Oracle® Health Sciences Clinical Development Analytics

Release Content Document

Release 2.1 for Plus Configuration

E28231-01

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1 Introduction

Welcome to the Oracle® Health Sciences Clinical Development Analytics 2.1 Release Content Document.

1.1 Purpose of Document

The Release Content Document (RCD) communicates information about new or changed functionality in the specified release of Oracle Health Sciences Clinical Development Analytics (CDA). Existing functionality from prior releases is not described.

2 Functionality

CDA v2.1 expands on v2.0 functionality in these ways:

1. Addition of new measures drawn from the Siebel Clinical database

2. Enhanced usability through enhanced reports and dashboards

3. Support for integration of data from multiple sources

2.1 New and Modified Dimensions and Facts

2.1.1 Dimensions

Following is a list of all the Dimensions in CDA 2.1:

- CRF

- CRF Book

- Geography

- Investigator

- Product

- Program

- Region

- Site

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- Site Visit

- Study

- Study-Site

- Study-Site Contacts

- Study-Site Team Member

- Subject

- Time

- Validation Procedure

The Site Visit dimension has been added in release 2.1. It has the following attributes:

Table 1   Attributes of Site Visit Dimension

Attribute Name	Business Description
Site Visit Action Link	ROW_ID for the Siebel Clinical Site Visit table; can be used in Siebel Clinical for an Action Link
Site Visit Comments	Comments about the Site Visit
Site Visit Completed Date	Indicates the date the site visit was completed
Site Visit Name	The visit name field in the source system
Site Visit Report Approved Date	Indicates the date the Site Visit Report was approved
Site Visit Report Completed Date	Indicates the date the Site Visit Report was completed
Site Visit Report Status	Indicates the status of the Site Visit Report
Site Visit Report Template	The template selected to create a site visit report in the source system
Site Visit Start Date	Indicates the date the Site Visit was started
Site Visit Status	Indicates the status of the Site Visit
Site Visit Type	Indicates the type of Site Visit

2.1.2 Facts

Following is a list of all the Facts in CDA 2.1.

- Discrepancies

- Discrepancy Review Statuses

- Document Metrics

- Follow Up Item Metrics

- Received CRFs

- Region Metrics

- Site Visit Metrics

- Study Metrics

- Study-Site Metrics

- Subject Metrics

The following two new Fact tables were added in CDA 2.1:

- Follow Up Item Metrics
- Site Visit Metrics

The new Fact tables have the following attributes:

Table 2   Measures in New Fact Tables

Fact Table	Grouping	Measure Name	Business Description
Follow Up Item Metrics	Intervals	# Days Follow Up Item Open	If a Follow Up Item is resolved, the number of days between Site Visit Completed Date and Follow Up Item Completed Date. If the Follow Up Item is not resolved, the number of days between Site Visit Completed Date and today's date.
Follow Up Item Metrics	Intervals	# Days Follow Up Item Outstanding	For outstanding Follow Up Items, the number of days between Parent Site Visit End and today's date.
Follow Up Item Metrics	Intervals	# Days from Site Visit Completed to Follow Up Item Completed	The number of days between Site Visit Completed and Follow Up Item Resolved dates.
Follow Up Item Metrics	Transactional Data	Follow Up Item Action Link	ROW_ID for the Siebel Clinical Follow Up Item table - can be used in Siebel Clinical for an Action Link
Follow Up Item Metrics	Transactional Data	Follow Up Item Comments	Indicates comments for Follow Up Items
Follow Up Item Metrics	Transactional Data	Follow Up Item Created Date	Indicates the date the Follow Up Item was created
Follow Up Item Metrics	Transactional Data	Follow Up Item Description	Indicates description of the Follow Up Item
Follow Up Item Metrics	Transactional Data	Follow Up Item Status	Indicates status of the Follow Up Item
Follow Up Item Metrics	Transactional Data	Follow Up Item Type	Indicates the type of Follow Up Item
Follow Up Item Metrics	Transactional Data	Follow Up Item Completed Date	Indicates the date the Follow Up Item was resolved
Follow Up Item Metrics	Transactional Data	Follow Up Item Due Date	Indicates the date the Follow Up Item is due
Site Visit Metrics	Counts	# Follow Up Items	Indicates the number of Follow Up Item records

