Oracle® Health Sciences Clinical Development Analytics

Release Content Document

Release 2.2 for Standard Configuration

E26020-03

December 2012

ORACLE®

Oracle Health Sciences Clinical Development Analytics Release Content Document, Release 2.2 for Standard Configuration

E26020-03

Contents

Preface

This Release Content Document helps you assess the business benefits of implementing Oracle Health Sciences Clinical Development Analytics (OHSCDA) Release 2.2. For more technical information, you can refer to Release Notes of a specific release.

Purpose

The Release Content Document (RCD) communicates information about new or changed functionality in the specified release of OHSCDA. Existing functionality from prior releases is not described.

Documentation Accessibility

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Related Documents

The following OHSCDA Release 2.2 for Standard Configuration user documentation is available:

- *Oracle® Health Sciences Clinical Development Analytics Installation Guide for Standard Configuration*

- *Oracle® Health Sciences Clinical Development Analytics User's Guide*

- *Oracle® Health Sciences Clinical Development Analytics Administrator's Guide for Standard Configuration*

- *Oracle® Health Sciences Clinical Development Analytics Electronic Technical Reference Manual for Standard Configuration*

Conventions

The following text conventions are used in this document:

Convention	Meaning
boldface	Boldface type indicates graphical user interface elements associated with an action, or terms defined in text or the glossary.
italic	Italic type indicates book titles, emphasis, or placeholder variables for which you supply particular values.
`monospace`	Monospace type indicates commands within a paragraph, URLs, code in examples, text that appears on the screen, or text that you enter.
[Attribute Name]	Square brackets around an attribute name indicate that the attribute is unsourced. This implies that it is present in the warehouse and CDA's OBIEE Repository, but CDA's ETL does not extract it from any source. These attributes are provided to simplify adding them to your CDA instance if you do have a source for them.

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Changes

This chapter contains the following topics:

1.1 Functionality

Oracle Health Sciences Clinical Development Analytics (CDA) v2.2 expands on v2.1 functionality in the following ways:

- Addition of Milestone and cycle time performance management
- Key performance indicators and targets at multiple levels
- New executive and region-level dashboards
- 4 new dimensions, 3 new facts and more than 400 new measures

> **Note:** CDA v2.2, contains a number of unsourced measures. Unsourced measures are present in the warehouse and CDA's OBIEE Repository, but CDA's ETL does not extract it from any source. They are unsourced because the source application databases, by default, do not include sources for these measures. In the tables below, these measures are indicated by square brackets [ ] around the measure name. Though unsourced, these attributes are provided to simplify adding them to your CDA instance if you do have a source for them: only the SDE needs to be changed.

- 84 new pre-built reports and 33 new dashboard pages

1.2 New and Modified Dimensions and Facts

This section contains the following topics:

1.2.1 Dimensions

Following is a list of all the Dimensions in OHSCDA 2.2:

- CRF
- CRF Book
- Geography
- Investigator
- Overall Level Targets
- Product
- Program
- Region
- Site
- Site Visit
- Study
- Study-Region
- Study-Region Team Member
- Study-Site
- Study-Site Contacts
- Study-Site Team Member
- Study Team Member
- Subject
- Therapeutic Area
- Time
- Validation Procedure

Following is a list of new Dimensions in OHSCDA 2.2:

- Overall Level Targets
- Study-Region
- Study-Region Team Member
- Study Team Member
- Therapeutic Area

The Overall Level Targets dimension has been added in release 2.2. It has the following attributes:

Table 1–1 Attributes of Overall Level Targets Dimension

Table 1–1   Attributes of Overall Level Targets Dimension

Attribute Name	Business Description
[Expected % Sites Recruiting 0 Subjects]	The Expected % Sites Recruiting 0 Subjects for all studies.
[Target Critical Document Package Complete to Site Initiated (# Days)]	The Target Critical Document Package Complete to Site Initiated (# Days) for all studies.

Table 1–1   (Cont.) Attributes of Overall Level Targets Dimension

Attribute Name	Business Description
[Target Last Subject Last Visit to Database Lock (# Days)]	The Target Last Subject Last Visit to Database Lock (# Days) for all studies.
[Target Protocol Approved to 1st Site Initiated (# Days)]	The Target Protocol Approved to 1st Site Initiated (# Days) for all studies.
[Target Protocol Approved to 1st Subject Enrolled (# Days)]	The Target Protocol Approved to 1st Subject Enrolled (# Days) for all studies.
[Target Protocol Approved to 1st Subject Randomized (# Days)]	The Target Protocol Approved to 1st Subject Randomized (# Days) for all studies.
[Target Protocol Approved to 1st Subject Screened (# Days)]	The Target Protocol Approved to 1st Subject Screened (# Days) for all studies.
[Target Site Visit Completed to Follow Up Item Completed (# Days)]	The Target Site Visit Completed to Follow Up Item Completed (# Days) for all studies.
[Target Site Visit Completed to Visit Report Approved (# Days)]	The Target Site Visit Completed to Visit Report Approved (# Days) for all studies.
[Target Site Visit Completed to Visit Report Completed (# Days)]	The Target Site Visit Completed to Visit Report Completed (# Days) for all studies.
[Target Site Visit Start to Site Visit Completed (# Days)]	The Target Site Visit Start to Site Visit Completed (# Days) for all studies.
[Target Visit Report Completed to Visit Report Approved (# Days)]	The Target Visit Report Completed to Visit Report Approved (# Days) for all studies.

The Study-Region dimension has been added in release 2.2. It has the following attributes:

Table 1–2 Attributes of Study-Region Dimension

Table 1–2   Attributes of Study-Region Dimension

Attribute Name	Business Description
[Clinical Study Report Date]	The Clinical Study Report Date for the Study.
[Protocol Approved Date]	The Protocol Approved Date for the Study.
[Planned LE 1st Critical Document Package Completed Date]	The latest estimate of the Planned 1st Critical Document Package Completed Date for the Study-Region.
[Planned LE 1st Initial IRB/EC Approval Date]	The latest estimate of the Planned 1st Initial IRB/EC Approval Date for the Study-Region.
[Planned LE 1st IRB/EC Submission Date]	The latest estimate of the Planned 1st IRB Submission Date for the Study-Region.
[Planned LE 1st Site Initiated Date]	The latest estimate of the Planned 1st Site Initiated Date for the Study-Region.
[Planned LE 1st Subject 1st Visit Date]	The latest estimate of the Planned 1st Subject 1st Visit Date for the Study-Region.
[Planned LE 1st Subject Enrolled Date]	The latest estimate of the Planned 1st Subject Enrolled Date for the Study-Region.
[Planned LE 1st Subject Randomized Date]	The latest estimate of the Planned 1st Subject Randomized Date for the Study-Region.
[Planned LE 1st Subject Screened Date]	The latest estimate of the Planned 1st Subject Screened Date for the Study-Region.

