Oracle® Health Sciences Clinical Development Analytics

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Contents

Audience xliii
Documentation Accessibility xliv
Finding Information and Patches on My Oracle Support xliv
Finding Documentation on Oracle Technology Network xlv
Related Documents xlvi
Conventions xlvii

Part I Using Oracle Health Sciences Clinical Development Analytics

1 Getting Started with Oracle Health Sciences Clinical Development Analytics

Overview 1-1
What Can I Do Using Oracle Health Sciences Clinical Development Analytics? 1-2
Architecture 1-2
Reporting 1-3
Regulatory Compliance 1-3
Tracking Data 1-4
Managing ETL Versions 1-4
Security 1-4

2 Using Oracle Health Sciences Clinical Development Analytics

Overview 2-1
Accessing Oracle Health Sciences Clinical Development Analytics 2-2
Logging In 2-2
Viewing a Dashboard 2-4
Using Oracle Business Intelligence 2-4
Oracle Business Intelligence Presentation Services Components 2-4
Oracle Business Intelligence Catalog 2-4
Oracle Business Intelligence Analysis Editor 2-5
Oracle Business Intelligence Interactive Home Page 2-5
Oracle Business Intelligence Interactive Dashboards 2-5
Oracle Business Intelligence Delivers 2-5
Performing Common Tasks in Oracle Business Intelligence 2-6
Exiting from Oracle Business Intelligence 2-6
Viewing Descriptions of Oracle BI Dashboards and Saved Analyses 2-6
Using Online Help 2-6

Printing an Oracle BI Dashboard or Saved Analysis 2-7
Emailing an Oracle BI Dashboard Page or Analysis 2-8
Exporting Oracle BI Results 2-8
Refreshing an Oracle BI Interactive Dashboard or Oracle BI Analysis 2-11
Refreshing Information in the Oracle BI Selection Pane 2-11
Navigating in Oracle Business Intelligence 2-11
What is Available to You After Accessing Oracle BI? 2-12
Using Oracle BI Global Header 2-12
Drilling Down in Oracle BI 2-14
Sorting Columns in Tables in Oracle BI 2-14
Using the Oracle BI My Account Page 2-14
Setting Your Oracle BI Preferences 2-15
Setting Your Oracle BI Time Zone 2-16

3 Working with Analyses

Predefined Analyses 3-1
Viewing a Predefined Analysis 3-2
Custom Analyses 3-3
Action Links 3-4
Viewing Analyses With Your Apple iPhone and iPad 3-4
Catalog Page 3-4
Dashboard Page 3-8
Indicators 3-10
Study Indicators 3-10
Study KPI Flag 3-10
Study Milestones Flag 3-11
Study Recruitment Flag 3-15
Study Retention Flag 3-17
Study-Region Indicators 3-17
Study-Region Milestones Flag 3-17
Study-Region Recruitment Flag 3-19
Study-Region Retention Flag 3-20
Study-Site Indicators 3-21
Study-Site Milestones Flag 3-21
Study-Site Recruitment Flag 3-23
Study-Site Retention Flag 3-24

Part II Appendixes

A Dashboards and Analyses

Oracle Health Sciences Clinical Development Analytics Dashboards A-1
CRA Dashboard A-1
CRA Dashboard Pages A-2
Data Manager - EDC Dashboard A-5
Data Manager - EDC Dashboard Pages A-5
Data Manager - Paper Dashboard A-8

Data Manager - Paper Dashboard Pages ... A-8
Executive Dashboard ... A-9
Executive Dashboard Pages ... A-10
Region Manager Dashboard ... A-11
Region Manager Dashboard Pages ... A-11
Study Manager Dashboard ... A-13
Study Manager Dashboard Pages ... A-14
Study Overview Dashboard ... A-15
Study Overview Dashboard Pages ... A-15
Study-Region Overview Dashboard ... A-19
Study-Region Overview Dashboard Pages ... A-19
Study-Site Overview Dashboard ... A-23
Study-Site Overview Dashboard Pages ... A-24
Index Dashboard ... A-27
Index Dashboard Pages ... A-27
Oracle Health Sciences Clinical Development Analytics Analyses ... A-27
Follow Up Items by Type (Multiple Study-Sites) (Report CDA-CO-810) ... A-33
Audience ... A-33
Report Type ... A-33
Location ... A-33
Dimensions ... A-33
Supplementary Prompts ... A-33
Reports Referenced ... A-34
Reports Referencing This Report ... A-34
Column Descriptions ... A-34
Follow Up Items by Type for Study-Site (Report CDA-CO-801) ... A-34
Audience ... A-34
Report Type ... A-34
Location ... A-34
Dimensions ... A-34
Supplementary Prompts ... A-34
Reports Referenced ... A-35
Reports Referencing This Report ... A-35
Column Descriptions ... A-35
Approval & Verification Rates - Worst Performers (Report CDA-DM-350) ... A-35
Audience ... A-35
Report Type ... A-35
Location ... A-35
Dimensions ... A-35
Supplementary Prompts ... A-35
Reports Referenced ... A-36
Reports Referencing This Report ... A-36
Column Descriptions ... A-36
Approved Reports that Missed Target: Visit Report Completed to Visit Report Approved (Report CDA-CO-825) A-36
Audience ... A-36
Report Type ... A-36

Location A-36
Dimensions A-36
Supplementary Prompts A-36
Reports Referenced A-36
Reports Referencing This Report A-37
Column Descriptions A-37
Average Days from Complete to Initially Approved (Report CDA-DM-325) A-37
Audience A-37
Report Type A-37
Location A-38
Dimensions A-38
Supplementary Prompts A-38
Reports Referenced A-38
Reports Referencing This Report A-38
Column Descriptions A-38
Average Days from Complete to Initially Verified (Report CDA-DM-330) A-38
Audience A-38
Report Type A-39
Location A-39
Dimensions A-39
Supplementary Prompts A-39
Reports Referenced A-39
Reports Referencing This Report A-39
Column Descriptions A-39
Average Duration in Categorized Discrepancy Review Status (Report CDA-DM-210) A-39
Audience A-39
Report Type A-40
Location A-40
Dimensions A-40
Supplementary Prompts A-40
Reports Referenced A-40
Reports Referencing This Report A-40
Column Descriptions A-40
Average Days Discrepancy Open (Report CDA-DM-205) A-40
Audience A-41
Report Type A-41
Location A-41
Dimensions A-41
Supplementary Prompts A-41
Reports Referenced A-41
Reports Referencing This Report A-41
Column Descriptions A-41
Average Duration of Open Discrepancies in Review Statuses (Report CDA-DM-215) A-41
Audience A-42
Report Type A-42
Location A-42
Dimensions A-42

Supplementary Prompts A-42
Reports Referenced A-42
Reports Referencing This Report A-42
Column Descriptions A-42
Completed Reports that Missed Target: Site Visit Completed to Visit Report Completed (Report CDA-CO-823) A-43
Audience A-43
Report Type A-43
Location A-43
Dimensions A-43
Supplementary Prompts A-43
Reports Referenced A-43
Reports Referencing This Report A-43
Column Descriptions A-43
Count of Currently Open Discrepancies by CRF and Type - Top N by Rank (Report CDA-DM-230) A-44
Audience A-44
Report Type A-44
Location A-44
Dimensions A-44
Supplementary Prompts A-44
Reports Referenced A-45
Reports Referencing This Report A-45
Column Descriptions A-45
Counts of Categorized Open Discrepancies, by Review Status (Report CDA-DM-220) A-45
Audience A-45
Report Type A-45
Location A-45
Dimensions A-45
Supplementary Prompts A-46
Reports Referenced A-46
Reports Referencing This Report A-46
Column Descriptions A-46
Counts of Discrepancies, by State and Review Status (Report CDA-DM-225) A-46
Audience A-46
Report Type A-46
Location A-46
Dimensions A-47
Supplementary Prompts A-47
Reports Referenced A-47
Reports Referencing This Report A-47
Column Descriptions A-47
Counts of Open Multivariate Discrepancies, by Procedure (Report CDA-DM-235) A-47
Audience A-47
Report Type A-47
Location A-48
Dimensions A-48

Supplementary Prompts A-48
Reports Referenced A-48
Reports Referencing This Report A-48
Column Descriptions A-48
Cumulative Enrollment and Early Term (Study-Site) (Report CDA-CO-418) A-48
Audience A-48
Report Type A-48
Location A-49
Dimensions A-49
Supplementary Prompts A-49
Reports Referenced A-49
Reports Referencing This Report A-49
Column Descriptions A-49
Cumulative Screening and Enrollment Bar (Study-Site) (Report CDA-CO-417) A-49
Audience A-49
Report Type A-49
Location A-50
Dimensions A-50
Supplementary Prompts A-50
Reports Referenced A-50
Reports Referencing This Report A-50
Column Descriptions A-50
Detail Study-Site Map (Report CDA-CO-1201) A-50
Audience A-50
Report Type A-50
Location A-51
Dimensions A-51
Supplementary Prompts A-51
Reports Referenced A-51
Reports Referencing This Report A-51
Column Descriptions A-51
Detailed Study Milestones Report (Report CDA-CO-102) A-51
Audience A-51
Report Type A-52
Location A-52
Dimensions A-52
Supplementary Prompts A-52
Reports Referenced A-52
Reports Referencing This Report A-52
Column Descriptions A-52
Discrepancies per Pages Entered - Top N (Report CDA-DM-255) A-69
Audience A-70
Report Type A-70
Location A-70
Dimensions A-70
Supplementary Prompts A-70
Reports Referenced A-70

Reports Referencing This Report A-70
Column Descriptions A-70
Discrepancies per Subjects Enrolled - Top N (Report CDA-DM-250) A-70
Audience A-70
Report Type A-71
Location A-71
Dimensions A-71
Supplementary Prompts A-71
Reports Referenced A-71
Reports Referencing This Report A-71
Column Descriptions A-71
Discrepancy Overview with Ratios (Report CDA-DM-240) A-71
Audience A-71
Report Type A-72
Location A-72
Dimensions A-72
Supplementary Prompts A-72
Reports Referenced A-72
Reports Referencing This Report A-72
Column Descriptions A-72
Document Collection Cycle Times - Days Outstanding by Type (Report CDA-CO-606) A-73
Audience A-73
Report Type A-73
Location A-73
Dimensions A-73
Supplementary Prompts A-73
Reports Referenced A-73
Reports Referencing This Report A-73
Column Descriptions A-73
Document Collection Cycle Times (Study-Site) (Report CDA-CO-604) A-74
Audience A-74
Report Type A-74
Location A-74
Dimensions A-74
Supplementary Prompts A-74
Reports Referenced A-74
Reports Referencing This Report A-74
Column Descriptions A-75
Document Collection Cycle Times -Turn Around Time by Type (Report CDA-CO-607) A-75
Audience A-75
Report Type A-75
Location A-75
Dimensions A-75
Supplementary Prompts A-76
Reports Referenced A-76
Reports Referencing This Report A-76
Column Descriptions A-76

Documents List (Multiple Study-Sites) (Report CDA-CO-601) A-76
Audience A-76
Report Type A-76
Location A-76
Dimensions A-76
Supplementary Prompts A-77
Reports Referenced A-77
Reports Referencing This Report A-77
Column Descriptions A-77
Documents List (Study Region) (Report CDA-CO-610) A-77
Audience A-77
Report Type A-77
Location A-78
Dimensions A-78
Supplementary Prompts A-78
Reports Referenced A-78
Reports Referencing This Report A-78
Column Descriptions A-78
Documents List (Study-Site) (Report CDA-CO-603) A-79
Audience A-79
Report Type A-79
Location A-79
Dimensions A-79
Supplementary Prompts A-79
Reports Referenced A-79
Reports Referencing This Report A-79
Column Descriptions A-79
Enrollment Overview By Site (Report CDA-CO-426) A-80
Audience A-80
Report Type A-80
Location A-80
Dimensions A-80
Supplementary Prompts A-80
Reports Referenced A-80
Reports Referencing This Report A-80
Column Descriptions A-80
Enrollment Progress Over Time (Study Level) (Report CDA-CO-408) A-81
Audience A-81
Report Type A-81
Location A-81
Dimensions A-81
Supplementary Prompts A-81
Reports Referenced A-81
Reports Referencing This Report A-82
Column Descriptions A-82
Enrollment Progress Over Time (Study-Region Level) (Report CDA-CO-435) A-82
Audience A-82

Report Type A-82
Location A-82
Dimensions A-83
Supplementary Prompts A-83
Reports Referenced A-83
Reports Referencing This Report A-83
Column Descriptions A-83
Enrollment Progress Over Time (Study-Site Level) (Report CDA-CO-423) A-83
Audience A-83
Report Type A-83
Location A-83
Dimensions A-84
Supplementary Prompts A-84
Reports Referenced A-84
Reports Referencing This Report A-84
Column Descriptions A-84
Executive Study-Site Map (Report CDA-CO-1203) A-84
Audience A-84
Report Type A-84
Location A-84
Dimensions A-84
Supplementary Prompts A-85
Reports Referenced A-85
Reports Referencing This Report A-85
Column Descriptions A-85
High Level Study-Site Map (Report CDA-CO-1202) A-85
Audience A-85
Report Type A-85
Location A-85
Dimensions A-86
Supplementary Prompts A-86
Reports Referenced A-86
Reports Referencing This Report A-86
Column Descriptions A-86
Initiated Study-Sites with Recruitment Counts (Report CDA-CO-412) A-86
Audience A-86
Report Type A-87
Location A-87
Dimensions A-87
Supplementary Prompts A-87
Reports Referenced A-87
Reports Referencing This Report A-87
Column Descriptions A-87
Investigator Contact and Studies List (Report CDA-CO-202) A-88
Audience A-88
Report Type A-88
Location A-88

Dimensions A-88
Supplementary Prompts A-88
Reports Referenced A-88
Reports Referencing This Report A-88
Column Descriptions A-89
Key Cycle Times for Paper Studies (Report CDA-DM-400) A-89
Audience A-89
Report Type A-89
Location A-89
Dimensions A-90
Supplementary Prompts A-90
Reports Referenced A-90
Reports Referencing This Report A-90
Column Descriptions A-90
Key EDC Cycle Times (Report CDA-DM-300) A-90
Audience A-90
Report Type A-91
Location A-91
Dimensions A-91
Supplementary Prompts A-91
Reports Referenced A-91
Reports Referencing This Report A-91
Column Descriptions A-91
Key EDC Processing Volumes (Report CDA-DM-305) A-92
Audience A-92
Report Type A-92
Location A-92
Dimensions A-92
Supplementary Prompts A-92
Reports Referenced A-92
Reports Referencing This Report A-92
Column Descriptions A-92
Key Paper Processing Volumes (Report CDA-DM-405) A-93
Audience A-93
Report Type A-93
Location A-93
Dimensions A-94
Supplementary Prompts A-94
Reports Referenced A-94
Reports Referencing This Report A-94
Column Descriptions A-94
Key Performance Indicators Over Time - Monitoring (Region Manager) (Report CDA-CO-1112) A-95
Audience A-95
Report Type A-95
Location A-95
Dimensions A-95
Supplementary Prompts A-95

Reports Referenced A-95
Reports Referencing This Report A-95
Column Descriptions A-95
Key Performance Indicators Over Time (Executive View) (Report CDA-CO-902) A-96
Audience A-96
Report Type A-96
Location A-96
Dimensions A-96
Supplementary Prompts A-96
Reports Referenced A-97
Reports Referencing This Report A-97
Column Descriptions A-97
KPI Summary - CDP Complete to Site Initiated (Executive View) (Report CDA-CO-905) . A-97
Audience A-97
Report Type A-97
Location A-97
Dimensions A-98
Supplementary Prompts A-98
Reports Referenced A-98
Reports Referencing This Report A-98
Column Descriptions A-98
KPI Summary - CDP Completed to Site Initiated (Region Manager View) (Report CDA-CO-1103) A-98
Audience A-98
Report Type A-99
Location A-99
Dimensions A-99
Supplementary Prompts A-99
Reports Referenced A-99
Reports Referencing This Report A-99
Column Descriptions A-99
KPI Summary - LSLV to Database Lock (Executive View) (Report CDA-CO-906) A-100
Audience A-100
Report Type A-100
Location A-100
Dimensions A-100
Supplementary Prompts A-100
Reports Referenced A-100
Reports Referencing This Report A-100
Column Descriptions A-100
KPI Summary - Protocol Approved to 1st Site Initiated (Executive View) (Report CDA-CO-907) A-101
Audience A-101
Report Type A-101
Location A-101
Dimensions A-101
Supplementary Prompts A-101

Reports Referenced A-101
Reports Referencing This Report A-101
Column Descriptions A-101
KPI Summary - Protocol Approved to 1st Subject Enrolled (Executive View) (Report CDA-CO-908) A-102
Audience A-102
Report Type A-102
Location A-102
Dimensions A-102
Supplementary Prompts A-102
Reports Referenced A-102
Reports Referencing This Report A-102
Column Descriptions A-103
KPI Summary - Site Visit Completed to Visit Report Completed (Executive View) (Report CDA-CO-909) A-103
Audience A-103
Report Type A-103
Location A-103
Dimensions A-103
Supplementary Prompts A-103
Reports Referenced A-103
Reports Referencing This Report A-104
Column Descriptions A-104
KPI Summary - Site Visit Completed to Visit Report Completed (Region Manager View) (Report CDA-CO-1104) A-104
Audience A-104
Report Type A-104
Location A-104
Dimensions A-104
Supplementary Prompts A-105
Reports Referenced A-105
Reports Referencing This Report A-105
Column Descriptions A-105
KPI Summary - Visit Report Completed to Approved (Region Manager View) (Report CDA-CO-1105) A-105
Audience A-105
Report Type A-105
Location A-106
Dimensions A-106
Supplementary Prompts A-106
Reports Referenced A-106
Reports Referencing This Report A-106
Column Descriptions A-106
KPI Summary - Visit Report Completed to Visit Report Approved (Executive View) (Report CDA-CO-910) A-106
Audience A-107
Report Type A-107
Location A-107

Dimensions A-107
Supplementary Prompts A-107
Reports Referenced A-107
Reports Referencing This Report A-107
Column Descriptions A-107
List Discrepancy Details (Report CDA-DM-245) A-108
Audience A-108
Report Type A-108
Location A-108
Dimensions A-108
Supplementary Prompts A-108
Reports Referenced A-108
Reports Referencing This Report A-108
Column Descriptions A-109
List of Follow Up Items (Report CDA-CO-803) A-109
Audience A-109
Report Type A-109
Location A-110
Dimensions A-110
Supplementary Prompts A-110
Reports Referenced A-110
Reports Referencing This Report A-110
Column Descriptions A-110
Listing of Subject-Pages, Awaiting EDC Processing (Report CDA-DM-310) A-110
Audience A-110
Report Type A-111
Location A-111
Dimensions A-111
Supplementary Prompts A-111
Reports Referenced A-111
Reports Referencing This Report A-111
Column Descriptions A-111
Listing of Subject-Pages, Awaiting Paper Processing (Report CDA-DM-410) A-112
Audience A-112
Report Type A-112
Location A-112
Dimensions A-112
Supplementary Prompts A-112
Reports Referenced A-112
Reports Referencing This Report A-112
Column Descriptions A-112
Low Approved to Entered Rate - Worst Performers (Report CDA-DM-335) A-113
Audience A-113
Report Type A-113
Location A-113
Dimensions A-113
Supplementary Prompts A-113

Reports Referenced A-114
Reports Referencing This Report A-114
Column Descriptions A-114
Low Verified to Entered Rate - Worst Performers (Report CDA-DM-340) A-114
Audience A-114
Report Type A-114
Location A-114
Dimensions A-114
Supplementary Prompts A-114
Reports Referenced A-114
Reports Referencing This Report A-115
Column Descriptions A-115
Median # Follow Up Items per Site for Study (Report CDA-CO-802) A-115
Audience A-115
Report Type A-115
Location A-115
Dimensions A-115
Supplementary Prompts A-115
Reports Referenced A-115
Reports Referencing This Report A-115
Column Descriptions A-116
Monitoring Report Approval - Turnaround Time vs. Goal (Report CDA-CO-813) A-116
Audience A-116
Report Type A-116
Location A-116
Dimensions A-116
Supplementary Prompts A-116
Reports Referenced A-116
Reports Referencing This Report A-116
Column Descriptions A-117
Monitoring Report Approval Turnaround Times (Report CDA-CO-817) A-117
Audience A-117
Report Type A-117
Location A-117
Dimensions A-117
Supplementary Prompts A-117
Reports Referenced A-117
Reports Referencing This Report A-118
Column Descriptions A-118
Monitoring Report Completion Turnaround Times (Report CDA-CO-820) A-118
Audience A-118
Report Type A-118
Location A-118
Dimensions A-118
Supplementary Prompts A-118
Reports Referenced A-119
Reports Referencing This Report A-119

Column Descriptions A-119
Monitoring Status Overview (Region Manager View) (Report CDA-CO-1101) A-119
Audience A-119
Report Type A-119
Location A-119
Dimensions A-119
Supplementary Prompts A-119
Reports Referenced A-119
Reports Referencing This Report A-120
Column Descriptions A-120
Monitoring Status Overview (Study Manager View) (Report CDA-CO-107) A-120
Audience A-120
Report Type A-120
Location A-120
Dimensions A-120
Supplementary Prompts A-120
Reports Referenced A-121
Reports Referencing This Report A-121
Column Descriptions A-121
Number of Studies (Report CDA-CO-1001) A-121
Audience A-121
Report Type A-121
Location A-121
Dimensions A-121
Supplementary Prompts A-122
Reports Referenced A-122
Reports Referencing This Report A-122
Column Descriptions A-122
Outstanding Approvals at Risk of Missing Target: Visit Report Completed to Visit Report Approved (Report CDA-CO-826) A-122
Audience A-122
Report Type A-122
Location A-122
Dimensions A-122
Supplementary Prompts A-122
Reports Referenced A-123
Reports Referencing This Report A-123
Column Descriptions A-123
Outstanding Approvals that Missed Target: Visit Report Completed to Visit Report Approved (Report CDA-CO-828) A-124
Audience A-124
Report Type A-124
Location A-124
Dimensions A-124
Supplementary Prompts A-124
Reports Referenced A-124
Reports Referencing This Report A-124

Column Descriptions A-125
Outstanding Documents List (Report CDA-CO-602) A-125
Audience A-125
Report Type A-125
Location A-125
Dimensions A-125
Supplementary Prompts A-126
Reports Referenced A-126
Reports Referencing This Report A-126
Column Descriptions A-126
Outstanding Follow up Items - Study Overview (Report CDA-CO-805) A-126
Audience A-126
Report Type A-126
Location A-126
Dimensions A-127
Supplementary Prompts A-127
Reports Referenced A-127
Reports Referencing This Report A-127
Column Descriptions A-127
Outstanding Follow up Items (CRA View) (Report CDA-CO-806) A-127
Audience A-127
Report Type A-127
Location A-128
Dimensions A-128
Supplementary Prompts A-128
Reports Referenced A-128
Reports Referencing This Report A-128
Column Descriptions A-128
Outstanding Follow up Items (Study Manager View) (Report CDA-CO-807) A-129
Audience A-129
Report Type A-129
Location A-129
Dimensions A-129
Supplementary Prompts A-129
Reports Referenced A-129
Reports Referencing This Report A-129
Column Descriptions A-129
Outstanding Follow up Items (Study-Region Overview) (Report CDA-CO-832) A-130
Audience A-130
Report Type A-130
Location A-130
Dimensions A-130
Supplementary Prompts A-130
Reports Referenced A-130
Reports Referencing This Report A-130
Column Descriptions A-131
Outstanding Follow up Items (Study-Site Overview) (Report CDA-CO-815) A-131

Audience A-131
Report Type A-132
Location A-132
Dimensions A-132
Supplementary Prompts A-132
Reports Referenced A-132
Reports Referencing This Report A-132
Column Descriptions A-132
Outstanding Monitoring Report Approvals (CRA View) (Report CDA-CO-814) A-133
Audience A-133
Report Type A-133
Location A-133
Dimensions A-133
Supplementary Prompts A-133
Reports Referenced A-133
Reports Referencing This Report A-133
Column Descriptions A-133
Outstanding Monitoring Report Approvals (Study Manager View) (Report CDA-CO-809) A-134
Audience A-134
Report Type A-134
Location A-134
Dimensions A-134
Supplementary Prompts A-134
Reports Referenced A-134
Reports Referencing This Report A-134
Column Descriptions A-134
Outstanding Monitoring Report Approvals (Study-Region) (Report CDA-CO-831) A-135
Audience A-135
Report Type A-135
Location A-135
Dimensions A-135
Supplementary Prompts A-135
Reports Referenced A-135
Reports Referencing This Report A-135
Column Descriptions A-136
Outstanding Monitoring Report Approvals (Study-Site) (Report CDA-CO-822) A-136
Audience A-136
Report Type A-136
Location A-137
Dimensions A-137
Supplementary Prompts A-137
Reports Referenced A-137
Reports Referencing This Report A-137
Column Descriptions A-137
Outstanding Monitoring Reports (CRA View) (Report CDA-CO-804) A-137
Audience A-137

Report Type A-138
Location A-138
Dimensions A-138
Supplementary Prompts A-138
Reports Referenced A-138
Reports Referencing This Report A-138
Column Descriptions A-138
Outstanding Monitoring Reports (Study-Region View) (Report CDA-CO-830) A-139
Audience A-139
Report Type A-139
Location A-139
Dimensions A-139
Supplementary Prompts A-139
Reports Referenced A-139
Reports Referencing This Report A-139
Column Descriptions A-139
Outstanding Monitoring Reports (Study-Site View) (Report CDA-CO-811) A-140
Audience A-140
Report Type A-140
Location A-140
Dimensions A-140
Supplementary Prompts A-140
Reports Referenced A-140
Reports Referencing This Report A-141
Column Descriptions A-141
Outstanding Reports at Risk of Missing Target: Visit Completed to Visit Report Completed (Report CDA-CO-824) A-141
Audience A-141
Report Type A-141
Location A-141
Dimensions A-141
Supplementary Prompts A-141
Reports Referenced A-142
Reports Referencing This Report A-142
Column Descriptions A-142
Outstanding Reports that Missed Target - Site Visit Completed to Visit Report Completed (Report CDA-CO-827) A-143
Audience A-143
Report Type A-143
Location A-143
Dimensions A-143
Supplementary Prompts A-143
Reports Referenced A-143
Reports Referencing This Report A-143
Column Descriptions A-144
Pages Awaiting Entry Completion (Report CDA-DM-450) A-144
Audience A-145
Report Type A-145

Location A-145
Dimensions A-145
Supplementary Prompts A-145
Reports Referenced A-145
Reports Referencing This Report A-145
Column Descriptions A-145
Paper Processing - Longest Cycle Times (Report CDA-DM-415) A-145
Audience A-145
Report Type A-146
Location A-146
Dimensions A-146
Supplementary Prompts A-146
Reports Referenced A-146
Reports Referencing This Report A-146
Column Descriptions A-146
Performance Metrics Summary Narrative - Site Visit (Report CDA-CO-1110) A-146
Audience A-146
Report Type A-147
Location A-147
Dimensions A-147
Supplementary Prompts A-147
Reports Referenced A-147
Reports Referencing This Report A-147
Column Descriptions A-147
Screen Failure Reason (Report CDA-CO-420) A-149
Audience A-149
Report Type A-149
Location A-150
Dimensions A-150
Supplementary Prompts A-150
Reports Referenced A-150
Reports Referencing This Report A-150
Column Descriptions A-150
Screen Failure Reason (Report CDA-CO-425) A-150
Audience A-150
Report Type A-150
Location A-150
Dimensions A-151
Supplementary Prompts A-151
Reports Referenced A-151
Reports Referencing This Report A-151
Column Descriptions A-151
Screen Failure Reason by Site (Report CDA-CO-300) A-151
Audience A-151
Report Type A-151
Location A-151
Dimensions A-152

Supplementary Prompts A-152
Reports Referenced A-152
Reports Referencing This Report A-152
Column Descriptions A-152
Screening Overview (Study Level) (Report CDA-CO-407) A-152
Audience A-152
Report Type A-152
Location A-152
Dimensions A-153
Supplementary Prompts A-153
Reports Referenced A-153
Reports Referencing This Report A-153
Column Descriptions A-153
Screening Overview (Study-Region Level) (Report CDA-CO-434) A-153
Audience A-153
Report Type A-153
Location A-154
Dimensions A-154
Supplementary Prompts A-154
Reports Referenced A-154
Reports Referencing This Report A-154
Column Descriptions A-154
Screening Overview (Study-Site Level) (Report CDA-CO-415) A-154
Audience A-154
Report Type A-155
Location A-155
Dimensions A-155
Supplementary Prompts A-155
Reports Referenced A-155
Reports Referencing This Report A-155
Column Descriptions A-155
Screening vs. Enrollment by Region (Report CDA-CO-400) A-156
Audience A-156
Report Type A-156
Location A-156
Dimensions A-156
Supplementary Prompts A-156
Reports Referenced A-156
Reports Referencing This Report A-156
Column Descriptions A-156
Site Detail (Report CDA-CO-209) A-157
Audience A-157
Report Type A-157
Location A-157
Dimensions A-157
Supplementary Prompts A-157
Reports Referenced A-157

Reports Referencing This Report A-157
Column Descriptions A-157
Site Enrollment Performance Compared to Site Visit Frequency (Report CDA-CO-110) .. A-158
Audience A-158
Report Type A-158
Location A-158
Dimensions A-158
Supplementary Prompts A-159
Reports Referenced A-159
Reports Referencing This Report A-159
Column Descriptions A-159
Site Initiation Over Time Bar Chart (Study Region) (Report CDA-CO-307) A-159
Audience A-159
Report Type A-159
Location A-159
Dimensions A-159
Supplementary Prompts A-160
Reports Referenced A-160
Reports Referencing This Report A-160
Column Descriptions A-160
Site Recruitment Performance - Single Study (Report CDA-CO-416) A-160
Audience A-160
Report Type A-160
Location A-160
Dimensions A-160
Supplementary Prompts A-161
Reports Referenced A-161
Reports Referencing This Report A-161
Column Descriptions A-161
Site Recruitment Performance (Report CDA-CO-413) A-161
Audience A-161
Report Type A-162
Location A-162
Dimensions A-162
Supplementary Prompts A-162
Reports Referenced A-162
Reports Referencing This Report A-162
Column Descriptions A-162
Site Recruitment Performance Charts (Executive View) (Report CDA-CO-436) A-162
Audience A-163
Report Type A-163
Location A-163
Dimensions A-163
Supplementary Prompts A-163
Reports Referenced A-163
Reports Referencing This Report A-163
Column Descriptions A-163

Site Visit Analysis (Report CDA-CO-821) A-164
Audience A-164
Report Type A-164
Location A-164
Dimensions A-164
Supplementary Prompts A-164
Reports Referenced A-164
Reports Referencing This Report A-164
Column Descriptions A-164
Site Visit Duration - Study (Report CDA-CO-808) A-165
Audience A-165
Report Type A-165
Location A-165
Dimensions A-165
Supplementary Prompts A-165
Reports Referenced A-165
Reports Referencing This Report A-165
Column Descriptions A-165
Site Visit Duration - Study Site (Report CDA-CO-800) A-166
Audience A-166
Report Type A-166
Location A-166
Dimensions A-166
Supplementary Prompts A-166
Reports Referenced A-166
Reports Referencing This Report A-166
Column Descriptions A-166
Site Visit Duration - Study-Region (Report CDA-CO-829) A-167
Audience A-167
Report Type A-167
Location A-167
Dimensions A-167
Supplementary Prompts A-167
Reports Referenced A-167
Reports Referencing This Report A-167
Column Descriptions A-167
Sites to Monitor - Days Since Last Visit - Recruitment Detail View (Report CDA-CO-816A) A-168
Audience A-168
Report Type A-168
Location A-168
Dimensions A-168
Supplementary Prompts A-168
Reports Referenced A-168
Reports Referencing This Report A-168
Column Descriptions A-169
Sites to Monitor - Days Since Last Visit - Retention Detail View (Report CDA-CO-816B) A-177
Audience A-177

Report Type A-177
Location A-177
Dimensions A-178
Supplementary Prompts A-178
Reports Referenced A-178
Reports Referencing This Report A-178
Column Descriptions A-178
Sites to Monitor - Days Since Last Visit - Study Close Detail View (Report CDA-CO-816C) A-183
Audience A-183
Report Type A-183
Location A-183
Dimensions A-183
Supplementary Prompts A-183
Reports Referenced A-183
Reports Referencing This Report A-183
Column Descriptions A-183
Sites to Monitor - Days Since Last Visit - Summary View (Report CDA-CO-816D) A-188
Audience A-188
Report Type A-188
Location A-189
Dimensions A-189
Supplementary Prompts A-189
Reports Referenced A-189
Reports Referencing This Report A-189
Column Descriptions A-189
Sites with No Visits Since Initiation - Recruitment Detail View (Report CDA-CO-812A). A-190
Audience A-190
Report Type A-190
Location A-190
Dimensions A-190
Supplementary Prompts A-190
Reports Referenced A-190
Reports Referencing This Report A-190
Column Descriptions A-190
Sites with No Visits Since Initiation - Retention Detail View (Report CDA-CO-812B) A-199
Audience A-199
Report Type A-199
Location A-199
Dimensions A-200
Supplementary Prompts A-200
Reports Referenced A-200
Reports Referencing This Report A-200
Column Descriptions A-200
Sites with No Visits Since Initiation - Summary View (Report CDA-CO-812C) A-204
Audience A-205
Report Type A-205

Location A-205
Dimensions A-205
Supplementary Prompts A-205
Reports Referenced A-205
Reports Referencing This Report A-205
Column Descriptions A-205
Study Documents List (Report CDA-CO-600) A-206
Audience A-206
Report Type A-206
Location A-206
Dimensions A-206
Supplementary Prompts A-207
Reports Referenced A-207
Reports Referencing This Report A-207
Column Descriptions A-207
Study Information (Report CDA-CO-103) A-207
Audience A-207
Report Type A-207
Location A-207
Dimensions A-208
Supplementary Prompts A-208
Reports Referenced A-208
Reports Referencing This Report A-208
Column Descriptions A-208
Study List - Initiation Details (Report CDA-CO-305) A-208
Audience A-208
Report Type A-208
Location A-208
Dimensions A-209
Supplementary Prompts A-209
Reports Referenced A-209
Reports Referencing This Report A-209
Column Descriptions A-209
Study List - KPI Performance (Report CDA-CO-904) A-210
Audience A-210
Report Type A-210
Location A-210
Dimensions A-210
Supplementary Prompts A-210
Reports Referenced A-211
Reports Referencing This Report A-211
Column Descriptions A-211
Study List - Milestone Performance (Report CDA-CO-109) A-223
Audience A-223
Report Type A-223
Location A-223
Dimensions A-223

Supplementary Prompts A-223
Reports Referenced A-223
Reports Referencing This Report A-224
Column Descriptions A-224
Study List - Recruitment Details (Report CDA-CO-406) A-235
Audience A-235
Report Type A-235
Location A-235
Dimensions A-235
Supplementary Prompts A-235
Reports Referenced A-235
Reports Referencing This Report A-235
Column Descriptions A-235
Study Milestone with Indicators (Study Overview) (Report CDA-CO-101) A-243
Audience A-243
Report Type A-243
Location A-243
Dimensions A-243
Supplementary Prompts A-243
Reports Referenced A-243
Reports Referencing This Report A-243
Column Descriptions A-244
Study Region Milestones with Indicators (Report CDA-CO-1106) A-261
Audience A-261
Report Type A-261
Location A-261
Dimensions A-261
Supplementary Prompts A-261
Reports Referenced A-261
Reports Referencing This Report A-261
Column Descriptions A-261
Study Region Milestones with Indicators (Single Study-Region) (Report CDA-CO-1116) A-277
Audience A-278
Report Type A-278
Location A-278
Dimensions A-278
Supplementary Prompts A-278
Reports Referenced A-278
Reports Referencing This Report A-278
Column Descriptions A-278
Study Region vs. Study - Site Start Up KPIs (Report CDA-CO-1111) A-294
Audience A-294
Report Type A-294
Location A-294
Dimensions A-294
Supplementary Prompts A-294
Reports Referenced A-295

Reports Referencing This Report A-295
Column Descriptions A-295
Study Regions with Red or Yellow Performance Flag (Report CDA-CO-1200) A-295
Audience A-295
Report Type A-295
Location A-295
Dimensions A-296
Supplementary Prompts A-296
Reports Referenced A-296
Reports Referencing This Report A-296
Column Descriptions A-296
Study Site Milestones with Indicators - Data Management View (Report CDA-CO-208A) A-300
Audience A-301
Report Type A-301
Location A-301
Dimensions A-301
Supplementary Prompts A-301
Reports Referenced A-301
Reports Referencing This Report A-301
Column Descriptions A-301
Study Site Milestones with Indicators - Monitoring View (Report CDA-CO-208B) A-302
Audience A-302
Report Type A-302
Location A-302
Dimensions A-302
Supplementary Prompts A-303
Reports Referenced A-303
Reports Referencing This Report A-303
Column Descriptions A-303
Study Site Milestones with Indicators - Recruitment Detail View (Report CDA-CO-208C) A-304
Audience A-304
Report Type A-304
Location A-304
Dimensions A-304
Supplementary Prompts A-304
Reports Referenced A-305
Reports Referencing This Report A-305
Column Descriptions A-305
Study Site Milestones with Indicators - Retention Detail View (Report CDA-CO-208D) .. A-313
Audience A-313
Report Type A-313
Location A-313
Dimensions A-314
Supplementary Prompts A-314
Reports Referenced A-314
Reports Referencing This Report A-314

Column Descriptions A-314
Study Site Milestones with Indicators - Site Start Up Detail View (Report CDA-CO-208E) A-318
Audience A-318
Report Type A-319
Location A-319
Dimensions A-319
Supplementary Prompts A-319
Reports Referenced A-319
Reports Referencing This Report A-319
Column Descriptions A-319
Study Site Milestones with Indicators - Study Close Detail View (Report CDA-CO-208F) A-322
Audience A-322
Report Type A-323
Location A-323
Dimensions A-323
Supplementary Prompts A-323
Reports Referenced A-323
Reports Referencing This Report A-323
Column Descriptions A-323
Study Site Milestones with Indicators - Summary View (Report CDA-CO-208G) A-329
Audience A-329
Report Type A-329
Location A-329
Dimensions A-329
Supplementary Prompts A-330
Reports Referenced A-330
Reports Referencing This Report A-330
Column Descriptions A-330
Study Sites Initiated but Zero Enrolled (Report CDA-CO-301) A-336
Audience A-336
Report Type A-336
Location A-336
Dimensions A-336
Supplementary Prompts A-336
Reports Referenced A-336
Reports Referencing This Report A-336
Column Descriptions A-336
Study Sites Initiated, only One Subject Enrolled (Report CDA-CO-302) A-337
Audience A-337
Report Type A-337
Location A-337
Dimensions A-337
Supplementary Prompts A-337
Reports Referenced A-337
Reports Referencing This Report A-338

Column Descriptions A-338
Study Team Member List (Report CDA-CO-111) A-338
Audience A-338
Report Type A-338
Location A-338
Dimensions A-338
Supplementary Prompts A-339
Reports Referenced A-339
Reports Referencing This Report A-339
Column Descriptions A-339
Study-Region Information (Report CDA-CO-1113) A-339
Audience A-339
Report Type A-339
Location A-339
Dimensions A-340
Supplementary Prompts A-340
Reports Referenced A-340
Reports Referencing This Report A-340
Column Descriptions A-340
Study-Region List - Initiation Details (Report CDA-CO-306) A-340
Audience A-340
Report Type A-340
Location A-341
Dimensions A-341
Supplementary Prompts A-341
Reports Referenced A-341
Reports Referencing This Report A-341
Column Descriptions A-341
Study-Region List - KPI Performance (Report CDA-CO-1108) A-348
Audience A-348
Report Type A-348
Location A-348
Dimensions A-348
Supplementary Prompts A-348
Reports Referenced A-348
Reports Referencing This Report A-349
Column Descriptions A-349
Study-Region List - Milestone Performance (Report CDA-CO-1109) A-349
Audience A-349
Report Type A-349
Location A-350
Dimensions A-350
Supplementary Prompts A-350
Reports Referenced A-350
Reports Referencing This Report A-350
Column Descriptions A-350
Study-Region List - Recruitment Details (Report CDA-CO-433) A-361

Audience A-361
Report Type A-361
Location A-361
Dimensions A-361
Supplementary Prompts A-361
Reports Referenced A-361
Reports Referencing This Report A-362
Column Descriptions A-362
Study-Region List and Recruitment Counts (Report CDA-CO-404) A-370
Audience A-370
Report Type A-370
Location A-371
Dimensions A-371
Supplementary Prompts A-371
Reports Referenced A-371
Reports Referencing This Report A-371
Column Descriptions A-371
Study-Region Team Member List (Report CDA-CO-1107) A-371
Audience A-371
Report Type A-372
Location A-372
Dimensions A-372
Supplementary Prompts A-372
Reports Referenced A-372
Reports Referencing This Report A-372
Column Descriptions A-372
Study-Site Information (Report CDA-CO-206) A-373
Audience A-373
Report Type A-373
Location A-373
Dimensions A-373
Supplementary Prompts A-373
Reports Referenced A-373
Reports Referencing This Report A-373
Column Descriptions A-373
Study-Site List by Recruitment Performance Group (Report CDA-CO-401) A-374
Audience A-374
Report Type A-374
Location A-374
Dimensions A-374
Supplementary Prompts A-374
Reports Referenced A-374
Reports Referencing This Report A-374
Column Descriptions A-374
Study-Site List with Indicators - Data Management View (Report CDA-CO-207A) A-375
Audience A-375
Report Type A-375

Location A-375
Dimensions A-375
Supplementary Prompts A-375
Reports Referenced A-375
Reports Referencing This Report A-376
Column Descriptions A-376
Study-Site List with Indicators - Monitoring View (Report CDA-CO-207B) A-376
Audience A-376
Report Type A-377
Location A-377
Dimensions A-377
Supplementary Prompts A-377
Reports Referenced A-377
Reports Referencing This Report A-377
Column Descriptions A-377
Study-Site List with Indicators - Recruitment Detail View (Report CDA-CO-207C) A-378
Audience A-378
Report Type A-378
Location A-378
Dimensions A-378
Supplementary Prompts A-379
Reports Referenced A-379
Reports Referencing This Report A-379
Column Descriptions A-379
Study-Site List with Indicators - Retention Detail View (Report CDA-CO-207D) A-387
Audience A-387
Report Type A-387
Location A-387
Dimensions A-388
Supplementary Prompts A-388
Reports Referenced A-388
Reports Referencing This Report A-388
Column Descriptions A-388
Study-Site List with Indicators - Site Start Up Detail View (Report CDA-CO-207E) A-392
Audience A-392
Report Type A-392
Location A-392
Dimensions A-392
Supplementary Prompts A-392
Reports Referenced A-392
Reports Referencing This Report A-392
Column Descriptions A-392
Study-Site List with Indicators - Study Close Detail View (Report CDA-CO-207F) A-396
Audience A-396
Report Type A-396
Location A-396
Dimensions A-396

Supplementary Prompts A-396
Reports Referenced A-396
Reports Referencing This Report A-396
Column Descriptions A-396
Study-Site List with Indicators - Summary View (Report CDA-CO-207G) A-402
Audience A-402
Report Type A-403
Location A-403
Dimensions A-403
Supplementary Prompts A-403
Reports Referenced A-403
Reports Referencing This Report A-403
Column Descriptions A-403
Study-Site Milestones with Indicators (CRA) - Monitoring View (Report CDA-CO-205A) A-407
Audience A-407
Report Type A-407
Location A-407
Dimensions A-407
Supplementary Prompts A-408
Reports Referenced A-408
Reports Referencing This Report A-408
Column Descriptions A-408
Study-Site Milestones with Indicators (CRA) - Recruitment Detail View (Report CDA-CO-205B) A-408
Audience A-409
Report Type A-409
Location A-409
Dimensions A-409
Supplementary Prompts A-409
Reports Referenced A-409
Reports Referencing This Report A-409
Column Descriptions A-409
Study-Site Milestones with Indicators (CRA) - Retention Detail View (Report CDA-CO-205C) .. A-418
Audience A-418
Report Type A-418
Location A-418
Dimensions A-418
Supplementary Prompts A-418
Reports Referenced A-419
Reports Referencing This Report A-419
Column Descriptions A-419
Study-Site Milestones with Indicators (CRA) - Site Start Up Detail View (Report CDA-CO-205D) A-423
Audience A-423
Report Type A-423
Location A-423

Dimensions A-424
Supplementary Prompts A-424
Reports Referenced A-424
Reports Referencing This Report A-424
Column Descriptions A-424
Study-Site Milestones with Indicators (CRA) - Study Close Detail View (Report CDA-CO-205E) A-427
Audience A-427
Report Type A-427
Location A-427
Dimensions A-428
Supplementary Prompts A-428
Reports Referenced A-428
Reports Referencing This Report A-428
Column Descriptions A-428
Study-Site Milestones with Indicators (CRA) - Summary View (Report CDA-CO-205F) . A-434
Audience A-434
Report Type A-434
Location A-434
Dimensions A-434
Supplementary Prompts A-434
Reports Referenced A-434
Reports Referencing This Report A-434
Column Descriptions A-434
Study-Site Milestones with Indicators (Single Study-Site) - Data Management View (Report CDA-CO-203A) A-438
Audience A-438
Report Type A-438
Location A-438
Dimensions A-438
Supplementary Prompts A-439
Reports Referenced A-439
Reports Referencing This Report A-439
Column Descriptions A-439
Study-Site Milestones with Indicators (Single Study-Site) - Monitoring View (Report CDA-CO-203B) A-439
Audience A-439
Report Type A-440
Location A-440
Dimensions A-440
Supplementary Prompts A-440
Reports Referenced A-440
Reports Referencing This Report A-440
Column Descriptions A-440
Study-Site Milestones with Indicators (Single Study-Site) - Recruitment Detail View (Report CDA-CO-203C) A-441
Audience A-441
Report Type A-441

Location A-441
Dimensions A-441
Supplementary Prompts A-441
Reports Referenced A-441
Reports Referencing This Report A-442
Column Descriptions A-442
Study-Site Milestones with Indicators (Single Study-Site) - Retention Detail View (Report CDA-CO-203D) A-450
Audience A-450
Report Type A-450
Location A-450
Dimensions A-450
Supplementary Prompts A-450
Reports Referenced A-450
Reports Referencing This Report A-451
Column Descriptions A-451
Study-Site Milestones with Indicators (Single Study-Site) - Site Start Up Detail View (Report CDA-CO-203E) A-455
Audience A-455
Report Type A-455
Location A-455
Dimensions A-455
Supplementary Prompts A-455
Reports Referenced A-455
Reports Referencing This Report A-456
Column Descriptions A-456
Study-Site Milestones with Indicators (Single Study-Site) - Study Close Detail View (Report CDA-CO-203F) A-459
Audience A-459
Report Type A-459
Location A-459
Dimensions A-459
Supplementary Prompts A-459
Reports Referenced A-459
Reports Referencing This Report A-459
Column Descriptions A-459
Study-Site Milestones with Indicators (Single Study-Site) - Summary View (Report CDA-CO-203G) A-465
Audience A-465
Report Type A-465
Location A-465
Dimensions A-465
Supplementary Prompts A-466
Reports Referenced A-466
Reports Referencing This Report A-466
Column Descriptions A-466
Study-Site Subject Recruitment Narrative (Report CDA-CO-405) A-469
Audience A-469

Report Type A-469
Location A-470
Dimensions A-470
Supplementary Prompts A-470
Reports Referenced A-470
Reports Referencing This Report A-470
Column Descriptions A-470
Study-Site Subject Retention (Report CDA-CO-500) A-470
Audience A-470
Report Type A-471
Location A-471
Dimensions A-471
Supplementary Prompts A-471
Reports Referenced A-471
Reports Referencing This Report A-471
Column Descriptions A-471
Study-Site Team Member List (Report CDA-CO-201) A-472
Audience A-472
Report Type A-472
Location A-472
Dimensions A-472
Supplementary Prompts A-472
Reports Referenced A-472
Reports Referencing This Report A-472
Column Descriptions A-472
Study-Sites with Red or Yellow Performance Flag (Report CDA-CO-204) A-473
Audience A-473
Report Type A-473
Location A-473
Dimensions A-473
Supplementary Prompts A-473
Reports Referenced A-473
Reports Referencing This Report A-473
Column Descriptions A-473
Subject Enrollment by Region (Report CDA-CO-414) A-474
Audience A-474
Report Type A-474
Location A-474
Dimensions A-474
Supplementary Prompts A-474
Reports Referenced A-475
Reports Referencing This Report A-475
Column Descriptions A-475
Subject Recruitment (Report CDA-CO-419) A-475
Audience A-475
Report Type A-475
Location A-475

Dimensions A-475
Supplementary Prompts A-475
Reports Referenced A-475
Reports Referencing This Report A-476
Column Descriptions A-476
Subject Recruitment (Study Region) (Report CDA-CO-1114) A-476
Audience A-476
Report Type A-476
Location A-476
Dimensions A-476
Supplementary Prompts A-476
Reports Referenced A-477
Reports Referencing This Report A-477
Column Descriptions A-477
Subject Retention (Report CDA-CO-504) A-477
Audience A-477
Report Type A-477
Location A-478
Dimensions A-478
Supplementary Prompts A-478
Reports Referenced A-478
Reports Referencing This Report A-478
Column Descriptions A-478
Subject Retention (Study Level) (Report CDA-CO-503) A-478
Audience A-478
Report Type A-478
Location A-479
Dimensions A-479
Supplementary Prompts A-479
Reports Referenced A-479
Reports Referencing This Report A-479
Column Descriptions A-479
Subject Retention (Study Region) (Report CDA-CO-1115) A-479
Audience A-479
Report Type A-480
Location A-480
Dimensions A-480
Supplementary Prompts A-480
Reports Referenced A-480
Reports Referencing This Report A-480
Column Descriptions A-480
Subject Retention (Study-Site Level) (Report CDA-CO-502) A-481
Audience A-481
Report Type A-481
Location A-481
Dimensions A-481
Supplementary Prompts A-481

Reports Referenced A-481
Reports Referencing This Report A-481
Column Descriptions A-481
Subject Retention Over Time (Study Level) (Report CDA-CO-501) A-482
Audience A-482
Report Type A-482
Location A-482
Dimensions A-482
Supplementary Prompts A-482
Reports Referenced A-482
Reports Referencing This Report A-482
Column Descriptions A-483
Subject Retention Over Time (Study-Site Level) (Report CDA-CO-510) A-483
Audience A-483
Report Type A-483
Location A-483
Dimensions A-484
Supplementary Prompts A-484
Reports Referenced A-484
Reports Referencing This Report A-484
Column Descriptions A-484
Subject Retention Over Time Chart (Study-Region Level) (Report CDA-CO-511) A-484
Audience A-485
Report Type A-485
Location A-485
Dimensions A-485
Supplementary Prompts A-485
Reports Referenced A-485
Reports Referencing This Report A-485
Column Descriptions A-485
Subjects Enrolled per Month, Over Time (Report CDA-CO-403) A-486
Audience A-486
Report Type A-486
Location A-486
Dimensions A-486
Supplementary Prompts A-486
Reports Referenced A-486
Reports Referencing This Report A-486
Column Descriptions A-486
Subjects who Failed Screening (Report CDA-CO-428) A-486
Audience A-487
Report Type A-487
Location A-487
Dimensions A-487
Supplementary Prompts A-487
Reports Referenced A-487
Reports Referencing This Report A-487

Column Descriptions A-487
Subjects Withdrawn List (Report CDA-CO-509) A-488
Audience A-488
Report Type A-488
Location A-488
Dimensions A-488
Supplementary Prompts A-488
Reports Referenced A-488
Reports Referencing This Report A-488
Column Descriptions A-488
Summary of Subjects Awaiting EDC Processing (Report CDA-DM-320) A-489
Audience A-489
Report Type A-489
Location A-489
Dimensions A-489
Supplementary Prompts A-489
Reports Referenced A-490
Reports Referencing This Report A-490
Column Descriptions A-490
Summary of Subjects Awaiting Paper Processing (Report CDA-DM-420) A-490
Audience A-490
Report Type A-490
Location A-490
Dimensions A-491
Supplementary Prompts A-491
Reports Referenced A-491
Reports Referencing This Report A-491
Column Descriptions A-491
Top Investigators Compared to All Investigators for Study, Total Enrollment (Report CDA-CO-702) A-491
Audience A-491
Report Type A-492
Location A-492
Dimensions A-492
Supplementary Prompts A-492
Reports Referenced A-492
Reports Referencing This Report A-492
Column Descriptions A-492
Top Investigators, % Planned Enrollment Completed (Report CDA-CO-700) A-493
Audience A-493
Report Type A-493
Location A-493
Dimensions A-493
Supplementary Prompts A-493
Reports Referenced A-493
Reports Referencing This Report A-493
Column Descriptions A-493

Top Investigators, Total Enrollment (Report CDA-CO-701) A-494
Audience A-494
Report Type A-494
Location A-494
Dimensions A-494
Supplementary Prompts A-494
Reports Referenced A-495
Reports Referencing This Report A-495
Column Descriptions A-495
Total Subject Enrollment by Region (Report CDA-CO-410) A-495
Audience A-495
Report Type A-495
Location A-495
Dimensions A-495
Supplementary Prompts A-495
Reports Referenced A-496
Reports Referencing This Report A-496
Column Descriptions A-496
Uninitiated Sites (Report CDA-CO-304) A-496
Audience A-496
Report Type A-496
Location A-496
Dimensions A-496
Supplementary Prompts A-496
Reports Referenced A-496
Reports Referencing This Report A-497
Column Descriptions A-497
Visit Frequency Compared to Subject Enrollment (Report CDA-CO-819) A-500
Audience A-500
Report Type A-500
Location A-500
Dimensions A-500
Supplementary Prompts A-500
Reports Referenced A-501
Reports Referencing This Report A-501
Column Descriptions A-501
Withdrawn Reason (Report CDA-CO-505) A-501
Audience A-501
Report Type A-501
Location A-501
Dimensions A-501
Supplementary Prompts A-501
Reports Referenced A-502
Reports Referencing This Report A-502
Column Descriptions A-502
Withdrawn Reason Overview (Report CDA-CO-508) A-502
Audience A-502

Report Type A-502
Location A-502
Dimensions A-502
Supplementary Prompts A-503
Reports Referenced A-503
Reports Referencing This Report A-503
Column Descriptions A-503

B Oracle Health Sciences Clinical Development Analytics Presentation Catalog

Dimensions in OHSCDA Presentation Catalog B-1
Facts in OHSCDA Presentation Catalog B-26
Oracle Clinical Sources for OHSCDA Presentation Catalog B-59
Oracle Clinical Sources B-59
Aliases B-90
Oracle's Siebel Clinical Sources for OHSCDA Presentation Catalog B-91

Glossary

Index

Preface

This guide provides information about how to use Oracle Health Sciences Clinical Development Analytics (OHSCDA).

This preface contains the following topics:

- Audience on page xliii
- Documentation Accessibility on page xliv
- Finding Information and Patches on My Oracle Support on page xliv
- Finding Documentation on Oracle Technology Network on page xlv
- Related Documents on page xlvi
- Conventions on page xlvii

Audience

The first and second chapters of this guide are intended for the following job classifications:

- Clinical Program/Study Manager, Clinical Data Manager, Clinical Research Associate, Clinical Data Entry Manager, Site Personnel, and Executive Management.

The other chapters in this guide are intended for the following job classifications:

- Data Warehouse Administrators, ETL Developers and Operators
- System Administrator

This guide assumes that you have the following general skills:

- Knowledge of Oracle Business Intelligence Enterprise Edition Plus.
- Knowledge of Oracle Healthcare Master Person Index.
- Knowledge of Oracle Business Intelligence Data Warehouse Administration Console.
- Knowledge of Informatica PowerCenter.
- Familiarity with Oracle Clinical.
- Familiarity with Oracle's Siebel Clinical.

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.

Finding Information and Patches on My Oracle Support

Your source for the latest information about Oracle Health Sciences Clinical Development Analytics is Oracle Support's self-service Web site, My Oracle Support (formerly MetaLink).

Before you install and use an Oracle software release, always visit the My Oracle Support Web site for the latest information, including alerts, release notes, documentation, and patches.

Creating a My Oracle Support Account

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

To register for My Oracle Support:

1. Open a Web browser to http://support.oracle.com.
2. Click the **Register here** link to create a My Oracle Support account. The registration page opens.
3. Follow the instructions on the registration page.

Signing In to My Oracle Support

To sign in to My Oracle Support:

1. Open a Web browser to http://support.oracle.com.
2. Click **Sign In**.
3. Enter your user name and password.
4. Click **Go** to open the My Oracle Support home page.

Searching for Knowledge Articles by ID Number or Text String

The fastest way to search for product documentation, release notes, and white papers is by the article ID number.

To search by the article ID number:

1. Sign in to My Oracle Support at http://support.oracle.com.
2. Locate the Search box in the upper right corner of the My Oracle Support page.
3. Click the sources icon to the left of the search box, and then select Article ID from the list.

4. Enter the article ID number in the text box.
5. Click the magnifying glass icon to the right of the search box (or press the Enter key) to execute your search.

   The Knowledge page displays the results of your search. If the article is found, click the link to view the abstract, text, attachments, and related products.

In addition to searching by article ID, you can use the following My Oracle Support tools to browse and search the knowledge base:

- Product Focus — On the Knowledge page, you can drill into a product area through the Browse Knowledge menu on the left side of the page. In the Browse any Product, By Name field, type in part of the product name, and then select the product from the list. Alternatively, you can click the arrow icon to view the complete list of Oracle products and then select your product. This option lets you focus your browsing and searching on a specific product or set of products.
- Refine Search — Once you have results from a search, use the Refine Search options on the right side of the Knowledge page to narrow your search and make the results more relevant.
- Advanced Search — You can specify one or more search criteria, such as source, exact phrase, and related product, to find knowledge articles and documentation.

Finding Patches on My Oracle Support

Be sure to check My Oracle Support for the latest patches, if any, for your product. You can search for patches by patch ID or number, or by product or family.

To locate and download a patch:

1. Sign in to My Oracle Support at `http://support.oracle.com`.
2. Click the **Patches & Updates** tab.

   The Patches & Updates page opens and displays the Patch Search region. You have the following options:

   - In the Patch ID or Number is field, enter the primary bug number of the patch you want. This option is useful if you already know the patch number.
   - To find a patch by product name, release, and platform, click the Product or Family link to enter one or more search criteria.
3. Click **Search** to execute your query. The Patch Search Results page opens.
4. Click the patch ID number. The system displays details about the patch. In addition, you can view the Read Me file before downloading the patch.
5. Click **Download**. Follow the instructions on the screen to download, save, and install the patch files.

Finding Documentation on Oracle Technology Network

The Oracle Technology Network Web site contains links to all Oracle user and reference documentation. To find user documentation for Oracle products:

1. Go to the Oracle Technology Network at

   `http://www.oracle.com/technetwork/index.html` and log in.
2. Mouse over the Support tab, then click the **Documentation** hyperlink.

   Alternatively, go to Oracle Documentation page at

http://www.oracle.com/technology/documentation/index.html

3. Navigate to the product you need and click the link.

   For example, scroll down to the Applications section and click Oracle Health Sciences Applications.

4. Click the link for the documentation you need.

Related Documents

For more information, see the following documents in the *Oracle Clinical Release 4.6* documentation set, the *Oracle Business Intelligence Data Warehouse Administration Console 10.1.3.4.1* documentation set, or the *Oracle Business Intelligence Enterprise Edition Release 10.1.3.4.1* documentation set:

Oracle Business Intelligence Enterprise Edition Documentation

The *Oracle Business Intelligence Suite Enterprise Edition Online Documentation Library* documentation set includes:

- *Oracle Business Intelligence Presentation Services Administration Guide*
- *Oracle Fusion Middleware User's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1)* (
- *Oracle Business Intelligence Web Services Guide*
- *Oracle Business Intelligence Server Administration Guide*

Oracle Business Intelligence Data Warehouse Administration Console (DAC) Documentation

The Oracle Business Intelligence Data Warehouse Administration Console (DAC) documentation set includes:

- *Oracle Business Intelligence Data Warehouse Administration Console User's Guide*
- *Oracle Business Intelligence Data Warehouse Administration Console Installation, Configuration, and Upgrade Guide*

Oracle Clinical Documentation

The *Oracle Clinical* documentation set includes:

- *Oracle Clinical Administrator's Guide*
- *Oracle Clinical Getting Started*
- *Interfacing from Oracle Clinical*
- *Oracle Clinical Conducting a Study*
- *Oracle Clinical Creating a Study*
- *Oracle Clinical Installation Guide*

Siebel Clinical Documentation

The *Siebel Clinical* documentation set includes:

- *Siebel Data Model Reference for Industry Applications*
- *Siebel Life Sciences Guide*

Oracle Healthcare Master Person Index Documentation

The Oracle Healthcare Master Person Index documentation set includes:

- *Oracle Healthcare Master Person Index Installation Guide*
- *Oracle Healthcare Master Person Index Release Notes*
- *Oracle Healthcare Master Person Index User's Guide*
- *Oracle Healthcare Master Person Index Configuration Guide*
- *Oracle Healthcare Master Person Index Configuration Reference*
- *Oracle Healthcare Master Person Index Data Manager's Guide*
- *Oracle Healthcare Master Person Index Match Engine Reference*
- *Oracle Healthcare Master Person Index Standardization Engine Reference*
- *Oracle Healthcare Master Person Index Analyzing and Cleansing Data User's Guide*
- *Oracle Healthcare Master Person Index Loading the Initial Data Set User's Guide*
- *Oracle Healthcare Master Person Index Command Line Reports and Database Maintenance User's Guide*
- *Oracle Healthcare Master Person Index Working With IHE Profiles*
- *Oracle Healthcare Master Person Index WebLogic User's Guide*

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.

Part I

Using Oracle Health Sciences Clinical Development Analytics

This part of the Oracle Health Sciences Clinical Development Analytics User and Administrator Guide describes how to use OHSCDA.

Part I contains the following chapters:

- Chapter 1, Getting Started with Oracle Health Sciences Clinical Development Analytics
- Chapter 2, Using Oracle Health Sciences Clinical Development Analytics
- Chapter 3, Working with Analyses

1

Getting Started with Oracle Health Sciences Clinical Development Analytics

This chapter contains the following topics:

- Overview on page 1-1
- Architecture on page 1-2
- Reporting on page 1-3
- Regulatory Compliance on page 1-3

Overview

Oracle Health Sciences Clinical Development Analytics (OHSCDA) is an analytical and transactional reporting application based on a predefined set of key performance indicators (KPIs), facts, and dimensions with support for predefined and custom reporting. OHSCDA provides rich support for merging data from multiple source databases into its single warehouse, providing a cross-enterprise view of operational data. OHSCDA also functions as a decision support system to monitor process bottlenecks and compliance deviations.

Clinical Development Organizations require insights into the following key Clinical Data Management and Clinical Trial Operations Management business processes areas that impact clinical trial performance:

- Clinical Data Collection Management: All required data must be collected with no data omitted or wrongly entered using electronic data capture.
- Clinical Data Cleanliness Management: Each discrepancy must be resolved, either by correcting the data that gave rise to it or by changing the rules that define the discrepancy.
- Study Startup and Site Activation: All sites that are selected to recruit subjects and administer the study must be activated. Impediments to site activation must be identified and resolved.
- Subject Recruitment: Study team must monitor if the subjects are enrolling, and the rate at which they are enrolling. If required, additional sites must be identified.
- Site Monitoring Visits: All internal standard operating procedures must be met and all required data relevant to subject visits must be collected properly and on time.

OHSCDA provides mechanisms to gain operational and clinical insights to and evaluate performance of your clinical trials, and take corrective action to reduce cycle times.

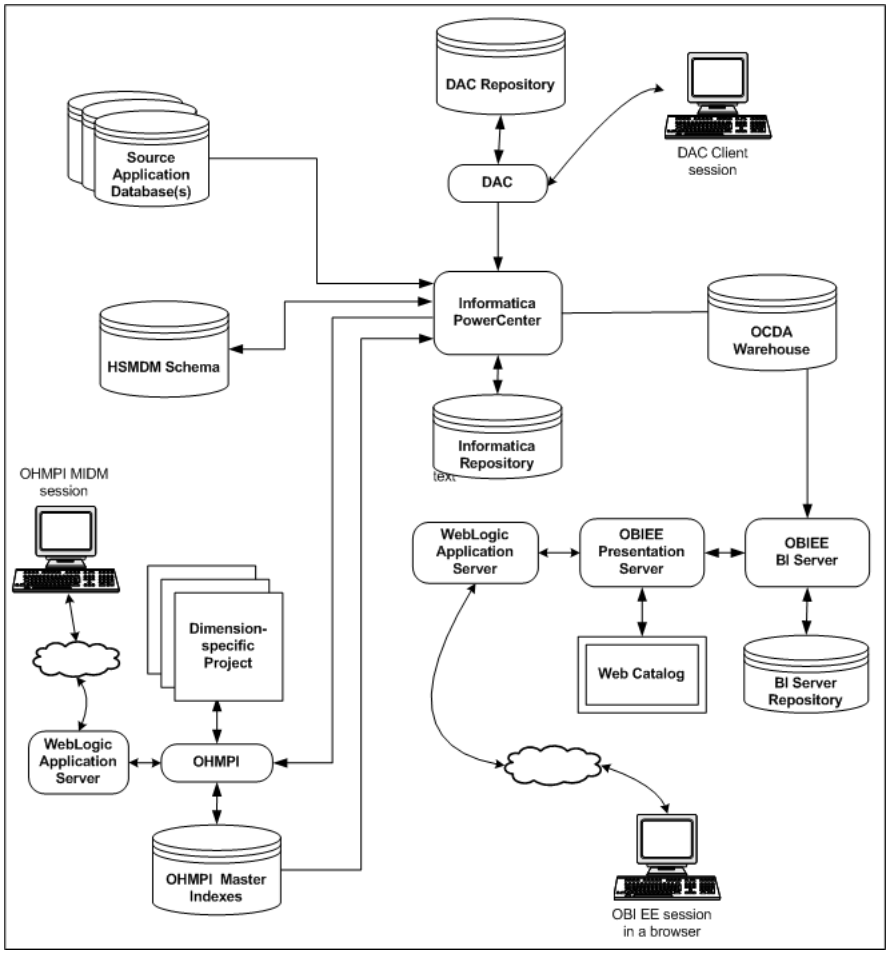
What Can I Do Using Oracle Health Sciences Clinical Development Analytics?

OHSCDA integrates clinical trial performance data from Oracle Clinical, Oracle's Siebel Clinical, and additional sources where appropriate, into a predefined data warehouse schema and generates both predefined and custom reports of key metrics across the clinical development spectrum. OHSCDA lets you perform the following functions:

- Extract all necessary clinical trial data from Oracle Clinical and Siebel Clinical into a predefined data warehouse, for viewing through the rich dashboard and report interface of Oracle Business Intelligence Enterprise Edition Plus (OBIEE).
- Extract such data from other database sources as well, subject to the development of separate Extract Transform Load (ETL) programs for each database source.
- Identify and merge duplicates while integrating data from multiple sources.
- View predefined analytical reports delivered with the application.
- Rapidly create new reports using the extensive predefined cycle time, quality and volume based metrics across data management and clinical operations processes.

Architecture

Figure 1–1 The Oracle Health Sciences Clinical Development Analytics Architecture



The OHSCDA architecture includes the following principal components:

- A predefined Intelligence application, based on Oracle Business Intelligence Enterprise Edition Plus (OBIEE), including Oracle BI Presentation Services, and a predefined set of Oracle BI reports, accessible through prebuilt interactive dashboards.
- A prebuilt clinical data warehouse schema, designed to drive both predefined and custom intelligence reports.
- Informatica PowerCenter based Extract Transform Load (ETL) programs, designed to extract clinical trial transactional data from Oracle Clinical and Siebel Clinical databases into the data warehouse schema.
- A predefined BI Server Repository including a unique mix of clinical measures (facts, dimensions), populated by the data warehouse schema.
- A set of predefined rules used by OHMPI to merge data from multiple sources into one consolidated data warehouse.

Reporting

OHSCDA provides reports for the following key functional areas:

- Clinical Data Collection Management: Reports on the data management workload and the rates at which work is progressing to provide insights to help minimize time to data lock.
- Clinical Data Cleanliness Management: Cleanliness reports track the discrepancy-resolution workload, rates of progress, durations in various statuses, and provide drill-down detail.
- Study Startup and Site Activation: Reports on sites that have not been activated and where they are in the process provide insight to help meet the recruitment goals.
- Subject Recruitment: Reports on subject enrollment helps evaluate if additional sites are needed or if protocol amendment is necessary.
- Site Monitoring Visits: Reports analyzing key metrics across the clinical monitoring process helps maintain compliance with internal standard operating procedures.

See Also:

- Chapter 2, Using Oracle Health Sciences Clinical Development Analytics
- Chapter 3, Working with Analyses
- Appendix A, Dashboards and Analyses

Regulatory Compliance

OHSCDA is designed as a single data-warehousing platform that facilitates integration of both non-regulated and regulated data. This single platform provides secure access to authorized users. It provides reduced total cost of ownership through reduced data integration costs and infrastructure maintenance costs, compared with multiple warehousing solutions.

The primary regulatory requirements include: (i) data tracking and (ii) Extract Transform Load (ETL) Version Management.

Tracking Data

The origin of any data displayed in a report must be traceable to its source, and all transformations applied to the data must be accessible. Data sourced from Oracle Clinical and Siebel Clinical is traced by the following criteria and rules:

- Load: When the data was loaded from the source database into the staging tables.
- Staging Mapping: The version of ETL mapping used to transform the data from source to staging table, and when it was executed.
- Target Mapping: The version of ETL mapping used to transform the data from the staging table to target tables, and when it was executed.
- Merged Dimensional Data: what records were used to created the merged record
- Transformations and calculations performed on the data within the OBIEE Repository can be versioned and saved permanently in a third-party versioning tool.
- Calculations can also be performed in reports managed through OBIEE Answers. The OBIEE Answers Administrator is responsible for controlling what calculations are performed, and who can perform them.

Managing ETL Versions

You can use a third-party versioning tool or in-built functionality of Informatica to manage ETL versions.

Security

Data within the data warehouse is secure from updates by unauthorized personnel, and can only be updated through controlled execution of ETL mappings.

The ability to modify ETL routines is restricted to a user group or role of ETL developers. Access to execute ETL routines is restricted to a specific privilege, which can be granted to a user group or role.

In addition, access to data is available for authorized personnel only constrained through user groups or roles.

See Also:

Oracle Clinical Administrator's Guide

2

Using Oracle Health Sciences Clinical Development Analytics

This chapter contains the following topics:

- Overview on page 2-1
- Accessing Oracle Health Sciences Clinical Development Analytics on page 2-2
- Using Oracle Business Intelligence on page 2-4
- Performing Common Tasks in Oracle Business Intelligence on page 2-6
- Navigating in Oracle Business Intelligence on page 2-11
- Using the Oracle BI My Account Page on page 2-14

> **Note:** The appearance of the user interface that you see in the application may vary from the figures displayed in the subsequent sections.

See Also:

Oracle Fusion Middleware User's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1

For ease of reference, the subsequent sections contain excerpts from *Oracle Fusion Middleware User's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1)*, altered to include specific information related to OHSCDA.

Overview

OHSCDA includes dashboards, analyses, and metrics that let you view relevant, interactive information—current as at the last date the data warehouse was refreshed.

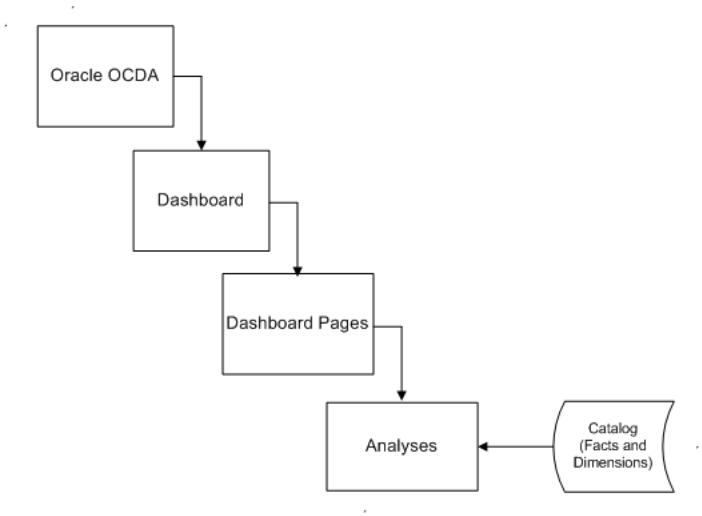
Dashboards are access points for information. Each dashboard is designed for a specific job responsibility. For example, a data manager can access only the Data Manager - EDC, Data Manager - Paper, Study Overview and Study-Site Overview dashboards.

When you access a dashboard, the information displayed changes based on your security privileges. For example, a Data Manager for Study 101 may (at the discretion of the OHSCDA Administrator) be restricted to seeing an analysis only on the status of data processing for Study 101, while Project Managers can see data processing information across all studies in their respective project.

A dashboard contains one or more related dashboard *pages*. A dashboard page contains a series of related *analyses*. An analysis can contain a tabular summary, pivot

table, or graph. You can drill down to detailed breakdown by clicking the linked data. You can also filter the data that you see in analyses using a set of *parameters* (called *filters*). Figure 2-1 displays the analysis hierarchy.

Figure 2–1 The Analysis Hierarchy



In addition to the dashboards and analyses that are packaged with OHSCDA, you can also create and manage analyses or dashboards if you have appropriate permissions. Use Oracle BI Answers to manage analyses.

OBIEE includes additional applications that are not directly used by OHSCDA. These include Oracle BI Delivers and Oracle BI Publisher. These applications extend the usefulness of the information provided by OHSCDA.

Use Oracle BI Delivers to detect specific analytic results and notify appropriate user or group about the result. Use Oracle BI Publisher to create formatted and printable analyses.

See Also:

- Chapter 3, Working with Analyses for more information about creating and managing analyses.
- Appendix B, Oracle Health Sciences Clinical Development Analytics Presentation Catalog for more information about the columns in OHSCDA that you can use to create and modify analyses.
- *Oracle Fusion Middleware User's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1).*

Accessing Oracle Health Sciences Clinical Development Analytics

Your security privileges determine what analyses you can see and what you can do in OHSCDA. To log in to OHSCDA, you must have a browser on your computer and a URL, username, and password provided by your company.