Table 2   (Cont.) Measures in New Fact Tables

Fact Table	Grouping	Measure Name	Business Description
Site Visit Metrics	Counts	# Follow Up Items Completed	The number of follow up items with a Follow Up Item Completed Date.
Site Visit Metrics	Counts	# Outstanding Follow Up Items	The number of unresolved Follow Up Items.
Site Visit Metrics	Intervals	# Days Visit Report Approval Outstanding	For outstanding visit report approvals, the number of days between Site Visit report completion and today's date.
Site Visit Metrics	Intervals	# Days Visit Report Completion Outstanding	For outstanding visit reports, the number of days between Site Visit End and today's date.
Site Visit Metrics	Intervals	# Days from Site Visit Completed to Visit Report Approved	The number of days between Site Visit Completed and Visit Report Approved dates.
Site Visit Metrics	Intervals	# Days from Site Visit Completed to Visit Report Completed	The number of days between Site Visit Completed and Visit Report Completed dates.
Site Visit Metrics	Intervals	# Days from Site Visit Start to Site Visit Completed	Indicates the number of days between when the Site Visit was Started and Completed.
Site Visit Metrics	Intervals	# Days from Visit Report Completed to Visit Report Approved	The number of days between Visit Report Completed and Visit Report Approved dates.

In addition to these two new fact tables, new measures were added to a number of existing fact tables. Table 3 indicates the measures added to existing fact tables in CDA 2.1:

Table 3   Fact Measures Added to Existing Fact Tables

Fact Table	Grouping	Measure Name	Business Description
Document Metrics	Counts	# Documents Outstanding	The number of documents with a Sent Date and no Received Date.
Document Metrics	Counts	# Documents Received	The number of documents with a Received Date.
Document Metrics	Intervals	# Days Until Document Expiration	The number of days between Document Expiration Date and today's date.
Document Metrics	Transactional Data	Document Domain	The domain of the document, such as study, region, study-site, contact, or account.

Table 3   (Cont.) Fact Measures Added to Existing Fact Tables

Fact Table	Grouping	Measure Name	Business Description
Study Metrics	Ratios	% Randomized vs. Planned - Study	The percentage of planned subjects randomized.
Study Metrics	Statistics	1st Site Initiated Date	The earliest of site initiated dates for a study.
Study Metrics	Statistics	Latest Site Initiated Date	The date of the most recent site initiated.
Study Metrics	Statistics	Latest Site Initiated Date	Latest Site Initiated Date
Study-Site Metrics	Counts	# Completed Site Visits	The number of Site Visit records with a Site Visit Completed Date
Study-Site Metrics	Counts	# Completed Visit Reports	The number of Visit Reports where Completed Date is not null.
Study-Site Metrics	Counts	# Site Visits	The number of Site Visit records
Study-Site Metrics	Counts	# Subjects Enrolled Since Last Site Visit	The number of subjects that have been enrolled since the most recent Site Visit End date.
Study-Site Metrics	Counts	# Subjects Randomized Since Last Site Visit	The number of subjects that have been randomized since the most recent Site Visit End date.
Study-Site Metrics	Counts	# Subjects Screened Since Last Site Visit	The number of subjects that have been screened since the most recent Site Visit End date.
Study-Site Metrics	Counts	# Visit Reports	The number of visit report records
Study-Site Metrics	Counts	# Visit Reports Awaiting Approval	The number of visit reports where Completed Date is not null and Approved Date is null
Study-Site Metrics	Counts	# Visit Reports Awaiting Completion	The number of visit reports with a site visit end date but no visit report completion date
Study-Site Metrics	Intervals	# Days Since Latest Site Visit	The number of dates since the most recent completed site visit.
Study-Site Metrics	Ratios	% Randomized vs. Planned - Study-Site	The percentage of planned subjects randomized.
Study-Site Metrics	Statistics	1st Site Visit Date since Site Initiated	The Site Visit Start Date of the first site visit that occurred after the Site Initiated Date.
Study-Site Metrics	Statistics	Latest Site Visit Completed Date	Most recent of all Site Visit Completed Dates for a Site