Table 1–2   (Cont.) Attributes of Study-Region Dimension

Attribute Name	Business Description
[Planned LE Last Critical Document Package Completed Date]	The latest estimate of the Planned Last Critical Document Package Completed Date for the Study-Region.
[Planned LE Last Site Initiated Date]	The latest estimate of the Planned Last Site Initiated Date for the Study-Region.
[Planned LE Last Subject 1st Visit Date]	The latest estimate of the Planned Last Subject 1st Visit Date for the Study-Region.
[Planned LE Last Subject Enrolled Date]	The latest estimate of the Planned Last Subject Enrolled Date for the Study-Region.
[Planned LE Last Subject Last Visit Date]	The latest estimate of the Planned Last Subject Last Visit Date for the Study-Region.
[Planned LE Last Subject Randomized Date]	The latest estimate of the Planned Last Subject Randomized Date for the Study-Region.
[Planned 1st Critical Document Package Completed Date]	The Planned 1st Critical Document Package Completed Date for the Study-Region.
[Planned 1st Initial IRB/EC Approval Date]	The Planned 1st Initial IRB/EC Approval Date for the Study-Region.
[Planned 1st IRB/EC Submission Date]	The Planned 1st IRB Submission Date for the Study-Region.
[Planned 1st Site Initiated Date]	The Planned 1st Site Initiated Date for the Study-Region.
[Planned 1st Subject 1st Visit Date]	The Planned 1st Subject 1st Visit Date for the Study-Region.
[Planned 1st Subject Enrolled Date]	The Planned 1st Subject Enrolled Date for the Study-Region.
[Planned 1st Subject Randomized Date]	The Planned 1st Subject Randomized Date for the Study-Region.
[Planned 1st Subject Screened Date]	The Planned 1st Subject Screened Date for the Study-Region.
[Planned Last Critical Document Package Completed Date]	The Planned Last Critical Document Package Completed Date for the Study-Region.
[Planned Last Site Initiated Date]	The Planned Last Site Initiated Date for the Study-Region.
[Planned Last Subject 1st Visit Date]	The Planned Last Subject 1st Visit Date for the Study-Region.
[Planned Last Subject Enrolled Date]	The Planned Last Subject Enrolled Date for the Study-Region.
[Planned Last Subject Last Visit Date]	The Planned Last Subject Last Visit Date for the Study-Region.
[Planned Last Subject Randomized Date]	The Planned Last Subject Randomized Date for the Study-Region.
[Expected % Sites Recruiting 0 Subjects]	The Expected % Sites Recruiting 0 Subjects for the Study-Region.
[Expected Early Termination Rate]	The expected early termination rate for the Study-Region.
[Expected Retention Rate]	The Expected Retention Rate for the Study-Region.
[Expected Screen Failure Rate]	The Expected Screen Failure Rate for the Study-Region.
[Target 1st Site Initiated to 1st Subject Enrolled (# Days)]	The Target 1st Site Initiated to 1st Subject Enrolled (# Days) for the Study-Region.
[Target 1st Site Initiated to Last Site Initiated (# Days)]	The Target 1st Site Initiated to Last Site Initiated (# Days) for the Study-Region.
[Target 1st Subject 1st Visit to Last Subject 1st Visit (# Days)]	The Target 1st Subject 1st Visit to Last Subject 1st Visit (# Days) for the Study-Region.
[Target 1st Subject Enrolled to Last Subject Enrolled (# Days)]	The Target 1st Subject Enrolled to Last Subject Enrolled (# Days) for the Study-Region.
[Target Critical Document Package Complete to Site Initiated (# Days)]	The Target Critical Document Package Complete to Site Initiated (# Days) for the Study-Region.

Table 1–2   (Cont.) Attributes of Study-Region Dimension

Attribute Name	Business Description
Region Name	The Region name.
Study-Region Action Link	Action Link for Siebel Clinical Regions. Can be used to link back to Region record in Siebel Clinical
Study-Region CRO	CRO for a Study-Region
Study-Region Manager	The manager for the Study-Region.
Study-Region Name	Protocol Region
Study-Region Name	The name of the Study-Region
Study-Region Status	Status of Study-Region
[Therapeutic Area]	The name of the Therapeutic Area.

The Study-Region Team Member dimension has been added in release 2.2. It has the following attributes:

Table 1–3 Attributes of Study-Region Team Member Dimension

Table 1–3   Attributes of Study-Region Team Member Dimension

Attribute Name	Business Description
Email	Team member email address.
End Date	Study-Region Team Member End Date field.
First Name	Study-Region Team Member First Name field.
Full Name	Study-Region Team Member Full Name field.
Last Name	Study-Region Team Member Last Name field.
Role	Study-Region Team Member Role field.
Start Date	Study-Region Team Member Start Date field.
Team Member Active	If the team member's end date is null, indicate that the team member is active.
Team Member Comment	Study-Region Team Member Comment field.

The Study Team Member dimension has been added in release 2.2. It has the following attributes:

Table 1–4 Attributes of Study Team Member Dimension

Table 1–4   Attributes of Study Team Member Dimension

Attribute Name	Business Description
Email	Team member Email address
End Date	End Date in the Team History view
First Name	Team member first name
Full Name	Last Name, First Name
Last Name	Team member last name
Role	Role in the Team History view
Start Date	Start Date in the Team History view

Table 1–4   (Cont.) Attributes of Study Team Member Dimension

Attribute Name	Business Description
Team Member Action Link	Action Link for Siebel Clinical Employee. Can be used to link back to Employee record in Siebel Clinical
Team Member Active	Indicates that the team member does not have an end date and is still actively on the team
Team Member Comment	Comment in the Team History view

The Therapeutic Area dimension has been added in release 2.2. It has the following attributes:

Table 1–5 Attributes of Therapeutic Area Dimension

Table 1–5   Attributes of Therapeutic Area Dimension

Attribute Name	Business Description
[Expected % Sites Recruiting 0 Subjects]	The Expected % Sites Recruiting 0 Subjects for the Therapeutic Area.
[Target Critical Document Package Complete to Site Initiated (# Days)]	The Target Critical Document Package Complete to Site Initiated (# Days) for the Therapeutic Area.
[Target Last Subject Last Visit to Database Lock (# Days)]	The Target Last Subject Last Visit to Database Lock (# Days) for the Therapeutic Area.
[Target Protocol Approved to 1st Site Initiated (# Days)]	The Target Protocol Approved to 1st Site Initiated (# Days) for the Therapeutic Area.
[Target Protocol Approved to 1st Subject Enrolled (# Days)]	The Target Protocol Approved to 1st Subject Enrolled (# Days) for the Therapeutic Area.
[Target Protocol Approved to 1st Subject Randomized (# Days)]	The Target Protocol Approved to 1st Subject Randomized (# Days) for the Therapeutic Area.
[Target Protocol Approved to 1st Subject Screened (# Days)]	The Target Protocol Approved to 1st Subject Screened (# Days) for the Therapeutic Area.
[Target Site Visit Completed to Follow Up Item Completed (# Days)]	The Target Site Visit Completed to Follow Up Item Completed (# Days) for the Therapeutic Area.
[Target Site Visit Completed to Visit Report Approved (# Days)]	The Target Site Visit Completed to Visit Report Approved (# Days) for the Therapeutic Area.
[Target Site Visit Completed to Visit Report Completed (# Days)]	The Target Site Visit Completed to Visit Report Completed (# Days) for the Therapeutic Area.
[Target Site Visit Start to Site Visit Completed (# Days)]	The Target Site Visit Start to Site Visit Completed (# Days) for the Therapeutic Area.
[Target Visit Report Completed to Visit Report Approved (# Days)]	The Target Visit Report Completed to Visit Report Approved (# Days) for the Therapeutic Area.
[Therapeutic Area]	The name of the Therapeutic Area.

1.2.2 Facts

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

- Discrepancies

- Discrepancy Review Statuses

- Document Metrics

- Follow Up Item Metrics

- Overall Metrics

- Program Metrics

- Received CRFs

- Region Metrics

- Site Visit Metrics

- Study Metrics

- Study-Region Metrics

- Study-Site Metrics

- Subject Metrics

- Subject Visit

- Therapeutic Area Metrics

The following five new Fact tables have been added in OHSCDA 2.2:

- Overall Metrics

- Program Metrics

- Study-Region Metrics

- Subject Visit

- Therapeutic Area Metrics

The new Fact tables have the following attributes:

Table 1–6   Measures in New Fact Tables

Fact Table	Grouping	Measure Name	Business Description
Overall Metrics	Counts	# Studies	The number of study records.
Overall Metrics	Medians	[Median # Protocol Amendments per Study]	The median of the number of protocol amendments that occurred for all studies.
Overall Metrics	Medians	[Median 1st Site Initiated to Last Site Initiated (# Days)]	The median of the following cycle time across all studies: 1st Site Initiated Date for Study to Last Site Initiated Date for Study.
Overall Metrics	Medians	Median 1st Site Initiated to Latest Site Initiated (# Days)	The median of the following cycle time across all studies: 1st Site Initiated Date for a Study to Latest Site Initiated Date for a Study.
Overall Metrics	Medians	[Median Critical Document Package Complete to Site Initiated (# Days)]	The median of the following cycle time across all Study-Sites: Critical Document Package Completed Date to Site Initiated Date.
Overall Metrics	Medians	Median Initial IRB/EC Approval to 1st Subject 1st Visit (# Days)	The median of the following cycle time across all Study-Sites: Initial IRB/EC Approval Date to 1st Subject 1st Visit Date.
Overall Metrics	Medians	Median Initial IRB/EC Approval to Site Initiated (# Days)	The median of the following cycle time across all Study-Sites: Initial IRB/EC Approval Date to Site Initiated Date.

