started, non-repeating visit. <*revision number*> - Instance of a repeating visit.
QUERY_TYPE	Type of query: • Patient • Visit • Form
FORMID	Numeric identifier of the form.
FORMDATAID	Unique form identifier for the instance of the form on which the query .exists. Can be joined back to IRV_ACTIVATED_FORMS and RD_ views using FORMDATAID.

IRV_CUR_QUERY	
Column Name (Key indicator)	**Description**
ITEMID	Internal numeric identifier of the item type with which the query is associated.
FORMINDEX	For a log form, the FORMINDEX is the instance of that form. For a normal form, the value will always be 1.
ITEMSETID	Numeric identifier for the itemset with which the query is associated. **Note:** This column contains a null value.
QREVS	Number of times the query has been revised.
MINQUERYREV	Identifier of the first query revision.
MAXQUERYREV	Identifier of the most recent query revision.
QUERYTYPE	Query type: 0 - Auto 1 - Manual
QTYPEAUTO	Query type is Autoquery: 0 - No 1 - Yes
QTYPEMANUAL	Query type is Manual: 0 - No 1 - Yes
QUERYSTATE	Query state: 0 - Open 1 - Pending 2 - Approved 3 - Closed 4 - Candidate 5 - Deleted
QOPENED	Query is opened: 0 - No 1 - Yes
QPENDING	Query is pending: 0 - No 1 - Yes

IRV_CUR_QUERY	
Column Name (Key indicator)	**Description**
QAPPROVED	Query is approved: 0 - No 1 - Yes
QCLOSED	Query is closed: 0 - No 1 - Yes
QCANDIDATE	Query is candidate: 0 - No 1 - Yes
QDELETED	Query is deleted: 0 - No 1 - Yes
QUERYGROUP	A string populated with the query type; for example, Manual Query or System Query.
QUERYDATA	Current query text.
RULEITEMID	Internal numeric identifier of the rule item that generated the query. Can be used to join to IRV_STUDYVERSION_QUERYRULES.
INFORMPARTIALURL_QUERY	Partial URL for the query. **Note:** This column contains a null value.
QORIGUSER	Numeric identifier of the user who generated the query.
DDS_DATE	Most recent time the data was updated.
QSTATUSTIME	Date and time the current query revision was made.
QMINCANDIDATE	Date and time when the query was first assigned the Candidate state.
LASTCANDIDATETEXT	Query text when the query was most recently assigned the Candidate state.
QMINOPENED	Date and time when the query was first assigned the Opened state.
LASTOPENEDTEXT	Query text when the query was most recently assigned the Opened state.
QMINANSWERED	Date and time when the query was first answered.
QMAXANSWERED	Date and time when the query was most recently answered.

IRV_CUR_QUERY	
Column Name (Key indicator)	**Description**
FIRSTANSWEREDTEXT	Query text when the query was first answered.
LASTANSWEREDTEXT	Query text when the query was most recently answered.
MINQUERYDATE	Date and time when the query was first modified.
MAXQUERYDATE	Date and time when the query was most recently modified.

IRV_USERS_SITES

This view contains user-site associations.

IRV_USERS_SITES	
Column Name (Key indicator)	**Description**
USERID	Internal numeric identifier for the user.
SITEID	Internal numeric identifier for the site.
RIGHTSGROUPID	Internal numeric identifier of the rights group to which the user is currently assigned.
USERNAME	Account name for the user.
RIGHTSGROUP	Name of the rights group to which the user is currently assigned.
SITENAME	Name of the site with which the user is associated.
DDS_DATE	Most recent time the data was updated. **Note:** This column contains a null value.

IRV_FORM_REVS

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

IRV_FORM_REVS	
Column Name (Key indicator)	**Description**
FORMID	Internal numeric identifier of the form.
FORMREV	Revision number for the form. **Note:** This column contains a null value.
FIRSTREV	First revision of the form: 0 - No 1 - Yes **Note:** This column contains a null value.
CURRENTREV	Most current revision of the form: 0 - No 1 - Yes **Note:** The value of this column is always 1.
FORMREFNAME	RefName for the form. **Note:** This column contains a null value.
FORMNAME	Internal character identifier for the form.
FORMMNEMONIC	Abbreviated name for the form. **Note:** This column contains a null value.
FORMNOTE	Form note, as displayed below the form name in the user interface. **Note:** This column contains a null value.
FORMTYPE	Form type: 0 – Unknown type 1 – Normal form 2 – Repeating form 3 – Visit Landing page **Note:** The value of this column is always 1.
FORMHELPURL	URL for the sponsor-provided form Help. **Note:** This column contains a null value.
QUESTIONWIDTH	Question width for the items on the form. **Note:** This column contains a null value.