Table 3   (Cont.) Fact Measures Added to Existing Fact Tables

Fact Table	Grouping	Measure Name	Business Description
Study-Site Metrics	Statistics	Latest Site Visit Start Date	Most recent of all Site Visit Completed Dates for a Site
Study-Site Metrics	Statistics	Next Site Visit Date	Earliest Site Visit with Start Visit after today.

2.2 New and Modified Dashboards and Reports

The sections below list changes related to Dashboards and Reports.

2.2.1 Dashboards

Following is the list of all the dashboards in CDA 2.1. New dashboards are listed in *italics*:

- *Index*
- *CRA*
- Data Manager - EDC
- Data Manager - Paper
- *Study Manager*
- *Study Overview*
- *Study-Site Overview*

2.2.2 Reports

Following is the list of all new reports in CDA 2.1:

Table 4   CDA 2.1 New Reports

Report Name	Report Description
CDA-CO-100 Legend: Detailed Study Milestones Report	Provides the legend for Detailed Study Milestones Report
CDA-CO-101 Study Milestone with Indicators (Study Overview)	Lists (for a study) key milestone dates and enrollment, enrollment progress, and study-health indicator. This report indicates whether a study requires action, and why.
CDA-CO-102 Detailed Study Milestones Report	Lists (for a study) key milestone dates and enrollment, enrollment progress, and study-health indicator. This report indicates whether a study requires action, and why.
CDA-CO-103 Study Information	Displays a summary of identifying information for a study, including Study #, Program, Product and Study Status.
CDA-CO-104 Legend: Detailed Study-Site Milestones Report	Provides the legend for Detailed Study-Site Milestones Report
CDA-CO-201 Study-Site Team Member List	Lists all of the team members for a study-site.
CDA-CO-202 Investigator Contact & Studies List	Lists contact information for an investigator, as well as a list of the studies they have participated in. This report provides contact information on principal investigators.

Table 4   (Cont.) CDA 2.1 New Reports

Report Name	Report Description
CDA-CO-203 Study-Site Milestones with Indicators (Single Study-Site)	Lists (for a study-site) key milestone dates and enrollment, enrollment progress, and study-site-health indicator. This report indicates whether a study-site requires action, and why.
CDA-CO-204 Study-Sites with Red or Yellow Performance Flag	Lists study-sites with an indicator of study-site health, where the indicator is red or yellow. This report indicates which study-sites require action and why.
CDA-CO-205 Study-Site Milestones with Indicators (CRA)	Lists study-sites with key milestone dates and enrollment, enrollment progress, and study-site-health indicator. This report indicates whether a study-site requires action, and why.
CDA-CO-206 Study-Site Information	Displays a summary of identifying information for a study-site, including Study #, Program, Study-Site ID, Principal Investigator and Study-Site Status.
CDA-CO-207 Study-Site List with Indicators	Lists study-sites with key milestone dates, subject information, and indicator of study-site health. This report indicates whether a study-site requires action and why.
CDA-CO-208 Study Site Milestones with Indicators	Lists the study sites for the study with key milestone dates, subject information, and indicator of study-site health. This report indicates whether a study-site requires action and why.
CDA-CO-300 Screen Failure Reason by Site Chart	Displays (by site) the number of subjects who failed screening. It is stacked by screen failure reason. This report indicates which screen failure reasons account for the most screen failures.
CDA-CO-301 Study Sites Initiated but Zero Enrolled	Lists all study-sites that have been initiated but have not yet enrolled a subject, including the time since initiation. This report indicates how poorly a study-site is performing with regard to enrolling the first subject post-initiation.
CDA-CO-302 Study Sites Initiated, only One Subject Enrolled	Lists all study-sites that have been initiated but have only enrolled one subject, including the time since that subject was enrolled. This report indicates how poorly a study-site is performing with regard to enrolling more than one subject post-initiation.
CDA-CO-304 Uninitiated Sites	Lists study-sites that have not yet been initiated, including whether they've received IRB/EC approval and number of outstanding documents. This report indicates which study-sites are awaiting initiation and possible reasons for delay.