Table 1–6   (Cont.) Measures in New Fact Tables

Fact Table	Grouping	Measure Name	Business Description
Overall Metrics	Medians	[Median Last Subject Last Visit to Database Lock (# Days)]	The median of the following cycle time across all studies: Last Subject Last Visit Date for Study to Database Lock Date.
Overall Metrics	Medians	[Median Protocol Approved to 1st Site Initiated (# Days)]	The median of the following cycle time across all studies: Protocol Approved Date to 1st Site Initiated Date for Study.
Overall Metrics	Medians	[Median Protocol Approved to 1st Subject Enrolled (# Days)]	The median of the following cycle time across all studies: Protocol Approved Date to 1st Subject Enrolled Date for Study.
Overall Metrics	Medians	[Median Protocol Approved to 1st Subject Randomized (# Days)]	The median of the following cycle time across all studies: Protocol Approved Date to 1st Subject Randomized Date for Study.
Overall Metrics	Medians	[Median Protocol Approved to 1st Subject Screened (# Days)]	The median of the following cycle time across all studies: Protocol Approved Date to 1st Subject Screened Date for Study.
Overall Metrics	Medians	Median Site Initiated to 1st Subject 1st Visit (# Days)	The median of the following cycle time across all Study-Sites: Site Initiated for Study-Site to 1st Subject 1st Visit Date for Study-Site.
Overall Metrics	Medians	Median Site Visit Completed to Follow Up Item Completed (# Days)	The median of the following cycle time across all completed site visits: Site Visit Completed Date to Follow Up Item Completed Date.
Overall Metrics	Medians	Median Site Visit Completed to Visit Report Approved (# Days)	The median of the following cycle time across all completed site visits: Site Visit Completed Date to Visit Report Approved Date.
Overall Metrics	Medians	Median Site Visit Completed to Visit Report Completed (# Days)	The median of the following cycle time across all completed site visits: Site Visit Completed Date to Visit Report Completed Date.
Overall Metrics	Medians	Median Site Visit Start to Site Visit Completed (# Days)	The median of the following cycle time across all completed site visits: Site Visit Start Date to Site Visit Completed Date.
Overall Metrics	Medians	Median Visit Report Completed to Visit Report Approved (# Days)	The median of the following cycle time across all completed site visits: Visit Report Completed Date to Visit Report Approved Date.
Overall Metrics	Ratios	% Sites Recruiting 0 Subjects	The percentage of initiated sites that have not enrolled any subjects, across all studies.
Overall Metrics	Ratios	% Sites Recruiting 1 or More Subjects	The percentage of Study-Sites that have at least one subject enrolled.
Overall Metrics	Ratios	% Sites Recruiting at Least 90% of Planned Subjects	The percentage of Study-Sites that have enrolled 90% or more of their planned subjects.
Program Metrics	Counts	# Studies	The number of study records.

Table 1–6   (Cont.) Measures in New Fact Tables

Fact Table	Grouping	Measure Name	Business Description
Program Metrics	Medians	Median # Days Between Site Visits	The median of the following cycle time across all site visits for a Program: number of days between consecutive Site Visit Start Dates for completed site visits.
Program Metrics	Medians	[Median # Protocol Amendments per Study]	The median of the number of protocol amendments that occurred for all studies in a Program.
Program Metrics	Medians	[Median 1st Site Initiated to Last Site Initiated (# Days)]	The median of the following cycle time across all studies in a Program: 1st Site Initiated Date for Study to Last Site Initiated Date for Study.
Program Metrics	Medians	Median 1st Site Initiated to Latest Site Initiated (# Days)	The median of the following cycle time across all studies in a Program: 1st Site Initiated Date for a Study to Latest Site Initiated Date for a Study.
Program Metrics	Medians	[Median Critical Document Package Complete to Site Initiated (# Days)]	The median of the following cycle time across all Study-Sites in a Program: Critical Document Package Completed Date to Site Initiated Date.
Program Metrics	Medians	Median Initial IRB/EC Approval to 1st Subject 1st Visit (# Days)	The median of the following cycle time across all Study-Sites in a Program: Initial IRB/EC Approval Date to 1st Subject 1st Visit Date.
Program Metrics	Medians	Median Initial IRB/EC Approval to Site Initiated (# Days)	The median of the following cycle time across all Study-Sites in a Program: Initial IRB/EC Approval Date to Site Initiated Date.
Program Metrics	Medians	[Median Last Subject Last Visit to Database Lock (# Days)]	The median of the following cycle time across all studies in a Program: Last Subject Last Visit Date for Study to Database Lock Date.
Program Metrics	Medians	[Median Protocol Approved to 1st Site Initiated (# Days)]	The median of the following cycle time across all studies in a Program: Protocol Approved Date to 1st Site Initiated Date for Study.
Program Metrics	Medians	[Median Protocol Approved to 1st Subject Enrolled (# Days)]	The median of the following cycle time across all studies in a Program: Protocol Approved Date to 1st Subject Enrolled Date for Study.
Program Metrics	Medians	[Median Protocol Approved to 1st Subject Randomized (# Days)]	The median of the following cycle time across all studies in a Program: Protocol Approved Date to 1st Subject Randomized Date for Study.
Program Metrics	Medians	[Median Protocol Approved to 1st Subject Screened (# Days)]	The median of the following cycle time across all studies in a Program: Protocol Approved Date to 1st Subject Screened Date for Study.
Program Metrics	Medians	Median Site Initiated to 1st Subject 1st Visit (# Days)	The median of the following cycle time across all Study-Sites in a Program: Site Initiated for Study-Site to 1st Subject 1st Visit Date for Study-Site.