Logging In

1. Open your browser and enter the URL provided by your company.

   Typically, the URL to access the dashboards will be

```
http://<system_name_or_ip_address>:<port_
number>/analytics/saw.dll?Dashboard
```

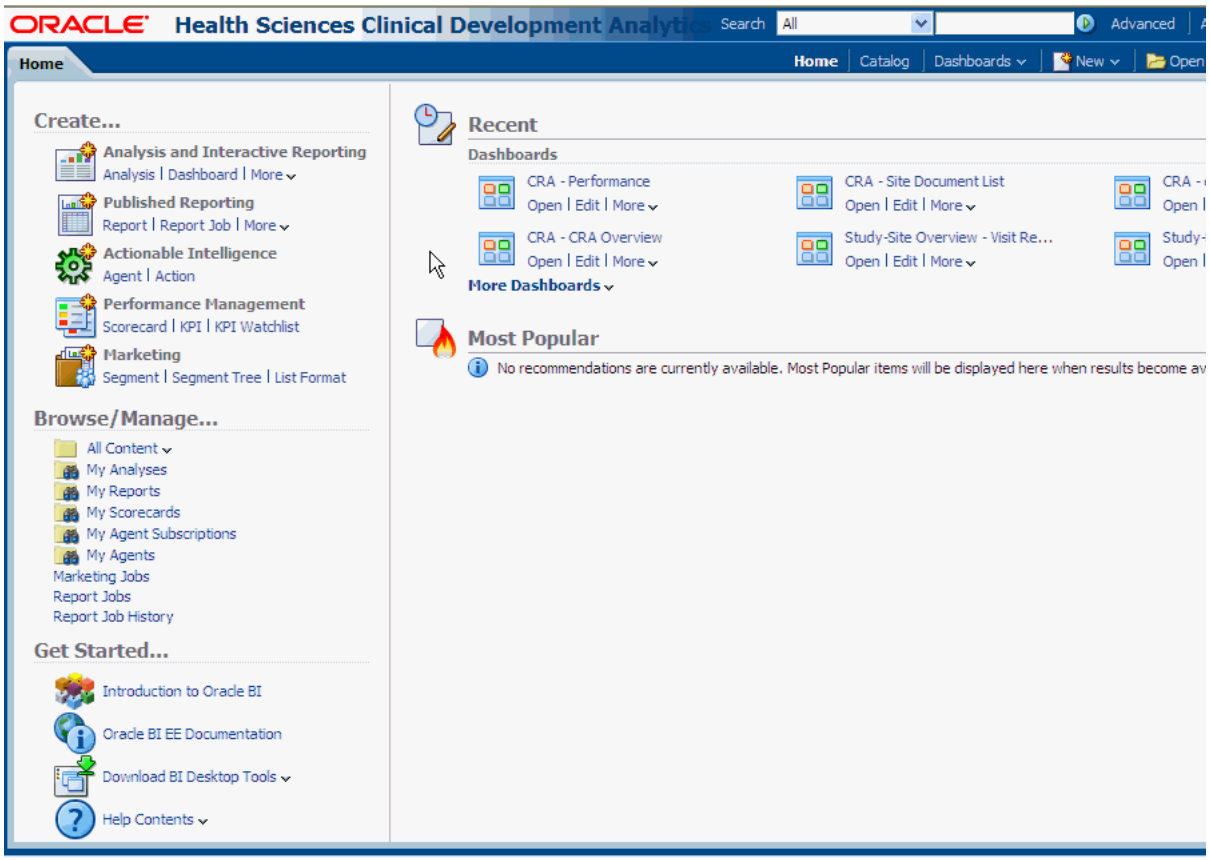
Figure 2-2 displays the OHSCDA login page.

Figure 2–2 Oracle Health Sciences Clinical Development Analytics Login Page

2. Enter your user ID and password.
3. Click **Sign In**.

   After your login credentials are authenticated, your default home page is displayed (as shown in Figure 2-3).

Figure 2–3 Default Homepage of an Administrator



Viewing a Dashboard

Perform the following steps to view a dashboard:

1. Log in to OHSCDA.
2. Click the **Dashboards** option at the top of the page.
3. Select a dashboard.

Using Oracle Business Intelligence

Clinical organizations track and store large amounts of clinical trial data. After the data has been organized and analyzed, it can provide an organization with the metrics to measure the state of a clinical trial. Oracle BI helps end users obtain, view, and analyze the data.

Oracle Business Intelligence Presentation Services Components

From an end-user perspective, Oracle BI Presentation Services consists of the following interfaces:

Oracle Business Intelligence Catalog

The Oracle BI Presentation Catalog can be used to store the objects, such as analyses and dashboards, that users create using Oracle BI EE. Users have their own personal folder (My Folders), where they can store the objects that they create. The objects in a

personal folder can be accessed only by the user who created and saved the content into that folder. Users can add sub-folders to their personal folders to organize their content in the way that is the most logical to them.

Users can also store objects in shared folders where other users or groups can access the objects. A combination of business logic security, catalog object security, and data level security determines who can view data and objects, edit objects, and delete objects from the catalog. An administrator creates and maintains the catalog's shared folder structure.

Oracle Business Intelligence Analysis Editor

Oracle BI Analysis Editor provides answers to business questions. This analysis editor interface allows users with the appropriate permissions to build and modify reports, also called analyses, that let end users explore and interact with information and present and visualize information using graphs, pivot tables, and analyses.

The results of an analysis can be formatted, saved, organized, and shared with others. An analysis can be configured to refresh results in real-time.

Analyses can be saved in the Oracle BI Presentation Catalog and integrated into OHSCDA home page or dashboards. Results can be enhanced through options such as graphing, result layout, calculation, and drill down features.

Appendix B, Oracle Health Sciences Clinical Development Analytics Presentation Catalog

Oracle Business Intelligence Interactive Home Page

The Home Page provides points of access for analytics information. When an end user accesses OHSCDA, the home page is the first page that appears.

The Home page provides a starting point for performing tasks in Oracle BI EE. The Home page is divided into sections that allow users to quickly begin a specific task, locate an object, or access technical documentation. It also includes sections that allow users to quickly access objects that have been recently viewed, created, or updated, and objects that are accessed the most often by the users assigned to the groups to which a user belongs.

Oracle Business Intelligence Interactive Dashboards

Dashboards are used to display reports that contain content specific to the needs of individual users or groups. Historical and current data sources can be merged into a single dashboard.

Users with the appropriate permissions can place results from Oracle BI Answers into dashboards for use by end users.

Oracle Business Intelligence Delivers

Oracle BI Delivers is the interface used to create Oracle Business Intelligence Alerts based on analytics results. Specific results can be detected within analyses and the appropriate people notified immediately through Web, wireless, and mobile communications channels.

Oracle BI Delivers uses intelligence bots called agents to detect specific results. Agents automatically perform a specified catalog analysis based on a defined schedule, and examine the results for a specific problem or opportunity. If the specific problem or opportunity is detected in the results, then an alert is generated and delivered to specified recipients and to subscribers to the agent, using the delivery options that are specified for each person.

Users with the appropriate permissions can use Oracle BI Delivers to set up the conditions to trigger an alert.

Note: OHSCDA does not directly use Oracle BI Delivers. You can use this feature to extend the usefulness of the information that OHSCDA provides.

Performing Common Tasks in Oracle Business Intelligence

This section explains how to perform the following common tasks in Oracle BI:

- Exiting from Oracle Business Intelligence
- Viewing Descriptions of Oracle BI Dashboards and Saved Analyses
- Using Online Help
- Printing an Oracle BI Dashboard or Saved Analysis
- Emailing an Oracle BI Dashboard Page or Analysis
- Exporting Oracle BI Results
- Refreshing an Oracle BI Interactive Dashboard or Oracle BI Analysis
- Refreshing Information in the Oracle BI Selection Pane

Exiting from Oracle Business Intelligence

Do not close the browser window to exit from Oracle BI. Perform the following step:

1. From any OHSCDA screen, click the **Sign Out** link.

Viewing Descriptions of Oracle BI Dashboards and Saved Analyses

Analysis and dashboard designers can supply a description when saving a dashboard or analysis in the Oracle BI Presentation Catalog. If no description is supplied, the description defaults to the name of the dashboard or saved analysis.

To view the description of a saved analysis:

1. Hover the cursor over the title of the saved analysis in the selection pane in Oracle BI Answers.

To view the description of a dashboard:

1. Hover the cursor over the name of the dashboard in Oracle BI Interactive Dashboards.

To view the description of a dashboard page:

1. Hover the cursor over the page tab.

Using Online Help

Oracle Business Intelligence includes OHSCDA-specific online help for both dashboards and analyses.

Dashboard pages include hyperlinks to (i) the master OHSCDA online help page, from which you can navigate throughout the help system, and (ii) topic-specific help pages for the selected dashboard.

Analysis pages include hyperlinks to topic-specific help for the selected analysis. Table 2-1 summarizes the available help links:

Table 2–1 Accessing Online Help

Click...	on...	to access...
OHSCDA Help	each dashboard page	master OHSCDA online help page.
CRA Reference	each page within this dashboard	specific help for this dashboard. This link changes for each dashboard as per the dashboard name. For example for Study Manager dashboard it will display Study Manager Reference link.
?	each analysis title bar	specific help for selected analysis.

Online help opens in a new browser window. You can scroll down the help page or use hyperlinks to navigate to other topics.

Note that you can use the following icon to view the OHSCDA release version:

Printing an Oracle BI Dashboard or Saved Analysis

You can display printer-friendly versions of existing dashboards and analyses. A printer-friendly version does not contain any extraneous links or other hypertext items.

You can print using HTML or Adobe PDF (Portable Document Format). Adobe PDF is the only print option available for Oracle BI Publisher analyses. Adobe Reader 6.0 or greater is required to print using Adobe PDF.

> **Note:** The HTML method of printing relies on the print handling capabilities of your browser. If you do not get the results you want, choose PDF to open, and then print the dashboard or analysis.

To print a dashboard or an analysis:

1. Navigate to an existing dashboard or an analysis.
2. To print an analysis, click the **Print** link, and then choose **Printable PDF** or **Printable HTML**.

   To print a dashboard page, click the following Page Options icon at the top of the dashboard, and choose Printable HTML or Printable PDF:

   - For HTML, a new window shows the selected item without the extraneous links. Choose **File > Print** on the browser menu.
   - For PDF, use the options available in the Adobe PDF window to save or print the file.

Emailing an Oracle BI Dashboard Page or Analysis

You can email a dashboard page or an analysis as an attachment. The format you use depends on your browser, such as Web Archive, Single File (.mht) in Internet Explorer or Mozilla Archive Format (.maf) in Mozilla and Firefox.

> **Note:** The Mozilla Archive Format capability is available as a separately downloaded plug-in.

In any browser, you can also save a dashboard page or analysis as a collection of HTML files. You can then zip and email the corresponding directory of associated files.

To email a dashboard page or analysis:

1. Navigate to the dashboard page or analysis that you want to send.
2. To email an analysis, click the **Print** link, and then choose **Printable HTML** or **Printable PDF**. To email a dashboard page, locate and click the **Page Options** icon at the top of the dashboard, select **Print** and then select **HTML** or **PDF**.

   A new browser window opens that contains the dashboard page or the analysis.
3. From the browser's toolbar, choose **File > Save As**.
4. Save the file to the desired location, with the appropriate file type for your browser.
5. Send the saved attachment using an email application.

> **Note:** The saved attachments can also be used as a means to archive and restore analyses as they exist at a particular point in time.

Exporting Oracle BI Results

Oracle BI provides options for exporting results of an analysis or view. These appear in Oracle BI Answers as options for the Export link. The Export link can also appear with a request in a dashboard.

- **PDF**

  This option displays the File Download dialog where you can open or save the results or view as a PDF file.

- **Excel 2003+**

  This option displays the File Download dialog where you can open or save the results or view as an XLS file. The file is saved in HTML format. Excel controls the positioning of the HTML.

- **Powerpoint 2003+**

  This option displays the File Download dialog where you can open or save the results or view as a PPT file.

- **Web Archive (.mht)**

  This option displays the File Download dialog where you can open or save the results or view as an MHT file. This enables you to export the underlying data for an existing analysis or view as a Web page (MHTML) file.

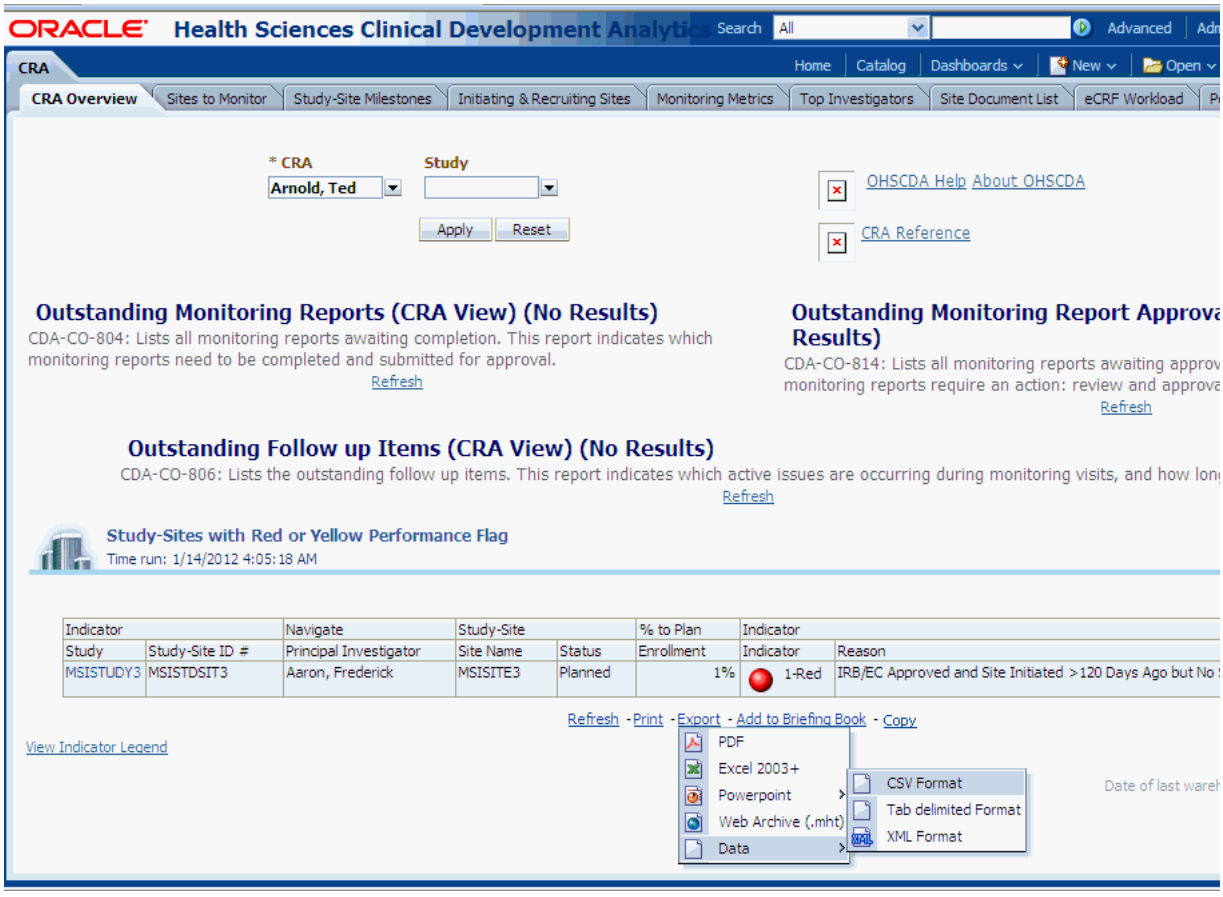
- **Data**

This option displays these options for exporting the data from the results or view:

- **CSV Format** - Displays the File Download dialog where you can open or save all the columns in the results or view as a CSV file. This export results in a comma-delimited list of values in a file that you can open in an application such as Excel.
- **Tab delimited Format** - Displays the File Download dialog where you can open or save all the columns in the results or view as a CSV file. This export results in a tab-separated list of values in a file that you can open in an application such as Excel.
- **XML Format** - Displays the File Download dialog where you can open or save the results or view as a TXT file. This file using the Microsoft MD Data Set standard for representing data in XML format.

Figure 2- 4 displays the export options for an analysis.

Figure 2–4 Export Options for an Analysis



To download results in Adobe PDF format:

1. Navigate to the analysis.
2. Click the **Export** link and choose either **PDF**.

   The File Download dialog box appears.
3. Save the file to the desired location, or open it in PDF.

To download results in Microsoft Excel format:

1. Navigate to the analysis.
2. Click the **Export** link and choose either **Excel 2003+**.

   The File Download dialog box appears.
3. Save the file to the desired location, or open it in Excel.
4. If desired, use Excel to refine the formatted results.

   See Also:

   Microsoft Excel documentation for more information.

To download results in Microsoft Powerpoint format:

1. Navigate to the analysis.
2. Click the **Export** link and choose either **Powerpoint 2003+**.

   The File Download dialog box appears.
3. Save the file to the desired location, or open it in Powerpoint.
4. If desired, use Powerpoint to refine the formatted results.

   See Also:

   Microsoft Powerpoint documentation for more information.

To download results as a Web archive:

1. Navigate to the request.
2. Click the **Export** link and choose **Web archive (.mht)**.

   The File Download dialog box appears.
3. Save the file on your hard drive.

To download results as a comma-separated list of values:

1. Navigate to the request.
2. Click the **Export** link and choose **Data** > **CSV Format**.

   The File Download dialog box appears.
3. Save the file on your hard drive.

To download results as a tab-separated list of values:

1. Navigate to the request.
2. Click the **Export** link and choose **Data** > **Tab delimited Format**.
3. Save the file on your hard drive.

To download results as an extended markup file:

1. Navigate to the request.
2. Click the **Export** link and choose **Data** > **XML Format**.

   The File Download dialog box appears.
3. Save the file on your hard drive.

Refreshing an Oracle BI Interactive Dashboard or Oracle BI Analysis

When executing an Oracle BI Interactive Dashboard or a request, Oracle BI uses temporary storage areas, called *caches*, to save frequently accessed or recently accessed results. Storing certain results in cache helps to improve Oracle BI performance. You can use the Refresh feature to make sure that your request bypasses saved information in the Oracle BI Presentation Services cache, and is issued to the Oracle Business Intelligence Server for processing.

> **Note:** The Oracle BI Server maintains its own cache. This cache is separate from the Oracle BI Presentation Services cache.

When you select a specific dashboard or request, Oracle BI Presentation Services checks its cache to determine if the identical results have recently been requested. If so, Oracle BI Presentation Services returns the most recent results, thereby avoiding unnecessary processing by the Oracle BI Server and the back-end database. If not, the request is issued to the Oracle BI Server for processing.

If the Oracle BI Server has cached results that can satisfy your request, the results are returned from that cache. If not, Oracle BI Server issues the request to the back-end database. You cannot force your request past the Oracle BI Server's cache.

Oracle BI administrators can configure cache settings for Oracle BI Presentation Services that control what is cached and for how long. For more information, refer to *Oracle Business Intelligence Presentation Services Administration Guide*. For information about the Oracle BI Server cache, refer to *Oracle Business Intelligence Server Administration Guide*.

To refresh a dashboard or request:

1. Navigate to an existing dashboard or request.
2. To refresh an analysis, locate and click the **Page Options** icon at the top of the dashboard and then click **Refresh**.

Refreshing Information in the Oracle BI Selection Pane

The Oracle BI selection pane appears in Oracle BI Analysis Editor criteria tab. When changes have been made to the saved content or to the Oracle BI Server metadata, you can refresh the display to access the most current information.

> **Note:** The information available in the selection pane is determined by your permissions and responsibilities.

To refresh the information in the selection pane:

- To refresh the information for saved analyses, filters, briefing books, and dashboard content, click the **Refresh** icon at the top of the catalog pane.
- To refresh the view of the Oracle BI Server metadata for subject areas, click the **Refresh** icon at the top of the selection pane and then select **Reload Server Metadata**.

Navigating in Oracle Business Intelligence

This section explains basic navigation within Oracle BI.

What is Available to You After Accessing Oracle BI?

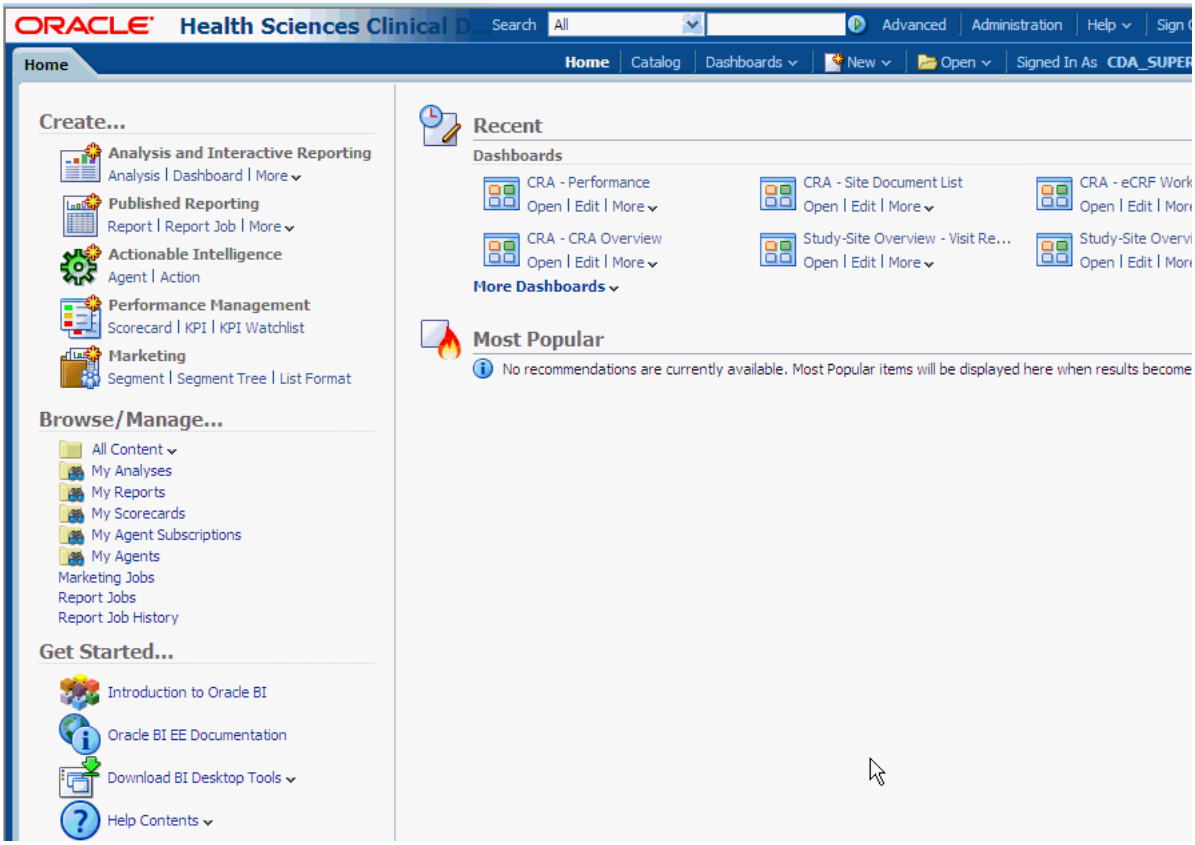
When you access Oracle BI, the first screen that is displayed is the BI home page. The Home page is divided into sections that let you quickly begin a specific task, locate an object, or access technical documentation. It also includes sections that allow you to quickly access objects that you have recently viewed, created, or updated, and objects that are accessed the most often by the users assigned to the groups to which you belong. The views that you can access are determined by your role and responsibilities

See Also:

Oracle® Fusion Middleware User's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1) (Introducing Oracle Business Intelligence Enterprise Edition), for more information about the Home Page.

Figure 2-4 shows an example home page.

Figure 2–5 Sample BI Home Page



Using Oracle BI Global Header

The global header provides quick access to commonly used functions and is always available from the user interface. For example, you can use the global header to begin a new task, search the Oracle BI Presentation Catalog, access the product documentation, or view a different object, without having to return to the Home page. The global header also includes the Home page link so that you can quickly access the Home page from other pages.

Figure 2–6 Oracle BI Global Header

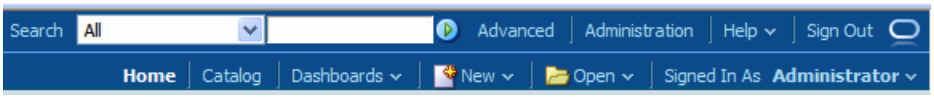


Table 2-1 describes the components of the Oracle BI global header.

Table 2–2 Oracle BI Global Header

Link	Description
Search	Enables you to search the catalog.
Advanced	Displays the Catalog page in search mode, where you can search for objects in the catalog. In search mode, the Search pane is displayed rather than the Folders pane within the page.
Administration	Available only if you are logged in as an administrator. Displays the "Administration page", where perform administration tasks such as managing privileges and metadata for maps. For information on the administration tasks, see *Oracle Fusion Middleware System Administrator's Guide for Oracle Business Intelligence Enterprise Edition* and *Oracle Fusion Middleware Security Guide for Oracle Business Intelligence Enterprise Edition*.
Help	Displays the following options: ■ *currentpage* Help (where *currentpage* is the name of the page, editor, or tab) — Dynamically changes to display the Help topic for the current page, editor, or tab. ■ Help Contents — Displays a cascading menu that provides options that link to the tables of contents for Oracle BI EE, BI Publisher, and Marketing. ■ Documentation — Displays the documentation library for Oracle BI EE. ■ OTN — Displays the Business Intelligence and Data Warehousing Technology Center page on the Oracle Technology Network (OTN). ■ About Oracle BI EE — Displays a dialog identifying the Oracle BI EE version and copyright information.
Alerts	Available only if one or more alerts have been generated for you. Displays the "Alerts dialog", where you can manage your alerts. An alert is a notification that is generated by an agent that delivers personalized and actionable content to specified recipients and to subscribers to the agent.
Home	Displays the Home page.
Catalog	Displays the "Catalog page", where you can locate objects in the catalog and perform tasks specific to those objects.
Dashboards	Contains links to all dashboards that are stored within the Dashboards sub-folder of the user's folder or any shared folder (note that dashboards not saved to the Dashboards sub-folders are not displayed from the global header's Dashboard list).
New	Displays a list of the objects that you can create. To create an object, select it from the list. The appropriate dialog or editor is displayed for you to create the object.

Table 2–2 (Cont.) Oracle BI Global Header

Link	Description
Open	Displays the following options: ■ Open — Displays the "Open dialog", where you can select the object with which you want to work. ■ Recent objects — Displays a list of the objects that you have recently viewed, created, or updated. You can use this list to select an object with which you want to work. ■ Most Popular objects — Displays a list of the objects that are accessed the most often by the users that are assigned to the groups to which you belong. You can use this list to select an object with which you want to work.
Signed In As *username*	where *username* is the user name that your current session is using. Displays the following options: ■ My Account — Displays the "My Account dialog", where you can specify your preferences, such as time zone, delivery devices, and delivery profile. For information about setting preferences, see "Setting Preferences". ■ Act As — Available only if your organization has enabled this functionality and you have been granted the appropriate permissions. Enables you to act as another user. For information, see "Acting for Other Users".

Drilling Down in Oracle BI

Many of the results that appear in Oracle BI represent hierarchical data structures. Oracle BI metadata specifies these hierarchies, and this allows you to access the different levels of detail within them. You can drill down to an actual item in the database.

Sorting Columns in Tables in Oracle BI

In a dashboard, the column headers of tables that can be sorted will display up and down arrows when you hover over a column header. You can click a column header to sort it.

Using the Oracle BI My Account Page

From the My Account page in Oracle BI, you can perform the following actions:

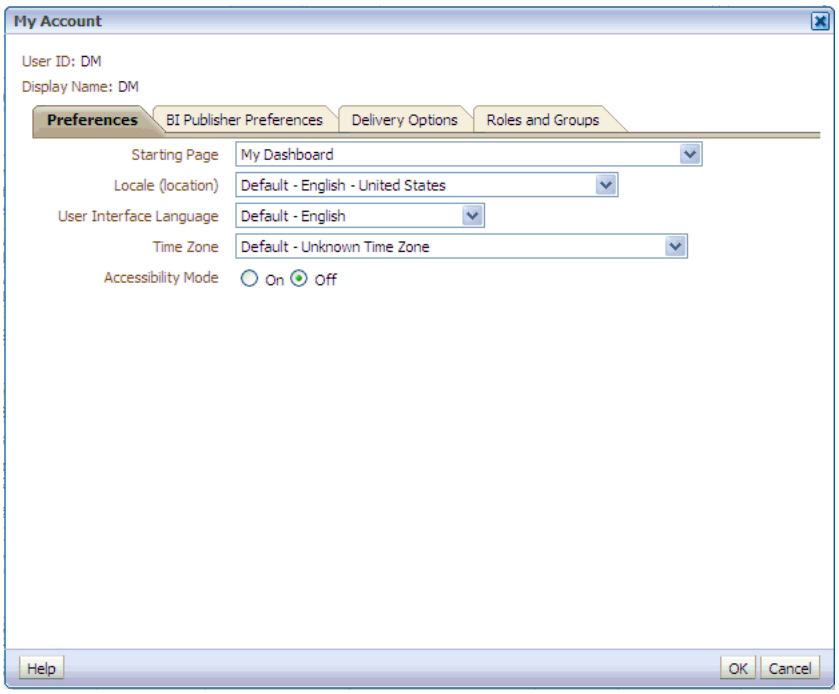
- View general account information, such as your display name and user ID.
- View and modify your preferences.
- Set your time zone.
- View and modify your Oracle BI Publisher preferences.
- View and modify your delivery options for Oracle BI Delivers agents.
- View a list of users who can access your analyses and dashboards. Depending on your privilege settings, not all of these options may be available.

To display your account settings:

1. Log in to OHSCDA.
2. Click **Signed in as username** where username is the user name your current session is using, and the **My Account** link. Your My Account page appears.

Your My Account page is as displayed in Figure 2-7.

Figure 2–7 Sample My Account Page



Setting Your Oracle BI Preferences

You can access the Preferences section of the My Account page to specify preferences such as a default dashboard, your locale, and a language in which to view the user interface screens.

To change your preferences:

1. Log in to OHSCDA.
2. Click **Signed in as username** where **username** is the user name your current session is using, and the **My Account** link.
3. In the Preferences section, perform one of the following actions:
   - In Default Dashboard, select the dashboard you want to display when you log in to Oracle BI.
   - In Locale, select the locale that you want to use for this session.
   - In User Interface Language, select the language in which you want Oracle BI to appear.
   - In Time Zone, select the time zone to apply when viewing content.
   - In currency, select the currency in which to view currency columns in dashboards and analyses. This box is available only if the administrator has configured the userpref_currencies.xml file.
   - Select Accessibility Mode to view content for Oracle BI EE in a browser or in a way that facilitates the use of a screen reader.

Setting Your Oracle BI Time Zone

You can use the time zone option to choose your Oracle BI account's preferred time zone. This option allows system users who do not reside in the same physical location to override the default time zone that was set by the system administrator. For example, the Oracle BI server that sends you alerts resides in the US Pacific time zone, but your work location is in the US Central time zone. After you set the Central time zone as your preferred time zone setting, the delivered time on your alerts appears in Central time.

Your account's time zone will automatically apply to any items that you create, modify, run, receive, and print.

The date and time columns included in analyses appear according to the analysis designer's specifications. The analysis designer can force a specific time zone to appear in the column, or allow the user's default time zone to appear in the column. A clock icon will appear in the column heading, and when you mouse over this icon, the name of the time zone used in the column is displayed.

To change your time zone preference:

1. Log in to OHSCDA.
2. Click **Logged in as username** where **username** is the user name your current session is using, that (if available), and the **My Account** link.
3. In the preference section, select a time zone from Time Zone.
4. Click **Ok**.

3

Working with Analyses

Using the Oracle BI Analysis Editor, you can run or display predefined reports (delivered with OHSCDA), and you can also create or modify custom analyses.

This chapter contains the following topics:

- Predefined Analyses on page 3-1
- Custom Analyses on page 3-3
- Action Links on page 3-4
- Viewing Analyses With Your Apple iPhone and iPad on page 3-4

See Also:

Oracle Business Intelligence Answers, Delivers, and Interactive Dashboards User Guide

For ease of reference, the subsequent sections contain excerpts from *Oracle Fusion Middleware User's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1)*, altered to include specific information related to OHSCDA.

Predefined Analyses

OHSCDA is delivered with 109 predefined analyses. A subset of these analyses is displayed on your dashboard pages based on the user group you are assigned to.

A analysis can contain data in a tabular format, pivot table, or graph. You can filter the data visible on the analysis based on certain criteria such as Study, Study Site, CRA. These filters are called *prompts*. Some analyses let you drill down to a more detailed analysis.

Following are some of the analysis-related tasks that you can perform:

- Create and modify analyses.
- Refresh the results.
- Print and Save analyses.
- Add analyses to the briefing book.
- Copy analyses.

See Also:

- Chapter 2, Using Oracle Health Sciences Clinical Development Analytics for more information about analysis-related tasks.
- Appendix A, Dashboards and Analyses for more information about predefined analyses.

- *Oracle Health Sciences Clinical Development Analytics Secure Installation and Configuration Guide* for instruction on installing OHSCDA.
- *Oracle Fusion Middleware User's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1)*

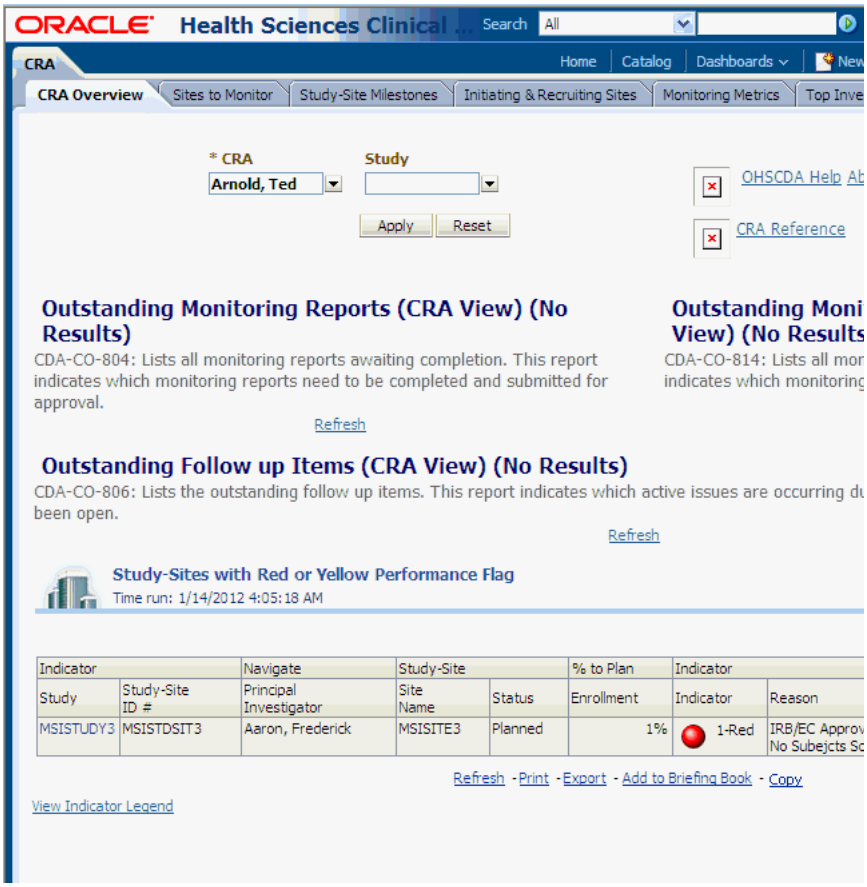
Viewing a Predefined Analysis

Perform the following steps to view a predefined analysis:

1. Log in to OHSCDA.
2. Using the global header, select the dashboard page that contains the analysis you want to view.

   Figure 3-1 displays the CRA dashboard of an administrator.

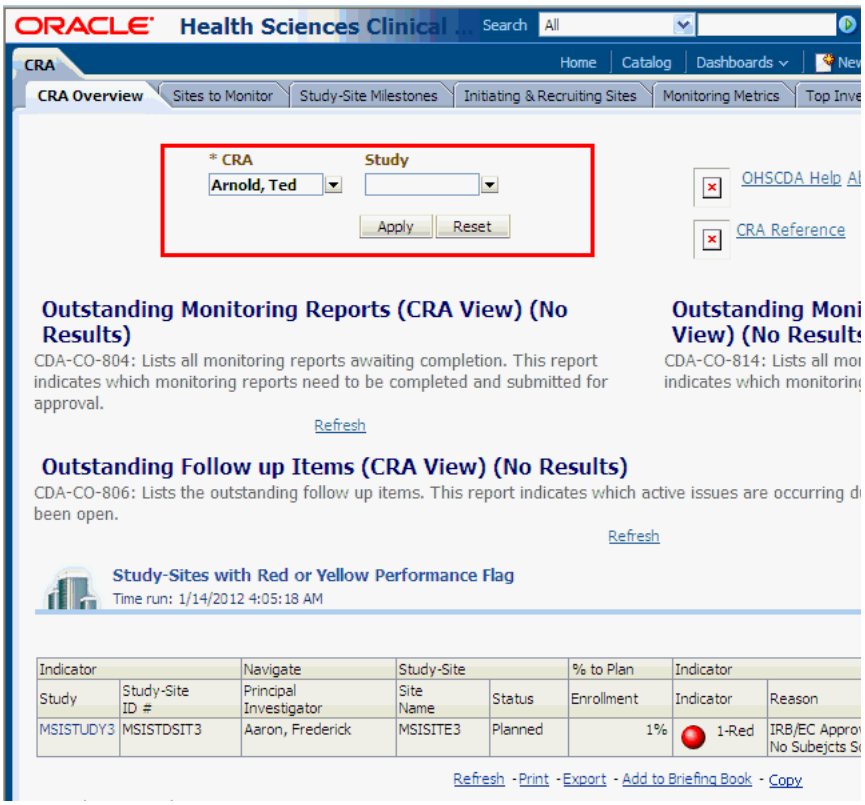
Figure 3–1 The CRA Dashboard



Note: Every predefined dashboard page displays the ETL Refresh Date at the bottom of the page. This date indicates the date when the data warehouse was last refreshed.

Parameters are displayed if you can filter the analyses. Figure 3-2 displays the parameters in the eCRF Workload page.

Figure 3–2 Parameters Displayed in the CRA Overview Tab of the CRA Dashboard



3. To filter the analysis based on selected criteria:
    1. Select the value from the parameters displayed.
    2. Click **Apply**.

See Also:

Oracle Fusion Middleware User's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1)

Custom Analyses

You can create a custom analysis if you have been assigned the required permissions and responsibilities. If you prefer, you can copy a pre-defined analysis and use it as a template for the new analysis.

Use the Oracle BI Answers user interface to create your own analysis. But before you proceed, consider the following points:

- Do not modify a predefined analysis. If you do, your changes will be overwritten when a new release of OHSCDA is installed. Alternatively, you can make a copy, and modify the copy.
- Define a Catalog Folder hierarchy that gives each Answers user a unique folder tree. Limit the right to move analyses into public folders to members of the OHSCDA Administrators group.
- Limit the right to place analyses onto shared dashboards to members of the OHSCDA Administrators group.

Action Links

An action link is a link to an action that you can embed in an analysis that, when clicked, runs an associated action. For more information, refer to *Oracle Business Intelligence Presentation Services Administration Guide*.

You can create action links for the following columns in OHSCDA 2.0.0.3:

- AD05-19 Investigator Action Link
- AD07-09 Product Action Link
- AD08-06 Site Action Link
- AD09-15 Study Action Link
- AD10-39 Study-Site Action Link
- AD14-08 Team Member Action Link
- AD15-19 Contact Action Link
- AD16-04 Program Action Link
- AD17-04 Region Action Link
- TD01-30 Subject Action Link

Viewing Analyses With Your Apple iPhone and iPad

Oracle Business Intelligence Mobile allows you to view Oracle BI EE content on supported mobile devices such as the Apple iPhone and Apple iPad. Using Oracle Business Intelligence Mobile, you can view and analyze BI content such as analyses and dashboards, BI Publisher content, scorecard content, and content delivered by agents. Oracle Business Intelligence Mobile for Apple iPhone and Apple iPad can be downloaded from the Apple iTunes App Store. Refer to the *Oracle® Fusion Middleware User's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1)* for further information.

Catalog Page

The Catalog page lets you locate objects in the catalog and perform tasks specific to those objects. The objects and options that are available to you are determined by your system privileges and the permissions assigned to individual folders and objects. You can get to the Catalog page by clicking Catalog in the Oracle BI global header.

Figure 3-4 shows an example of a Catalog page.

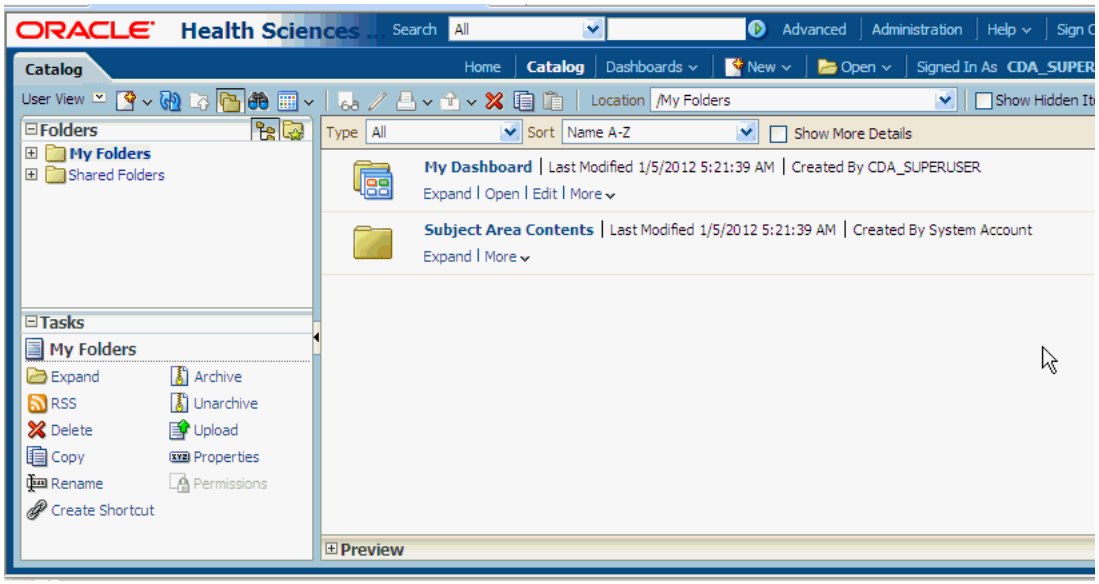


Figure 3–3 Example of a Catalog Page

The following table lists the components of the Catalog page:

Table 3–1 Components of the Catalog Page

Component	Description
Folders Pane	Displays the catalog as a directory hierarchy or only those folders and objects that you created or marked as your favorites.
Search Pane	Provides search criteria and initiates a catalog search. The search pane appears by default when you click Advanced on the global toolbar.

Table 3–1 (Cont.) Components of the Catalog Page

Component	Description
Tasks Pane	Initiate tasks specific to an object. Following are the options in the tasks pane: ■ Expand — Use this button to display the contents of a selected folder. ■ RSS - Use this option to subscribe to RSS feed. ■ Delete — Use this button to remove a folder or object that you created from the catalog. If you delete shared folders or objects, then other users who have added shared objects will lose access. ■ Copy — Use to duplicate a folder or object and paste it in another directory. ■ Rename — Use to change the name of a folder or object. ■ Create Shortcut— Use to create a shortcut to the object or folder. ■ Properties — Use to view or modify the selected object's properties. ■ Permissions — Use to enable users privileges to view folders and objects.
Preview Pane	Provides a preview of the object that you selected in the Catalog area. This pane is not visible until you click the button to display it.
Location	Displays the directory path of a selected object. Use as a way to determine where you are within the directory structure.
Show Hidden Items	When you select this option, hidden folders, are displayed.

Table 3–1 (Cont.) Components of the Catalog Page

Component	Description
Toolbar	Following are the buttons in the toolbar. The buttons vary between object types. ■ New — Use to create new objects. After you select the object to create, the object's editor displays where you can begin building the object. ■ Refresh — Use to update the catalog with content or folder changes. ■ Up — Use to navigate to a parent folder or directory. ■ Show/Hide folders panes — Use to hide or show the Folders pane and Tasks pane. ■ Search — Use to display the Search pane. Deselect this button to display the Folders pane. ■ Change list view type — Use this list to select how much information about folders and objects to display in the Catalog area. – Descriptive — Select to display the object or folder's name, type, owner, and date modified and Expand, Open, Edit, and More links. This view enables you to perform tasks directly from the object's listing. – Details — Select to display the object or folder's name, type, owner, and date modified. – List — Select to display object and folder name, only. ■ View — Use to view the selected object. ■ Edit — Use to modify a selected object using the associated editor or run a script, URL, or Web service action. ■ Print — Use to print the current page or the information in the Preview pane. ■ Export — Use to export a copy of an object or the object's data to a variety of formats (for example, PDF or XLS). ■ Delete — Use to remove a selected object or folder from the catalog. ■ Copy — Use to copy a selected object or folder to paste in another directory. ■ Paste — Use to paste a copied object to another location.

Table 3–1 (Cont.) Components of the Catalog Page

Component	Description
Catalog Area	Workspace that displays the results of your search, opens folders to browse content, and initiates tasks specific to an object. Following are the components of the catalog area: ■ Type - Use this list to specify which object type to display in the catalog area. ■ Sort - This field displays if you selected either the List or Descriptive view type in the Change list view type list located in the "Catalog Page" toolbar. Use this list to specify how you want to sort the objects in the Catalog area. ■ Show More Details - This field displays if you selected the Descriptive view type in the Change list view type list located in the "Catalog Page" toolbar. Use this to display more information about specific object types. ■ Object/Folder Links - Use to view a list of catalog objects and to initiate a specific tasks from an object.

To view saved analyses as stored in the Catalog:

1. Log in to OHSCDA and click the **Catalog** link in the global header.
2. Expand the appropriate folder in the catalog area and select the analysis you want to view.

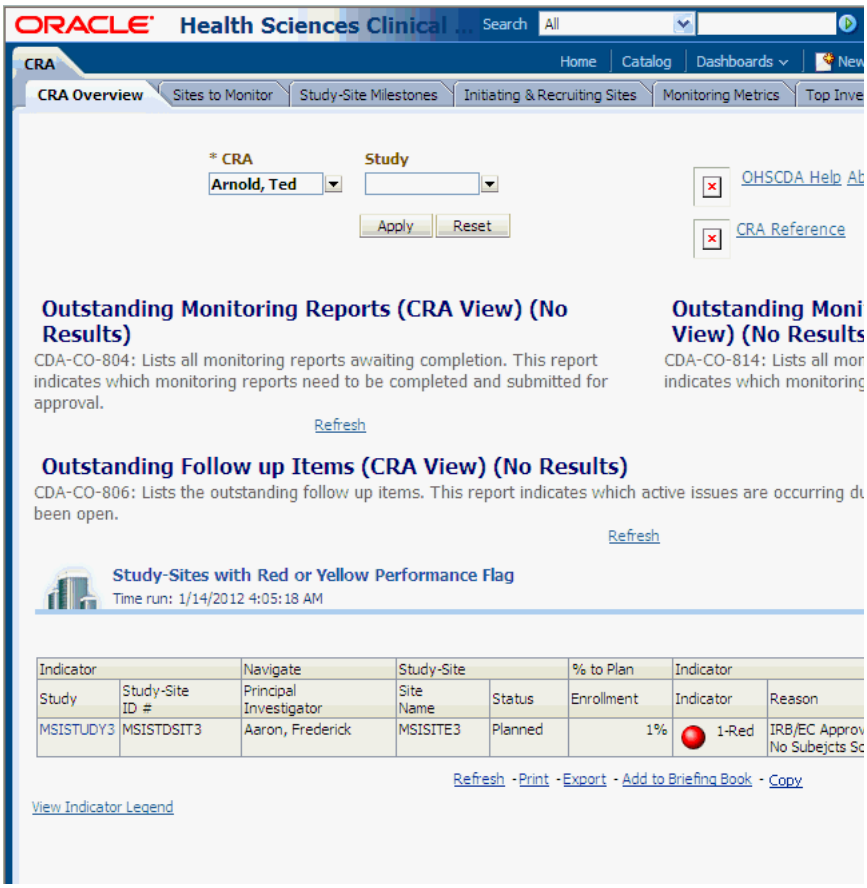
See Also:

Appendix B, Oracle Health Sciences Clinical Development Analytics Presentation Catalog

Dashboard Page

The dashboard page lets you view and navigate a dashboard. Figure 3-9 shows an example of a dashboard page.

Figure 3–4 Example of a Dashboard Page



Following are the components of a dashboard page:

- Page Tabs: Use the tabs across the top of the viewer to select the dashboard page to view and navigate.
- Toolbar: Contains the Page Options button, which displays the following options:

> **Note:** You might not see some of the options depending on you user privileges.

  - Edit Dashboard — Use this button to display the Dashboard builder, where you modify the dashboard, if you have the appropriate permissions.
  - Print — Use this option to print the current dashboard page as either HTML or PDF.
  - Refresh — Use this option to refresh the results of analyses included in the dashboard page.
  - Add to Briefing Book — Use this option to add the contents of a dashboard page to a briefing book. (This option is not available on an empty dashboard page or if the Show Add to Briefing Book box in the "Dashboard Properties dialog", has not been selected for the page.)
  - Create Bookmark Link — Use this option to create a bookmark link.
  - Create Prompted Link — Use this option to create a prompted link.

- Apply Saved Customization — Use this option to apply a saved customization — either a personal saved customization or a shared saved customization.
- Save Current Customization — Use this option to save your current customization.
- Edit Saved Customizations — Displays the Edit Saved Customizations dialog where you edit details of your saved customizations.
- Clear My Customization — Use this option to clear your current customization.

To view saved analyses organized by dashboard:

1. Log in to OHSCDA and click Dashboard in the global header. A drop-down of saved analyses appears.
2. Select the analysis you wish to view.

Indicators

This section describes the indicators in OHSCDA 2.2.

Study Indicators

The following section describes indicators for studies.

Study KPI Flag

The Study Key Performance Indicator (KPI) Flag provides a single red, yellow or green icon, which indicates that one or more study-level KPIs is at risk of missing a target (yellow) or has missed a target (red). If none of the KPIs is red or yellow, the Study KPI Flag shows green.

The Study KPI Flag is intended for use as an actionable measure, identifying situations where you may be able to affect the outcome in some way. Consequently, it only evaluates cycles that have not yet completed. For example, Protocol Approved to 1st Subject Enrolled is only evaluated if the 1st Subject has not yet been enrolled.

The Study KPI Flag evaluates the following KPIs:

- Last Subject Last Visit to Database Lock
- Protocol Approved to 1st Subject Enrolled
- Protocol Approved to 1st Site Initiated

Each KPI is evaluated based on the following rules:

Last Subject Last Visit to DB Lock Last Subject Last Visit (LSLV) to Database (DB) Lock calculation is evaluated when LSLV is complete but DB Lock has not yet been reached.

Red

KPI at risk of missing target. The Target cycle time will be reached in the next 30 days.

High Level Reason - Missed KPI (s)

Detail Reason - Missed KPI: Last Subject Last Visit to Database Lock

Yellow

KPI has missed target. The time since LSLV is greater than the Target cycle time.

High Level Reason - KPI(s) at Risk

Detail Reason - KPI(s) at Risk (30 days): Last Subject Last Visit to Database Lock

Protocol Approved to 1st Subject Enrolled Protocol Approved to 1st Subject Enrolled is evaluated when protocol has been approved but 1st subject has not yet been enrolled.

Red

KPI has missed target. The time since protocol approved is greater than the Target cycle time.

High Level Reason - Missed KPI (s)

Detail Reason - Missed KPI: Protocol Approved to 1st Subject Enrolled

Yellow

KPI at risk of missing target. The Target cycle time will be reached in the next 30 days.

High Level Reason - KPI(s) at Risk

Detail Reason - KPI(s) at Risk (30 days): Protocol Approved to 1st Subject Enrolled

Protocol Approved to 1st Site Initiated Protocol Approved to 1st Site Initiated is evaluated when protocol has been approved but 1st site has not yet been initiated. If protocol has been approved and neither has the 1st site been initiated nor 1st subject enrolled, the system evaluates Protocol Approved to 1st Subject Enrolled before evaluating Protocol Approved to 1st Site Initiated.

Red

KPI has missed target. The time since protocol approved is greater than the Target cycle time.

High Level Reason - Missed KPI (s)

Detail Reason - Missed KPI: Protocol Approved to 1st Site Initiated

Yellow

KPI at risk of missing target. The Target cycle time will be reached in the next 30 days.

High Level Reason - KPI(s) at Risk

Detail Reason - KPI(s) at Risk (30 days): Protocol Approved to 1st Site Initiated

Study Milestones Flag

The Study Milestone Flag provides a single red, yellow or green icon, which indicates that one or more study-level milestones is at risk of missing a planned/latest estimate (LE) date (yellow) or has missed a planned/LE date (red). If none of the milestones is red or yellow, the Study Milestone Flag shows green.

All dates evaluate the LE date, if populated. If the LE date is not populated, the planned date is used. If neither the Planned nor LE dates is populated, the milestone is not evaluated.

The Study Milestone Flag is intended for use as an actionable measure, identifying situations where you may be able to affect the outcome in some way. Consequently, it only evaluates milestones where a planned or LE date exists but an actual date has not yet been entered.

The Study Milestone Flag evaluates the following milestones:

- Protocol Approved Date
- 1st Site Initiated Date
- 1st Critical Document Package Completed Date
- 1st Subject Enrolled Date
- Last Subject Enrolled Date
- Last Subject Last Visit Date
- Database Lock Date
- Clinical Study Report Date

Each milestone is evaluated based on the following rules:

Protocol Approved Date Protocol Approved Date is evaluated only when none of the following post-protocol approval activities have occurred (Actual date is null):

- 1st Site Initiated Date
- 1st Critical Document Package Completed Date
- 1st Subject Enrolled Date
- Last Subject Enrolled Date
- Last Subject Last Visit Date
- Database Lock Date
- Clinical Study Report Date

Red

The Planned or LE date is in the past.

High Level Reason - Missed Milestone(s)

Detail Reason - Missed Milestone: Protocol Approved Date

Yellow

The Planned or LE Date is in the next 30 days.

High Level Reason - Milestone at Risk

Detail Reason - Milestone at Risk: Protocol Approved Date

1st Site Initiated Date 1st Site Initiated Date is evaluated only when none of the following activities have occurred (Actual date is null):

- 1st Critical Document Package Completed Date
- 1st Subject Enrolled Date
- Last Subject Enrolled Date
- Last Subject Last Visit Date
- Database Lock Date
- Clinical Study Report Date

Red

The Planned or LE date is in the past.

High Level Reason - Missed Milestone(s)

Detail Reason - Missed Milestone: 1st Site Initiated Date

Yellow

The Planned or LE Date is in the next 30 days.

High Level Reason - Milestone at Risk

Detail Reason - Milestone at Risk: 1st Site Initiated Date

1st Critical Document Package Completed Date 1st Critical Document Package Completed Date is evaluated only when none of the following activities have occurred (Actual date is null):

- 1st Subject Enrolled Date
- Last Subject Enrolled Date
- Last Subject Last Visit Date
- Database Lock Date
- Clinical Study Report Date

Red

The Planned or LE date is in the past.

High Level Reason - Missed Milestone(s)

Detail Reason - Missed Milestone: 1st Critical Document Package Completed Date

Yellow

The Planned or LE Date is in the next 30 days.

High Level Reason - Milestone at Risk

Detail Reason - Milestone at Risk: 1st Critical Document Package Completed Date

Last Subject Enrolled Date Last Subject Enrolled Date is evaluated only when none of the following activities have occurred (Actual date is null):

- Last Subject Last Visit Date
- Database Lock Date
- Clinical Study Report Date

Red

The Planned or LE date is in the past.

High Level Reason - Missed Milestone(s)

Detail Reason - Missed Milestone: Last Subject Enrolled Date

Yellow

The Planned or LE Date is in the next 30 days.

High Level Reason - Milestone at Risk

Detail Reason - Milestone at Risk: Last Subject Enrolled Date

Last Subject Last Visit Date Last Subject Last Visit Date is evaluated only when none of the following activities have occurred (Actual date is null):

- Database Lock Date
- Clinical Study Report Date

Red

The Planned or LE date is in the past.

High Level Reason - Missed Milestone(s)

Detail Reason - Missed Milestone: Last Subject Last Visit Date

Yellow

The Planned or LE Date is in the next 30 days.

High Level Reason - Milestone at Risk

Detail Reason - Milestone at Risk: Last Subject Last Visit Date

Database Lock Date Database Lock Date is evaluated only when none of the following activities have occurred (Actual date is null):

- Clinical Study Report Date

Red

The Planned or LE date is in the past.

High Level Reason - Missed Milestone(s)

Detail Reason - Missed Milestone: Last Subject Last Visit Date

Yellow

The Planned or LE Date is in the next 30 days.

High Level Reason - Milestone at Risk

Detail Reason - Milestone at Risk: Last Subject Last Visit Date

Last Subject Last Visit Date Last Subject Last Visit Date is evaluated only when none of the following activities have occurred (Actual date is null):

- Database Lock Date
- Clinical Study Report Date

Red

The Planned or LE date is in the past.

High Level Reason - Missed Milestone(s)

Detail Reason - Missed Milestone: Last Subject Last Visit Date

Yellow

The Planned or LE Date is in the next 30 days.

High Level Reason - Milestone at Risk

Detail Reason - Milestone at Risk: Last Subject Last Visit Date

Study Recruitment Flag

The Study Recruitment Flag provides a single red, yellow or green icon, which indicates whether recruitment is progressing normally. The Study Recruitment Flag is set up to evaluate three different scenarios:

- **Enrollment Delay** - The enrollment delay flag is triggered when there hasn't been an enrollment within 120 days (red) or 90 days (yellow) of 1st Site Initiated.
- **Screen Failure Rate** - The screen failure rate flag is triggered when the screen fail rate is 20% or more (red) or 10-20% more than the expected screen failure rate for the study.
- **Enrollment Lag** - The enrollment lag flag is triggered based on how much of the planned enrollment period is remaining, using Planned / LE and Actual 1st Subject Enrolled Date, and Planned / LE Last Subject Enrolled Date:
  - Late Enrollment (25% or less of planned enrollment period remaining) - triggered when less than 100% of planned subjects have been enrolled and it has been more than 30 days (red) or 15-30 days (yellow) since the last enrollment.
  - Mid Enrollment (25-50% of planned enrollment period remaining) - triggered when less than 100% of planned subjects have been enrolled and it has been more than 45 days (red) or 30-45 days (yellow) since the last enrollment.
  - Early Enrollment (50% or more of planned enrollment period remaining) - triggered when less than 100% of planned subjects have been enrolled and it has been more than 60 days (red) or 45-60 days (yellow) since the last enrollment.

If any one of the scenarios above is red, the Study Recruitment Flag is red. If none are red and one or more is yellow, the Study Recruitment Flag is yellow. If none is red or yellow, the Study Recruitment Flag shows green.

The Study Recruitment Flag is intended for use as an actionable measure, identifying situations where you may be able to affect the outcome in some way. As a result, it only evaluates recruitment if the Last Subject Enrolled Date and Database Lock Dates have not yet been populated.

Each milestone is evaluated based on the following rules:

Study Enrollment Delay

Red

120 days or more have passed since 1st Site Initiated and there are no subjects enrolled.

High Level Reason - Enrollment Delay

Detail Reason - 1st Site Initiated > 120 Days Ago but no 1st Subject Enrolled

Yellow

90-120 days have passed since 1st Site Initiated and there are no subjects enrolled.

High Level Reason - Enrollment Delay

Detail Reason - 1st Site Initiated > 90 Days Ago but no 1st Subject Enrolled

Study Screen Failure Rate Red

120 days or more have passed since 1st Site Initiated and there are no subjects enrolled.

High Level Reason - Screen Fail Rate

Detail Reason - Screen Fail Rate > 20% Variance from Expected for Study

Yellow

90-120 days have passed since 1st Site Initiated and there are no subjects enrolled.

High Level Reason - Screen Fail Rate

Detail Reason - Fail Rate between 10-20% Variance from Expected for Study

Study Enrollment Lag - Late Enrollment

Red

Less than 100% planned enrollment completed, 30 days or more have passed since last enrollment and 25% or less of enrollment period remains.

High Level Reason - Enrollment Lag

Detail Reason - 30 Days Since Last Enrollment and Less than 25% of Enrollment Period Remaining (includes % planned enrollment completed)

Yellow

Less than 100% planned enrollment completed, 15-30 days have passed since last enrollment and 25% or less of enrollment period remains.

High Level Reason - Enrollment Lag

Detail Reason - 15 Days Since Last Enrollment and Less than 25% of Enrollment Period Remaining (includes % planned enrollment completed)

Study Enrollment Lag - Mid-Enrollment

Red

Less than 100% planned enrollment completed, 45 days or more have passed since last enrollment and 25-50% of enrollment period remains.

High Level Reason - Enrollment Lag

Detail Reason - 45 Days Since Last Enrollment and 25-50% of Enrollment Period Remaining (includes % planned enrollment completed)

Yellow

Less than 100% planned enrollment completed, 30 days have passed since last enrollment and 25-50% of enrollment period remains.

High Level Reason - Enrollment Lag

Detail Reason - 30 Days Since Last Enrollment and 25-50% of Enrollment Period Remaining (includes % planned enrollment completed)

Study Enrollment Lag - Early Enrollment

Red

Less than 100% planned enrollment completed, 60 days or more have passed since last enrollment and more than 50% of enrollment period remains.

High Level Reason - Enrollment Lag

Detail Reason - 60 Days Since Last Enrollment and more than 50% of Enrollment Period Remaining (includes % planned enrollment completed)

Yellow

Less than 100% planned enrollment completed, 45-60 days have passed since last enrollment and more than 50% of enrollment period remains.

High Level Reason - Enrollment Lag

Detail Reason - 45 Days Since Last Enrollment and more than 50% of Enrollment Period Remaining (includes % planned enrollment completed)

Study Retention Flag

The Study Retention Flag provides a single red, yellow or green icon, which indicates that the early termination rate for the study is more than 20% (red) or 1-20% more than the expected early termination rate. If the actual early termination rate for the study is less than or equal to the expected rate, the Study Retention Flag shows green.

The Study Retention Flag is intended for use as an actionable measure, identifying situations where you may be able to affect the outcome in some way. As a result, it only evaluates studies that have an actual early term rate and where 25% or more of planned subjects have been enrolled.

Study Retention Study Retention is evaluated when % Subjects Early Terminated is not null and where % Planned Subjects Enrolled in the study is greater than or equal to 25%.

Red

Actual early termination rate is 20% or more over expected early termination rate for the study.

High Level Reason - Early Term Rate

Detail Reason - Early Termination Rate > 20% over Expected for Study

Yellow

Actual early termination rate is between 1-20% over expected early termination rate for the study.

High Level Reason - Early Term Rate

Detail Reason - Early Termination Rate between 1-20% over Expected for Study

Study-Region Indicators

The following section describes indicators for study-regions.

Study-Region Milestones Flag

The Study-Region Milestone Flag provides a single red, yellow or green icon, which indicates that one or more study-region-level milestones is at risk of missing a planned/latest estimate (LE) date (yellow) or has missed a planned/LE date (red). If none of the milestones is red or yellow, the Study-Region Milestone Flag shows green.

All dates evaluate the LE date, if populated. If the LE date is not populated, the planned date is used. If neither the Planned nor LE dates are populated, the milestone is not evaluated.

The Study-Region Milestone Flag is intended for use as an actionable measure, identifying situations where you may be able to affect the outcome in some way. As a result, it only evaluates milestones where a planned or LE date exists but an actual date has not yet been entered.

The Study Milestone Flag evaluates the following milestones:

- 1st Site Initiated Date
- 1st Critical Document Package Completed Date
- 1st Subject Enrolled Date
- Last Subject Enrolled Date
- Last Subject Last Visit Date

Each milestone is evaluated based on the following rules:

1st Site Initiated Date 1st Site Initiated Date is evaluated only when none of the following activities have occurred (Actual date is null):

- 1st Critical Document Package Completed Date
- 1st Subject Enrolled Date
- Last Subject Enrolled Date
- Last Subject Last Visit Date

Red

The Planned or LE date is in the past.

High Level Reason - Missed Milestone(s)

Detail Reason - Missed Milestone: 1st Site Initiated Date

Yellow

The Planned or LE Date is in the next 30 days.

High Level Reason - Milestone at Risk

Detail Reason - Milestone at Risk: 1st Site Initiated Date

1st Critical Document Package Completed Date 1st Critical Document Package Completed Date is evaluated only when none of the following activities have occurred (Actual date is null):

- 1st Subject Enrolled Date
- Last Subject Enrolled Date
- Last Subject Last Visit Date

Red

The Planned or LE date is in the past.

High Level Reason - Missed Milestone(s)

Detail Reason - Missed Milestone: 1st Critical Document Package Completed Date

Yellow

The Planned or LE Date is in the next 30 days.

High Level Reason - Milestone at Risk

Detail Reason - Milestone at Risk: 1st Critical Document Package Completed Date

Last Subject Enrolled Date Last Subject Enrolled Date is evaluated only when none of the following activities have occurred (Actual date is null):

- Last Subject Last Visit Date

Red

The Planned or LE date is in the past.

High Level Reason - Missed Milestone(s)

Detail Reason - Missed Milestone: Last Subject Enrolled Date

Yellow

The Planned or LE Date is in the next 30 days.

High Level Reason - Milestone at Risk

Detail Reason - Milestone at Risk: Last Subject Enrolled Date

Last Subject Last Visit Date

Red

The Planned or LE date is in the past.

High Level Reason - Missed Milestone(s)

Detail Reason - Missed Milestone: Last Subject Last Visit Date

Yellow

The Planned or LE Date is in the next 30 days.

High Level Reason - Milestone at Risk

Detail Reason - Milestone at Risk: Last Subject Last Visit Date

Study-Region Recruitment Flag

The Study-Region Recruitment Flag provides a single red, yellow or green icon, which indicates whether recruitment is progressing normally. The Study Recruitment Flag is set up to evaluate three different scenarios:

- **Screening Delay** - The screening delay flag is triggered when there hasn't been a first subject screened within 90 days (red) or 60 days (yellow) of 1st Site Initiated for this study-region.
- **Enrollment Delay** - The enrollment delay flag is triggered when there hasn't been an enrollment within 120 days (red) or 90 days (yellow) of 1st Site Initiated for this study-region.
- **Screen Failure Rate** - The screen failure rate flag is triggered when the screen fail rate for this study-region is 20% or more (red) or 10-20% more than the expected screen failure rate for the study.
- **Enrollment Lag** - The enrollment lag flag is triggered when there is at least one subject enrolled, there is less than 50% planned enrollment completed, and it's been more than 60 days (red) or 90 days (yellow) since the last enrollment for this study-region.

If any one of the scenarios above is red, the Study Recruitment Flag is red. If none are red and one or more is yellow, the Study Recruitment Flag is yellow. If none is red or yellow, the Study Recruitment Flag shows green.

The Study Recruitment Flag is intended for use as an actionable measure, identifying situations where you may be able to affect the outcome in some way. As a result, it only evaluates recruitment if the Last Subject Enrolled Date and Database Lock Dates have not yet been populated.

Each milestone is evaluated based on the following rules:

Study-Region Enrollment Delay

Red

120 days or more have passed since 1st Site Initiated and there are no subjects enrolled.

High Level Reason - Enrollment Delay

Detail Reason - 1st Site Initiated > 120 Days Ago but no 1st Subject Enrolled

Yellow

90-120 days have passed since 1st Site Initiated and there are no subjects enrolled.

High Level Reason - Enrollment Delay

Detail Reason - 1st Site Initiated > 90 Days Ago but no 1st Subject Enrolled

Study-Region Screen Failure Rate

Red

120 days or more have passed since 1st Site Initiated and there are no subjects enrolled.

High Level Reason - Screen Fail Rate

Detail Reason - Screen Fail Rate > 20% Variance from Expected for Study

Yellow

90-120 days have passed since 1st Site Initiated and there are no subjects enrolled.

High Level Reason - Screen Fail Rate

Detail Reason - Fail Rate between 10-20% Variance from Expected for Study

Study-Region Enrollment Lag

Red

Site enrollment is less than 50% and more than 60 days have passed since last enrollment.

High Level Reason - Enrollment Lag

Detail Reason - Site Enrollment Under 50% and > 60 Days Since Last Enrollment

Yellow

Site enrollment is less than 50% and 30-60 days have passed since last enrollment.

High Level Reason - Enrollment Lag

Detail Reason - Site Enrollment Under 50% and > 30 Days Since Last Enrollment

Study-Region Retention Flag

The Study-Region Retention Flag provides a single red, yellow or green icon, which indicates that the early termination rate for the study-region is more than 20% (red) or

1-20% more than the expected early termination rate for the study. If the actual early termination rate for the study is less than or equal to the expected rate, the Study-Region Retention Flag shows green.

The Study-Region Retention Flag is intended for use as an actionable measure, identifying situations where you may be able to affect the outcome in some way. As a result, it only evaluates study-regions that have an actual early term rate and where 25% or more of planned subjects have been enrolled.

Study-Region Retention Study-Region Retention is evaluated when % Subjects Early Terminated is not null and where % Planned Subjects Enrolled in the study-region is greater than or equal to 25%.

Red

Actual early termination rate is 20% or more over expected early termination rate for the study.

High Level Reason - Early Term Rate

Detail Reason - Early Termination Rate > 20% over Expected for Study

Yellow

Actual early termination rate is between 1-20% over expected early termination rate for the study.

High Level Reason - Early Term Rate

Detail Reason - Early Termination Rate between 1-20% over Expected for Study

Study-Site Indicators

The following section describes indicators for study-sites.

Study-Site Milestones Flag

The Study-Site Milestone Flag provides a single red, yellow or green icon, which indicates that one or more study-site-level milestones is at risk of missing a planned/latest estimate (LE) date (yellow) or has missed a planned/LE date (red). If none of the milestones is red or yellow, the Study-Site Milestone Flag shows green.

All dates evaluate the LE date, if populated. If the LE date is not populated, the planned date is used. If neither the Planned nor LE dates are populated, the milestone is not evaluated.

The Study-Site Milestone Flag is intended for use as an actionable measure, identifying situations where you may be able to affect the outcome in some way. As a result, it only evaluates milestones where a planned or LE date exists but an actual date has not yet been entered.

The Study Milestone Flag evaluates the following milestones:

- Site Initiated Date
- Critical Document Package Completed Date
- 1st Subject Enrolled Date
- Last Subject Enrolled Date
- Last Subject Last Visit Date

Each milestone is evaluated based on the following rules:

Site Initiated Date Site Initiated Date is evaluated only when none of the following activities have occurred (Actual date is null):

- Critical Document Package Completed Date
- Subject Enrolled Date
- Last Subject Enrolled Date
- Last Subject Last Visit Date

Red

The Planned or LE date is in the past.

High Level Reason - Missed Milestone(s)

Detail Reason - Missed Milestone: Site Initiated Date

Yellow

The Planned or LE Date is in the next 30 days.

High Level Reason - Milestone at Risk

Detail Reason - Milestone at Risk: Site Initiated Date

Critical Document Package Completed Date Critical Document Package Completed Date is evaluated only when none of the following activities have occurred (Actual date is null):

- Subject Enrolled Date
- Last Subject Enrolled Date
- Last Subject Last Visit Date

Red

The Planned or LE date is in the past.

High Level Reason - Missed Milestone(s)

Detail Reason - Missed Milestone: Critical Document Package Completed Date

Yellow

The Planned or LE Date is in the next 30 days.

High Level Reason - Milestone at Risk

Detail Reason - Milestone at Risk: Critical Document Package Completed Date

Last Subject Enrolled Date Last Subject Enrolled Date is evaluated only when none of the following activities have occurred (Actual date is null):

- Last Subject Last Visit Date

Red

The Planned or LE date is in the past.

High Level Reason - Missed Milestone(s)

Detail Reason - Missed Milestone: Last Subject Enrolled Date

Yellow

The Planned or LE Date is in the next 30 days.

High Level Reason - Milestone at Risk

Detail Reason - Milestone at Risk: Last Subject Enrolled Date

Last Subject Last Visit Date

Red

The Planned or LE date is in the past.

High Level Reason - Missed Milestone(s)

Detail Reason - Missed Milestone: Last Subject Last Visit Date

Yellow

The Planned or LE Date is in the next 30 days.

High Level Reason - Milestone at Risk

Detail Reason - Milestone at Risk: Last Subject Last Visit Date

Study-Site Recruitment Flag

The Study-Site Recruitment Flag provides a single red, yellow or green icon, which indicates whether recruitment is progressing normally. The Study Recruitment Flag is set up to evaluate four different scenarios:

- **Screening Delay** - The screening delay flag is triggered when there hasn't been a first subject screened within 90 days (red) or 60 days (yellow) of Site Initiated for this study-site.
- **Enrollment Delay** - The enrollment delay flag is triggered when there hasn't been an enrollment within 120 days (red) or 90 days (yellow) of Site Initiated for this study-site.
- **Screen Failure Rate** - The screen failure rate flag is triggered when the screen fail rate for this study-site is 20% or more (red) or 10-20% more than the expected screen failure rate for the study.
- **Enrollment Lag** - The enrollment lag flag is triggered when there is at least one subject enrolled, there is less than 50% planned enrollment completed, and it's been more than 60 days (red) or 90 days (yellow) since the last enrollment for this study-site.

If any one of the scenarios above is red, the Study Recruitment Flag is red. If none are red and one or more is yellow, the Study Recruitment Flag is yellow. If none is red or yellow, the Study Recruitment Flag shows green.

The Study Recruitment Flag is intended for use as an actionable measure, identifying situations where you may be able to affect the outcome in some way. As a result, it only evaluates recruitment if the Last Subject Enrolled Date and Database Lock Dates have not yet been populated.

Each milestone is evaluated based on the following rules:

Study-Site Enrollment Delay

Red

120 days or more have passed since Site Initiated and there are no subjects enrolled.

High Level Reason - Enrollment Delay

Detail Reason - 1st Site Initiated > 120 Days Ago but no 1st Subject Enrolled

Yellow

90-120 days have passed since Site Initiated and there are no subjects enrolled.

High Level Reason - Enrollment Delay

Detail Reason - 1st Site Initiated > 90 Days Ago but no 1st Subject Enrolled

Study-Site Screen Failure Rate

Red

120 days or more have passed since Site Initiated and there are no subjects enrolled.

High Level Reason - Screen Fail Rate

Detail Reason - Screen Fail Rate > 20% Variance from Expected for Study

Yellow

90-120 days have passed since Site Initiated and there are no subjects enrolled.

High Level Reason - Screen Fail Rate

Detail Reason - Fail Rate between 10-20% Variance from Expected for Study

Study-Site Enrollment Lag

Red

Site enrollment is less than 50% and more than 60 days have passed since last enrollment.

High Level Reason - Enrollment Lag

Detail Reason - Site Enrollment Under 50% and > 60 Days Since Last Enrollment

Yellow

Site enrollment is less than 50% and 30-60 days have passed since last enrollment.

High Level Reason - Enrollment Lag

Detail Reason - Site Enrollment Under 50% and > 30 Days Since Last Enrollment

Study-Site Retention Flag

The Study-Site Retention Flag provides a single red, yellow or green icon, which indicates that the early termination rate for the study-site is more than 20% (red) or 1-20% more than the expected early termination rate for the study. If the actual early termination rate for the study is less than or equal to the expected rate, the Study-Site Retention Flag shows green.

The Study-Site Retention Flag is intended for use as an actionable measure, identifying situations where you may be able to affect the outcome in some way. As a result, it only evaluates study-sites that have an actual early term rate and where 25% or more of planned subjects have been enrolled.

Study-Site Retention Study-Site Retention is evaluated when % Subjects Early Terminated is not null and where % Planned Subjects Enrolled in the study-site is greater than or equal to 25%.

Red

Actual early termination rate is 20% or more over expected early termination rate for the study.

High Level Reason - Early Term Rate

Detail Reason - Early Termination Rate > 20% over Expected for Study

Yellow

Actual early termination rate is between 1-20% over expected early termination rate for the study.