Table 4   (Cont.) CDA 2.1 New Reports

Report Name	Report Description
CDA-CO-305 Study List - Initiation Details	Lists studies that are not in a status of Completed or Planned and have not achieved 100% enrollment. Displays planned and actual number of sites, including how many are initiated, screening, and enrolling. This report provides a list of ongoing studies that have not yet achieved 100% enrollment, including number of study-sites to reach certain achievements.
CDA-CO-400 Screening vs. Enrollment by Region Chart	Displays cumulative screening and enrollment by study region. This report indicates how each region in a study is progressing toward recruitment goals.
CDA-CO-401 Study-Site List by Recruitment Performance Group	Lists study-sites grouped by those with no subjects enrolled and those with 1 or more subjects enrolled. This report indicates which study-sites are performing better than others.
CDA-CO-403 Subjects Enrolled per Month, Over Time	Displays the number of subjects enrolled per month. This report indicates the pattern of enrollment over time at a study-site.
CDA-CO-404 Study-Region List & Recruitment Counts	Lists all study regions and recruitment counts. This report indicates how well each region is progressing toward recruitment goals.
CDA-CO-405 Study-Site Subject Recruitment Narrative	Displays a summary of recruitment information for a study-site. This report indicates planned recruitment vs. actual screening, enrollment and randomization information for a single study-site.
CDA-CO-406 Study List - Recruitment Details	Lists studies that are not in a status of Completed or Planned and have not achieved 100% enrollment. Displays planned and actual recruitment information. This report provides a list of ongoing studies that have not yet achieved 100% enrollment, including recruitment information.
CDA-CO-407 Screening Overview (Study Level)	Displays a summary of screening information for a study. This report indicates planned recruitment vs. actual screening, enrollment and randomization information for a single study.
CDA-CO-408 Enrollment Progress Over Time (Study Level)	Shows cumulative actual enrollment over time, compared to static plan (50%, 75%, 90% and 100%) for a study. This report indicates the progress of subject recruitment. It also indicates how well we are progressing against planned enrollment.
CDA-CO-410 Total Subject Enrollment by Region	Shows cumulative actual enrollment by region. This report indicates which regions are contributing the most to recruitment.

Table 4   (Cont.) CDA 2.1 New Reports

Report Name	Report Description
CDA-CO-411 Comparative Site Enrollment Bar Chart	Shows cumulative actual enrollment over time compared to plan for study. Each bar in the report is stacked by study-site. This report indicates the progress of subject recruitment, and which sites are contributing the most/least to enrollment.
CDA-CO-412 Initiated Study-Sites with Recruitment Counts	Lists initiated study-sites and their progress toward recruitment goals, as well as details including days since initiation and days since latest enrollment.
CDA-CO-413 Site Recruitment Performance Pie Chart	Shows the study-sites with 1 or more subjects enrolled, no subjects enrolled, greater than 90% of planned enrollment completed, or enrolling more than 1 subject but less than 90% of planned enrollment. This report indicates the distribution of top performing and non-performing study-sites.
CDA-CO-414 Subject Enrollment by Region Pie Chart	Shows the distribution of subject enrollment by region. This report indicates which regions are contributing the most to recruitment.
CDA-CO-415 Screening Overview (Study-Site Level)	Displays a summary of screening information for a study-site. This report indicates planned recruitment vs. actual screening, enrollment and randomization information for a single study-site.
CDA-CO-416 Site Recruitment Performance Charts - Single Study	Shows the study-sites with 1 or more subjects enrolled, no subjects enrolled, or greater than 90% of planned enrollment completed, by region. Each bar displays the number of sites, and the line displays the percentage of sites. This report indicates how many sites are performing well or poorly with regard to subject recruitment.
CDA-CO-417 Cumulative Screening and Enrollment Bar Chart (Study-Site)	Displays planned number of subjects for the study-site compared to actual screened and enrolled. This report indicates how well the study-site is progressing toward recruitment goals.
CDA-CO-418 Cumulative Enrollment and Early Term Chart (Study-Site)	Displays planned number of subjects for the study-site compared to enrolled and early terminated. This report indicates how well the study-site is progressing toward retention goals.
CDA-CO-419 Subject Recruitment	Displays a summary of recruitment information for a study. This report indicates planned recruitment vs. actual screening, enrollment and randomization information for a single study.
CDA-CO-420 Screen Failure Reason Chart	Displays number screen failures for a study-site, by screen failure reason. This report indicates the distribution of screen failure reasons among subjects who failed screening.