Table 1–6   (Cont.) Measures in New Fact Tables

Fact Table	Grouping	Measure Name	Business Description
Program Metrics	Medians	Median Site Visit Completed to Follow Up Item Completed (# Days)	The median of the following cycle time across all completed site visits in a Program: Site Visit Completed Date to Follow Up Item Completed Date.
Program Metrics	Medians	Median Site Visit Completed to Visit Report Approved (# Days)	The median of the following cycle time across all completed site visits for a Program: Site Visit Completed Date to Visit Report Approved Date.
Program Metrics	Medians	Median Site Visit Completed to Visit Report Completed (# Days)	The median of the following cycle time across all completed site visits for a Program: Site Visit Completed Date to Visit Report Completed Date.
Program Metrics	Medians	Median Site Visit Start to Site Visit Completed (# Days)	The median of the following cycle time across all completed site visits for a Program: Site Visit Start Date to Site Visit Completed Date.
Program Metrics	Medians	Median Visit Report Completed to Visit Report Approved (# Days)	The median of the following cycle time across all completed site visits in a Program: Visit Report Completed Date to Visit Report Approved Date.
Program Metrics	Ratios	% Sites Recruiting 0 Subjects	The percentage of initiated sites that have not enrolled any subjects, for all Study-Sites in a Program.
Program Metrics	Ratios	% Sites Recruiting 1 or More Subjects	The percentage of Study-Sites that have at least one subject enrolled.
Program Metrics	Ratios	% Sites Recruiting at Least 90% of Planned Subjects	The percentage of Study-Sites that have enrolled 90% or more of their planned subjects.
Study-Region Metrics	Actual Milestones	[1st Critical Document Package Completed Date]	The earliest Critical Document Package Completed Date for all Study-Sites in the Study-Region.
Study-Region Metrics	Actual Milestones	1st Initial IRB/EC Approval Date	The first Initial IRB/EC Approval Date for all Study-Sites in the Study-Region.
Study-Region Metrics	Actual Milestones	[1st IRB/EC Submission Date]	The first IRB/EC Submission Date for all Study-Sites in the Study-Region.
Study-Region Metrics	Actual Milestones	1st Site Initiated Date	The first Site Initiated Date for all Study-Sites in the Study-Region.
Study-Region Metrics	Actual Milestones	1st Subject 1st Visit Date	The date of the first visit across all subjects for the Study-Region.
Study-Region Metrics	Actual Milestones	1st Subject Enrolled Date	First Subject Enrolled
Study-Region Metrics	Actual Milestones	1st Subject Randomized Date	First Subject Randomized
Study-Region Metrics	Actual Milestones	1st Subject Screened Date	First Subject Screened
Study-Region Metrics	Actual Milestones	Date Achieved 90% Planned Enrollment	The date on which the Study-Region achieved 90% of planned subject enrollment.

Table 1–6   (Cont.) Measures in New Fact Tables

Fact Table	Grouping	Measure Name	Business Description
Study-Region Metrics	Actual Milestones	[Last Critical Document Package Completed Date]	The Last Critical Document Package Completed Date for the Study-Region.
Study-Region Metrics	Actual Milestones	[Last Site Initiated Date]	The Last Site Initiated Date for the Study-Region.
Study-Region Metrics	Actual Milestones	[Last Subject 1st Visit Date]	The Last Subject 1st Visit Date for the Study-Region.
Study-Region Metrics	Actual Milestones	[Last Subject Enrolled Date]	The Last Subject Enrolled Date for the Study-Region.
Study-Region Metrics	Actual Milestones	[Last Subject Last Visit Date]	The Last Subject Last Visit Date for the Study-Region.
Study-Region Metrics	Actual Milestones	[Last Subject Randomized Date]	The Last Subject Randomized Date for the Study-Region.
Study-Region Metrics	Actual Milestones	[Latest Critical Document Package Completed Date]	The Latest Critical Document Package Completed Date for the Study-Region.
Study-Region Metrics	Actual Milestones	Latest Site Initiated Date	The Latest Site Initiated Date for the Study-Region.
Study-Region Metrics	Actual Milestones	Latest Subject 1st Visit Date	The Latest 1st Visit Date across all subjects for the Study-Region.
Study-Region Metrics	Actual Milestones	Latest Subject Enrolled Date	Most recent date on which a subject enrolled in the study
Study-Region Metrics	Actual Milestones	Latest Subject Latest Visit Date	The Latest Visit Date across all subjects for the Study-Region.
Study-Region Metrics	Actual Milestones	Latest Subject Randomized Date	Most recent date on which a subject was randomized
Study-Region Metrics	Counts	# Sites Recruiting 0 Subjects	The number of initiated Study-Sites with 0 subjects enrolled.
Study-Region Metrics	Counts	# Sites Recruiting 1 or More Subjects	The number of initiated Study-Sites with one or more subjects enrolled.
Study-Region Metrics	Counts	# Sites Recruiting at Least 90% of Planned Subjects	The number of Study-Sites where the number of subjects enrolled divided by the number of subjects planned for the site is greater than or equal to 90%.
Study-Region Metrics	Counts	# Sites with 1 or More Subjects Screened	Number of study-sites with 1 or more subjects screened
Study-Region Metrics	Counts	# Study-Sites	The number of Study-Site records.
Study-Region Metrics	Counts	# Study-Sites Initiated	The number of initiated Study-Sites.
Study-Region Metrics	Counts	# Study-Sites Planned for Study-Region	# Planned Sites for the study-region
Study-Region Metrics	Counts	# Subjects Planned for Study-Region	# Planned Subjects for the study-region
Study-Region Metrics	Cycle Times	[1st Critical Document Package Complete to 1st Site Initiated (# Days)]	The number of days between 1st Critical Document Package Completed Date for the Study-Region and 1st Site Initiated Date for the Study-Region.

Table 1–6   (Cont.) Measures in New Fact Tables

Fact Table	Grouping	Measure Name	Business Description
Study-Region Metrics	Cycle Times	1st Initial IRB/EC Approval to 1st Site Initiated (# Days)	The number of days between 1st Initial IRB/EC Approval Date for a Study-Region to 1st Site Initiated Date for a Study-Region.
Study-Region Metrics	Cycle Times	1st Initial IRB/EC Approval to 1st Subject 1st Visit (# Days)	The number of days between 1st Initial IRB/EC Approval Date for a Study-Region and First Subject First Visit Date for a Study-Region.
Study-Region Metrics	Cycle Times	1st Site Initiated to 1st Subject Enrolled (# Days)	The number of days between 1st Site Initated Date for a Study-Region and 1st Subject Enrolled Date for a Study-Region.
Study-Region Metrics	Cycle Times	[1st Site Initiated to Last Site Initiated (# Days)]	The number of days from 1st Site Initiated Date for a Study to Last Site Initiated Date for a Study-Region.
Study-Region Metrics	Cycle Times	1st Site Initiated to Latest Site Initiated (# Days)	The number of days from 1st Site Initiated Date for a Study to Latest Site Initiated Date for a Study-Region.
Study-Region Metrics	Cycle Times	[1st Subject 1st Visit to Last Subject 1st Visit (# Days)]	The number of days from 1st Subject 1st Visit Date for a Study-Region to Last Subject 1st Visit Date for a Study-Region.
Study-Region Metrics	Cycle Times	1st Subject 1st Visit to Latest Subject 1st Visit (# Days)	The number of days from 1st Subject 1st Visit Date for a Study-Region to Latest Subject 1st Visit Date for a Study-Region.
Study-Region Metrics	Cycle Times	[1st Subject Enrolled to Last Subject Enrolled (# Days)]	The number of days from 1st Subject Enrolled Date for a Study-Region to Last Subject Enrolled Date for a Study-Region.
Study-Region Metrics	Cycle Times	1st Subject Enrolled to Latest Subject Enrolled (# Days)	The number of days from 1st Subject Enrolled Date for a Study-Region to Latest Subject Enrolled Date for a Study-Region.
Study-Region Metrics	Flags	Milestone Detail Reason	Detail reason for the Study-Region Milestone Flag
Study-Region Metrics	Flags	Milestone Flag	Milestone Flag for the Study-Region.
Study-Region Metrics	Flags	Milestone High Level Reason	High level reason for the Study-Region Milestone Flag
Study-Region Metrics	Flags	Recruitment Detail Reason	Detail reason for the Study-Region Recruitment Flag
Study-Region Metrics	Flags	Recruitment Flag	Recruitment Flag for the Study-Region.
Study-Region Metrics	Flags	Recruitment High Level Reason	High level reason for the Study-Region Recruitment Flag
Study-Region Metrics	Flags	Retention Detail Reason	Detail reason for the Study-Region Retention Flag
Study-Region Metrics	Flags	Retention Flag	Retention Flag for the Study-Region.
Study-Region Metrics	Flags	Retention High Level Reason	High level reason for the Study-Region Retention Flag