High Level Reason - Early Term Rate

Detail Reason - Early Termination Rate between 1-20% over Expected for Study

Part II

Appendixes

Part II contains the following appendixes:

- Appendix A, Dashboards and Analyses
- Appendix B, Oracle Health Sciences Clinical Development Analytics Presentation Catalog

A

Dashboards and Analyses

This section describes predefined dashboards and analyses delivered with Oracle Health Sciences Clinical Development Analytics (OHSCDA):

- Oracle Health Sciences Clinical Development Analytics Dashboards on page A-1
- Oracle Health Sciences Clinical Development Analytics Analyses on page 27

Oracle Health Sciences Clinical Development Analytics Dashboards

OHSCDA is delivered with seven dashboards. These dashboards can be accessed by users with a specific job responsibility and security privileges. Each dashboard has tabbed pages that displays reports.

OHSCDA includes the following dashboards:

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

Log in to OHSCDA, and select the dashboard you want to view.

CRA Dashboard

This is the basic dashboard for a Clinical Research Associate (CRA). It provides some initial reports for a CRA, and is intended as starting point for an implementation.

This dashboard can be accessed by a Study Manager or CRA. It provides reports related to site status and performance, subject recruitment and retention, site monitoring, and document tracking.

This dashboard includes the following prompts, which are common to all its pages:

- **CRA**: Lists All CRAs within a Study (required)

- **Study**: Lists all Studies.

CRA Dashboard Pages

This dashboard includes the following tabbed pages:

- CRA Overview Page
- Sites to Monitor Page
- Study-Site Milestones Page
- Initiating & Recruiting Sites Page
- Monitoring Metrics Page
- Top Investigators Page
- Site Document List Page
- eCRF Workload Page
- Performance Page
- Map of Study Sites Page

CRA Overview Page Displays reports on which monitoring reports require completion or approval, as well as lists study-sites with key information and an indicator of study-site health.

The CRA Overview page includes the following reports:

- Outstanding Monitoring Reports (CRA View) (Report CDA-CO-804)
- Outstanding Monitoring Report Approvals (CRA View) (Report CDA-CO-814)
- Outstanding Follow up Items (CRA View) (Report CDA-CO-806)
- Study-Sites with Red or Yellow Performance Flag (Report CDA-CO-204)

Sites to Monitor Page Displays reports detailing length of time since initiation or last monitoring visit.

The Sites to Monitor page includes the following reports:

- Sites to Monitor - Days Since Last Visit - Recruitment Detail View (Report CDA-CO-816A)
- Sites to Monitor - Days Since Last Visit - Retention Detail View (Report CDA-CO-816B)
- Sites to Monitor - Days Since Last Visit - Study Close Detail View (Report CDA-CO-816C)
- Sites to Monitor - Days Since Last Visit - Summary View (Report CDA-CO-816D)
- Sites with No Visits Since Initiation - Recruitment Detail View (Report CDA-CO-812A)
- Sites with No Visits Since Initiation - Retention Detail View (Report CDA-CO-812B)
- Sites with No Visits Since Initiation - Summary View (Report CDA-CO-812C)

Study-Site Milestones Page Displays a report that lists study-sites with key milestone dates.

The Study-Site Milestones page includes the following page-specific prompts:

- **Study-Site ID #**: Lists Sites within a Study, by site number.
- **Study-Site Status**: Lists the Statuses of a Study-Site.
- **Study Region**: Lists the Regions for a Study.
- **Principal Investigator**: Lists the Principal Investigators for a Study-Site.

The Study-Site Milestones page includes the following reports:

- Study-Site Milestones with Indicators (CRA) - Monitoring View (Report CDA-CO-205A)
- Study-Site Milestones with Indicators (CRA) - Recruitment Detail View (Report CDA-CO-205B)
- Study-Site Milestones with Indicators (CRA) - Retention Detail View (Report CDA-CO-205C)
- Study-Site Milestones with Indicators (CRA) - Site Start Up Detail View (Report CDA-CO-205D)
- Study-Site Milestones with Indicators (CRA) - Study Close Detail View (Report CDA-CO-205E)
- Study-Site Milestones with Indicators (CRA) - Summary View (Report CDA-CO-205F)

Initiating & Recruiting Sites Page

Displays reports on uninitiated sites and documents, and initiated sites and recruitment.

The Initiating and Recruiting Sites page includes the following page-specific prompts:

- **Study-Site ID #**: Lists Sites within a Study, by site number.
- **Study-Site Status**: Lists the Statuses of a Study-Site.
- **Study Region**: Lists the Regions for a Study.
- **Principal Investigator**: Lists the Principal Investigators for a Study-Site.

The Initiating and Recruiting page includes the following reports:

- Uninitiated Sites (Report CDA-CO-304)
- Initiated Study-Sites with Recruitment Counts (Report CDA-CO-412)

Monitoring Metrics Page Displays reports on cycle times for monitoring report completion and approval, as well as site visit frequency.

The Monitoring Metrics page includes the following page-specific prompts:

Year and Month Between: Supplemental prompt for those reports that include charts displaying data over time.

Metric is in Top: Supplemental prompt for those reports that might display a long list of metrics.

The Monitoring Metrics page includes the following reports:

- Monitoring Report Completion Turnaround Times (Report CDA-CO-820)
- # Follow Up Items by Type (Multiple Study-Sites) (Report CDA-CO-810)
- Visit Frequency Compared to Subject Enrollment (Report CDA-CO-819)

Study-Site Milestones Page Displays a report that lists study-sites with key milestone dates.

The Study-Site Milestones page includes the following page-specific prompts:

- **Study-Site ID #**: Lists Sites within a Study, by site number.
- **Study-Site Status**: Lists the Statuses of a Study-Site.
- **Study Region**: Lists the Principal Investigators for a Study-Site.

This page includes the following reports:

- Study-Site Milestones with Indicators (CRA) - Monitoring View (Report CDA-CO-205A)
- Study-Site Milestones with Indicators (CRA) - Recruitment Detail View (Report CDA-CO-205B)
- Study-Site Milestones with Indicators (CRA) - Retention Detail View (Report CDA-CO-205C)
- Study-Site Milestones with Indicators (CRA) - Site Start Up Detail View (Report CDA-CO-205D)
- Study-Site Milestones with Indicators (CRA) - Study Close Detail View (Report CDA-CO-205E)
- Study-Site Milestones with Indicators (CRA) - Summary View (Report CDA-CO-205F)

Top Investigators Page Displays reports showing the top N investigators by % site enrollment completed or total enrollment. Also displays top investigators' contribution compared to all other investigators.

The Top Investigators page includes the following page-specific prompts:

- **Metric is in Top**: Supplemental prompt for those reports that might display a long list of metrics.

The Top Investigators page includes the following reports:

- Top Investigators, % Planned Enrollment Completed (Report CDA-CO-700)
- Top Investigators, Total Enrollment (Report CDA-CO-701)
- Top Investigators Compared to All Investigators for Study, Total Enrollment (Report CDA-CO-702)

Site Document List Page

Displays a report that lists document tracking information for site documents.

The Site Document List page includes the following page-specific prompts:

- **Study-Site ID #**: Lists Sites within a Study, by site number.
- **Study-Site Status**: Lists the Statuses of a Study-Site.
- **Study Region**: Lists the Regions for a Study.
- **Principal Investigator**: Lists the Principal Investigators for a Study-Site.
- **Activity Type**: Lists the Activity Types for documents.
- **Document Name**: Lists the Document Names.
- **Document Sent Date Between**: Date range for Document Sent Date.

- **Document Received Date Between**: Date range for Document Received Date.
- **Document Expiration Date Between**: Date range for Document Expiration Date.

The Site Document List page includes the following report:

- Documents List (Multiple Study-Sites) (Report CDA-CO-601)

eCRF Workload Page Displays reports on the current workload.

This eCRF Workload page includes the following reports:

- Key EDC Processing Volumes (Report CDA-DM-305)

Performance Page Displays reports on key cycle times.

The Performance page includes the following page-specific prompts:

- **Metric is in Top**: Supplemental prompt for those reports that might display a long list of metrics.

The Performance page includes the following reports:

- Average Duration in Categorized Discrepancy Review Status (Report CDA-DM-210)
- Average Duration of Open Discrepancies in Review Statuses (Report CDA-DM-215)
- Key EDC Cycle Times (Report CDA-DM-300)
- Average Days from Complete to Initially Approved (Report CDA-DM-325)
- Average Days from Complete to Initially Verified (Report CDA-DM-330)

Map of Study Sites Page

The Map of Study Sites page includes the following report:

- Detail Study-Site Map (Report CDA-CO-1201)

Data Manager - EDC Dashboard

This dashboard is the Data Management dashboard for EDC studies. It can be accessed by a Data Manager, Study Manager or Project Manager and provides numerous reports and charts to monitor performance of EDC studies.

The Data Manager - EDC dashboard includes these prompts, which are common to all its pages:

- **Study**: Lists Studies within a Program.
- **Study Site**: Lists Sites within a Study.

The eCRF Workload, Discrepancy Workload, Quality, Key Rates and Performance pages also include the following prompts:

- **Sponsor**: Lists the name of the Sponsor companies for which this study is being conducted.
- **Program**: Lists the name of the Programs that owns the Study.

Data Manager - EDC Dashboard Pages

This dashboard includes the following tabbed pages:

- Home Page

- eCRF Workload Page
- Discrepancy Workload Page
- Quality Page
- Key Rates Page
- Performance Page
- Study Discrepancies Page
- Study Processing Summary Page
- Study Processing Detail Page

Home Page Displays key study based reports.

The Home page includes the following page-specific prompts:

- **Metric is in Bottom**: Supplemental prompt for those reports that might display a long list of metrics.
- **Metric is in Top**: Supplemental prompt for those reports that might display a long list of metrics.

The Home page includes the following reports:

- Average Days Discrepancy Open (Report CDA-DM-205)
- Count of Currently Open Discrepancies by CRF and Type - Top N by Rank (Report CDA-DM-230)
- Counts of Open Multivariate Discrepancies, by Procedure (Report CDA-DM-235)
- Approval & Verification Rates - Worst Performers (Report CDA-DM-350)

eCRF Workload Page Displays reports on the current workload.

The eCRF Workload page includes the following reports:

- Key EDC Processing Volumes (Report CDA-DM-305)

Discrepancy Workload Page Displays reports on discrepancy workload.

The Discrepancy Workload page includes the following reports:

- Counts of Categorized Open Discrepancies, by Review Status (Report CDA-DM-220)
- Counts of Discrepancies, by State and Review Status (Report CDA-DM-225)
- Discrepancy Overview with Ratios (Report CDA-DM-240)

Quality Page Displays reports on the key quality indicators.

The Quality page includes the following page-specific prompts:

- **Metric is in Top**: Supplemental prompt for those reports that might display a long list of metrics.

The Quality page includes the following reports:

- Discrepancies per Subjects Enrolled - Top N (Report CDA-DM-250)
- Discrepancies per Pages Entered - Top N (Report CDA-DM-255)

Key Rates Page Displays reports on the key performance rates.

The Key Rates page includes the following page-specific prompts:

- **Metric is in Bottom**: Supplemental prompt for those reports that might display a long list of metrics.

The Key Rates page includes the following reports:

- Low Approved to Entered Rate - Worst Performers (Report CDA-DM-335)
- Low Verified to Entered Rate - Worst Performers (Report CDA-DM-340)

Performance Page Displays reports on key cycle times.

The Performance page includes the following page-specific prompts:

- **Metric is in Top**: Supplemental prompt for those reports that might display a long list of metrics.

The Performance page includes the following reports:

- Average Duration in Categorized Discrepancy Review Status (Report CDA-DM-210)
- Average Duration of Open Discrepancies in Review Statuses (Report CDA-DM-215)
- Key EDC Cycle Times (Report CDA-DM-300)
- Average Days from Complete to Initially Approved (Report CDA-DM-325)
- Average Days from Complete to Initially Verified (Report CDA-DM-330)

Study Discrepancies Page Displays reports on the key study based discrepancy indicators.

The Study Discrepancies page includes the following page-specific prompts:

- **Metric is in Top**: Supplemental prompt for those reports that might display a long list of metrics.

The Study Discrepancies page includes the following reports:

- Average Days Discrepancy Open (Report CDA-DM-205)
- Count of Currently Open Discrepancies by CRF and Type - Top N by Rank (Report CDA-DM-230)
- Counts of Open Multivariate Discrepancies, by Procedure (Report CDA-DM-235)

Study Processing Summary Page Displays reports on eCRFs waiting processing summary.

The Study Processing Summary page includes the following page-specific prompts:

- **Subject ID**: Lists IDs for the subject about whom the data were collected.

The Study Processing Summary page includes the following reports:

- Summary of Subjects Awaiting EDC Processing (Report CDA-DM-320)

Study Processing Detail Page Displays reports on eCRFs waiting processing detail.

The Study Processing Detail page includes the following reports:

- Listing of Subject-Pages, Awaiting EDC Processing (Report CDA-DM-310)

Data Manager - Paper Dashboard

This dashboard is Data Management dashboard for paper studies. It can be accessed by a Data Manager (DM), and provides numerous reports and charts to monitor performance of Paper studies.

This dashboard includes the following prompts, which are common to all its pages:

- **Study**: Lists Studies within a Program.
- **Study Site**: Lists Sites within a Study.

The Page Workload, Discrepancy Workload, Quality and Performance pages also include the following prompts:

- **Sponsor**: Lists the name of the Sponsor companies for which this study is being conducted.
- **Program**: Lists the name of the Programs that owns the Study.

Data Manager - Paper Dashboard Pages

This dashboard includes the following tabbed pages:

- Home Page
- Page Workload Page
- Discrepancy Workload Page
- Quality Page
- Performance Page
- Study Processing Summary Page
- Study Processing Detail Page

Home Page Displays key study based reports.

The Home page includes the following page-specific prompts:

- **Metric is in Top**: Supplemental prompt for those reports that might display a long list of metrics.

The Home page includes the following reports:

- Average Days Discrepancy Open (Report CDA-DM-205)
- Count of Currently Open Discrepancies by CRF and Type - Top N by Rank (Report CDA-DM-230)
- Counts of Open Multivariate Discrepancies, by Procedure (Report CDA-DM-235)
- Key Paper Processing Volumes (Report CDA-DM-405)
- Pages Awaiting Entry Completion (Report CDA-DM-450)

Page Workload Page Displays reports on the current workload.

The Page Workload page includes the following reports:

- Key Paper Processing Volumes (Report CDA-DM-405)

Discrepancy Workload Page Displays reports on the discrepancy workload.

The Discrepancy Workload page includes the following reports:

- Counts of Categorized Open Discrepancies, by Review Status (Report CDA-DM-220)
- Counts of Discrepancies, by State and Review Status (Report CDA-DM-225)
- Discrepancy Overview with Ratios (Report CDA-DM-240)

Quality Page Displays reports on the key quality indicators.

The Quality page includes the following page-specific prompts:

- **Metric is in Top**: Supplemental prompt for those reports that might display a long list of metrics.

The Quality page includes the following reports:

- Discrepancies per Subjects Enrolled - Top N (Report CDA-DM-250)
- Discrepancies per Pages Entered - Top N (Report CDA-DM-255)

Performance Page Displays reports on the key performance rates.

The Performance page includes the following page-specific prompts:

- **Metric is in Top**: Supplemental prompt for those reports that might display a long list of metrics.

The Performance page includes the following reports:

- Average Duration in Categorized Discrepancy Review Status (Report CDA-DM-210)
- Average Duration of Open Discrepancies in Review Statuses (Report CDA-DM-215)
- Key Cycle Times for Paper Studies (Report CDA-DM-400)
- Paper Processing - Longest Cycle Times (Report CDA-DM-415)

Study Processing Summary Page Displays reports on paper CRFs waiting processing summary.

The Study Processing Summary page includes the following page-specific prompts:

- **Subject ID**: Lists IDs for the subject about whom the data were collected.

The Study Processing Summary page includes the following reports:

- Summary of Subjects Awaiting Paper Processing (Report CDA-DM-420)

Study Processing Detail Page Displays reports on paper CRFs waiting processing detail.

The Study Processing Detail page includes the following reports:

- Listing of Subject-Pages, Awaiting Paper Processing (Report CDA-DM-410)

Executive Dashboard

This dashboard includes the following prompts, which are common to all its pages:

- **Program**: Lists the name of the Programs that owns the Study.
- **Therapeutic Area**
- **Study-phase**
- **Protocol Approved Date**

- **Clinical Study Report Date**

Executive Dashboard Pages

This dashboard includes the following tabbed pages:

- Overview Page
- KPI Summary Page
- Site Performance Summary Page
- Study List Page
- Top Investigators Page
- Study-Site Map Page

Overview Page

Displays report links with the following attributes:

- Section Title - Study Performance Reports
- Show Section Header - True
- Show Section Title - True
- Collapsible - False

The Overview page includes the following page-specific prompt:

- **Year Between**: Supplemental prompt for those reports that include charts displaying data over year.

The Overview page includes the following reports:

- Study List - KPI Performance (Report CDA-CO-904)
- Study List - Milestone Performance (Report CDA-CO-109)
- Number of Studies (Report CDA-CO-1001)
- Key Performance Indicators Over Time (Executive View) (Report CDA-CO-902)
- Executive Study-Site Map (Report CDA-CO-1203)

KPI Summary Page

The KPI Summary page includes the following page-specific prompt:

- **Year Between**: Supplemental prompt for those reports that include charts displaying data over year.

The KPI Summary page includes the following KPI Summary reports:

- KPI Summary - Protocol Approved to 1st Site Initiated (Executive View) (Report CDA-CO-907)
- KPI Summary - Protocol Approved to 1st Subject Enrolled (Executive View) (Report CDA-CO-908)
- KPI Summary - CDP Complete to Site Initiated (Executive View) (Report CDA-CO-905)
- KPI Summary - LSLV to Database Lock (Executive View) (Report CDA-CO-906)
- KPI Summary - Site Visit Completed to Visit Report Completed (Executive View) (Report CDA-CO-909)

- KPI Summary - Visit Report Completed to Visit Report Approved (Executive View) (Report CDA-CO-910)

Site Performance Summary Page

The Site Performance Summary page includes the following reports:

- Site Recruitment Performance Charts (Executive View) (Report CDA-CO-436)
- Site Recruitment Performance (Report CDA-CO-413)

Study List Page

The Study List page includes the following page-specific prompts:

- **Study**: Lists Studies within a Program.
- **Study Status**: Lists Study Status for a Study.
- **Study Manager**: List Study Manager for a Study.

The Study List page includes the following report:

- Detailed Study Milestones Report (Report CDA-CO-102)

Top Investigators Page

The Top Investigators page includes the following page-specific prompt:

- **Metric is in Top**: Supplemental prompt for those reports that might display a long list of metrics.

The Top Investigators page includes the following report:

- Top Investigators, % Planned Enrollment Completed (Report CDA-CO-700)
- Top Investigators Compared to All Investigators for Study, Total Enrollment (Report CDA-CO-702)
- Top Investigators, Total Enrollment (Report CDA-CO-701)

Study-Site Map Page

The Study-Site Map page includes the following report:

- High Level Study-Site Map (Report CDA-CO-1202)

Region Manager Dashboard

This dashboard includes the following prompts, which are common to all its pages:

- **Study-Region Manager**
- **Region Name**
- **Program**
- **Therapeutic Area**
- **Protocol Approved Date**
- **Clinical Study Report Date**

Region Manager Dashboard Pages

This dashboard includes the following tabbed pages:

- Overview Page

- Visit Reports & Follow Up Items
- Milestones and Schedule
- KPI Summary Page
- Monitoring Metrics Page
- Initiating and Recruiting Study Regions Page
- Top Investigators Page
- Map of Study Sites Page

Overview Page

Displays report links with the following attributes:

- Section Title - Study-Region Performance Reports
- Show Section Header - True
- Show Section Title - True
- Collapsible - False

The Overview page includes the following reports:

- Study-Region List - Milestone Performance (Report CDA-CO-1109)
- Study-Region List - KPI Performance (Report CDA-CO-1108)
- Monitoring Status Overview (Region Manager View) (Report CDA-CO-1101)
- Study Regions with Red or Yellow Performance Flag (Report CDA-CO-1200)
- Study-Sites with Red or Yellow Performance Flag (Report CDA-CO-204)

Visit Reports & Follow Up Items

The Visit Reports & Follow Up Items page includes the following reports:

- Outstanding Monitoring Report Approvals (Study Manager View) (Report CDA-CO-809)
- Outstanding Follow up Items (Study Manager View) (Report CDA-CO-807)
- Monitoring Report Completion Turnaround Times (Report CDA-CO-820)
- Monitoring Report Approval Turnaround Times (Report CDA-CO-817)

Milestones and Schedule

The Milestones and Schedule page includes the following report:

- Study Region Milestones with Indicators (CDA-CO-1106)

KPI Summary Page

The KPI Summary page includes the following reports:

- Performance Metrics Summary Narrative - Site Visit (Report CDA-CO-1110)
- Study Region vs. Study - Site Start Up KPIs (Report CDA-CO-1111)
- KPI Summary - CDP Completed to Site Initiated (Region Manager View) (Report CDA-CO-1103)
- KPI Summary - Site Visit Completed to Visit Report Completed (Region Manager View) (Report CDA-CO-1104)

- KPI Summary - Visit Report Completed to Approved (Region Manager View) (Report CDA-CO-1105)

Monitoring Metrics Page

The Monitoring Metrics page includes the following page-specific prompts:

- **Site Visit Type**: Lists types of site visits.
- **Site Visit Start Date Between**: Supplemental prompt for those reports that include charts displaying data over time.
- **Year Between**: Supplemental prompt for those reports that include charts displaying data over year.

The Monitoring Metrics page includes the following reports:

- Monitoring Report Completion Turnaround Times (Report CDA-CO-820)
- Key Performance Indicators Over Time - Monitoring (Region Manager) (Report CDA-CO-1112)
- Visit Frequency Compared to Subject Enrollment (Report CDA-CO-819)
- # Follow Up Items by Type (Multiple Study-Sites) (Report CDA-CO-810)

Initiating and Recruiting Study Regions Page

The Initiating and Recruiting Study Regions page includes the following reports:

- Study-Region List - Initiation Details (Report CDA-CO-306)
- Study-Region List - Recruitment Details (Report CDA-CO-433)

Top Investigators Page

The Top Investigators page includes the following page-specific prompt:

- **Metric is in Top**: Supplemental prompt for those reports that might display a long list of metrics.

The Top Investigators page includes the following reports:

- Top Investigators, % Planned Enrollment Completed (Report CDA-CO-700)
- Top Investigators Compared to All Investigators for Study, Total Enrollment (Report CDA-CO-702)
- Top Investigators, Total Enrollment (Report CDA-CO-701)

Map of Study Sites Page

The Map of Study Sites page includes the following report:

- High Level Study-Site Map (Report CDA-CO-1202)

Study Manager Dashboard

This dashboard can be accessed by a Study Manager. It provides reports related to study status and performance, subject recruitment and retention, site monitoring metrics, and investigator performance.

This dashboard includes the following prompts, which are common to all its pages:

- **Program**: Lists the name of the Programs that owns the Study.
- **Study**: Lists Studies within a Program.

- **Study Manager**: Lists Study Manager for a Study.
- **Study Status**: Lists Study Status for a Study.

Study Manager Dashboard Pages

This dashboard includes the following tabbed pages:

- Study Manager Overview Page
- Initiating & Recruiting Studies Page
- Monitoring Metrics Page
- Top Investigators Page
- KPI Summary Page
- Map of Study Sites Page

Study Manager Overview Page Displays report links with the following attributes:

- Section Title - Study Performance Reports
- Show Section Header - True
- Show Section Title - True
- Collapsible - False

The Study Manager Overview page includes the following reports:

- Study List - KPI Performance (Report CDA-CO-904)
- Study List - Milestone Performance (Report CDA-CO-109)
- Monitoring Status Overview (Study Manager View) (Report CDA-CO-107)

Initiating & Recruiting Studies Page Displays reports on studies actively initiating and actively recruiting.

The Initiating & Recruiting Studies page includes the following reports:

- Study List - Initiation Details (Report CDA-CO-305)
- Study List - Recruitment Details (Report CDA-CO-406)

Monitoring Metrics Page Displays reports on monitoring reports awaiting approval, outstanding follow up items, and monitoring report completion and approval cycle times.

The Monitoring Metrics page includes the following page-specific prompts:

Year/Month Between: Supplemental prompt for those reports that include charts displaying data over time.

Site Visit Type: Lists types of site visits.

The Monitoring Metrics page includes the following reports:

- Monitoring Report Completion Turnaround Times (Report CDA-CO-820)
- Outstanding Monitoring Report Approvals (Study Manager View) (Report CDA-CO-809)
- Monitoring Report Approval Turnaround Times (Report CDA-CO-817)
- Outstanding Follow up Items (Study Manager View) (Report CDA-CO-807)

Top Investigators Page Displays reports showing the top N investigators by % site enrollment completed or total enrollment. Also, displays top investigators' contribution compared to all other investigators.

The Top Investigators page includes the following page-specific prompts:

- **Metric is in Top**: Supplemental prompt for those reports that might display a long list of metrics.

The Top Investigators page includes the following reports:

- Top Investigators, % Planned Enrollment Completed (Report CDA-CO-700)
- Top Investigators, Total Enrollment (Report CDA-CO-701)
- Top Investigators Compared to All Investigators for Study, Total Enrollment (Report CDA-CO-702)

KPI Summary Page

The KPI Summary page includes the following page-specific prompt:

- **Year Between**: Supplemental prompt for those reports that include charts displaying data over year.

The KPI Summary page includes the following reports:

- Performance Metrics Summary Narrative - Site Visit (Report CDA-CO-1110)
- Study Region vs. Study - Site Start Up KPIs (Report CDA-CO-1111)
- KPI Summary - CDP Completed to Site Initiated (Region Manager View) (Report CDA-CO-1103)
- KPI Summary - Site Visit Completed to Visit Report Completed (Region Manager View) (Report CDA-CO-1104)
- KPI Summary - Visit Report Completed to Approved (Region Manager View) (Report CDA-CO-1105)

Map of Study Sites Page

The Map of Study Sites page includes the following report:

- High Level Study-Site Map (Report CDA-CO-1202)

Study Overview Dashboard

This dashboard can be accessed by a Study Manager or CRA. It provides reports related to study status and performance, site performance within the study, subject recruitment and retention, investigator performance, site performance, study region performance, site monitoring and document tracking.

This dashboard includes the following prompts, which are common to all its pages:

- **Program**: Lists the name of the Programs that owns the Study.
- **Study**: Lists Studies within a Program.
- **Study Status**: Lists Study Status for a Study.
- **Study Manager**: Lists Study Manager for a Study.

Study Overview Dashboard Pages

This dashboard includes the following tabbed pages:

- Study Overview Page
- Study-Site Milestones Page
- Screening Overview Page
- Recruitment Overview Page
- Retention Overview Page
- Top Investigators Page
- Non Performing Investigators Page
- Site Performance Page
- Site Region Performance Page
- Monitoring Metrics Page
- Site Document List Page
- Site Document Metrics Page
- Study Team Page
- Map of Study Sites Page

Study Overview Page Displays reports that contain identifying information for a study as well has high level overviews of milestones and subject recruitment and retention.

The Study Overview page includes the following page-specific prompts:

- **Study Region**: Supplemental prompt for those reports that don't make sense unless run for a small set of study-sites or study regions.
- **Year and Month Between**: Supplemental prompt for those reports that include charts displaying data over time.

The Study Overview page includes the following reports:

- Study Information (Report CDA-CO-103)
- Subject Retention (Report CDA-CO-504)
- Study Milestone with Indicators (Study Overview) (Report CDA-CO-101)
- Enrollment Progress Over Time (Study Level) (Report CDA-CO-408)

Study-Site Milestones Page Displays a report that lists all sites for the study and which milestones have been met.

The Study-Site Milestones page includes the following page-specific prompts:

- **Study Region**: Supplemental prompt for those reports that don't make sense unless run for a small set of study-sites or study regions.
- **Study-Site ID#**: List of Study-Sites for a Study.

The Study-Site Milestones page includes the following reports:

- Study Site Milestones with Indicators - Data Management View (Report CDA-CO-208A)
- Study Site Milestones with Indicators - Monitoring View (Report CDA-CO-208B)
- Study Site Milestones with Indicators - Recruitment Detail View (Report CDA-CO-208C)

- Study Site Milestones with Indicators - Retention Detail View (Report CDA-CO-208D)
- Study Site Milestones with Indicators - Site Start Up Detail View (Report CDA-CO-208E)
- Study Site Milestones with Indicators - Study Close Detail View (Report CDA-CO-208F)
- Study Site Milestones with Indicators - Summary View (Report CDA-CO-208G)

Screening Overview Page Displays reports on a study's progress toward screening, including screen failure reason analysis.

The Screening Overview page includes the following page-specific prompt:

- **Metric is in Top**: Supplemental prompt for those reports that might display a long list of metrics.

The Screening Overview page includes the following reports:

- Screening Overview (Study Level) (Report CDA-CO-407)
- Screening vs. Enrollment by Region (Report CDA-CO-400)
- Screen Failure Reason by Site (Report CDA-CO-300)
- Screen Failure Reason (Report CDA-CO-425)

Recruitment Overview Page Displays reports on a study's progress toward recruitment, including recruitment over time.

The Recruitment Overview page includes the following page-specific prompts:

- **Study Region**: Supplemental prompt for those reports that don't make sense unless run for a small set of study-sites or study regions.
- **Year and Month Between**: Supplemental prompt for those reports that include charts displaying data over time.

The Recruitment Overview page includes the following reports:

- Enrollment Progress Over Time (Study Level) (Report CDA-CO-408)
- Study-Region List and Recruitment Counts (Report CDA-CO-404)

Retention Overview Page Displays reports on a study's retention pattern, including withdrawn reason analysis and retention vs. enrollment over time.

The Retention Overview page includes the following page-specific prompts:

- **Year and Month Between**: Supplemental prompt for those reports that include charts displaying data over time.
- **Metric is in Top**: Supplemental prompt for those reports that might display a long list of metrics.

The Retention Overview page includes the following reports:

- Subject Retention (Study Level) (Report CDA-CO-503)
- Subject Retention Over Time (Study Level) (Report CDA-CO-501)
- Withdrawn Reason (Report CDA-CO-505)
- Withdrawn Reason Overview (Report CDA-CO-508)

Top Investigators Page Displays reports showing the top N investigators by % site enrollment completed or total enrollment. Also, displays top investigators' contribution compared to all other investigators.

The Top Investigators page includes the following page-specific prompts:

- **Metric is in Top**: Supplemental prompt for those reports that might display a long list of metrics.

The Top Investigators page includes the following reports:

- Top Investigators, % Planned Enrollment Completed (Report CDA-CO-700)
- Top Investigators, Total Enrollment (Report CDA-CO-701)
- Top Investigators Compared to All Investigators for Study, Total Enrollment (Report CDA-CO-702)

Non Performing Investigators Page Displays reports that list initiated sites / investigators enrolling no subjects, or only one subject.

The Non Performing Investigators page includes the following reports:

- Top Investigators, % Planned Enrollment Completed (Report CDA-CO-700)
- Study Sites Initiated but Zero Enrolled (Report CDA-CO-301)
- Study Sites Initiated, only One Subject Enrolled (Report CDA-CO-302)

Site Performance Page Displays reports on the distribution of top performing and non performing investigators.

The Site Performance page includes the following reports:

- Site Recruitment Performance - Single Study (Report CDA-CO-416)
- Site Recruitment Performance (Report CDA-CO-413)
- Site Enrollment Performance Compared to Site Visit Frequency (Report CDA-CO-110)
- Study-Site List by Recruitment Performance Group (Report CDA-CO-401)

Site Region Performance Page Displays reports on the distribution of enrollment across study regions, and by site for each study region.

The Study Region Performance page includes the following reports:

- Total Subject Enrollment by Region (Report CDA-CO-410)
- Subject Enrollment by Region (Report CDA-CO-414)
- Enrollment Overview By Site (Report CDA-CO-426)

Monitoring Metrics Page Displays reports on patterns in site visit length and monthly enrollment, as well as lists outstanding follow up items for the study.

The Monitoring Metrics page includes the following page-specific prompts:

- **Site Visit Start Date Between**: Supplemental prompt for those reports that include charts displaying data over time.
- **Site Visit Type**: Lists types of site visits.

The Monitoring Metrics page includes the following reports:

- Site Visit Analysis (Report CDA-CO-821)

- Visit Frequency Compared to Subject Enrollment (Report CDA-CO-819)
- Outstanding Follow up Items - Study Overview (Report CDA-CO-805)

Site Document List Page Displays a report that lists document tracking information for study documents.

The Site Document List page includes the following report:

- Study Documents List (Report CDA-CO-600)

Site Document Metrics Page Displays reports on cycle times for site document collection.

The Site Document Metrics page includes the following page-specific prompt:

- **Metric is in Top**: Supplemental prompt for those reports that might display a long list of metrics.

The Site Document Metrics page includes the following reports:

- Document Collection Cycle Times -Turn Around Time by Type (Report CDA-CO-607)
- Document Collection Cycle Times - Days Outstanding by Type (Report CDA-CO-606)
- Document Collection Cycle Times (Study-Site) (Report CDA-CO-604)

Study Team Page

The Study Team page includes the following report:

- Study Team Member List (Report CDA-CO-111)

Map of Study Sites Page

The Map of Study Sites page includes the following report:

- High Level Study-Site Map (Report CDA-CO-1202)

Study-Region Overview Dashboard

This dashboard includes the following prompts, which are common to all its pages:

- **Study**
- **Therapeutic Area**
- **Program**
- **Region**
- **Study-Region**
- **Study-Region Manager**
- **Study Status**
- **Study-Region Status**

Study-Region Overview Dashboard Pages

This dashboard includes the following tabbed pages:

- Overview Page
- Study-Site Milestones Page

- Screening Overview Page
- Recruitment Overview Page
- Retention Overview Page
- Sites to Monitor Page
- Top Investigators Page
- Non Performing Investigators Page
- Site Performance Page
- Monitoring Reports and Follow Up Items Page
- Study-Region Team Page
- Region Document List Page
- Site Document Metrics Page
- Map of Study-Sites Page

Overview Page

Displays report links with the following attributes:

- Section Title - Study-Region Performance Reports
- Show Section Header - True
- Show Section Title - True
- Collapsible - False

The Overview page includes the following reports:

- Study-Region Information (Report CDA-CO-1113)
- Study Region Milestones with Indicators (Single Study-Region) (Report CDA-CO-1116)
- Subject Recruitment (Study Region) (Report CDA-CO-1114)
- Subject Retention (Study Region) (Report CDA-CO-1115)
- Site Initiation Over Time Bar Chart (Study Region) (Report CDA-CO-307)
- Subject Retention Over Time Chart (Study-Region Level) (Report CDA-CO-511)

Study-Site Milestones Page

The Study-Site Milestones page includes the following reports:

- Study-Region Information (Report CDA-CO-1113)
- Study-Site Milestones with Indicators (CRA) - Monitoring View (Report CDA-CO-205A)
- Study-Site Milestones with Indicators (CRA) - Recruitment Detail View (Report CDA-CO-205B)
- Study-Site Milestones with Indicators (CRA) - Retention Detail View (Report CDA-CO-205C)
- Study-Site Milestones with Indicators (CRA) - Site Start Up Detail View (Report CDA-CO-205D)

- Study-Site Milestones with Indicators (CRA) - Study Close Detail View (Report CDA-CO-205E)
- Study-Site Milestones with Indicators (CRA) - Summary View (Report CDA-CO-205F)

Screening Overview Page

The Screening Overview page includes the following reports:

- Screening Overview (Study-Region Level) (Report CDA-CO-434)
- Screening vs. Enrollment by Region (Report CDA-CO-400)
- Screen Failure Reason by Site (Report CDA-CO-300)
- Screen Failure Reason (Report CDA-CO-425)

Recruitment Overview Page

The Recruitment Overview page includes the following page-specific prompt:

- **Year Between**: Supplemental prompt for those reports that include charts displaying data over year.

The Recruitment Overview page includes the following reports:

- Subject Recruitment (Study Region) (Report CDA-CO-1114)
- Enrollment Progress Over Time (Study-Region Level) (Report CDA-CO-435)
- Initiated Study-Sites with Recruitment Counts (Report CDA-CO-412)

Retention Overview Page

The Retention Overview page includes the following page-specific prompt:

- **Year Between**: Supplemental prompt for those reports that include charts displaying data over year.

The Retention Overview page includes the following reports:

- Subject Retention (Study Region) (Report CDA-CO-1115)
- Withdrawn Reason (Report CDA-CO-505)
- Subject Retention Over Time Chart (Study-Region Level) (Report CDA-CO-511)
- Withdrawn Reason Overview (Report CDA-CO-508)

Sites to Monitor Page

The Sites to Monitor page includes the following reports:

- Sites with No Visits Since Initiation - Recruitment Detail View (Report CDA-CO-812A)
- Sites with No Visits Since Initiation - Retention Detail View (Report CDA-CO-812B)
- Sites with No Visits Since Initiation - Summary View (Report CDA-CO-812C)
- Sites to Monitor - Days Since Last Visit - Recruitment Detail View (Report CDA-CO-816A)
- Sites to Monitor - Days Since Last Visit - Retention Detail View (Report CDA-CO-816B)

- Sites to Monitor - Days Since Last Visit - Study Close Detail View (Report CDA-CO-816C)
- Sites to Monitor - Days Since Last Visit - Summary View (Report CDA-CO-816D)

Top Investigators Page

The Top Investigators page includes the following page-specific prompt:

- **Metric is in Top**: Supplemental prompt for those reports that might display a long list of metrics.

The Top Investigators page includes the following reports:

- Top Investigators, % Planned Enrollment Completed (Report CDA-CO-700)
- Top Investigators Compared to All Investigators for Study, Total Enrollment (Report CDA-CO-702)
- Top Investigators, Total Enrollment (Report CDA-CO-701)

Non Performing Investigators Page

The Non Performing Investigators page includes the following reports:

- Study Sites Initiated but Zero Enrolled (Report CDA-CO-301)
- Study Sites Initiated, only One Subject Enrolled (Report CDA-CO-302)

Site Performance Page

The Site Performance page includes the following reports:

- Site Recruitment Performance - Single Study (Report CDA-CO-416)
- Study-Site List by Recruitment Performance Group (Report CDA-CO-401)

Monitoring Reports and Follow Up Items Page

The Monitoring Reports and Follow Up Items page includes the following page-specific prompts:

- **Site Visit Type**: Lists types of site visits.
- **Site Visit Start Date Between**: Supplemental prompt for those reports that include charts displaying data over time.
- **Follow Up Item Type**: Lists types of follow up item.

The Monitoring Reports and Follow Up Items page includes the following report:

- Site Visit Duration - Study-Region (Report CDA-CO-829)
- Site Visit Duration - Study (Report CDA-CO-808)
- Outstanding Monitoring Reports (Study-Region View) (Report CDA-CO-830)
- Outstanding Monitoring Report Approvals (Study-Region) (Report CDA-CO-831)
- Outstanding Follow up Items (Study-Region Overview) (Report CDA-CO-832)

Study-Region Team Page

The Study-Region Team page includes the following page-specific prompts:

- **Active**: Lists active status for team members.
- **Role**: Lists roles for team members.

- **Start Date**: Supplemental prompt for those reports that include charts displaying data over a period of time.
- **End Date**: Supplemental prompt for those reports that include charts displaying data over a period of time.

The Study-Region Team page includes the following report:

- Study-Region Team Member List (Report CDA-CO-1107)

Region Document List Page

The Region Document List page includes the following page-specific prompts:

- **Activity Type**: Lists the Activity Types for documents.
- **Document Name**: Lists the Document Names.
- **Document Sent Date Between**: Date range for Document Sent Date.
- **Document Received Date Between**: Date range for Document Received Date.
- **Document Expiration Date Between**: Date range for Document Expiration Date.

The Region Document List page includes the following report:

- Documents List (Study Region) (Report CDA-CO-610)

Site Document Metrics Page

The Site Document Metrics page includes the following reports:

- Document Collection Cycle Times -Turn Around Time by Type (Report CDA-CO-607)
- Document Collection Cycle Times - Days Outstanding by Type (Report CDA-CO-606)
- Document Collection Cycle Times (Study-Site) (Report CDA-CO-604)

Map of Study-Sites Page

The Map of Study-Sites page includes the following report:

- High Level Study-Site Map (Report CDA-CO-1202)

Study-Site Overview Dashboard

This dashboard can be accessed by a Study Manager or CRA. It provides reports related to site status and performance, subject recruitment and retention within the study-site, site monitoring, and document tracking.

This dashboard includes the following prompts, which are common to all its pages:

- **Program**: Lists the name of the Programs that owns the Study.
- **Study**: Lists Studies within a Program.
- **Study Region**: Lists Regions within a Study.
- **Study-Site ID#**: Lists Study-Sites within a Study.
- **Principal Investigator**: Lists Principal Investigator for a Study-Site.
- **Study-Site Status**: Lists Study Status for a Study.

Study-Site Overview Dashboard Pages

This dashboard includes the following tabbed pages:

- Study-Site Overview Page
- Screening & Recruitment Overview Page
- Retention Overview Page
- Monitoring Metrics Page
- Study-Site Team Page
- Site Document List Page
- Site Document Metrics Page
- Visit Reports & Follow Up Items Page

Study-Site Overview Page Displays reports that contain identifying information for a study-site as well has high level overviews of milestones and subject recruitment and retention.

The Study-Site Overview page includes the following page-specific prompts:

- **Year and Month Between**: Supplemental prompt for those reports that include charts displaying data over time.

The Study-Site Overview page includes the following reports:

- Study-Site Information (Report CDA-CO-206)
- Study-Site Subject Recruitment Narrative (Report CDA-CO-405)
- Study-Site Subject Retention (Report CDA-CO-500)
- Study-Site Milestones with Indicators (Single Study-Site) - Data Management View (Report CDA-CO-203A)
- Study-Site Milestones with Indicators (Single Study-Site) - Monitoring View (Report CDA-CO-203B)
- Study-Site Milestones with Indicators (Single Study-Site) - Recruitment Detail View (Report CDA-CO-203C)
- Study-Site Milestones with Indicators (Single Study-Site) - Retention Detail View (Report CDA-CO-203D)
- Study-Site Milestones with Indicators (Single Study-Site) - Site Start Up Detail View (Report CDA-CO-203E)
- Study-Site Milestones with Indicators (Single Study-Site) - Study Close Detail View (Report CDA-CO-203F)
- Study-Site Milestones with Indicators (Single Study-Site) - Summary View (Report CDA-CO-203G)
- Cumulative Screening and Enrollment Bar (Study-Site) (Report CDA-CO-417)
- Cumulative Enrollment and Early Term (Study-Site) (Report CDA-CO-418)

Screening & Recruitment Overview Page Displays reports on a study-site's progress toward screening and enrollment, including screen failure reason analysis and screening or recruitment over time.

The Screening & Recruitment Overview page includes the following page-specific prompt:

- **Year and Month Between**: Supplemental prompt for those reports that include charts displaying data over time.

The Screening & Recruitment Overview page includes the following reports:

- Screening Overview (Study-Site Level) (Report CDA-CO-415)
- Cumulative Screening and Enrollment Bar (Study-Site) (Report CDA-CO-417)
- Enrollment Progress Over Time (Study-Site Level) (Report CDA-CO-423)
- Screen Failure Reason (Report CDA-CO-420)

Retention Overview Page Displays reports on a study-site's retention pattern, including withdrawn reason analysis and retention vs. enrollment over time.

The Retention Overview page includes the following page-specific prompts:

- **Year and Month Between**: Supplemental prompt for those reports that include charts displaying data over time.
- **Metric is in Top**: Supplemental prompt for those reports that might display a long list of metrics.

The Retention Overview page includes the following reports:

- Subject Retention (Study-Site Level) (Report CDA-CO-502)
- Subject Retention Over Time (Study Level) (Report CDA-CO-501)
- Withdrawn Reason (Report CDA-CO-505)
- Cumulative Enrollment and Early Term (Study-Site) (Report CDA-CO-418)

Monitoring Metrics Page Displays reports on site visit length trends, subject enrollment over time, and distribution of follow up items by type.

The Monitoring Metrics page includes the following page-specific prompts:

- **Site Visit Start Date Between**: Supplemental prompt for those reports that include charts displaying data over time.
- **Site Visit Type**: Lists types of site visits.
- **Metric is in Top**: Supplemental prompt for those reports that might display a long list of metrics.

The Monitoring Metrics page includes the following reports:

- Site Visit Duration - Study Site (Report CDA-CO-800)
- Site Visit Duration - Study (Report CDA-CO-808)
- # Follow Up Items by Type for Study-Site (Report CDA-CO-801)
- Median # Follow Up Items per Site for Study (Report CDA-CO-802)

Study-Site Team Page Displays a report that lists team members assigned to the study-site.

The Study-Site Team page includes the following page-specific prompts:

- **Role**: Lists roles for team members.
- **Team Member Active**: Select the check box for whether or not team member is active.

- **Start Date Between**: Supplemental prompt for those reports that include charts displaying data over a period of time.
- **End Date Between**: Supplemental prompt for those reports that include charts displaying data over a period of time.

The Study-Site Team page includes the following report:

- Study-Site Team Member List (Report CDA-CO-201)

Site Document List Page Displays a report that lists document tracking information for site documents.

The Site Document List page includes the following page-specific prompts:

- **Activity Type**: Lists the Activity Types for documents.
- **Document Name**: Lists the Document Names.
- **Document Sent Date Between**: Date range for Document Sent Date.
- **Document Received Date Between**: Date range for Document Received Date.
- **Document Expiration Date Between**: Date range for Document Expiration Date

The Site Document List page includes the following report:

- Documents List (Study-Site) (Report CDA-CO-603)

Site Document Metrics Page Displays reports on cycle times for site document collection.

The Site Document Metrics page includes the following page-specific prompt:

- **Activity Type**: Lists the Activity Types for documents.
- **Document Name**: Lists the Document Names.
- **Metric is in Top**: Supplemental prompt for those reports that might display a long list of metrics.

The Site Document Metrics page includes the following reports:

- Document Collection Cycle Times -Turn Around Time by Type (Report CDA-CO-607)
- Document Collection Cycle Times - Days Outstanding by Type (Report CDA-CO-606)
- Document Collection Cycle Times (Study-Site) (Report CDA-CO-604)

Visit Reports & Follow Up Items Page Displays reports that contain identifying information for a study as well has high level overviews of milestones and subject recruitment and retention.

The Visit Reports & Follow Up Items page includes the following page-specific prompts:

- **Site Visit Start Date Between**: Supplemental prompt for those reports that include charts displaying data over time.
- **Site Visit Type**: Lists types of site visits.

The Visit Reports & Follow Up Items page includes the following reports:

- Outstanding Monitoring Reports (Study-Site View) (Report CDA-CO-811)
- Outstanding Monitoring Report Approvals (Study-Site) (Report CDA-CO-822)

- Outstanding Follow up Items (Study-Site Overview) (Report CDA-CO-815)

Index Dashboard

This dashboard can be accessed by any user. It provides users with an at a glance listing of all dashboards and analyses and allows users to navigate directly to specific dashboard pages or analyses.

Index Dashboard Pages

This dashboard includes the following tabbed pages:

- Dashboard & Dashboard Page Index Page
- Dashboard Page & Analysis Index Page

Dashboard & Dashboard Page Index Page Displays a listing of all dashboards and dashboard pages.

Dashboard Page & Analysis Index Page Displays a listing of all dashboard pages and their analyses including analyses that do not appear directly on dashboard pages but can only be accessed by navigating from other analyses.

Oracle Health Sciences Clinical Development Analytics Analyses

OHSCDA includes the following analyses:

- # Follow Up Items by Type (Multiple Study-Sites) (Report CDA-CO-810)
- # Follow Up Items by Type for Study-Site (Report CDA-CO-801)
- Approval & Verification Rates - Worst Performers (Report CDA-DM-350)
- Approved Reports that Missed Target: Visit Report Completed to Visit Report Approved (Report CDA-CO-825)
- Average Days from Complete to Initially Approved (Report CDA-DM-325)
- Average Days from Complete to Initially Verified (Report CDA-DM-330)
- Average Duration in Categorized Discrepancy Review Status (Report CDA-DM-210)
- Average Days Discrepancy Open (Report CDA-DM-205)
- Average Duration of Open Discrepancies in Review Statuses (Report CDA-DM-215)
- Completed Reports that Missed Target: Site Visit Completed to Visit Report Completed (Report CDA-CO-823)
- Count of Currently Open Discrepancies by CRF and Type - Top N by Rank (Report CDA-DM-230)
- Counts of Categorized Open Discrepancies, by Review Status (Report CDA-DM-220)
- Counts of Discrepancies, by State and Review Status (Report CDA-DM-225)
- Counts of Open Multivariate Discrepancies, by Procedure (Report CDA-DM-235)
- Cumulative Enrollment and Early Term (Study-Site) (Report CDA-CO-418)
- Cumulative Screening and Enrollment Bar (Study-Site) (Report CDA-CO-417)

- Detail Study-Site Map (Report CDA-CO-1201)
- Detailed Study Milestones Report (Report CDA-CO-102)
- Discrepancies per Pages Entered - Top N (Report CDA-DM-255)
- Discrepancies per Subjects Enrolled - Top N (Report CDA-DM-250)
- Discrepancy Overview with Ratios (Report CDA-DM-240)
- Document Collection Cycle Times - Days Outstanding by Type (Report CDA-CO-606)
- Document Collection Cycle Times (Study-Site) (Report CDA-CO-604)
- Document Collection Cycle Times -Turn Around Time by Type (Report CDA-CO-607)
- Documents List (Multiple Study-Sites) (Report CDA-CO-601)
- Documents List (Study Region) (Report CDA-CO-610)
- Documents List (Study-Site) (Report CDA-CO-603)
- Enrollment Overview By Site (Report CDA-CO-426)
- Enrollment Progress Over Time (Study Level) (Report CDA-CO-408)
- Enrollment Progress Over Time (Study-Region Level) (Report CDA-CO-435)
- Enrollment Progress Over Time (Study-Site Level) (Report CDA-CO-423)
- Executive Study-Site Map (Report CDA-CO-1203)
- High Level Study-Site Map (Report CDA-CO-1202)
- Initiated Study-Sites with Recruitment Counts (Report CDA-CO-412)
- Investigator Contact and Studies List (Report CDA-CO-202)
- Key Cycle Times for Paper Studies (Report CDA-DM-400)
- Key EDC Cycle Times (Report CDA-DM-300)
- Key EDC Processing Volumes (Report CDA-DM-305)
- Key Paper Processing Volumes (Report CDA-DM-405)
- Key Performance Indicators Over Time - Monitoring (Region Manager) (Report CDA-CO-1112)
- Key Performance Indicators Over Time (Executive View) (Report CDA-CO-902)
- KPI Summary - CDP Complete to Site Initiated (Executive View) (Report CDA-CO-905)
- KPI Summary - CDP Completed to Site Initiated (Region Manager View) (Report CDA-CO-1103)
- KPI Summary - LSLV to Database Lock (Executive View) (Report CDA-CO-906)
- KPI Summary - Protocol Approved to 1st Site Initiated (Executive View) (Report CDA-CO-907)
- KPI Summary - Protocol Approved to 1st Subject Enrolled (Executive View) (Report CDA-CO-908)
- KPI Summary - Site Visit Completed to Visit Report Completed (Executive View) (Report CDA-CO-909)

- KPI Summary - Site Visit Completed to Visit Report Completed (Region Manager View) (Report CDA-CO-1104)
- KPI Summary - Visit Report Completed to Approved (Region Manager View) (Report CDA-CO-1105)
- KPI Summary - Visit Report Completed to Visit Report Approved (Executive View) (Report CDA-CO-910)
- List Discrepancy Details (Report CDA-DM-245)
- List of Follow Up Items (Report CDA-CO-803)
- Listing of Subject-Pages, Awaiting EDC Processing (Report CDA-DM-310)
- Listing of Subject-Pages, Awaiting Paper Processing (Report CDA-DM-410)
- Low Approved to Entered Rate - Worst Performers (Report CDA-DM-335)
- Low Verified to Entered Rate - Worst Performers (Report CDA-DM-340)
- Median # Follow Up Items per Site for Study (Report CDA-CO-802)
- Monitoring Report Approval - Turnaround Time vs. Goal (Report CDA-CO-813)
- Monitoring Report Approval Turnaround Times (Report CDA-CO-817)
- Monitoring Report Completion Turnaround Times (Report CDA-CO-820)
- Monitoring Status Overview (Region Manager View) (Report CDA-CO-1101)
- Monitoring Status Overview (Study Manager View) (Report CDA-CO-107)
- Number of Studies (Report CDA-CO-1001)
- Outstanding Approvals at Risk of Missing Target: Visit Report Completed to Visit Report Approved (Report CDA-CO-826)
- Outstanding Approvals that Missed Target: Visit Report Completed to Visit Report Approved (Report CDA-CO-828)
- Outstanding Documents List (Report CDA-CO-602)
- Outstanding Follow up Items - Study Overview (Report CDA-CO-805)
- Outstanding Follow up Items (CRA View) (Report CDA-CO-806)
- Outstanding Follow up Items (Study Manager View) (Report CDA-CO-807)
- Outstanding Follow up Items (Study-Region Overview) (Report CDA-CO-832)
- Outstanding Follow up Items (Study-Site Overview) (Report CDA-CO-815)
- Outstanding Monitoring Report Approvals (CRA View) (Report CDA-CO-814)
- Outstanding Monitoring Report Approvals (Study Manager View) (Report CDA-CO-809)
- Outstanding Monitoring Report Approvals (Study-Region) (Report CDA-CO-831)
- Outstanding Monitoring Report Approvals (Study-Site) (Report CDA-CO-822)
- Outstanding Monitoring Reports (CRA View) (Report CDA-CO-804)
- Outstanding Monitoring Reports (Study-Region View) (Report CDA-CO-830)
- Outstanding Monitoring Reports (Study-Site View) (Report CDA-CO-811)
- Outstanding Reports at Risk of Missing Target: Visit Completed to Visit Report Completed (Report CDA-CO-824)

- Outstanding Reports that Missed Target - Site Visit Completed to Visit Report Completed (Report CDA-CO-827)
- Pages Awaiting Entry Completion (Report CDA-DM-450)
- Paper Processing - Longest Cycle Times (Report CDA-DM-415)
- Performance Metrics Summary Narrative - Site Visit (Report CDA-CO-1110)
- Screen Failure Reason (Report CDA-CO-420)
- Screen Failure Reason (Report CDA-CO-425)
- Screen Failure Reason by Site (Report CDA-CO-300)
- Screening Overview (Study Level) (Report CDA-CO-407)
- Screening Overview (Study-Region Level) (Report CDA-CO-434)
- Screening Overview (Study-Site Level) (Report CDA-CO-415)
- Screening vs. Enrollment by Region (Report CDA-CO-400)
- Site Detail (Report CDA-CO-209)
- Site Enrollment Performance Compared to Site Visit Frequency (Report CDA-CO-110)
- Site Initiation Over Time Bar Chart (Study Region) (Report CDA-CO-307)
- Site Recruitment Performance - Single Study (Report CDA-CO-416)
- Site Recruitment Performance (Report CDA-CO-413)
- Site Recruitment Performance Charts (Executive View) (Report CDA-CO-436)
- Site Visit Analysis (Report CDA-CO-821)
- Site Visit Duration - Study (Report CDA-CO-808)
- Site Visit Duration - Study Site (Report CDA-CO-800)
- Site Visit Duration - Study-Region (Report CDA-CO-829)
- Sites to Monitor - Days Since Last Visit - Recruitment Detail View (Report CDA-CO-816A)
- Sites to Monitor - Days Since Last Visit - Retention Detail View (Report CDA-CO-816B)
- Sites to Monitor - Days Since Last Visit - Study Close Detail View (Report CDA-CO-816C)
- Sites to Monitor - Days Since Last Visit - Summary View (Report CDA-CO-816D)
- Sites with No Visits Since Initiation - Recruitment Detail View (Report CDA-CO-812A)
- Sites with No Visits Since Initiation - Retention Detail View (Report CDA-CO-812B)
- Sites with No Visits Since Initiation - Summary View (Report CDA-CO-812C)
- Study Documents List (Report CDA-CO-600)
- Study Information (Report CDA-CO-103)
- Study List - Initiation Details (Report CDA-CO-305)
- Study List - KPI Performance (Report CDA-CO-904)

- Study List - Milestone Performance (Report CDA-CO-109)
- Study List - Recruitment Details (Report CDA-CO-406)
- Study Milestone with Indicators (Study Overview) (Report CDA-CO-101)
- Study Region Milestones with Indicators (Report CDA-CO-1106)
- Study Region Milestones with Indicators (Single Study-Region) (Report CDA-CO-1116)
- Study Region vs. Study - Site Start Up KPIs (Report CDA-CO-1111)
- Study Regions with Red or Yellow Performance Flag (Report CDA-CO-1200)
- Study Site Milestones with Indicators - Data Management View (Report CDA-CO-208A)
- Study Site Milestones with Indicators - Monitoring View (Report CDA-CO-208B)
- Study Site Milestones with Indicators - Recruitment Detail View (Report CDA-CO-208C)
- Study Site Milestones with Indicators - Retention Detail View (Report CDA-CO-208D)
- Study Site Milestones with Indicators - Site Start Up Detail View (Report CDA-CO-208E)
- Study Site Milestones with Indicators - Study Close Detail View (Report CDA-CO-208F)
- Study Site Milestones with Indicators - Summary View (Report CDA-CO-208G)
- Study Sites Initiated but Zero Enrolled (Report CDA-CO-301)
- Study Sites Initiated, only One Subject Enrolled (Report CDA-CO-302)
- Study Team Member List (Report CDA-CO-111)
- Study-Region Information (Report CDA-CO-1113)
- Study-Region List - Initiation Details (Report CDA-CO-306)
- Study-Region List - KPI Performance (Report CDA-CO-1108)
- Study-Region List - Milestone Performance (Report CDA-CO-1109)
- Study-Region List - Recruitment Details (Report CDA-CO-433)
- Study-Region List and Recruitment Counts (Report CDA-CO-404)
- Study-Region Team Member List (Report CDA-CO-1107)
- Study-Site Information (Report CDA-CO-206)
- Study-Site List by Recruitment Performance Group (Report CDA-CO-401)
- Study-Site List with Indicators - Data Management View (Report CDA-CO-207A)
- Study-Site List with Indicators - Monitoring View (Report CDA-CO-207B)
- Study-Site List with Indicators - Recruitment Detail View (Report CDA-CO-207C)
- Study-Site List with Indicators - Retention Detail View (Report CDA-CO-207D)
- Study-Site List with Indicators - Site Start Up Detail View (Report CDA-CO-207E)
- Study-Site List with Indicators - Study Close Detail View (Report CDA-CO-207F)
- Study-Site List with Indicators - Summary View (Report CDA-CO-207G)

- Study-Site Milestones with Indicators (CRA) - Monitoring View (Report CDA-CO-205A)
- Study-Site Milestones with Indicators (CRA) - Recruitment Detail View (Report CDA-CO-205B)
- Study-Site Milestones with Indicators (CRA) - Retention Detail View (Report CDA-CO-205C)
- Study-Site Milestones with Indicators (CRA) - Site Start Up Detail View (Report CDA-CO-205D)
- Study-Site Milestones with Indicators (CRA) - Study Close Detail View (Report CDA-CO-205E)
- Study-Site Milestones with Indicators (CRA) - Summary View (Report CDA-CO-205F)
- Study-Site Milestones with Indicators (Single Study-Site) - Data Management View (Report CDA-CO-203A)
- Study-Site Milestones with Indicators (Single Study-Site) - Monitoring View (Report CDA-CO-203B)
- Study-Site Milestones with Indicators (Single Study-Site) - Recruitment Detail View (Report CDA-CO-203C)
- Study-Site Milestones with Indicators (Single Study-Site) - Retention Detail View (Report CDA-CO-203D)
- Study-Site Milestones with Indicators (Single Study-Site) - Site Start Up Detail View (Report CDA-CO-203E)
- Study-Site Milestones with Indicators (Single Study-Site) - Study Close Detail View (Report CDA-CO-203F)
- Study-Site Milestones with Indicators (Single Study-Site) - Summary View (Report CDA-CO-203G)
- Study-Site Subject Recruitment Narrative (Report CDA-CO-405)
- Study-Site Subject Retention (Report CDA-CO-500)
- Study-Site Team Member List (Report CDA-CO-201)
- Study-Sites with Red or Yellow Performance Flag (Report CDA-CO-204)
- Subject Enrollment by Region (Report CDA-CO-414)
- Subject Recruitment (Report CDA-CO-419)
- Subject Recruitment (Study Region) (Report CDA-CO-1114)
- Subject Retention (Report CDA-CO-504)
- Subject Retention (Study Level) (Report CDA-CO-503)
- Subject Retention (Study Region) (Report CDA-CO-1115)
- Subject Retention (Study-Site Level) (Report CDA-CO-502)
- Subject Retention Over Time (Study Level) (Report CDA-CO-501)
- Subject Retention Over Time (Study-Site Level) (Report CDA-CO-510)
- Subject Retention Over Time Chart (Study-Region Level) (Report CDA-CO-511)
- Subjects Enrolled per Month, Over Time (Report CDA-CO-403)

- Subjects who Failed Screening (Report CDA-CO-428)
- Subjects Withdrawn List (Report CDA-CO-509)
- Summary of Subjects Awaiting EDC Processing (Report CDA-DM-320)
- Summary of Subjects Awaiting Paper Processing (Report CDA-DM-420)
- Top Investigators Compared to All Investigators for Study, Total Enrollment (Report CDA-CO-702)
- Top Investigators, % Planned Enrollment Completed (Report CDA-CO-700)
- Top Investigators, Total Enrollment (Report CDA-CO-701)
- Total Subject Enrollment by Region (Report CDA-CO-410)
- Uninitiated Sites (Report CDA-CO-304)
- Visit Frequency Compared to Subject Enrollment (Report CDA-CO-819)
- Withdrawn Reason (Report CDA-CO-505)
- Withdrawn Reason Overview (Report CDA-CO-508)

To locate a report, you need to select a dashboard and access a page that contains the report.

Follow Up Items by Type (Multiple Study-Sites) (Report CDA-CO-810)

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.

Audience

- Study Manager
- Region Manager
- CRA

Report Type

- Graph, Table (optional)

Location

- **CRA** dashboard, **Monitoring Metrics** page
- **Region Manager** dashboard, **Monitoring Metrics** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Detailed Study Milestones Report (Report CDA-CO-102)

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the # Follow Up Items by Type (multiple Study-Sites) report.

Table A–1 # Follow Up Items by Type (multiple Study-Sites) (Report CDA-CO-810)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Study, Site, and Investigator	Study-Site.Study, Site, and Investigator
NA	Count of Follow Up Items	COUNT(- Follow Up Item Metrics.Follow Up Item Created Date)
NA	Follow Up Item Type	Follow Up Item Metrics.Follow Up Item Type

Follow Up Items by Type for Study-Site (Report CDA-CO-801)

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.

Audience

- Study Manager
- CRA

Report Type

- Graph, Table (optional)

Location

- **Study-Site Overview** dashboard, **Monitoring Metrics** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- List of Follow Up Items (Report CDA-CO-803)

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the # Follow Up Items by Type for Study-Site report.

Table A–2 # Follow Up Items by Type for Study-Site (Report CDA-CO-801)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	Count of Follow Up Items	COUNT(- Follow Up Item Metrics.Follow Up Item Created Date)
NA	Follow Up Item Type	Follow Up Item Metrics.Follow Up Item Type

Approval & Verification Rates - Worst Performers (Report CDA-DM-350)

Identifies the top combined approval and verification rates for EDC studies. This report can be used to compare across sites to see quickly identify which sites and CRAs are taking the longest to approve and verify pages. This indicates the resource shortfalls, process inefficiencies, and potential training needs.

Audience

- Data Manager
- CRA
- Project Manager

Report Type

- Graph, table (optional)

Location

- **Data Manager - EDC** dashboard, **Home** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Approval and Verification Rates - Worst Performers report.

Table A–3 Approval and Verification Rates - Worst Performers (Report CDA-DM-350)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	Study	Study-Site.Study Name
NA	Approved	Received CRFs.% eCRFs Approved / Entry Complete
NA	Verified	Received CRFs.% eCRFs Verified / Entry Complete

Approved Reports that Missed Target: Visit Report Completed to Visit Report Approved (Report CDA-CO-825)

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.

Audience

- Region Manager

Report Type

- Table

Location

None

Dimensions

- Study-Site, Site Visit

Supplementary Prompts

- NA

Reports Referenced

None

Reports Referencing This Report

You can navigate to the following reports from this report:

- Performance Metrics Summary Narrative - Site Visit (Report CDA-CO-1110)

Column Descriptions

Table A–4 describes the columns in the Approved Reports that Missed Target: Visit Report Completed to Visit Report Approved analysis

Table A–4 Approved Reports that Missed Target: Visit Report Completed to Visit Report Approved (Report CDA-CO-825)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study	"Study-Site"."Study"
Study-Site	Study Region	"Study-Site"."Study Region"
Study-Site	Study-Site ID #	"Study-Site"."Study-Site ID #"
Study-Site	Principal Investigator	"Study-Site"."Principal Investigator"
Study-Site	Study-Site Status	"Study-Site"."Study-Site Status"
Site Visit	Site Visit Name	"Site Visit"."Site Visit Name"
Site Visit	Site Visit Type	"Site Visit"."Site Visit Type"
Site Visit	Site Visit Start Date	"Site Visit"."Site Visit Start Date"
Site Visit	Site Visit Completed Date	"Site Visit"."Site Visit Completed Date"
Site Visit	Site Visit Report Completed Date	"Site Visit"."Site Visit Report Completed Date"
Site Visit	[Site Visit Report Approved Date]	"Site Visit"."[Site Visit Report Approved Date]"
Overall Level Targets	[Target Visit Report Completed to Visit Report Approved (# Days)]	"Overall Level Targets"."[Target Visit Report Completed to Visit Report Approved (# Days)]"
- Site Visit Metrics	[# Days from Visit Report Completed to Visit Report Approved]	"- Site Visit Metrics"."[# Days from Visit Report Completed to Visit Report Approved]"

Average Days from Complete to Initially Approved (Report CDA-DM-325)

Identifies the average number of days for eCRFs to be approved following entry completion. This report indicates the lag between when an eCRF was entered to when it was initially approved. This measure can be used to compare site performance, and to highlight poor performing sites. When compared across studies, it can be an indicator of study site team inefficiencies.

Audience

- Data Manager
- CRA
- Project Manager

Report Type

- Graph, table (optional)

Location

- **CRA** dashboard, **Performance** page
- **Data Manager - EDC** dashboard, **Performance** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Average Days from Complete to Initially Approved - Top 25 report.

Table A–5 Average Days from Complete to Initially Approved - Top N (Report CDA-DM-325)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	Study	Study-Site.Study Name
NA	Avg # Days from eCRF Entry Complete to Initially Approved	Received CRFs.Avg # Days from eCRF Entry Complete to Initially Approved

Average Days from Complete to Initially Verified (Report CDA-DM-330)

Identifies the average number of days for eCRFs to be verified following entry completion. This report indicates the lag between when an eCRF was entered to when it was initially verified. This measure can be used to compare site performance, and can be used to infer the performance of the sites' CRA. When compared across studies, it can be an indicator of study team inefficiencies.

Audience

- Data Manager
- CRA
- Project Manager

Report Type

- Graph, table (optional)

Location

- **CRA** dashboard, **Performance** page
- **Data Manager - EDC** dashboard, **Performance** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Average Days from Complete to Initially Verified - Top 25 report.

Table A–6 Average Days from Complete to Initially Verified - Top (Report CDA-DM-330)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	Study	Study-Site.Study Name
NA	Avg # Days from eCRF Complete to Initially Verified	Received CRFs.Avg # Days from eCRF Complete to Initially Verified

Average Duration in Categorized Discrepancy Review Status (Report CDA-DM-210)

Identifies the average number of days discrepancies are within a grouping of review status. This report indicates which functional teams (or categories) are taking the longest to resolve or progress a discrepancy. This information can be used to identify process and resource inefficiencies.

Audience

- Data Manager
- CRA
- Project Manager

Report Type

- Table Pivot table: rows=Study; columns=Categorized Review Status; cells=Average duration in Review Status, in days

Location

- **CRA** dashboard, **Performance** page
- **Data Manager - EDC** dashboard, **Performance** page
- **Data Manager - Paper** dashboard, **Performance** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Average Duration in Categorized Discrepancy Review Status report.

Table A–7 Average Duration in Categorized Discrepancy Review Status (Report CDA-DM-210)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study-Site	Study Name	Study-Site.Study Name
Discrepancies	State	Discrepancies.Discrepancy State
Discrepancies	Categorized Review Status	Discrepancy Review Statuses.Discrepancy Review Status
Discrepancies	Average duration in Review Status	Discrepancy Review Statuses.Avg # Days Discrepancy Ever in Review Status
Discrepancies	# Discrepancies	Discrepancies.# Total Discrepancies

Average Days Discrepancy Open (Report CDA-DM-205)

Identifies distribution of open discrepancies, by the number of days they have been open. This report indicates which sites have the oldest currently open discrepancies.

Audience

- Data Manager
- CRA

Report Type

- Graph, table (optional)

Location

- **Data Manager - EDC** dashboard, **Home** page
- **Data Manager - EDC** dashboard, **Study Discrepancies** page
- **Data Manager - Paper** dashboard, **Home** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- List Discrepancy Details (Report CDA-DM-245)

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Average Duration of Currently Open Discrepancies, by Site report.

Table A–8 Average Duration of Currently Open Discrepancies, by Site (Report CDA-DM-205)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	Site Name	Study Site.Site Name
NA	Avg Duration of Currently Open Discrepancies	Study-site Metrics.Avg Duration of Currently Open Discrepancies

Average Duration of Open Discrepancies in Review Statuses (Report CDA-DM-215)

Identifies the average number of days discrepancies are open within a review status. This report indicates the average length of time that discrepancies are remaining at a specific review state. This information can be used to identify process and resource inefficiencies.

Audience

- Data Manager
- CRA
- Project Manager

Report Type

- Table Pivot table: rows=Study; columns=Review Status; cells=Average duration in Review Status Graph

Location

- **Data Manager - EDC** dashboard, **Performance** page
- **Data Manager - Paper** dashboard, **Performance** page

Dimensions

- Study-Site

Supplementary Prompts

- Discrepancies.Discrepancy State

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Average Duration of Open Discrepancies in Review Statuses report.

Table A–9 Average Duration of Open Discrepancies in Review Statuses (Report CDA-DM-215)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	Study Name	Study-Site.Study Name
NA	Review Status	Discrepancy Review Statuses.Discrepancy Review Status
NA	Average duration in Review Status, in Days	Discrepancy Review Statuses.Avg # Days Open Discrepancy Ever in Review Status

Completed Reports that Missed Target: Site Visit Completed to Visit Report Completed (Report CDA-CO-823)

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.

Audience

- Region Manager

Report Type

- Table

Location

None

Dimensions

- Study-Site, Site Visit

Supplementary Prompts

- NA

Reports Referenced

None

Reports Referencing This Report

You can navigate to the following reports from this report:

- Performance Metrics Summary Narrative - Site Visit (Report CDA-CO-1110)

Column Descriptions

Table A–10 describes the columns in the Completed Reports that Missed Target: Site Visit Completed to Visit Report Completed analysis

Table A–10 Completed Reports that Missed Target: Site Visit Completed to Visit Report Completed (Report CDA-CO-823)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study	"Study-Site"."Study"
Study-Site	Study Region	"Study-Site"."Study Region"
Study-Site	Study-Site ID #	"Study-Site"."Study-Site ID #"
Study-Site	Principal Investigator	"Study-Site"."Principal Investigator"
Study-Site	Study-Site Status	"Study-Site"."Study-Site Status"

Table A–10 (Cont.) Completed Reports that Missed Target: Site Visit Completed to Visit Report Completed (Report CDA-CO-823)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Site Visit	Site Visit Name	"Site Visit"."Site Visit Name"
Site Visit	Site Visit Type	"Site Visit"."Site Visit Type"
Site Visit	Site Visit Start Date	"Site Visit"."Site Visit Start Date"
Site Visit	Site Visit Completed Date	"Site Visit"."Site Visit Completed Date"
Overall Level Targets	[Target Site Visit Completed to Visit Report Completed (# Days)]	"Overall Level Targets"."[Target Site Visit Completed to Visit Report Completed (# Days)]"
- Site Visit Metrics	# Days from Site Visit Completed to Visit Report Completed	"- Site Visit Metrics"."# Days from Site Visit Completed to Visit Report Completed"

Count of Currently Open Discrepancies by CRF and Type - Top N by Rank (Report CDA-DM-230)

Identifies the top CRFs which are producing the most discrepancies. A CRF which is associated with a high number of discrepancies is often an indication that the validation procedure or the CRF have been poorly designed. Alternatively, it can indicate a misunderstanding on the completion guidelines for the CRF, and can therefore imply a training need for the study site. Early identification of such issues, at an early stage in the study, can dramatically reduce the number of discrepancies created.

Audience

- Data Manager

Report Type

- Graph, table (optional)

Location

- **Data Manager - EDC** dashboard, **Home** page
- **Data Manager - EDC** dashboard, **Study Discrepancies** page
- **Data Manager - Paper** dashboard, **Home** page

Dimensions

- CRF

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- List Discrepancy Details (Report CDA-DM-245)

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Count of Currently Open Discrepancies by CRF and Type - Top N by Rank report.

Table A–11 Count of Currently Open Discrepancies by CRF and Type - Top N by Rank (Report CDA-DM-230)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	CRF Name	CRF.Name
NA	# Open Discrepancies	Discrepancies.# Open Discrepancies
NA	Type	Discrepancies.Type

Counts of Categorized Open Discrepancies, by Review Status (Report CDA-DM-220)

Identifies how many discrepancies are open, by review status. This report indicates the number of open discrepancies, within a number of categorized review groups. This information can be used to identify which functional team or area has the most outstanding discrepancies, which could indicate a resource shortage.

Audience

- Data Manager
- CRA
- Project Manager

Report Type

- Table Pivot table: rows=Study; columns=Categorized Review Status; cells=#Open Discrepancies Graph attached to the Pivot table

Location

- **Data Manager - EDC** dashboard, **Discrepancy Workload** page
- **Data Manager - Paper** dashboard, **Discrepancy Workload** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- List Discrepancy Details (Report CDA-DM-245)

Reports Referencing This Report

You can navigate to this report from the following reports:

- Discrepancy Overview with Ratios (Report CDA-DM-240)

Column Descriptions

The table describes the columns in the Counts of Categorized Open Discrepancies, by Review Status report.

Table A–12 Counts of Categorized Open Discrepancies, by Review Status (Report CDA-DM-220)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study-Site	Study Name	Study-Site.Study Name
Discrepancies	Categorized Review Status	Discrepancy Review Statuses.Discrepancy Review Status
Discrepancies	# Open Discrepancies	Discrepancies.# Total Discrepancies

Counts of Discrepancies, by State and Review Status (Report CDA-DM-225)

Identifies the number of open and closed discrepancies, by review status. This report indicates which review states are creating the largest volumes of discrepancies. This information can be used to identify high discrepancy volumes with a review state which may indicate lack of resource or process inefficiency.

Audience

- Data Manager
- Project Manager

Report Type

- Table Pivot table: rows=Study; columns=Review Status; cells=#Discrepancies

Location

- **Data Manager - EDC** dashboard, **Discrepancy Workload** page
- **Data Manager - Paper** dashboard, **Discrepancy Workload** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Counts of Discrepancies, by State and Review Status report.