Table 4 (Cont.) CDA 2.1 New Reports

Report Name	Report Description
CDA-CO-500 Study-Site Subject Retention	Displays a summary of retention information for a study-site. This report indicates planned recruitment vs. actual retention information for a single study-site.
CDA-CO-501 Subject Retention Over Time Chart (Study Level)	Shows cumulative subjects completed and early terminated over time, compared to static planned subjects enrolled (50%, 75%, 90% and 100%) for a study. This report indicates the progress of subject retention and early termination.
CDA-CO-502 Subject Retention (Study-Site Level)	Displays a summary of retention information for a study-site. This report indicates planned recruitment vs. actual retention information for a single study-site.
CDA-CO-503 Subject Retention (Study Level)	Displays a summary of retention information for a study. This report indicates planned recruitment vs. actual retention information for a single study.
CDA-CO-504 Subject Retention	Displays a summary of retention information for a study. This report indicates planned recruitment vs. actual retention information for a single study.
CDA-CO-600 Study Documents List	Lists all study documents collected, including document status, sent date, received date, and comments. This report indicates which study-level documents have been collected or are missing.
CDA-CO-601 Documents List (Multiple Study-Sites)	Lists all site documents collected, including document status, sent date, received date, and comments. This report indicates which study-site-level documents have been collected or are missing.
CDA-CO-602 Outstanding Documents List	Lists all site documents that have been sent but not received from the study-site. This report indicates which study-site-level documents need to be collected.
CDA-CO-603 Documents List (Study-Site)	Lists all site documents collected, including document status, sent date, received date, and comments. This report indicates which study-site-level documents have been collected or are missing.
CDA-CO-604 Document Collection Cycle Times Table (Study-Site)	Lists the cycle times for all documents collected for the study. This report indicates the number of days a document has been outstanding, or how long it took to receive from the site.
CDA-CO-700 Top Investigators, % Planned Enrollment Completed	Lists the top investigators based on % planned enrollment completed for study-sites that are either completely enrolled or study-sites that are closed. This report indicates who the top performing investigators in the study are.