Table 1–6   (Cont.) Measures in New Fact Tables

Fact Table	Grouping	Measure Name	Business Description
Study-Region Metrics	Medians	Median # Days Between Site Visits	The median of the following cycle time across all site visits for a Study-Region: number of days between consecutive Site Visit Start Dates for completed site visits.
Study-Region Metrics	Medians	Median # Follow Up Items per Site Visit	The median of the number of follow up items per site visit for all completed site visits that occurred for a Study-Region.
Study-Region Metrics	Medians	[Median Critical Document Package Complete to Site Initiated (# Days)]	The median of the following cycle time across all Study-Sites in a Study-Region: Critical Document Package Completed Date to Site Initiated Date.
Study-Region Metrics	Medians	Median Initial IRB/EC Approval to 1st Subject 1st Visit (# Days)	The median of the following cycle time across all Study-Sites in a Study-Region: Initial IRB/EC Approval Date to 1st Subject 1st Visit Date.
Study-Region Metrics	Medians	Median Initial IRB/EC Approval to Site Initiated (# Days)	The median of the following cycle time across all Study-Sites in a Study-Region: Initial IRB/EC Approval Date to Site Initiated Date.
Study-Region Metrics	Medians	Median Site Initiated to 1st Subject 1st Visit (# Days)	The median of the following cycle time across all Study-Sites in a Study-Region: Site Initiated for Study-Site to 1st Subject 1st Visit Date for Study-Site.
Study-Region Metrics	Medians	Median Site Initiated to 1st Subject Enrolled (# Days)	The median of the following cycle time across all Study-Sites in a Study-Region: Site Initiated for Study-Site to 1st Subject Enrolled Date for Study-Site.
Study-Region Metrics	Medians	Median Site Visit Start to Site Visit Completed (# Days)	The median of the following cycle time across all completed site visits for a Region: Site Visit Start Date to Site Visit Completed Date.
Study-Region Metrics	Ratios	% Enrolled to Total Planned at Study-Region	Ratio of number of enrolled subjects to total planned number of subjects for the study region.
Study-Region Metrics	Ratios	% of Planned Sites Initiated	The percentage of Study-Sites planned for the Study-Region that have been initiated.
Study-Region Metrics	Ratios	% Over/Under Enrolled	The percentage of planned subjects over (+) or under (-) enrolled for the Study-Region.
Study-Region Metrics	Ratios	% Planned Subjects Randomized	The percentage of planned subjects randomized minus 100.
Study-Region Metrics	Ratios	% Sites Recruiting 0 Subjects	The percentage of initiated sites that have not enrolled any subjects, for all Study-Sites in a Study-Region.

Table 1–6   (Cont.) Measures in New Fact Tables

Fact Table	Grouping	Measure Name	Business Description
Study-Region Metrics	Ratios	% Sites Recruiting 1 or More Subjects	the number of sites recruiting one or more Subjects divided by the number of Sites Initiated.
Study-Region Metrics	Ratios	% Sites Recruiting at Least 90% of Planned Subjects	the number of sites recruiting at least 90% of planned subjects divided by the number of Sites Initiated.
Study-Region Metrics	Ratios	% Subjects Early Terminated for Study-Region	The number of subjects early terminated at Study-Site divided by the number of subjects enrolled at Study-Region
Study-Region Metrics	Ratios	Screen Failure Rate	The number of subjects who failed screening divided by the number of subjects screened for the Study-Region.
Subject Visit	Subject Visits	Subject Visit Completed Date	The Subject Visit Completed Date.
Subject Visit	Subject Visits	Subject Visit Completed Flag	Indicates whether the Subject Visit was completed.
Subject Visit	Subject Visits	Subject Visit Description	The Subject Visit Description.
Subject Visit	Subject Visits	Subject Visit Due Date	The Subject Visit Due Date.
Subject Visit	Subject Visits	Subject Visit Max Due Date	The maximum date on which the subject visit would be due.
Subject Visit	Subject Visits	Subject Visit Min Due Date	The minimum date on which the subject visit would be due.
Subject Visit	Subject Visits	Subject Visit Planned Date	The Subject Visit Planned Date
Subject Visit	Subject Visits	Subject Visit Protocol Deviation	Indicates whether there is a protocol deviation on the subject visit.
Subject Visit	Subject Visits	Subject Visit Protocol Violation	Indicates whether there is a protocol violation on the subject visit.
Subject Visit	Subject Visits	Subject Visit Sequence	The Subject Visit Sequence.
Subject Visit	Subject Visits	Subject Visit Template Version	The Subject Visit Template Version.
Subject Visit	Subject Visits	Subject Visit Type	The Subject Visit Type.
Therapeutic Area Metrics	Counts	# Studies	The number of study records.
Therapeutic Area Metrics	Medians	Median # Days Between Site Visits	The median of the following cycle time across all site visits for a Therapeutic Area: number of days between consecutive Site Visit Start Dates for completed site visits.
Therapeutic Area Metrics	Medians	[Median # Protocol Amendments per Study]	The median of the number of protocol amendments that occurred for all studies in a Therapeutic Area.
Therapeutic Area Metrics	Medians	[Median 1st Site Initiated to Last Site Initiated (# Days)]	The median of the following cycle time across all studies in a Therapeutic Area: 1st Site Initiated for Date Study to Last Site Initiated Date for Study.

Table 1–6   (Cont.) Measures in New Fact Tables

Fact Table	Grouping	Measure Name	Business Description
Therapeutic Area Metrics	Medians	Median 1st Site Initiated to Latest Site Initiated (# Days)	The median of the following cycle time across all studies in a Therapeutic Area: 1st Site Initiated Date for a Study to Latest Site Initiated Date for a Study.
Therapeutic Area Metrics	Medians	[Median Critical Document Package Complete to Site Initiated (# Days)]	The median of the following cycle time across all Study-Sites in a Therapeutic Area: Critical Document Package Completed Date to Site Initiated Date.
Therapeutic Area Metrics	Medians	Median Initial IRB/EC Approval to 1st Subject 1st Visit (# Days)	The median of the following cycle time across all Study-Sites in a Therapeutic Area: Initial IRB/EC Approval Date to 1st Subject 1st Visit Date.
Therapeutic Area Metrics	Medians	Median Initial IRB/EC Approval to Site Initiated (# Days)	The median of the following cycle time across all Study-Sites in a Therapeutic Area: Initial IRB/EC Approval Date to Site Initiated Date.
Therapeutic Area Metrics	Medians	[Median Last Subject Last Visit to Database Lock (# Days)]	The median of the following cycle time across all studies in a Therapeutic Area: Last Subject Last Visit Date for Study to Database Lock Date.
Therapeutic Area Metrics	Medians	[Median Protocol Approved to 1st Site Initiated (# Days)]	The median of the following cycle time across all studies for Therapeutic Area: Protocol Approved Date to 1st Site Initiated Date for Study.
Therapeutic Area Metrics	Medians	[Median Protocol Approved to 1st Subject Enrolled (# Days)]	The median of the following cycle time across all studies in a Therapeutic Area: Protocol Approved Date to 1st Subject Enrolled Date for Study.
Therapeutic Area Metrics	Medians	[Median Protocol Approved to 1st Subject Randomized (# Days)]	The median of the following cycle time across all studies in a Therapeutic Area: Protocol Approved Date to 1st Subject Randomized Date for Study.
Therapeutic Area Metrics	Medians	[Median Protocol Approved to 1st Subject Screened (# Days)]	The median of the following cycle time across all studies in a Therapeutic Area: Protocol Approved Date to 1st Subject Screened Date for Study.
Therapeutic Area Metrics	Medians	Median Site Initiated to 1st Subject 1st Visit (# Days)	The median of the following cycle time across all Study-Sites in a Therapeutic Area: Site Initiated for Study-Site to 1st Subject 1st Visit Date for Study-Site.
Therapeutic Area Metrics	Medians	Median Site Visit Completed to Follow Up Item Completed (# Days)	The median of the following cycle time across all completed site visits in a Therapeutic Area: Site Visit Completed Date to Follow Up Item Completed Date.