IRV_FORM_REVS	
Column Name (Key indicator)	**Description**
CONTROLWIDTH	Width for the controls on the form. **Note:** This column contains a null value.
REPEATINGFORM	Form can appear multiple times in a visit: 0 - No 1 - Yes
FORMUNIQUEKEY	Each combination of forms having KEYFORM=1. Must be unique within the visit: 0 - No 1 - Yes **Note:** The value of this column is always 1.
FORMDESIGNNOTE	Design note for the form, as provided by the study designer. **Note:** This column contains a null value.
DDS_DATE	Most recent time the data was updated. **Note:** This column contains a null value.

IRV_STUDYVERSION_ARMS

This view contains one row for each study arm in the study.

IRV_STUDYVERSION_ARMS	
Column Name (Key Indicator)	**Description**
STUDYVERSIONID	Numeric identifier of the study version. **Note:** The value of this column is always 1.
STUDYID	Numeric identifier of the study.
STUDYREV	Revision number of the study. **Note:** The value of this column is always 1.
ARMID	Internal numeric identifier of the study arm.
ARMNAME	Display name of the study arm.

IRV_STUDYVERSION_QUERYRULES

This view contains one row for each study validation rule in the study.

IRV_STUDYVERSION _QUERYRULES	
Column Name (Key Indicator)	**Description**
STUDYVERSIONID	Numeric identifier of the study version. **Note:** The value of this column is always 1.
STUDYID	Numeric identifier of the study.
STUDYREV	Revision number of the study. **Note:** The value of this column is always 1.
VALIDATION_ID	Internal identifier of the validation performed by the edit check.
RULEITEMID	Internal identifier of the action taken by the edit check.
NAME	Internal name of the validation.
VALIDATION	Description of the validation performed by the edit check.
ACTION	Action taken by the edit check.

IRV_ACTIVATED_FORMS

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

IRV_ACTIVATED_FORMS	
Column Name (Key indicator)	**Description**
SVECPROWID	Oracle ROWID. **Note:** This column contains a null value.
FROWID	Oracle ROWID. **Note:** This column contains a null value.
CSVROWID	Oracle ROWID. **Note:** This column contains a null value.
SFROWID	Oracle ROWID. **Note:** This column contains a null value.
FHROWID	Oracle ROWID. **Note:** This column contains a null value.
FTROWID	Oracle ROWID. **Note:** This column contains a null value.
SUBJECTVISITID	Numeric identifier of the subject visit.
SUBJECTVISITREV	Revision number of the subject visit. **Note:** This column contains a null value.
SUBJECTID	Numeric identifier for the subject.
STUDYID	Numeric identifier for the study associated with the form. **Note:** This column contains a null value.
SITEID	Internal numeric identifier of the site.
STUDYVERSIONID	Numeric identifier of the study version. **Note:** The value of this column is always 1.
VISITID	Internal numeric identifier of the visit.
VISITINDEX	Identifier of the instance of the visit: 1 - Started, non-repeating visit. <*revision number*> - Instance of a repeating visit.
DOV	Date of visit. For a log form, the first entry date of the flat table. For a normal form, the actual date from M_VISIT. Can be blank if there is no Visit Landing page.

IRV_ACTIVATED_FORMS	
Column Name (Key indicator)	**Description**
VISITDELETED	Visit associated with the form has been deleted: 0 - No 1 - Yes **Note:** This column contains a null value.
FORMID	Internal numeric identifier of the form.
FORMDATAID	Unique form identifier for an instance of a form. Can be joined back to RD views.
FORMREV	Revision number for the form. **Note:** The value of this column is always 1.
FORMINDEX	For a log form, the FORMINDEX is the instance of that form. For a normal form, the value will always be 1.
INFORMACTIVATIONTIME	Date when the visit with which the form is associated was activated.
FORMTYPE	Form type: 0 – Unknown type 1 – Normal form 2 – Repeating form 3 – Visit Landing page
FHREVS	Count of times the form state has changed.
MINFORMHISTORYID	Identifier of the first form history revision. **Note:** This column contains a null value.
MINFORMHISTORYREV	Revision number of the first form history revision. **Note:** This column contains a null value.
MAXFORMHISTORYID	Identifier of the most recent form history revision. **Note:** This column contains a null value.
MAXFORMHISTORYREV	Revision number of the most recent form history revision. **Note:** This column contains a null value.
HISTORICALORDER	Sequential numeric identifier that corresponds to the current form state revision transaction. **Note:** This column contains a null value.
USERID	Numeric identifier of the user who last changed the form state.
FORMHISTORYTIME	Time of the most recent form state change.