Table A–13 Counts of Discrepancies, by State and Review Status (Report CDA-DM-225)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study-Site	Study	Study-Site.Study Name
Discrepancies	Review Status	Discrepancy Review Statuses.Discrepancy Review Status
Discrepancies	State	Discrepancies.Discrepancy State
Discrepancies	# Discrepancies	Discrepancies.# Total Discrepancies

Counts of Open Multivariate Discrepancies, by Procedure (Report CDA-DM-235)

Identifies the distribution of discrepancies, by validation procedure. This report indicates which validation procedures are creating the most discrepancies. A procedure which is associated with a high number of discrepancies is often an indication that the validation procedure has been poorly designed, or that the related actual data exceeds any expected parameters.

Alternatively, it may indicate a misunderstanding on the completion guidelines for the CRF, and may therefore imply a training need for the study site. Early identification of such issues, at an early stage in the study, can dramatically reduce the number of discrepancies created.

Audience

- Data Manager

Report Type

- Graph, Table (optional)

Location

- **Data Manager - EDC** dashboard, **Home** page
- **Data Manager - EDC** dashboard, **Study Discrepancies** page
- **Data Manager - Paper** dashboard, **Home** page

Dimensions

None

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- List Discrepancy Details (Report CDA-DM-245)

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Counts of Open Multivariate Discrepancies, by Procedure report.

Table A–14 Counts of Open Multivariate Discrepancies, by Procedure (Report CDA-DM-235)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Discrepancies	Validation Procedure Name	Discrepancies.Validation Procedure Name
Discrepancies	# Open Discrepancies	Discrepancies.# Open Discrepancies

Cumulative Enrollment and Early Term (Study-Site) (Report CDA-CO-418)

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.

Audience

- Study Manager
- CRA

Report Type

- Graph, Table (optional)

Location

- **Study-Site Overview** dashboard, **Study-Site Overview, Retention Overview** page

Dimensions

- All-Purpose Date

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Cumulative Enrollment and Early Term (Study-Site) report.

Table A–15 Cumulative Enrollment and Early Term (Study-Site) (Report CDA-CO-418)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Year and Month	All Purpose Date.Year and Month
NA	# Subjects Planned for Study-Site	MAX(- Study-site Metrics.# Subjects Planned for Study-Site)
NA	# Enrolled	RSUM(- Study-site Metrics.# Subjects Enrolled)
NA	# Early Terminations	Study-site Metrics.# Early Terminations

Cumulative Screening and Enrollment Bar (Study-Site) (Report CDA-CO-417)

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.

Audience

- Study Manager
- CRA

Report Type

- Graph, Table (optional)

Location

- **Study-Site Overview** dashboard, **Study-Site Overview** page
- **Study-Site Overview** dashboard, **Screening and Recruitment Overview** page

Dimensions

- All-Purpose Date

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Cumulative Screening and Enrollment Bar (Study-Site) report.

Table A–16 Cumulative Screening and Enrollment Bar (Study-Site) (Report CDA-CO-417)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Year and Month	All Purpose Date.Year and Month
NA	# Subjects Planned for Study-Site	MAX(- Study-site Metrics.# Subjects Planned for Study-Site)
NA	# Screened	RSUM(- Study-site Metrics.# Screened)
NA	# Enrolled	RSUM(- Study-site Metrics.# Subjects Enrolled)

Detail Study-Site Map (Report CDA-CO-1201)

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.

Audience

- CRA

Report Type

- Map

Location

- **CRA** dashboard, **Study-Site Map** page

Dimensions

None

Supplementary Prompts

- NA

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–17 describes the columns in the Detail Study-Site Map analysis

Table A–17 Detail Study-Site Map (Report CDA-CO-1201)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study-Site ID #	NA
Study-Site	Street Address	NA
Study-Site	City	NA
Study-Site	Country	NA
Study-Site	Latitude	NA
Study-Site	Longitude	NA
Study-Site Metrics	# Enrolled	NA
Study-Site Metrics	# Days Since Last Enrollment for Study-Site	NA
Study-Site Metrics	# Subjects Enrolled Since Latest Site Visit	NA
Study-Site Metrics	# Days Since Latest Site Visit	NA

Detailed Study Milestones Report (Report CDA-CO-102)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study Manager** dashboard, **Study Manager Overview** page
- **Executive Overview** dashboard, **Study List**

Dimensions

- Study

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Detailed Study Milestones Report.

Table A–18 Detailed Study Milestones Report (Report CDA-CO-102)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study	Program	Study.Program
NA	Product	Study.Product
NA	Study	Study.Study
NA	Short Title	Study.Study Short Title
NA	Status	Study.Study Status
NA	Study Manager	Study.Study Manager
NA	Navigate to detail	NA
- Study Original Planned Dates	Planned 1st Site Initiated Date	CONCAT(CONCAT('Planned: ',CAST("- Study Original Planned Dates"."Planned 1st Site Initiated Date" AS char)),CONCAT(CONCAT(' LE: ',CAST("- Study Original Planned Dates"."Planned 1st Site Initiated Date" AS CHAR)),CONCAT(' Actual: ',CAST("- Study Metrics"."1st Site Initiated Date" AS CHAR))))

Table A–18 (Cont.) Detailed Study Milestones Report (Report CDA-CO-102)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Original Planned Dates	Planned 1st Site Initiated Date	CONCAT(CONCAT('Planned: ',CAST("- Study Original Planned Dates"."Planned 1st Site Initiated Date" AS char)),CONCAT(CONCAT(' LE: ',CAST("- Study Original Planned Dates"."Planned 1st Site Initiated Date" AS CHAR)),CONCAT(' Actual: ',CAST("- Study Metrics"."1st Site Initiated Date" AS CHAR))))
- Study Metrics	1st Site Initiated Date	CONCAT(CONCAT('Planned: ',CAST("- Study Original Planned Dates"."Planned 1st Site Initiated Date" AS char)),CONCAT(CONCAT(' LE: ',CAST("- Study Original Planned Dates"."Planned 1st Site Initiated Date" AS CHAR)),CONCAT(' Actual: ',CAST("- Study Metrics"."1st Site Initiated Date" AS CHAR))))
- Study Original Planned Dates	[Planned Last Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Site Initiated Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Site Initiated Date]"as char(40)))
- Study Latest Estimated Dates	[Planned LE Last Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Site Initiated Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Site Initiated Date]"as char(40)))

Table A–18 (Cont.) Detailed Study Milestones Report (Report CDA-CO-102)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Metrics	Latest Site Initiated Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Site Initiated Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Site Initiated Date]"as char(40)))
- Study Metrics	[Last Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Site Initiated Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Site Initiated Date]"as char(40)))
- Study Targets	[Expected Screen Failure Rate]	CONCAT('Expected:',cast(MIN("- Study Targets"."[Expected Screen Failure Rate]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."Screen Failure Rate" as char(40)))
- Study Metrics	Screen Failure Rate	CONCAT('Expected:',cast(MIN("- Study Targets"."[Expected Screen Failure Rate]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."Screen Failure Rate" as char(40)))
- Study Metrics	% Planned Subjects Enrolled (Study)	CONCAT('Actual:' , cast(MAX("- Study Metrics"."% Planned Subjects Enrolled (Study)") as char(40)))
- Study Metrics	% Planned Subjects Randomized (Study)	CONCAT('Actual:' , cast(MAX("- Study Metrics"."% Planned Subjects Randomized (Study)") as char(40)))
- Study Targets	Expected Early Termination Rate	CONCAT('Expected:',cast(MIN("- Study Targets"."Expected Early Termination Rate") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."% Subjects Early Terminated for Study" as char(40)))

Table A–18 (Cont.) Detailed Study Milestones Report (Report CDA-CO-102)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Metrics	% Subjects Early Terminated for Study	CONCAT('Expected:',cast(MIN("- Study Targets"."Expected Early Termination Rate") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."% Subjects Early Terminated for Study" as char(40)))
- Study Metrics	% of Planned Sites Initiated	"- Study Metrics"."% of Planned Sites Initiated"
- Study Original Planned Dates	[Planned 1st Subject Screened Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Screened Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject Screened Date" as char(40)))
- Study Latest Estimated Dates	[Planned LE 1st Subject Screened Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Screened Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject Screened Date" as char(40)))
- Study Metrics	1st Subject Screened Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Screened Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject Screened Date" as char(40)))
- Study Original Planned Dates	[Planned 1st Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject Enrolled Date" as char(40)))

Table A–18 (Cont.) Detailed Study Milestones Report (Report CDA-CO-102)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Latest Estimated Dates	[Planned LE 1st Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject Enrolled Date" as char(40)))
- Study Metrics	1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject Enrolled Date" as char(40)))
- Study Original Planned Dates	[Planned 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject Randomized Date" as char(40)))
- Study Latest Estimated Dates	[Planned LE 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject Randomized Date" as char(40)))
- Study Metrics	1st Subject Randomized Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject Randomized Date" as char(40)))

Table A–18 (Cont.) Detailed Study Milestones Report (Report CDA-CO-102)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Original Planned Dates	[Planned 1st Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study Latest Estimated Dates	[Planned LE 1st Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study Metrics	1st Subject 1st Visit Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study Original Planned Dates	[Planned Last Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Enrollment Date" as char(40)))||' '||CONCAT(' ActualL(Last):',cast("- Study Metrics"."[Last Subject Enrolled Date]" as char(40)))

Table A–18 (Cont.) Detailed Study Milestones Report (Report CDA-CO-102)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Latest Estimated Dates	[Planned LE Last Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Enrollment Date" as char(40)))||' '||CONCAT(' ActualL(Last):',cast("- Study Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study Metrics	Latest Subject Enrollment Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Enrollment Date" as char(40)))||' '||CONCAT(' ActualL(Last):',cast("- Study Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study Metrics	[Last Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Enrollment Date" as char(40)))||' '||CONCAT(' ActualL(Last):',cast("- Study Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study Original Planned Dates	[Planned Last Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Randomized Date]" as char(40)))

Table A–18 (Cont.) Detailed Study Milestones Report (Report CDA-CO-102)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Randomized Date" as char(40))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study Metrics	Latest Subject Randomized Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Randomized Date" as char(40))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study Metrics	[Last Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Randomized Date" as char(40))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study Original Planned Dates	[Planned Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject 1st Visit Date" as char(40))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject 1st Visit Date]" as char(40)))

Table A–18 (Cont.) Detailed Study Milestones Report (Report CDA-CO-102)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Latest Estimated Dates	[Planned LE Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study Metrics	Latest Subject 1st Visit Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study Metrics	[Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study Original Planned Dates	[Planned Last Subject Last Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Last Visit Date]" as char(40)))

Table A–18 (Cont.) Detailed Study Milestones Report (Report CDA-CO-102)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Latest Estimated Dates	[Planned LE Last Subject Last Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study Metrics	Latest Subject Latest Visit Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study Metrics	[Last Subject Last Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Discrepancies	# Open Discrepancies	"- Discrepancies"."# Open Discrepancies"
- Discrepancies	# Total Discrepancies	"- Discrepancies"."# Total Discrepancies"
- Discrepancies	# Days Discrepancy Open	("- Discrepancies"."# Days Discrepancy Open"/"- Discrepancies"."# Total Discrepancies")
- Discrepancies	# Total Discrepancies	("- Discrepancies"."# Days Discrepancy Open"/"- Discrepancies"."# Total Discrepancies")
- Received CRFs	# eCRFs To Be Approved	CONCAT('Actual:',cast("- Received CRFs"."# eCRFs To Be Approved" as char(40)))

Table A–18 (Cont.) Detailed Study Milestones Report (Report CDA-CO-102)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Received CRFs	# eCRFs To be Verified	CONCAT('Actual:',cast("- Received CRFs"."# eCRFs To be Verified" as char(40)))
- Received CRFs	# CRFs Soft- Locked	CONCAT('Actual:',cast("- Received CRFs"."# CRFs Soft-Locked" as char(40)))
- Received CRFs	% CRFs Soft Locked / Entry Complete	CONCAT('Actual:',cast(("- Received CRFs"."% CRFs Soft Locked / Entry Complete") as char(40)))
- Received CRFs	# CRFs Hard-Locked	CONCAT('Actual:',cast("- Received CRFs"."# CRFs Hard-Locked" as char(40)))
- Received CRFs	% CRFs Hard Locked / Entry Complete	CONCAT('Actual:',cast(("- Received CRFs"."% CRFs Hard Locked / Entry Complete") as char(40)))
- Study Metrics	KPI Flag	"- Study Metrics"."KPI Flag"
- Study Metrics	KPI Detail Reason	"- Study Metrics"."KPI Detail Reason"
Overall Level Targets	[Expected % Sites Recruiting 0 Subjects]	CONCAT('[Overall Target]:',cast(MIN("Overall Level Targets"."[Expected % Sites Recruiting 0 Subjects]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Metrics"."% Sites Recruiting 0 Subjects" as char(40)))
- Study Metrics	% Sites Recruiting 0 Subjects	CONCAT('[Overall Target]:',cast(MIN("Overall Level Targets"."[Expected % Sites Recruiting 0 Subjects]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Metrics"."% Sites Recruiting 0 Subjects" as char(40)))
Overall Level Targets	[Target Protocol Approved to 1st Site Initiated (# Days)]	CONCAT('[Overall Target]:',cast(MIN("Overall Level Targets"."[Target Protocol Approved to 1st Site Initiated (# Days)]") as char(40)))||' '||CONCAT('Actual:' , cast(MAX(ROUND("- Study Metrics"."[Protocol Approved to 1st Site Initiated (# Days)]",1)) as char(40)))
- Study Metrics	[Protocol Approved to 1st Site Initiated (# Days)]	CONCAT('[Overall Target]:',cast(MIN("Overall Level Targets"."[Target Protocol Approved to 1st Site Initiated (# Days)]") as char(40)))||' '||CONCAT('Actual:' , cast(MAX(ROUND("- Study Metrics"."[Protocol Approved to 1st Site Initiated (# Days)]",1)) as char(40)))

Table A–18 (Cont.) Detailed Study Milestones Report (Report CDA-CO-102)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Overall Level Targets	[Target Protocol Approved to 1st Subject Enrolled (# Days)]	CONCAT('[Overall Target]:',cast(MIN("Overall Level Targets"."[Target Protocol Approved to 1st Subject Enrolled (# Days)]") as char(40))||' '||CONCAT(' Actual:' , cast(MAX(ROUND("- Study Metrics"."[Protocol Approved to 1st Subject Enrolled (# Days)]",1)) as char(40)))
- Study Metrics	[Protocol Approved to 1st Subject Enrolled (# Days)]	CONCAT('[Overall Target]:',cast(MIN("Overall Level Targets"."[Target Protocol Approved to 1st Subject Enrolled (# Days)]") as char(40))||' '||CONCAT(' Actual:' , cast(MAX(ROUND("- Study Metrics"."[Protocol Approved to 1st Subject Enrolled (# Days)]",1)) as char(40)))
Overall Level Targets	[Target Critical Document Package Complete to Site Initiated (# Days)]	CONCAT('[Overall Target]:',cast(MIN("Overall Level Targets"."[Target Critical Document Package Complete to Site Initiated (# Days)]") as char(40))||' '||CONCAT(' Actual:' , cast(ROUND("- Study Metrics"."[Median Critical Document Package Complete to Site Initiated (# Days)]",1) as char(40)))
- Study Metrics	[Median Critical Document Package Complete to Site Initiated (# Days)]	CONCAT('[Overall Target]:',cast(MIN("Overall Level Targets"."[Target Critical Document Package Complete to Site Initiated (# Days)]") as char(40))||' '||CONCAT(' Actual:' , cast(ROUND("- Study Metrics"."[Median Critical Document Package Complete to Site Initiated (# Days)]",1) as char(40)))
Overall Level Targets	[Target Site Visit Completed to Visit Report Completed (# Days)]	CONCAT('[Overall Target]:',cast(MIN("Overall Level Targets"."[Target Site Visit Completed to Visit Report Completed (# Days)]") as char(40))||' '||CONCAT(' Actual:' , cast(MAX(ROUND("- Study Metrics"."Median Site Visit Completed to Visit Report Completed (# Days)",1)) as char(40)))
- Study Metrics	Median Site Visit Completed to Visit Report Completed (# Days)	CONCAT('[Overall Target]:',cast(MIN("Overall Level Targets"."[Target Site Visit Completed to Visit Report Completed (# Days)]") as char(40))||' '||CONCAT(' Actual:' , cast(MAX(ROUND("- Study Metrics"."Median Site Visit Completed to Visit Report Completed (# Days)",1)) as char(40)))

Table A–18 (Cont.) Detailed Study Milestones Report (Report CDA-CO-102)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Overall Level Targets	[Target Visit Report Completed to Visit Report Approved (# Days)]	CONCAT('[Overall Target]:',cast(MIN("Overall Level Targets"."[Target Visit Report Completed to Visit Report Approved (# Days)]") as char(40)))||' '||CONCAT(' Actual:' , cast(MAX(ROUND("- Study Metrics"."Median Visit Report Completed to Visit Report Approved (# Days)",2)) as char(40)))
- Study Metrics	Median Visit Report Completed to Visit Report Approved (# Days)	CONCAT('[Overall Target]:',cast(MIN("Overall Level Targets"."[Target Visit Report Completed to Visit Report Approved (# Days)]") as char(40)))||' '||CONCAT(' Actual:' , cast(MAX(ROUND("- Study Metrics"."Median Visit Report Completed to Visit Report Approved (# Days)",2)) as char(40)))
Overall Level Targets	[Target Last Subject Last Visit to Database Lock (# Days)]	CONCAT('[Overall Target]:',cast(MIN("Overall Level Targets"."[Target Last Subject Last Visit to Database Lock (# Days)]") as char(40)))||' '||CONCAT(' Actual:' , cast(MAX(ROUND("- Study Metrics"."Latest Subject Latest Visit to Database Lock (# Days)",2)) as char(40)))
- Study Metrics	Latest Subject Latest Visit to Database Lock (# Days)	CONCAT('[Overall Target]:',cast(MIN("Overall Level Targets"."[Target Last Subject Last Visit to Database Lock (# Days)]") as char(40)))||' '||CONCAT(' Actual:' , cast(MAX(ROUND("- Study Metrics"."Latest Subject Latest Visit to Database Lock (# Days)",2)) as char(40)))
- Study Metrics	Recruitment Flag	"- Study Metrics"."Recruitment Flag"
- Study Metrics	Recruitment Detail Reason	"- Study Metrics"."Recruitment Detail Reason"
- Study Metrics	Milestone Flag	"- Study Metrics"."Milestone Flag"
- Study Metrics	Milestone Detail Reason	"- Study Metrics"."Milestone Detail Reason"
- Study Metrics	Retention Flag	"- Study Metrics"."Retention Flag"
- Study Metrics	Retention Detail Reason	"- Study Metrics"."Retention Detail Reason"
- Study Metrics	# Study-Sites Planned for Study	CONCAT('Planned:',cast(MIN("- Study Metrics"."# Study-Sites Planned for Study") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study Metrics"."# Study-Sites Initiated") as char(40)))

Table A–18 (Cont.) Detailed Study Milestones Report (Report CDA-CO-102)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Metrics	# Study-Sites Initiated	CONCAT('Planned:',cast(MIN("- Study Metrics"."# Study-Sites Planned for Study") as char(40))||' '||CONCAT(' Actual:',cast(MAX("- Study Metrics"."# Study-Sites Initiated") as char(40)))
- Study Original Planned Dates	[Planned 1st IRB/EC Submission Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st IRB/EC Submission Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st IRB/EC Submission Date]") as char(40))||' '||CONCAT(' Actual:',cast("- Study Metrics"."[1st IRB/EC Submission Date]" as char(40)))
- Study Latest Estimated Dates	[Planned LE 1st IRB/EC Submission Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st IRB/EC Submission Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st IRB/EC Submission Date]") as char(40))||' '||CONCAT(' Actual:',cast("- Study Metrics"."[1st IRB/EC Submission Date]" as char(40)))
- Study Metrics	[1st IRB/EC Submission Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st IRB/EC Submission Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st IRB/EC Submission Date]") as char(40))||' '||CONCAT(' Actual:',cast("- Study Metrics"."[1st IRB/EC Submission Date]" as char(40)))
- Study Original Planned Dates	[Planned 1st Initial IRB/EC Approval Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Initial IRB/EC Approval Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Initial IRB/EC Approval Date]") as char(40))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Initial IRB/EC Approval Date" as char(40)))

Table A–18 (Cont.) Detailed Study Milestones Report (Report CDA-CO-102)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Latest Estimated Dates	[Planned LE 1st Initial IRB/EC Approval Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Initial IRB/EC Approval Date" as char(40)))
- Study Metrics	1st Initial IRB/EC Approval Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Initial IRB/EC Approval Date" as char(40)))
- Study Original Planned Dates	[Planned 1st Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."[1st Critical Document Package Completed Date]" as char(40)))
- Study Latest Estimated Dates	[Planned LE 1st Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."[1st Critical Document Package Completed Date]" as char(40)))

Table A–18 (Cont.) Detailed Study Milestones Report (Report CDA-CO-102)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Metrics	[1st Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Critical Document Package Completed Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Critical Document Package Completed Date]") as char(40))||' '||CONCAT(' Actual:',cast("- Study Metrics"."[1st Critical Document Package Completed Date]" as char(40)))
- Study Original Planned Dates	[Planned Last Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Critical Document Package Completed Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Critical Document Package Completed Date]") as char(40))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."[Latest Critical Document Package Completed Date]" as char(40))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Critical Document Package Completed Date]" as char(40)))
- Study Latest Estimated Dates	[Planned LE Last Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Critical Document Package Completed Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Critical Document Package Completed Date]") as char(40))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."[Latest Critical Document Package Completed Date]" as char(40))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Critical Document Package Completed Date]" as char(40)))

Table A–18 (Cont.) Detailed Study Milestones Report (Report CDA-CO-102)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Metrics	[Latest Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."[Latest Critical Document Package Completed Date]" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Critical Document Package Completed Date]" as char(40)))
- Study Metrics	[Last Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."[Latest Critical Document Package Completed Date]" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Critical Document Package Completed Date]" as char(40)))
- Study Original Planned Dates	[Planned Database Lock Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Database Lock Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Database Lock Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Key Dates"."Database Lock Date" as char(40)))
- Study Latest Estimated Dates	[Planned LE Database Lock Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Database Lock Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Database Lock Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Key Dates"."Database Lock Date" as char(40)))

Table A–18 (Cont.) Detailed Study Milestones Report (Report CDA-CO-102)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Key Dates	Database Lock Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Database Lock Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Database Lock Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Key Dates"."Database Lock Date" as char(40)))
- Study Original Planned Dates	[Planned Clinical Study Report Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Clinical Study Report Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Clinical Study Report Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Key Dates"."[Clinical Study Report Date]" as char(40)))
- Study Latest Estimated Dates	[Planned LE Clinical Study Report Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Clinical Study Report Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Clinical Study Report Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Key Dates"."[Clinical Study Report Date]" as char(40)))
- Study Key Dates	[Clinical Study Report Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Clinical Study Report Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Clinical Study Report Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Key Dates"."[Clinical Study Report Date]" as char(40)))
- Study Key Dates	[Protocol Approved Date]	CONCAT('Actual:' , cast(MAX("- Study Key Dates"."[Protocol Approved Date]") as char(40)))
- Received CRFs	# CRFs Awaiting Entry Completion	"- Received CRFs"."# CRFs Awaiting Entry Completion"

Discrepancies per Pages Entered - Top N (Report CDA-DM-255)

Identifies the rate of discrepancies per pages entered. This report displays the top studies and associated sites which have the highest numbers of discrepancies per page. This information can be used to identify poor performance across studies and across sites.

Audience

- Data Manager

Report Type

- Graph, table (optional)

Location

- **Data Manager - EDC** dashboard, **Quality** page
- **Data Manager - Paper** dashboard, **Quality** page

Dimensions

- Study-Site

Supplementary Prompts

- Top N

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Discrepancies per Pages Entered - Top N report.

Table A–19 Discrepancies per Pages Entered - Top N (Report CDA-DM-255)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	Study	Study-Site.Study Name
NA	Total Discrepancies per CRF	Study-site Metrics.Total Discrepancies per CRF

Discrepancies per Subjects Enrolled - Top N (Report CDA-DM-250)

Identifies the rate of discrepancies per subjects enrolled. This report identifies the top studies and associated sites which have the highest numbers of discrepancies per enrolled subject. This information can be used to identify poor performance across studies and across sites.

Audience

- Data Manager

Report Type

- Graph, Table (optional)

Location

- **Data Manager - EDC** dashboard, **Quality** page
- **Data Manager - Paper** dashboard, **Quality** page

Dimensions

- Study-Site

Supplementary Prompts

- Top N

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Discrepancies per Subjects Enrolled report.

Table A–20 Discrepancies per Subjects Enrolled - Top N (Report CDA-DM-250)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	Study Name	Study-Site.Study Name
NA	Total Discrepancies per Enrolled Subject	Study-Site Metrics.Total Discrepancies per Enrolled Subject

Discrepancy Overview with Ratios (Report CDA-DM-240)

Identifies how many discrepancies are open and closed. In addition, the report also shows ratios of the number of discrepancies per CRF entered. If these ratios vary significantly by site they may indicate a poor performing site with a training need.

Also, comparing these measures across studies can highlight inefficiencies between study teams, although it is important to also note that study variances are often a factor of study complexity and therapeutic area.

Audience

- Data Manager
- CRA

Report Type

- Table

Location

- **Data Manager - EDC** dashboard, **Discrepancy Workload** page
- **Data Manager - Paper** dashboard, **Discrepancy Workload** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Counts of Categorized Open Discrepancies, by Review Status (Report CDA-DM-220)

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Discrepancy Overview with Ratios report.

Table A–21 Discrepancy Overview with Ratios (Report CDA-DM-240)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study-Site	Study Name	Study-Site.Study Name
NA	# Subjects Enrolled	Study-site Metrics.# Subjects Enrolled
NA	# CRFs Present	Received CRFs.# CRFs Present
# Discrepancies	Open	Discrepancies.# Open Discrepancies
# Discrepancies	Closed	Discrepancies.# Closed Discrepancies
# Discrepancies	Total	Discrepancies.# Total Discrepancies
Discrepancies per Received CRF	Open	Study-site Metrics.Open Discrepancies per CRF
Discrepancies per Received CRF	Total	Study-site Metrics.Total Discrepancies per CRF

Document Collection Cycle Times - Days Outstanding by Type (Report CDA-CO-606)

Displays (by document type) the median days a document has been outstanding. This report indicates how long have documents been outstanding. It also indicates the documents that lag the most.

Audience

- Study Manager
- Region Manager
- CRA

Report Type

- Graph, table (optional)

Location

- **Study Overview** dashboard, **Site Document Metrics** page
- **Study-Site Overview** dashboard, **Site Document Metrics** page
- **Study-Region Overview** dashboard, **Study-Site Document Metrics** page

Dimensions

None

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Document Collection Cycle Times - Days Outstanding by Type report.

Table A–22 Document Collection Cycle Times - Days Outstanding by Type (Report CDA-CO-606)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	Document Type	Document Metrics.Activity Type

Table A–22 (Cont.) Document Collection Cycle Times - Days Outstanding by Type (Report CDA-CO-606)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	Median # Days Document Outstanding	Document Metrics.Avg # Days Document Outstanding MEDIAN(- Document Metrics.# Days Document Outstanding BY - Document Metrics.Activity Type)

Document Collection Cycle Times (Study-Site) (Report CDA-CO-604)

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.

Audience

- Study Manager
- Region Manager
- CRA

Report Type

- Table

Location

- **Study Overview** dashboard, **Site Document Metrics** page
- **Study-Site Overview** dashboard, **Site Document Metrics** page
- **Study-Region Overview** dashboard, **Study-Site Document Metrics** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Document Collection Cycle Times (Study-Site) report.

Table A–23 Document Collection Cycle Times (Study-Site) (Report CDA-CO-604)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Activity Type	Document Metrics.Activity Type
NA	Study Region	Study-Site.Study Region
NA	Study-Site ID #	Study-Site.Study-Site ID #
NA	Principal Investigator	Study-Site.Principal Investigator
NA	Document Name	Document Metrics.Document Name
NA	Document Sent Date	Document Metrics.Document Sent Date
NA	Document Received Date	Document Metrics.Document Received Date
NA	# Days from Document Sent to Document Received	Document Metrics.# Days from Document Sent to Document Received
NA	# Days Document Outstanding	Document Metrics.# Days Document Outstanding

Document Collection Cycle Times -Turn Around Time by Type (Report CDA-CO-607)

Displays (by document type) the average turn around time from document sent to document received. This report indicates if essential documents are being gathered on time, and how long does it typically take to receive a document. It also indicates the documents that lag the most.

Audience

- Study Manager
- Region Manager
- CRA

Report Type

- Graph, table (optional)

Location

- **Study Overview** dashboard, **Site Document Metrics** page
- **Study-Site Overview** dashboard, **Site Document Metrics** page
- **Study-Region Overview** dashboard, **Study-Site Document Metrics** page

Dimensions

None

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Document Collection Cycle Times -Turn Around Time by Type report.

Table A–24 Document Collection Cycle Times -Turn Around Time by Type (Report CDA-CO-607)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	Document Type	Document Metrics.Activity Type
NA	Median # Days from Document Sent to Document Received	Document Metrics.Avg # Days from Document Sent to Document Received MEDIAN(-Document Metrics.# Days from Document Sent to Document Received BY - Document Metrics.Activity Type)

Documents List (Multiple Study-Sites) (Report CDA-CO-601)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **CRA** dashboard, **Study-Site Document List** page

Dimensions

- None

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Documents List (Multiple Study-Sites) report.

Table A–25 Documents List (Multiple Study-Sites) (Report CDA-CO-601)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Study	Study-Site.Study
NA	Study-Site ID #	Study-Site.Study-Site ID #
NA	Principal Investigator	Study-Site.Principal Investigator
NA	Activity Type	Document Metrics.Activity Type
NA	Document Name	Document Metrics.Document Name
NA	Document Sent Date	Document Metrics.Document Sent Date
NA	Days Since Doc Sent	TIMESTAMPDIFF(SQL_TSI_DAY, - Document Metrics.Document Sent Date,NOW())
NA	Document Received Date	Document Metrics.Document Received Date
NA	Document Expiration Date	Document Metrics.Document Expiration Date
NA	Indicator	TBD
NA	Document Comments	Document Metrics.Document Comments

Documents List (Study Region) (Report CDA-CO-610)

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.

Audience

- Region Manager

Report Type

- Table

Location

- **Study-Region Overview** dashboard, **Region Document List** page

Dimensions

- NA

Supplementary Prompts

- Document Page Prompt Filter (existing Filter from the previous release

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–26 describes the columns in the Documents List (Study Region) analysis

Table A–26 Documents List (Study Region) (Report CDA-CO-610)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Document Metrics	Activity Type	"- Document Metrics"."Activity Type"
- Document Metrics	Document Name	"- Document Metrics"."Document Name"
- Document Metrics	Document Sent Date	"- Document Metrics"."Document Sent Date"
- Document Metrics	Document Received Date	"- Document Metrics"."Document Received Date"
- Document Metrics	Document Expiration Date	"- Document Metrics"."Document Expiration Date"
- Document Metrics	Document Comments	"- Document Metrics"."Document Comments"
- Document Metrics	Document Expiration Date Indicator	CASE WHEN "- Document Metrics"."Document Expiration Date" < VALUEOF(CURRENT_ DAY) THEN '1-Red' WHEN "- Document Metrics"."Document Expiration Date" > VALUEOF(CURRENT_DAY) AND "- Document Metrics"."Document Expiration Date" <= TIMESTAMPADD(SQL_TSI_ DAY, 30,VALUEOF(CURRENT_ DAY)) THEN '2-Yellow' WHEN "- Document Metrics"."Document Expiration Date" > TIMESTAMPADD(SQL_TSI_ DAY, 30,VALUEOF(CURRENT_ DAY)) THEN '3-Green' END

Documents List (Study-Site) (Report CDA-CO-603)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study-Site Overview** dashboard, **Study-Site Document List** page

Dimensions

None

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Documents List (Study-Site) report.

Table A–27 Documents List (Study-Site) (Report CDA-CO-603)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Activity Type	Document Metrics.Activity Type
NA	Document Name	Document Metrics.Document Name
NA	Document Sent Date	Document Metrics.Document Sent Date
NA	Days Since Doc Sent	TIMESTAMPDIFF(SQL_TSI_DAY, - Document Metrics.Document Sent Date,NOW())
NA	Document Received Date	Document Metrics.Document Received Date

Table A–27 (Cont.) Documents List (Study-Site) (Report CDA-CO-603)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Document Expiration Date	Document Metrics.Document Expiration Date
NA	Indicator	TBD
NA	Document Comments	Document Metrics.Document Comments

Enrollment Overview By Site (Report CDA-CO-426)

Lists (by program, study, and region) all sites and the number of planned and actual subjects enrolled. This report indicates how well are we progressing against planned 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.

Audience

- Study Manager
- CRA

Report Type

- Pivot Table

Location

- **Study Overview** dashboard, **Study Region Performance** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Site Detail (Report CDA-CO-209)

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Enrollment Overview By Site report.

Table A–28 Enrollment Overview By Site (Report CDA-CO-426)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	Study Region	Study-Site.Study Region
NA	Study Region Status	Region.Region Status
NA	Study-Site ID#	Study-Site.Study-Site ID#
NA	Site Name	Study-Site.Site Name
NA	Principal Investigator	Study-Site.Principal Investigator
NA	Study-Site Status	Study-Site.Study-Site Status
NA	CRA	Study-Site.CRA
NA	# Subjects Planned for Study-Site	Study-site Metrics.# Subjects Planned for Study-Site
NA	# Enrolled	Study-site Metrics.# Subjects Enrolled

Enrollment Progress Over Time (Study Level) (Report CDA-CO-408)

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.

Audience

- Study Manager
- CRA

Report Type

- Graph, Table (optional)

Location

- **Study Overview** dashboard, **Study Overview, Recruitment Overview** page

Dimensions

- Study-Site
- All-Purpose Date

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Enrollment Progress Over Time (Study Level) report.

Table A–29 Enrollment Progress Over Time (Study Level) (Report CDA-CO-408)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Year and Month	- All Purpose Date.Year and Month
NA	Study	Study-Site.Study
NA	Study-Site ID #	Study-Site.Study-Site ID #
NA	1	MAX(SUM(CASE WHEN - Study Metrics.# Subjects Planned for Study>0 THEN - Study Metrics.# Subjects Planned for Study ELSE 0 END))
NA	0.9	MAX(SUM(CASE WHEN - Study Metrics.# Subjects Planned for Study>0 THEN - Study Metrics.# Subjects Planned for Study ELSE 0 END) * .9)
NA	0.75	MAX(SUM(CASE WHEN - Study Metrics.# Subjects Planned for Study>0 THEN - Study Metrics.# Subjects Planned for Study ELSE 0 END) * .75)
NA	0.5	MAX(SUM(CASE WHEN - Study Metrics.# Subjects Planned for Study>0 THEN - Study Metrics.# Subjects Planned for Study ELSE 0 END) * .5)
NA	# Subjects Enrolled (Cumulative)	RSUM(- Study-site Metrics.# Subjects Enrolled)

Enrollment Progress Over Time (Study-Region Level) (Report CDA-CO-435)

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.

Audience

- Region Manager, Study Manager, Executive Manager, Program Manager

Report Type

- View Selector (Chart, Table)

Location

- **Study-Region Overview** dashboard, **Recruitment Overview** page

Dimensions

- Study-Region

Supplementary Prompts

- NA

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–30 describes the columns in the Enrollment Progress Over Time (Study-Region Level) analysis

Table A–30 Enrollment Progress Over Time (Study-Region Level) (Report CDA-CO-435)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- All Purpose Date	Year and Month	"- All Purpose Date"."Year and Month"
Study-Region	Study	"Study-Region"."Study"
Study-Region	Region Name	"Study-Region"."Region Name"
- Study-Site Metrics	# Enrolled	IFNULL(RSUM("- Study-Site Metrics"."# Enrolled"), 0) + @{pv_subj_enrolled_stdy_reg}

Enrollment Progress Over Time (Study-Site Level) (Report CDA-CO-423)

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.

Audience

- Study Manager
- CRA

Report Type

- Graph, Table (optional)

Location

- **Study-Site Overview** dashboard, **Screening and Recruitment Overview** page

Dimensions

- Study-Site All-Purpose Date

Supplementary Prompts

- Page Specific Year and Month Between prompt

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Enrollment Progress Over Time (Study-Site Level) report.

Table A–31 Enrollment Progress Over Time (Study-Site Level) (Report CDA-CO-423)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	# Subjects Enrolled (Cumulative)	RSUM(- Study-site Metrics.# Subjects Enrolled)
NA	Year and Month	All Purpose Date.Year and Month

Executive Study-Site Map (Report CDA-CO-1203)

Displays the following metrics by country: # Sites Recruiting 0 Subjects, # Sites Recruiting 1 or More Subjects, # Sites Recruiting at Least 90% of Planned Subjects, Median Initial IRB/EC Approval to Site Initiated (# Days), Median Site Initiated to 1st Subject Enrolled (# Days) and # Study-Sites Initiated.

Audience

- Executive

Report Type

- Map

Location

- **Executive** dashboard, **Map of Study-Sites, Region manager** dashboard, **Study-Region Overview** dashboard, **Overview** page

Dimensions

None

Supplementary Prompts

- NA

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–32 describes the columns in the Executive Study-Site Map analysis

Table A–32 Executive Study-Site Map (Report CDA-CO-1203)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Country	NA
Study-Region Metrics	# Sites Recruiting 0 Subjects	NA
Study-Region Metrics	# Sites Recruiting 1 or More Subjects	NA
Study-Region Metrics	# Sites Recruiting at Least 90% of Planned Subjects	NA
Study-Region Metrics	Median Initial IRB/EC Approval to Site Initiated (# Days)	NA
Study-Region Metrics	Median Site Initiated to 1st Subject Enrolled (# Days)	NA
Study-Region Metrics	# Study-Sites Initiated	NA

High Level Study-Site Map (Report CDA-CO-1202)

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.

Audience

- Region Manager, Study Manager, CRA, Executive

Report Type

- Map

Location

- **Executive** dashboard, **Study-Site Map**, **Region manager** dashboard, **Map of Study-Sites Study Overview** dashboard, **Map of Study-Sites Study Manager** dashboard, **Map of Study-Sites** page

Dimensions

None

Supplementary Prompts

NA

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–33 describes the columns in the High Level Study-Site Map analysis

Table A–33 High Level Study-Site Map (Report CDA-CO-1202)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study-Site ID #	NA
Study-Site	Street Address	NA
Study-Site	City	NA
Study-Site	Country	NA
Study-Site Metrics	# Enrolled	NA
Study-Site Metrics	# Current Active Subjects	NA
Study-Site Metrics	# Early Terminations	NA
Study-Site Metrics	# Days Since Last Enrollment for Study-Site	NA
Study-Site Metrics	# Subjects Enrolled Since Latest Site Visit	NA
Study-Site Metrics	# Days Since Latest Site Visit	NA

Initiated Study-Sites with Recruitment Counts (Report CDA-CO-412)

Lists initiated study-sites and their progress toward recruitment goals, as well as details including days since initiation and days since latest enrollment.

Audience

- Study Manager
- Region Manager
- CRA

Report Type

- Table

Location

- **CRA** dashboard, **Initiating and Recruiting Study-Sites** page
- **Study-Region Overview** dashboard, **Recruitment Overview** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Initiated Study-Sites with Recruitment Counts report.

Table A–34 Initiated Study-Sites with Recruitment Counts (Report CDA-CO-412)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study	Study-Site.Study
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Study-Site Status	Study-Site.Study-Site Status
% to Plan	Enrollment	Study-site Metrics.% Enrolled to Total Planned at Study-Site
% to Plan	Randomization	Study-site Metrics.% Randomized vs. Planned - Study-Site
# Subjects	Planned for Study-Site	Study-site Metrics.# Subjects Planned for Study-Site
# Subjects	# Screened	Study-site Metrics.# Screened
# Subjects	# Screen Failure	Study-site Metrics.# Screen Failure
# Subjects	# Subjects Enrolled	Study-site Metrics.# Subjects Enrolled
# Subjects	# Randomized	Study-site Metrics.# Randomized

Table A–34 (Cont.) Initiated Study-Sites with Recruitment Counts (Report CDA-CO-412)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Site Initiation	Site Initiated Date	Study-Site.Site Initiated Date
Site Initiation	# Days Since Initiation	Study-site Metrics.# Days Since Initiation
Latest Subject Enrolled	Date	Study-site Metrics.Latest Subject Enrolled Date
Latest Subject Enrolled	# Days Since	Study-site Metrics.# Days Since Last Enrollment for Study-site
NA	Navigate to detail	NA

Investigator Contact and Studies List (Report CDA-CO-202)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

None

Dimensions

- Study-Site
- Principal Investigator

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

- Top Investigators, % Planned Enrollment Completed (Report CDA-CO-700)
- Top Investigators, Total Enrollment (Report CDA-CO-701)

Column Descriptions

The table describes the columns in the Investigator Contact and Studies List report.

Table A–35 Investigator Contact and Studies List (Report CDA-CO-202)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Principal Investigator	Study-Site.Principal Investigator
NA	Investigator Email Address	Investigator.Investigator Email Address
NA	Investigator Fax/Phone #	Investigator.Investigator Fax/Phone #
NA	Investigator Street Address	Investigator.Investigator Street Address
NA	Investigator Street Address 2	Investigator.Investigator Street Address 2
NA	Investigator Street Address 3	Investigator.Investigator Street Address 3
NA	Investigator City	Investigator.Investigator City
NA	Investigator State	Investigator.Investigator State
NA	Investigator Postal Code	Investigator.Investigator Postal Code
NA	Investigator Country	Investigator.Investigator Country
NA	Study	Study-Site.Study
NA	Study-Site ID #	Study-Site.Study-Site ID #
NA	Site Name	Study-Site.Site Name
NA	Study-Site Status	Study-Site.Study-Site Status
NA	# Subjects Planned for Study-Site	Study-site Metrics.# Subjects Planned for Study-Site
NA	# Enrolled	Study-site Metrics.# Subjects Enrolled
NA	% of Planned Site Enrollment Completed	Study-site Metrics.% of Planned Site Enrollment Completed

Key Cycle Times for Paper Studies (Report CDA-DM-400)

Identifies key cycle times for paper studies, and can be used to compare studies against each other. This report indicates key lags in process steps and potential inefficiencies.

Audience

- Data Manager
- Project Manager

Report Type

- Table

Location

- **Data Manager - Paper** dashboard, **Performance** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Key Cycle Times for Paper Studies report.

Table A–36 Key Cycle Times for Paper Studies (Report CDA-DM-400)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study-Site	Study Name	Study-Site.Study Name
NA	# Subjects Enrolled	Study-site Metrics.# Subjects Enrolled
# pCRFs	Present	Received CRFs.# pCRFs Present
# pCRFs	Entry Complete	Received CRFs.# pCRFs Entry Complete
Average Days	Visit to First Entry	Received CRFs.Avg # Days from pCRF Visit to First Entry
Average Days	First Entry to Second Entry Complete	Received CRFs.Avg # Days from pCRF First Entry to Second Entry Complete
Average Days	Visit to Entry Complete	Received CRFs.Avg # Days from pCRF Visit to Entry Complete
Average Days	Entry Complete to Soft Locked	Received CRFs.Avg # Days from pCRF Entry Complete to Soft Locked

Key EDC Cycle Times (Report CDA-DM-300)

Identifies the key cycle times for EDC studies, and can be used to compare sites within study, and to compare studies against each other. This report indicates key lags in process steps, and potential inefficiencies.

Audience

- Data Manager
- CRA
- Project Manager

Report Type

- Table

Location

- **CRA** dashboard, **Performance** page
- **Data Manager - EDC** dashboard, **Performance** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Key EDC Cycle Times report.

Table A–37 Key EDC Cycle Times (Report CDA-DM-300)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	NA	Study-Site.Program
Study-Site	Study Name	Study-Site.Study Name
NA	#Subjects Enrolled	Study-site Metrics.# Subjects Enrolled
NA	# Entry Complete	Received CRFs.# eCRFs Entry Complete
Average Days From Visit To	Entry Complete	Received CRFs.Avg # Days from eCRF Visit to eCRF Complete
Average Days From Entry Completion To	Initially Approved	Received CRFs.Avg # Days from eCRF Entry Complete to Initially Approved
Average Days From Entry Completion To	Initially Verified	Received CRFs.Avg # Days from eCRF Complete to Initially Verified
Average Days From Entry Completion To	Soft Locked	Received CRFs.Avg # Days from eCRF Complete to Soft Locked

Key EDC Processing Volumes (Report CDA-DM-305)

Identifies the key processing volumes for EDC studies. This report displays page processing volumes for EDC studies. It also displays eCRFs processed and to be processed.

Ratios of approved and verified data can also be used to show progress through the study. This report can be used to understand resource requirements based on work volumes.

Audience

- Data Manager
- CRA
- Project Manager

Report Type

- Table

Location

- **CRA** dashboard, **eCRF Workload** page
- **Data Manager - EDC** dashboard, **eCRF Workload** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- List Discrepancy Details (Report CDA-DM-245)
- Summary of Subjects Awaiting EDC Processing (Report CDA-DM-320)

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Key EDC Processing Volumes report.

Table A–38 Key EDC Processing Volumes (Report CDA-DM-305)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study-Site	Study Name	Study-Site.Study Name
NA	#Subjects Enrolled	Study-site Metrics.# Subjects Enrolled
NA	# Open Discrepancies	Discrepancies.# Open Discrepancies
# eCRFs	Entry Complete	Received CRFs.# eCRFs Entry Complete
# eCRFs	Not Verified	Received CRFs.# eCRFs Not Verified
# eCRFs	Verified	Received CRFs.# eCRFs Verified
# eCRFs	Not Approved	Received CRFs.# eCRFs To Be Approved
# eCRFs	Approved	Received CRFs.# eCRFs Approved
# eCRFs	Soft Locked	Received CRFs.# eCRFs Soft Locked
# eCRFs	Hard Locked	Received CRFs.# eCRFs Hard Locked
% of Entry-Complete eCRFs	Approved	Received CRFs.% eCRFs Approved / Entry Complete
% of Entry-Complete eCRFs	Verified Foot 1 Conditional Formatting Threshold: Yellow - between 30 and 50 Conditional Formatting Threshold: Red - less than or equal to 30	Received CRFs.% eCRFs Verified / Entry Complete
% of Entry-Complete eCRFs	Soft Locked	Received CRFs.% eCRFs Soft Locked / Entry Complete
% of Entry-Complete eCRFs	Hard Locked	Received CRFs.% eCRFs Hard Locked / Entry Complete
NA	Navigate to Detail	NA

Key Paper Processing Volumes (Report CDA-DM-405)

Identifies key page processing volumes for paper studies. This report displays pages processed and to be processed. This information can be used to understand resource requirements based on work volumes.

Audience

- Data Manager
- Project Manager

Report Type

- Table

Location

- **Data Manager - Paper** dashboard, **Page Workload** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Summary of Subjects Awaiting Paper Processing (Report CDA-DM-420)

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Key Paper Processing Volumes report.

Table A–39 Key Paper Processing Volumes (Report CDA-DM-405)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study-Site	Study	Study-Site.Study Name
NA	#Subjects Enrolled	Study-site Metrics.# Subjects Enrolled
NA	# Open Discrepancies	Discrepancies.# Open Discrepancies Note: This is all discrepancies, not just those arising from CRFs.
# CRFs	Present	Received CRFs.# pCRFs Present
# CRFs	Awaiting First Entry Completion	Received CRFs.# pCRFs Awaiting Pass 1 Entry Completion
# CRFs	Awaiting Second Entry Completion	Received CRFs.# pCRFs Awaiting Pass 2 Entry Completion
# CRFs	Entry Complete	Received CRFs.# pCRFs Entry Complete
# CRFs	Blank	Received CRFs.# pCRFs Blank
# CRFs	Soft Locked	Received CRFs.# pCRFs Soft Locked
# CRFs	Hard Locked	Received CRFs.# pCRFs Hard Locked
% of Entry-Complete eCRFs	Soft Locked	Received CRFs.% pCRFs Soft Locked / Entry Complete
% of Entry-Complete eCRFs	Hard Locked	Received CRFs.% pCRFs Hard Locked / Entry Complete
NA	Navigate to Detail	NA

Key Performance Indicators Over Time - Monitoring (Region Manager) (Report CDA-CO-1112)

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 Monitoring Report Completed to Monitoring Report Approved
- # Days from Follow Up Item Identified to Follow Up Item Resolved

Audience

- Region Manager

Report Type

- View Selector (Chart, Table)

Location

- **Region Manager** dashboard, **Monitoring Metrics** page

Dimensions

- Visit Report Completed Date

Supplementary Prompts

- Site Visit Start Date page prompt

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–40 describes the columns in the Key Performance Indicators Over Time: Monitoring (Region Manager) analysis.

Table A–40 Key Performance Indicators Over Time: Monitoring (Region Manager) (Report CDA-CO-1112)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Visit Report Completed Date	Year and Month	"- Visit Report Completed Date"."Year and Month"
- Study-Site Metrics	# Site Visits	"- Study-Site Metrics"."# Site Visits"

Table A–40 (Cont.) Key Performance Indicators Over Time: Monitoring (Region Manager) (Report CDA-CO-1112)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Site Visit Metrics	# Days from Site Visit Completed to Visit Report Completed	MEDIAN("- Site Visit Metrics"."# Days from Site Visit Completed to Visit Report Completed")
- Site Visit Metrics	[# Days from Visit Report Completed to Visit Report Approved]	MEDIAN("- Site Visit Metrics"."[# Days from Visit Report Completed to Visit Report Approved]")
- Follow Up Item Metrics	# Days from Site Visit Completed to Follow Up Item Completed	MEDIAN("- Follow Up Item Metrics"."# Days from Site Visit Completed to Follow Up Item Completed")

Key Performance Indicators Over Time (Executive View) (Report CDA-CO-902)

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.

Audience

- Executive

Report Type

- Line Graph (View selector)

Location

- **Executive** dashboard, **Overview** page

Dimensions

- All Purpose Date

Supplementary Prompts

- Year Prompt

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–41 describes the columns in the Key Performance Indicators Over Time (Executive View) analysis

Table A–41 Key Performance Indicators Over Time (Executive View) (Report CDA-CO-902)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- All Purpose Date	Year	"- All Purpose Date"."Year"
- Study-Site Metrics	Critical Document Package Complete to Site Initiated (# Days)	MEDIAN("- Study-Site Metrics"."Critical Document Package Complete to Site Initiated (# Days)")
- Study Metrics	[Last Subject Last Visit to Database Lock (# Days)]	MEDIAN("- Study Metrics"."[Last Subject Last Visit to Database Lock (# Days)]")
- Study Metrics	[Protocol Approved to 1st Site Initiated (# Days)]	MEDIAN("- Study Metrics"."[Protocol Approved to 1st Site Initiated (# Days)]")
- Study Metrics	[Protocol Approved to 1st Subject Enrolled (# Days)]	MEDIAN("- Study Metrics"."[Protocol Approved to 1st Subject Enrolled (# Days)]")
- Site Visit Metrics	# Days from Site Visit Completed to Visit Report Completed	MEDIAN("- Site Visit Metrics"."# Days from Site Visit Completed to Visit Report Completed")
- Site Visit Metrics	[# Days from Visit Report Completed to Visit Report Approved]	MEDIAN("- Site Visit Metrics"."[# Days from Visit Report Completed to Visit Report Approved]")

KPI Summary - CDP Complete to Site Initiated (Executive View) (Report CDA-CO-905)

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.

Audience

- Executive

Report Type

- Multiple Graphs (View selector)

Location

- **Executive** dashboard, **KPI Summary** page

Dimensions

- All Purpose Date

Supplementary Prompts

- NA

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–42 describes the columns in the KPI Summary: CDP Complete to Site Initiated (Executive View) analysis

Table A–42 KPI Summary: CDP Complete to Site Initiated (Executive View) (Report CDA-CO-905)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- All Purpose Date	Year and Quarter	"- All Purpose Date"."Year and Quarter"
- Study-Site Metrics	# Study-Sites	"- Study-Site Metrics"."# Study-Sites"
Overall Level Targets	[Target Critical Document Package Complete to Site Initiated (# Days)]	"Overall Level Targets"."[Target Critical Document Package Complete to Site Initiated (# Days)]"
- Study-Site Metrics	Critical Document Package Complete to Site Initiated (# Days)	MEDIAN("- Study-Site Metrics"."Critical Document Package Complete to Site Initiated (# Days)")

KPI Summary - CDP Completed to Site Initiated (Region Manager View) (Report CDA-CO-1103)

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.

Audience

- Region Manager Study Manager

Report Type

- View Selector (Multiple Graphs)

Location

- **Study Manager** dashboard, **KPI Summary Region Manager dashboard, KPI Summary** dashboard, **KPI Summary Region Manager** dashboard, **KPI Summary** page

Dimensions

- Study-Site, All Purpose Date

Supplementary Prompts

- Year and Month Prompt

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–43 describes the columns in the KPI Summary: CDP Completed to Site Initiated (Region Manager View) analysis

Table A–43 KPI Summary: CDP Completed to Site Initiated (Region Manager View) (Report CDA-CO-1103)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- All Purpose Date	Year and Quarter	"- All Purpose Date"."Year and Quarter"
Overall Level Targets	[Target Critical Document Package Complete to Site Initiated (# Days)]	"Overall Level Targets"."[Target Critical Document Package Complete to Site Initiated (# Days)]"
- Study-Site Metrics	Critical Document Package Complete to Site Initiated (# Days)	MEDIAN("- Study-Site Metrics"."Critical Document Package Complete to Site Initiated (# Days)")
- Study-Site Metrics	# Study-Sites	"- Study-Site Metrics"."# Study-Sites"
- Overall Metrics	[Median Critical Document Package Complete to Site Initiated (# Days)]	"- Overall Metrics"."[Median Critical Document Package Complete to Site Initiated (# Days)]"
- All Purpose Date	Year	"- All Purpose Date"."Year"

KPI Summary - LSLV to Database Lock (Executive View) (Report CDA-CO-906)

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.

Audience

- Executive

Report Type

- Multiple Graphs (View selector)

Location

- **Executive** dashboard, **KPI Summary** page

Dimensions

- All Purpose Date, Overall Level Targets

Supplementary Prompts

- Year Prompt

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–44 describes the columns in the KPI Summary: LSLV to Database Lock (Executive View) analysis

Table A–44 KPI Summary: LSLV to Database Lock (Executive View) (Report CDA-CO-906)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- All Purpose Date	Year and Quarter	"- All Purpose Date"."Year and Quarter"
- Study Metrics	# Studies	"- Study Metrics"."# Studies"
Overall Level Targets	[Target Last Subject Last Visit to Database Lock (# Days)]	"Overall Level Targets"."[Target Last Subject Last Visit to Database Lock (# Days)]"

Table A–44 (Cont.) KPI Summary: LSLV to Database Lock (Executive View) (Report CDA-CO-906)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Metrics	[Last Subject Last Visit to Database Lock (# Days)]	MEDIAN("- Study Metrics"."[Last Subject Last Visit to Database Lock (# Days)]")

KPI Summary - Protocol Approved to 1st Site Initiated (Executive View) (Report CDA-CO-907)

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.

Audience

- Executive

Report Type

- Multiple Graphs (View selector)

Location

- **Executive** dashboard, **KPI Summary** page

Dimensions

- 1st Site Initiated Date, Overall Level Targets

Supplementary Prompts

- NA

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–45 describes the columns in the KPI Summary: Protocol Approved to 1st Site Initiated (Executive View) analysis

Table A–45 KPI Summary: Protocol Approved to 1st Site Initiated (Executive View) (Report CDA-CO-907)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- 1st Site Initiated Date	Year and Quarter	"- 1st Site Initiated Date"."Year and Quarter"
- Study Metrics	# Studies	"- Study Metrics"."# Studies"
Overall Level Targets	[Target Protocol Approved to 1st Site Initiated (# Days)]	"Overall Level Targets"."[Target Protocol Approved to 1st Site Initiated (# Days)]"
- Study Metrics	[Protocol Approved to 1st Site Initiated (# Days)]	MEDIAN("- Study Metrics"."[Protocol Approved to 1st Site Initiated (# Days)]")

KPI Summary - Protocol Approved to 1st Subject Enrolled (Executive View) (Report CDA-CO-908)

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.

Audience

- Executive

Report Type

- Multiple Graphs (View selector)

Location

- **Executive** dashboard, **KPI Summary** page

Dimensions

- 1st Subject Enrolled Date, Overall level Targets

Supplementary Prompts

- Year Prompt

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–46 describes the columns in the KPI Summary: Protocol Approved to 1st Subject Enrolled (Executive View) analysis

Table A–46 KPI Summary: Protocol Approved to 1st Subject Enrolled (Executive View) (Report CDA-CO-908)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- 1st Subject Enrolled Date	Year and Quarter	"- 1st Subject Enrolled Date"."Year and Quarter"
- Study Metrics	# Studies	"- Study Metrics"."# Studies"
Overall Level Targets	[Target Protocol Approved to 1st Subject Enrolled (# Days)]	MAX("Overall Level Targets"."[Target Protocol Approved to 1st Subject Enrolled (# Days)]")
- Study Metrics	[Protocol Approved to 1st Subject Enrolled (# Days)]	MEDIAN("- Study Metrics"."[Protocol Approved to 1st Subject Enrolled (# Days)]")

KPI Summary - Site Visit Completed to Visit Report Completed (Executive View) (Report CDA-CO-909)

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.

Audience

- Executive

Report Type

- Multiple Graphs (View selector)

Location

- **Executive** dashboard, **KPI Summary** page

Dimensions

- Visit Report Completed Date, Overall Level Targets

Supplementary Prompts

- Year Prompt

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–47 describes the columns in the KPI Summary: Site Visit Completed to Visit Report Completed (Executive View) analysis

Table A–47 KPI Summary: Site Visit Completed to Visit Report Completed (Executive View) (Report CDA-CO-909)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Visit Report Completed Date	Year and Quarter	"- Visit Report Completed Date"."Year and Quarter"
- Study-Site Metrics	# Site Visits	"- Study-Site Metrics"."# Site Visits"
Overall Level Targets	[Target Site Visit Completed to Visit Report Completed (# Days)]	"Overall Level Targets"."[Target Site Visit Completed to Visit Report Completed (# Days)]"
- Site Visit Metrics	# Days from Site Visit Completed to Visit Report Completed	MEDIAN("- Site Visit Metrics"."# Days from Site Visit Completed to Visit Report Completed")

KPI Summary - Site Visit Completed to Visit Report Completed (Region Manager View) (Report CDA-CO-1104)

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.

Audience

- Region Manager
- Study Manager

Report Type

- View Selector (Multiple Graphs)

Location

- **Study Manager** dashboard, **KPI Summary Region Manager dashboard, KPI Summary** dashboard, **KPI Summary Region Manager** dashboard, **KPI Summary** page

Dimensions

- All Purpose Date

Supplementary Prompts

- Year Prompt

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–48 describes the columns in the KPI Summary: Site Visit Completed to Visit Report Completed (Region Manager View) analysis

Table A–48 KPI Summary: Site Visit Completed to Visit Report Completed (Region Manager View) (Report CDA-CO-1104)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Visit Report Completed Date	Year and Quarter	"- Visit Report Completed Date"."Year and Quarter"
- Study-Site Metrics	# Site Visits	"- Study-Site Metrics"."# Site Visits"
Overall Level Targets	[Target Site Visit Completed to Visit Report Completed (# Days)]	"Overall Level Targets"."[Target Site Visit Completed to Visit Report Completed (# Days)]"
- Site Visit Metrics	# Days from Site Visit Completed to Visit Report Completed	MEDIAN("- Site Visit Metrics"."# Days from Site Visit Completed to Visit Report Completed")
- Overall Metrics	Median Site Visit Completed to Visit Report Completed (# Days)	"- Overall Metrics"."Median Site Visit Completed to Visit Report Completed (# Days)"
- Visit Report Completed Date	Year	"- Visit Report Completed Date"."Year"

KPI Summary - Visit Report Completed to Approved (Region Manager View) (Report CDA-CO-1105)

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.

Audience

- Region Manager Study Manager

Report Type

- View Selector (Multiple Graphs)

Location

- **Study Manager** dashboard, **KPI Summary Region Manager dashboard, KPI Summary** dashboard, **KPI Summary Region Manager** dashboard, **KPI Summary** page

Dimensions

- Visit Report Approved Date

Supplementary Prompts

- Year Prompt

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–49 describes the columns in the KPI Summary: Visit Report Completed to Approved (Region Manager View) analysis

Table A–49 KPI Summary: Visit Report Completed to Approved (Region Manager View) (Report CDA-CO-1105)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Visit Report Approved Date	Year and Quarter	"- Visit Report Approved Date"."Year and Quarter"
- Study-Site Metrics	# Site Visits	"- Study-Site Metrics"."# Site Visits"
Overall Level Targets	[Target Visit Report Completed to Visit Report Approved (# Days)]	"Overall Level Targets"."[Target Visit Report Completed to Visit Report Approved (# Days)]"
- Site Visit Metrics	[# Days from Site Visit Completed to Visit Report Approved]	MEDIAN("- Site Visit Metrics"."[# Days from Site Visit Completed to Visit Report Approved]")
- Overall Metrics	Median Visit Report Completed to Visit Report Approved (# Days)	"- Overall Metrics"."Median Visit Report Completed to Visit Report Approved (# Days)"
- Visit Report Approved Date	Year	"- Visit Report Approved Date"."Year"

KPI Summary - Visit Report Completed to Visit Report Approved (Executive View) (Report CDA-CO-910)

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.

Audience

- Executive

Report Type

- Multiple Graphs (View selector)

Location

- **Executive** dashboard, **KPI Summary** page

Dimensions

- Visit Report Approved Date, Overall Level Targets

Supplementary Prompts

- Year Prompt

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–50 describes the columns in the KPI Summary: Visit Report Completed to Visit Report Approved (Executive View) analysis

Table A–50 KPI Summary: Visit Report Completed to Visit Report Approved (Executive View) (Report CDA-CO-910)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Visit Report Approved Date	Year and Quarter	"- Visit Report Approved Date"."Year and Quarter"
- Study-Site Metrics	# Site Visits	"- Study-Site Metrics"."# Site Visits"
Overall Level Targets	[Target Site Visit Completed to Visit Report Approved (# Days)]	"Overall Level Targets"."[Target Site Visit Completed to Visit Report Approved (# Days)]"
- Site Visit Metrics	[# Days from Visit Report Completed to Visit Report Approved]	MEDIAN("- Site Visit Metrics"."[# Days from Visit Report Completed to Visit Report Approved]")
Site Visit	[Site Visit Report Approved Date]	"Site Visit"."[Site Visit Report Approved Date]"

List Discrepancy Details (Report CDA-DM-245)

Lists open discrepancies and associated details, and is used as a detailed drill down report to list all discrepancies and associated details. This report can be used to explore the open discrepancies, and identify any patterns or clusters through the use of sorting.

Audience

- Data Manager

Report Type

- Table

Location

None

Dimensions

- CRF
- Study-Site
- Subject

Supplementary Prompts

- Subject.Subject ID
- Discrepancies.Visit Name
- Discrepancies.CRF Name
- Discrepancies.Validation Procedure Name
- Discrepancies.Current Review Status
- Discrepancies.Discrepancy State

Reports Referenced

None

Reports Referencing This Report

You can navigate to this report from the following reports:

- Counts of Categorized Open Discrepancies, by Review Status (Report CDA-DM-220)
- Count of Currently Open Discrepancies by CRF and Type - Top N by Rank (Report CDA-DM-230)
- Counts of Open Multivariate Discrepancies, by Procedure (Report CDA-DM-235)

- Key EDC Processing Volumes (Report CDA-DM-305)
- Summary of Subjects Awaiting EDC Processing (Report CDA-DM-320)

Column Descriptions

The table describes the columns in the List Discrepancy Details report.

Table A–51 List Discrepancy Details (Report CDA-DM-245)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	NA	Study-Site.Program
Study-Site	Study	Study-Site.Study Name
NA	Site	Study-Site.Site Name
NA	Subject ID	Subject.Subject ID
Visit	Name	Discrepancies.Visit Name
Visit	Number	Discrepancies.Complete Visit Number
NA	Days Open	Discrepancies.# Days Discrepancy Open
CRF	Name	CRF.Name
CRF	Page Section	Discrepancies.CRF Page Section
CRF	Question Group	Discrepancies.CRF Question Group
CRF	Question Name	Discrepancies.CRF Question Name
CRF	Question Occurrence	Discrepancies.CRF Question Occurrence
Discrepancy	Discrepancy ID	Discrepancies.Discrepancy ID
Discrepancy	Procedure Name	Discrepancies.Validation Procedure Name
Discrepancy	Review Status	Discrepancies.Current Review Status
Discrepancy	Comment Text	Discrepancies.Comment Text
Discrepancy	Sent in DCF	Discrepancies.Sent in DCF
Discrepancy	State	Discrepancies.Discrepancy State

List of Follow Up Items (Report CDA-CO-803)

Lists follow up items, including type, comments, and key dates.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

None

Dimensions

None

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

- # Follow Up Items by Type (Multiple Study-Sites) (Report CDA-CO-810)

Column Descriptions

The table describes the columns in the List of Follow Up Items report.

Table A–52 List of Follow Up Items (Report CDA-CO-803)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Follow Up Item	Type	Follow Up Item Metrics.Follow Up Item Type
Follow Up Item	Description	Follow Up Item Metrics.Follow Up Item Description
Follow Up Item	Comments	Follow Up Item Metrics.Follow Up Item Comments
Follow Up Item	Status	Follow Up Item Metrics.Follow Up Item Status
Follow Up Item	Created Date	Follow Up Item Metrics.Follow Up Item Created Date
Follow Up Item	Due Date	Follow Up Item Metrics.Follow Up Item Due Date
Follow Up Item	Completed Date	Follow Up Item Metrics.Follow Up Item Completed Date

Listing of Subject-Pages, Awaiting EDC Processing (Report CDA-DM-310)

Identifies specific eCRFs, and the process steps they are awaiting. This report lists, for a subject, the eCRFs which are awaiting processing. This information can be used to drive an activity.

Audience

- Data Manager

Report Type

- Table

Location

- **Data Manager - EDC** dashboard, **Study Processing Detail** page

Dimensions

- CRF
- Study-Site
- Subject

Supplementary Prompts

- Study
- Study-Site

Reports Referenced

None

Reports Referencing This Report

You can navigate to this report from the following reports:

- Summary of Subjects Awaiting EDC Processing (Report CDA-DM-320)

Column Descriptions

The table describes the columns in the Key EDC processing volumes report.

Table A–53 Listing of Subject-Pages, Awaiting EDC Processing (Report CDA-DM-310)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	NA	Study-Site.Program
NA	NA	Study-Site.Study Name
Study-Site	Site	Study-Site.Site Name
Subject	Subject ID	Subject.Subject ID
Visit	Name	Received CRFs.Visit Name
Visit	Number	Received CRFs.Complete Visit Number
Visit	Date	Received CRFs.Visit Date
CRF	Name	CRF.Name
Processing Required	Not Verified	Received CRFs.Is not in Verified state
Processing Required	Awaiting Re-verification	Received CRFs.Is Awaiting Re-Verification

Table A–53 (Cont.) Listing of Subject-Pages, Awaiting EDC Processing (Report

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Processing Required	Not Approved	Received CRFs.Is not in Approved state
Processing Required	Requires Re-Approval	Received CRFs.s Awaiting Re-Approval

Listing of Subject-Pages, Awaiting Paper Processing (Report CDA-DM-410)

Identifies specific CRFs, and the process steps they are awaiting. This report lists, for a subject, the pages which are awaiting processing. This information can be used to drive activity.

Audience

- Data Manager

Report Type

- Table

Location

- **Data Manager - Paper** dashboard, **Study Processing Detail** page

Dimensions

- CRF
- Subject

Supplementary Prompts

- Study
- Study-Site

Reports Referenced

None

Reports Referencing This Report

You can navigate to this report from the following reports:

- Summary of Subjects Awaiting Paper Processing (Report CDA-DM-420)

Column Descriptions

The table describes the columns in the Listing of Subject-Pages, Awaiting Paper Processing report.

Table A–54 Listing of Subject-Pages, Awaiting Paper Processing (Report CDA-DM-410)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	NA	Study-Site.Program
NA	NA	Study-Site.Study Name
Subject	Subject ID	Subject.Subject ID
Visit	Name	Received CRFs.Visit Name
Visit	Number	Received CRFs.Complete Visit Number
Visit	Date	Received CRFs.Visit Date
CRF	Name	CRF.Name
Processing Required	Awaiting First Entry	Received CRFs.Is Awaiting First Entry completion
Processing Required	Awaiting Second Entry	Received CRFs.Is Awaiting Second entry completion

Low Approved to Entered Rate - Worst Performers (Report CDA-DM-335)

Identifies sites who are slow at approving eCRFs. This report indicates the top 25 sites whose approval rates are less than 80% of those eCRFs entered. This information can be identify poor performing sites. Note: The 80% rate is based on those studies where the sites are requested to approve eCRFs immediately after entry. For those studies where this process is not relevant, the 80% threshold can be reduced.

Audience

- Data Manager
- CRA
- Project Manager

Report Type

- Graph, table (optional)

Location

- **Data Manager - EDC** dashboard, **Key Rates** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Low Approved to Entered Rate - Worst Performers report.

Table A–55 Low Approved to Entered Rate - Worst Performers (Report CDA-DM-335)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	NA	Study-Site.Study Name
Received CRFs	% eCRFs Approved / Entry Complete	Received CRFs.% eCRFs Approved / Entry Complete

Low Verified to Entered Rate - Worst Performers (Report CDA-DM-340)

Identifies sites where verification has been slow. This report displays the top sites whose verification rates are less than 50% of those pages entered. This information can be used to identify CRA resource shortfalls.

Audience

- Data Manager
- CRA
- Project Manager

Report Type

- Graph, table (optional)

Location

- **Data Manager - EDC** dashboard, **Key Rates** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Low Verified to Entered Rate - Worst Performers report.

Table A–56 Low Verified to Entered Rate - Worst Performers (Report CDA-DM-340)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	NA	Study-Site.Study Name
Received CRFs	% eCRFs Verified / Entry Complete	Received CRFs.% eCRFs Verified / Entry Complete

Median # Follow Up Items per Site for Study (Report CDA-CO-802)

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.

Audience

- Study Manager
- CRA

Report Type

- Graph, Table (optional)

Location

- **Study-Site Overview** dashboard, **Monitoring Metrics** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Median # Follow Up Items per Site for Study report.

Table A–57 Median # Follow Up Items per Site for Study (Report CDA-CO-802)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	Count of Follow Up Items	COUNT(- Follow Up Item Metrics.Follow Up Item Created Date)
NA	Follow Up Item Type	Follow Up Item Metrics.Follow Up Item Type
NA	Study	Study-Site.Study

Monitoring Report Approval - Turnaround Time vs. Goal (Report CDA-CO-813)

Displays monitoring report approval cycle times in the form of a scatter plot, compared to a static goal, over time. This report indicates how many visit report approvals have fallen above or below a threshold over time.

Audience

- Study Manager
- CRA

Report Type

- Graph, Table (optional)

Location

- **Study Manager** dashboard, **Monitoring Metrics** page
- **CRA** dashboard, **Monitoring Metrics** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Monitoring Report Approval - Turnaround Time vs. Goal report.

Table A–58 Monitoring Report Approval - Turnaround Time vs. Goal (Report CDA-CO-813)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Site Visit Report Completed Date	Site Visit.Site Visit Report Completed Date
NA	# Days from Visit Report Completed to Visit Report Approved	- Site Visit Metrics.# Days from Visit Report Completed to Visit Report Approved
NA	Target	12

Monitoring Report Approval Turnaround Times (Report CDA-CO-817)

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.

Audience

- Study Manager
- Region Manager
- CRA

Report Type

- Graph, Table (optional)

Location

- **Study Manager** dashboard, **Monitoring Metrics** page
- **Region Manager** dashboard, **Visit Reports & Follow Up Items** page

Dimensions

- All Purpose Date

Supplementary Prompts

Year Prompt

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Monitoring Report Approval Turnaround Times report.

Table A–59 Monitoring Report Approval Turnaround Times (Report CDA-CO-817)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Year and Month	All Purpose Date.Year and Month
NA	# Days from Visit Report Completed to Visit Report Approved	Site Visit Metrics.# Days from Visit Report Completed to Visit Report Approved
NA	Category	TBD

Monitoring Report Completion Turnaround Times (Report CDA-CO-820)

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.

Audience

- Study Manager
- Region Manager
- CRA

Report Type

- Graph, Table (optional)

Location

- **Study Manager** dashboard, **Monitoring Metrics** page
- **CRA** dashboard, **Monitoring Metrics** page
- **Region Manager** dashboard, **Visit Reports & Follow Up Items** page
- **Monitoring Metrics** page

Dimensions

- All Purpose Date

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Monitoring Report Completion Turnaround Times report.

Table A–60 Monitoring Report Completion Turnaround Times (Report CDA-CO-820)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Year and Month	All Purpose Date.Year and Month
NA	# Days from Site Visit Completed to Visit Report Completed	Site Visit Metrics.# Days from Site Visit Completed to Visit Report Completed
NA	Indicator	TBD

Monitoring Status Overview (Region Manager View) (Report CDA-CO-1101)

Shows count of outstanding visit reports, visit report approvals and follow up items

Audience

- Region Manager

Report Type

- Narrative

Location

- **Region Manager** dashboard, **Overview** page

Dimensions

- Study-Site

Supplementary Prompts

- NA

Reports Referenced

You can navigate to the following reports from this report:

- Outstanding Monitoring Reports (CRA View) (Report CDA-CO-804)

- Outstanding Monitoring Report Approvals (Study Manager View) (Report CDA-CO-809)
- Outstanding Follow up Items (Study Manager View) (Report CDA-CO-807)

Reports Referencing This Report

You can navigate to the following reports from this report:

- Outstanding Follow up Items (Study Manager View) (Report CDA-CO-807)
- Outstanding Monitoring Report Approvals (Study Manager View) (Report CDA-CO-809)

Column Descriptions

Table A–61 describes the columns in the Monitoring Status Overview (Region Manager View) analysis

Table A–61 Monitoring Status Overview (Region Manager View) (Report CDA-CO-1101)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Metrics	# Visit Reports Awaiting Completion	sum("- Study-Site Metrics"."# Visit Reports Awaiting Completion")
- Study-Site Metrics	[# Visit Reports Awaiting Approval]	sum("- Study-Site Metrics"."[# Visit Reports Awaiting Approval]")
- Site Visit Metrics	# Outstanding Follow Up Items	sum ("- Site Visit Metrics"."# Outstanding Follow Up Items")

Monitoring Status Overview (Study Manager View) (Report CDA-CO-107)

Shows count of outstanding visit reports, visit report approvals and follow up items

Audience

- Study Manager

Report Type

- Narrative

Location

- **Study Manager** dashboard, **Overview** page

Dimensions

- Study

Supplementary Prompts

- NA

Reports Referenced

You can navigate to the following reports from this report:

- Outstanding Monitoring Reports (CRA View) (Report CDA-CO-804)
- Outstanding Follow up Items (Study Manager View) (Report CDA-CO-807)
- Outstanding Monitoring Report Approvals (Study Manager View) (Report CDA-CO-809)

Reports Referencing This Report

None

Column Descriptions

Table A–62 describes the columns in the Monitoring Status Overview (Study Manager View) analysis.