Table 1–6   (Cont.) Measures in New Fact Tables

Fact Table	Grouping	Measure Name	Business Description
Therapeutic Area Metrics	Medians	Median Site Visit Completed to Visit Report Approved (# Days)	The median of the following cycle time across all completed site visits for a Therapeutic Area: Site Visit Completed Date to Visit Report Approved Date.
Therapeutic Area Metrics	Medians	Median Site Visit Completed to Visit Report Completed (# Days)	The median of the following cycle time across all completed site visits for a Therapeutic Area: Site Visit Completed Date to Visit Report Completed Date.
Therapeutic Area Metrics	Medians	Median Site Visit Start to Site Visit Completed (# Days)	The median of the following cycle time across all completed site visits for a Therapeutic Area: Site Visit Start Date to Site Visit Completed Date.
Therapeutic Area Metrics	Medians	Median Visit Report Completed to Visit Report Approved (# Days)	The median of the following cycle time across all completed site visits in a Therapeutic Area: Visit Report Completed Date to Visit Report Approved Date.
Therapeutic Area Metrics	Ratios	% Sites Recruiting 0 Subjects	The percentage of initiated sites that have not enrolled any subjects, for all Study-Sites in a Therapeutic Area.
Therapeutic Area Metrics	Ratios	% Sites Recruiting 1 or More Subjects	the number of sites recruiting one or more Subjects divided by the number of Sites Initiated.
Therapeutic Area Metrics	Ratios	% Sites Recruiting at Least 90% of Planned Subjects	the number of sites recruiting at least 90% of planned subjects divided by the number of Sites Initiated.

1.3 New and Modified Dashboards and Reports

The sections below list changes related to Dashboards and Reports.

1.3.1 Dashboards

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

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

1.3.2 Reports

Following is the list of all new reports in OHSCDA 2.2:

Table 1–7   OHSCDA 2.2 New Reports

Report Name	Report Description
CDA-CO-1001: Number of Studies	Pie chart that shows count of studies. Column selector allows user to view by Therapeutic Area, Program, Phase, or Indicator (KPI, Milestone, Enrollment or Retention)
CDA-CO-107: Monitoring Status Overview (Study Manager View)	Shows count of outstanding visit reports, visit report approvals and follow up items
CDA-CO-109: Study List: Milestone Performance	Provides a list of studies with planned, latest estimate and actual milestones, and a milestone indicator. This report indicates whether a study has exceeding planned dates for outstanding milestones.
CDA-CO-110: Site Enrollment Performance Compared to Site Visit Frequency	Provides a scatter plot displaying the number of completed site visits for a study-site compared to the study-site's contribution to the total enrollment for the study (% of Total Enrolled in Study). This report helps to identify which study-sites provide the most enrollment value for the least monitoring effort and vice versa.
CDA-CO-1101: Monitoring Status Overview (Region Manager View)	Shows count of outstanding visit reports, visit report approvals and follow up items
CDA-CO-1103: KPI Summary: CDP Completed to Site Initiated (Region Manager View)	Line and line-bar graphs that show the region median compared to overall median and overall target for Critical Document Package Completed to Site Initiated (# Days), by quarter. Also includes a count of the number of studies that makes up the region median. This report compares region performance to overall performance and overall target for a given KPI.
CDA-CO-1104: KPI Summary: Site Visit Completed to Visit Report Completed (Region Manager View)	Line and line-bar graphs that show the region median compared to overall median and overall target for Site Visit Completed to Visit Report Completed (# Days), by quarter.. Also includes a count of the number of studies that makes up the region median. This report compares region performance to overall performance and overall target for a given KPI.
CDA-CO-1105: KPI Summary: Visit Report Completed to Approved (Region Manager View)	Line and line-bar graphs that show the region median compared to overall median and overall target for Visit Report Completed to Visit Report Approved (# Days), by quarter. Also includes a count of the number of studies that makes up the region median. This report compares region performance to overall performance and overall target for a given KPI.
CDA-CO-1106: Study Region Milestones with Indicators	A list of study-regions including key planned, latest estimate and actual milestone dates as well as progress tracking for site start up, recruitment, retention, data management, and study close. Includes study-region-health indicators for recruitment, retention, milestones and KPIs. This report indicates which study-regions require action, and why.
CDA-CO-1107: Study-Region Team Member List	Lists all of the team members for a study-region.
CDA-CO-1108: Study-Region List: KPI Performance	Provides a list of study-regions with target/actual KPIs and a KPI indicator. This report indicates whether a study-region is performing within target range for KPIs.

Table 1–7 (Cont.) OHSCDA 2.2 New Reports

Report Name	Report Description
CDA-CO-1109: Study-Region List: Milestone Performance	Provides a list of study-regions with planned, latest estimate and actual milestones, and a milestone indicator.
	This report indicates whether a study-region has exceeding planned dates for outstanding milestones.
CDA-CO-111: Study Team Member List	Lists all of the team members for a study.
CDA-CO-1110: Performance Metrics Summary Narrative: Site Visit	Displays a summary of site visit performance metrics for monitoring report completion and approval cycle times. For completed cycles, it displays the number and percentage of missed targets. For cycles that have not yet completed, it displays the number and percentage of missed targets and those at risk of missing a target.
	This report includes hyperlinks to related lists of monitoring reports.
CDA-CO-1111: Study Region vs. Study: Site Start Up KPIs	Line bar chart with bar for each study-region reflecting value for each study region and a point for study median. Column selector for each of the following metrics:
	1st Initial IRB/EC Approval to 1st Site Initiated (# Days)
	1st Initial IRB/EC Approval to 1st Subject 1st Visit (# Days)
	1st Site Initiated to 1st Subject Enrolled (# Days)
CDA-CO-1112: Key Performance Indicators Over Time: Monitoring (Region Manager)	Line-bar graph that shows the region median for the following monitoring measures compared to the number of completed site visits, by month:
	# Days from Site Visit Completed to Visit Report Completed
	# Days from Visit Report Completed to Visit Report Approved
	# Days from Follow Up Item Identified to Follow Up Item Resolved
CDA-CO-1113: Study-Region Information	Displays a summary of identifying information for a study-region, including Region Name, Study #, and Study-Region Status.
CDA-CO-1114: Subject Recruitment (Study Region)	Displays a summary of recruitment information for a study-region.
	This report indicates planned recruitment vs. actual screening, enrollment and randomization information for a single study-region.
CDA-CO-1115: Subject Retention (Study Region)	Displays a summary of retention information for a study-region. This report indicates planned recruitment vs. actual retention information for a single study-region.
CDA-CO-1116: Study Region Milestones with Indicators (Single Study-Region)	Lists (for a study-region) key planned, latest estimate and actual milestone dates as well as progress tracking for site start up, recruitment, retention, data management, and study close. Includes study-region-health indicators for recruitment, retention, milestones and KPIs.
	This report indicates whether a study-region requires action, and why.
CDA-CO-1200: Study Regions with Red or Yellow Performance Flag	Lists study-regions with an indicator of study-region health, where the indicator is red or yellow.
	This report indicates which study-regions require action and why.
CDA-CO-1201: # Initiated Sites Map (Region)	Displays study-sites geographically by # Enrolled, # Days Since Last Enrollment for Study-Site, # Subjects Enrolled Since Latest Site Visit and # Days Since Latest Site Visit
CDA-CO-1202: # Initiated Sites Map	Displays study-sites geographically by # Enrolled, # Days Since Last Enrollment for Study-Site, # Subjects Enrolled Since Latest Site Visit and # Days Since Latest Site Visit. Also displays the following metrics by country: # Enrolled, # Current Active Subjects and # Early Terminations.