Table 4   (Cont.) CDA 2.1 New Reports

Report Name	Report Description
CDA-CO-701 Top Investigators, Total Enrollment	Lists the top investigators based on total number of subjects enrolled for study-sites that are either completely enrolled or study-sites that are closed. This report indicates who the top performing investigators in the study are.
CDA-CO-702 Top Investigators Compared to All Investigators for Study, Total Enrollment Chart	Lists the top investigators based on % planned enrollment completed for study-sites that are either completely enrolled or study-sites that are closed. This report indicates who the top performing investigators in the study are.
CDA-CO-800 Site Visit Duration - Study Site	Displays the minimum, median, and maximum duration of site visits that have taken place at this study-site, as well as the total number of completed site visits. This report indicates the amount of time it might take to complete a site visit for a study-site.
CDA-CO-801 # Follow Up Items by Type for Study-Site	Displays the number of follow up items identified for a study-site, by type. This report indicates which types of issues are occurring at a study-site most frequently.
CDA-CO-802 Median # Follow Up Items per Site for Study	Displays the median number of follow up items identified across all study-sites for a study, by type. This report indicates which types of issues are occurring at in the study most frequently.
CDA-CO-803 List of Follow Up Items	Lists follow up items, including type, comments, and key dates.
CDA-CO-804 Outstanding Monitoring Reports (CRA View)	Lists all monitoring reports awaiting completion.This report indicates which monitoring reports need to be completed and submitted for approval.
CDA-CO-805 Outstanding Follow up Items - Study Overview	Lists the outstanding follow up items for the study. This report indicates which active issues the study is encountering during monitoring visits, and how long they've been open.
CDA-CO-806 Outstanding Follow up Items (CRA View)	Lists the outstanding follow up items. This report indicates which active issues are occurring during monitoring visits, and how long they've been open.
CDA-CO-807 Outstanding Follow up Items (Study Manager View)	Lists the outstanding follow up items for the study. This report indicates which active issues the study is encountering during monitoring visits, and how long they've been open.
CDA-CO-808 Site Visit Duration - Study	Displays the median duration of site visits that have taken place across all study-sites for this study, as well as the total number of completed site visits. This report indicates the median amount of time it might take to complete a site visit for a study.
CDA-CO-809 Outstanding Monitoring Report Approvals (Study Manager View)	Lists the monitoring reports that have been completed but not yet approved. This report indicates which monitoring reports require approval.

Table 4   (Cont.) CDA 2.1 New Reports

Report Name	Report Description
CDA-CO-810 # Follow Up Items by Type (multiple Study-Sites)	Displays the number of follow up items by study-site, stacked by type. This report indicates which types of issues are occurring at a study-site most frequently.
CDA-CO-811 Outstanding Monitoring Reports (Study-Site View)	Lists all monitoring reports awaiting completion at the study-site. This report indicates which monitoring reports need to be completed and submitted for approval.
CDA-CO-812 Sites with No Visits Since Initiation	Lists study-sites that have been initiated, but that have not yet had an interim monitoring visit. Includes subject recruitment information. This report indicates which sites might need to be monitored by identifying initiated sites that have not had an interim monitoring visit since initiation, and whether they have screen or enrolled subjects.
CDA-CO-814 Outstanding Monitoring Report Approvals (CRA View)	Lists all monitoring reports awaiting approval. This report indicates which monitoring reports require an action: review and approval.
CDA-CO-815 Outstanding Follow up Items (Study-Site Overview)	Lists all follow up items that have not been completed. This report indicates which follow up items need to be resolved.
CDA-CO-816 Sites to Monitor - Days Since Last visit	Lists study-sites, sorted by the number of days that have passed since the last site visit. This report indicates which sites might need to be monitored by identifying which study-sites have had the most time elapse since the most recent site visit, as well as how many subjects have been enrolled in that time.
CDA-CO-817 Monitoring Report Approval Turnaround Times	Displays the number of visit report approvals within 10 days, between 10 and 20 days, and greater than 20 days. Displays the information over time. This report indicates how many visit report approvals fall within designated thresholds.
CDA-CO-819 Visit Frequency Compared to Subject Enrollment	Shows the number of site visits and number of subjects enrolled over time. This report indicates the relationship between subject enrollment and the number of site visits.
CDA-CO-820 Monitoring Report Completion Turnaround Times	Displays the number of visit reports completed within 10 days, between 10 and 20 days, and greater than 20 days. Displays the information over time. This report indicates how many visit report completions fall within designated thresholds.
CDA-CO-821 Site Visit Analysis Chart	Shows the number of site visits and median days form site visit start to site visit completed, over time. This report indicates the relationship between site visit duration and the number of site visits completed.
CDA-CO-822 Outstanding Monitoring Report Approvals (Study-Site)	Lists all monitoring reports awaiting approval at the study-site. This report indicates which monitoring reports require an action: review and approval.