Table A–62 Monitoring Status Overview (Study Manager View) (Report CDA-CO-107)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Metrics	# Visit Reports Awaiting Completion	sum("- Study-Site Metrics"."# Visit Reports Awaiting Completion")
- Study-Site Metrics	[# Visit Reports Awaiting Approval]	sum("- Study-Site Metrics"."[# Visit Reports Awaiting Approval]")
- Site Visit Metrics	# Outstanding Follow Up Items	sum ("- Site Visit Metrics"."# Outstanding Follow Up Items")

Number of Studies (Report CDA-CO-1001)

Pie chart that shows count of studies. Column selector allows user to view by Therapeutic Area, Program, or Phase.

Audience

- Executive

Report Type

- Pie Chart (View Selector)

Location

- **Executive** dashboard, **Overview** page

Dimensions

- Study

Supplementary Prompts

- NA

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–63 describes the columns in the Number of Studies analysis

Table A–63 Number of Studies (Report CDA-CO-1001)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Metrics	# Studies	"- Study Metrics"."# Studies"
Study	Study Phase	"Study"."Study Phase"
Study	Program	"Study"."Program"
Study	Therapeutic Area	"Study"."Therapeutic Area"

Outstanding Approvals at Risk of Missing Target: Visit Report Completed to Visit Report Approved (Report CDA-CO-826)

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

Audience

- Region Manager

Report Type

- Table

Location

None

Dimensions

- Study-Site, Site Visit

Supplementary Prompts

- NA

Reports Referenced

None

Reports Referencing This Report

You can navigate to the following reports from this report:

- Performance Metrics Summary Narrative - Site Visit (Report CDA-CO-1110)

Column Descriptions

Table A–64 describes the columns in the Outstanding Approvals at Risk of Missing Target: Visit Report Completed to Visit Report Approved analysis

Table A–64 Outstanding Approvals at Risk of Missing Target: Visit Report Completed to Visit Report Approved (Report CDA-CO-826)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study	"Study-Site"."Study"
Study-Site	Study Region	"Study-Site"."Study Region"
Study-Site	Study-Site ID #	"Study-Site"."Study-Site ID #"
Study-Site	Principal Investigator	"Study-Site"."Principal Investigator"
Study-Site	Study-Site Status	"Study-Site"."Study-Site Status"
Site Visit	Site Visit Name	"Site Visit"."Site Visit Name"
Site Visit	Site Visit Type	"Site Visit"."Site Visit Type"
Site Visit	Site Visit Start Date	"Site Visit"."Site Visit Start Date"
Site Visit	Site Visit Completed Date	"Site Visit"."Site Visit Completed Date"
Site Visit	Site Visit Report Completed Date	"Site Visit"."Site Visit Report Completed Date"
Site Visit	Site Visit Report Completed Date	TIMESTAMPDIFF(SQL_TSI_DAY,"Site Visit"."Site Visit Report Completed Date",VALUEOF("CURRENT_DAY"))
Overall Level Targets	[Target Site Visit Completed to Visit Report Completed (# Days)]	"Overall Level Targets"."[Target Site Visit Completed to Visit Report Completed (# Days)]"
Site Visit	Site Visit Report Completed Date	"Site Visit"."Site Visit Report Completed Date"
Site Visit	[Site Visit Report Approved Date]	"Site Visit"."[Site Visit Report Approved Date]"
Site Visit	Days Since Completed	CASE WHEN TIMESTAMPDIFF(SQL_TSI_DAY,"Site Visit"."Site Visit Report Completed Date",VALUEOF(CURRENT_DAY)) >=("Overall Level Targets"."[Target Visit Report Completed to Visit Report Approved (# Days)]" - 5) THEN 1 ELSE 0 END

Table A–64 (Cont.) Outstanding Approvals at Risk of Missing Target: Visit Report Completed to Visit Report Approved (Report CDA-CO-826)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Overall Level Targets	[Target Visit Report Completed to Visit Report Approved (# Days)]	CASE WHEN TIMESTAMPDIFF(SQL_TSI_DAY,"Site Visit"."Site Visit Report Completed Date",VALUEOF(CURRENT_DAY)) >=("Overall Level Targets"."[Target Visit Report Completed to Visit Report Approved (# Days)]" - 5) THEN 1 ELSE 0 END

Outstanding Approvals that Missed Target: Visit Report Completed to Visit Report Approved (Report CDA-CO-828)

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.

Audience

- Region Manager

Report Type

- Table

Location

None

Dimensions

- Study-Site, Site Visit

Supplementary Prompts

- NA

Reports Referenced

None

Reports Referencing This Report

You can navigate to the following reports from this report:

- Performance Metrics Summary Narrative - Site Visit (Report CDA-CO-1110)

Column Descriptions

Table A–65 describes the columns in the Outstanding Approvals that Missed Target: Visit Report Completed to Visit Report Approved analysis

Table A–65 Outstanding Approvals that Missed Target: Visit Report Completed to Visit Report Approved (Report CDA-CO-828)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study	"Study-Site"."Study"
Study-Site	Study Region	"Study-Site"."Study Region"
Study-Site	Study-Site ID #	"Study-Site"."Study-Site ID #"
Study-Site	Principal Investigator	"Study-Site"."Principal Investigator"
Study-Site	Study-Site Status	"Study-Site"."Study-Site Status"
Site Visit	Site Visit Name	"Site Visit"."Site Visit Name"
Site Visit	Site Visit Type	"Site Visit"."Site Visit Type"
Site Visit	Site Visit Start Date	"Site Visit"."Site Visit Start Date"
Site Visit	Site Visit Completed Date	"Site Visit"."Site Visit Completed Date"
Site Visit	Site Visit Report Completed Date	"Site Visit"."Site Visit Report Completed Date"
Site Visit	Days Since Completed	TIMESTAMPDIFF(SQL_TSI_DAY,"Site Visit"."Site Visit Report Completed Date",VALUEOF(CURRENT_DAY))
Overall Level Targets	[Target Visit Report Completed to Visit Report Approved (# Days)]	"Overall Level Targets"."[Target Visit Report Completed to Visit Report Approved (# Days)]"

Outstanding Documents List (Report CDA-CO-602)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

None

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

- Uninitiated Sites (Report CDA-CO-304)

Column Descriptions

The table describes the columns in the Outstanding Documents List report.

Table A–66 Outstanding Documents List (Report CDA-CO-602)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Study	Study-Site.Study
NA	Study-Site ID #	Study-Site.Study-Site ID #
NA	Principal Investigator	Study-Site.Principal Investigator
NA	Activity Type	Document Metrics.Activity Type
NA	Document Name	Document Metrics.Document Name
NA	Days Since Doc Sent	TIMESTAMPDIFF(SQL_TSI_DAY, - Document Metrics.Document Sent Date,NOW())
NA	Document Comments	Document Metrics.Document Comments

Outstanding Follow up Items - Study Overview (Report CDA-CO-805)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study Overview** dashboard, **Monitoring Metrics** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Outstanding Follow up Items - Study Overview report.

Table A–67 Outstanding Follow up Items - Study Overview (Report CDA-CO-805)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	CRA	Study-Site.CRA
Site Visit Follow Up Item Metrics	Follow Up Item Type	Follow Up Item Metrics.Follow Up Item Type
Site Visit Follow Up Item Metrics	Follow Up Item Status	Follow Up Item Metrics.Follow Up Item Status
Site Visit Follow Up Item Metrics	Follow Up Item Description	Follow Up Item Metrics.Follow Up Item Description
Site Visit Follow Up Item Metrics	Follow Up Item Comments	Follow Up Item Metrics.Follow Up Item Comments
Site Visit Follow Up Item Metrics	# Days Follow Up Item Open	Follow Up Item Metrics.# Days Follow Up Item Open
Indicator	Indicator	TBD

Outstanding Follow up Items (CRA View) (Report CDA-CO-806)

Lists the outstanding follow up items. This report indicates which active issues are occurring during monitoring visits, and how long they've been open.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **CRA** dashboard, **CRA Overview** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Outstanding Follow up Items (CRA View) report.

Table A–68 Outstanding Follow up Items (CRA View) (Report CDA-CO-806)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study	Study-Site.Study
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Site Visit Metrics	Type	Site Visit.Site Visit Type
Site Visit Metrics	Start Date	Site Visit.Site Visit Start Date
Site Visit Metrics	Completed Date	Site Visit.Site Visit Completed Date
Site Visit Follow Up Item Metrics	Type	Follow Up Item Metrics.Follow Up Item Type
Site Visit Follow Up Item Metrics	Status	Follow Up Item Metrics.Follow Up Item Status
Site Visit Follow Up Item Metrics	Description	Follow Up Item Metrics.Follow Up Item Description
Site Visit Follow Up Item Metrics	Comments	Follow Up Item Metrics.Follow Up Item Comments
Site Visit Follow Up Item Metrics	# Days Outstanding	Follow Up Item Metrics.# Days Follow Up Item Outstanding
NA	Indicator	TBD

Outstanding Follow up Items (Study Manager View) (Report CDA-CO-807)

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.

Audience

- Study Manager
- Region Manager
- CRA

Report Type

- Table

Location

- **Study Manager** dashboard, **Monitoring Metrics** page
- **Region Manager** dashboard, **Visit Reports & Follow Up Items** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Outstanding Follow up Items (Study Manager View) report.

Table A–69 Outstanding Follow up Items (Study Manager View) (Report CDA-CO-807)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study	Study-Site.Study
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	CRA	Study-Site.CRA

Table A–69 (Cont.) Outstanding Follow up Items (Study Manager View) (Report

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Site Visit Follow Up Item Metrics	Type	Follow Up Item Metrics.Follow Up Item Type
Site Visit Follow Up Item Metrics	Status	Follow Up Item Metrics.Follow Up Item Status
Site Visit Follow Up Item Metrics	Description	Follow Up Item Metrics.Follow Up Item Description
Site Visit Follow Up Item Metrics	Comments	Follow Up Item Metrics.Follow Up Item Comments
Site Visit Follow Up Item Metrics	# Days Open	Follow Up Item Metrics.# Days Follow Up Item Open
NA	Indicator	TBD

Outstanding Follow up Items (Study-Region Overview) (Report CDA-CO-832)

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.

Audience

- Study Manager CRA

Report Type

- Table

Location

- **Study-Region Overview** dashboard, **Visit Reports and Follow Up Items** page

Dimensions

- Study-Site

Supplementary Prompts

- Visit Reports and Follow Up Items page prompt

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–70 describes the columns in the Outstanding Follow up Items (Study-Region Overview) analysis

Table A–70 Outstanding Follow up Items (Study-Region Overview) (Report CDA-CO-832)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Region	Region Name	"Study-Region"."Region Name"
Study-Site	Study	"Study-Site"."Study"
Study-Site	Study-Site ID #	"Study-Site"."Study-Site ID #"
Study-Site	Principal Investigator	"Study-Site"."Principal Investigator"
Study-Site	Study-Site Status	"Study-Site"."Study-Site Status"
Study-Site	CRA	"Study-Site"."CRA"
Site Visit	Site Visit Type	"Site Visit"."Site Visit Type"
Site Visit	Site Visit Start Date	"Site Visit"."Site Visit Start Date"
Site Visit	Site Visit Completed Date	"Site Visit"."Site Visit Completed Date"
- Follow Up Item Metrics	Follow Up Item Type	"- Follow Up Item Metrics"."Follow Up Item Type"
- Follow Up Item Metrics	Follow Up Item Status	"- Follow Up Item Metrics"."Follow Up Item Status"
- Follow Up Item Metrics	Follow Up Item Description	"- Follow Up Item Metrics"."Follow Up Item Description"
- Follow Up Item Metrics	Follow Up Item Comments	"- Follow Up Item Metrics"."Follow Up Item Comments"
- Follow Up Item Metrics	# Days Follow Up Item Open	"- Follow Up Item Metrics"."# Days Follow Up Item Open"
- Follow Up Item Metrics	# Days Follow Up Item Outstanding	"- Follow Up Item Metrics"."# Days Follow Up Item Outstanding"
- Follow Up Item Metrics	Indicator	CASE WHEN ROUND("- Follow Up Item Metrics"."# Days Follow Up Item Outstanding" , 1)>60 THEN '1-Red' WHEN ROUND("- Follow Up Item Metrics"."# Days Follow Up Item Outstanding", 1) BETWEEN 30 AND 60 THEN '2-Yellow' WHEN ROUND("- Follow Up Item Metrics"."# Days Follow Up Item Outstanding", 1)<30 THEN '3-Green' ELSE '' END

Outstanding Follow up Items (Study-Site Overview) (Report CDA-CO-815)

Lists all follow up items that have not been completed. This report indicates which follow up items need to be resolved.

Audience

- Study Manager

- CRA

Report Type

- Table

Location

- **Study-Site Overview** dashboard, **Visit Reports and Follow up Items** page

Dimensions

- Site Visit

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Outstanding Follow up Items (Study-Site Overview) report.

Table A–71 Outstanding Follow up Items (Study-Site Overview) (Report CDA-CO-815)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Site Visit Metrics	Type	Site Visit.Site Visit Type
Site Visit Metrics	Start Date	Site Visit.Site Visit Start Date
Site Visit Metrics	Completed Date	Site Visit.Site Visit Completed Date
Site Visit Follow Up Item Metrics	Type	Follow Up Item Metrics.Follow Up Item Type
Site Visit Follow Up Item Metrics	Status	Follow Up Item Metrics.Follow Up Item Status
Site Visit Follow Up Item Metrics	Description	Follow Up Item Metrics.Follow Up Item Description
Site Visit Follow Up Item Metrics	Comments	Follow Up Item Metrics.Follow Up Item Comments
Site Visit Follow Up Item Metrics	# Days Open	Follow Up Item Metrics.# Days Follow Up Item Open

Outstanding Monitoring Report Approvals (CRA View) (Report CDA-CO-814)

Lists all monitoring reports awaiting approval. This report indicates which monitoring reports require an action: review and approval.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **CRA** dashboard, **CRA Overview** page

Dimensions

- Study-Site
- Site Visit

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Outstanding Monitoring Report Approvals (CRA View) report.

Table A–72 Outstanding Monitoring Report Approvals (CRA View) (Report CDA-CO-814)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Study	Study-Site.Study
NA	Study-Site ID #	Study-Site.Study-Site ID #
NA	Principal Investigator	Study-Site.Principal Investigator
NA	Site Visit Type	Site Visit.Site Visit Type
NA	Site Visit Start Date	Site Visit.Site Visit Start Date

Table A–72 (Cont.) Outstanding Monitoring Report Approvals (CRA View) (Report

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Site Visit Completed Date	Site Visit.Site Visit Completed Date
NA	# Days Visit Report Approval Outstanding	Site Visit Metrics.# Days Visit Report Approval Outstanding
NA	Indicator	TBD

Outstanding Monitoring Report Approvals (Study Manager View) (Report CDA-CO-809)

Lists the monitoring reports that have been completed but not yet approved. This report indicates which monitoring reports require approval.

Audience

- Study Manager
- Region Manager
- CRA

Report Type

- Table

Location

- **Study Manager** dashboard, **Monitoring Metrics** page
- **Region Manager** dashboard, **Visit Reports & Follow Up Items** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Outstanding Monitoring Report Approvals (Study Manager View) report.

Table A–73 Outstanding Monitoring Report Approvals (Study Manager View) (Report CDA-CO-809)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Study	Study-Site.Study
NA	Study-Site ID #	Study-Site.Study-Site ID #
NA	Principal Investigator	Study-Site.Principal Investigator
NA	CRA	Study-Site.CRA
NA	Study-Site Status	Study-Site.Study-Site Status
NA	Site Visit Completed Date	Site Visit.Site Visit Completed Date
NA	Site Visit Type	Site Visit.Site Visit Type
NA	# Days Visit Report Approval Outstanding	Site Visit Metrics.# Days Visit Report Approval Outstanding
NA	Indicator	TBD

Outstanding Monitoring Report Approvals (Study-Region) (Report CDA-CO-831)

Lists all monitoring reports awaiting approval in the study region. This report indicates which monitoring reports require an action: review and approval.

Audience

- Study Manager CRA

Report Type

- Table

Location

- **Study-Region Overview** dashboard, **Monitoring Reports and Follow Up Items** page

Dimensions

- Study-Site

Supplementary Prompts

- NA

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–74 describes the columns in the Outstanding Visit Report Approvals (Study-Region) analysis

Table A–74 Outstanding Visit Report Approvals (Study-Region) (Report CDA-CO-831)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study	"Study-Site"."Study"
Study-Region	Region Name	"Study-Region"."Region Name"
Study-Site	Study-Site ID #	"Study-Site"."Study-Site ID #"
Study-Site	Principal Investigator	"Study-Site"."Principal Investigator"
Study-Site	Study-Site Status	"Study-Site"."Study-Site Status"
Study-Site	CRA	"Study-Site"."CRA"
Site Visit	Site Visit Type	"Site Visit"."Site Visit Type"
Site Visit	Site Visit Start Date	"Site Visit"."Site Visit Start Date"
Site Visit	Site Visit Completed Date	"Site Visit"."Site Visit Completed Date"
Site Visit	Site Visit Report Completed Date	"Site Visit"."Site Visit Report Completed Date"
- Site Visit Metrics	# Days Visit Report Approval Outstanding	"- Site Visit Metrics"."# Days Visit Report Approval Outstanding"
- Site Visit Metrics	Indicator	CASE when ROUND("- Site Visit Metrics"."# Days Visit Report Approval Outstanding", 1)>20 THEN '1-Red' WHEN (ROUND("- Site Visit Metrics"."# Days Visit Report Approval Outstanding", 1) >=10 and ROUND("- Site Visit Metrics"."# Days Visit Report Approval Outstanding" , 1)<= 20)THEN '2-Yellow' WHEN ROUND("- Site Visit Metrics"."# Days Visit Report Approval Outstanding", 1) < 10 THEN '3-Green' ELSE '3-Green' END

Outstanding Monitoring Report Approvals (Study-Site) (Report CDA-CO-822)

Lists all monitoring reports awaiting approval at the study-site. This report indicates which monitoring reports require an action: review and approval.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study-Site Overview** dashboard, **Visit Reports and Follow up Items** page

Dimensions

- Site Visit

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Outstanding Monitoring Report Approvals (Study-Site) report.

Table A–75 Outstanding Monitoring Report Approvals (Study-Site) (Report CDA-CO-822)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Site Visit Type	Site Visit.Site Visit Type
NA	Site Visit Start Date	Site Visit.Site Visit Start Date
NA	Site Visit Completed Date	Site Visit.Site Visit Completed Date
NA	Site Visit Report Completed Date	Site Visit.Site Visit Report Completed Date
NA	# Days Visit Report Approval Outstanding	Site Visit Metrics.# Days Visit Report Approval Outstanding
NA	Indicator	CASE when - Site Visit Metrics.# Days Visit Report Approval Outstanding>20 THEN '1-Red' WHEN - Site Visit Metrics.# Days Visit Report Approval Outstanding between 11 and 20 THEN '2-Yellow' ELSE '3-Green' END

Outstanding Monitoring Reports (CRA View) (Report CDA-CO-804)

Lists all monitoring reports awaiting completion. This report indicates which monitoring reports need to be completed and submitted for approval.

Audience

- Study Manager

- CRA

Report Type

- Table

Location

- **CRA** dashboard, **CRA Overview** page

Dimensions

- Study-Site
- Site Visit

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

- Monitoring Status Overview (Study Manager View) (Report CDA-CO-107)
- Monitoring Status Overview (Region Manager View) (Report CDA-CO-1101)

Column Descriptions

The table describes the columns in the Outstanding Monitoring Reports (CRA View) report.

Table A–76 Outstanding Monitoring Reports (CRA View) (Report CDA-CO-804)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Study	Study-Site.Study
NA	Study-Site ID #	Study-Site.Study-Site ID #
NA	Principal Investigator	Study-Site.Principal Investigator
NA	Site Visit Type	Site Visit.Site Visit Type
NA	Site Visit Start Date	Site Visit.Site Visit Start Date
NA	Site Visit Completed Date	Site Visit.Site Visit Completed Date
NA	# Days Visit Report Completion Outstanding	Site Visit Metrics.# Days Visit Report Completion Outstanding
NA	Indicator	TBD

Outstanding Monitoring Reports (Study-Region View) (Report CDA-CO-830)

Lists all monitoring reports awaiting completion at the study region. This report indicates which monitoring reports need to be completed and submitted for approval.

Audience

- Region Manager Study Manager CRA

Report Type

- Table

Location

- **Study-Region Overview** dashboard, **Monitoring Reports and Follow Up Items** page

Dimensions

- Study-Site, Site Visit

Supplementary Prompts

- NA

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–77 describes the columns in the Outstanding Visit Reports (Study-Region View) analysis

Table A–77 Outstanding Visit Reports (Study-Region View) (Report CDA-CO-830)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study	"Study-Site"."Study"
Study-Region	Region Name	"Study-Region"."Region Name"
Study-Site	Study-Site ID #	"Study-Site"."Study-Site ID #"
Study-Site	Principal Investigator	"Study-Site"."Principal Investigator"
Study-Site	Study-Site Status	"Study-Site"."Study-Site Status"
Study-Site	CRA	"Study-Site"."CRA"
Site Visit	Site Visit Type	"Site Visit"."Site Visit Type"

Table A–77 (Cont.) Outstanding Visit Reports (Study-Region View) (Report CDA-CO-830)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Site Visit	Site Visit Start Date	"Site Visit"."Site Visit Start Date"
Site Visit	Site Visit Completed Date	"Site Visit"."Site Visit Completed Date"
- Site Visit Metrics	# Days Visit Report Completion Outstanding	"- Site Visit Metrics"."# Days Visit Report Completion Outstanding"
- Site Visit Metrics	Indicator	CASE WHEN ROUND("- Site Visit Metrics"."# Days Visit Report Completion Outstanding", 1)>20 THEN '1-Red' WHEN (ROUND("- Site Visit Metrics"."# Days Visit Report Completion Outstanding" , 1)>= 10 and ROUND("- Site Visit Metrics"."# Days Visit Report Completion Outstanding" , 1)<= 20) THEN '2-Yellow' WHEN ROUND("- Site Visit Metrics"."# Days Visit Report Completion Outstanding", 1) <10 then '3-Green' else '3-Green' END

Outstanding Monitoring Reports (Study-Site View) (Report CDA-CO-811)

Lists all monitoring reports awaiting completion at the study-site. This report indicates which monitoring reports need to be completed and submitted for approval.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study-Site Overview** dashboard, **Visit Reports and Follow up Items** page

Dimensions

- Site Visit

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Outstanding Monitoring Reports (Study-Site View) report.

Table A–78 Outstanding Monitoring Reports (Study-Site View) (Report CDA-CO-811)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Site Visit Type	Site Visit.Site Visit Type
NA	Site Visit Start Date	Site Visit.Site Visit Start Date
NA	Site Visit Completed Date	Site Visit.Site Visit Completed Date
NA	# Days Visit Report Completion Outstanding	Site Visit Metrics.# Days Visit Report Completion Outstanding
NA	Indicator	CASE WHEN - Site Visit Metrics.# Days Visit Report Completion Outstanding >20 THEN '1-Red' WHEN - Site Visit Metrics.# Days Visit Report Completion Outstanding between 10 and 20 THEN '2-Yellow' ELSE '3-Green' END

Outstanding Reports at Risk of Missing Target: Visit Completed to Visit Report Completed (Report CDA-CO-824)

Lists all completed site visits that don't 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.

Audience

- Region Manager

Report Type

- Table

Location

None

Dimensions

- Study-Site, Site Visit

Supplementary Prompts

- NA

Reports Referenced

None

Reports Referencing This Report

You can navigate to the following reports from this report:

- Performance Metrics Summary Narrative - Site Visit (Report CDA-CO-1110)

Column Descriptions

Table A–79 describes the columns in the Outstanding Reports at Risk of Missing Target: Visit Completed to Visit Report Completed analysis

Table A–79 Outstanding Reports at Risk of Missing Target: Visit Completed to Visit Report Completed (Report CDA-CO-824)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study	"Study-Site"."Study"
Study-Site	Study Region	"Study-Site"."Study Region"
Study-Site	Study-Site ID #	"Study-Site"."Study-Site ID #"
Study-Site	Principal Investigator	"Study-Site"."Principal Investigator"
Study-Site	Study-Site Status	"Study-Site"."Study-Site Status"
Site Visit	Site Visit Name	"Site Visit"."Site Visit Name"
Site Visit	Site Visit Type	"Site Visit"."Site Visit Type"
Site Visit	Site Visit Start Date	"Site Visit"."Site Visit Start Date"
Site Visit	Site Visit Completed Date	"Site Visit"."Site Visit Completed Date"
Site Visit	Site Visit Completed Date	TIMESTAMPDIFF(SQL_TSI_DAY,"Site Visit"."Site Visit Completed Date",VALUEOF("CURRENT_DAY"))
Overall Level Targets	[Target Site Visit Completed to Visit Report Completed (# Days)]	"Overall Level Targets"."[Target Site Visit Completed to Visit Report Completed (# Days)]"
- Site Visit Metrics	# Days from Site Visit Start to Site Visit Completed	"- Site Visit Metrics"."# Days from Site Visit Start to Site Visit Completed"
Site Visit	Site Visit Completed Date	"Site Visit"."Site Visit Completed Date"
Site Visit	Site Visit Report Completed Date	"Site Visit"."Site Visit Report Completed Date"
Site Visit	Days Since Completed	CASE WHEN TIMESTAMPDIFF(SQL_TSI_DAY,"Site Visit"."Site Visit Completed Date",VALUEOF(CURRENT_DAY)) >=("Overall Level Targets"."[Target Site Visit Completed to Visit Report Completed (# Days)]" - 5) THEN 1 ELSE 0 END

Table A–79 (Cont.) Outstanding Reports at Risk of Missing Target: Visit Completed to Visit Report Completed (Report CDA-CO-824)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Overall Level Targets	[Target Site Visit Completed to Visit Report Completed (# Days)]	CASE WHEN TIMESTAMPDIFF(SQL_TSI_DAY,"Site Visit"."Site Visit Completed Date",VALUEOF(CURRENT_DAY)) >=("Overall Level Targets"."[Target Site Visit Completed to Visit Report Completed (# Days)]" - 5) THEN 1 ELSE 0 END

Outstanding Reports that Missed Target - Site Visit Completed to Visit Report Completed (Report CDA-CO-827)

Lists all completed site visits that don't 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.

Audience

- Region Manager

Report Type

- Table

Location

None

Dimensions

- Study-Site, Site Visit

Supplementary Prompts

- NA

Reports Referenced

None

Reports Referencing This Report

You can navigate to the following reports from this report:

- Performance Metrics Summary Narrative - Site Visit (Report CDA-CO-1110)

Column Descriptions

Table A–80 describes the columns in the Outstanding Reports that Missed Target: Site Visit Completed to Visit Report Completed analysis

Table A–80 Outstanding Reports that Missed Target: Site Visit Completed to Visit Report Completed (Report CDA-CO-827)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study	"Study-Site"."Study"
Study-Site	Study Region	"Study-Site"."Study Region"
Study-Site	Study-Site ID #	"Study-Site"."Study-Site ID #"
Study-Site	Principal Investigator	"Study-Site"."Principal Investigator"
Study-Site	Study-Site Status	"Study-Site"."Study-Site Status"
Site Visit	Site Visit Name	"Site Visit"."Site Visit Name"
Site Visit	Site Visit Type	"Site Visit"."Site Visit Type"
Site Visit	Site Visit Start Date	"Site Visit"."Site Visit Start Date"
Site Visit	Site Visit Completed Date	"Site Visit"."Site Visit Completed Date"
Site Visit	Site Visit Completed Date	TIMESTAMPDIFF(SQL_TSI_DAY,"Site Visit"."Site Visit Completed Date",VALUEOF("CURRENT_DAY"))
Overall Level Targets	[Target Site Visit Completed to Visit Report Completed (# Days)]	"Overall Level Targets"."[Target Site Visit Completed to Visit Report Completed (# Days)]"
Site Visit	Site Visit Completed Date	"Site Visit"."Site Visit Completed Date"
Site Visit	Days Since Completed	CASE WHEN TIMESTAMPDIFF(SQL_TSI_DAY,"Site Visit"."Site Visit Completed Date",VALUEOF(CURRENT_DAY)) > "Overall Level Targets"."[Target Site Visit Completed to Visit Report Completed (# Days)]" THEN 1 ELSE 0 END
Overall Level Targets	[Target Site Visit Completed to Visit Report Completed (# Days)]	CASE WHEN TIMESTAMPDIFF(SQL_TSI_DAY,"Site Visit"."Site Visit Completed Date",VALUEOF(CURRENT_DAY)) > "Overall Level Targets"."[Target Site Visit Completed to Visit Report Completed (# Days)]" THEN 1 ELSE 0 END
Site Visit	Site Visit Report Completed Date	"Site Visit"."Site Visit Report Completed Date"

Pages Awaiting Entry Completion (Report CDA-DM-450)

Identifies specific subjects who have CRFs awaiting processing. This report indicates those subjects which require processing, and the number of CRFs to be processed. This information can be used as a summary work log to drive activity.

Audience

- Data Entry Manager
- Data Manager

Report Type

- Graph, table (optional)

Location

- **Data Manager - Paper** dashboard, **Home** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Pages Awaiting Entry Completion report.

Table A–81 Pages Awaiting Entry Completion (Report CDA-DM-450)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	NA	Study-Site.Study Name
# CRFs	Awaiting First Entry Completion	Received CRFs.# pCRFs Awaiting Pass 1 Entry Completion
# CRFs	Awaiting Second Entry Completion	Received CRFs.# pCRFs Awaiting Pass 2 Entry Completion

Paper Processing - Longest Cycle Times (Report CDA-DM-415)

Identifies the cycle times from subject visit to entry completion. This report displays the top studies with the longest cycle times for paper processing. This information can be used to highlight process inefficiencies and potential resource shortfalls.

Audience

- Data Manager

Report Type

- Graph, table (optional)

Location

- **Data Manager - Paper** dashboard, **Performance** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Paper Processing - Longest Cycle Times report.

Table A–82 Paper Processing - Longest Cycle Times (Report CDA-DM-415)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	NA	Study-Site.Study Name
Received CRFs	Avg # Days from First Entry to Second Entry Complete	Received CRFs.Avg # Days from pCRF First Entry to Second Entry Complete
Received CRFs	Avg # Days from Visit to First Entry	Received CRFs.Avg # Days from pCRF Visit to First Entry

Performance Metrics Summary Narrative - Site Visit (Report CDA-CO-1110)

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.

Audience

- Region Manager Study Manager

Report Type

- Narrative

Location

- **Study Manager** dashboard, **KPI Summary Region Manager dashboard, KPI Summary** page

Dimensions

- Site Visit

Supplementary Prompts

- NA

Reports Referenced

You can navigate to the following reports from this report:

- Completed Reports that Missed Target: Site Visit Completed to Visit Report Completed (Report CDA-CO-823)
- Outstanding Reports that Missed Target - Site Visit Completed to Visit Report Completed (Report CDA-CO-827)
- Outstanding Reports at Risk of Missing Target: Visit Completed to Visit Report Completed (Report CDA-CO-824)
- Approved Reports that Missed Target: Visit Report Completed to Visit Report Approved (Report CDA-CO-825)
- Outstanding Approvals that Missed Target: Visit Report Completed to Visit Report Approved (Report CDA-CO-828)
- Outstanding Approvals at Risk of Missing Target: Visit Report Completed to Visit Report Approved (Report CDA-CO-826)

Reports Referencing This Report

None

Column Descriptions

Table A–83 describes the columns in the Performance Metrics Summary Narrative: Site Visit analysis

Table A–83 Performance Metrics Summary Narrative: Site Visit (Report CDA-CO-1110)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Metrics	# Completed Visits	"- Study-Site Metrics"."# Completed Site Visits"

Table A–83 (Cont.) Performance Metrics Summary Narrative: Site Visit (Report

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Site Visit Metrics	# Visit Reports that Missed Target	SUM(CASE WHEN "- Site Visit Metrics"."# Days from Site Visit Completed to Visit Report Completed" > "Overall Level Targets"."[Target Site Visit Completed to Visit Report Completed (# Days)]" THEN 1 ELSE 0 END)
Overall Level Targets	# Visit Reports that Missed Target (%)	SUM(CASE WHEN "- Site Visit Metrics"."# Days from Site Visit Completed to Visit Report Completed" > "Overall Level Targets"."[Target Site Visit Completed to Visit Report Completed (# Days)]" THEN 1 ELSE 0 END)
- Study-Site Metrics	# Completed Visits Awaiting Monitoring Report	"- Study-Site Metrics"."# Visit Reports Awaiting Completion"
- Site Visit Metrics	# Visits that Missed Target	SUM(CASE WHEN "- Site Visit Metrics"."# Days from Site Visit Completed to Visit Report Completed" > "Overall Level Targets"."[Target Site Visit Completed to Visit Report Completed (# Days)]" THEN 1 ELSE 0 END)/("- Study-Site Metrics"."# Visit Reports")* 100
Site Visit	# Visits at Risk of Missing Target	SUM(CASE WHEN "Site Visit"."Site Visit Completed Date" IS NOT NULL AND "Site Visit"."Site Visit Report Completed Date" IS NOT NULL AND TIMESTAMPDIFF(SQL_TSI_DAY,"Site Visit"."Site Visit Completed Date",VALUEOF("CURRENT_DAY")) > "Overall Level Targets"."[Target Site Visit Completed to Visit Report Completed (# Days)]" THEN 1 ELSE 0 END)
Site Visit	# Visits with Monitoring Report Approved	FILTER("- Study-Site Metrics"."# Visit Reports" USING ("Site Visit"."[Site Visit Report Approved Date]" IS NOT NULL))
- Site Visit Metrics	# Visits that Missed Target	SUM(CASE WHEN "- Site Visit Metrics"."[# Days from Visit Report Completed to Visit Report Approved]" > "Overall Level Targets"."[Target Visit Report Completed to Visit Report Approved (# Days)]" THEN 1 ELSE 0 END)
- Study-Site Metrics	# Completed Reports Awaiting Approval	"- Study-Site Metrics"."[# Visit Reports Awaiting Approval]"

Table A–83 (Cont.) Performance Metrics Summary Narrative: Site Visit (Report

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Site Visit	# Visits that Missed Target	SUM(CASE WHEN "Site Visit"."Site Visit Report Completed Date" IS NOT NULL AND "Site Visit"."[Site Visit Report Approved Date]" IS NULL AND TIMESTAMPDIFF(SQL_TSI_DAY,"Site Visit"."Site Visit Report Completed Date",VALUEOF("CURRENT_DAY")) > "Overall Level Targets"."[Target Visit Report Completed to Visit Report Approved (# Days)]" THEN 1 ELSE 0 END)/ "- Study-Site Metrics"."[# Visit Reports Awaiting Approval]" * 100
Site Visit	# Visits at Risk of Missing Target	SUM(CASE WHEN "Site Visit"."Site Visit Report Completed Date" IS NOT NULL AND "Site Visit"."[Site Visit Report Approved Date]" IS NULL AND TIMESTAMPDIFF(SQL_TSI_DAY,"Site Visit"."Site Visit Report Completed Date",VALUEOF("CURRENT_DAY")) >= ("Overall Level Targets"."[Target Visit Report Completed to Visit Report Approved (# Days)]"-5) AND TIMESTAMPDIFF(SQL_TSI_DAY,"Site Visit"."Site Visit Report Completed Date",VALUEOF("CURRENT_DAY")) <= "Overall Level Targets"."[Target Visit Report Completed to Visit Report Approved (# Days)]" THEN 1 ELSE 0 END)/"- Study-Site Metrics"."[# Visit Reports Awaiting Approval]" * 100

Screen Failure Reason (Report CDA-CO-420)

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.

Audience

- Study Manager
- CRA

Report Type

- Graph, Table (optional)

Location

- **Study-Site Overview** dashboard, **Screening and Recruitment Overview** page

Dimensions

- Subject

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Subjects who Failed Screening (Report CDA-CO-428)

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Screen Failure Reason report.

Table A–84 Screen Failure Reason (Report CDA-CO-420)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Screen Failure Reason	Subject.Screen Failure Reason
NA	Count of Screen Failure Reasons	COUNT(Subject.Screen Failure Reason)

Screen Failure Reason (Report CDA-CO-425)

Displays (by screen failure reason) the number of subjects who failed screening. This report indicates which screen failure reasons account for the most screen failures.

Audience

- Study Manager
- Region Manager
- CRA

Report Type

- Graph, table (optional)

Location

- **Study Overview** dashboard, **Screening Overview** page
- **Study-Region Overview** dashboard, **Screening Overview** page

Dimensions

- Subject

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Subjects who Failed Screening (Report CDA-CO-428)

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Screen Failure Reason report.

Table A–85 Screen Failure Reason (Report CDA-CO-425)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Subject	Screen Failure Reason	Subject.Screen Failure Reason
NA	Subject Status	COUNT(- Subject Metrics.Subject Status)

Screen Failure Reason by Site (Report CDA-CO-300)

Displays (by site) the number of subjects who failed screening. This report indicates which screen failure reasons account for the most screen failures.

Audience

- Study Manager
- CRA

Report Type

- Graph, table (optional)

Location

- **Study Overview** dashboard, **Screening Overview** page
- **Study Region Overview** dashboard, **Screening Overview** page

Dimensions

- Subject
- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Subjects who Failed Screening (Report CDA-CO-428)

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Screen Failure Reason by Site report.

Table A–86 Screen Failure Reason by Site (Report CDA-CO-300)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	Subject Status	COUNT(- Subject Metrics.Subject Status)
Subject	Screen Failure Reason	Subject.Screen Failure Reason
Study-Site	Study, Site, and Investigator	Study-Site.Study, Site, and Investigator

Screening Overview (Study Level) (Report CDA-CO-407)

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.

Audience

- Study Manager
- CRA

Report Type

- Narrative

Location

- **Study Overview** dashboard, **Screening Overview** page

Dimensions

None

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Screening Overview (Study Level) report.

Table A–87 Screening Overview (Study Level) (Report CDA-CO-407)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	# Planned	Study Metrics.# Subjects Planned for Study
NA	# Screened	Study-Site Metrics.# Screened
NA	# Re-Screened	Study-Site Metrics.# Re-Screened
NA	# Screen Failure	Study-site Metrics.# Screen Failure
NA	# Enrolled	Study-site Metrics.# Subjects Enrolled
NA	% Enrolled / Planned	Study Metrics.% Enrolled / Planned in Study
NA	# Randomized	Study-site Metrics.# Randomized
NA	% Randomized / Planned	Study Metrics.% Randomized vs. Planned Study

Screening Overview (Study-Region Level) (Report CDA-CO-434)

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.

Audience

- Region Manager

Report Type

- Narrative

Location

- **Study-Region Overview** dashboard, **Screening Overview** page

Dimensions

- Study-Region

Supplementary Prompts

- NA

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–88 describes the columns in the Screening Overview (Study-Region Level) analysis

Table A–88 Screening Overview (Study-Region Level) (Report CDA-CO-434)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Region Metrics	# Subjects Planned for Study-Region	"- Study Region Metrics"."# Subjects Planned for Study-Region"
- Study-Site Metrics	# Screened	"- Study-Site Metrics"."# Screened"
- Study-Site Metrics	# Re-Screened	"- Study-Site Metrics"."# Re-Screened"
- Study-Site Metrics	# Screen Failure	"- Study-site Metrics"."# Screen Failure"
- Study-Site Metrics	# Enrolled	"- Study-site Metrics"."# Enrolled"
- Study Region Metrics	% Enrolled to Total Planned at Study Region	"- Study Region Metrics"."% Enrolled to Total Planned at Study Region"
- Study-Site Metrics	# Randomized	"- Study-site Metrics"."# Randomized"
- Study Region Metrics	% Planned Subjects Randomized	"- Study Region Metrics"."% Planned Subjects Randomized"

Screening Overview (Study-Site Level) (Report CDA-CO-415)

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.

Audience

- Study Manager
- CRA

Report Type

- Narrative

Location

- **Study-Site Overview** dashboard, **Screening and Recruitment Overview** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Screening Overview (Study-Site Level) report.

Table A–89 Screening Overview (Study-Site Level) (Report CDA-CO-415)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
For Study:	# Planned	Study Metrics.# Subjects Planned for Study
For Study-Site:	# Planned	Study-site Metrics.# Subjects Planned for Study-Site
NA	# Screened	Study-site Metrics.# Screened
NA	# Re-Screened	Study-site Metrics.# Re-Screened
NA	# Screen Failure	Study-site Metrics.# Screen Failure
NA	# Enrolled	Study-site Metrics.# Subjects Enrolled
NA	% Planned Site Enrollment Completed	Study-site Metrics.% of Planned Site Enrollment Completed
NA	% of Total Enrolled in Study	Study-site Metrics.% of Total Enrolled in Study
NA	# Randomized	Study-site Metrics.# Randomized
NA	% Randomized / Planned - Study	Study Metrics.% Randomized vs. Planned - Study

Table A–89 (Cont.) Screening Overview (Study-Site Level) (Report CDA-CO-415)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	% of Total Randomized in Study	Study-site Metrics.% of Total Randomized in Study

Screening vs. Enrollment by Region (Report CDA-CO-400)

Displays cumulative screening and enrollment by study region. This report indicates how each region in a study is progressing toward recruitment goals.

Audience

- Study Manager
- CRA
- Region Manager

Report Type

- Graph, Table (optional)

Location

- **Study Overview** dashboard, **Screening Overview** page
- **Study Region Overview** dashboard, **Screening Overview** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Screening vs. Enrollment by Region report.

Table A–90 Screening vs. Enrollment by Region (Report CDA-CO-400)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	Study Region	Study-Site.Study Region
NA	# Enrolled	Study-site Metrics.# Subjects Enrolled
NA	# Screened	Study-site Metrics.# Screened

Site Detail (Report CDA-CO-209)

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.

Audience

- Study Manager
- CRA

Report Type

- Pivot Table

Location

None

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

You can navigate to this report from the following reports:

- Enrollment Overview By Site (Report CDA-CO-426)

Column Descriptions

The table describes the columns in the Site Detail report.

Table A–91 Site Detail (Report CDA-CO-209)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	Program	Study-Site.Program
NA	Product Name	Study-Site.Product Name
NA	Study	Study-Site.Study
NA	Study Status	Study.Study Status
NA	Study Region	Study-Site.Study Region
NA	Region Status	Region.Region Status
NA	Site Name	Study-Site.Site Name
NA	Principal Investigator	Study-Site.Principal Investigator
NA	CRA	Study-Site.CRA
NA	Study-Site Status	Study-Site.Study-Site Status
NA	First Subject Screened Date	Study-Site Metrics.First Subject Screened Date
NA	First Subject Enrolled Date	Study-Site Metrics.First Subject Enrolled Date
NA	First Subject Randomized Date	Study-Site Metrics.First Subject Randomized Date
NA	# Subjects Planned for Study-Site	Study-site Metrics.# Subjects Planned for Study-Site
NA	# Screened	Study-site Metrics.# Screened
NA	# Re-Screened	Study-site Metrics.# Re-Screened
NA	# Subjects Enrolled	Study-site Metrics.# Subjects Enrolled
NA	# Randomized	Study-site Metrics.# Randomized

Site Enrollment Performance Compared to Site Visit Frequency (Report CDA-CO-110)

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.

Audience

- Study Manager

Report Type

- Scatter Plot

Location

- **Study Overview** dashboard, **Site Performance** page

Dimensions

- Study-Site

Supplementary Prompts

- NA

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–92 describes the columns in the Site Enrollment Performance Compared to Site Visit Frequency analysis

Table A–92 Site Enrollment Performance Compared to Site Visit Frequency (Report CDA-CO-110)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study	"Study-Site"."Study"
Study-Site	Study-Site ID #	"Study-Site"."Study-Site ID #"
Study-Site	Principal Investigator	"Study-Site"."Principal Investigator"
- Study-Site Metrics	% of Total Enrolled in Study	"- Study-Site Metrics"."% of Total Enrolled in Study"
- Study-Site Metrics	# Completed Site Visits	"- Study-Site Metrics"."# Completed Site Visits"

Site Initiation Over Time Bar Chart (Study Region) (Report CDA-CO-307)

Line-bar graph that shows the number of sites initiated compared to the number of sites planned for a Study-Region.

Audience

- Region Manager, Study Manager, Executive Manager, Program Manager

Report Type

- View Selector (Chart, Table)

Location

- **Study-Region Overview** dashboard, **Overview** page

Dimensions

- All Purpose Date

Supplementary Prompts

- NA

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–93 describes the columns in the Site Initiation Over Time Bar Chart (Study Region) analysis

Table A–93 Site Initiation Over Time Bar Chart (Study Region) (Report CDA-CO-307)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- All Purpose Date	Year and Month	"- All Purpose Date"."Year and Month"
- Study Region Metrics	# Study-Sites Planned for Study-Region	"- Study Region Metrics"."# Study-Sites Planned for Study-Region"
- Study Region Metrics	# Study-Sites Initiated	"- Study Region Metrics"."# Study-Sites Initiated"

Site Recruitment Performance - Single Study (Report CDA-CO-416)

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.

Audience

- Study Manager
- CRA

Report Type

- Graph, Table (optional)

Location

- **Study Overview** dashboard, **Site Performance** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Site Recruitment Performance - Single Study report.

Table A–94 Site Recruitment Performance - Single Study (Report CDA-CO-416)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Study Region	Study-Site.Study Region
NA	# Study-Sites	Study Metrics.# Study-Sites
NA	# Study-Sites with 1 or more Subjects Enrolled	Study Metrics.# Study-Sites with 1 or more Subjects Enrolled
NA	# Study-Sites with no Subjects Enrolled	Study Metrics.# Study-Sites - - Study Metrics.# Study-Sites with 1 or more Subjects Enrolled
NA	# Study-Sites Recruiting > 90% Planned Subjects	SUM(CASE WHEN - Study-site Metrics.% Enrolled to Total Planned at Study-Site>90.00 THEN 1 END BY Study-Site.Study Region)
NA	% with 1 or more Subjects Enrolled	((- Study Metrics.# Study-Sites with 1 or more Subjects Enrolled) *100) / (- Study Metrics.# Study-Sites)
NA	% with no Subjects Enrolled	((- Study Metrics.# Study-Sites - - Study Metrics.# Study-Sites with 1 or more Subjects Enrolled) *100) / (- Study Metrics.# Study-Sites)
NA	% Study-Sites Recruiting > 90% Planned Subjects	(SUM(CASE WHEN - Study-site Metrics.% Enrolled to Total Planned at Study-Site>90 THEN 1 END BY Study-Site.Study Region)*100)/- Study Metrics.# Study-Sites

Site Recruitment Performance (Report CDA-CO-413)

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.

Audience

- Executive
- Region Manager
- Study Manager
- CRA

Report Type

- Graph, Table (optional)

Location

- **Study Overview** dashboard, **Site Performance** page
- **Executive** dashboard, **Site Recruitment Performance Summary** page
- **Study-Region Overview** dashboard, **Site Performance** page

Dimensions

None

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Site Recruitment Performance report.

Table A–95 Site Recruitment Performance (Report CDA-CO-413)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Category	TBD
NA	Study-Site ID #	Study-Site.Study-Site ID #

Site Recruitment Performance Charts (Executive View) (Report CDA-CO-436)

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.

Audience

- Region Manager

Report Type

- View Selector (Chart, Table)

Location

- **Executive** dashboard, **Site Recruitment Performance Summary** page

Dimensions

- Study-Site

Supplementary Prompts

- NA

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–96 describes the columns in the Site Recruitment Performance Charts (Executive View) analysis

Table A–96 Site Recruitment Performance Charts (Executive View) (Report CDA-CO-436)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Program	NA
Study Metrics	# Study-Sites	NA
Study Metrics	# Study-Sites with 1 or more Subjects Enrolled	NA
Study Metrics	# Sites Recruiting 0 Subjects	NA
Study Metrics	# Sites Recruiting at Least 90% of Planned Subjects	NA
Study Metrics	% Sites Recruiting 0 Subjects	NA
Study Metrics	% Sites Recruiting 1 or More Subjects	NA
Study Metrics	% Sites Recruiting at Least 90% of Planned Subjects	NA

Site Visit Analysis (Report CDA-CO-821)

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.

Audience

- Study Manager
- CRA

Report Type

- Graph, Table (optional)

Location

- **Study Overview** dashboard, **Monitoring Metrics** page

Dimensions

- All-Purpose Date

Supplementary Prompts

Year Prompt

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Site Visit Analysis report.

Table A–97 Site Visit Analysis (Report CDA-CO-821)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Year and Month	All Purpose Date.Year and Month
NA	# Site Visits	Study-site Metrics.# Site Visits
NA	Median # Days from Site Visit Start to Site Visit Completed	MEDIAN(- Site Visit Metrics.# Days from Site Visit Start to Site Visit Completed)

Site Visit Duration - Study (Report CDA-CO-808)

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.

Audience

- Study Manager
- Region Manager
- CRA

Report Type

- Narrative

Location

- **Study-Site Overview** dashboard, **Monitoring Metrics** page
- **Region Manager** dashboard, **Visit Reports & Follow Up Items** page

Dimensions

- Site Visit

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Site Visit Duration - Study report.

Table A–98 Site Visit Duration - Study (Report CDA-CO-808)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Median Site Visit Duration for Study	MEDIAN (- Site Visit Metrics.# Days from Site Visit Start to Site Visit Completed)
NA	Total Number Completed Site Visits for Study	COUNT (Site Visit.Site Visit Completed Date)

Site Visit Duration - Study Site (Report CDA-CO-800)

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.

Audience

- Study Manager
- CRA

Report Type

- Narrative

Location

- **Study-Site Overview** dashboard, **Monitoring Metrics** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Site Visit Duration - Study Site report.

Table A–99 Site Visit Duration - Study Site (Report CDA-CO-800)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	Min Site Visit Duration	MIN(- Site Visit Metrics.# Days from Site Visit Start to Site Visit Completed)
NA	Median Site Visit Duration	MEDIAN(- Site Visit Metrics.# Days from Site Visit Start to Site Visit Completed)
NA	Max Site Visit Duration	MAX(- Site Visit Metrics.# Days from Site Visit Start to Site Visit Completed)

Table A–99 (Cont.) Site Visit Duration - Study Site (Report CDA-CO-800)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	Total Number Completed Site Visits for Study-Site	COUNT (Site Visit.Site Visit Completed Date)

Site Visit Duration - Study-Region (Report CDA-CO-829)

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.

Audience

- Region Manager

Report Type

- Narrative

Location

- **Study-Region Overview** dashboard, **Visit Reports and Follow Up Items** page

Dimensions

- Site Visit

Supplementary Prompts

- NA

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–100 describes the columns in the Site Visit Duration - Study-Region analysis.

Table A–100 Site Visit Duration - Study-Region (Report CDA-CO-829)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Site Visit Metrics	Min Site Visit Duration	MIN("- Site Visit Metrics"."# Days from Site Visit Start to Site Visit Completed")

Table A–100 (Cont.) Site Visit Duration - Study-Region (Report CDA-CO-829)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Site Visit Metrics	Median Site Visit Duration	MEDIAN("- Site Visit Metrics"."# Days from Site Visit Start to Site Visit Completed")
- Site Visit Metrics	Max Site Visit Duration	MAX("- Site Visit Metrics"."# Days from Site Visit Start to Site Visit Completed")
Site Visit	Total Number Completed Site Visits for Study-Region	COUNT("Site Visit"."Site Visit Completed Date")

Sites to Monitor - Days Since Last Visit - Recruitment Detail View (Report CDA-CO-816A)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **CRA** dashboard, **Sites to Monitor** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Overview Dashboard

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Sites to Monitor - Days Since Last Visit - Recruitment Detail View report.

Table A–101 Sites to Monitor - Days Since Last Visit - Recruitment Detail View (Report CDA-CO-816A)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study	Study-Site.Study
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Site Name	Study-Site.Site Name
- Study-Site Metrics	Recruitment Flag	"- Study-Site Metrics"."Recruitment Flag"
- Study-Site Metrics	Recruitment Detail Reason	"- Study-Site Metrics"."Recruitment Detail Reason"
- Study-Site Metrics	Milestone Indicator	"- Study-Site Metrics"."Milestone Indicator"
- Study-Site Metrics	Milestone Detail Reason	"- Study-Site Metrics"."Milestone Detail Reason"
- Study Targets	[Expected Screen Failure Rate]	CONCAT('Planned:',cast(MAX(ROUND("- Study Targets"."[Expected Screen Failure Rate]", 2)) as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."Screen Failure Rate", 2) as char(40)))
- Study-Site Metrics	Screen Failure Rate	CONCAT('Planned:',cast(MAX(ROUND("- Study Targets"."[Expected Screen Failure Rate]", 2)) as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."Screen Failure Rate", 2) as char(40)))
- Study-Site Metrics	% Enrolled to Total Planned at Study-Site	"- Study-Site Metrics"."% Enrolled to Total Planned at Study-Site"
- Study-Site Metrics	% Randomized vs. Planned - Study-Site	"- Study-Site Metrics"."% Randomized vs. Planned - Study-Site"
- Study-Site Original Planned Dates	[Planned 1st Subject Screened Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Screened Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]" as char(40)))||' '||CONCAT('Actual :',EVALUATE('TO_CHAR(%1,%2)' as varchar(20),"- Study-Site Metrics"."1st Subject Screened Date" , 'dd-Mon-yyyy'))

Table A–101 (Cont.) Sites to Monitor - Days Since Last Visit - Recruitment Detail View (Report CDA-CO-816A)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject Screened Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Screened Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]" as char(40)))||' '||CONCAT('Actual :',EVALUATE('TO_ CHAR(%1,%2)' as varchar(20),"- Study-Site Metrics"."1st Subject Screened Date" , 'dd-Mon-yyyy'))
- Study-Site Metrics	1st Subject Screened Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Screened Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]" as char(40)))||' '||CONCAT('Actual :',EVALUATE('TO_ CHAR(%1,%2)' as varchar(20),"- Study-Site Metrics"."1st Subject Screened Date" , 'dd-Mon-yyyy'))
- Study-Site Original Planned Dates	[Planned 1st Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))

Table A–101 (Cont.) Sites to Monitor - Days Since Last Visit - Recruitment Detail View (Report CDA-CO-816A)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Metrics	1st Subject Enrolled Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Original Planned Dates	[Planned 1st Subject Randomized Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject Randomized Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Metrics	1st Subject Randomized Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Original Planned Dates	[Planned 1st Subject 1st Visit Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject 1st Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject 1st Visit Date" as char(40)))

Table A–101 (Cont.) Sites to Monitor - Days Since Last Visit - Recruitment Detail View (Report CDA-CO-816A)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject 1st Visit Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject 1st Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study-Site Metrics	1st Subject 1st Visit Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject 1st Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Enrolled Date]" as char(40)))

Table A–101 (Cont.) Sites to Monitor - Days Since Last Visit - Recruitment Detail View (Report CDA-CO-816A)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Metrics	Latest Subject Enrolled Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study-Site Metrics	[Last Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject Randomized Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Randomized Date]" as char(40)))

Table A–101 (Cont.) Sites to Monitor - Days Since Last Visit - Recruitment Detail View (Report CDA-CO-816A)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study-Site Metrics	Latest Subject Randomized Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study-Site Metrics	[Last Subject Randomized Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Randomized Date]" as char(40)))

Table A–101 (Cont.) Sites to Monitor - Days Since Last Visit - Recruitment Detail View (Report CDA-CO-816A)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Original Planned Dates	[Planned Last Subject 1st Visit Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject 1st Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject 1st Visit Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject 1st Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study-Site Metrics	Latest Subject 1st Visit Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject 1st Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))

Table A–101 (Cont.) Sites to Monitor - Days Since Last Visit - Recruitment Detail View (Report CDA-CO-816A)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Metrics	[Last Subject 1st Visit Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject 1st Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject Last Visit Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Last Visit Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))

Table A–101 (Cont.) Sites to Monitor - Days Since Last Visit - Recruitment Detail View (Report CDA-CO-816A)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Metrics	Latest Subject Latest Visit Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Site Metrics	[Last Subject Last Visit Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
NA	Navigate to detail	NA

Sites to Monitor - Days Since Last Visit - Retention Detail View (Report CDA-CO-816B)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **CRA** dashboard, **Sites to Monitor** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Overview Dashboard

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Sites to Monitor - Days Since Last Visit - Retention Detail View report.

Table A–102 Sites to Monitor - Days Since Last Visit - Retention Detail View (Report CDA-CO-816B)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study	Study-Site.Study
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Site Name	Study-Site.Site Name
- Study-Site Metrics	Milestone Indicator	"- Study-Site Metrics"."Milestone Indicator"
- Study-Site Metrics	Milestone Detail Reason	"- Study-Site Metrics"."Milestone Detail Reason"
- Study-Site Original Planned Dates	[Planned 1st Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Enrolled Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]" as char(40))))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))

Table A–102 (Cont.) Sites to Monitor - Days Since Last Visit - Retention Detail View (Report CDA-CO-816B)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Metrics	1st Subject Enrolled Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Original Planned Dates	[Planned 1st Subject Randomized Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject Randomized Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Metrics	1st Subject Randomized Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))

Table A–102 (Cont.) Sites to Monitor - Days Since Last Visit - Retention Detail View (Report CDA-CO-816B)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Original Planned Dates	[Planned Last Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study-Site Metrics	Latest Subject Enrolled Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Enrolled Date]" as char(40)))

Table A–102 (Cont.) Sites to Monitor - Days Since Last Visit - Retention Detail View (Report CDA-CO-816B)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Metrics	[Last Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject Randomized Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Randomized Date]" as char(40)))

Table A–102 (Cont.) Sites to Monitor - Days Since Last Visit - Retention Detail View (Report CDA-CO-816B)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Metrics	Latest Subject Randomized Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual Last:',cast("- Study-Site Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study-Site Metrics	[Last Subject Randomized Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual Last:',cast("- Study-Site Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study-Site Metrics	Retention Flag	"- Study-Site Metrics"."Retention Flag"
- Study-Site Metrics	Retention Detail Reason	"- Study-Site Metrics"."Retention Detail Reason"
- Study-Site Study-Site Targets	Expected Early Termination Rate	CONCAT('Expected:',MIN(cast(ROUND("- Study-Site Study-Site Targets"."Expected Early Termination Rate", 2) as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site", 2) as char(40)))
- Study-Site Metrics	% Subjects Early Terminated for Study-Site	CONCAT('Expected:',MIN(cast(ROUND("- Study-Site Study-Site Targets"."Expected Early Termination Rate", 2) as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site", 2) as char(40)))
NA	Navigate to detail	NA

Sites to Monitor - Days Since Last Visit - Study Close Detail View (Report CDA-CO-816C)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **CRA** dashboard, **Sites to Monitor** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Overview Dashboard

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Sites to Monitor - Days Since Last Visit - Study Close Detail View report.

Table A–103 Sites to Monitor - Days Since Last Visit - Study Close Detail View (Report CDA-CO-816C)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study	Study-Site.Study
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Site Name	Study-Site.Site Name

Table A–103 (Cont.) Sites to Monitor - Days Since Last Visit - Study Close Detail View (Report CDA-CO-816C)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Received CRFs	# CRFs Awaiting Entry Completion	"- Received CRFs"."# CRFs Awaiting Entry Completion"
- Received CRFs	# eCRFs To Be Approved	"- Received CRFs"."# eCRFs To Be Approved"
- Received CRFs	# eCRFs To be Verified	"- Received CRFs"."# eCRFs To be Verified"
- Received CRFs	# CRFs Soft- Locked	"- Received CRFs"."# CRFs Soft-Locked"
- Received CRFs	% CRFs Soft Locked / Entry Complete	"- Received CRFs"."% CRFs Soft Locked / Entry Complete"
- Received CRFs	# CRFs Hard-Locked	"- Received CRFs"."# CRFs Hard-Locked"
- Received CRFs	% CRFs Hard Locked / Entry Complete	"- Received CRFs"."% CRFs Hard Locked / Entry Complete"
- Study-Site Metrics	Milestone Indicator	"- Study-Site Metrics"."Milestone Indicator"
- Study-Site Metrics	Milestone Detail Reason	"- Study-Site Metrics"."Milestone Detail Reason"
- Study-Site Metrics	% Enrolled to Total Planned at Study-Site	"- Study-Site Metrics"."% Enrolled to Total Planned at Study-Site"
- Study-Site Original Planned Dates	[Planned Last Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Enrolled Date]" as char(40)))

Table A–103 (Cont.) Sites to Monitor - Days Since Last Visit - Study Close Detail View (Report CDA-CO-816C)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Metrics	Latest Subject Enrolled Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study-Site Metrics	[Last Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject Randomized Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Randomized Date]" as char(40)))

Table A–103 (Cont.) Sites to Monitor - Days Since Last Visit - Study Close Detail View (Report CDA-CO-816C)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study-Site Metrics	Latest Subject Randomized Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study-Site Metrics	[Last Subject Randomized Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Randomized Date]" as char(40)))

Table A–103 (Cont.) Sites to Monitor - Days Since Last Visit - Study Close Detail View (Report CDA-CO-816C)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Original Planned Dates	[Planned Last Subject Last Visit Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Last Visit Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Site Metrics	Latest Subject Latest Visit Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))

Table A–103 (Cont.) Sites to Monitor - Days Since Last Visit - Study Close Detail View (Report CDA-CO-816C)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Metrics	[Last Subject Last Visit Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual Last:',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Site Metrics	Retention Flag	"- Study-Site Metrics"."Retention Flag"
- Study-Site Metrics	Retention Detail Reason	"- Study-Site Metrics"."Retention Detail Reason"
- Study-Site Study-Site Targets	Expected Early Termination Rate	CONCAT('Expected:',MIN(cast(ROUND("- Study-Site Study-Site Targets"."Expected Early Termination Rate", 2) as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site", 2) as char(40)))
- Study-Site Metrics	% Subjects Early Terminated for Study-Site	CONCAT('Expected:',MIN(cast(ROUND("- Study-Site Study-Site Targets"."Expected Early Termination Rate", 2) as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site", 2) as char(40)))
NA	Navigate to detail	NA

Sites to Monitor - Days Since Last Visit - Summary View (Report CDA-CO-816D)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **CRA** dashboard, **Sites to Monitor** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Overview Dashboard

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Sites to Monitor - Days Since Last Visit - Summary View report.

Table A–104 Sites to Monitor - Days Since Last Visit - Summary View (Report CDA-CO-816D)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study	Study-Site.Study
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Site Name	Study-Site.Site Name
- Discrepancies	# Open Discrepancies	"- Discrepancies"."# Open Discrepancies"
- Received CRFs	# eCRFs To Be Approved	"- Received CRFs"."# eCRFs To Be Approved"
- Received CRFs	# eCRFs To be Verified	"- Received CRFs"."# eCRFs To be Verified"
- Study-Site Metrics	# Days Since Latest Site Visit	"- Study-Site Metrics"."# Days Since Latest Site Visit"
- Study-Site Metrics	Next Site Visit Date	"- Study-Site Metrics"."Next Site Visit Date"
- Study-Site Metrics	Next Site Visit Type	"- Study-Site Metrics"."Next Site Visit Type"
- Study-Site Metrics	# Subjects Enrolled Since Latest Site Visit	"- Study-Site Metrics"."# Subjects Enrolled Since Latest Site Visit"
- Study-Site Metrics	# Visit Reports Awaiting Completion	"- Study-Site Metrics"."# Visit Reports Awaiting Completion"
- Study-Site Metrics	[# Visit Reports Awaiting Approval]	"- Study-Site Metrics"."[# Visit Reports Awaiting Approval]"

Table A–104 (Cont.) Sites to Monitor - Days Since Last Visit - Summary View (Report CDA-CO-816D)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Site Visit Metrics	# Outstanding Follow Up Items	"- Site Visit Metrics"."# Outstanding Follow Up Items"
NA	Navigate to detail	NA

Sites with No Visits Since Initiation - Recruitment Detail View (Report CDA-CO-812A)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **CRA** dashboard, **Sites to Monitor** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Overview Dashboard

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Sites with No Visits Since Initiation - Recruitment Detail View report.

Table A–105 Sites with No Visits Since Initiation - Recruitment Detail View (Report CDA-CO-812A)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study-Site	Study	Study-Site.Study
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Site Name	Study-Site.Site Name
- Study-Site Metrics	Recruitment Flag	"- Study-Site Metrics"."Recruitment Flag"
- Study-Site Metrics	Recruitment Detail Reason	"- Study-Site Metrics"."Recruitment Detail Reason"
- Study-Site Metrics	Milestone Indicator	"- Study-Site Metrics"."Milestone Indicator"
- Study-Site Metrics	Milestone Detail Reason	"- Study-Site Metrics"."Milestone Detail Reason"
- Study Targets	[Expected Screen Failure Rate]	CONCAT('Planned:',cast(MAX(ROUND("- Study Targets"."[Expected Screen Failure Rate]", 2)) as char(40)))||' '||CONCAT(' Actual:' , cast(ROUND("- Study-Site Metrics"."Screen Failure Rate", 2) as char(40)))
- Study-Site Metrics	Screen Failure Rate	CONCAT('Planned:',cast(MAX(ROUND("- Study Targets"."[Expected Screen Failure Rate]", 2)) as char(40)))||' '||CONCAT(' Actual:' , cast(ROUND("- Study-Site Metrics"."Screen Failure Rate", 2) as char(40)))
- Study-Site Metrics	% Enrolled to Total Planned at Study-Site	"- Study-Site Metrics"."% Enrolled to Total Planned at Study-Site"
- Study-Site Metrics	% Randomized vs. Planned - Study-Site	"- Study-Site Metrics"."% Randomized vs. Planned - Study-Site"
- Study-Site Original Planned Dates	[Planned 1st Subject Screened Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Screened Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]" as char(40)))||' '||CONCAT('Actual :',EVALUATE('TO_ CHAR(%1,%2)' as varchar(20),"- Study-Site Metrics"."1st Subject Screened Date" , 'dd-Mon-yyyy'))

Table A–105 (Cont.) Sites with No Visits Since Initiation - Recruitment Detail View (Report CDA-CO-812A)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject Screened Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Screened Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]" as char(40)))||' '||CONCAT('Actual :',EVALUATE('TO_ CHAR(%1,%2)' as varchar(20),"- Study-Site Metrics"."1st Subject Screened Date" , 'dd-Mon-yyyy'))
- Study-Site Metrics	1st Subject Screened Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Screened Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]" as char(40)))||' '||CONCAT('Actual :',EVALUATE('TO_ CHAR(%1,%2)' as varchar(20),"- Study-Site Metrics"."1st Subject Screened Date" , 'dd-Mon-yyyy'))
- Study-Site Original Planned Dates	[Planned 1st Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))

Table A–105 (Cont.) Sites with No Visits Since Initiation - Recruitment Detail View (Report CDA-CO-812A)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	1st Subject Enrolled Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Original Planned Dates	[Planned 1st Subject Randomized Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject Randomized Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Metrics	1st Subject Randomized Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Original Planned Dates	[Planned 1st Subject 1st Visit Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject 1st Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject 1st Visit Date" as char(40)))

Table A–105 (Cont.) Sites with No Visits Since Initiation - Recruitment Detail View (Report CDA-CO-812A)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject 1st Visit Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject 1st Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study-Site Metrics	1st Subject 1st Visit Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject 1st Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Enrolled Date]" as char(40)))

Table A–105 (Cont.) Sites with No Visits Since Initiation - Recruitment Detail View (Report CDA-CO-812A)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	Latest Subject Enrolled Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study-Site Metrics	[Last Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject Randomized Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Randomized Date]" as char(40)))

Table A–105 (Cont.) Sites with No Visits Since Initiation - Recruitment Detail View (Report CDA-CO-812A)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study-Site Metrics	Latest Subject Randomized Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study-Site Metrics	[Last Subject Randomized Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Randomized Date]" as char(40)))

Table A–105 (Cont.) Sites with No Visits Since Initiation - Recruitment Detail View (Report CDA-CO-812A)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Original Planned Dates	[Planned Last Subject 1st Visit Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject 1st Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject 1st Visit Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject 1st Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study-Site Metrics	Latest Subject 1st Visit Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject 1st Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))

Table A–105 (Cont.) Sites with No Visits Since Initiation - Recruitment Detail View (Report CDA-CO-812A)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	[Last Subject 1st Visit Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject 1st Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject Last Visit Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Last Visit Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))

Table A–105 (Cont.) Sites with No Visits Since Initiation - Recruitment Detail View (Report CDA-CO-812A)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	Latest Subject Latest Visit Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Site Metrics	[Last Subject Last Visit Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
NA	Navigate to Detail	NA

Sites with No Visits Since Initiation - Retention Detail View (Report CDA-CO-812B)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **CRA** dashboard, **Sites to Monitor** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Overview Dashboard

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Sites with No Visits Since Initiation - Retention Detail View report.

Table A–106 Sites with No Visits Since Initiation - Retention Detail View (Report CDA-CO-812B)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study-Site	Study	Study-Site.Study
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Site Name	Study-Site.Site Name
- Study-Site Metrics	Milestone Indicator	"- Study-Site Metrics"."Milestone Indicator"
- Study-Site Metrics	Milestone Detail Reason	"- Study-Site Metrics"."Milestone Detail Reason"
- Study-Site Original Planned Dates	[Planned 1st Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))

Table A–106 (Cont.) Sites with No Visits Since Initiation - Retention Detail View (Report CDA-CO-812B)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Metrics	1st Subject Enrolled Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Original Planned Dates	[Planned 1st Subject Randomized Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject Randomized Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Metrics	1st Subject Randomized Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))

Table A–106 (Cont.) Sites with No Visits Since Initiation - Retention Detail View (Report CDA-CO-812B)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Original Planned Dates	[Planned Last Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study-Site Metrics	Latest Subject Enrolled Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Enrolled Date]" as char(40)))

Table A–106 (Cont.) Sites with No Visits Since Initiation - Retention Detail View (Report CDA-CO-812B)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	[Last Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject Randomized Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual Last:',cast("- Study-Site Metrics"."[Last Subject Randomized Date]" as char(40)))

Table A–106 (Cont.) Sites with No Visits Since Initiation - Retention Detail View (Report CDA-CO-812B)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	Latest Subject Randomized Date	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual Last:',cast("- Study-Site Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study-Site Metrics	[Last Subject Randomized Date]	CONCAT('Planned:',MIN(cast("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]" as char(40)))||' '||CONCAT('Actual Latest:',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual Last:',cast("- Study-Site Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study-Site Metrics	Retention Flag	"- Study-Site Metrics"."Retention Flag"
- Study-Site Metrics	Retention Detail Reason	"- Study-Site Metrics"."Retention Detail Reason"
- Study-Site Study-Site Targets	Expected Early Termination Rate	CONCAT('Expected:',MIN(cast(ROUND("- Study-Site Study-Site Targets"."Expected Early Termination Rate", 2) as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site", 2) as char(40)))
- Study-Site Metrics	% Subjects Early Terminated for Study-Site	CONCAT('Expected:',MIN(cast(ROUND("- Study-Site Study-Site Targets"."Expected Early Termination Rate", 2) as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site", 2) as char(40)))

Sites with No Visits Since Initiation - Summary View (Report CDA-CO-812C)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **CRA** dashboard, **Sites to Monitor** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Overview Dashboard

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Sites with No Visits Since Initiation - Summary View report.

Table A–107 Sites with No Visits Since Initiation - Summary View (Report CDA-CO-812C)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study-Site	Study	Study-Site.Study
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Site Name	Study-Site.Site Name
- Discrepancies	# Open Discrepancies	"- Discrepancies"."# Open Discrepancies"

Table A–107 (Cont.) Sites with No Visits Since Initiation - Summary View (Report CDA-CO-812C)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Received CRFs	# eCRFs To Be Approved	"- Received CRFs"."# eCRFs To Be Approved"
- Received CRFs	# eCRFs To be Verified	"- Received CRFs"."# eCRFs To be Verified"
- Received CRFs	# CRFs Soft- Locked	"- Received CRFs"."# CRFs Soft-Locked"
- Study-Site Metrics	# Days Since Latest Site Visit	"- Study-Site Metrics"."# Days Since Latest Site Visit"
- Study-Site Metrics	Next Site Visit Date	"- Study-Site Metrics"."Next Site Visit Date"
- Study-Site Metrics	Next Site Visit Type	"- Study-Site Metrics"."Next Site Visit Type"
- Study-Site Metrics	# Subjects Enrolled Since Latest Site Visit	"- Study-Site Metrics"."# Subjects Enrolled Since Latest Site Visit"
- Study-Site Metrics	# Visit Reports Awaiting Completion	"- Study-Site Metrics"."# Visit Reports Awaiting Completion"
- Study-Site Metrics	[# Visit Reports Awaiting Approval]	"- Study-Site Metrics"."[# Visit Reports Awaiting Approval]"
- Site Visit Metrics	# Outstanding Follow Up Items	"- Site Visit Metrics"."# Outstanding Follow Up Items"
NA	Navigate to Detail	NA

Study Documents List (Report CDA-CO-600)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study Overview** dashboard, **Study Document List** page

Dimensions

None

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Study Documents List report.

Table A–108 Study Documents List (Report CDA-CO-600)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	Activity Type	Document Metrics.Activity Type
NA	Document Name	Document Metrics.Document Name
NA	Document Sent Date	Document Metrics.Document Sent Date
NA	Document Received Date	Document Metrics.Document Received Date
NA	Document Expiration Date	Document Metrics.Document Expiration Date
NA	Document Comments	Document Metrics.Document Comments
NA	Document Expiration Date Indicator	TBD

Study Information (Report CDA-CO-103)

Displays a summary of identifying information for a study, including Study #, Program, Product and Study Status.

Audience

- Study Manager
- CRA

Report Type

- Narrative

Location

- **Study Overview** dashboard, **Study Overview** page

Dimensions

- Study

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Study Information report.

Table A–109 Study Information (Report CDA-CO-103)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Study	Study.Study
NA	Program	Study.Program
NA	Product	Study.Product
NA	Short Title	Study.Study Short Title
NA	Status	Study.Study Status
NA	Phase	Study.Study Phase
NA	Study Manager	Study.Study Manager

Study List - Initiation Details (Report CDA-CO-305)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study Manager** dashboard, **Initiating and Recruiting Studies** page

Dimensions

- Study

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Study List - Initiation Details report.

Table A–110 Study List - Initiation Details (Report CDA-CO-305)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study	Program	Study.Program
Study	Study	Study.Study
Study	Status	Study.Study Status
Study	Study Manager	"Study"."Study Manager"
- Study Metrics	Milestone Flag	"- Study Metrics"."Milestone Flag"
- Study Metrics	Milestone Detail Reason	"- Study Metrics"."Milestone Detail Reason"
Study Metrics, Counts	# Study-Sites Planned for Study	NA
Study Metrics, Counts	# Study-Sites Initiated	NA
Study Metrics, Counts	# Sites with 1 or More Subjects Screened	NA
Study Metrics, Counts	# Study-Sites with 1 or more Subjects Enrolled	NA
Study Metrics, Ratios	% of Planned Sites Initiated	NA
Study, Original Planned Dates	[Planned 1st IRB/EC Submission Date]	NA
Study, Latest Estimated Dates	[Planned LE 1st IRB/EC Submission Date]	NA
Study Metrics, Actual Milestones	[1st IRB/EC Submission Date]	NA
Study, Original Planned Dates	[Planned 1st Initial IRB/EC Approval Date]	NA
Study, Latest Estimated Dates	[Planned LE 1st Initial IRB/EC Approval Date]	NA
Study Metrics, Actual Milestones	1st Initial IRB/EC Approval Date	NA
Study, Original Planned Dates	[Planned 1st Site Initiated Date]	NA
Study, Latest Estimated Dates	[Planned LE 1st Site Initiated Date]	NA

Table A–110 (Cont.) Study List - Initiation Details (Report CDA-CO-305)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study Metrics, Actual Milestones	1st Site Initiated Date	NA
Study, Original Planned Dates	[Planned Last Site Initiated Date]	NA
Study, Latest Estimated Dates	[Planned LE Last Site Initiated Date]	NA
Study Metrics, Actual Milestones	Latest Site Initiated Date	NA
Study Metrics, Actual Milestones	[Last Site Initiated Date]	NA
Study, Original Planned Dates	[Planned 1st Critical Document Package Completed Date]	NA
Study, Latest Estimated Dates	[Planned LE 1st Critical Document Package Completed Date]	NA
Study Metrics, Actual Milestones	[1st Critical Document Package Completed Date]	NA
Study, Original Planned Dates	[Planned Last Critical Document Package Completed Date]	NA
Study, Latest Estimated Dates	[Planned LE Last Critical Document Package Completed Date]	NA
Study Metrics, Actual Milestones	[Latest Critical Document Package Completed Date]	NA
Study Metrics, Actual Milestones	[Last Critical Document Package Completed Date]	NA
NA	Navigate to Detail	NA

Study List - KPI Performance (Report CDA-CO-904)

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.