IRV_ACTIVATED_FORMS	
Column Name (Key indicator)	**Description**
TRANSACTIONID	Numeric identifier of the most recent transaction to change the form state. **Note:** This column contains a null value.
REASON	Reason for most recent form state change. **Note:** This column contains a null value.
STATEHIST	Current form state. **Note:** This column contains a null value.
ORIGINALSTATE	Previous form state. **Note:** This column contains a null value.
ACTION	Action that may have occurred in conjunction with the most recent form state change. **Note:** This column contains a null value.
LOCKEDSTATE	Form is in the Locked state: 0 - No 1 - Yes
LOCKEDMINSTATE	First date and time the form was placed in the Locked state.
LOCKEDMAXSTATE	Most recent date and time the form was placed in the Locked state.
FROZENSTATE	Form is in the Frozen state: 0 - No 1 - Yes
FROZENMINSTATE	First date and time the form was placed in the Frozen state.
FROZENMAXSTATE	Most recent date and time the form was placed in the Frozen state.
COMPLETEDSTATE	Form is in the Completed state: 0 - No 1 - Yes
COMPLETEDMINSTATE	First date and time the form was placed in the Completed state.
COMPLETEDMAXSTATE	Most recent date and time the form was placed in the Completed state.

IRV_ACTIVATED_FORMS	
Column Name (Key indicator)	**Description**
STARTEDSTATE	Form is in the Started state: 0 - No 1 - Yes
STARTEDMINSTATE	First date and time the form was placed in the Started state.
STARTEDMAXSTATE	Most recent date and time the form was placed in the Started state.
SIGNEDSTATE	Form is in the Signed state: 0 - No 1 - Yes
SIGNEDMINSTATE	First date and time the form was placed in the Signed state.
SIGNEDMAXSTATE	Most recent date and time the form was placed in the Signed state.
REMOVEVIEWSTATE	Form is in the Remote View state: 0 - No 1 - Yes
REMOTEVIEWMINSTATE	First date and time the form was placed in the Remote View state.
REMOTEVIEWMAXSTATE	Most recent date and time the form was placed in the Remote View state.
DMREVIEWEDSTATE	Form is in the DM Reviewed state: 0 - No 1 - Yes
DMREVIEWEDMINSTATE	First date and time the form was placed in the DM Reviewed state.
DMREVIEWEDMAXSTATE	Most recent date and time the form was placed in the DM Reviewed state.
SDVREADYSTATE	Form is in the SV Ready state: 0 - No 1 - Yes **Note:** This column contains a null value.
FMINSDVREADYSTATE	First date and time the form was placed in the SV Ready state. **Note:** This column contains a null value.

IRV_ACTIVATED_FORMS	
Column Name (Key indicator)	**Description**
FMAXSDVREADYSTATE	Most recent date and time the form was placed in the SV Ready state. **Note:** This column contains a null value.
SDVPARTIALSTATE	Form is in the SV Partial state: 0 - No 1 - Yes **Note:** This column contains a null value.
FMINSDVPARTIALSTATE	First date and time the form was placed in the SV Partial state. **Note:** This column contains a null value.
FMAXSDVPARTIALSTATE	Most recent date and time the form was placed in the SV Partial state. **Note:** This column contains a null value.
SDVCOMPLETESTATE	Form is in the SV Complete state: 0 - No 1 - Yes **Note:** This column contains a null value.
FMINSDVCOMPLETESTATE	First date and time the form was placed in the SV Complete state. **Note:** This column contains a null value.
FMAXSDVCOMPLETESTATE	Most recent date and time the form was placed in the SV Complete state. **Note:** This column contains a null value.