Table 1–7   (Cont.) OHSCDA 2.2 New Reports

Report Name	Report Description
CDA-CO-203A: Study-Site Milestones with Indicators (Single Study-Site) - Data Management View	Lists (for a study-site) key metrics for CRFs and discrepancies as well as progress tracking for data management. This report indicates whether a study-site requires action, and why.
CDA-CO-203B: Study-Site Milestones with Indicators (Single Study-Site) - Monitoring View	Lists (for a study-site) key monitoring dates as well as progress tracking for site monitoring. This report indicates whether a study-site requires action, and why.
CDA-CO-203C: Study-Site Milestones with Indicators (Single Study-Site) - Recruitment Detail View	Lists (for a study-site) key planned, latest estimate and actual milestone dates as well as progress tracking for site recruitment. Includes study-site-health indicators for recruitment and milestones. This report indicates whether a study-site requires action, and why.
CDA-CO-203D: Study-Site Milestones with Indicators (Single Study-Site) - Retention Detail View	Lists (for a study-site) key planned, latest estimate and actual milestone dates as well as progress tracking for site retention. Includes study-site-health indicators for retention and milestones. This report indicates whether a study-site requires action, and why.
CDA-CO-203E: Study-Site Milestones with Indicators (Single Study-Site) - Site Start Up Detail View	Lists (for a study-site) key planned, latest estimate and actual milestone dates as well as progress tracking for site start up. Includes study-site-health indicator for milestones. This report indicates whether a study-site requires action, and why.
CDA-CO-203F: Study-Site Milestones with Indicators (Single Study-Site) - Study Close Detail View	Lists (for a study-site) key planned, latest estimate and actual milestone dates as well as progress tracking for study close. Includes study-site-health indicator for milestones. This report indicates whether a study-site requires action, and why.
CDA-CO-203G: Study-Site Milestones with Indicators (Single Study-Site) - Summary View	Lists (for a study-site) key planned, latest estimate and actual milestone dates as well as progress tracking for site start up, recruitment, retention, and study close. Includes study-site-health indicators for recruitment, retention and milestones. This report indicates whether a study-site requires action, and why.
CDA-CO-205A: Study-Site Milestones with Indicators (CRA) - Monitoring View	A list of study-sites including key monitoring metrics as well as progress tracking for site monitoring. This report indicates which study-sites require action, and why.
CDA-CO-205B: Study-Site Milestones with Indicators (CRA) - Recruitment Detail View	A list of study-sites including key planned, latest estimate and actual milestone dates as well as progress tracking for site recruitment. Includes study-site-health indicators for recruitment and milestones. This report indicates which study-sites require action, and why.
CDA-CO-205C: Study-Site Milestones with Indicators (CRA) - Retention Detail View	A list of study-sites including key planned, latest estimate and actual milestone dates as well as progress tracking for site retention. Includes study-site-health indicators for retention and milestones. This report indicates which study-sites require action, and why.
CDA-CO-205D: Study-Site Milestones with Indicators (CRA) - Site Start Up Detail View	A list of study-sites including key planned, latest estimate and actual milestone dates as well as progress tracking for site start up. Includes study-site-health indicators for milestones. This report indicates which study-sites require action, and why.
CDA-CO-205E: Study-Site Milestones with Indicators (CRA) - Study Close Detail View	A list of study-sites including key planned, latest estimate and actual milestone dates as well as progress tracking for study close. Includes study-site-health indicators for milestones. This report indicates which study-sites require action, and why.

Table 1–7   (Cont.) OHSCDA 2.2 New Reports

Report Name	Report Description
CDA-CO-205F: Study-Site Milestones with Indicators (CRA) - Summary View	A list of study-sites including key planned, latest estimate and actual milestone dates as well as progress tracking for site start up, recruitment and retention. Includes study-site-health indicators for recruitment, retention and milestones.
	This report indicates which study-sites require action, and why.
CDA-CO-207A: Study-Site List with Indicators - Data Management View	A list of study-sites including key CRF and discrepancy metrics as well as progress tracking for data management.
	This report indicates which study-sites require action, and why.
CDA-CO-207B: Study-Site List with Indicators - Monitoring View	A list of study-sites including key monitoring metrics as well as progress tracking for site monitoring.
	This report indicates which study-sites require action, and why.
CDA-CO-207C: Study-Site List with Indicators - Recruitment Detail View	A list of study-sites including key planned, latest estimate and actual milestone dates as well as progress tracking for site recruitment. Includes study-site-health indicators for recruitment and milestones.
	This report indicates which study-sites require action, and why.
CDA-CO-207D: Study-Site List with Indicators - Retention Detail View	A list of study-sites including key planned, latest estimate and actual milestone dates as well as progress tracking for site retention. Includes study-site-health indicators for retention, milestones.
	This report indicates which study-sites require action, and why.
CDA-CO-207E: Study-Site List with Indicators - Site Start Up Detail View	A list of study-sites including key planned, latest estimate and actual milestone dates as well as progress tracking for site start up. Includes study-site-health indicators for milestones.
	This report indicates which study-sites require action, and why.
CDA-CO-207F: Study-Site List with Indicators - Study Close Detail View	A list of study-sites including key planned, latest estimate and actual milestone dates as well as progress tracking for study close. Includes study-site-health indicators for milestones.
	This report indicates which study-sites require action, and why.
CDA-CO-207G: Study-Site List with Indicators - Summary View	A list of study-sites including key planned, latest estimate and actual milestone dates as well as progress tracking for site start up, recruitment, and retention. Includes study-site-health indicators for recruitment, retention and milestones.
	This report indicates which study-sites require action, and why.
CDA-CO-208A: Study-Site Milestones with Indicators - Data Management View	A list of study-sites including key CRF and discrepancy metrics as well as progress tracking for site data management.
	This report indicates which study-sites require action, and why.
CDA-CO-208B: Study-Site Milestones with Indicators - Monitoring View	A list of study-sites including key monitoring metrics as well as progress tracking for site monitoring.
	This report indicates which study-sites require action, and why.
CDA-CO-208C: Study-Site Milestones with Indicators - Recruitment Detail View	A list of study-sites including key planned, latest estimate and actual milestone dates as well as progress tracking for site recruitment. Includes study-site-health indicators for recruitment and milestones.
	This report indicates which study-sites require action, and why.
CDA-CO-208D: Study-Site Milestones with Indicators - Retention Detail View	A list of study-sites including key planned, latest estimate and actual milestone dates as well as progress tracking for site retention. Includes study-site-health indicators for retention and milestones.
	This report indicates which study-sites require action, and why.

Table 1–7   (Cont.) OHSCDA 2.2 New Reports

Report Name	Report Description
CDA-CO-208E: Study-Site Milestones with Indicators - Site Start Up Detail View	A list of study-sites including key planned, latest estimate and actual milestone dates as well as progress tracking for site start up. Includes study-site-health indicators for milestones.
	This report indicates which study-sites require action, and why.
CDA-CO-208F: Study-Site Milestones with Indicators - Study Close Detail View	A list of study-sites including key planned, latest estimate and actual milestone dates as well as progress tracking for study close. Includes study-site-health indicators for milestones.
	This report indicates which study-sites require action, and why.
CDA-CO-208G: Study-Site Milestones with Indicators - Summary View	A list of study-sites including key planned, latest estimate and actual milestone dates as well as progress tracking for site start up, recruitment and retention. Includes study-site-health indicators for recruitment, retention, and milestones.
	This report indicates which study-sites require action, and why.
CDA-CO-306: Study-Region List - Initiation Details	Lists study-regions in studies that have an approved protocol but no last subject enrolled date. Displays planned and actual number of sites, including how many are initiated, screening, and enrolling. Also displays key planned and actual milestones, as well as a milestone performance indicator.
	This report provides a list of ongoing study-regions that have not yet achieved 100% enrollment, including number of study-sites to reach certain achievements.
CDA-CO-307: Site Initiation Over Time Bar Chart (Study Region)	Line-bar graph that shows the number of sites initiated compared to the number of sites planned for a Study-Region.
CDA-CO-433: Study-Region List - Recruitment Details	Lists study-regions that have initiated their first site, have not achieved 100% enrollment, and have not enrolled their last subject. Displays planned and actual recruitment information and milestones, including recruitment and milestone performance indicators.
	This report provides a list of ongoing study-regions that have not yet achieved 100% enrollment, including recruitment information.
CDA-CO-434: Screening Overview (Study-Region 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-435: Enrollment Progress Over Time (Study-Region Level)	Shows cumulative actual enrollment over time, compared to static plan (50%, 75%, 90% and 100%) for a study-site. This report indicates the progress of subject recruitment. It also indicates how well we are progressing against planned enrollment.
CDA-CO-436: Site Recruitment Performance Charts (Executive View)	Shows the study-sites with 1 or more subjects enrolled, no subjects enrolled, or greater than 90% of planned enrollment completed, by program. 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-511: Subject Retention Over Time Chart (Study-Region 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.