Audience

- Executive

Report Type

- Table (View Selector)

Location

None

Dimensions

- Study

Supplementary Prompts

- NA

Reports Referenced

You can navigate to the following reports from this report:

- Detailed Study Milestones Report (Report CDA-CO-102)
- Study Overview Dashboard

Reports Referencing This Report

You can navigate to the following reports from this report:

- Study Region Milestones with Indicators (Report CDA-CO-1106)

Column Descriptions

Table A–111 describes the columns in the Study List: KPI Performance analysis

Table A–111 Study List: KPI Performance (Report CDA-CO-904)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study	Program	"Study"."Program"
Study	Study	"Study"."Study"
Study	Study Status	"Study"."Study Status"
Study	Study Manager	"Study"."Study Manager"
- Study Metrics	KPI Indicator	"- Study Metrics"."KPI Indicator"
- Study Metrics	KPI Detail Reason	"- Study Metrics"."KPI Detail Reason"
Overall Level Targets	[Expected % Sites Recruiting 0 Subjects]	CONCAT('Overall Target:',MIN(cast(ROUND("Overall Level Targets"."[Expected % Sites Recruiting 0 Subjects]", 2) as char(40)))) || ' '||CONCAT('Actual:' , cast(ROUND("- Study Metrics"."% Sites Recruiting 0 Subjects", 2) as char(40)))
- Study Metrics	% Sites Recruiting 0 Subjects	CONCAT('Overall Target:',MIN(cast(ROUND("Overall Level Targets"."[Expected % Sites Recruiting 0 Subjects]", 2) as char(40)))) || ' '||CONCAT('Actual:' , cast(ROUND("- Study Metrics"."% Sites Recruiting 0 Subjects", 2) as char(40)))
Overall Level Targets	[Target Protocol Approved to 1st Site Initiated (# Days)]	CONCAT('Overall Target:',MIN(cast(ROUND("Overall Level Targets"."[Target Protocol Approved to 1st Site Initiated (# Days)]", 2) as char(40)))) || ' '||CONCAT('Actual:' , MIN(cast(ROUND("- Study Metrics"."[Protocol Approved to 1st Site Initiated (# Days)]", 2) as char(40))))

Table A–111 (Cont.) Study List: KPI Performance (Report CDA-CO-904)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Metrics	[Protocol Approved to 1st Site Initiated (# Days)]	CONCAT('Overall Target:',MIN(cast(ROUND("Over all Level Targets"."[Target Protocol Approved to 1st Site Initiated (# Days)]", 2) as char(40))))||' '||CONCAT('Actual:' , MIN(cast(ROUND("- Study Metrics"."[Protocol Approved to 1st Site Initiated (# Days)]", 2) as char(40))))
Overall Level Targets	[Target Protocol Approved to 1st Subject Enrolled (# Days)]	CONCAT('Overall Target:',MIN(cast(ROUND("Over all Level Targets"."[Target Protocol Approved to 1st Subject Enrolled (# Days)]", 2) as char(40))))||' '||CONCAT('Actual:' ,MIN(cast(ROUND("- Study Metrics"."[Protocol Approved to 1st Subject Enrolled (# Days)]", 2) as char(40))))
- Study Metrics	[Protocol Approved to 1st Subject Enrolled (# Days)]	CONCAT('Overall Target:',MIN(cast(ROUND("Over all Level Targets"."[Target Protocol Approved to 1st Subject Enrolled (# Days)]", 2) as char(40))))||' '||CONCAT('Actual:' ,MIN(cast(ROUND("- Study Metrics"."[Protocol Approved to 1st Subject Enrolled (# Days)]", 2) as char(40))))
Overall Level Targets	[Target Critical Document Package Complete to Site Initiated (# Days)]	CONCAT('Overall Target:',MIN(cast(ROUND("Over all Level Targets"."[Target Critical Document Package Complete to Site Initiated (# Days)]", 2) as char(40))))||' '||CONCAT('Actual:',MIN(cast(ROUND("- Study Metrics"."[Median Critical Document Package Complete to Site Initiated (# Days)]", 2) as char(40))))
- Study Metrics	[Median Critical Document Package Complete to Site Initiated (# Days)]	CONCAT('Overall Target:',MIN(cast(ROUND("Over all Level Targets"."[Target Critical Document Package Complete to Site Initiated (# Days)]", 2) as char(40))))||' '||CONCAT('Actual:',MIN(cast(ROUND("- Study Metrics"."[Median Critical Document Package Complete to Site Initiated (# Days)]", 2) as char(40))))

Table A–111 (Cont.) Study List: KPI Performance (Report CDA-CO-904)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Overall Level Targets	[Target Site Visit Completed to Visit Report Completed (# Days)]	CONCAT('Overall Target:',MIN(cast(ROUND("Overall Level Targets"."[Target Site Visit Completed to Visit Report Completed (# Days)]", 2) as char(40))))||' '||CONCAT('Actual:',MIN(cast(ROUND("- Study Metrics"."Median Site Visit Completed to Visit Report Completed (# Days)", 2) as char(40))))
- Study Metrics	Median Site Visit Completed to Visit Report Completed (# Days)	CONCAT('Overall Target:',MIN(cast(ROUND("Overall Level Targets"."[Target Site Visit Completed to Visit Report Completed (# Days)]", 2) as char(40))))||' '||CONCAT('Actual:',MIN(cast(ROUND("- Study Metrics"."Median Site Visit Completed to Visit Report Completed (# Days)", 2) as char(40))))
Overall Level Targets	[Target Visit Report Completed to Visit Report Approved (# Days)]	CONCAT('Overall Target:',MIN(cast(ROUND("Overall Level Targets"."[Target Visit Report Completed to Visit Report Approved (# Days)]", 2) as char(40))))||' '||CONCAT('Actual:',MIN(cast(ROUND("- Site Visit Metrics"."[# Days from Visit Report Completed to Visit Report Approved]", 2) as char(40))))
- Site Visit Metrics	[# Days from Visit Report Completed to Visit Report Approved]	CONCAT('Overall Target:',MIN(cast(ROUND("Overall Level Targets"."[Target Visit Report Completed to Visit Report Approved (# Days)]", 2) as char(40))))||' '||CONCAT('Actual:',MIN(cast(ROUND("- Site Visit Metrics"."[# Days from Visit Report Completed to Visit Report Approved]", 2) as char(40))))
Overall Level Targets	[Target Last Subject Last Visit to Database Lock (# Days)]	CONCAT('Overall Target:',MIN(cast(ROUND("Overall Level Targets"."[Target Last Subject Last Visit to Database Lock (# Days)]", 2) as char(40))))||' '||CONCAT('Actual:' , MIN(cast(ROUND("- Study Metrics"."Latest Subject Latest Visit to Database Lock (# Days)", 2) as char(40))))

Table A–111 (Cont.) Study List: KPI Performance (Report CDA-CO-904)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Metrics	Latest Subject Latest Visit to Database Lock (# Days)	CONCAT('Overall Target:',MIN(cast(ROUND("Over all Level Targets"."[Target Last Subject Last Visit to Database Lock (# Days)]", 2) as char(40))))||' '||CONCAT('Actual:' , MIN(cast(ROUND("- Study Metrics"."Latest Subject Latest Visit to Database Lock (# Days)", 2) as char(40))))
Overall Level Targets	[Target Protocol Approved to 1st Site Initiated (# Days)]	CONCAT('Overall Target:',MIN(cast(ROUND("Over all Level Targets"."[Target Protocol Approved to 1st Site Initiated (# Days)]", 2) as char(40))))||' '||CONCAT('Actual:' , MIN(cast(ROUND("- Study Metrics"."[Protocol Approved to 1st Site Initiated (# Days)]", 2) as char(40))))
- Study Metrics	[Protocol Approved to 1st Site Initiated (# Days)]	CONCAT('Overall Target:',MIN(cast(ROUND("Over all Level Targets"."[Target Protocol Approved to 1st Site Initiated (# Days)]", 2) as char(40))))||' '||CONCAT('Actual:' , MIN(cast(ROUND("- Study Metrics"."[Protocol Approved to 1st Site Initiated (# Days)]", 2) as char(40))))
- Study Key Dates	[Protocol Approved Date]	MIN("- Study Key Dates"."[Protocol Approved Date]")
- Study Original Planned Dates	[Planned 1st Site Initiated Date]	CONCAT('Planned:',MIN(cast("- Study Original Planned Dates"."[Planned 1st Site Initiated Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study Latest Estimated Dates"."[Planned LE 1st Site Initiated Date]" as char(40))))
- Study Latest Estimated Dates	[Planned LE 1st Site Initiated Date]	CONCAT('Planned:',MIN(cast("- Study Original Planned Dates"."[Planned 1st Site Initiated Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study Latest Estimated Dates"."[Planned LE 1st Site Initiated Date]" as char(40))))

Table A–111 (Cont.) Study List: KPI Performance (Report CDA-CO-904)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Overall Level Targets	[Target Protocol Approved to 1st Subject Enrolled (# Days)]	CONCAT('Overall Target:',MIN(cast(ROUND("Overall Level Targets"."[Target Protocol Approved to 1st Subject Enrolled (# Days)]", 2) as char(40))))||' '||CONCAT('Actual:' , MIN(cast(ROUND("- Study Metrics"."[Protocol Approved to 1st Subject Enrolled (# Days)]", 2) as char(40))))
- Study Metrics	[Protocol Approved to 1st Subject Enrolled (# Days)]	CONCAT('Overall Target:',MIN(cast(ROUND("Overall Level Targets"."[Target Protocol Approved to 1st Subject Enrolled (# Days)]", 2) as char(40))))||' '||CONCAT('Actual:' , MIN(cast(ROUND("- Study Metrics"."[Protocol Approved to 1st Subject Enrolled (# Days)]", 2) as char(40))))
- Study Key Dates	[Protocol Approved Date]	MIN("- Study Key Dates"."[Protocol Approved Date]")
- Study Original Planned Dates	[Planned 1st Subject Enrolled Date]	CONCAT('Planned:',cast("- Study Original Planned Dates"."[Planned 1st Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]" as char(40))))
- Study Latest Estimated Dates	[Planned LE 1st Subject Enrolled Date]	CONCAT('Planned:',cast("- Study Original Planned Dates"."[Planned 1st Subject Enrolled Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]" as char(40))))
Overall Level Targets	[Target Last Subject Last Visit to Database Lock (# Days)]	CONCAT('Overall Target:',MIN(cast(ROUND("Overall Level Targets"."[Target Last Subject Last Visit to Database Lock (# Days)]", 2) as char(40))))||' '||CONCAT('Actual:' , MIN(cast(ROUND("- Study Metrics"."[Last Subject Last Visit to Database Lock (# Days)]", 2) as char(40))))

Table A–111 (Cont.) Study List: KPI Performance (Report CDA-CO-904)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Metrics	[Last Subject Last Visit to Database Lock (# Days)]	CONCAT('Overall Target:',MIN(cast(ROUND("Over all Level Targets"."[Target Last Subject Last Visit to Database Lock (# Days)]", 2) as char(40))))||' '||CONCAT('Actual:' , MIN(cast(ROUND("- Study Metrics"."[Last Subject Last Visit to Database Lock (# Days)]", 2) as char(40))))
- Study Original Planned Dates	[Planned Database Lock Date]	MIN("- Study Original Planned Dates"."[Planned Database Lock Date]")
- Study Original Planned Dates	[Planned Database Lock Date]	CONCAT('Planned:',MIN(cast("- Study Original Planned Dates"."[Planned Database Lock Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study Latest Estimated Dates"."[Planned LE Database Lock Date]" as char(40))))
- Study Latest Estimated Dates	[Planned LE Database Lock Date]	CONCAT('Planned:',MIN(cast("- Study Original Planned Dates"."[Planned Database Lock Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study Latest Estimated Dates"."[Planned LE Database Lock Date]" as char(40))))
- Study Metrics	1st Site Initiated Date	CASE WHEN ("- Study Metrics"."1st Site Initiated Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Key Dates"."[Protocol Approved Date]", VALUEOF("CURRENT_DAY")) > "Overall Level Targets"."[Target Protocol Approved to 1st Site Initiated (# Days)]") THEN 'RED' WHEN ("- Study Metrics"."1st Site Initiated Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Key Dates"."[Protocol Approved Date]", VALUEOF("CURRENT_DAY")) > ("Overall Level Targets"."[Target Protocol Approved to 1st Site Initiated (# Days)]"-30)) THEN 'YELLOW' END

Table A–111 (Cont.) Study List: KPI Performance (Report CDA-CO-904)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Key Dates	[Protocol Approved Date]	CASE WHEN ("- Study Metrics"."1st Site Initiated Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Key Dates"."[Protocol Approved Date]", VALUEOF("CURRENT_DAY")) > "Overall Level Targets"."[Target Protocol Approved to 1st Site Initiated (# Days)]") THEN 'RED' WHEN ("- Study Metrics"."1st Site Initiated Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Key Dates"."[Protocol Approved Date]", VALUEOF("CURRENT_DAY")) > ("Overall Level Targets"."[Target Protocol Approved to 1st Site Initiated (# Days)]"-30)) THEN 'YELLOW' END
Overall Level Targets	[Target Protocol Approved to 1st Site Initiated (# Days)]	CASE WHEN ("- Study Metrics"."1st Site Initiated Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Key Dates"."[Protocol Approved Date]", VALUEOF("CURRENT_DAY")) > "Overall Level Targets"."[Target Protocol Approved to 1st Site Initiated (# Days)]") THEN 'RED' WHEN ("- Study Metrics"."1st Site Initiated Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Key Dates"."[Protocol Approved Date]", VALUEOF("CURRENT_DAY")) > ("Overall Level Targets"."[Target Protocol Approved to 1st Site Initiated (# Days)]"-30)) THEN 'YELLOW' END
- Study Metrics	1st Site Initiated Date	CASE WHEN ("- Study Metrics"."1st Site Initiated Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Key Dates"."[Protocol Approved Date]", VALUEOF("CURRENT_DAY")) > "Overall Level Targets"."[Target Protocol Approved to 1st Site Initiated (# Days)]") THEN 'RED' WHEN ("- Study Metrics"."1st Site Initiated Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Key Dates"."[Protocol Approved Date]", VALUEOF("CURRENT_DAY")) > ("Overall Level Targets"."[Target Protocol Approved to 1st Site Initiated (# Days)]"-30)) THEN 'YELLOW' END

Table A–111 (Cont.) Study List: KPI Performance (Report CDA-CO-904)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Key Dates	[Protocol Approved Date]	CASE WHEN ("- Study Metrics"."1st Site Initiated Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Key Dates"."[Protocol Approved Date]", VALUEOF("CURRENT_DAY")) > "Overall Level Targets"."[Target Protocol Approved to 1st Site Initiated (# Days)]") THEN 'RED' WHEN ("- Study Metrics"."1st Site Initiated Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Key Dates"."[Protocol Approved Date]", VALUEOF("CURRENT_DAY")) > ("Overall Level Targets"."[Target Protocol Approved to 1st Site Initiated (# Days)]"-30)) THEN 'YELLOW' END
Overall Level Targets	[Target Protocol Approved to 1st Site Initiated (# Days)]	CASE WHEN ("- Study Metrics"."1st Site Initiated Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Key Dates"."[Protocol Approved Date]", VALUEOF("CURRENT_DAY")) > "Overall Level Targets"."[Target Protocol Approved to 1st Site Initiated (# Days)]") THEN 'RED' WHEN ("- Study Metrics"."1st Site Initiated Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Key Dates"."[Protocol Approved Date]", VALUEOF("CURRENT_DAY")) > ("Overall Level Targets"."[Target Protocol Approved to 1st Site Initiated (# Days)]"-30)) THEN 'YELLOW' END
- Study Metrics	1st Site Initiated Date	"- Study Metrics"."1st Site Initiated Date"

Table A–111 (Cont.) Study List: KPI Performance (Report CDA-CO-904)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Metrics	1st Subject Enrolled Date	CASE WHEN ("- Study Metrics"."1st Subject Enrolled Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Key Dates"."[Protocol Approved Date]", VALUEOF("CURRENT_DAY")) > "Overall Level Targets"."[Target Protocol Approved to 1st Subject Enrolled (# Days)]") THEN 'RED' WHEN ("- Study Metrics"."1st Subject Enrolled Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Key Dates"."[Protocol Approved Date]", VALUEOF("CURRENT_DAY")) > ("Overall Level Targets"."[Target Protocol Approved to 1st Subject Enrolled (# Days)]"-30)) THEN 'YELLOW' END
- Study Key Dates	[Protocol Approved Date]	CASE WHEN ("- Study Metrics"."1st Subject Enrolled Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Key Dates"."[Protocol Approved Date]", VALUEOF("CURRENT_DAY")) > "Overall Level Targets"."[Target Protocol Approved to 1st Subject Enrolled (# Days)]") THEN 'RED' WHEN ("- Study Metrics"."1st Subject Enrolled Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Key Dates"."[Protocol Approved Date]", VALUEOF("CURRENT_DAY")) > ("Overall Level Targets"."[Target Protocol Approved to 1st Subject Enrolled (# Days)]"-30)) THEN 'YELLOW' END
Overall Level Targets	[Target Protocol Approved to 1st Subject Enrolled (# Days)]	CASE WHEN ("- Study Metrics"."1st Subject Enrolled Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Key Dates"."[Protocol Approved Date]", VALUEOF("CURRENT_DAY")) > "Overall Level Targets"."[Target Protocol Approved to 1st Subject Enrolled (# Days)]") THEN 'RED' WHEN ("- Study Metrics"."1st Subject Enrolled Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Key Dates"."[Protocol Approved Date]", VALUEOF("CURRENT_DAY")) > ("Overall Level Targets"."[Target Protocol Approved to 1st Subject Enrolled (# Days)]"-30)) THEN 'YELLOW' END

Table A–111 (Cont.) Study List: KPI Performance (Report CDA-CO-904)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Metrics	1st Subject Enrolled Date	CASE WHEN ("- Study Metrics"."1st Subject Enrolled Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Key Dates"."[Protocol Approved Date]", VALUEOF("CURRENT_DAY")) > "Overall Level Targets"."[Target Protocol Approved to 1st Subject Enrolled (# Days)]") THEN 'RED' WHEN ("- Study Metrics"."1st Subject Enrolled Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Key Dates"."[Protocol Approved Date]", VALUEOF("CURRENT_DAY")) > ("Overall Level Targets"."[Target Protocol Approved to 1st Subject Enrolled (# Days)]"-30)) THEN 'YELLOW' END
- Study Key Dates	[Protocol Approved Date]	CASE WHEN ("- Study Metrics"."1st Subject Enrolled Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Key Dates"."[Protocol Approved Date]", VALUEOF("CURRENT_DAY")) > "Overall Level Targets"."[Target Protocol Approved to 1st Subject Enrolled (# Days)]") THEN 'RED' WHEN ("- Study Metrics"."1st Subject Enrolled Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Key Dates"."[Protocol Approved Date]", VALUEOF("CURRENT_DAY")) > ("Overall Level Targets"."[Target Protocol Approved to 1st Subject Enrolled (# Days)]"-30)) THEN 'YELLOW' END
Overall Level Targets	[Target Protocol Approved to 1st Subject Enrolled (# Days)]	CASE WHEN ("- Study Metrics"."1st Subject Enrolled Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Key Dates"."[Protocol Approved Date]", VALUEOF("CURRENT_DAY")) > "Overall Level Targets"."[Target Protocol Approved to 1st Subject Enrolled (# Days)]") THEN 'RED' WHEN ("- Study Metrics"."1st Subject Enrolled Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Key Dates"."[Protocol Approved Date]", VALUEOF("CURRENT_DAY")) > ("Overall Level Targets"."[Target Protocol Approved to 1st Subject Enrolled (# Days)]"-30)) THEN 'YELLOW' END

Table A–111 (Cont.) Study List: KPI Performance (Report CDA-CO-904)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Key Dates	Database Lock Date	CASE WHEN ("- Study Key Dates"."Database Lock Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Metrics"."Last Subject Last Visit Date", VALUEOF("CURRENT_DAY")) > "- Study Targets"."[Target Last Subject Last Visit to Database Lock (# Days)]") THEN 'RED' WHEN ("- Study Key Dates"."Database Lock Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Metrics"."Last Subject Last Visit Date", VALUEOF("CURRENT_DAY")) > ("Overall Level Targets"."[Target Last Subject Last Visit to Database Lock (# Days)]"-30)) THEN 'YELLOW' END
- Study Metrics	Last Subject Last Visit Date	CASE WHEN ("- Study Key Dates"."Database Lock Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Metrics"."Last Subject Last Visit Date", VALUEOF("CURRENT_DAY")) > "- Study Targets"."[Target Last Subject Last Visit to Database Lock (# Days)]") THEN 'RED' WHEN ("- Study Key Dates"."Database Lock Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Metrics"."Last Subject Last Visit Date", VALUEOF("CURRENT_DAY")) > ("Overall Level Targets"."[Target Last Subject Last Visit to Database Lock (# Days)]"-30)) THEN 'YELLOW' END
- Study Targets	[Target Last Subject Last Visit to Database Lock (# Days)]	CASE WHEN ("- Study Key Dates"."Database Lock Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Metrics"."Last Subject Last Visit Date", VALUEOF("CURRENT_DAY")) > "- Study Targets"."[Target Last Subject Last Visit to Database Lock (# Days)]") THEN 'RED' WHEN ("- Study Key Dates"."Database Lock Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Metrics"."Last Subject Last Visit Date", VALUEOF("CURRENT_DAY")) > ("Overall Level Targets"."[Target Last Subject Last Visit to Database Lock (# Days)]"-30)) THEN 'YELLOW' END

Table A–111 (Cont.) Study List: KPI Performance (Report CDA-CO-904)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Key Dates	Database Lock Date	CASE WHEN ("- Study Key Dates"."Database Lock Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Metrics"."Last Subject Last Visit Date", VALUEOF("CURRENT_DAY")) > "- Study Targets"."[Target Last Subject Last Visit to Database Lock (# Days)]") THEN 'RED' WHEN ("- Study Key Dates"."Database Lock Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Metrics"."Last Subject Last Visit Date", VALUEOF("CURRENT_DAY")) > ("Overall Level Targets"."[Target Last Subject Last Visit to Database Lock (# Days)]"-30)) THEN 'YELLOW' END
- Study Metrics	Last Subject Last Visit Date	CASE WHEN ("- Study Key Dates"."Database Lock Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Metrics"."Last Subject Last Visit Date", VALUEOF("CURRENT_DAY")) > "- Study Targets"."[Target Last Subject Last Visit to Database Lock (# Days)]") THEN 'RED' WHEN ("- Study Key Dates"."Database Lock Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Metrics"."Last Subject Last Visit Date", VALUEOF("CURRENT_DAY")) > ("Overall Level Targets"."[Target Last Subject Last Visit to Database Lock (# Days)]"-30)) THEN 'YELLOW' END
Overall Level Targets	[Target Last Subject Last Visit to Database Lock (# Days)]	CASE WHEN ("- Study Key Dates"."Database Lock Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Metrics"."Last Subject Last Visit Date", VALUEOF("CURRENT_DAY")) > "- Study Targets"."[Target Last Subject Last Visit to Database Lock (# Days)]") THEN 'RED' WHEN ("- Study Key Dates"."Database Lock Date" IS NULL) AND (TIMESTAMPDIFF(SQL_TSI_DAY,"- Study Metrics"."Last Subject Last Visit Date", VALUEOF("CURRENT_DAY")) > ("Overall Level Targets"."[Target Last Subject Last Visit to Database Lock (# Days)]"-30)) THEN 'YELLOW' END
- Study Metrics	1st Subject Enrolled Date	"- Study Metrics"."1st Subject Enrolled Date"

Table A–111 (Cont.) Study List: KPI Performance (Report CDA-CO-904)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Metrics	[Last Subject Last Visit Date]	"- Study Metrics"."[Last Subject Last Visit Date]"
- Study Key Dates	[Protocol Approved Date]	MIN("- Study Key Dates"."[Protocol Approved Date]")
- Study Key Dates	Database Lock Date	MIN("- Study Key Dates"."Database Lock Date")
Overall Level Targets	[Target Protocol Approved to 1st Site Initiated (# Days)]	"Overall Level Targets"."[Target Protocol Approved to 1st Site Initiated (# Days)]"
Overall Level Targets	[Target Protocol Approved to 1st Subject Enrolled (# Days)]	"Overall Level Targets"."[Target Protocol Approved to 1st Subject Enrolled (# Days)]"
Overall Level Targets	[Target Last Subject Last Visit to Database Lock (# Days)]	"Overall Level Targets"."[Target Last Subject Last Visit to Database Lock (# Days)]"

Study List - Milestone Performance (Report CDA-CO-109)

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.

Audience

- Study Manager

Report Type

- Table

Location

None

Dimensions

- Study

Supplementary Prompts

- NA

Reports Referenced

You can navigate to the following reports from this report:

- Detailed Study Milestones Report (Report CDA-CO-102)

- Study Overview Dashboard
- Study Milestone with Indicators (Study Overview) (Report CDA-CO-101)

Reports Referencing This Report

You can navigate from the following reports to this report:

- Study Region Milestones with Indicators (Report CDA-CO-1106)

Column Descriptions

Table A–112 describes the columns in the Study List: Milestone Performance analysis

Table A–112 Study List: Milestone Performance (Report CDA-CO-109)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study	Program	"Study"."Program"
Study	Study	"Study"."Study"
Study	Study Short Title	"Study"."Study Short Title"
Study	Study Status	"Study"."Study Status"
Study	Study Manager	"Study"."Study Manager"
- Study Region Metrics	Milestone Flag	"- Study Region Metrics"."Milestone Flag"
- Study Region Metrics	Milestone Detail Reason	"- Study Region Metrics"."Milestone Detail Reason"
- Study Original Planned Dates	[Planned 1st IRB/EC Submission Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st IRB/EC Submission Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st IRB/EC Submission Date]") as char(40))) || ' '|| CONCAT('Actual :',EVALUATE('TO_ CHAR(%1,%2)' as varchar(20),"- Study Metrics"."[1st IRB/EC Submission Date]" , 'dd-Mon-yyyy'))
- Study Latest Estimated Dates	[Planned LE 1st IRB/EC Submission Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st IRB/EC Submission Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st IRB/EC Submission Date]") as char(40))) || ' '|| CONCAT('Actual :',EVALUATE('TO_ CHAR(%1,%2)' as varchar(20),"- Study Metrics"."[1st IRB/EC Submission Date]" , 'dd-Mon-yyyy'))

Table A–112 (Cont.) Study List: Milestone Performance (Report CDA-CO-109)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Metrics	[1st IRB/EC Submission Date]	CONCAT('Planned:',cast(MIN("-Study Original Planned Dates"."[Planned 1st IRB/EC Submission Date]") as char(40))||' '||CONCAT('LE:' , cast(MAX("-Study Latest Estimated Dates"."[Planned LE 1st IRB/EC Submission Date]") as char(40))||' '|| CONCAT('Actual :',EVALUATE('TO_CHAR(%1,%2)' as varchar(20),"-Study Metrics"."[1st IRB/EC Submission Date]" , 'dd-Mon-yyyy'))
- Study Original Planned Dates	[Planned 1st Initial IRB/EC Approval Date]	CONCAT('Planned:',cast(MIN("-Study Original Planned Dates"."[Planned 1st Initial IRB/EC Approval Date]") as char(40))||' '||CONCAT('LE:' , cast(MAX("-Study Latest Estimated Dates"."[Planned LE 1st Initial IRB/EC Approval Date]") as char(40))||' '||CONCAT('Actual:',cast("-Study Metrics"."1st Initial IRB/EC Approval Date" as char(40)))
- Study Latest Estimated Dates	[Planned LE 1st Initial IRB/EC Approval Date]	CONCAT('Planned:',cast(MIN("-Study Original Planned Dates"."[Planned 1st Initial IRB/EC Approval Date]") as char(40))||' '||CONCAT('LE:' , cast(MAX("-Study Latest Estimated Dates"."[Planned LE 1st Initial IRB/EC Approval Date]") as char(40))||' '||CONCAT('Actual:',cast("-Study Metrics"."1st Initial IRB/EC Approval Date" as char(40)))
- Study Metrics	1st Initial IRB/EC Approval Date	CONCAT('Planned:',cast(MIN("-Study Original Planned Dates"."[Planned 1st Initial IRB/EC Approval Date]") as char(40))||' '||CONCAT('LE:' , cast(MAX("-Study Latest Estimated Dates"."[Planned LE 1st Initial IRB/EC Approval Date]") as char(40))||' '||CONCAT('Actual:',cast("-Study Metrics"."1st Initial IRB/EC Approval Date" as char(40)))

Table A–112 (Cont.) Study List: Milestone Performance (Report CDA-CO-109)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Original Planned Dates	[Planned 1st Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Site Initiated Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Site Initiated Date]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Metrics"."1st Site Initiated Date" as char(40)))
- Study Latest Estimated Dates	[Planned LE 1st Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Site Initiated Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Site Initiated Date]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Metrics"."1st Site Initiated Date" as char(40)))
- Study Metrics	1st Site Initiated Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Site Initiated Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Site Initiated Date]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Metrics"."1st Site Initiated Date" as char(40)))
- Study Original Planned Dates	[Planned Last Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Site Initiated Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Site Initiated Date]") as char(40)))||' '||CONCAT('Actual(Latest):',cast ("- Study Metrics"."Latest Site Initiated Date" as char(40)))||' '||CONCAT('Actual(Last):',cast(" - Study Metrics"."[Last Site Initiated Date]" as char(40)))
- Study Latest Estimated Dates	[Planned LE Last Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Site Initiated Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Site Initiated Date]") as char(40)))||' '||CONCAT('Actual(Latest):',cast ("- Study Metrics"."Latest Site Initiated Date" as char(40)))||' '||CONCAT('Actual(Last):',cast(" - Study Metrics"."[Last Site Initiated Date]" as char(40)))

Table A–112 (Cont.) Study List: Milestone Performance (Report CDA-CO-109)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Metrics	Latest Site Initiated Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Site Initiated Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Site Initiated Date]") as char(40)))||' '||CONCAT('Actual(Latest):',cast ("- Study Metrics"."Latest Site Initiated Date" as char(40)))||' '||CONCAT('Actual(Last):',cast(" - Study Metrics"."[Last Site Initiated Date]" as char(40)))
- Study Metrics	[Last Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Site Initiated Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Site Initiated Date]") as char(40)))||' '||CONCAT('Actual(Latest):',cast ("- Study Metrics"."Latest Site Initiated Date" as char(40)))||' '||CONCAT('Actual(Last):',cast(" - Study Metrics"."[Last Site Initiated Date]" as char(40)))
- Study Original Planned Dates	[Planned 1st Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Metrics"."[1st Critical Document Package Completed Date]" as char(40)))
- Study Latest Estimated Dates	[Planned LE 1st Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Metrics"."[1st Critical Document Package Completed Date]" as char(40)))

Table A–112 (Cont.) Study List: Milestone Performance (Report CDA-CO-109)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Metrics	[1st Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Metrics"."[1st Critical Document Package Completed Date]" as char(40)))
- Study Original Planned Dates	[Planned Last Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('Actual(Latest):',cast ("- Study Metrics"."[Latest Critical Document Package Completed Date]" as char(40)))||' '||CONCAT('Actual(Last):',cast(" - Study Metrics"."[Last Critical Document Package Completed Date]" as char(40)))
- Study Latest Estimated Dates	[Planned LE Last Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('Actual(Latest):',cast ("- Study Metrics"."[Latest Critical Document Package Completed Date]" as char(40)))||' '||CONCAT('Actual(Last):',cast(" - Study Metrics"."[Last Critical Document Package Completed Date]" as char(40)))

Table A–112 (Cont.) Study List: Milestone Performance (Report CDA-CO-109)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Metrics	[Latest Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('Actual(Latest):',cast ("- Study Metrics"."[Latest Critical Document Package Completed Date]" as char(40)))||' '||CONCAT('Actual(Last):',cast(" - Study Metrics"."[Last Critical Document Package Completed Date]" as char(40)))
- Study Metrics	[Last Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('Actual(Latest):',cast ("- Study Metrics"."[Latest Critical Document Package Completed Date]" as char(40)))||' '||CONCAT('Actual(Last):',cast(" - Study Metrics"."[Last Critical Document Package Completed Date]" as char(40)))
- Study Original Planned Dates	[Planned 1st Subject Screened Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Screened Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Metrics"."1st Subject Screened Date" as char(40)))
- Study Latest Estimated Dates	[Planned LE 1st Subject Screened Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Screened Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Metrics"."1st Subject Screened Date" as char(40)))

Table A–112 (Cont.) Study List: Milestone Performance (Report CDA-CO-109)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Metrics	1st Subject Screened Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Screened Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Metrics"."1st Subject Screened Date" as char(40)))
- Study Original Planned Dates	[Planned 1st Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Metrics"."1st Subject Enrolled Date" as char(40)))
- Study Latest Estimated Dates	[Planned LE 1st Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Metrics"."1st Subject Enrolled Date" as char(40)))
- Study Metrics	1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Metrics"."1st Subject Enrolled Date" as char(40)))
- Study Original Planned Dates	[Planned 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Metrics"."1st Subject Randomized Date" as char(40)))

Table A–112 (Cont.) Study List: Milestone Performance (Report CDA-CO-109)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Latest Estimated Dates	[Planned LE 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40))) || ' '||CONCAT('Actual:',cast("- Study Metrics"."1st Subject Randomized Date" as char(40)))
- Study Metrics	1st Subject Randomized Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40))) || ' '||CONCAT('Actual:',cast("- Study Metrics"."1st Subject Randomized Date" as char(40)))
- Study Original Planned Dates	[Planned Last Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40))) || ' '||CONCAT('Actual(Latest):',cast ("- Study Metrics"."Latest Subject Enrollment Date" as char(40))) || ' '||CONCAT('Actual(Last):',cast(" - Study Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study Latest Estimated Dates	[Planned LE Last Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40))) || ' '||CONCAT('Actual(Latest):',cast ("- Study Metrics"."Latest Subject Enrollment Date" as char(40))) || ' '||CONCAT('Actual(Last):',cast(" - Study Metrics"."[Last Subject Enrolled Date]" as char(40)))

Table A–112 (Cont.) Study List: Milestone Performance (Report CDA-CO-109)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Metrics	Latest Subject Enrollment Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40))) || ' '||CONCAT('Actual(Latest):',cast ("- Study Metrics"."Latest Subject Enrollment Date" as char(40))) || ' '||CONCAT('Actual(Last):',cast(" - Study Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study Metrics	[Last Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40))) || ' '||CONCAT('Actual(Latest):',cast ("- Study Metrics"."Latest Subject Enrollment Date" as char(40))) || ' '||CONCAT('Actual(Last):',cast(" - Study Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study Original Planned Dates	[Planned Last Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40))) || ' '||CONCAT('Actual(Latest):',cast ("- Study Metrics"."Latest Subject Randomized Date" as char(40))) || ' '||CONCAT('Actual(Last):',cast(" - Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))

Table A–112 (Cont.) Study List: Milestone Performance (Report CDA-CO-109)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40))||' '||CONCAT('Actual(Latest):',cast ("- Study Metrics"."Latest Subject Randomized Date" as char(40))||' '||CONCAT('Actual(Last):',cast(" - Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study Metrics	Latest Subject Randomized Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40))||' '||CONCAT('Actual(Latest):',cast ("- Study Metrics"."Latest Subject Randomized Date" as char(40))||' '||CONCAT('Actual(Last):',cast(" - Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Metrics	[Last Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40))||' '||CONCAT('Actual(Latest):',cast ("- Study Metrics"."Latest Subject Randomized Date" as char(40))||' '||CONCAT('Actual(Last):',cast(" - Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))

Table A–112 (Cont.) Study List: Milestone Performance (Report CDA-CO-109)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Original Planned Dates	[Planned Last Subject Last Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40))) || ' '||CONCAT('Actual(Latestt):',cast("- Study Metrics"."Latest Subject Latest Visit Date" as char(40))) || ' '||CONCAT('Actual(Last):',cast("- Study Metrics"."[Last Subject Last Visit Date]"as char(40)))
- Study Latest Estimated Dates	[Planned LE Last Subject Last Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40))) || ' '||CONCAT('Actual(Latestt):',cast("- Study Metrics"."Latest Subject Latest Visit Date" as char(40))) || ' '||CONCAT('Actual(Last):',cast("- Study Metrics"."[Last Subject Last Visit Date]"as char(40)))
- Study Metrics	Latest Subject Latest Visit Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40))) || ' '||CONCAT('Actual(Latestt):',cast("- Study Metrics"."Latest Subject Latest Visit Date" as char(40))) || ' '||CONCAT('Actual(Last):',cast("- Study Metrics"."[Last Subject Last Visit Date]"as char(40)))
- Study Metrics	[Last Subject Last Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40))) || ' '||CONCAT('Actual(Latestt):',cast("- Study Metrics"."Latest Subject Latest Visit Date" as char(40))) || ' '||CONCAT('Actual(Last):',cast("- Study Metrics"."[Last Subject Last Visit Date]"as char(40)))

Study List - Recruitment Details (Report CDA-CO-406)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study Manager** dashboard, **Initiating and Recruiting Studies** page

Dimensions

- Study

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Study List - Recruitment Details report.

Table A–113 Study List - Recruitment Details (Report CDA-CO-406)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study	Program	Study.Program
Study	Study	Study.Study
Study	Status	Study.Study Status
Study	Study Manager	"Study"."Study Manager"
- Study Metrics	Recruitment Flag	"- Study Metrics"."Recruitment Flag"

Table A–113 (Cont.) Study List - Recruitment Details (Report CDA-CO-406)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study Metrics	Recruitment Detail Reason	"- Study Metrics"."Recruitment Detail Reason"
- Study Metrics	Milestone Flag	"- Study Metrics"."Milestone Flag"
- Study Metrics	Milestone Detail Reason	"- Study Metrics"."Milestone Detail Reason"
- Study Targets	[Expected Screen Failure Rate]	CONCAT('Expected:',cast(MIN(ROUND("- Study Targets"."[Expected Screen Failure Rate]",2)) as char(40)))||' '||CONCAT('Actual:',cast(ROUND("- Study Metrics"."Screen Failure Rate",2) as char(40)))
- Study Metrics	Screen Failure Rate	CONCAT('Expected:',cast(MIN(ROUND("- Study Targets"."[Expected Screen Failure Rate]",2)) as char(40)))||' '||CONCAT('Actual:',cast(ROUND("- Study Metrics"."Screen Failure Rate",2) as char(40)))
- Study Metrics	% Planned Subjects Enrolled (Study)	CONCAT('Actual:',cast(ROUND("- Study Metrics"."% Planned Subjects Enrolled (Study)",2) as char(40)))
- Study Metrics	% Planned Subjects Randomized (Study)	CONCAT('Actual:',cast(ROUND("- Study Metrics"."% Planned Subjects Randomized (Study)",2) as char(40)))
- Study Original Planned Dates	[Planned 1st Subject Screened Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Screened Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Metrics"."1st Subject Screened Date" as char(40)))
- Study Latest Estimated Dates	[Planned LE 1st Subject Screened Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Screened Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Metrics"."1st Subject Screened Date" as char(40)))

Table A–113 (Cont.) Study List - Recruitment Details (Report CDA-CO-406)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study Metrics	1st Subject Screened Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Screened Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject Screened Date" as char(40)))
- Study Original Planned Dates	[Planned 1st Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject Enrolled Date" as char(40)))
- Study Latest Estimated Dates	[Planned LE 1st Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject Enrolled Date" as char(40)))
- Study Metrics	1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject Enrolled Date" as char(40)))
- Study Original Planned Dates	[Planned 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject Randomized Date" as char(40)))

Table A–113 (Cont.) Study List - Recruitment Details (Report CDA-CO-406)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study Latest Estimated Dates	[Planned LE 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject Randomized Date" as char(40)))
- Study Metrics	1st Subject Randomized Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject Randomized Date" as char(40)))
- Study Original Planned Dates	[Planned 1st Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study Latest Estimated Dates	[Planned LE 1st Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study Metrics	1st Subject 1st Visit Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject 1st Visit Date" as char(40)))

Table A–113 (Cont.) Study List - Recruitment Details (Report CDA-CO-406)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study Original Planned Dates	[Planned Last Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Enrollment Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study Latest Estimated Dates	[Planned LE Last Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Enrollment Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study Metrics	Latest Subject Enrollment Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Enrollment Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study Metrics	[Last Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Enrollment Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Enrolled Date]" as char(40)))

Table A–113 (Cont.) Study List - Recruitment Details (Report CDA-CO-406)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study Original Planned Dates	[Planned Last Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study Metrics	Latest Subject Randomized Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Randomized Date]" as char(40)))

Table A–113 (Cont.) Study List - Recruitment Details (Report CDA-CO-406)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study Metrics	[Last Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Randomized Date" as char(40))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study Original Planned Dates	[Planned Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject 1st Visit Date" as char(40))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study Latest Estimated Dates	[Planned LE Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject 1st Visit Date" as char(40))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study Metrics	Latest Subject 1st Visit Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject 1st Visit Date" as char(40))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject 1st Visit Date]" as char(40)))

Table A–113 (Cont.) Study List - Recruitment Details (Report CDA-CO-406)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study Metrics	[Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study Original Planned Dates	[Planned Last Subject Last Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study Latest Estimated Dates	[Planned LE Last Subject Last Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study Metrics	Latest Subject Latest Visit Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Last Visit Date]" as char(40)))

Table A–113 (Cont.) Study List - Recruitment Details (Report CDA-CO-406)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study Metrics	[Last Subject Last Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Last Visit Date]" as char(40)))
NA	Navigate to Detail	NA

Study Milestone with Indicators (Study Overview) (Report CDA-CO-101)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study Overview** dashboard, **Study Overview** page

Dimensions

None

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

- Detailed Study Milestones Report (Report CDA-CO-102)

- Study List - Initiation Details (Report CDA-CO-305)
- Study List - Recruitment Details (Report CDA-CO-406)

Column Descriptions

The table describes the columns in the Study Milestone with Indicators (Study Overview) report.

Table A–114 Study Milestone with Indicators (Study Overview) (Report CDA-CO-101)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study	Program	"Study"."Program"
Study	Study	"Study"."Study"
Study	Study Manager	"Study"."Study Manager"
- Study Metrics	Recruitment Flag	"- Study Metrics"."Recruitment Flag"
- Study Metrics	Recruitment Detail Reason	"- Study Metrics"."Recruitment Detail Reason"
- Study Metrics	Retention Flag	"- Study Metrics"."Retention Flag"
- Study Metrics	Retention Detail Reason	"- Study Metrics"."Retention Detail Reason"
- Study Metrics	Milestone Flag	"- Study Metrics"."Milestone Flag"
- Study Metrics	Milestone Detail Reason	"- Study Metrics"."Milestone Detail Reason"
- Study Targets	[Expected Screen Failure Rate]	CONCAT('[Expected]:',cast(MIN("- Study Targets"."[Expected Screen Failure Rate]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Metrics"."Screen Failure Rate" as char(40)))
- Study Metrics	Screen Failure Rate	CONCAT('[Expected]:',cast(MIN("- Study Targets"."[Expected Screen Failure Rate]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Metrics"."Screen Failure Rate" as char(40)))
- Study Metrics	% of Planned Sites Initiated	CONCAT('Actual:',cast("- Study Metrics"."% of Planned Sites Initiated" as char(40)))
- Study Metrics	% Planned Subjects Enrolled (Study)	CONCAT('Actual:',cast("- Study Metrics"."% Planned Subjects Enrolled (Study)" as char(40)))
- Study Targets	Expected Early Termination Rate	CONCAT('[Expected]:',cast(MIN("- Study Targets"."Expected Early Termination Rate") as char(40)))||' '||CONCAT('Actual:',cast(MAX("- Study Metrics"."% Subjects Early Terminated for Study") as char(40)))
- Study Metrics	% Subjects Early Terminated for Study	CONCAT('[Expected]:',cast(MIN("- Study Targets"."Expected Early Termination Rate") as char(40)))||' '||CONCAT('Actual:',cast(MAX("- Study Metrics"."% Subjects Early Terminated for Study") as char(40)))

Table A–114 (Cont.) Study Milestone with Indicators (Study Overview) (Report

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Metrics	% Planned Subjects Randomized (Study)	CONCAT('Actual:',cast("- Study Metrics"."% Planned Subjects Randomized (Study)" as char(40)))
- Study Key Dates	[Protocol Approved Date]	CONCAT('Actual:',cast(MIN("- Study Key Dates"."[Protocol Approved Date]") as char(40)))
- Study Original Planned Dates	[Planned Database Lock Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Database Lock Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Database Lock Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MIN("- Study Key Dates"."Database Lock Date") as char(40)))
- Study Latest Estimated Dates	[Planned LE Database Lock Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Database Lock Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Database Lock Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MIN("- Study Key Dates"."Database Lock Date") as char(40)))
- Study Key Dates	Database Lock Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Database Lock Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Database Lock Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MIN("- Study Key Dates"."Database Lock Date") as char(40)))
- Discrepancies	# Open Discrepancies	"- Discrepancies"."# Open Discrepancies"
- Discrepancies	# Total Discrepancies	"- Discrepancies"."# Total Discrepancies"
- Discrepancies	# Days Discrepancy Open	("- Discrepancies"."# Days Discrepancy Open"/ "- Discrepancies"."# Total Discrepancies")
- Discrepancies	# Total Discrepancies	("- Discrepancies"."# Days Discrepancy Open"/ "- Discrepancies"."# Total Discrepancies")
- Received CRFs	# eCRFs To Be Approved	"- Received CRFs"."# eCRFs To Be Approved"
- Received CRFs	# eCRFs To be Verified	"- Received CRFs"."# eCRFs To be Verified"
- Received CRFs	# CRFs Soft- Locked	"- Received CRFs"."# CRFs Soft-Locked"

Table A–114 (Cont.) Study Milestone with Indicators (Study Overview) (Report

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Received CRFs	% CRFs Soft Locked / Entry Complete	"- Received CRFs"."% CRFs Soft Locked / Entry Complete"
- Received CRFs	# CRFs Hard-Locked	"- Received CRFs"."# CRFs Hard-Locked"
- Received CRFs	% CRFs Hard Locked / Entry Complete	"- Received CRFs"."% CRFs Hard Locked / Entry Complete"
- Study Original Planned Dates	[Planned 1st Subject Screened Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Screened Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study Metrics"."1st Subject Screened Date") as char(40)))
- Study Latest Estimated Dates	[Planned LE 1st Subject Screened Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Screened Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study Metrics"."1st Subject Screened Date") as char(40)))
- Study Metrics	1st Subject Screened Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Screened Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study Metrics"."1st Subject Screened Date") as char(40)))
- Study Original Planned Dates	[Planned 1st Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject Enrolled Date" as char(40)))

Table A–114 (Cont.) Study Milestone with Indicators (Study Overview) (Report

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Latest Estimated Dates	[Planned LE 1st Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject Enrolled Date" as char(40)))
- Study Metrics	1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject Enrolled Date" as char(40)))
- Study Original Planned Dates	[Planned 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject Randomized Date" as char(40)))
- Study Latest Estimated Dates	[Planned LE 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject Randomized Date" as char(40)))
- Study Metrics	1st Subject Randomized Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject Randomized Date" as char(40)))

Table A–114 (Cont.) Study Milestone with Indicators (Study Overview) (Report

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Original Planned Dates	[Planned 1st Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study Latest Estimated Dates	[Planned LE 1st Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study Metrics	1st Subject 1st Visit Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study Original Planned Dates	[Planned Last Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Enrollment Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Enrolled Date]"as char(40)))

Table A–114 (Cont.) Study Milestone with Indicators (Study Overview) (Report

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Latest Estimated Dates	[Planned LE Last Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Enrollment Date" as char(40))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Enrolled Date]"as char(40)))
- Study Metrics	Latest Subject Enrollment Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Enrollment Date" as char(40))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Enrolled Date]"as char(40)))
- Study Metrics	[Last Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Enrollment Date" as char(40))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Enrolled Date]"as char(40)))
- Study Original Planned Dates	[Planned Last Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40))||' '||CONCAT(' Actual(Latest):' , cast("- Study Metrics"."Latest Subject Randomized Date" as char(40))||' '||CONCAT(' Actual(Last):' , cast("- Study Metrics"."[Last Subject Randomized Date]" as char(40)))

Table A–114 (Cont.) Study Milestone with Indicators (Study Overview) (Report

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):' , cast("- Study Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):' , cast("- Study Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study Metrics	Latest Subject Randomized Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):' , cast("- Study Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):' , cast("- Study Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study Metrics	[Last Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):' , cast("- Study Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):' , cast("- Study Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study Original Planned Dates	[Planned Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject 1st Visit Date]" as char(40)))

Table A–114 (Cont.) Study Milestone with Indicators (Study Overview) (Report

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Latest Estimated Dates	[Planned LE Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study Metrics	Latest Subject 1st Visit Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study Metrics	[Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study Original Planned Dates	[Planned Last Subject Last Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Last Visit Date]" as char(40)))

Table A–114 (Cont.) Study Milestone with Indicators (Study Overview) (Report

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Latest Estimated Dates	[Planned LE Last Subject Last Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study Metrics	Latest Subject Latest Visit Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study Metrics	[Last Subject Last Visit Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study Metrics	# Study-Sites Planned for Study	CONCAT('Planned:',cast(MIN("- Study Metrics"."# Study-Sites Planned for Study") as char(40)))||' '||CONCAT(' Actual:',cast(MIN("- Study Metrics"."# Study-Sites Initiated") as char(40)))
- Study Metrics	# Study-Sites Initiated	CONCAT('Planned:',cast(MIN("- Study Metrics"."# Study-Sites Planned for Study") as char(40)))||' '||CONCAT(' Actual:',cast(MIN("- Study Metrics"."# Study-Sites Initiated") as char(40)))

Table A–114 (Cont.) Study Milestone with Indicators (Study Overview) (Report

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Original Planned Dates	[Planned 1st IRB/EC Submission Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."[1st IRB/EC Submission Date]" as char(40)))
- Study Latest Estimated Dates	[Planned LE 1st IRB/EC Submission Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."[1st IRB/EC Submission Date]" as char(40)))
- Study Metrics	[1st IRB/EC Submission Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."[1st IRB/EC Submission Date]" as char(40)))
- Study Original Planned Dates	[Planned 1st Initial IRB/EC Approval Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Initial IRB/EC Approval Date" as char(40)))
- Study Latest Estimated Dates	[Planned LE 1st Initial IRB/EC Approval Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Initial IRB/EC Approval Date" as char(40)))

Table A–114 (Cont.) Study Milestone with Indicators (Study Overview) (Report

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Metrics	1st Initial IRB/EC Approval Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Initial IRB/EC Approval Date" as char(40)))
- Study Original Planned Dates	[Planned 1st Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Site Initiated Date" as char(40)))
- Study Latest Estimated Dates	[Planned LE 1st Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Site Initiated Date" as char(40)))
- Study Metrics	1st Site Initiated Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."1st Site Initiated Date" as char(40)))
- Study Original Planned Dates	[Planned Last Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Site Initiated Date]") as char(40)))||' '||CONCAT(' Latestl:',cast("- Study Metrics"."Latest Site Initiated Date" as char(40)))||' '||CONCAT(' Last:',cast("- Study Metrics"."[Last Site Initiated Date]" as char(40)))

Table A–114 (Cont.) Study Milestone with Indicators (Study Overview) (Report

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Latest Estimated Dates	[Planned LE Last Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Site Initiated Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Site Initiated Date]") as char(40))||' '||CONCAT(' Latestl:',cast("- Study Metrics"."Latest Site Initiated Date" as char(40))||' '||CONCAT(' Last:',cast("- Study Metrics"."[Last Site Initiated Date]" as char(40)))
- Study Metrics	Latest Site Initiated Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Site Initiated Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Site Initiated Date]") as char(40))||' '||CONCAT(' Latestl:',cast("- Study Metrics"."Latest Site Initiated Date" as char(40))||' '||CONCAT(' Last:',cast("- Study Metrics"."[Last Site Initiated Date]" as char(40)))
- Study Metrics	[Last Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Site Initiated Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Site Initiated Date]") as char(40))||' '||CONCAT(' Latestl:',cast("- Study Metrics"."Latest Site Initiated Date" as char(40))||' '||CONCAT(' Last:',cast("- Study Metrics"."[Last Site Initiated Date]" as char(40)))
- Study Original Planned Dates	[Planned 1st Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Critical Document Package Completed Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Critical Document Package Completed Date]") as char(40))||' '||CONCAT(' Actual:',cast("- Study Metrics"."[1st Critical Document Package Completed Date]" as char(40)))

Table A–114 (Cont.) Study Milestone with Indicators (Study Overview) (Report

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Latest Estimated Dates	[Planned LE 1st Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."[1st Critical Document Package Completed Date]" as char(40)))
- Study Metrics	[1st Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned 1st Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE 1st Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study Metrics"."[1st Critical Document Package Completed Date]" as char(40)))
- Study Original Planned Dates	[Planned Last Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."[Latest Critical Document Package Completed Date]" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Critical Document Package Completed Date]" as char(40)))

Table A–114 (Cont.) Study Milestone with Indicators (Study Overview) (Report

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Latest Estimated Dates	[Planned LE Last Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."[Latest Critical Document Package Completed Date]" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Critical Document Package Completed Date]" as char(40)))
- Study Metrics	[Latest Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."[Latest Critical Document Package Completed Date]" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Critical Document Package Completed Date]" as char(40)))
- Study Metrics	[Last Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Last Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Last Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study Metrics"."[Latest Critical Document Package Completed Date]" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study Metrics"."[Last Critical Document Package Completed Date]" as char(40)))

Table A–114 (Cont.) Study Milestone with Indicators (Study Overview) (Report

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Original Planned Dates	[Planned Clinical Study Report Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Clinical Study Report Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Clinical Study Report Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MIN("- Study Key Dates"."[Clinical Study Report Date]") as char(40)))
- Study Latest Estimated Dates	[Planned LE Clinical Study Report Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Clinical Study Report Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Clinical Study Report Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MIN("- Study Key Dates"."[Clinical Study Report Date]") as char(40)))
- Study Key Dates	[Clinical Study Report Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Clinical Study Report Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Clinical Study Report Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MIN("- Study Key Dates"."[Clinical Study Report Date]") as char(40)))
- Received CRFs	# CRFs Awaiting Entry Completion	"- Received CRFs"."# CRFs Awaiting Entry Completion"
- Study Metrics	KPI Flag	"- Study Metrics"."KPI Flag"
- Study Metrics	KPI Detail Reason	"- Study Metrics"."KPI Detail Reason"
Overall Level Targets	[Expected % Sites Recruiting 0 Subjects]	CONCAT('[Overall Target]:',cast(MAX("Overall Level Targets"."[Expected % Sites Recruiting 0 Subjects]") as char(40)))||' '||CONCAT(' Actual:' ,cast(MAX("- Study Metrics"."% Sites Recruiting 0 Subjects") as char(40)))
- Study Metrics	% Sites Recruiting 0 Subjects	CONCAT('[Overall Target]:',cast(MAX("Overall Level Targets"."[Expected % Sites Recruiting 0 Subjects]") as char(40)))||' '||CONCAT(' Actual:' ,cast(MAX("- Study Metrics"."% Sites Recruiting 0 Subjects") as char(40)))

Table A–114 (Cont.) Study Milestone with Indicators (Study Overview) (Report

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Overall Level Targets	[Target Protocol Approved to 1st Site Initiated (# Days)]	CONCAT('[Overall Target]:',cast(MAX("Overall Level Targets"."[Target Protocol Approved to 1st Site Initiated (# Days)]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study Metrics"."[Protocol Approved to 1st Site Initiated (# Days)]") as char(40)))
- Study Metrics	[Protocol Approved to 1st Site Initiated (# Days)]	CONCAT('[Overall Target]:',cast(MAX("Overall Level Targets"."[Target Protocol Approved to 1st Site Initiated (# Days)]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study Metrics"."[Protocol Approved to 1st Site Initiated (# Days)]") as char(40)))
Overall Level Targets	[Target Protocol Approved to 1st Subject Enrolled (# Days)]	CONCAT('[Overall Target]:',cast(MAX("Overall Level Targets"."[Target Protocol Approved to 1st Subject Enrolled (# Days)]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study Metrics"."[Protocol Approved to 1st Subject Enrolled (# Days)]") as char(40)))
- Study Metrics	[Protocol Approved to 1st Subject Enrolled (# Days)]	CONCAT('[Overall Target]:',cast(MAX("Overall Level Targets"."[Target Protocol Approved to 1st Subject Enrolled (# Days)]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study Metrics"."[Protocol Approved to 1st Subject Enrolled (# Days)]") as char(40)))
Overall Level Targets	[Target Critical Document Package Complete to Site Initiated (# Days)]	CONCAT('[Overall Target]:',cast(MAX("Overall Level Targets"."[Target Critical Document Package Complete to Site Initiated (# Days)]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study Metrics"."[Median Critical Document Package Complete to Site Initiated (# Days)]") as char(40)))
- Study Metrics	[Median Critical Document Package Complete to Site Initiated (# Days)]	CONCAT('[Overall Target]:',cast(MAX("Overall Level Targets"."[Target Critical Document Package Complete to Site Initiated (# Days)]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study Metrics"."[Median Critical Document Package Complete to Site Initiated (# Days)]") as char(40)))

Table A–114 (Cont.) Study Milestone with Indicators (Study Overview) (Report

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Overall Level Targets	[Target Site Visit Completed to Visit Report Completed (# Days)]	CONCAT('[Overall Target]:',cast(MAX("Overall Level Targets"."[Target Site Visit Completed to Visit Report Completed (# Days)]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study Metrics"."Median Site Visit Completed to Visit Report Completed (# Days)") as char(40)))
- Study Metrics	Median Site Visit Completed to Visit Report Completed (# Days)	CONCAT('[Overall Target]:',cast(MAX("Overall Level Targets"."[Target Site Visit Completed to Visit Report Completed (# Days)]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study Metrics"."Median Site Visit Completed to Visit Report Completed (# Days)") as char(40)))
Overall Level Targets	[Target Visit Report Completed to Visit Report Approved (# Days)]	CONCAT('[Overall Target]:',cast(MAX("Overall Level Targets"."[Target Visit Report Completed to Visit Report Approved (# Days)]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study Metrics"."Median Visit Report Completed to Visit Report Approved (# Days)") as char(40)))
- Study Metrics	Median Visit Report Completed to Visit Report Approved (# Days)	CONCAT('[Overall Target]:',cast(MAX("Overall Level Targets"."[Target Visit Report Completed to Visit Report Approved (# Days)]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study Metrics"."Median Visit Report Completed to Visit Report Approved (# Days)") as char(40)))
Overall Level Targets	[Target Last Subject Last Visit to Database Lock (# Days)]	CONCAT('[Overall Target]:',cast(MAX("Overall Level Targets"."[Target Last Subject Last Visit to Database Lock (# Days)]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study Metrics"."Latest Subject Latest Visit to Database Lock (# Days)") as char(40)))
- Study Metrics	Latest Subject Latest Visit to Database Lock (# Days)	CONCAT('[Overall Target]:',cast(MAX("Overall Level Targets"."[Target Last Subject Last Visit to Database Lock (# Days)]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study Metrics"."Latest Subject Latest Visit to Database Lock (# Days)") as char(40)))

Study Region Milestones with Indicators (Report CDA-CO-1106)

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.

Audience

- Region Manager, Study Manager, Executive Manager, Program Manager

Report Type

- View Selector (Multiple Tables)

Location

- **Region Manager** dashboard, **Study-Region Milestones and Schedule** page

Dimensions

- Study-Region

Supplementary Prompts

- NA

Reports Referenced

You can navigate to the following reports from this report:

- Study-Region Team Member List (Report CDA-CO-1107)
- Study-Region Overview Dashboard
- Study Overview Dashboard

Reports Referencing This Report

None

Column Descriptions

Table A–115 describes the columns in the Study Region Milestones with Indicators analysis

Table A–115 Study Region Milestones with Indicators (Report CDA-CO-1106)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study	Study	"Study"."Study"
Study-Region	Region Name	"Study-Region"."Region Name"

Table A–115 (Cont.) Study Region Milestones with Indicators (Report CDA-CO-1106)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Region	Study-Region Status	"Study-Region"."Study-Region Status"
Study-Region	Study-Region Manager	"Study-Region"."Study-Region Manager"
Study	Study Short Title	"Study"."Study Short Title"
- Study Region Metrics	Recruitment Flag	"- Study Region Metrics"."Recruitment Flag"
- Study Region Metrics	Recruitment Detail Reason	"- Study Region Metrics"."Recruitment Detail Reason"
- Study Region Metrics	Retention Flag	"- Study Region Metrics"."Retention Flag"
- Study Region Metrics	Retention Detail Reason	"- Study Region Metrics"."Retention Detail Reason"
- Study Region Metrics	Milestone Flag	"- Study Region Metrics"."Milestone Flag"
- Study Region Metrics	Milestone Detail Reason	"- Study Region Metrics"."Milestone Detail Reason"
- Study Region Metrics	% of Planned Sites Initiated	CONCAT('Actual:' , cast(ROUND("- Study Region Metrics"."% of Planned Sites Initiated" ,2) as char(40)))
- Study-Region Targets	[Expected Screen Failure Rate]	CONCAT('Expected:',cast(MIN("- Study-Region Targets"."[Expected Screen Failure Rate]") as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study Region Metrics"."Screen Failure Rate",2) as char(40)))
- Study Region Metrics	Screen Failure Rate	CONCAT('Expected:',cast(MIN("- Study-Region Targets"."[Expected Screen Failure Rate]") as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study Region Metrics"."Screen Failure Rate",2) as char(40)))
- Study Region Metrics	% Enrolled to Total Planned at Study Region	CONCAT('Actual:' , cast(ROUND("- Study Region Metrics"."% Enrolled to Total Planned at Study Region",2) as char(40)))
- Study-Region Targets	[Expected Early Termination Rate]	CONCAT('Expected:',cast(MIN("- Study-Region Targets"."[Expected Early Termination Rate]") as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study Region Metrics"."% Subjects Early Terminated for Study-Region",2) as char(40)))

Table A–115 (Cont.) Study Region Milestones with Indicators (Report CDA-CO-1106)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Region Metrics	% Subjects Early Terminated for Study-Region	CONCAT('Expected:',cast(MIN("- Study-Region Targets"."[Expected Early Termination Rate]") as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study Region Metrics"."% Subjects Early Terminated for Study-Region",2) as char(40)))
- Study Region Metrics	% Planned Subjects Randomized	CONCAT('Actual:' , cast(ROUND("- Study Region Metrics"."% Planned Subjects Randomized",2) as char(40)))
- Study Key Dates	[Protocol Approved Date]	max("- Study Key Dates"."[Protocol Approved Date]")
- Study Original Planned Dates	[Planned Database Lock Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Database Lock Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Database Lock Date]") as char(40)))||' '||CONCAT('Actual:',cast(MAX("- Study Key Dates"."Database Lock Date") as char(40)))
- Study Latest Estimated Dates	[Planned LE Database Lock Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Database Lock Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Database Lock Date]") as char(40)))||' '||CONCAT('Actual:',cast(MAX("- Study Key Dates"."Database Lock Date") as char(40)))
- Study Key Dates	Database Lock Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Database Lock Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Database Lock Date]") as char(40)))||' '||CONCAT('Actual:',cast(MAX("- Study Key Dates"."Database Lock Date") as char(40)))
- Discrepancies	# Open Discrepancies	"- Discrepancies"."# Open Discrepancies"
- Discrepancies	# Total Discrepancies	"- Discrepancies"."# Total Discrepancies"
- Discrepancies	# Days Discrepancy Open	("- Discrepancies"."# Days Discrepancy Open"/"- Discrepancies"."# Total Discrepancies")

Table A–115 (Cont.) Study Region Milestones with Indicators (Report CDA-CO-1106)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Discrepancies	# Total Discrepancies	("- Discrepancies"."# Days Discrepancy Open"/"- Discrepancies"."# Total Discrepancies")
- Received CRFs	# eCRFs To Be Approved	"- Received CRFs"."# eCRFs To Be Approved"
- Received CRFs	# eCRFs To be Verified	"- Received CRFs"."# eCRFs To be Verified"
- Received CRFs	# CRFs Soft- Locked	"- Received CRFs"."# CRFs Soft-Locked"
- Received CRFs	% CRFs Soft Locked / Entry Complete	"- Received CRFs"."% CRFs Soft Locked / Entry Complete"
- Received CRFs	# CRFs Hard-Locked	"- Received CRFs"."# CRFs Hard-Locked"
- Received CRFs	% CRFs Hard Locked / Entry Complete	"- Received CRFs"."% CRFs Hard Locked / Entry Complete"
- Study-Region Original Planned Dates	[Planned 1st Subject Screened Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Subject Screened Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT('Actual:' , cast("- Study Region Metrics"."1st Subject Screened Date" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE 1st Subject Screened Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Subject Screened Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT('Actual:' , cast("- Study Region Metrics"."1st Subject Screened Date" as char(40)))
- Study Region Metrics	1st Subject Screened Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Subject Screened Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT('Actual:' , cast("- Study Region Metrics"."1st Subject Screened Date" as char(40)))

Table A–115 (Cont.) Study Region Milestones with Indicators (Report CDA-CO-1106)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Original Planned Dates	[Planned 1st Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("-Study-Region Original Planned Dates"."[Planned 1st Subject Enrolled Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("-Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]") as char(40))) || ' '||CONCAT('Actual :',EVALUATE('TO_CHAR(%1,%2)' as varchar(20),"-Study Region Metrics"."1st Subject Enrolled Date" , 'dd-Mon-yyyy'))
- Study-Region Latest Estimated Dates	[Planned LE 1st Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("-Study-Region Original Planned Dates"."[Planned 1st Subject Enrolled Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("-Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]") as char(40))) || ' '||CONCAT('Actual :',EVALUATE('TO_CHAR(%1,%2)' as varchar(20),"-Study Region Metrics"."1st Subject Enrolled Date" , 'dd-Mon-yyyy'))
- Study Region Metrics	1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("-Study-Region Original Planned Dates"."[Planned 1st Subject Enrolled Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("-Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]") as char(40))) || ' '||CONCAT('Actual :',EVALUATE('TO_CHAR(%1,%2)' as varchar(20),"-Study Region Metrics"."1st Subject Enrolled Date" , 'dd-Mon-yyyy'))
- Study-Region Original Planned Dates	[Planned 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("-Study-Region Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("-Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40))) || ' '||CONCAT('Actual:' , cast("-Study Region Metrics"."1st Subject Randomized Date" as char(40)))

Table A–115 (Cont.) Study Region Milestones with Indicators (Report CDA-CO-1106)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Latest Estimated Dates	[Planned LE 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("-Study-Region Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("-Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT('Actual:' , cast("-Study Region Metrics"."1st Subject Randomized Date" as char(40)))
- Study Region Metrics	1st Subject Randomized Date	CONCAT('Planned:',cast(MIN("-Study-Region Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("-Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT('Actual:' , cast("-Study Region Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Region Original Planned Dates	[Planned 1st Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("-Study-Region Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("-Study-Region Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT('Actual:' , cast("-Study Region Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE 1st Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("-Study-Region Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("-Study-Region Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT('Actual:' , cast("-Study Region Metrics"."1st Subject 1st Visit Date" as char(40)))

Table A–115 (Cont.) Study Region Milestones with Indicators (Report CDA-CO-1106)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Region Metrics	1st Subject 1st Visit Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40))||' '||CONCAT('Actual:' , cast("- Study Region Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study-Region Original Planned Dates	[Planned Last Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40))||' '||CONCAT('Actual(Latest):' , cast("- Study Region Metrics"."Latest Subject Enrolled Date" as char(40))||' '||CONCAT('Actual(Last):' , cast("- Study Region Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE Last Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40))||' '||CONCAT('Actual(Latest):' , cast("- Study Region Metrics"."Latest Subject Enrolled Date" as char(40))||' '||CONCAT('Actual(Last):' , cast("- Study Region Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study Region Metrics	Latest Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40))||' '||CONCAT('Actual(Latest):' , cast("- Study Region Metrics"."Latest Subject Enrolled Date" as char(40))||' '||CONCAT('Actual(Last):' , cast("- Study Region Metrics"."[Last Subject Enrolled Date]" as char(40)))

Table A–115 (Cont.) Study Region Milestones with Indicators (Report CDA-CO-1106)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Region Metrics	[Last Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40)))||' '||CONCAT('Actual(Latest):' , cast("- Study Region Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual(Last):' , cast("- Study Region Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study-Region Original Planned Dates	[Planned Last Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT('Actual(Latest):',cast ("- Study Region Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual(Last):',cast(" - Study Region Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT('Actual(Latest):',cast ("- Study Region Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual(Last):',cast(" - Study Region Metrics"."[Last Subject Randomized Date]" as char(40)))

Table A–115 (Cont.) Study Region Milestones with Indicators (Report CDA-CO-1106)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Region Metrics	Latest Subject Randomized Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT('Actual(Latest):',cast ("- Study Region Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual(Last):',cast(" - Study Region Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study Region Metrics	[Last Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT('Actual(Latest):',cast ("- Study Region Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual(Last):',cast(" - Study Region Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study-Region Original Planned Dates	[Planned Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT('Actual(Last):',cast(" - Study Region Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT('Actual(Last):',cast(" - Study Region Metrics"."[Last Subject 1st Visit Date]" as char(40)))

Table A–115 (Cont.) Study Region Milestones with Indicators (Report CDA-CO-1106)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Latest Estimated Dates	[Planned LE Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40))) || ' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."Latest Subject 1st Visit Date" as char(40))) || ' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study Region Metrics	Latest Subject 1st Visit Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40))) || ' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."Latest Subject 1st Visit Date" as char(40))) || ' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study Region Metrics	[Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40))) || ' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."Latest Subject 1st Visit Date" as char(40))) || ' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Subject 1st Visit Date]" as char(40)))

Table A–115 (Cont.) Study Region Milestones with Indicators (Report CDA-CO-1106)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Original Planned Dates	[Planned Last Subject Last Visit Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40))||' '||CONCAT('Actual(Latest):',cast ("- Study Region Metrics"."Latest Subject Latest Visit Date" as char(40))||' '||CONCAT('Actual(Last):',cast(" - Study Region Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE Last Subject Last Visit Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40))||' '||CONCAT('Actual(Latest):',cast ("- Study Region Metrics"."Latest Subject Latest Visit Date" as char(40))||' '||CONCAT('Actual(Last):',cast(" - Study Region Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study Region Metrics	Latest Subject Latest Visit Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40))||' '||CONCAT('Actual(Latest):',cast ("- Study Region Metrics"."Latest Subject Latest Visit Date" as char(40))||' '||CONCAT('Actual(Last):',cast(" - Study Region Metrics"."[Last Subject Last Visit Date]" as char(40)))

Table A–115 (Cont.) Study Region Milestones with Indicators (Report CDA-CO-1106)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Region Metrics	[Last Subject Last Visit Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT('Actual(Latest):',cast ("- Study Region Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT('Actual(Last):',cast(" - Study Region Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study Region Metrics	# Study-Sites Planned for Study-Region	CONCAT('Planned:',cast("- Study Region Metrics"."# Study-Sites Planned for Study-Region" as char(40)))||' '||CONCAT('Actual:' , cast("- Study Region Metrics"."# Study-Sites Initiated" as char(40)))
- Study Region Metrics	# Study-Sites Initiated	CONCAT('Planned:',cast("- Study Region Metrics"."# Study-Sites Planned for Study-Region" as char(40)))||' '||CONCAT('Actual:' , cast("- Study Region Metrics"."# Study-Sites Initiated" as char(40)))
- Study-Region Original Planned Dates	[Planned 1st IRB/EC Submission Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st IRB/EC Submission Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st IRB/EC Submission Date]") as char(40)))||' '||CONCAT('Actual:',cast(MIN(" - Study Region Metrics"."[1st IRB/EC Submission Date]") as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE 1st IRB/EC Submission Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st IRB/EC Submission Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st IRB/EC Submission Date]") as char(40)))||' '||CONCAT('Actual:',cast(MIN(" - Study Region Metrics"."[1st IRB/EC Submission Date]") as char(40)))

Table A–115 (Cont.) Study Region Milestones with Indicators (Report CDA-CO-1106)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Region Metrics	[1st IRB/EC Submission Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st IRB/EC Submission Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st IRB/EC Submission Date]") as char(40))) || ' '||CONCAT('Actual:',cast(MIN("- Study Region Metrics"."[1st IRB/EC Submission Date]") as char(40)))
- Study-Region Original Planned Dates	[Planned 1st Initial IRB/EC Approval Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Initial IRB/EC Approval Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Initial IRB/EC Approval Date]") as char(40))) || ' '||CONCAT('Actual:',cast("- Study Region Metrics"."1st Initial IRB/EC Approval Date" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE 1st Initial IRB/EC Approval Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Initial IRB/EC Approval Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Initial IRB/EC Approval Date]") as char(40))) || ' '||CONCAT('Actual:',cast("- Study Region Metrics"."1st Initial IRB/EC Approval Date" as char(40)))
- Study Region Metrics	1st Initial IRB/EC Approval Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Initial IRB/EC Approval Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Initial IRB/EC Approval Date]") as char(40))) || ' '||CONCAT('Actual:',cast("- Study Region Metrics"."1st Initial IRB/EC Approval Date" as char(40)))

Table A–115 (Cont.) Study Region Milestones with Indicators (Report CDA-CO-1106)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Original Planned Dates	[Planned 1st Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Site Initiated Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Site Initiated Date]") as char(40)))||' '||CONCAT('Actual:',Cast(MIN("- Study Region Metrics"."1st Site Initiated Date") as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE 1st Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Site Initiated Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Site Initiated Date]") as char(40)))||' '||CONCAT('Actual:',Cast(MIN("- Study Region Metrics"."1st Site Initiated Date") as char(40)))
- Study Region Metrics	1st Site Initiated Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Site Initiated Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Site Initiated Date]") as char(40)))||' '||CONCAT('Actual:',Cast(MIN("- Study Region Metrics"."1st Site Initiated Date") as char(40)))
- Study-Region Original Planned Dates	[Planned Last Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Site Initiated Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Site Initiated Date]") as char(40)))||' '||CONCAT('Actual(Latest):',cast ("- Study Region Metrics"."Latest Site Initiated Date" as char(40)))||' '||CONCAT('Actual(Last):',cast(" - Study Region Metrics"."[Last Site Initiated Date]" as char(40)))

Table A–115 (Cont.) Study Region Milestones with Indicators (Report CDA-CO-1106)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Latest Estimated Dates	[Planned LE Last Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Site Initiated Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Site Initiated Date]") as char(40))) || ' '||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."Latest Site Initiated Date" as char(40))) || ' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Site Initiated Date]" as char(40)))
- Study Region Metrics	Latest Site Initiated Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Site Initiated Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Site Initiated Date]") as char(40))) || ' '||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."Latest Site Initiated Date" as char(40))) || ' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Site Initiated Date]" as char(40)))
- Study Region Metrics	[Last Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Site Initiated Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Site Initiated Date]") as char(40))) || ' '||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."Latest Site Initiated Date" as char(40))) || ' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Site Initiated Date]" as char(40)))
- Study-Region Original Planned Dates	[Planned 1st Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Critical Document Package Completed Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Critical Document Package Completed Date]") as char(40))) || ' '||CONCAT('Actual:',cast("- Study Region Metrics"."[1st Critical Document Package Completed Date]" as char(40)))

Table A–115 (Cont.) Study Region Milestones with Indicators (Report CDA-CO-1106)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Latest Estimated Dates	[Planned LE 1st Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Region Metrics"."[1st Critical Document Package Completed Date]" as char(40)))
- Study Region Metrics	[1st Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Region Metrics"."[1st Critical Document Package Completed Date]" as char(40)))
- Study-Region Original Planned Dates	[Planned Last Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('Actual(Latest):',cast ("- Study Region Metrics"."[Latest Critical Document Package Completed Date]"as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE Last Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('Actual(Latest):',cast ("- Study Region Metrics"."[Latest Critical Document Package Completed Date]"as char(40)))

Table A–115 (Cont.) Study Region Milestones with Indicators (Report CDA-CO-1106)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Region Metrics	[Latest Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Critical Document Package Completed Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Critical Document Package Completed Date]") as char(40))) || ' '||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."[Latest Critical Document Package Completed Date]"as char(40)))
- Study Original Planned Dates	[Planned Clinical Study Report Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Clinical Study Report Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Clinical Study Report Date]") as char(40))) || ' '||CONCAT('Actual:',cast(MAX("- Study Key Dates"."[Clinical Study Report Date]") as char(40)))
- Study Latest Estimated Dates	[Planned LE Clinical Study Report Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Clinical Study Report Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Clinical Study Report Date]") as char(40))) || ' '||CONCAT('Actual:',cast(MAX("- Study Key Dates"."[Clinical Study Report Date]") as char(40)))
- Study Key Dates	[Clinical Study Report Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Clinical Study Report Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Clinical Study Report Date]") as char(40))) || ' '||CONCAT('Actual:',cast(MAX("- Study Key Dates"."[Clinical Study Report Date]") as char(40)))

Study Region Milestones with Indicators (Single Study-Region) (Report CDA-CO-1116)

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.