Following is the list of all renumbered reports in CDA 2.1:

Table 5   CDA 2.1 Renumbered Reports

Original Report Number	New Report Name	New Report Description
3SS02-3	CDA-CO-209 Site Detail Table	Lists (by program, study, and region) site details, including status, and first subject screened, enrolled and randomized dates. This report indicates the progress of site selection and number of sites ready to enroll. It also indicates the sites and investigators selected.
3SS07-2	CDA-CO-210 Site Status by Region Chart	Displays (by region) the number of sites in each status. This report indicates the progress of each region towards enrollment. It also indicates the progress of site selection and the number of sites that are ready to enroll.
3SS02-1b	CDA-CO-421 Planned Sites vs. Sites Screening & Enrolling Chart (Top 10)	Displays (by study) the number of planned sites, the number of sites that have screened 1 or more subjects, and the number of sites that have enrolled 1 or more subjects. Top 10 based on # Enrolled. This report indicates the progress of site activation. It also indicates the number of sites that are enrolling and screening.
3SS02-1d	CDA-CO-422 Planned Sites vs. Sites Screening & Enrolling Chart (Bottom 10)	Displays (by study) the number of planned sites, the number of sites that have screened 1 or more subjects, and the number of sites that have enrolled 1 or more subjects. Bottom 10 based on # Enrolled. This report indicates the progress of site activation. It also indicates the number of sites that are enrolling and screening.
8SDP-10b	CDA-CO-427 Enrollment Overview By Region Chart	Displays (by study) the number of subjects enrolled. This report indicates the progress each region is making towards enrollment. It also shows the progress of subject recruitment, and how many subjects have been screened, enrolled, and randomized. This report also indicates the progress of each region towards enrollment.
8SDP-28	CDA-CO-429 Screening Overview By Region Chart	Displays (by study), the number of subjects screened. Each bar in the report is stacked by region. This report indicates how many subjects are in which status. It also indicates the number of subjects that have been screened, enrolled and randomized, and the progress of each region towards enrollment.
8SDP-29	CDA-CO-430 Randomization Overview By Site Table	Lists all sites and the number of subjects planned and number of subjects randomized. This report indicates how many subjects are in which status. It also indicates the number of subjects that have been screened, enrolled and randomized.

Table 5   (Cont.) CDA 2.1 Renumbered Reports

Original Report Number	New Report Name	New Report Description
8SDP-30	CDA-CO-432 Randomization Overview By Region Chart	Displays (by study) the number of subjects randomized. Each bar in the report is stacked by region. This report indicates how many subjects are in which status. It also indicates the number of subjects that have been screened, enrolled, and randomized. This report also displays the progress of each region towards enrollment.
4PR02-2b	CDA-CO-506 Withdrawn Reason Counts by Site Table	Lists (by program, study, and region) all sites that have early terminations and the number of early terminations that fall into a given withdrawn reason. This report indicates which withdrawn reasons account for the most early terminations.
5SC01-1	CDA-CO-507 Patient Retention Table	Lists (by program, study, and region) all sites and the number of subjects enrolled, completed, early terminated, as well as the percentage of subjects early terminated. This report indicates the progress of subject retention, and the rate of subject retention.
3SS04-1	CDA-CO-605 Document Collection Cycle Times Table	Lists (by program, study, and region) all documents collected, the number of days from sent to received, and the number of days outstanding if not received. The report indicates how long have documents been outstanding, and how long does it typically take to receive documents. It also indicates the documents that lag the most.
8SDP-1	CDA-CO-608 Documents List	Lists (by program, study, region and site) all documents collected, including document status, sent date, received date, and comments. This report indicates which documents are missing. It also indicates the essential documents are missing for those sites that are not ready to enroll.
8SDP-2	CDA-CO-609 Outstanding Documents by Category, Type	Displays (by document category) the number of documents currently outstanding. Each bar in the report is stacked by document type. This report indicates the documents that are missing.

2.3 Multi-source Integration

When data for the CDA warehouse is drawn from two or more transactional databases, multi-source integration provides an infrastructure and processes for ensuring that lists of values for dimensions (such as Investigator, Study, and Site) have no duplicates.

2.4 Product Dependencies

The following changes have been made to Oracle Health Sciences Clinical Development Analytics dependencies:

- Oracle Life Sciences Data Hub (LSH) has been upgraded from 2.1.3 to 2.2.

3 Documentation Accessibility

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

Access to Oracle Support

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