Table 1–7   (Cont.) OHSCDA 2.2 New Reports

Report Name	Report Description
CDA-CO-610: Documents List (Study Region)	Lists all study-region 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-812A: Sites with No Visits Since Initiation - Recruitment Detail View	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 screened or enrolled subjects.
CDA-CO-812B: Sites with No Visits Since Initiation - Retention Detail View	Lists study-sites that have been initiated, but that have not yet had an interim monitoring visit. Includes subject retention 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 randomized or enrolled subjects.
CDA-CO-812C: Sites with No Visits Since Initiation - Summary View	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 enrolled subjects.
CDA-CO-816A: Sites to Monitor - Days Since Last Visit - Recruitment Detail View	Lists study-sites, sorted by the number of days that have passed since the last site visit. Includes planned and actual milestones and recruitment details.
	This report indicates which sites might need to be monitored.
CDA-CO-816B: Sites to Monitor - Days Since Last Visit - Retention Detail View	Lists study-sites, sorted by the number of days that have passed since the last site visit. Includes planned and actual milestones and retention details.
	This report indicates which sites might need to be monitored.
CDA-CO-816C: Sites to Monitor - Days Since Last Visit - Study Close Detail View	Lists study-sites, sorted by the number of days that have passed since the last site visit. Includes planned and actual milestones and retention details.
	This report indicates which sites might need to be monitored.
CDA-CO-816D: Sites to Monitor - Days Since Last Visit - Summary View	Lists study-sites, sorted by the number of days that have passed since the last site visit. Includes planned and actual milestones and monitoring details.
	This report indicates which sites might need to be monitored.
CDA-CO-823: Completed Reports that Missed Target: Site Visit Completed to Visit Report Completed	Lists all monitoring reports that have been completed, where the number of days from Site Visit Completed to Visit Report Completed exceeds the overall target.
CDA-CO-824: Outstanding Reports at Risk of Missing Target: Visit Completed to Visit Report Completed	Lists all completed site visits that do not have completed visit reports, where the number of days since Site Visit Completed is within 5 days of meeting overall target.
	This report indicates which outstanding reports are at risk of missing the overall target.
CDA-CO-825: Approved Reports that Missed Target: Visit Report Completed to Visit Report Approved	Lists all monitoring reports that have been approved, where the number of days from Visit Report Completed to Visit Report Approved exceeds the overall target.

Table 1–7 (Cont.) OHSCDA 2.2 New Reports

Report Name	Report Description
CDA-CO-826: Outstanding Approvals at Risk of Missing Target: Visit Report Completed to Visit Report Approved	Lists all completed monitoring reports that have not yet been approved, where the number of days since Monitoring Report Completed is within 5 days of meeting overall target.
	This report indicates which outstanding approvals are at risk of missing the overall target
CDA-CO-827: Outstanding Reports that Missed Target: Site Visit Completed to Visit Report Completed	Lists all completed site visits that do not have completed visit reports, where the number of days since Site Visit Completed is greater than the overall target.
	This report indicates which outstanding reports have already missed the overall target.
CDA-CO-828: Outstanding Approvals that Missed Target: Visit Report Completed to Visit Report Approved	Lists all completed monitoring reports that have not yet been approved, where the number of days since Monitoring Report Completed is greater than the overall target.
	This report indicates which outstanding approvals have already missed the overall target.
CDA-CO-829: Site Visit Duration - Study-Region	Displays the minimum, median, and maximum duration of site visits that have taken place in this study-region, 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 in this study-region.
CDA-CO-830: Outstanding Visit Reports (Study-Region View)	Lists all visit reports awaiting completion at the study-region.
	This report indicates which visit reports need to be completed and submitted for approval.
CDA-CO-831: Outstanding Visit Report Approvals (Study-Region)	Lists all visit reports awaiting approval in the study-region.
	This report indicates which visit reports require an action: review and approval.
CDA-CO-832: Outstanding Follow up Items (Study-Region Overview)	Lists all follow up items that have not been completed in the study-region.
	This report indicates which follow up items need to be resolved.
CDA-CO-902: Key Performance Indicators Over Time (Executive View)	Line graph that shows the following measures by quarter at the overall level:
	Median Critical Document Package Complete to Site Initiated Median LSLV to DB Lock
	Median Protocol Approved to 1st Site Initiated
	Median Protocol Approved to 1st Subject Enrolled
	Median Site Visit Completed to Visit Report Completed
	Median Visit Report Completed to Visit Report Approved
	This report shows the overall time trend for KPIs at the executive level.
CDA-CO-904: Study List: KPI Performance	Provides a list of studies with target/actual KPIs and a KPI indicator.
	This report indicates whether a study is performing within target range for KPIs.
CDA-CO-905: KPI Summary: CDP Complete to Site Initiated (Executive View)	Line and line-bar graphs that show the overall median compared to the overall target for Critical Document Package Complete to Site Initiated (# Days), by quarter. Also includes a count of the number of studies that make up the overall median.
	This report compares overall performance to the overall target for a given KPI.

Table 1–7   (Cont.) OHSCDA 2.2 New Reports

Report Name	Report Description
CDA-CO-906: KPI Summary: LSLV to Database Lock (Executive View)	Line and line-bar graphs that show the overall median compared to the overall target for Last Subject Last Visit to Database Lock (# Days), by quarter. Also includes a count of the number of studies that make up the overall median.
	This report compares overall performance to the overall target for a given KPI.
CDA-CO-907: KPI Summary: Protocol Approved to 1st Site Initiated (Executive View)	Line and line-bar graphs that show the overall median compared to the overall target for Protocol Approved to 1st Site Initiated (# Days), by quarter. Also includes a count of the number of studies that make up the overall median.
	This report compares overall performance to the overall target for a given KPI.
CDA-CO-908: KPI Summary: Protocol Approved to 1st Subject Enrolled (Executive View)	Line and line-bar graphs that show the overall median compared to the overall target for Protocol Approved to 1st Subject Enrolled (# Days), by quarter. Also includes a count of the number of studies that make up the overall median.
	This report compares overall performance to the overall target for a given KPI.
CDA-CO-909: KPI Summary: Site Visit Completed to Visit Report Completed (Executive View)	Line and line-bar graphs that show the overall median compared to the overall target for Site Visit Completed to Visit Report Completed (# Days), by quarter. Also includes a count of the number of studies that make up the overall median.
	This report compares overall performance to the overall target for a given KPI.
CDA-CO-910: KPI Summary: Visit Report Completed to Visit Report Approved (Executive View)	Line and line-bar graphs that show the overall median compared to the overall target for Visit Report Completed to Visit Report Approved (# Days), by quarter. Also includes a count of the number of studies that make up the overall median.
	This report compares overall performance to the overall target for a given KPI.

1.4 Multi-source Integration

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