Audience

- Region Manager
- Study Manager
- Executive Manager
- Program Manager

Report Type

- View Selector (Multiple Tables)

Location

- **Study-Region Overview** dashboard, **Overview** page

Dimensions

- Study-Region

Supplementary Prompts

- NA

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–116 describes the columns in the Study Region Milestones with Indicators (Single Study-Region) analysis

Table A–116 Study Region Milestones with Indicators (Single Study-Region) (Report CDA-CO-1116)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Region Metrics	Recruitment Flag	"- Study Region Metrics"."Recruitment Flag"
- Study Region Metrics	Recruitment Detail Reason	"- Study Region Metrics"."Recruitment Detail Reason"
- Study Region Metrics	Retention Flag	"- Study Region Metrics"."Retention Flag"
- Study Region Metrics	Retention Detail Reason	"- Study Region Metrics"."Retention Detail Reason"

Table A–116 (Cont.) Study Region Milestones with Indicators (Single Study-Region) (Report CDA-CO-1116)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Region Metrics	Milestone Flag	"- Study Region Metrics"."Milestone Flag"
- Study Region Metrics	Milestone Detail Reason	"- Study Region Metrics"."Milestone Detail Reason"
- Study Region Metrics	% of Planned Sites Initiated	CONCAT('Actual:' , cast(ROUND("- Study Region Metrics"."% of Planned Sites Initiated",2) as char(40)))
- Study-Region Targets	[Expected Screen Failure Rate]	CONCAT('Expected:',cast(MIN("- Study-Region Targets"."[Expected Screen Failure Rate]") as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study Region Metrics"."Screen Failure Rate",2) as char(40)))
- Study Region Metrics	Screen Failure Rate	CONCAT('Expected:',cast(MIN("- Study-Region Targets"."[Expected Screen Failure Rate]") as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study Region Metrics"."Screen Failure Rate",2) as char(40)))
- Study Region Metrics	% Enrolled to Total Planned at Study Region	CONCAT('Actual:' , cast(ROUND("- Study Region Metrics"."% Enrolled to Total Planned at Study Region",2) as char(40)))
- Study-Region Targets	[Expected Early Termination Rate]	CONCAT('Expected:',cast(MIN("- Study-Region Targets"."[Expected Early Termination Rate]") as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study Region Metrics"."% Subjects Early Terminated for Study-Region",2) as char(40)))
- Study Region Metrics	% Subjects Early Terminated for Study-Region	CONCAT('Expected:',cast(MIN("- Study-Region Targets"."[Expected Early Termination Rate]") as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study Region Metrics"."% Subjects Early Terminated for Study-Region",2) as char(40)))
- Study Region Metrics	% Planned Subjects Randomized	CONCAT('Actual:' , cast(ROUND("- Study Region Metrics"."% Planned Subjects Randomized",2) as char(40)))
- Study Key Dates	[Protocol Approved Date]	max("- Study Key Dates"."[Protocol Approved Date]")

Table A–116 (Cont.) Study Region Milestones with Indicators (Single Study-Region) (Report CDA-CO-1116)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Original Planned Dates	[Planned Database Lock Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Database Lock Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Database Lock Date]") as char(40)))||' '||CONCAT('Actual:',cast(MAX("- Study Key Dates"."Database Lock Date") as char(40)))
- Study Latest Estimated Dates	[Planned LE Database Lock Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Database Lock Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Database Lock Date]") as char(40)))||' '||CONCAT('Actual:',cast(MAX("- Study Key Dates"."Database Lock Date") as char(40)))
- Study Key Dates	Database Lock Date	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Database Lock Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Database Lock Date]") as char(40)))||' '||CONCAT('Actual:',cast(MAX("- Study Key Dates"."Database Lock Date") as char(40)))
- Discrepancies	# Open Discrepancies	"- Discrepancies"."# Open Discrepancies"
- Discrepancies	# Total Discrepancies	"- Discrepancies"."# Total Discrepancies"
- Discrepancies	# Days Discrepancy Open	("- Discrepancies"."# Days Discrepancy Open"/"- Discrepancies"."# Total Discrepancies")
- Discrepancies	# Total Discrepancies	("- Discrepancies"."# Days Discrepancy Open"/"- Discrepancies"."# Total Discrepancies")
- Received CRFs	# eCRFs To Be Approved	"- Received CRFs"."# eCRFs To Be Approved"
- Received CRFs	# eCRFs To be Verified	"- Received CRFs"."# eCRFs To be Verified"
- Received CRFs	# CRFs Soft- Locked	"- Received CRFs"."# CRFs Soft-Locked"
- Received CRFs	% CRFs Soft Locked / Entry Complete	"- Received CRFs"."% CRFs Soft Locked / Entry Complete"
- Received CRFs	# CRFs Hard-Locked	"- Received CRFs"."# CRFs Hard-Locked"
- Received CRFs	% CRFs Hard Locked / Entry Complete	"- Received CRFs"."% CRFs Hard Locked / Entry Complete"

Table A–116 (Cont.) Study Region Milestones with Indicators (Single Study-Region) (Report CDA-CO-1116)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Original Planned Dates	[Planned 1st Subject Screened Date]	CONCAT('Planned:',cast(MIN("-Study-Region Original Planned Dates"."[Planned 1st Subject Screened Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("-Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT('Actual :',EVALUATE('TO_CHAR(%1,%2)' as varchar(20),"-Study Region Metrics"."1st Subject Screened Date" , 'dd-Mon-yyyy'))
- Study-Region Latest Estimated Dates	[Planned LE 1st Subject Screened Date]	CONCAT('Planned:',cast(MIN("-Study-Region Original Planned Dates"."[Planned 1st Subject Screened Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("-Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT('Actual :',EVALUATE('TO_CHAR(%1,%2)' as varchar(20),"-Study Region Metrics"."1st Subject Screened Date" , 'dd-Mon-yyyy'))
- Study Region Metrics	1st Subject Screened Date	CONCAT('Planned:',cast(MIN("-Study-Region Original Planned Dates"."[Planned 1st Subject Screened Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("-Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT('Actual :',EVALUATE('TO_CHAR(%1,%2)' as varchar(20),"-Study Region Metrics"."1st Subject Screened Date" , 'dd-Mon-yyyy'))
- Study-Region Original Planned Dates	[Planned 1st Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("-Study-Region Original Planned Dates"."[Planned 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("-Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT('Actual:' , cast("-Study Region Metrics"."1st Subject Enrolled Date" as char(40)))

Table A–116 (Cont.) Study Region Milestones with Indicators (Single Study-Region) (Report CDA-CO-1116)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Latest Estimated Dates	[Planned LE 1st Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("-Study-Region Original Planned Dates"."[Planned 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("-Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT('Actual:' , cast("-Study Region Metrics"."1st Subject Enrolled Date" as char(40)))
- Study Region Metrics	1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("-Study-Region Original Planned Dates"."[Planned 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("-Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT('Actual:' , cast("-Study Region Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Region Original Planned Dates	[Planned 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("-Study-Region Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("-Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT('Actual:' , cast("-Study Region Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("-Study-Region Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("-Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT('Actual:' , cast("-Study Region Metrics"."1st Subject Randomized Date" as char(40)))

Table A–116 (Cont.) Study Region Milestones with Indicators (Single Study-Region) (Report CDA-CO-1116)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Region Metrics	1st Subject Randomized Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40))||' '||CONCAT('Actual:' , cast("- Study Region Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Region Original Planned Dates	[Planned 1st Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40))||' '||CONCAT('Actual:' , cast("- Study Region Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE 1st Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40))||' '||CONCAT('Actual:' , cast("- Study Region Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study Region Metrics	1st Subject 1st Visit Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40))||' '||CONCAT('Actual:' , cast("- Study Region Metrics"."1st Subject 1st Visit Date" as char(40)))

Table A–116 (Cont.) Study Region Milestones with Indicators (Single Study-Region) (Report CDA-CO-1116)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Original Planned Dates	[Planned Last Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40)))||' '||CONCAT('Actual(Latest):' , cast("- Study Region Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual(Last):' , cast("- Study Region Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE Last Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40)))||' '||CONCAT('Actual(Latest):' , cast("- Study Region Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual(Last):' , cast("- Study Region Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study Region Metrics	Latest Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40)))||' '||CONCAT('Actual(Latest):' , cast("- Study Region Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual(Last):' , cast("- Study Region Metrics"."[Last Subject Enrolled Date]" as char(40)))

Table A–116 (Cont.) Study Region Milestones with Indicators (Single Study-Region) (Report CDA-CO-1116)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Region Metrics	[Last Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40)))||' '||CONCAT('Actual(Latest):' , cast("- Study Region Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual(Last):' , cast("- Study Region Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study-Region Original Planned Dates	[Planned Last Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT('Actual(Latest):',cast ("- Study Region Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual(Last):',cast(" - Study Region Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT('Actual(Latest):',cast ("- Study Region Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual(Last):',cast(" - Study Region Metrics"."[Last Subject Randomized Date]" as char(40)))

Table A–116 (Cont.) Study Region Milestones with Indicators (Single Study-Region) (Report CDA-CO-1116)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Region Metrics	Latest Subject Randomized Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT('Actual(Latest):',cast ("- Study Region Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual(Last):',cast(" - Study Region Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study Region Metrics	[Last Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT('Actual(Latest):',cast ("- Study Region Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual(Last):',cast(" - Study Region Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study-Region Original Planned Dates	[Planned Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT('Actual(Latest):','Ne ed to add')||' '||CONCAT('Actual(Last):',cast(" - Study Region Metrics"."[Last Subject 1st Visit Date]" as char(40)))

Table A–116 (Cont.) Study Region Milestones with Indicators (Single Study-Region) (Report CDA-CO-1116)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Latest Estimated Dates	[Planned LE Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT('Actual(Latest):','Need to add')||' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study Region Metrics	[Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT('Actual(Latest):','Need to add')||' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study-Region Original Planned Dates	[Planned Last Subject Last Visit Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE Last Subject Last Visit Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Subject Last Visit Date]" as char(40)))

Table A–116 (Cont.) Study Region Milestones with Indicators (Single Study-Region) (Report CDA-CO-1116)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Region Metrics	Latest Subject Latest Visit Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40))) || ' '||CONCAT('Actual(Latest):',cast ("- Study Region Metrics"."Latest Subject Latest Visit Date" as char(40))) || ' '||CONCAT('Actual(Last):',cast(" - Study Region Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study Region Metrics	[Last Subject Last Visit Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40))) || ' '||CONCAT('Actual(Latest):',cast ("- Study Region Metrics"."Latest Subject Latest Visit Date" as char(40))) || ' '||CONCAT('Actual(Last):',cast(" - Study Region Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study Region Metrics	# Study-Sites Planned for Study-Region	CONCAT('Planned:',cast("- Study Region Metrics"."# Study-Sites Planned for Study-Region" as char(40))) || ' '||CONCAT('Actual:' , cast("- Study Region Metrics"."# Study-Sites Initiated" as char(40)))
- Study Region Metrics	# Study-Sites Initiated	CONCAT('Planned:',cast("- Study Region Metrics"."# Study-Sites Planned for Study-Region" as char(40))) || ' '||CONCAT('Actual:' , cast("- Study Region Metrics"."# Study-Sites Initiated" as char(40)))

Table A–116 (Cont.) Study Region Milestones with Indicators (Single Study-Region) (Report CDA-CO-1116)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Original Planned Dates	[Planned 1st IRB/EC Submission Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st IRB/EC Submission Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st IRB/EC Submission Date]") as char(40))) || ' '||CONCAT('Actual:',cast(MIN("- Study Region Metrics"."[1st IRB/EC Submission Date]") as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE 1st IRB/EC Submission Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st IRB/EC Submission Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st IRB/EC Submission Date]") as char(40))) || ' '||CONCAT('Actual:',cast(MIN("- Study Region Metrics"."[1st IRB/EC Submission Date]") as char(40)))
- Study Region Metrics	[1st IRB/EC Submission Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st IRB/EC Submission Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st IRB/EC Submission Date]") as char(40))) || ' '||CONCAT('Actual:',cast(MIN("- Study Region Metrics"."[1st IRB/EC Submission Date]") as char(40)))
- Study-Region Original Planned Dates	[Planned 1st Initial IRB/EC Approval Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Initial IRB/EC Approval Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Initial IRB/EC Approval Date]") as char(40))) || ' '||CONCAT('Actual:',cast("- Study Region Metrics"."1st Initial IRB/EC Approval Date" as char(40)))

Table A–116 (Cont.) Study Region Milestones with Indicators (Single Study-Region) (Report CDA-CO-1116)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Latest Estimated Dates	[Planned LE 1st Initial IRB/EC Approval Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Region Metrics"."1st Initial IRB/EC Approval Date" as char(40)))
- Study Region Metrics	1st Initial IRB/EC Approval Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Region Metrics"."1st Initial IRB/EC Approval Date" as char(40)))
- Study-Region Original Planned Dates	[Planned 1st Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Site Initiated Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Site Initiated Date]") as char(40)))||' '||CONCAT('Actual:',Cast(MIN("- Study Region Metrics"."1st Site Initiated Date") as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE 1st Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Site Initiated Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Site Initiated Date]") as char(40)))||' '||CONCAT('Actual:',Cast(MIN("- Study Region Metrics"."1st Site Initiated Date") as char(40)))
- Study Region Metrics	1st Site Initiated Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Site Initiated Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Site Initiated Date]") as char(40)))||' '||CONCAT('Actual:',Cast(MIN("- Study Region Metrics"."1st Site Initiated Date") as char(40)))

Table A–116 (Cont.) Study Region Milestones with Indicators (Single Study-Region) (Report CDA-CO-1116)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Original Planned Dates	[Planned Last Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Site Initiated Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Site Initiated Date]") as char(40))) || ' '||CONCAT('Actual(Latest):',cast ("- Study Region Metrics"."Latest Site Initiated Date" as char(40))) || ' '||CONCAT('Actual(Last):',cast(" - Study Region Metrics"."[Last Site Initiated Date]" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE Last Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Site Initiated Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Site Initiated Date]") as char(40))) || ' '||CONCAT('Actual(Latest):',cast ("- Study Region Metrics"."Latest Site Initiated Date" as char(40))) || ' '||CONCAT('Actual(Last):',cast(" - Study Region Metrics"."[Last Site Initiated Date]" as char(40)))
- Study Region Metrics	Latest Site Initiated Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Site Initiated Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Site Initiated Date]") as char(40))) || ' '||CONCAT('Actual(Latest):',cast ("- Study Region Metrics"."Latest Site Initiated Date" as char(40))) || ' '||CONCAT('Actual(Last):',cast(" - Study Region Metrics"."[Last Site Initiated Date]" as char(40)))
- Study Region Metrics	[Last Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Site Initiated Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Site Initiated Date]") as char(40))) || ' '||CONCAT('Actual(Latest):',cast ("- Study Region Metrics"."Latest Site Initiated Date" as char(40))) || ' '||CONCAT('Actual(Last):',cast(" - Study Region Metrics"."[Last Site Initiated Date]" as char(40)))

Table A–116 (Cont.) Study Region Milestones with Indicators (Single Study-Region) (Report CDA-CO-1116)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Original Planned Dates	[Planned 1st Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Region Metrics"."[1st Critical Document Package Completed Date]" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE 1st Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Region Metrics"."[1st Critical Document Package Completed Date]" as char(40)))
- Study Region Metrics	[1st Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Region Metrics"."[1st Critical Document Package Completed Date]" as char(40)))
- Study-Region Original Planned Dates	[Planned Last Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Critical Document Package Completed Date]") as char(40)))||' '||CONCAT('Actual(Latest):',cast ("- Study Region Metrics"."[Latest Critical Document Package Completed Date]"as char(40)))

Table A–116 (Cont.) Study Region Milestones with Indicators (Single Study-Region) (Report CDA-CO-1116)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Latest Estimated Dates	[Planned LE Last Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Critical Document Package Completed Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Critical Document Package Completed Date]") as char(40))) || ' '||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."[Latest Critical Document Package Completed Date]"as char(40)))
- Study Region Metrics	[Latest Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Critical Document Package Completed Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Critical Document Package Completed Date]") as char(40))) || ' '||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."[Latest Critical Document Package Completed Date]"as char(40)))
- Study Original Planned Dates	[Planned Clinical Study Report Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Clinical Study Report Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Clinical Study Report Date]") as char(40))) || ' '||CONCAT('Actual:',cast(MAX("- Study Key Dates"."[Clinical Study Report Date]") as char(40)))
- Study Latest Estimated Dates	[Planned LE Clinical Study Report Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Clinical Study Report Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Clinical Study Report Date]") as char(40))) || ' '||CONCAT('Actual:',cast(MAX("- Study Key Dates"."[Clinical Study Report Date]") as char(40)))

Table A–116 (Cont.) Study Region Milestones with Indicators (Single Study-Region) (Report CDA-CO-1116)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Key Dates	[Clinical Study Report Date]	CONCAT('Planned:',cast(MIN("- Study Original Planned Dates"."[Planned Clinical Study Report Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study Latest Estimated Dates"."[Planned LE Clinical Study Report Date]") as char(40)))||' '||CONCAT('Actual:',cast(MAX("- Study Key Dates"."[Clinical Study Report Date]") as char(40)))
- Received CRFs	# CRFs Awaiting Entry Completion	"- Received CRFs"."# CRFs Awaiting Entry Completion"
Study-Region	Study-Region Name	"Study-Region"."Study-Region Name"
Study-Region	Study	"Study-Region"."Study"

Study Region vs. Study - Site Start Up KPIs (Report CDA-CO-1111)

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:

- Initial IRB/EC Approval to Site Initiated (# Days)
- Initial IRB/EC Approval to 1st Subject 1st Visit (# Days)
- Site Initiated to 1st Subject Enrolled (# Days)

Audience

- Region Manager
- Study Manager

Report Type

- View Selector (Line Graph)

Location

- **Study Manager** dashboard, **KPI Summary Region Manager dashboard, KPI Summary** page

Dimensions

- Study-Region

Supplementary Prompts

- NA

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–117 describes the columns in the Study Region vs. Study: Site Start Up KPIs analysis

Table A–117 Study Region vs. Study: Site Start Up KPIs (Report CDA-CO-1111)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Region	Study-Region Name	"Study-Region"."Study-Region Name"
- Study Metrics	1st Site Initiated to 1st Subject Enrolled (# Days)	"- Study Metrics"."1st Site Initiated to 1st Subject Enrolled (# Days)"
- Study Region Metrics	1st Site Initiated to 1st Subject Enrolled (# Days)	MEDIAN("- Study Region Metrics"."1st Site Initiated to 1st Subject Enrolled (# Days)")
- Study Metrics	1st Initial IRB/EC Approval to 1st Subject 1st Visit (# Days)	"- Study Metrics"."1st Initial IRB/EC Approval to 1st Subject 1st Visit (# Days)"
- Study Region Metrics	1st Initial IRB/EC Approval to 1st Subject 1st Visit (# Days)	MEDIAN("- Study Region Metrics"."1st Initial IRB/EC Approval to 1st Subject 1st Visit (# Days)")
- Study Metrics	1st Initial IRB/EC Approval to 1st Site Initiated (# Days)	"- Study Metrics"."1st Initial IRB/EC Approval to 1st Site Initiated (# Days)"
- Study Region Metrics	1st Initial IRB/EC Approval to 1st Site Initiated (# Days)	MEDIAN("- Study Region Metrics"."1st Initial IRB/EC Approval to 1st Site Initiated (# Days)")

Study Regions with Red or Yellow Performance Flag (Report CDA-CO-1200)

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.

Audience

- Region Manager

Report Type

- Table

Location

- **Region Manager** dashboard, **Overview** page

Dimensions

None

Supplementary Prompts

NA

Reports Referenced

You can navigate to the following report from this report:

- Study-Region Team Member List (Report CDA-CO-1107)

Reports Referencing This Report

None

Column Descriptions

Table A–118 describes the columns in the Study Regions with Red or Yellow Performance Flag analysis

Table A–118 Study Regions with Red or Yellow Performance Flag (Report CDA-CO-1200)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Region	Region Name	NA
Study	Study	NA
Study	Study Short Title	NA
Study-Region	Study-Region Status	NA
Study-Region	Study-Region Manager	NA
Study-Region Metrics, Flags	Recruitment Flag	NA
Study-Region Metrics, Flags	Recruitment Detail Reason	NA
Study-Region Metrics, Flags	Milestone Flag	NA
Study-Region Metrics, Flags	Milestone Detail Reason	NA
Study-Region, Study-Region Targets	[Expected Screen Failure Rate]	NA
Study-Region Metrics, Ratios	Screen Failure Rate	NA
Study-Region Metrics, Ratios	% Enrolled to Total Planned at Study-Region	NA
Study-Region Metrics, Ratios	% Planned Subjects Randomized	NA
Study-Region, Original Planned Dates	[Planned 1st Subject Screened Date]	NA
Study-Region, Latest Estimated Dates	[Planned LE 1st Subject Screened Date]	NA
Study-Region Metrics, Actual Milestones	1st Subject Screened Date	NA
Study-Region, Original Planned Dates	[Planned 1st Subject Enrolled Date]	NA

Table A–118 (Cont.) Study Regions with Red or Yellow Performance Flag (Report CDA-CO-1200)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Region, Latest Estimated Dates	[Planned LE 1st Subject Enrolled Date]	NA
Study-Region Metrics, Actual Milestones	1st Subject Enrolled Date	NA
Study-Region, Original Planned Dates	[Planned 1st Subject Randomized Date]	NA
Study-Region, Latest Estimated Dates	[Planned LE 1st Subject Randomized Date]	NA
Study-Region Metrics, Actual Milestones	1st Subject Randomized Date	NA
Study-Region, Original Planned Dates	[Planned 1st Subject 1st Visit Date]	NA
Study-Region, Latest Estimated Dates	[Planned LE 1st Subject 1st Visit Date]	NA
Study-Region Metrics, Actual Milestones	1st Subject 1st Visit Date	NA
Study-Region, Original Planned Dates	[Planned Last Subject Enrolled Date]	NA
Study-Region, Latest Estimated Dates	[Planned LE Last Subject Enrolled Date]	NA
Study-Region Metrics, Actual Milestones	Latest Subject Enrolled Date	NA
Study-Region Metrics, Actual Milestones	[Last Subject Enrolled Date]	NA
Study-Region, Original Planned Dates	[Planned Last Subject Randomized Date]	NA
Study-Region, Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	NA
Study-Region Metrics, Actual Milestones	Latest Subject Randomized Date	NA
Study-Region Metrics, Actual Milestones	[Last Subject Randomized Date]	NA
Study-Region, Original Planned Dates	[Planned Last Subject 1st Visit Date]	NA
Study-Region, Latest Estimated Dates	[Planned LE Last Subject 1st Visit Date]	NA
Study-Region Metrics, Actual Milestones	Latest Subject 1st Visit Date	NA
Study-Region Metrics, Actual Milestones	[Last Subject 1st Visit Date]	NA
Study-Region, Original Planned Dates	[Planned Last Subject Last Visit Date]	NA
Study-Region, Latest Estimated Dates	[Planned LE Last Subject Last Visit Date]	NA
Study-Region Metrics, Actual Milestones	Latest Subject Latest Visit Date	NA
Study-Region Metrics, Actual Milestones	[Last Subject Last Visit Date]	NA
Study-Region Metrics, Flags	Retention Flag	NA
Study-Region Metrics, Flags	Retention Detail Reason	NA

Table A–118 (Cont.) Study Regions with Red or Yellow Performance Flag (Report CDA-CO-1200)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Region Metrics, Flags	Milestone Flag	NA
Study-Region Metrics, Flags	Milestone Detail Reason	NA
Study-Region	[Expected Early Termination Rate]	NA
Study-Region Metrics	% Subjects Early Terminated for Study-Region	NA
Study-Region, Original Planned Dates	[Planned 1st Subject Enrolled Date]	NA
Study-Region, Latest Estimated Dates	[Planned LE 1st Subject Enrolled Date]	NA
Study-Region Metrics, Actual Milestones	1st Subject Enrolled Date	NA
Study-Region, Original Planned Dates	[Planned 1st Subject Randomized Date]	NA
Study-Region, Latest Estimated Dates	[Planned LE 1st Subject Randomized Date]	NA
Study-Region Metrics, Actual Milestones	1st Subject Randomized Date	NA
Study-Region, Original Planned Dates	[Planned Last Subject Enrolled Date]	NA
Study-Region, Latest Estimated Dates	[Planned LE Last Subject Enrolled Date]	NA
Study-Region Metrics, Actual Milestones	Latest Subject Enrolled Date	NA
Study-Region Metrics, Actual Milestones	[Last Subject Enrolled Date]	NA
Study-Region, Original Planned Dates	[Planned Last Subject Randomized Date]	NA
Study-Region, Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	NA
Study-Region Metrics, Actual Milestones	Latest Subject Randomized Date	NA
Study-Region Metrics, Actual Milestones	[Last Subject Randomized Date]	NA
Study-Region Metrics, Flags	Milestone Flag	NA
Study-Region Metrics, Flags	Milestone Detail Reason	NA
Study-Region Metrics, Counts	# Study-Sites Planned for Study-Region	NA
Study-Region Metrics, Counts	# Study-Sites Initiated	NA
Study-Region Metrics, Ratios	% of Planned Sites Initiated	NA
Study-Region, Original Planned Dates	[Planned 1st IRB/EC Submission Date]	NA
Study-Region, Latest Estimated Dates	[Planned LE 1st IRB/EC Submission Date]	NA
Study-Region Metrics, Actual Milestones	[1st IRB/EC Submission Date]	NA
Study-Region, Original Planned Dates	[Planned 1st Initial IRB/EC Approval Date]	NA
Study-Region, Latest Estimated Dates	[Planned LE 1st Initial IRB/EC Approval Date]	NA

Table A–118 (Cont.) Study Regions with Red or Yellow Performance Flag (Report CDA-CO-1200)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Region Metrics, Actual Milestones	1st Initial IRB/EC Approval Date	NA
Study-Region, Original Planned Dates	[Planned 1st Site Initiated Date]	NA
Study-Region, Latest Estimated Dates	[Planned LE 1st Site Initiated Date]	NA
Study-Region Metrics, Actual Milestones	1st Site Initiated Date	NA
Study-Region, Original Planned Dates	[Planned Last Site Initiated Date]	NA
Study-Region, Latest Estimated Dates	[Planned LE Last Site Initiated Date]	NA
Study-Region Metrics, Actual	Latest Site Initiated Date	NA
Study-Region Metrics, Actual Milestones	[Last Site Initiated Date]	NA
Study-Region, Original Planned Dates	[Planned 1st Critical Document Package Completed Date]	NA
Study-Region, Latest Estimated Dates	[Planned LE 1st Critical Document Package Completed Date]	NA
Study-Region Metrics, Actual Milestones	[1st Critical Document Package Completed Date]	NA
Study-Region, Original Planned Dates	[Planned Last Critical Document Package Completed Date]	NA
Study-Region, Latest Estimated Dates	[Planned LE Last Critical Document Package Completed Date]	NA
Study-Region Metrics, Actual Milestones	[Latest Critical Document Package Completed Date]	NA
Study-Region Metrics, Actual Milestones	[Last Critical Document Package Completed Date]	NA
Study-Region Metrics, Flags	Milestone Flag	NA
Study-Region Metrics, Flags	Milestone Detail Reason	NA
Study-Region Metrics, Ratios	% Enrolled to Total Planned at Study-Region	NA
Study-Region	[Expected Early Termination Rate]	NA
Study-Region Metrics	% Subjects Early Terminated for Study-Region	NA
Study-Region, Original Planned Dates	[Planned Last Subject Enrolled Date]	NA
Study-Region, Latest Estimated Dates	[Planned LE Last Subject Enrolled Date]	NA
Study-Region Metrics, Actual Milestones	Latest Subject Enrolled Date	NA
Study-Region Metrics, Actual Milestones	[Last Subject Enrolled Date]	NA
Study-Region, Original Planned Dates	[Planned Last Subject Randomized Date]	NA
Study-Region, Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	NA

Table A–118 (Cont.) Study Regions with Red or Yellow Performance Flag (Report CDA-CO-1200)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Region Metrics, Actual Milestones	Latest Subject Randomized Date	NA
Study-Region Metrics, Actual Milestones	[Last Subject Randomized Date]	NA
Study-Region, Original Planned Dates	[Planned Last Subject Last Visit Date]	NA
Study-Region, Latest Estimated Dates	[Planned LE Last Subject Last Visit Date]	NA
Study-Region Metrics, Actual Milestones	Latest Subject Latest Visit Date	NA
Study-Region Metrics, Actual Milestones	[Last Subject Last Visit Date]	NA
Study, Original Planned Dates	[Planned Database Lock Date]	NA
Study, Latest Estimate Dates	[Planned LE Database Lock Date]	NA
Study, Key Dates	Database Lock Date	NA
Study, Original Planned Dates	[Planned Clinical Study Report Date]	NA
Study, Latest Estimate Dates	[Planned LE Clinical Study Report Date]	NA
Study, Key Dates	[Clinical Study Report Date]	NA
Study-Region Metrics, Flags	Recruitment Flag	NA
Study-Region Metrics, Flags	Recruitment Detail Reason	NA
Study-Region Metrics, Flags	Retention Flag	NA
Study-Region Metrics, Flags	Retention Detail Reason	NA
Study-Region Metrics, Flags	Milestone Flag	NA
Study-Region Metrics, Flags	Milestone Detail Reason	NA
Study-Region Metrics, Ratios	% of Planned Sites Initiated	NA
Study-Region, Study-Region Targets	[Expected Screen Failure Rate]	NA
Study-Region Metrics, Ratios	Screen Failure Rate	NA
Study-Region Metrics, Ratios	% Enrolled to Total Planned at Study-Region	NA
Study-Region	[Expected Early Termination Rate]	NA
Study-Region Metrics	% Subjects Early Terminated for Study-Region	NA
Study	[Protocol Approved Date]	NA
Study, Original Planned Dates	[Planned Database Lock Date]	NA
Study, Latest Estimate Dates	[Planned LE Database Lock Date]	NA
Study, Key Dates	Database Lock Date	NA

Study Site Milestones with Indicators - Data Management View (Report CDA-CO-208A)

Lists the 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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study Overview** dashboard, **Study-Site Milestones** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Team Member List (Report CDA-CO-201)

Reports Referencing This Report

- Study Region Milestones with Indicators (Report CDA-CO-1106)
- Study-Region List - KPI Performance (Report CDA-CO-1108)
- Study-Region List - Milestone Performance (Report CDA-CO-1109)
- Study-Region List - Initiation Details (Report CDA-CO-306)
- Study-Region List - Recruitment Details (Report CDA-CO-433)

Column Descriptions

The table describes the columns in the Study Site Milestones with Indicators - Data Management View report.

Table A–119 Study Site Milestones with Indicators - Data Management View (Report CDA-CO-208A)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study Region	Study-Site.Study Region
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Status	Study-Site.Study-Site Status

Table A–119 (Cont.) Study Site Milestones with Indicators - Data Management View (Report CDA-CO-208A)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Navigate to Detail	NA
- Discrepancies	# Open Discrepancies	"- Discrepancies"."# Open Discrepancies"
- Discrepancies	# Total Discrepancies	"- Discrepancies"."# Total Discrepancies"
- Discrepancies	# Days Discrepancy Open	"- Discrepancies"."# Days Discrepancy Open"/"- Discrepancies"."# Total Discrepancies"
- Discrepancies	# Total Discrepancies	"- Discrepancies"."# Days Discrepancy Open"/"- Discrepancies"."# Total Discrepancies"
- Received CRFs	# CRFs Awaiting Entry Completion	"- Received CRFs"."# CRFs Awaiting Entry Completion"
- Received CRFs	# eCRFs To Be Approved	"- Received CRFs"."# eCRFs To Be Approved"
- Received CRFs	# eCRFs To be Verified	"- Received CRFs"."# eCRFs To be Verified"
- Received CRFs	# CRFs Soft- Locked	"- Received CRFs"."# CRFs Soft-Locked"
- Received CRFs	% CRFs Soft Locked / Entry Complete	"- Received CRFs"."% CRFs Soft Locked / Entry Complete"
- Received CRFs	# CRFs Hard-Locked	"- Received CRFs"."# CRFs Hard-Locked"
- Received CRFs	% CRFs Hard Locked / Entry Complete	"- Received CRFs"."% CRFs Hard Locked / Entry Complete"

Study Site Milestones with Indicators - Monitoring View (Report CDA-CO-208B)

Lists the study-sites including key monitoring metrics as well as progress tracking for site monitoring. This report indicates which study-sites require action, and why.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study Overview** dashboard, **Study-Site Milestones** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Team Member List (Report CDA-CO-201)

Reports Referencing This Report

- Study Region Milestones with Indicators (Report CDA-CO-1106)
- Study-Region List - KPI Performance (Report CDA-CO-1108)
- Study-Region List - Milestone Performance (Report CDA-CO-1109)
- Study-Region List - Initiation Details (Report CDA-CO-306)
- Study-Region List - Recruitment Details (Report CDA-CO-433)

Column Descriptions

The table describes the columns in the Study Site Milestones with Indicators - Monitoring View report.

Table A–120 Study Site Milestones with Indicators - Monitoring View (Report CDA-CO-208B)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study-Site	Study Region	Study-Site.Study Region
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Status	Study-Site.Study-Site Status
NA	Navigate to Detail	NA
- Study-Site Metrics	Next Site Visit Date	"- Study-Site Metrics"."Next Site Visit Date"
- Study-Site Metrics	# Days Since Last Enrolllment for Study-Site	TRUNCATE("- Study-Site Metrics"."# Days Since Last Enrolllment for Study-Site",0)
- Discrepancies	# Open Discrepancies	"- Discrepancies"."# Open Discrepancies"
- Received CRFs	# eCRFs To Be Approved	"- Received CRFs"."# eCRFs To Be Approved"
- Received CRFs	# eCRFs To be Verified	"- Received CRFs"."# eCRFs To be Verified"
- Received CRFs	# CRFs Soft- Locked	"- Received CRFs"."# CRFs Soft-Locked"
- Received CRFs	% CRFs Soft Locked / Entry Complete	"- Received CRFs"."% CRFs Soft Locked / Entry Complete"
- Study-Site Metrics	Latest Site Visit Completed Date	"- Study-Site Metrics"."Latest Site Visit Completed Date"

Table A–120 (Cont.) Study Site Milestones with Indicators - Monitoring View (Report CDA-CO-208B)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	# Days Since Latest Site Visit	TRUNCATE("- Study-Site Metrics"."# Days Since Latest Site Visit",0)
- Study-Site Metrics	# Visit Reports Awaiting Completion	"- Study-Site Metrics"."# Visit Reports Awaiting Completion"
- Study-Site Metrics	[# Visit Reports Awaiting Approval]	"- Study-Site Metrics"."[# Visit Reports Awaiting Approval]"
- Site Visit Metrics	# Outstanding Follow Up Items	"- Site Visit Metrics"."# Outstanding Follow Up Items"
- Study-Site Metrics	Next Site Visit Type	"- Study-Site Metrics"."Next Site Visit Type"
- Study-Site Metrics	Latest Site Visit Type	"- Study-Site Metrics"."Latest Site Visit Type"
- Study-Site Metrics	# Subjects Enrolled Since Latest Site Visit	"- Study-Site Metrics"."# Subjects Enrolled Since Latest Site Visit"

Study Site Milestones with Indicators - Recruitment Detail View (Report CDA-CO-208C)

Lists the 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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study Overview** dashboard, **Study-Site Milestones** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Team Member List (Report CDA-CO-201)

Reports Referencing This Report

- Study Region Milestones with Indicators (Report CDA-CO-1106)
- Study-Region List - KPI Performance (Report CDA-CO-1108)
- Study-Region List - Milestone Performance (Report CDA-CO-1109)
- Study-Region List - Initiation Details (Report CDA-CO-306)
- Study-Region List - Recruitment Details (Report CDA-CO-433)

Column Descriptions

The table describes the columns in the Study Site Milestones with Indicators - Recruitment Detail View report.

Table A–121 Study Site Milestones with Indicators - Recruitment Detail View (Report CDA-CO-208C)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study-Site	Study Region	Study-Site.Study Region
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Status	Study-Site.Study-Site Status
NA	Navigate to Detail	NA
- Study-Site Metrics	Recruitment Flag	"- Study-Site Metrics"."Recruitment Flag"
- Study-Site Metrics	Recruitment High Level Reason	"- Study-Site Metrics"."Recruitment High Level Reason"
- Study-Site Metrics	Recruitment Detail Reason	"- Study-Site Metrics"."Recruitment Detail Reason"
- Study-Site Metrics	Milestone Flag	"- Study-Site Metrics"."Milestone Flag"
- Study-Site Metrics	Milestone High Level Reason	"- Study-Site Metrics"."Milestone High Level Reason"
- Study-Site Metrics	Milestone Detail Reason	"- Study-Site Metrics"."Milestone Detail Reason"
- Study Targets	[Expected Screen Failure Rate]	CONCAT('Expected:',cast(MAX("- Study Targets"."[Expected Screen Failure Rate]") as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("-Study-Site Metrics"."Screen Failure Rate",2) as char(40)))
- Study-Site Metrics	Screen Failure Rate	CONCAT('Expected:',cast(MAX("- Study Targets"."[Expected Screen Failure Rate]") as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("-Study-Site Metrics"."Screen Failure Rate",2) as char(40)))

Table A–121 (Cont.) Study Site Milestones with Indicators - Recruitment Detail View (Report CDA-CO-208C)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	% Enrolled to Total Planned at Study-Site	CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Enrolled to Total Planned at Study-Site",2) as char(40)))
- Study-Site Metrics	% Randomized vs. Planned - Study-Site	CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Randomized vs. Planned - Study-Site",2) as char(40)))
- Study-Site Original Planned Dates	Planned 1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Latest Estimated Dates	Planned LE 1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Metrics	1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Original Planned Dates	[Planned 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))

Table A–121 (Cont.) Study Site Milestones with Indicators - Recruitment Detail View (Report CDA-CO-208C)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Metrics	1st Subject Randomized Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Original Planned Dates	[Planned 1st Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study-Site Metrics	1st Subject 1st Visit Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject 1st Visit Date" as char(40)))

Table A–121 (Cont.) Study Site Milestones with Indicators - Recruitment Detail View (Report CDA-CO-208C)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Original Planned Dates	[Planned 1st Subject Screened Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Screened Date]")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Screened Date" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject Screened Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Screened Date]")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Screened Date" as char(40)))
- Study-Site Metrics	1st Subject Screened Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Screened Date]")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Screened Date" as char(40)))
- Study-Site Original Planned Dates	Planned Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))

Table A–121 (Cont.) Study Site Milestones with Indicators - Recruitment Detail View (Report CDA-CO-208C)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	Planned LE Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	Latest Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))

Table A–121 (Cont.) Study Site Milestones with Indicators - Recruitment Detail View (Report CDA-CO-208C)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Metrics	Latest Subject Randomized Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Metrics	[Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))

Table A–121 (Cont.) Study Site Milestones with Indicators - Recruitment Detail View (Report CDA-CO-208C)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Original Planned Dates	[Planned Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study-Site Metrics	Latest Subject 1st Visit Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))

Table A–121 (Cont.) Study Site Milestones with Indicators - Recruitment Detail View (Report CDA-CO-208C)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	[Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject Last Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Last Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))

Table A–121 (Cont.) Study Site Milestones with Indicators - Recruitment Detail View (Report CDA-CO-208C)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	Latest Subject Latest Visit Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Site Metrics	[Last Subject Last Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))

Study Site Milestones with Indicators - Retention Detail View (Report CDA-CO-208D)

Lists the 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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study Overview** dashboard, **Study-Site Milestones** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Team Member List (Report CDA-CO-201)

Reports Referencing This Report

- Study Region Milestones with Indicators (Report CDA-CO-1106)
- Study-Region List - KPI Performance (Report CDA-CO-1108)
- Study-Region List - Milestone Performance (Report CDA-CO-1109)
- Study-Region List - Initiation Details (Report CDA-CO-306)
- Study-Region List - Recruitment Details (Report CDA-CO-433)

Column Descriptions

The table describes the columns in the Study Site Milestones with Indicators - Retention Detail View report.

Table A–122 Study Site Milestones with Indicators - Retention Detail View (Report CDA-CO-208D)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study-Site	Study Region	Study-Site.Study Region
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Status	Study-Site.Study-Site Status
NA	Navigate to Detail	NA
- Study-Site Metrics	Retention Flag	"- Study-Site Metrics"."Retention Flag"
- Study-Site Metrics	Retention High Level Reason	"- Study-Site Metrics"."Retention High Level Reason"
- Study-Site Metrics	Milestone Flag	"- Study-Site Metrics"."Milestone Flag"
- Study-Site Metrics	Milestone High Level Reason	"- Study-Site Metrics"."Milestone High Level Reason"
- Study-Site Metrics	Milestone Detail Reason	"- Study-Site Metrics"."Milestone Detail Reason"

Table A–122 (Cont.) Study Site Milestones with Indicators - Retention Detail View (Report CDA-CO-208D)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Study-Site Targets	Expected Early Termination Rate	CONCAT('Expected:',cast(MAX("- Study-Site Study-Site Targets"."Expected Early Termination Rate") as char(40)))||' '||CONCAT(' Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site",2)as char(40)))
- Study-Site Metrics	% Subjects Early Terminated for Study-Site	CONCAT('Expected:',cast(MAX("- Study-Site Study-Site Targets"."Expected Early Termination Rate") as char(40)))||' '||CONCAT(' Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site",2)as char(40)))
- Study-Site Original Planned Dates	Planned 1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Latest Estimated Dates	Planned LE 1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Metrics	1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))

Table A–122 (Cont.) Study Site Milestones with Indicators - Retention Detail View (Report CDA-CO-208D)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Original Planned Dates	[Planned 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Metrics	1st Subject Randomized Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Original Planned Dates	Planned Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))

Table A–122 (Cont.) Study Site Milestones with Indicators - Retention Detail View (Report CDA-CO-208D)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	Planned LE Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	Latest Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))

Table A–122 (Cont.) Study Site Milestones with Indicators - Retention Detail View (Report CDA-CO-208D)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Metrics	Latest Subject Randomized Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Metrics	[Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))

Study Site Milestones with Indicators - Site Start Up Detail View (Report CDA-CO-208E)

Lists the 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.

Audience

- Study Manager

- CRA

Report Type

- Table

Location

- **Study Overview** dashboard, **Study-Site Milestones** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Team Member List (Report CDA-CO-201)

Reports Referencing This Report

- Study Region Milestones with Indicators (Report CDA-CO-1106)
- Study-Region List - KPI Performance (Report CDA-CO-1108)
- Study-Region List - Milestone Performance (Report CDA-CO-1109)
- Study-Region List - Initiation Details (Report CDA-CO-306)
- Study-Region List - Recruitment Details (Report CDA-CO-433)

Column Descriptions

The table describes the columns in the Study Site Milestones with Indicators - Site Start Up Detail View report.

Table A–123 Study Site Milestones with Indicators - Site Start Up Detail View (Report CDA-CO-208E)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study-Site	Study Region	Study-Site.Study Region
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Status	Study-Site.Study-Site Status
NA	Navigate to Detail	NA
- Study-Site Metrics	Milestone Flag	"- Study-Site Metrics"."Milestone Flag"
- Study-Site Metrics	Milestone High Level Reason	"- Study-Site Metrics"."Milestone High Level Reason"

Table A–123 (Cont.) Study Site Milestones with Indicators - Site Start Up Detail View (Report CDA-CO-208E)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	Milestone Detail Reason	"- Study-Site Metrics"."Milestone Detail Reason"
- Document Metrics	# Documents Outstanding	"- Document Metrics"."# Documents Outstanding"
- Study-Site Original Planned Dates	[Planned Site Initiated Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."Site Initiated Date") as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Site Initiated Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."Site Initiated Date") as char(40)))
- Study-Site Key Dates	Site Initiated Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."Site Initiated Date") as char(40)))
- Study-Site Original Planned Dates	[Planned IRB/EC Submission Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MIN("- Study-Site Key Dates"."[Initial IRB/EC Submission Date]") as char(40)))

Table A–123 (Cont.) Study Site Milestones with Indicators - Site Start Up Detail View (Report CDA-CO-208E)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE IRB/EC Submission Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MIN("- Study-Site Key Dates"."[Initial IRB/EC Submission Date]") as char(40)))
- Study-Site Key Dates	[Initial IRB/EC Submission Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MIN("- Study-Site Key Dates"."[Initial IRB/EC Submission Date]") as char(40)))
- Study-Site Original Planned Dates	[Planned Initial IRB/EC Approval Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Key Dates"."Initial IRB/EC Approval Date" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Initial IRB/EC Approval Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Key Dates"."Initial IRB/EC Approval Date" as char(40)))
- Study-Site Key Dates	Initial IRB/EC Approval Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Key Dates"."Initial IRB/EC Approval Date" as char(40)))

Table A–123 (Cont.) Study Site Milestones with Indicators - Site Start Up Detail View (Report CDA-CO-208E)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Original Planned Dates	[Planned Critical Document Package Completed Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."[Critical Document Package Completed Date]") as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Critical Document Package Completed Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."[Critical Document Package Completed Date]") as char(40)))
- Study-Site Key Dates	[Critical Document Package Completed Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."[Critical Document Package Completed Date]") as char(40)))

Study Site Milestones with Indicators - Study Close Detail View (Report CDA-CO-208F)

Lists the 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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study Overview** dashboard, **Study-Site Milestones** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Team Member List (Report CDA-CO-201)

Reports Referencing This Report

- Study Region Milestones with Indicators (Report CDA-CO-1106)
- Study-Region List - KPI Performance (Report CDA-CO-1108)
- Study-Region List - Milestone Performance (Report CDA-CO-1109)
- Study-Region List - Initiation Details (Report CDA-CO-306)
- Study-Region List - Recruitment Details (Report CDA-CO-433)

Column Descriptions

The table describes the columns in the Study Site Milestones with Indicators - Study Close Detail View report.

Table A–124 Study Site Milestones with Indicators - Study Close Detail View (Report CDA-CO-208F)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study-Site	Study Region	Study-Site.Study Region
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Status	Study-Site.Study-Site Status
NA	Navigate to Detail	NA
- Study-Site Metrics	Milestone Flag	"- Study-Site Metrics"."Milestone Flag"
- Study-Site Metrics	Milestone High Level Reason	"- Study-Site Metrics"."Milestone High Level Reason"
- Study-Site Metrics	Milestone Detail Reason	"- Study-Site Metrics"."Milestone Detail Reason"

Table A–124 (Cont.) Study Site Milestones with Indicators - Study Close Detail View (Report CDA-CO-208F)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	% Enrolled to Total Planned at Study-Site	CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Enrolled to Total Planned at Study-Site",2) as char(40)))
- Study-Site Study-Site Targets	Expected Early Termination Rate	CONCAT('Expected:',cast(MAX(" - Study-Site Study-Site Targets"."Expected Early Termination Rate") as char(40)))||' '||CONCAT(' Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site",2)as char(40)))
- Study-Site Metrics	% Subjects Early Terminated for Study-Site	CONCAT('Expected:',cast(MAX(" - Study-Site Study-Site Targets"."Expected Early Termination Rate") as char(40)))||' '||CONCAT(' Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site",2)as char(40)))
- Study-Site Original Planned Dates	Planned Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Latest Estimated Dates	Planned LE Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))

Table A–124 (Cont.) Study Site Milestones with Indicators - Study Close Detail View (Report CDA-CO-208F)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	Latest Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))

Table A–124 (Cont.) Study Site Milestones with Indicators - Study Close Detail View (Report CDA-CO-208F)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	Latest Subject Randomized Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Metrics	[Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject Last Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))

Table A–124 (Cont.) Study Site Milestones with Indicators - Study Close Detail View (Report CDA-CO-208F)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Last Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Site Metrics	Latest Subject Latest Visit Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Site Metrics	[Last Subject Last Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Received CRFs	# CRFs Awaiting Entry Completion	"- Received CRFs"."# CRFs Awaiting Entry Completion"
- Received CRFs	# eCRFs To Be Approved	"- Received CRFs"."# eCRFs To Be Approved"
- Received CRFs	# eCRFs To be Verified	"- Received CRFs"."# eCRFs To be Verified"
- Received CRFs	# CRFs Soft- Locked	"- Received CRFs"."# CRFs Soft-Locked"
- Received CRFs	% CRFs Soft Locked / Entry Complete	"- Received CRFs"."% CRFs Soft Locked / Entry Complete"

Table A–124 (Cont.) Study Site Milestones with Indicators - Study Close Detail View (Report CDA-CO-208F)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Received CRFs	# CRFs Hard-Locked	"- Received CRFs"."# CRFs Hard-Locked"
- Received CRFs	% CRFs Hard Locked / Entry Complete	"- Received CRFs"."% CRFs Hard Locked / Entry Complete"
- Study Original Planned Dates	[Planned Database Lock Date]	CONCAT('Planned:',cast(MAX("- Study Original Planned Dates"."[Planned Database Lock Date]")as char(40))) || ' ' ||CONCAT('LE:',cast(MAX("- Study Latest Estimated Dates"."[Planned LE Database Lock Date]") as char(40))) || ' ' ||CONCAT('Actual:',cast(MAX(" - Study Key Dates"."Database Lock Date") as char(40)))
- Study Latest Estimated Dates	[Planned LE Database Lock Date]	CONCAT('Planned:',cast(MAX("- Study Original Planned Dates"."[Planned Database Lock Date]")as char(40))) || ' ' ||CONCAT('LE:',cast(MAX("- Study Latest Estimated Dates"."[Planned LE Database Lock Date]") as char(40))) || ' ' ||CONCAT('Actual:',cast(MAX(" - Study Key Dates"."Database Lock Date") as char(40)))
- Study Key Dates	Database Lock Date	CONCAT('Planned:',cast(MAX("- Study Original Planned Dates"."[Planned Database Lock Date]")as char(40))) || ' ' ||CONCAT('LE:',cast(MAX("- Study Latest Estimated Dates"."[Planned LE Database Lock Date]") as char(40))) || ' ' ||CONCAT('Actual:',cast(MAX(" - Study Key Dates"."Database Lock Date") as char(40)))
- Study Original Planned Dates	[Planned Clinical Study Report Date]	CONCAT('Planned:',cast(MAX("- Study Original Planned Dates"."[Planned Clinical Study Report Date]")as char(40))) || ' ' ||CONCAT('LE:',cast(MAX("- Study Latest Estimated Dates"."[Planned LE Clinical Study Report Date]") as char(40))) || ' ' ||CONCAT('Actual:',cast(MAX(" - Study Key Dates"."[Clinical Study Report Date]") as char(40)))

Table A–124 (Cont.) Study Site Milestones with Indicators - Study Close Detail View (Report CDA-CO-208F)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study Latest Estimated Dates	[Planned LE Clinical Study Report Date]	CONCAT('Planned:',cast(MAX("- Study Original Planned Dates"."[Planned Clinical Study Report Date]")as char(40))) || ' ' ||CONCAT('LE:',cast(MAX("- Study Latest Estimated Dates"."[Planned LE Clinical Study Report Date]") as char(40))) || ' ' ||CONCAT('Actual:',cast(MAX(" - Study Key Dates"."[Clinical Study Report Date]") as char(40)))
- Study Key Dates	[Clinical Study Report Date]	CONCAT('Planned:',cast(MAX("- Study Original Planned Dates"."[Planned Clinical Study Report Date]")as char(40))) || ' ' ||CONCAT('LE:',cast(MAX("- Study Latest Estimated Dates"."[Planned LE Clinical Study Report Date]") as char(40))) || ' ' ||CONCAT('Actual:',cast(MAX(" - Study Key Dates"."[Clinical Study Report Date]") as char(40)))

Study Site Milestones with Indicators - Summary View (Report CDA-CO-208G)

Lists the 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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study Overview** dashboard, **Study-Site Milestones** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Team Member List (Report CDA-CO-201)

Reports Referencing This Report

- Study Region Milestones with Indicators (Report CDA-CO-1106)
- Study-Region List - KPI Performance (Report CDA-CO-1108)
- Study-Region List - Milestone Performance (Report CDA-CO-1109)
- Study-Region List - Initiation Details (Report CDA-CO-306)
- Study-Region List - Recruitment Details (Report CDA-CO-433)

Column Descriptions

The table describes the columns in the Study Site Milestones with Indicators - Summary View report.

Table A–125 Study Site Milestones with Indicators - Summary View (Report CDA-CO-208G)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study-Site	Study Region	Study-Site.Study Region
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Status	Study-Site.Study-Site Status
NA	Navigate to Detail	NA
- Study-Site Metrics	Recruitment Flag	"- Study-Site Metrics"."Recruitment Flag"
- Study-Site Metrics	Recruitment High Level Reason	"- Study-Site Metrics"."Recruitment High Level Reason"
- Study-Site Metrics	Recruitment Detail Reason	"- Study-Site Metrics"."Recruitment Detail Reason"
- Study-Site Metrics	Retention Flag	"- Study-Site Metrics"."Retention Flag"
- Study-Site Metrics	Retention High Level Reason	"- Study-Site Metrics"."Retention High Level Reason"
- Study-Site Metrics	Milestone Flag	"- Study-Site Metrics"."Milestone Flag"
- Study-Site Metrics	Milestone High Level Reason	"- Study-Site Metrics"."Milestone High Level Reason"
- Study-Site Metrics	Milestone Detail Reason	"- Study-Site Metrics"."Milestone Detail Reason"

Table A–125 (Cont.) Study Site Milestones with Indicators - Summary View (Report CDA-CO-208G)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study Targets	[Expected Screen Failure Rate]	CONCAT('Expected:',cast(MAX("- Study Targets"."[Expected Screen Failure Rate]") as char(40))||' '||CONCAT(' Actual:' , cast(ROUND("- Study-Site Metrics"."Screen Failure Rate",2) as char(40)))
- Study-Site Metrics	Screen Failure Rate	CONCAT('Expected:',cast(MAX("- Study Targets"."[Expected Screen Failure Rate]") as char(40))||' '||CONCAT(' Actual:' , cast(ROUND("- Study-Site Metrics"."Screen Failure Rate",2) as char(40)))
- Study-Site Metrics	% Enrolled to Total Planned at Study-Site	CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Enrolled to Total Planned at Study-Site",2) as char(40)))
- Study-Site Study-Site Targets	Expected Early Termination Rate	CONCAT('Expected:',cast(MAX("- Study-Site Study-Site Targets"."Expected Early Termination Rate") as char(40))||' '||CONCAT(' Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site",2)as char(40)))
- Study-Site Metrics	% Subjects Early Terminated for Study-Site	CONCAT('Expected:',cast(MAX("- Study-Site Study-Site Targets"."Expected Early Termination Rate") as char(40))||' '||CONCAT(' Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site",2)as char(40)))
- Study-Site Metrics	Next Site Visit Date	"- Study-Site Metrics"."Next Site Visit Date"
- Study-Site Original Planned Dates	Planned 1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Latest Estimated Dates	Planned LE 1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))

Table A–125 (Cont.) Study Site Milestones with Indicators - Summary View (Report CDA-CO-208G)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Original Planned Dates	Planned Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Latest Estimated Dates	Planned LE Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	Latest Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))

Table A–125 (Cont.) Study Site Milestones with Indicators - Summary View (Report CDA-CO-208G)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	# Days Since Last Enrolllment for Study-Site	TRUNCATE("- Study-Site Metrics"."# Days Since Last Enrolllment for Study-Site",0)
- Study-Site Original Planned Dates	[Planned Site Initiated Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."Site Initiated Date") as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Site Initiated Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."Site Initiated Date") as char(40)))
- Study-Site Key Dates	Site Initiated Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."Site Initiated Date") as char(40)))

Table A–125 (Cont.) Study Site Milestones with Indicators - Summary View (Report CDA-CO-208G)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Original Planned Dates	[Planned IRB/EC Submission Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MIN("- Study-Site Key Dates"."[Initial IRB/EC Submission Date]") as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE IRB/EC Submission Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MIN("- Study-Site Key Dates"."[Initial IRB/EC Submission Date]") as char(40)))
- Study-Site Key Dates	[Initial IRB/EC Submission Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MIN("- Study-Site Key Dates"."[Initial IRB/EC Submission Date]") as char(40)))
- Study-Site Original Planned Dates	[Planned Initial IRB/EC Approval Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Key Dates"."Initial IRB/EC Approval Date" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Initial IRB/EC Approval Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Key Dates"."Initial IRB/EC Approval Date" as char(40)))

Table A–125 (Cont.) Study Site Milestones with Indicators - Summary View (Report CDA-CO-208G)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Key Dates	Initial IRB/EC Approval Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Key Dates"."Initial IRB/EC Approval Date" as char(40)))
- Study-Site Original Planned Dates	[Planned Critical Document Package Completed Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."[Critical Document Package Completed Date]") as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Critical Document Package Completed Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."[Critical Document Package Completed Date]") as char(40)))
- Study-Site Key Dates	[Critical Document Package Completed Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."[Critical Document Package Completed Date]") as char(40)))
- Study-Site Metrics	Next Site Visit Type	"- Study-Site Metrics"."Next Site Visit Type"

Table A–125 (Cont.) Study Site Milestones with Indicators - Summary View (Report CDA-CO-208G)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	# Subjects Enrolled Since Latest Site Visit	"- Study-Site Metrics"."# Subjects Enrolled Since Latest Site Visit"

Study Sites Initiated but Zero Enrolled (Report CDA-CO-301)

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.

Audience

- Study Manager
- CRA
- Region Manager

Report Type

- Table

Location

- **Study Overview** dashboard, **Non Performing Investigators** page
- **Study Region Overview** dashboard, **Non-Performing Investigators** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study Overview Dashboard
- Investigator Contact and Studies List (Report CDA-CO-202)

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Study Sites Initiated but Zero Enrolled report.

Table A–126 Study Sites Initiated but Zero Enrolled (Report CDA-CO-301)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study-Site	Study Region	Study-Site.Study Region
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Site Name	Study-Site.Site Name
Study-Site	Status	Study-Site.Study-Site Status
Study-Region	Region Name	Study-Region.Region Name
Site Initiated	Date	Study-Site.Site Initiated Date
Site Initiated	Days Since	Study-site Metrics.Days Since Initiation
NA	Navigate to Detail	NA

Study Sites Initiated, only One Subject Enrolled (Report CDA-CO-302)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study Overview** dashboard, **Non Performing Investigators** page
- **Study Region Overview** dashboard, **Non-Performing Investigators** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study Overview Dashboard

- Investigator Contact and Studies List (Report CDA-CO-202)

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Study Sites Initiated, only One Subject Enrolled report.

Table A–127 Study Sites Initiated, only One Subject Enrolled (Report CDA-CO-302)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study-Site	Study Region	Study-Site.Study Region
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Site Name	Study-Site.Site Name
Study-Site	Status	Study-Site.Study-Site Status
Site Initiated	Actual	Study-Site.Site Initiated Date
Site Initiated	Days Since	Study-site Metrics.Days Since Initiation
- Study-Site Metrics	Latest Subject Enrolled Date	"- Study-site Metrics"."Latest Subject Enrolled Date"
- Study-Site Metrics	# Days Since Last Enrollment for Study-site	"- Study-site Metrics"."# Days Since Last Enrollment for Study-site"
NA	Navigate to Detail	NA

Study Team Member List (Report CDA-CO-111)

Lists all of the team members for a study.

Audience

- Study Manager

Report Type

- Table

Location

- **Study Overview** dashboard, **Study Team** page

Dimensions

- Study Team Member

Supplementary Prompts

- NA

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–128 describes the columns in the Study Team Member List analysis

Table A–128 Study Team Member List (Report CDA-CO-111)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study	Study	"Study"."Study"
Study Team Member	Full Name	"Study Team Member"."Full Name"
Study Team Member	Role	"Study Team Member"."Role"
Study Team Member	Start Date	"Study Team Member"."Start Date"
Study Team Member	End Date	"Study Team Member"."End Date"
Study Team Member	Email	"Study Team Member"."Email"
Study Team Member	Team Member Active	"Study Team Member"."Team Member Active"

Study-Region Information (Report CDA-CO-1113)

Displays a summary of identifying information for a study-region, including Region Name, Study #, and Study-Region Status.

Audience

- Region Manager
- Study Manager
- Executive Manager
- Program Manager

Report Type

- Narrative

Location

- **Study-Region Overview** dashboard, **Overview Study-Site Milestones** page

Dimensions

- Study, Study-Region

Supplementary Prompts

NA

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–129 describes the columns in the Study-Region Information analysis.

Table A–129 Study-Region Information (Report CDA-CO-1113)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Region	Region Name	"Study-Region"."Region Name"
Study	Study	"Study"."Study"
Study	Study Short Title	"Study"."Study Short Title"
Study-Region	Study-Region Manager	"Study-Region"."Study-Region Manager"
Study-Region	Study-Region Status	"Study-Region"."Study-Region Status"
Study-Region	Study-Region Name	"Study-Region"."Study-Region Name"

Study-Region List - Initiation Details (Report CDA-CO-306)

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.

Audience

- Study Manager Region Manager

Report Type

- Table

Location

- **Region Manager** dashboard, **Initiating and Recruiting Study Region** page

Dimensions

- Study, Study-Region

Supplementary Prompts

- NA

Reports Referenced

You can navigate to the following reports from this report:

- Study-Region Team Member List (Report CDA-CO-1107)
- Study Overview Dashboard
- Study-Region Overview Dashboard

Reports Referencing This Report

None

Column Descriptions

Table A–130 describes the columns in the Study-Region List - Initiation Details analysis

Table A–130 Study-Region List - Initiation Details (Report CDA-CO-306)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Region	Region Name	"Study-Region"."Region Name"
Study	Study	"Study"."Study"
Study	Study Short Title	"Study"."Study Short Title"
Study-Region	Study-Region Status	"Study-Region"."Study-Region Status"
Study-Region	Study-Region Manager	"Study-Region"."Study-Region Manager"
- Study Region Metrics	Milestone Indicator	"- Study Region Metrics"."Milestone Indicator"
- Study Region Metrics	Milestone Detail Reason	"- Study Region Metrics"."Milestone Detail Reason"
- Study Region Metrics	# Study-Sites Planned for Study-Region	CONCAT('Planned:' , cast("- Study Region Metrics"."# Study-Sites Planned for Study-Region" as char(40))) || ' ' || CONCAT('Actual:' , cast("- Study Region Metrics"."# Study-Sites Initiated" as char(40)))

Table A–130 (Cont.) Study-Region List - Initiation Details (Report CDA-CO-306)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Region Metrics	# Study-Sites Initiated	CONCAT('Planned:' , cast("- Study Region Metrics"."# Study-Sites Planned for Study-Region" as char(40)))|| ' ' || CONCAT('Actual:' , cast("- Study Region Metrics"."# Study-Sites Initiated" as char(40)))
- Study Region Metrics	# Sites Recruiting 1 or More Subjects	CONCAT('Actual:' , cast("- Study Region Metrics"."# Sites Recruiting 1 or More Subjects" as char(40)))
- Study Region Metrics	% of Planned Sites Initiated	CONCAT('Actual:',cast(ROUND("- Study Region Metrics"."% of Planned Sites Initiated", 2) as char(40)))
- Study-Region Original Planned Dates	[Planned 1st IRB/EC Submission Date]	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned 1st IRB/EC Submission Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE 1st IRB/EC Submission Date]" as char(40))))||' '||CONCAT('Actual:' , cast("- Study Region Metrics"."[1st IRB/EC Submission Date]" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE 1st IRB/EC Submission Date]	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned 1st IRB/EC Submission Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE 1st IRB/EC Submission Date]" as char(40))))||' '||CONCAT('Actual:' , cast("- Study Region Metrics"."[1st IRB/EC Submission Date]" as char(40)))
- Study Region Metrics	[1st IRB/EC Submission Date]	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned 1st IRB/EC Submission Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE 1st IRB/EC Submission Date]" as char(40))))||' '||CONCAT('Actual:' , cast("- Study Region Metrics"."[1st IRB/EC Submission Date]" as char(40)))

Table A–130 (Cont.) Study-Region List - Initiation Details (Report CDA-CO-306)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Original Planned Dates	[Planned 1st Initial IRB/EC Approval Date]	CONCAT('Planned:',MAX(cast("-Study-Region Original Planned Dates"."[Planned 1st Initial IRB/EC Approval Date]" as char(40))))||' '||CONCAT('LE:',MAX(cast("-Study-Region Latest Estimated Dates"."[Planned LE 1st Initial IRB/EC Approval Date]" as char(40))))||' '||CONCAT('Actual:' , cast("-Study Region Metrics"."1st Initial IRB/EC Approval Date" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE 1st Initial IRB/EC Approval Date]	CONCAT('Planned:',MAX(cast("-Study-Region Original Planned Dates"."[Planned 1st Initial IRB/EC Approval Date]" as char(40))))||' '||CONCAT('LE:',MAX(cast("-Study-Region Latest Estimated Dates"."[Planned LE 1st Initial IRB/EC Approval Date]" as char(40))))||' '||CONCAT('Actual:' , cast("-Study Region Metrics"."1st Initial IRB/EC Approval Date" as char(40)))
- Study Region Metrics	1st Initial IRB/EC Approval Date	CONCAT('Planned:',MAX(cast("-Study-Region Original Planned Dates"."[Planned 1st Initial IRB/EC Approval Date]" as char(40))))||' '||CONCAT('LE:',MAX(cast("-Study-Region Latest Estimated Dates"."[Planned LE 1st Initial IRB/EC Approval Date]" as char(40))))||' '||CONCAT('Actual:' , cast("-Study Region Metrics"."1st Initial IRB/EC Approval Date" as char(40)))
- Study-Region Original Planned Dates	[Planned 1st Site Initiated Date]	CONCAT('Planned:',MIN(cast("-Study-Region Original Planned Dates"."[Planned 1st Site Initiated Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("-Study-Region Latest Estimated Dates"."[Planned LE 1st Site Initiated Date]" as char(40))))||' '||CONCAT('Actual :',EVALUATE('TO_CHAR(%1,%2)' as varchar(20),"-Study Region Metrics"."1st Site Initiated Date" , 'dd-Mon-yyyy'))

Table A–130 (Cont.) Study-Region List - Initiation Details (Report CDA-CO-306)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Latest Estimated Dates	[Planned LE 1st Site Initiated Date]	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned 1st Site Initiated Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE 1st Site Initiated Date]" as char(40))))||' '||CONCAT('Actual :',EVALUATE('TO_ CHAR(%1,%2)' as varchar(20),"- Study Region Metrics"."1st Site Initiated Date" , 'dd-Mon-yyyy'))
- Study Region Metrics	1st Site Initiated Date	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned 1st Site Initiated Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE 1st Site Initiated Date]" as char(40))))||' '||CONCAT('Actual :',EVALUATE('TO_ CHAR(%1,%2)' as varchar(20),"- Study Region Metrics"."1st Site Initiated Date" , 'dd-Mon-yyyy'))
- Study-Region Original Planned Dates	[Planned Last Site Initiated Date]	CONCAT('Planned:',MAX(cast("- Study-Region Original Planned Dates"."[Planned Last Site Initiated Date]" as char(40))))||' '||CONCAT('LE:',MAX(cast("- Study-Region Latest Estimated Dates"."[Planned LE Last Site Initiated Date]" as char(40))))||' '||CONCAT('Actual Latest:' , cast("- Study Region Metrics"."Latest Site Initiated Date" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study Region Metrics"."[Last Site Initiated Date]" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE Last Site Initiated Date]	CONCAT('Planned:',MAX(cast("- Study-Region Original Planned Dates"."[Planned Last Site Initiated Date]" as char(40))))||' '||CONCAT('LE:',MAX(cast("- Study-Region Latest Estimated Dates"."[Planned LE Last Site Initiated Date]" as char(40))))||' '||CONCAT('Actual Latest:' , cast("- Study Region Metrics"."Latest Site Initiated Date" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study Region Metrics"."[Last Site Initiated Date]" as char(40)))

Table A–130 (Cont.) Study-Region List - Initiation Details (Report CDA-CO-306)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Region Metrics	Latest Site Initiated Date	CONCAT('Planned:',MAX(cast("- Study-Region Original Planned Dates"."[Planned Last Site Initiated Date]" as char(40))))||' '||CONCAT('LE:',MAX(cast("- Study-Region Latest Estimated Dates"."[Planned LE Last Site Initiated Date]" as char(40))))||' '||CONCAT('Actual Latest:' , cast("- Study Region Metrics"."Latest Site Initiated Date" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study Region Metrics"."[Last Site Initiated Date]" as char(40)))
- Study Region Metrics	[Last Site Initiated Date]	CONCAT('Planned:',MAX(cast("- Study-Region Original Planned Dates"."[Planned Last Site Initiated Date]" as char(40))))||' '||CONCAT('LE:',MAX(cast("- Study-Region Latest Estimated Dates"."[Planned LE Last Site Initiated Date]" as char(40))))||' '||CONCAT('Actual Latest:' , cast("- Study Region Metrics"."Latest Site Initiated Date" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study Region Metrics"."[Last Site Initiated Date]" as char(40)))
- Study-Region Original Planned Dates	[Planned 1st Critical Document Package Completed Date]	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned 1st Critical Document Package Completed Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE 1st Critical Document Package Completed Date]" as char(40))))||' '||CONCAT('Actual Latest:' , cast("- Study Region Metrics"."Latest Site Initiated Date" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study Region Metrics"."[1st Critical Document Package Completed Date]" as char(40)))

Table A–130 (Cont.) Study-Region List - Initiation Details (Report CDA-CO-306)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Latest Estimated Dates	[Planned LE 1st Critical Document Package Completed Date]	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned 1st Critical Document Package Completed Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE 1st Critical Document Package Completed Date]" as char(40))))||' '||CONCAT('Actual Latest:' , cast("- Study Region Metrics"."Latest Site Initiated Date" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study Region Metrics"."[1st Critical Document Package Completed Date]" as char(40)))
- Study Region Metrics	Latest Site Initiated Date	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned 1st Critical Document Package Completed Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE 1st Critical Document Package Completed Date]" as char(40))))||' '||CONCAT('Actual Latest:' , cast("- Study Region Metrics"."Latest Site Initiated Date" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study Region Metrics"."[1st Critical Document Package Completed Date]" as char(40)))
- Study Region Metrics	[1st Critical Document Package Completed Date]	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned 1st Critical Document Package Completed Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE 1st Critical Document Package Completed Date]" as char(40))))||' '||CONCAT('Actual Latest:' , cast("- Study Region Metrics"."Latest Site Initiated Date" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study Region Metrics"."[1st Critical Document Package Completed Date]" as char(40)))

Table A–130 (Cont.) Study-Region List - Initiation Details (Report CDA-CO-306)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Original Planned Dates	[Planned Last Critical Document Package Completed Date]	CONCAT('Planned:',MAX(cast("- Study-Region Original Planned Dates"."[Planned Last Critical Document Package Completed Date]" as char(40))))||' '||CONCAT('LE:',MAX(cast("- Study-Region Latest Estimated Dates"."[Planned LE Last Critical Document Package Completed Date]" as char(40))))||' '||CONCAT('Actual Latest:' , cast("- Study Region Metrics"."[Latest Critical Document Package Completed Date]" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study Region Metrics"."[Last Critical Document Package Completed Date]" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE Last Critical Document Package Completed Date]	CONCAT('Planned:',MAX(cast("- Study-Region Original Planned Dates"."[Planned Last Critical Document Package Completed Date]" as char(40))))||' '||CONCAT('LE:',MAX(cast("- Study-Region Latest Estimated Dates"."[Planned LE Last Critical Document Package Completed Date]" as char(40))))||' '||CONCAT('Actual Latest:' , cast("- Study Region Metrics"."[Latest Critical Document Package Completed Date]" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study Region Metrics"."[Last Critical Document Package Completed Date]" as char(40)))
- Study Region Metrics	[Latest Critical Document Package Completed Date]	CONCAT('Planned:',MAX(cast("- Study-Region Original Planned Dates"."[Planned Last Critical Document Package Completed Date]" as char(40))))||' '||CONCAT('LE:',MAX(cast("- Study-Region Latest Estimated Dates"."[Planned LE Last Critical Document Package Completed Date]" as char(40))))||' '||CONCAT('Actual Latest:' , cast("- Study Region Metrics"."[Latest Critical Document Package Completed Date]" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study Region Metrics"."[Last Critical Document Package Completed Date]" as char(40)))

Table A–130 (Cont.) Study-Region List - Initiation Details (Report CDA-CO-306)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Region Metrics	[Last Critical Document Package Completed Date]	CONCAT('Planned:',MAX(cast("- Study-Region Original Planned Dates"."[Planned Last Critical Document Package Completed Date]" as char(40)))||' '||CONCAT('LE:',MAX(cast("- Study-Region Latest Estimated Dates"."[Planned LE Last Critical Document Package Completed Date]" as char(40)))||' '||CONCAT('Actual Latest:' , cast("- Study Region Metrics"."[Latest Critical Document Package Completed Date]" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study Region Metrics"."[Last Critical Document Package Completed Date]" as char(40)))

Study-Region List - KPI Performance (Report CDA-CO-1108)

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.

Audience

- Region Manager

Report Type

- Table

Location

None

Dimensions

- Study

Supplementary Prompts

- NA

Reports Referenced

You can navigate to the following reports from this report:

- Study-Region Team Member List (Report CDA-CO-1107)

- Study-Region Overview Dashboard
- Study Overview Dashboard

Reports Referencing This Report

None

Column Descriptions

Table A–131 describes the columns in the Performance Metrics Summary Narrative: Site Visit analysis

Table A–131 Study-Region List: KPI Performance (Report CDA-CO-1108)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Region	Region Name	NA
Study	Study	NA
Study	Study Short Title	NA
Study-Region	Study-Region Status	NA
Study-Region	Study-Region Manager	NA
Study-Region Metrics	% Sites Recruiting 0 Subjects	NA
Overall Level Targets	[Expected % Sites Recruiting 0 Subjects]	NA
Study-Region Metrics	[Median Critical Document Package Complete to Site Initiated (# Days)]	NA
Overall Level Targets	[Target Critical Document Package Complete to Site Initiated (# Days)]	NA
-	Median Site Visit Completed to Visit Report Completed	median("- Site Visit Metrics"."# Days from Site Visit Completed to Visit Report Completed")
Overall Level Targets	[Target Site Visit Completed to Visit Report Completed (# Days)]	NA
-	Median Visit Report Completed to Visit Report Approved	median("- Site Visit Metrics"."[# Days from Visit Report Completed to Visit Report Approved]"
Overall Level Targets	[Target Visit Report Completed to Visit Report Approved (# Days)]	NA

Study-Region List - Milestone Performance (Report CDA-CO-1109)

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.

Audience

- Region Manager

Report Type

- Table

Location

None

Dimensions

- Study-Region, Study

Supplementary Prompts

- NA

Reports Referenced

You can navigate to the following reports from this report:

- Study-Region Team Member List (Report CDA-CO-1107)
- Study-Region Overview Dashboard
- Study Overview Dashboard

Reports Referencing This Report

None

Column Descriptions

Table A–132 describes the columns in the Study-Region List: Milestone Performance analysis

Table A–132 Study-Region List: Milestone Performance (Report CDA-CO-1109)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Region	Region Name	"Study-Region"."Region Name"
Study	Study	"Study"."Study"
Study	Study Short Title	"Study"."Study Short Title"
Study-Region	Study-Region Status	"Study-Region"."Study-Region Status"
Study-Region	Study-Region Manager	"Study-Region"."Study-Region Manager"
- Study Region Metrics	Milestone Flag	"- Study Region Metrics"."Milestone Flag"
- Study Region Metrics	Milestone Detail Reason	"- Study Region Metrics"."Milestone Detail Reason"

Table A–132 (Cont.) Study-Region List: Milestone Performance (Report CDA-CO-1109)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Original Planned Dates	[Planned 1st IRB/EC Submission Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st IRB/EC Submission Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st IRB/EC Submission Date]") as char(40))) || ' '||CONCAT('Actual:',cast(MIN("- Study Region Metrics"."[1st IRB/EC Submission Date]") as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE 1st IRB/EC Submission Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st IRB/EC Submission Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st IRB/EC Submission Date]") as char(40))) || ' '||CONCAT('Actual:',cast(MIN("- Study Region Metrics"."[1st IRB/EC Submission Date]") as char(40)))
- Study Region Metrics	[1st IRB/EC Submission Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st IRB/EC Submission Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st IRB/EC Submission Date]") as char(40))) || ' '||CONCAT('Actual:',cast(MIN("- Study Region Metrics"."[1st IRB/EC Submission Date]") as char(40)))
- Study-Region Original Planned Dates	[Planned 1st Initial IRB/EC Approval Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Initial IRB/EC Approval Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Initial IRB/EC Approval Date]") as char(40))) || ' '||CONCAT('Actual:',cast("- Study Region Metrics"."1st Initial IRB/EC Approval Date" as char(40)))

Table A–132 (Cont.) Study-Region List: Milestone Performance (Report CDA-CO-1109)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Latest Estimated Dates	[Planned LE 1st Initial IRB/EC Approval Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Region Metrics"."1st Initial IRB/EC Approval Date" as char(40)))
- Study Region Metrics	1st Initial IRB/EC Approval Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT('Actual:',cast("- Study Region Metrics"."1st Initial IRB/EC Approval Date" as char(40)))
- Study-Region Original Planned Dates	[Planned 1st Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Site Initiated Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Site Initiated Date]") as char(40)))||' '||CONCAT('Actual:',Cast(MIN("- Study Region Metrics"."1st Site Initiated Date") as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE 1st Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Site Initiated Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Site Initiated Date]") as char(40)))||' '||CONCAT('Actual:',Cast(MIN("- Study Region Metrics"."1st Site Initiated Date") as char(40)))
- Study Region Metrics	1st Site Initiated Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Site Initiated Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Site Initiated Date]") as char(40)))||' '||CONCAT('Actual:',Cast(MIN("- Study Region Metrics"."1st Site Initiated Date") as char(40)))

Table A–132 (Cont.) Study-Region List: Milestone Performance (Report CDA-CO-1109)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Original Planned Dates	[Planned Last Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Site Initiated Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Site Initiated Date]") as char(40))) || ' '||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."Latest Site Initiated Date" as char(40))) || ' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Site Initiated Date]" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE Last Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Site Initiated Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Site Initiated Date]") as char(40))) || ' '||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."Latest Site Initiated Date" as char(40))) || ' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Site Initiated Date]" as char(40)))
- Study Region Metrics	Latest Site Initiated Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Site Initiated Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Site Initiated Date]") as char(40))) || ' '||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."Latest Site Initiated Date" as char(40))) || ' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Site Initiated Date]" as char(40)))
- Study Region Metrics	[Last Site Initiated Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Site Initiated Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Site Initiated Date]") as char(40))) || ' '||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."Latest Site Initiated Date" as char(40))) || ' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Site Initiated Date]" as char(40)))

Table A–132 (Cont.) Study-Region List: Milestone Performance (Report CDA-CO-1109)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Original Planned Dates	[Planned 1st Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Critical Document Package Completed Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Critical Document Package Completed Date]") as char(40))) || ' '||CONCAT('Actual:',cast("- Study Region Metrics"."[1st Critical Document Package Completed Date]" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE 1st Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Critical Document Package Completed Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Critical Document Package Completed Date]") as char(40))) || ' '||CONCAT('Actual:',cast("- Study Region Metrics"."[1st Critical Document Package Completed Date]" as char(40)))
- Study Region Metrics	[1st Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Critical Document Package Completed Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Critical Document Package Completed Date]") as char(40))) || ' '||CONCAT('Actual:',cast("- Study Region Metrics"."[1st Critical Document Package Completed Date]" as char(40)))
- Study-Region Original Planned Dates	[Planned Last Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Critical Document Package Completed Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Critical Document Package Completed Date]") as char(40))) || ' '||CONCAT('Actual(Latest):',cast ("- Study Region Metrics"."[Latest Critical Document Package Completed Date]" as char(40))) || ' '||CONCAT('Actual(Last):',cast(" - Study Region Metrics"."[Last Critical Document Package Completed Date]" as char(40)))

Table A–132 (Cont.) Study-Region List: Milestone Performance (Report CDA-CO-1109)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Latest Estimated Dates	[Planned LE Last Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Critical Document Package Completed Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Critical Document Package Completed Date]") as char(40))) || ' '||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."[Latest Critical Document Package Completed Date]" as char(40))) || ' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Critical Document Package Completed Date]" as char(40)))
- Study Region Metrics	[Latest Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Critical Document Package Completed Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Critical Document Package Completed Date]") as char(40))) || ' '||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."[Latest Critical Document Package Completed Date]" as char(40))) || ' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Critical Document Package Completed Date]" as char(40)))
- Study Region Metrics	[Last Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Critical Document Package Completed Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Critical Document Package Completed Date]") as char(40))) || ' '||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."[Latest Critical Document Package Completed Date]" as char(40))) || ' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Critical Document Package Completed Date]" as char(40)))

Table A–132 (Cont.) Study-Region List: Milestone Performance (Report CDA-CO-1109)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Original Planned Dates	[Planned 1st Subject Screened Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Subject Screened Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||CONCAT('Actual:',cast("- Study Region Metrics"."1st Subject Screened Date" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE 1st Subject Screened Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Subject Screened Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||CONCAT('Actual:',cast("- Study Region Metrics"."1st Subject Screened Date" as char(40)))
- Study Region Metrics	1st Subject Screened Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Subject Screened Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||CONCAT('Actual:',cast("- Study Region Metrics"."1st Subject Screened Date" as char(40)))
- Study-Region Original Planned Dates	[Planned 1st Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]") as char(40)))||CONCAT('Actual:',cast("- Study Region Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE 1st Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Subject Enrolled Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]") as char(40)))||CONCAT('Actual:',cast("- Study Region Metrics"."1st Subject Enrolled Date" as char(40)))

Table A–132 (Cont.) Study-Region List: Milestone Performance (Report CDA-CO-1109)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Region Metrics	1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Subject Enrolled Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]") as char(40))) || CONCAT('Actual:',cast("- Study Region Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Region Original Planned Dates	[Planned 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40))) || CONCAT('Actual:',cast("- Study Region Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40))) || CONCAT('Actual:',cast("- Study Region Metrics"."1st Subject Randomized Date" as char(40)))
- Study Region Metrics	1st Subject Randomized Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40))) || CONCAT('Actual:',cast("- Study Region Metrics"."1st Subject Randomized Date" as char(40)))

Table A–132 (Cont.) Study-Region List: Milestone Performance (Report CDA-CO-1109)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Original Planned Dates	[Planned Last Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40)))||' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Subject Enrolled Date]" as char(40)))||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."Latest Subject Enrolled Date" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE Last Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40)))||' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Subject Enrolled Date]" as char(40)))||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."Latest Subject Enrolled Date" as char(40)))
- Study Region Metrics	[Last Subject Enrolled Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40)))||' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Subject Enrolled Date]" as char(40)))||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."Latest Subject Enrolled Date" as char(40)))
- Study Region Metrics	Latest Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Enrolled Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]") as char(40)))||' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Subject Enrolled Date]" as char(40)))||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."Latest Subject Enrolled Date" as char(40)))

Table A–132 (Cont.) Study-Region List: Milestone Performance (Report CDA-CO-1109)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Original Planned Dates	[Planned Last Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40))||' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Subject Randomized Date]" as char(40))||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."Latest Subject Randomized Date" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40))||' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Subject Randomized Date]" as char(40))||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."Latest Subject Randomized Date" as char(40)))
- Study Region Metrics	[Last Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40))||' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40))||' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Subject Randomized Date]" as char(40))||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."Latest Subject Randomized Date" as char(40)))

Table A–132 (Cont.) Study-Region List: Milestone Performance (Report CDA-CO-1109)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Region Metrics	Latest Subject Randomized Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40))) || ' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Subject Randomized Date]" as char(40))) ||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."Latest Subject Randomized Date" as char(40)))
- Study-Region Original Planned Dates	[Planned Last Subject Last Visit Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40))) || ' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Subject Last Visit Date]" as char(40))) ||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."Latest Subject Latest Visit Date" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE Last Subject Last Visit Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40))) || ' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Subject Last Visit Date]" as char(40))) ||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."Latest Subject Latest Visit Date" as char(40)))
- Study Region Metrics	[Last Subject Last Visit Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40))) || ' '||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40))) || ' '||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Subject Last Visit Date]" as char(40))) ||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."Latest Subject Latest Visit Date" as char(40)))

Table A–132 (Cont.) Study-Region List: Milestone Performance (Report CDA-CO-1109)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Region Metrics	Latest Subject Latest Visit Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40))) || ' ' ||CONCAT('LE:' , cast(MAX("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40))) || ' ' ||CONCAT('Actual(Last):',cast("- Study Region Metrics"."[Last Subject Last Visit Date]" as char(40))) ||CONCAT('Actual(Latest):',cast("- Study Region Metrics"."Latest Subject Latest Visit Date" as char(40)))

Study-Region List - Recruitment Details (Report CDA-CO-433)

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.

Audience

- Study Manager Region Manager

Report Type

- Table

Location

- **Region Manager** dashboard, **Initiating and Recruiting Study Region** page

Dimensions

- Study, Study-Region

Supplementary Prompts

- NA

Reports Referenced

You can navigate to the following reports from this report:

- Study-Region Team Member List (Report CDA-CO-1107)
- Study Overview Dashboard

- Study-Region Overview Dashboard

Reports Referencing This Report

None

Column Descriptions

Table A–133 describes the columns in the Study-Region List - Recruitment Details analysis

Table A–133 Study-Region List - Recruitment Details (Report CDA-CO-433)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Region	Region Name	"Study-Region"."Region Name"
Study	Study	"Study"."Study"
Study	Study Short Title	"Study"."Study Short Title"
Study-Region	Study-Region Status	"Study-Region"."Study-Region Status"
Study-Region	Study-Region Manager	"Study-Region"."Study-Region Manager"
Study-Region	Study-Region Name	"Study-Region"."Study-Region Name"
Study-Region	Study	"Study-Region"."Study"
- Study Region Metrics	Retention Indicator	"- Study Region Metrics"."Retention Indicator"
- Study Region Metrics	Retention Detail Reason	"- Study Region Metrics"."Retention Detail Reason"
- Study Region Metrics	Milestone Indicator	"- Study Region Metrics"."Milestone Indicator"
- Study Region Metrics	Milestone Detail Reason	"- Study Region Metrics"."Milestone Detail Reason"
- Study-Region Targets	[Expected Screen Failure Rate]	CONCAT('Expected:' , MIN(cast(ROUND("- Study-Region Targets"."[Expected Screen Failure Rate]", 2) as char(40)))) || ' '||CONCAT('Actual:' , cast(ROUND("- Study Region Metrics"."Screen Failure Rate", 2) as char(40)))
- Study Region Metrics	Screen Failure Rate	CONCAT('Expected:' , MIN(cast(ROUND("- Study-Region Targets"."[Expected Screen Failure Rate]", 2) as char(40)))) || ' '||CONCAT('Actual:' , cast(ROUND("- Study Region Metrics"."Screen Failure Rate", 2) as char(40)))
- Study Region Metrics	% Enrolled to Total Planned at Study Region	"- Study Region Metrics"."% Enrolled to Total Planned at Study Region"
- Study Region Metrics	% Planned Subjects Randomized	"- Study Region Metrics"."% Planned Subjects Randomized"

Table A–133 (Cont.) Study-Region List - Recruitment Details (Report CDA-CO-433)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Original Planned Dates	[Planned 1st Subject Screened Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Subject Screened Date]") as char(40)))||' '||CONCAT('LE:',cast(MIN("- Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '|| CONCAT('Actual:' , cast("- Study-Site Metrics"."1st Subject Screened Date" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE 1st Subject Screened Date]	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Subject Screened Date]") as char(40)))||' '||CONCAT('LE:',cast(MIN("- Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '|| CONCAT('Actual:' , cast("- Study-Site Metrics"."1st Subject Screened Date" as char(40)))
- Study-Site Metrics	1st Subject Screened Date	CONCAT('Planned:',cast(MIN("- Study-Region Original Planned Dates"."[Planned 1st Subject Screened Date]") as char(40)))||' '||CONCAT('LE:',cast(MIN("- Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '|| CONCAT('Actual:' , cast("- Study-Site Metrics"."1st Subject Screened Date" as char(40)))
- Study-Region Original Planned Dates	[Planned 1st Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned 1st Subject Enrolled Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]" as char(40))))||' '|| CONCAT('Actual:' , cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE 1st Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned 1st Subject Enrolled Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]" as char(40))))||' '|| CONCAT('Actual:' , cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))

Table A–133 (Cont.) Study-Region List - Recruitment Details (Report CDA-CO-433)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Metrics	1st Subject Enrolled Date	CONCAT('Planned:',MIN(cast("-Study-Region Original Planned Dates"."[Planned 1st Subject Enrolled Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("-Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Enrolled Date]" as char(40))))||' '|| CONCAT('Actual:' , cast("-Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Region Original Planned Dates	[Planned 1st Subject Randomized Date]	CONCAT('Planned:',MIN(cast("-Study-Region Original Planned Dates"."[Planned 1st Subject Randomized Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("-Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]" as char(40))))||' '|| CONCAT('Actual:' , cast("-Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE 1st Subject Randomized Date]	CONCAT('Planned:',MIN(cast("-Study-Region Original Planned Dates"."[Planned 1st Subject Randomized Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("-Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]" as char(40))))||' '|| CONCAT('Actual:' , cast("-Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Metrics	1st Subject Randomized Date	CONCAT('Planned:',MIN(cast("-Study-Region Original Planned Dates"."[Planned 1st Subject Randomized Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("-Study-Region Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]" as char(40))))||' '|| CONCAT('Actual:' , cast("-Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Region Original Planned Dates	[Planned 1st Subject 1st Visit Date]	CONCAT('Planned:',MIN(cast("-Study-Region Original Planned Dates"."[Planned 1st Subject 1st Visit Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("-Study-Region Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]" as char(40))))||' '|| CONCAT('Actual:' , cast("-Study-Site Metrics"."1st Subject 1st Visit Date" as char(40)))

Table A–133 (Cont.) Study-Region List - Recruitment Details (Report CDA-CO-433)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Latest Estimated Dates	[Planned LE 1st Subject 1st Visit Date]	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned 1st Subject 1st Visit Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]" as char(40))))||' '|| CONCAT('Actual:' , cast("- Study-Site Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study-Site Metrics	1st Subject 1st Visit Date	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned 1st Subject 1st Visit Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]" as char(40))))||' '|| CONCAT('Actual:' , cast("- Study-Site Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study-Region Original Planned Dates	[Planned Last Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned Last Subject Enrolled Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]" as char(40))))||' '|| CONCAT('Actual Latest:' , cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study-Site Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE Last Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned Last Subject Enrolled Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]" as char(40))))||' '|| CONCAT('Actual Latest:' , cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study-Site Metrics"."[Last Subject Enrolled Date]" as char(40)))

Table A–133 (Cont.) Study-Region List - Recruitment Details (Report CDA-CO-433)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Metrics	Latest Subject Enrolled Date	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned Last Subject Enrolled Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]" as char(40))))||' '|| CONCAT('Actual Latest:' , cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study-Site Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study-Site Metrics	[Last Subject Enrolled Date]	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned Last Subject Enrolled Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Enrolled Date]" as char(40))))||' '|| CONCAT('Actual Latest:' , cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study-Site Metrics"."[Last Subject Enrolled Date]" as char(40)))
- Study-Region Original Planned Dates	[Planned Last Subject Randomized Date]	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned Last Subject Randomized Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]" as char(40))))||' '|| CONCAT('Actual Latest:' , cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study-Site Metrics"."[Last Subject Randomized Date]" as char(40)))

Table A–133 (Cont.) Study-Region List - Recruitment Details (Report CDA-CO-433)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned Last Subject Randomized Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]" as char(40))))||' '|| CONCAT('Actual Latest:' , cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study-Site Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study-Site Metrics	Latest Subject Randomized Date	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned Last Subject Randomized Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]" as char(40))))||' '|| CONCAT('Actual Latest:' , cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study-Site Metrics"."[Last Subject Randomized Date]" as char(40)))
- Study-Site Metrics	[Last Subject Randomized Date]	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned Last Subject Randomized Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]" as char(40))))||' '|| CONCAT('Actual Latest:' , cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study-Site Metrics"."[Last Subject Randomized Date]" as char(40)))

Table A–133 (Cont.) Study-Region List - Recruitment Details (Report CDA-CO-433)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Region Original Planned Dates	[Planned Last Subject 1st Visit Date]	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned Last Subject 1st Visit Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]" as char(40))))||' '|| CONCAT('Actual Latest:' , cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE Last Subject 1st Visit Date]	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned Last Subject 1st Visit Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]" as char(40))))||' '|| CONCAT('Actual Latest:' , cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study-Site Metrics	Latest Subject 1st Visit Date	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned Last Subject 1st Visit Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]" as char(40))))||' '|| CONCAT('Actual Latest:' , cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))

Table A–133 (Cont.) Study-Region List - Recruitment Details (Report CDA-CO-433)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Metrics	[Last Subject 1st Visit Date]	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned Last Subject 1st Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]" as char(40)))||' '|| CONCAT('Actual Latest:' , cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study-Region Original Planned Dates	[Planned Last Subject Last Visit Date]	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned Last Subject Last Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]" as char(40)))||' '|| CONCAT('Actual Latest:' , cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Region Latest Estimated Dates	[Planned LE Last Subject Last Visit Date]	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned Last Subject Last Visit Date]" as char(40)))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]" as char(40)))||' '|| CONCAT('Actual Latest:' , cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))

Table A–133 (Cont.) Study-Region List - Recruitment Details (Report CDA-CO-433)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Metrics	Latest Subject Latest Visit Date	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned Last Subject Last Visit Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]" as char(40))))||' '|| CONCAT('Actual Latest:' , cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Site Metrics	[Last Subject Last Visit Date]	CONCAT('Planned:',MIN(cast("- Study-Region Original Planned Dates"."[Planned Last Subject Last Visit Date]" as char(40))))||' '||CONCAT('LE:',MIN(cast("- Study-Region Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]" as char(40))))||' '|| CONCAT('Actual Latest:' , cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT('Actual Last:' , cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study Region Metrics	1st Site Initiated Date	"- Study Region Metrics"."1st Site Initiated Date"
- Study Metrics	% Planned Subjects Enrolled (Study)	"- Study Metrics"."% Planned Subjects Enrolled (Study)"
- Study Metrics	[Last Subject Enrolled Date]	"- Study Metrics"."[Last Subject Enrolled Date]"

Study-Region List and Recruitment Counts (Report CDA-CO-404)

Lists all study regions and recruitment counts. This report indicates how well each region is progressing toward recruitment goals.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study Overview** dashboard, **Recruitment Overview** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Study-Region List and Recruitment Counts report.

Table A–134 Study-Region List and Recruitment Counts (Report CDA-CO-404)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study Region	Name	Study-Site.Study Region
Study Region	Status	Study-Site.Study Region Status
# Subjects	Planned for Region	Region Metrics.# Subjects Planned for Region
# Subjects	Planned for Study-Site	Study-site Metrics.# Subjects Planned for Study-Site
# Subjects	Screened	Study-site Metrics.# Screened
# Subjects	Screen Failure	Study-site Metrics.# Screen Failure
# Subjects	Subjects Enrolled	Study-site Metrics.# Subjects Enrolled
# Subjects	Randomized	Study-site Metrics.# Randomized
% to Plan	Site Enrollment	Study-site Metrics.% of Planned Site Enrollment Completed

Study-Region Team Member List (Report CDA-CO-1107)

Lists all of the team members for a study-region.

Audience

- Region Manager

Report Type

- Table

Location

- **Study-Region Overview** dashboard, **Study-Region Team** page

Dimensions

- Study-Region Team Member

Supplementary Prompts

- NA

Reports Referenced

None

Reports Referencing This Report

You can navigate to the following reports from this report:

- Study Region Milestones with Indicators (Report CDA-CO-1106)
- Study-Region List - KPI Performance (Report CDA-CO-1108)
- Study-Region List - Milestone Performance (Report CDA-CO-1109)
- Study-Region List - Initiation Details (Report CDA-CO-306)
- Study-Region List - Recruitment Details (Report CDA-CO-433)

Column Descriptions

Table A–135 describes the columns in the Study-Region Team Member List analysis.

Table A–135 Study-Region Team Member List (Report CDA-CO-1107)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Region Team Member	Full Name	"Study-Region Team Member"."Full Name"
Study-Region Team Member	Role	"Study-Region Team Member"."Role"
Study-Region Team Member	Start Date	"Study-Region Team Member"."Start Date"
Study-Region Team Member	End Date	"Study-Region Team Member"."End Date"
Study-Region Team Member	Email	"Study-Region Team Member"."Email"
Study-Region Team Member	Team Member Active	"Study-Region Team Member"."Team Member Active"

Study-Site Information (Report CDA-CO-206)

Displays a summary of identifying information for a study-site, including Study #, Program, Study-Site ID, Principal Investigator and Study-Site Status.

Audience

- Study Manager
- CRA

Report Type

- Narrative

Location

- **Study-Site Overview** dashboard, **Study-Site Overview** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Study-Site Information report.

Table A–136 Study-Site Information (Report CDA-CO-206)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Program	Study-Site.Program
NA	Study	Study-Site.Study
NA	Study-Site ID #	Study-Site.Study-Site ID #
NA	Principal Investigator	Study-Site.Principal Investigator
NA	Site Name	Study-Site.Site Name
NA	CRA	Study-Site.CRA
NA	Status	Study-Site.Study-Site Status
NA	Study Region	Study-Site.Study Region

Study-Site List by Recruitment Performance Group (Report CDA-CO-401)

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.

Audience

- Study Manager
- Region Manager
- CRA

Report Type

- Table

Location

- **Study Overview** dashboard, **Site Performance** page
- **Study-Region Overview** dashboard, **Site Performance** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Overview Dashboard

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Study-Site List by Recruitment Performance Group report.

Table A–137 Study-Site List by Recruitment Performance Group (Report CDA-CO-401)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	Study Region	Study-Site.Study Region
Study-Site	Study	"Study-Site"."Study"
NA	Study-Site ID #	Study-Site.Study-Site ID #

Table A–137 (Cont.) Study-Site List by Recruitment Performance Group (Report

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	Principal Investigator	Study-Site.Principal Investigator
NA	Site Name	Study-Site.Site Name
NA	Study-Site Status	Study-Site.Study-Site Status
NA	CRA	Study-Site.CRA
NA	# Enrolled	- Study-site Metrics.# Subjects Enrolled
NA	% of Planned Site Enrollment Completed	- Study-site Metrics.% of Planned Site Enrollment Completed
NA	# Days Since Last Enrollment for Study-site	- Study-site Metrics.# Days Since Last Enrollment for Study-site
NA	Navigate to Detail	NA

Study-Site List with Indicators - Data Management View (Report CDA-CO-207A)

Lists 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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study Region Overview** dashboard, **Study-Site Milestones** page
- **CRA, Study-Site Milestones** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Overview Dashboard

- Study-Site Team Member List (Report CDA-CO-201)

Reports Referencing This Report

- Detailed Study Milestones Report (Report CDA-CO-102)
- Study List - Initiation Details (Report CDA-CO-305)

Column Descriptions

The table describes the columns in the Study-Site List with Indicators - Data Management View report.

Table A–138 Study-Site List with Indicators - Data Management View (Report CDA-CO-207A)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study	Study-Site.Study
Study-Site	Study Region	Study-Site.Study Region
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Study-Site Status	Study-Site.Study-Site Status
Study-Site	CRA	Study-Site.CRA
- Discrepancies	# Open Discrepancies	"- Discrepancies"."# Open Discrepancies"
- Discrepancies	# Total Discrepancies	"- Discrepancies"."# Total Discrepancies"
- Discrepancies	# Days Discrepancy Open	"- Discrepancies"."# Days Discrepancy Open"/"- Discrepancies"."# Total Discrepancies"
- Received CRFs	# CRFs Awaiting Entry Completion	"- Received CRFs"."# CRFs Awaiting Entry Completion"
- Received CRFs	# eCRFs To Be Approved	"- Received CRFs"."# eCRFs To Be Approved"
- Received CRFs	# eCRFs To be Verified	"- Received CRFs"."# eCRFs To be Verified"
- Received CRFs	# CRFs Soft- Locked	"- Received CRFs"."# CRFs Soft-Locked"
- Received CRFs	% CRFs Soft Locked / Entry Complete	"- Received CRFs"."% CRFs Soft Locked / Entry Complete"
- Received CRFs	# CRFs Hard-Locked	"- Received CRFs"."# CRFs Hard-Locked"
- Received CRFs	% CRFs Hard Locked / Entry Complete	"- Received CRFs"."% CRFs Hard Locked / Entry Complete"

Study-Site List with Indicators - Monitoring View (Report CDA-CO-207B)

Lists study-sites including key monitoring metrics as well as progress tracking for site monitoring. This report indicates which study-sites require action, and why.

Audience

- Study Manager

- CRA

Report Type

- Table

Location

- **Study Region Overview** dashboard, **Study-Site Milestones** page
- **CRA, Study-Site Milestones** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Overview Dashboard
- Study-Site Team Member List (Report CDA-CO-201)

Reports Referencing This Report

- Detailed Study Milestones Report (Report CDA-CO-102)
- Study List - Initiation Details (Report CDA-CO-305)

Column Descriptions

The table describes the columns in the Study-Site List - Monitoring View with Indicators report.

Table A–139 Study-Site List with Indicators - Monitoring View (Report CDA-CO-207B)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study	Study-Site.Study
Study-Site	Study Region	Study-Site.Study Region
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Study-Site Status	Study-Site.Study-Site Status
Study-Site	CRA	Study-Site.CRA
- Study-Site Metrics	Next Site Visit Date	"- Study-Site Metrics"."Next Site Visit Date"
- Study-Site Metrics	# Days Since Latest Site Visit	TRUNCATE("- Study-Site Metrics"."# Days Since Latest Site Visit",0)

Table A–139 (Cont.) Study-Site List with Indicators - Monitoring View (Report

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Metrics	# Days Since Last Enrolllment for Study-Site	TRUNCATE("- Study-Site Metrics"."# Days Since Last Enrolllment for Study-Site",0)
- Discrepancies	# Open Discrepancies	"- Discrepancies"."# Open Discrepancies"
- Received CRFs	# eCRFs To Be Approved	"- Received CRFs"."# eCRFs To Be Approved"
- Received CRFs	# eCRFs To be Verified	"- Received CRFs"."# eCRFs To be Verified"
- Study-Site Metrics	Latest Site Visit Completed Date	"- Study-Site Metrics"."Latest Site Visit Completed Date"
- Study-Site Metrics	# Visit Reports Awaiting Completion	"- Study-Site Metrics"."# Visit Reports Awaiting Completion"
- Study-Site Metrics	[# Visit Reports Awaiting Approval]	"- Study-Site Metrics"."[# Visit Reports Awaiting Approval]"
- Site Visit Metrics	# Outstanding Follow Up Items	"- Site Visit Metrics"."# Outstanding Follow Up Items"
- Study-Site Metrics	Next Site Visit Type	"- Study-Site Metrics"."Next Site Visit Type"
- Study-Site Metrics	Latest Site Visit Type	"- Study-Site Metrics"."Latest Site Visit Type"
- Study-Site Metrics	# Subjects Enrolled Since Latest Site Visit	"- Study-Site Metrics"."# Subjects Enrolled Since Latest Site Visit"

Study-Site List with Indicators - Recruitment Detail View (Report CDA-CO-207C)

Lists 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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study Region Overview** dashboard, **Study-Site Milestones** page
- **CRA, Study-Site Milestones** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Overview Dashboard
- Study-Site Team Member List (Report CDA-CO-201)

Reports Referencing This Report

- Detailed Study Milestones Report (Report CDA-CO-102)
- Study List - Initiation Details (Report CDA-CO-305)

Column Descriptions

The table describes the columns in the Study-Site List with Indicators - Recruitment Detail View report.

Table A–140 Study-Site List with Indicators - Recruitment Detail View (Report CDA-CO-207C)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study	Study-Site.Study
Study-Site	Study Region	Study-Site.Study Region
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Study-Site Status	Study-Site.Study-Site Status
Study-Site	CRA	Study-Site.CRA
- Study-Site Metrics	Milestone Flag	"- Study-Site Metrics"."Milestone Flag"
- Study-Site Metrics	Milestone High Level Reason	"- Study-Site Metrics"."Milestone High Level Reason"
- Study-Site Metrics	Milestone Detail Reason	"- Study-Site Metrics"."Milestone Detail Reason"
- Study Targets	[Expected Screen Failure Rate]	CONCAT('Expected:',cast(MAX("- Study Targets"."[Expected Screen Failure Rate]") as char(40))||' '||CONCAT('Actual:' , cast(ROUND("-Study-Site Metrics"."Screen Failure Rate",2) as char(40)))
- Study-Site Metrics	Screen Failure Rate	CONCAT('Expected:',cast(MAX("- Study Targets"."[Expected Screen Failure Rate]") as char(40))||' '||CONCAT('Actual:' , cast(ROUND("-Study-Site Metrics"."Screen Failure Rate",2) as char(40)))

Table A–140 (Cont.) Study-Site List with Indicators - Recruitment Detail View (Report CDA-CO-207C)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Metrics	% Enrolled to Total Planned at Study-Site	CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Enrolled to Total Planned at Study-Site",2) as char(40)))
- Study-Site Metrics	% Randomized vs. Planned - Study-Site	CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Randomized vs. Planned - Study-Site",2) as char(40)))
- Study-Site Original Planned Dates	Planned 1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Latest Estimated Dates	Planned LE 1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Metrics	1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Original Planned Dates	[Planned 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))

Table A–140 (Cont.) Study-Site List with Indicators - Recruitment Detail View (Report CDA-CO-207C)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Metrics	1st Subject Randomized Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Original Planned Dates	[Planned 1st Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study-Site Metrics	1st Subject 1st Visit Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject 1st Visit Date" as char(40)))

Table A–140 (Cont.) Study-Site List with Indicators - Recruitment Detail View (Report CDA-CO-207C)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Original Planned Dates	[Planned 1st Subject Screened Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Screened Date]")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Screened Date" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject Screened Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Screened Date]")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Screened Date" as char(40)))
- Study-Site Metrics	1st Subject Screened Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Screened Date]")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Screened Date" as char(40)))
- Study-Site Original Planned Dates	Planned Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))

Table A–140 (Cont.) Study-Site List with Indicators - Recruitment Detail View (Report CDA-CO-207C)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	Planned LE Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	Latest Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))

Table A–140 (Cont.) Study-Site List with Indicators - Recruitment Detail View (Report CDA-CO-207C)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Metrics	Latest Subject Randomized Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Metrics	[Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))

Table A–140 (Cont.) Study-Site List with Indicators - Recruitment Detail View (Report CDA-CO-207C)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Original Planned Dates	[Planned Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study-Site Metrics	Latest Subject 1st Visit Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))

Table A–140 (Cont.) Study-Site List with Indicators - Recruitment Detail View (Report CDA-CO-207C)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Metrics	[Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject Last Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Last Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))

Table A–140 (Cont.) Study-Site List with Indicators - Recruitment Detail View (Report CDA-CO-207C)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Metrics	Latest Subject Latest Visit Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Site Metrics	[Last Subject Last Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))

Study-Site List with Indicators - Retention Detail View (Report CDA-CO-207D)

Lists 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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study Region Overview** dashboard, **Study-Site Milestones** page
- **CRA, Study-Site Milestones** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Overview Dashboard
- Study-Site Team Member List (Report CDA-CO-201)

Reports Referencing This Report

- Detailed Study Milestones Report (Report CDA-CO-102)
- Study List - Initiation Details (Report CDA-CO-305)

Column Descriptions

The table describes the columns in the Study-Site List with Indicators - Retention Detail View report.

Table A–141 Study-Site List with Indicators - Retention Detail View (Report CDA-CO-207D)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study	Study-Site.Study
Study-Site	Study Region	Study-Site.Study Region
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Study-Site Status	Study-Site.Study-Site Status
Study-Site	CRA	Study-Site.CRA
- Study-Site Metrics	Milestone Flag	"- Study-Site Metrics"."Milestone Flag"
- Study-Site Metrics	Milestone High Level Reason	"- Study-Site Metrics"."Milestone High Level Reason"
- Study-Site Metrics	Milestone Detail Reason	"- Study-Site Metrics"."Milestone Detail Reason"
- Study-Site Study-Site Targets	Expected Early Termination Rate	CONCAT('Expected:',cast(MAX("- Study-Site Study-Site Targets"."Expected Early Termination Rate") as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site",2)as char(40)))

Table A–141 (Cont.) Study-Site List with Indicators - Retention Detail View (Report CDA-CO-207D)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Metrics	% Subjects Early Terminated for Study-Site	CONCAT('Expected:',cast(MAX("- Study-Site Study-Site Targets"."Expected Early Termination Rate") as char(40)))||' '||CONCAT(' Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site",2)as char(40)))
- Study-Site Original Planned Dates	Planned 1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Latest Estimated Dates	Planned LE 1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Metrics	1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Original Planned Dates	[Planned 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))

Table A–141 (Cont.) Study-Site List with Indicators - Retention Detail View (Report CDA-CO-207D)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Metrics	1st Subject Randomized Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Original Planned Dates	Planned Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Latest Estimated Dates	Planned LE Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))

Table A–141 (Cont.) Study-Site List with Indicators - Retention Detail View (Report CDA-CO-207D)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Metrics	Latest Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))

Study-Site List with Indicators - Site Start Up Detail View (Report CDA-CO-207E)

Lists 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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study Region Overview** dashboard, **Study-Site Milestones** page
- **CRA, Study-Site Milestones** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Overview Dashboard
- Study-Site Team Member List (Report CDA-CO-201)

Reports Referencing This Report

- Detailed Study Milestones Report (Report CDA-CO-102)
- Study List - Initiation Details (Report CDA-CO-305)

Column Descriptions

The table describes the columns in the Study-Site List with Indicators - Site Start Up Detail View report.

Table A–142 Study-Site List with Indicators - Site Start Up Detail View (Report CDA-CO-207E)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study	Study-Site.Study

Table A–142 (Cont.) Study-Site List with Indicators - Site Start Up Detail View (Report CDA-CO-207E)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study Region	Study-Site.Study Region
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Study-Site Status	Study-Site.Study-Site Status
Study-Site	CRA	Study-Site.CRA
- Study-Site Metrics	Milestone Flag	"- Study-Site Metrics"."Milestone Flag"
- Study-Site Metrics	Milestone High Level Reason	"- Study-Site Metrics"."Milestone High Level Reason"
- Study-Site Metrics	Milestone Detail Reason	"- Study-Site Metrics"."Milestone Detail Reason"
- Document Metrics	# Documents Outstanding	"- Document Metrics"."# Documents Outstanding"
- Study-Site Original Planned Dates	[Planned Site Initiated Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40))||' '||CONCAT(' Actual:',cast(MIN("- Study-Site Key Dates"."Site Initiated Date") as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Site Initiated Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40))||' '||CONCAT(' Actual:',cast(MIN("- Study-Site Key Dates"."Site Initiated Date") as char(40)))
- Study-Site Key Dates	Site Initiated Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40))||' '||CONCAT(' Actual:',cast(MIN("- Study-Site Key Dates"."Site Initiated Date") as char(40)))

Table A–142 (Cont.) Study-Site List with Indicators - Site Start Up Detail View (Report CDA-CO-207E)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Original Planned Dates	[Planned IRB/EC Submission Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MIN("- Study-Site Key Dates"."[Initial IRB/EC Submission Date]") as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE IRB/EC Submission Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MIN("- Study-Site Key Dates"."[Initial IRB/EC Submission Date]") as char(40)))
- Study-Site Key Dates	[Initial IRB/EC Submission Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MIN("- Study-Site Key Dates"."[Initial IRB/EC Submission Date]") as char(40)))
- Study-Site Original Planned Dates	[Planned Initial IRB/EC Approval Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Key Dates"."Initial IRB/EC Approval Date" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Initial IRB/EC Approval Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Key Dates"."Initial IRB/EC Approval Date" as char(40)))

Table A–142 (Cont.) Study-Site List with Indicators - Site Start Up Detail View (Report CDA-CO-207E)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Key Dates	Initial IRB/EC Approval Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Key Dates"."Initial IRB/EC Approval Date" as char(40)))
- Study-Site Original Planned Dates	[Planned Critical Document Package Completed Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."[Critical Document Package Completed Date]") as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Critical Document Package Completed Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."[Critical Document Package Completed Date]") as char(40)))
- Study-Site Key Dates	[Critical Document Package Completed Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."[Critical Document Package Completed Date]") as char(40)))

Study-Site List with Indicators - Study Close Detail View (Report CDA-CO-207F)

Lists 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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study Region Overview** dashboard, **Study-Site Milestones** page
- **CRA, Study-Site Milestones** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Overview Dashboard
- Study-Site Team Member List (Report CDA-CO-201)

Reports Referencing This Report

- Detailed Study Milestones Report (Report CDA-CO-102)
- Study List - Initiation Details (Report CDA-CO-305)

Column Descriptions

The table describes the columns in the Study-Site List with Indicators - Study Close Detail View report.

Table A–143 Study-Site List with Indicators - Study Close Detail View (Report CDA-CO-207F)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study	Study-Site.Study

Table A–143 (Cont.) Study-Site List with Indicators - Study Close Detail View (Report CDA-CO-207F)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study Region	Study-Site.Study Region
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Study-Site Status	Study-Site.Study-Site Status
Study-Site	CRA	Study-Site.CRA
- Study-Site Metrics	Milestone Flag	"- Study-Site Metrics"."Milestone Flag"
- Study-Site Metrics	Milestone High Level Reason	"- Study-Site Metrics"."Milestone High Level Reason"
- Study-Site Metrics	Milestone Detail Reason	"- Study-Site Metrics"."Milestone Detail Reason"
- Study-Site Metrics	% Enrolled to Total Planned at Study-Site	CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Enrolled to Total Planned at Study-Site",2) as char(40)))
- Study-Site Study-Site Targets	Expected Early Termination Rate	CONCAT('Expected:',cast(MAX("- Study-Site Study-Site Targets"."Expected Early Termination Rate") as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site",2)as char(40)))
- Study-Site Metrics	% Subjects Early Terminated for Study-Site	CONCAT('Expected:',cast(MAX("- Study-Site Study-Site Targets"."Expected Early Termination Rate") as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site",2)as char(40)))
- Study-Site Original Planned Dates	Planned Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT('Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))

Table A–143 (Cont.) Study-Site List with Indicators - Study Close Detail View (Report CDA-CO-207F)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	Planned LE Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	Latest Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))

Table A–143 (Cont.) Study-Site List with Indicators - Study Close Detail View (Report CDA-CO-207F)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Metrics	Latest Subject Randomized Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Metrics	[Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))

Table A–143 (Cont.) Study-Site List with Indicators - Study Close Detail View (Report CDA-CO-207F)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Original Planned Dates	[Planned Last Subject Last Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Last Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Site Metrics	Latest Subject Latest Visit Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))

Table A–143 (Cont.) Study-Site List with Indicators - Study Close Detail View (Report CDA-CO-207F)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Metrics	[Last Subject Last Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40))||' '||CONCAT('LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40))||' '||CONCAT('Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40))||' '||CONCAT('Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Received CRFs	# CRFs Awaiting Entry Completion	"- Received CRFs"."# CRFs Awaiting Entry Completion"
- Received CRFs	# eCRFs To Be Approved	"- Received CRFs"."# eCRFs To Be Approved"
- Received CRFs	# eCRFs To be Verified	"- Received CRFs"."# eCRFs To be Verified"
- Received CRFs	# CRFs Soft- Locked	"- Received CRFs"."# CRFs Soft-Locked"
- Received CRFs	% CRFs Soft Locked / Entry Complete	"- Received CRFs"."% CRFs Soft Locked / Entry Complete"
- Received CRFs	# CRFs Hard-Locked	"- Received CRFs"."# CRFs Hard-Locked"
- Received CRFs	% CRFs Hard Locked / Entry Complete	"- Received CRFs"."% CRFs Hard Locked / Entry Complete"
- Study Original Planned Dates	[Planned Database Lock Date]	CONCAT('Planned:',cast(MAX("- Study Original Planned Dates"."[Planned Database Lock Date]")as char(40))) || ' ' ||CONCAT('LE:',cast(MAX("- Study Latest Estimated Dates"."[Planned LE Database Lock Date]") as char(40))) || ' ' ||CONCAT('Actual:',cast(MAX("- Study Key Dates"."Database Lock Date") as char(40)))
- Study Latest Estimated Dates	[Planned LE Database Lock Date]	CONCAT('Planned:',cast(MAX("- Study Original Planned Dates"."[Planned Database Lock Date]")as char(40))) || ' ' ||CONCAT('LE:',cast(MAX("- Study Latest Estimated Dates"."[Planned LE Database Lock Date]") as char(40))) || ' ' ||CONCAT('Actual:',cast(MAX("- Study Key Dates"."Database Lock Date") as char(40)))

Table A–143 (Cont.) Study-Site List with Indicators - Study Close Detail View (Report CDA-CO-207F)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Key Dates	Database Lock Date	CONCAT('Planned:',cast(MAX("- Study Original Planned Dates"."[Planned Database Lock Date]")as char(40))) || ' ' ||CONCAT('LE:',cast(MAX("- Study Latest Estimated Dates"."[Planned LE Database Lock Date]") as char(40))) || ' ' ||CONCAT('Actual:',cast(MAX("- Study Key Dates"."Database Lock Date") as char(40)))
- Study Original Planned Dates	[Planned Clinical Study Report Date]	CONCAT('Planned:',cast(MAX("- Study Original Planned Dates"."[Planned Clinical Study Report Date]")as char(40))) || ' ' ||CONCAT('LE:',cast(MAX("- Study Latest Estimated Dates"."[Planned LE Clinical Study Report Date]") as char(40))) || ' ' ||CONCAT('Actual:',cast(MAX("- Study Key Dates"."[Clinical Study Report Date]") as char(40)))
- Study Latest Estimated Dates	[Planned LE Clinical Study Report Date]	CONCAT('Planned:',cast(MAX("- Study Original Planned Dates"."[Planned Clinical Study Report Date]")as char(40))) || ' ' ||CONCAT('LE:',cast(MAX("- Study Latest Estimated Dates"."[Planned LE Clinical Study Report Date]") as char(40))) || ' ' ||CONCAT('Actual:',cast(MAX("- Study Key Dates"."[Clinical Study Report Date]") as char(40)))
- Study Key Dates	[Clinical Study Report Date]	CONCAT('Planned:',cast(MAX("- Study Original Planned Dates"."[Planned Clinical Study Report Date]")as char(40))) || ' ' ||CONCAT('LE:',cast(MAX("- Study Latest Estimated Dates"."[Planned LE Clinical Study Report Date]") as char(40))) || ' ' ||CONCAT('Actual:',cast(MAX("- Study Key Dates"."[Clinical Study Report Date]") as char(40)))

Study-Site List with Indicators - Summary View (Report CDA-CO-207G)

Lists 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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study Region Overview** dashboard, **Study-Site Milestones** page
- **CRA, Study-Site Milestones** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Overview Dashboard
- Study-Site Team Member List (Report CDA-CO-201)

Reports Referencing This Report

- Detailed Study Milestones Report (Report CDA-CO-102)
- Study List - Initiation Details (Report CDA-CO-305)

Column Descriptions

The table describes the columns in the Study-Site List with Indicators - Summary View report.

Table A–144 Study-Site List with Indicators - Summary View (Report CDA-CO-207G)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study	Study-Site.Study
Study-Site	Study Region	Study-Site.Study Region
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Study-Site Status	Study-Site.Study-Site Status
Study-Site	CRA	Study-Site.CRA
- Study-Site Metrics	Milestone Flag	"- Study-Site Metrics"."Milestone Flag"

Table A–144 (Cont.) Study-Site List with Indicators - Summary View (Report

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Metrics	Milestone High Level Reason	"- Study-Site Metrics"."Milestone High Level Reason"
- Study-Site Metrics	Milestone Detail Reason	"- Study-Site Metrics"."Milestone Detail Reason"
- Study-Site Metrics	Recruitment Flag	"- Study-Site Metrics"."Recruitment Flag"
- Study-Site Metrics	Recruitment High Level Reason	"- Study-Site Metrics"."Recruitment High Level Reason"
- Study-Site Metrics	Recruitment Detail Reason	"- Study-Site Metrics"."Recruitment Detail Reason"
- Study-Site Metrics	Retention Flag	"- Study-Site Metrics"."Retention Flag"
- Study-Site Metrics	Retention High Level Reason	"- Study-Site Metrics"."Retention High Level Reason"
- Study Targets	[Expected Screen Failure Rate]	CONCAT('Expected:',cast(MAX(" - Study Targets"."[Expected Screen Failure Rate]") as char(40)))||' '||CONCAT(' Actual:' , cast(ROUND("- Study-Site Metrics"."Screen Failure Rate",2) as char(40)))
- Study-Site Metrics	Screen Failure Rate	CONCAT('Expected:',cast(MAX(" - Study Targets"."[Expected Screen Failure Rate]") as char(40)))||' '||CONCAT(' Actual:' , cast(ROUND("- Study-Site Metrics"."Screen Failure Rate",2) as char(40)))
- Study-Site Metrics	% Enrolled to Total Planned at Study-Site	CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Enrolled to Total Planned at Study-Site",2) as char(40)))
- Study-Site Study-Site Targets	Expected Early Termination Rate	CONCAT('Expected:',cast(MAX(" - Study-Site Study-Site Targets"."Expected Early Termination Rate") as char(40)))||' '||CONCAT(' Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site",2)as char(40)))
- Study-Site Metrics	% Subjects Early Terminated for Study-Site	CONCAT('Expected:',cast(MAX(" - Study-Site Study-Site Targets"."Expected Early Termination Rate") as char(40)))||' '||CONCAT(' Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site",2)as char(40)))
- Study-Site Metrics	Next Site Visit Date	"- Study-Site Metrics"."Next Site Visit Date"

Table A–144 (Cont.) Study-Site List with Indicators - Summary View (Report

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Original Planned Dates	Planned 1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Latest Estimated Dates	Planned LE 1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Metrics	1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Original Planned Dates	Planned Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))

Table A–144 (Cont.) Study-Site List with Indicators - Summary View (Report

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	Planned LE Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	Latest Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	# Days Since Last Enrolllment for Study-Site	TRUNCATE("- Study-Site Metrics"."# Days Since Last Enrolllment for Study-Site",0)
- Study-Site Original Planned Dates	[Planned Site Initiated Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MIN("- Study-Site Key Dates"."Site Initiated Date") as char(40)))

Table A–144 (Cont.) Study-Site List with Indicators - Summary View (Report

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE Site Initiated Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40))||' '||CONCAT(' Actual:',cast(MIN("- Study-Site Key Dates"."Site Initiated Date") as char(40)))
- Study-Site Key Dates	Site Initiated Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40))||' '||CONCAT(' Actual:',cast(MIN("- Study-Site Key Dates"."Site Initiated Date") as char(40)))
- Study-Site Metrics	Next Site Visit Type	"- Study-Site Metrics"."Next Site Visit Type"
- Study-Site Metrics	# Subjects Enrolled Since Latest Site Visit	"- Study-Site Metrics"."# Subjects Enrolled Since Latest Site Visit"

Study-Site Milestones with Indicators (CRA) - Monitoring View (Report CDA-CO-205A)

Lists study-sites including key monitoring metrics as well as progress tracking for site monitoring. This report indicates which study-sites require action, and why.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **CRA** dashboard, **Study-Site Milestones** page
- **Study Region Overview** dashboard, **Study-Site Milestones** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Team Member List (Report CDA-CO-201)

Reports Referencing This Report

- Study-Sites with Red or Yellow Performance Flag (Report CDA-CO-204)

Column Descriptions

The table describes the columns in the Study-Site Milestones with Indicators (CRA) - Monitoring View report.

Table A–145 Study-Site Milestones with Indicators (CRA) - Monitoring View (Report CDA-CO-205A)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Study	Study-Site.Study
Study-Site	Study Region	Study-Site.Study Region
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Status	Study-Site.Study-Site Status
NA	Navigate to Detail	NA
- Study-Site Metrics	Next Site Visit Date	"- Study-Site Metrics"."Next Site Visit Date"
- Study-Site Metrics	Next Site Visit Type	"- Study-Site Metrics"."Next Site Visit Type"
- Study-Site Metrics	Latest Site Visit Completed Date	"- Study-Site Metrics"."Latest Site Visit Completed Date"
- Study-Site Metrics	Latest Site Visit Type	"- Study-Site Metrics"."Latest Site Visit Type"
- Study-Site Metrics	# Days Since Latest Site Visit	TRUNCATE("- Study-Site Metrics"."# Days Since Latest Site Visit",0)
- Study-Site Metrics	# Visit Reports Awaiting Completion	"- Study-Site Metrics"."# Visit Reports Awaiting Completion"
- Study-Site Metrics	[# Visit Reports Awaiting Approval]	"- Study-Site Metrics"."[# Visit Reports Awaiting Approval]"
- Site Visit Metrics	# Outstanding Follow Up Items	"- Site Visit Metrics"."# Outstanding Follow Up Items"
- Study-Site Metrics	# Subjects Enrolled Since Latest Site Visit	"- Study-Site Metrics"."# Subjects Enrolled Since Latest Site Visit"

Study-Site Milestones with Indicators (CRA) - Recruitment Detail View (Report CDA-CO-205B)

Lists 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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **CRA** dashboard, **Study-Site Milestones** page
- **Study Region Overview** dashboard, **Study-Site Milestones** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Team Member List (Report CDA-CO-201)

Reports Referencing This Report

- Study-Sites with Red or Yellow Performance Flag (Report CDA-CO-204)

Column Descriptions

The table describes the columns in the Study-Site Milestones with Indicators (CRA) - Recruitment Detail View report.

Table A–146 Study-Site Milestones with Indicators (CRA) - Recruitment Detail View (Report CDA-CO-205B)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study-Site	Study	Study-Site.Study
Study-Site	Study Region	Study-Site.Study Region
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Status	Study-Site.Study-Site Status

Table A–146 (Cont.) Study-Site Milestones with Indicators (CRA) - Recruitment Detail View (Report CDA-CO-205B)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	Navigate to Detail	NA
- Study-Site Metrics	Recruitment Flag	"- Study-Site Metrics"."Recruitment Flag"
- Study-Site Metrics	Recruitment High Level Reason	"- Study-Site Metrics"."Recruitment High Level Reason"
- Study-Site Metrics	Recruitment Detail Reason	"- Study-Site Metrics"."Recruitment Detail Reason"
- Study-Site Metrics	Milestone Flag	"- Study-Site Metrics"."Milestone Flag"
- Study-Site Metrics	Milestone High Level Reason	"- Study-Site Metrics"."Milestone High Level Reason"
- Study-Site Metrics	Milestone Detail Reason	"- Study-Site Metrics"."Milestone Detail Reason"
- Study Targets	[Expected Screen Failure Rate]	CONCAT('Expected:',cast(MAX(" - Study Targets"."[Expected Screen Failure Rate]") as char(40)))||' '||CONCAT(' Actual:' , cast(ROUND("- Study-Site Metrics"."Screen Failure Rate",2) as char(40)))
- Study-Site Metrics	Screen Failure Rate	CONCAT('Expected:',cast(MAX(" - Study Targets"."[Expected Screen Failure Rate]") as char(40)))||' '||CONCAT(' Actual:' , cast(ROUND("- Study-Site Metrics"."Screen Failure Rate",2) as char(40)))
- Study-Site Metrics	% Enrolled to Total Planned at Study-Site	CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Enrolled to Total Planned at Study-Site",2) as char(40)))
- Study-Site Metrics	% Randomized vs. Planned - Study-Site	CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Randomized vs. Planned - Study-Site",2) as char(40)))
- Study-Site Original Planned Dates	Planned 1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))

Table A–146 (Cont.) Study-Site Milestones with Indicators (CRA) - Recruitment Detail View (Report CDA-CO-205B)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	Planned LE 1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Metrics	1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Original Planned Dates	[Planned 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Metrics	1st Subject Randomized Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))

Table A–146 (Cont.) Study-Site Milestones with Indicators (CRA) - Recruitment Detail View (Report CDA-CO-205B)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Original Planned Dates	[Planned 1st Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study-Site Metrics	1st Subject 1st Visit Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study-Site Original Planned Dates	[Planned 1st Subject Screened Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Screened Date]")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Screened Date" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject Screened Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Screened Date]")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Screened Date" as char(40)))

Table A–146 (Cont.) Study-Site Milestones with Indicators (CRA) - Recruitment Detail View (Report CDA-CO-205B)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	1st Subject Screened Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Screened Date]")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Screened Date" as char(40)))
- Study-Site Original Planned Dates	Planned Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Latest Estimated Dates	Planned LE Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	Latest Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))

Table A–146 (Cont.) Study-Site Milestones with Indicators (CRA) - Recruitment Detail View (Report CDA-CO-205B)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))

Table A–146 (Cont.) Study-Site Milestones with Indicators (CRA) - Recruitment Detail View (Report CDA-CO-205B)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	Latest Subject Randomized Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Metrics	[Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))

Table A–146 (Cont.) Study-Site Milestones with Indicators (CRA) - Recruitment Detail View (Report CDA-CO-205B)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study-Site Metrics	Latest Subject 1st Visit Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study-Site Metrics	[Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))

Table A–146 (Cont.) Study-Site Milestones with Indicators (CRA) - Recruitment Detail View (Report CDA-CO-205B)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Original Planned Dates	[Planned Last Subject Last Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Last Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Site Metrics	Latest Subject Latest Visit Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))

Table A–146 (Cont.) Study-Site Milestones with Indicators (CRA) - Recruitment Detail View (Report CDA-CO-205B)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	[Last Subject Last Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT('Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT('Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))

Study-Site Milestones with Indicators (CRA) - Retention Detail View (Report CDA-CO-205C)

Lists 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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **CRA** dashboard, **Study-Site Milestones** page
- **Study Region Overview** dashboard, **Study-Site Milestones** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Team Member List (Report CDA-CO-201)

Reports Referencing This Report

- Study-Sites with Red or Yellow Performance Flag (Report CDA-CO-204)

Column Descriptions

The table describes the columns in the Study-Site Milestones with Indicators (CRA) - Retention Detail View report.

Table A–147 Study-Site Milestones with Indicators (CRA) - Retention Detail View (Report CDA-CO-205C)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study-Site	Study	Study-Site.Study
Study-Site	Study Region	Study-Site.Study Region
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Status	Study-Site.Study-Site Status
NA	Navigate to Detail	NA
- Study-Site Metrics	Retention Flag	"- Study-Site Metrics"."Retention Flag"
- Study-Site Metrics	Retention High Level Reason	"- Study-Site Metrics"."Retention High Level Reason"
- Study-Site Metrics	Milestone Flag	"- Study-Site Metrics"."Milestone Flag"
- Study-Site Metrics	Milestone High Level Reason	"- Study-Site Metrics"."Milestone High Level Reason"
- Study-Site Metrics	Milestone Detail Reason	"- Study-Site Metrics"."Milestone Detail Reason"
- Study-Site Study-Site Targets	Expected Early Termination Rate	CONCAT('Expected:',cast(MAX("- Study-Site Study-Site Targets"."Expected Early Termination Rate") as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site",2)as char(40)))
- Study-Site Metrics	% Subjects Early Terminated for Study-Site	CONCAT('Expected:',cast(MAX("- Study-Site Study-Site Targets"."Expected Early Termination Rate") as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site",2)as char(40)))

Table A–147 (Cont.) Study-Site Milestones with Indicators (CRA) - Retention Detail View (Report CDA-CO-205C)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Original Planned Dates	Planned 1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Latest Estimated Dates	Planned LE 1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Metrics	1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Original Planned Dates	[Planned 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))

Table A–147 (Cont.) Study-Site Milestones with Indicators (CRA) - Retention Detail View (Report CDA-CO-205C)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	1st Subject Randomized Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Original Planned Dates	Planned Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Latest Estimated Dates	Planned LE Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	Latest Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))

Table A–147 (Cont.) Study-Site Milestones with Indicators (CRA) - Retention Detail View (Report CDA-CO-205C)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))

Table A–147 (Cont.) Study-Site Milestones with Indicators (CRA) - Retention Detail View (Report CDA-CO-205C)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	Latest Subject Randomized Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Metrics	[Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))

Study-Site Milestones with Indicators (CRA) - Site Start Up Detail View (Report CDA-CO-205D)

Lists 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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **CRA** dashboard, **Study-Site Milestones** page

- **Study Region Overview** dashboard, **Study-Site Milestones** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Team Member List (Report CDA-CO-201)

Reports Referencing This Report

- Study-Sites with Red or Yellow Performance Flag (Report CDA-CO-204)

Column Descriptions

The table describes the columns in the Study-Site Milestones with Indicators (CRA) - Site Start Up Detail View report.

Table A–148 Study-Site Milestones with Indicators (CRA) - Site Start Up Detail View (Report CDA-CO-205D)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study-Site	Study	Study-Site.Study
Study-Site	Study Region	Study-Site.Study Region
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Status	Study-Site.Study-Site Status
NA	Navigate to Detail	NA
- Study-Site Metrics	Milestone Flag	"- Study-Site Metrics"."Milestone Flag"
- Study-Site Metrics	Milestone High Level Reason	"- Study-Site Metrics"."Milestone High Level Reason"
- Study-Site Metrics	Milestone Detail Reason	"- Study-Site Metrics"."Milestone Detail Reason"
- Document Metrics	# Documents Outstanding	"- Document Metrics"."# Documents Outstanding"
- Study-Site Original Planned Dates	[Planned Site Initiated Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40)))||' '||CONCAT('Actual:',cast(MAX("- Study-Site Key Dates"."Site Initiated Date") as char(40)))

Table A–148 (Cont.) Study-Site Milestones with Indicators (CRA) - Site Start Up Detail View (Report CDA-CO-205D)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE Site Initiated Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."Site Initiated Date") as char(40)))
- Study-Site Key Dates	Site Initiated Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."Site Initiated Date") as char(40)))
- Study-Site Original Planned Dates	[Planned IRB/EC Submission Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MIN("- Study-Site Key Dates"."[Initial IRB/EC Submission Date]") as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE IRB/EC Submission Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MIN("- Study-Site Key Dates"."[Initial IRB/EC Submission Date]") as char(40)))
- Study-Site Key Dates	[Initial IRB/EC Submission Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MIN("- Study-Site Key Dates"."[Initial IRB/EC Submission Date]") as char(40)))

Table A–148 (Cont.) Study-Site Milestones with Indicators (CRA) - Site Start Up Detail View (Report CDA-CO-205D)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Original Planned Dates	[Planned Initial IRB/EC Approval Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Key Dates"."Initial IRB/EC Approval Date" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Initial IRB/EC Approval Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Key Dates"."Initial IRB/EC Approval Date" as char(40)))
- Study-Site Key Dates	Initial IRB/EC Approval Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Key Dates"."Initial IRB/EC Approval Date" as char(40)))
- Study-Site Original Planned Dates	[Planned Critical Document Package Completed Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."[Critical Document Package Completed Date]") as char(40)))

Table A–148 (Cont.) Study-Site Milestones with Indicators (CRA) - Site Start Up Detail View (Report CDA-CO-205D)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE Critical Document Package Completed Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."[Critical Document Package Completed Date]") as char(40)))
- Study-Site Key Dates	[Critical Document Package Completed Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."[Critical Document Package Completed Date]") as char(40)))

Study-Site Milestones with Indicators (CRA) - Study Close Detail View (Report CDA-CO-205E)

Lists 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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **CRA** dashboard, **Study-Site Milestones** page
- **Study Region Overview** dashboard, **Study-Site Milestones** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Team Member List (Report CDA-CO-201)

Reports Referencing This Report

- Study-Sites with Red or Yellow Performance Flag (Report CDA-CO-204)

Column Descriptions

The table describes the columns in the Study-Site Milestones with Indicators (CRA) - Study Close Detail View report.

Table A–149 Study-Site Milestones with Indicators (CRA) - Study Close Detail View (Report CDA-CO-205E)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study-Site	Study	Study-Site.Study
Study-Site	Study Region	Study-Site.Study Region
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Status	Study-Site.Study-Site Status
NA	Navigate to Detail	NA
- Study-Site Metrics	Milestone Flag	"- Study-Site Metrics"."Milestone Flag"
- Study-Site Metrics	Milestone Detail Reason	"- Study-Site Metrics"."Milestone Detail Reason"
- Study-Site Metrics	% Enrolled to Total Planned at Study-Site	CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Enrolled to Total Planned at Study-Site",2) as char(40)))
- Study-Site Study-Site Targets	Expected Early Termination Rate	CONCAT('Expected:',cast(MAX("- Study-Site Study-Site Targets"."Expected Early Termination Rate") as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site",2)as char(40)))

Table A–149 (Cont.) Study-Site Milestones with Indicators (CRA) - Study Close Detail View (Report CDA-CO-205E)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	% Subjects Early Terminated for Study-Site	CONCAT('Expected:',cast(MAX("- Study-Site Study-Site Targets"."Expected Early Termination Rate") as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site",2)as char(40)))
- Study-Site Original Planned Dates	Planned Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT('Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Latest Estimated Dates	Planned LE Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT('Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	Latest Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT('Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT('Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))

Table A–149 (Cont.) Study-Site Milestones with Indicators (CRA) - Study Close Detail View (Report CDA-CO-205E)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))

Table A–149 (Cont.) Study-Site Milestones with Indicators (CRA) - Study Close Detail View (Report CDA-CO-205E)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	Latest Subject Randomized Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Metrics	[Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject Last Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))

Table A–149 (Cont.) Study-Site Milestones with Indicators (CRA) - Study Close Detail View (Report CDA-CO-205E)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Last Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Site Metrics	Latest Subject Latest Visit Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Site Metrics	[Last Subject Last Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study Original Planned Dates	[Planned Database Lock Date]	CONCAT('Planned:',cast(MAX("- Study Original Planned Dates"."[Planned Database Lock Date]")as char(40))) || ' ' ||CONCAT('LE:',cast(MAX("- Study Latest Estimated Dates"."[Planned LE Database Lock Date]") as char(40))) || ' ' ||CONCAT('Actual:',cast(MAX("- Study Key Dates"."Database Lock Date") as char(40)))

Table A–149 (Cont.) Study-Site Milestones with Indicators (CRA) - Study Close Detail View (Report CDA-CO-205E)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study Latest Estimated Dates	[Planned LE Database Lock Date]	CONCAT('Planned:',cast(MAX("- Study Original Planned Dates"."[Planned Database Lock Date]")as char(40))) || ' ' ||CONCAT('LE:',cast(MAX("- Study Latest Estimated Dates"."[Planned LE Database Lock Date]") as char(40))) || ' ' ||CONCAT('Actual:',cast(MAX("- Study Key Dates"."Database Lock Date") as char(40)))
- Study Key Dates	Database Lock Date	CONCAT('Planned:',cast(MAX("- Study Original Planned Dates"."[Planned Database Lock Date]")as char(40))) || ' ' ||CONCAT('LE:',cast(MAX("- Study Latest Estimated Dates"."[Planned LE Database Lock Date]") as char(40))) || ' ' ||CONCAT('Actual:',cast(MAX("- Study Key Dates"."Database Lock Date") as char(40)))
- Study Original Planned Dates	[Planned Clinical Study Report Date]	CONCAT('Planned:',cast(MAX("- Study Original Planned Dates"."[Planned Clinical Study Report Date]")as char(40))) || ' ' ||CONCAT('LE:',cast(MAX("- Study Latest Estimated Dates"."[Planned LE Clinical Study Report Date]") as char(40))) || ' ' ||CONCAT('Actual:',cast(MAX("- Study Key Dates"."[Clinical Study Report Date]") as char(40)))
- Study Latest Estimated Dates	[Planned LE Clinical Study Report Date]	CONCAT('Planned:',cast(MAX("- Study Original Planned Dates"."[Planned Clinical Study Report Date]")as char(40))) || ' ' ||CONCAT('LE:',cast(MAX("- Study Latest Estimated Dates"."[Planned LE Clinical Study Report Date]") as char(40))) || ' ' ||CONCAT('Actual:',cast(MAX("- Study Key Dates"."[Clinical Study Report Date]") as char(40)))
- Study Key Dates	[Clinical Study Report Date]	CONCAT('Planned:',cast(MAX("- Study Original Planned Dates"."[Planned Clinical Study Report Date]")as char(40))) || ' ' ||CONCAT('LE:',cast(MAX("- Study Latest Estimated Dates"."[Planned LE Clinical Study Report Date]") as char(40))) || ' ' ||CONCAT('Actual:',cast(MAX("- Study Key Dates"."[Clinical Study Report Date]") as char(40)))

Study-Site Milestones with Indicators (CRA) - Summary View (Report CDA-CO-205F)

Lists 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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **CRA** dashboard, **Study-Site Milestones** page
- **Study Region Overview** dashboard, **Study-Site Milestones** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Team Member List (Report CDA-CO-201)

Reports Referencing This Report

- Study-Sites with Red or Yellow Performance Flag (Report CDA-CO-204)

Column Descriptions

The table describes the columns in the Study-Site Milestones with Indicators (CRA) - Summary View report.

Table A–150 Study-Site Milestones with Indicators (CRA) - Summary View (Report CDA-CO-205F)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study-Site	Study	Study-Site.Study
Study-Site	Study Region	Study-Site.Study Region
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #

Table A–150 (Cont.) Study-Site Milestones with Indicators (CRA) - Summary View (Report CDA-CO-205F)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Status	Study-Site.Study-Site Status
NA	Navigate to Detail	NA
- Study-Site Metrics	Recruitment Flag	"- Study-Site Metrics"."Recruitment Flag"
- Study-Site Metrics	Recruitment High Level Reason	"- Study-Site Metrics"."Recruitment High Level Reason"
- Study-Site Metrics	Retention Flag	"- Study-Site Metrics"."Retention Flag"
- Study-Site Metrics	Retention High Level Reason	"- Study-Site Metrics"."Retention High Level Reason"
- Study-Site Metrics	Milestone Flag	"- Study-Site Metrics"."Milestone Flag"
- Study-Site Metrics	Milestone High Level Reason	"- Study-Site Metrics"."Milestone High Level Reason"
- Study Targets	[Expected Screen Failure Rate]	CONCAT('Expected:',cast(MAX("- Study Targets"."[Expected Screen Failure Rate]") as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."Screen Failure Rate",2) as char(40)))
- Study-Site Metrics	Screen Failure Rate	CONCAT('Expected:',cast(MAX("- Study Targets"."[Expected Screen Failure Rate]") as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."Screen Failure Rate",2) as char(40)))
- Study-Site Metrics	% Enrolled to Total Planned at Study-Site	CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Enrolled to Total Planned at Study-Site",2) as char(40)))
- Study-Site Study-Site Targets	Expected Early Termination Rate	CONCAT('Expected:',cast(MAX("- Study-Site Study-Site Targets"."Expected Early Termination Rate") as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site",2)as char(40)))
- Study-Site Metrics	% Subjects Early Terminated for Study-Site	CONCAT('Expected:',cast(MAX("- Study-Site Study-Site Targets"."Expected Early Termination Rate") as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site",2)as char(40)))
- Study-Site Metrics	Next Site Visit Date	"- Study-Site Metrics"."Next Site Visit Date"
- Study-Site Metrics	Next Site Visit Type	"- Study-Site Metrics"."Next Site Visit Type"

Table A–150 (Cont.) Study-Site Milestones with Indicators (CRA) - Summary View (Report CDA-CO-205F)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Original Planned Dates	Planned 1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Latest Estimated Dates	Planned LE 1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Metrics	1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Original Planned Dates	Planned Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))

Table A–150 (Cont.) Study-Site Milestones with Indicators (CRA) - Summary View (Report CDA-CO-205F)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	Planned LE Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	Latest Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	# Days Since Last Enrolllment for Study-Site	TRUNCATE("- Study-Site Metrics"."# Days Since Last Enrolllment for Study-Site",0)
- Study-Site Original Planned Dates	[Planned Site Initiated Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."Site Initiated Date") as char(40)))

Table A–150 (Cont.) Study-Site Milestones with Indicators (CRA) - Summary View (Report CDA-CO-205F)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE Site Initiated Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."Site Initiated Date") as char(40)))
- Study-Site Key Dates	Site Initiated Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."Site Initiated Date") as char(40)))

Study-Site Milestones with Indicators (Single Study-Site) - Data Management View (Report CDA-CO-203A)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study-Site Overview** dashboard, **Study-Site Overview** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Study-Site Milestones with Indicators (Single Study-Site) - Data Management View report.

Table A–151 Study-Site Milestones with Indicators (Single Study-Site) - Data Management View (Report CDA-CO-203A)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Discrepancies	# Open Discrepancies	"- Discrepancies"."# Open Discrepancies"
- Discrepancies	# Total Discrepancies	"- Discrepancies"."# Total Discrepancies"
- Discrepancies	# Days Discrepancy Open	"- Discrepancies"."# Days Discrepancy Open"/"- Discrepancies"."# Total Discrepancies"
- Discrepancies	# Total Discrepancies	"- Discrepancies"."# Days Discrepancy Open"/"- Discrepancies"."# Total Discrepancies"
- Received CRFs	# CRFs Awaiting Entry Completion	"- Received CRFs"."# CRFs Awaiting Entry Completion"
- Received CRFs	# eCRFs To Be Approved	"- Received CRFs"."# eCRFs To Be Approved"
- Received CRFs	# eCRFs To be Verified	"- Received CRFs"."# eCRFs To be Verified"
- Received CRFs	# CRFs Soft- Locked	"- Received CRFs"."# CRFs Soft-Locked"
- Received CRFs	% CRFs Soft Locked / Entry Complete	"- Received CRFs"."% CRFs Soft Locked / Entry Complete"
- Received CRFs	# CRFs Hard-Locked	"- Received CRFs"."# CRFs Hard-Locked"
- Received CRFs	% CRFs Hard Locked / Entry Complete	"- Received CRFs"."% CRFs Hard Locked / Entry Complete"

Study-Site Milestones with Indicators (Single Study-Site) - Monitoring View (Report CDA-CO-203B)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study-Site Overview** dashboard, **Study-Site Overview** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Study-Site Milestones with Indicators (Single Study-Site) - Monitoring View report.

Table A–152 Study-Site Milestones with Indicators (Single Study-Site) - Monitoring View (Report CDA-CO-203B)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	Next Site Visit Date	"- Study-Site Metrics"."Next Site Visit Date"
- Study-Site Metrics	Next Site Visit Type	"- Study-Site Metrics"."Next Site Visit Type"
- Study-Site Metrics	Latest Site Visit Completed Date	"- Study-Site Metrics"."Latest Site Visit Completed Date"
- Study-Site Metrics	Latest Site Visit Type	"- Study-Site Metrics"."Latest Site Visit Type"
- Study-Site Metrics	# Days Since Latest Site Visit	TRUNCATE("- Study-Site Metrics"."# Days Since Latest Site Visit",0)
- Study-Site Metrics	Median # Days Between Site Visits	"- Study-Site Metrics"."Median # Days Between Site Visits"
- Study-Site Metrics	# Subjects Enrolled Since Latest Site Visit	"- Study-Site Metrics"."# Subjects Enrolled Since Latest Site Visit"

Table A–152 (Cont.) Study-Site Milestones with Indicators (Single Study-Site) - Monitoring View (Report CDA-CO-203B)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Discrepancies	# Open Discrepancies	"- Discrepancies"."# Open Discrepancies"
- Received CRFs	# eCRFs To Be Approved	"- Received CRFs"."# eCRFs To Be Approved"
- Received CRFs	# eCRFs To be Verified	"- Received CRFs"."# eCRFs To be Verified"
- Study-Site Metrics	# Visit Reports Awaiting Completion	"- Study-Site Metrics"."# Visit Reports Awaiting Completion"
- Study-Site Metrics	[# Visit Reports Awaiting Approval]	"- Study-Site Metrics"."[# Visit Reports Awaiting Approval]"
- Site Visit Metrics	# Outstanding Follow Up Items	"- Site Visit Metrics"."# Outstanding Follow Up Items"

Study-Site Milestones with Indicators (Single Study-Site) - Recruitment Detail View (Report CDA-CO-203C)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study-Site Overview** dashboard, **Study-Site Overview** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Study-Site Milestones with Indicators (Single Study-Site) - Recruitment Detail View report.

Table A–153 Study-Site Milestones with Indicators (Single Study-Site) - Recruitment Detail View (Report CDA-CO-203C)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	Recruitment Flag	"- Study-Site Metrics"."Recruitment Flag"
- Study-Site Metrics	Recruitment Detail Reason	"- Study-Site Metrics"."Recruitment Detail Reason"
- Study-Site Metrics	Milestone Flag	"- Study-Site Metrics"."Milestone Flag"
- Study-Site Metrics	Milestone Detail Reason	"- Study-Site Metrics"."Milestone Detail Reason"
- Study Targets	[Expected Screen Failure Rate]	CONCAT('Expected:',cast(MAX("- Study Targets"."[Expected Screen Failure Rate]") as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."Screen Failure Rate",2) as char(40)))
- Study-Site Metrics	Screen Failure Rate	CONCAT('Expected:',cast(MAX("- Study Targets"."[Expected Screen Failure Rate]") as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."Screen Failure Rate",2) as char(40)))
- Study-Site Metrics	% Enrolled to Total Planned at Study-Site	CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Enrolled to Total Planned at Study-Site",2) as char(40)))
- Study-Site Metrics	% Randomized vs. Planned - Study-Site	CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Randomized vs. Planned - Study-Site",2) as char(40)))
- Study-Site Original Planned Dates	Planned 1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT('Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))

Table A–153 (Cont.) Study-Site Milestones with Indicators (Single Study-Site) - Recruitment Detail View (Report CDA-CO-203C)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	Planned LE 1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Metrics	1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Original Planned Dates	[Planned 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Metrics	1st Subject Randomized Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))

Table A–153 (Cont.) Study-Site Milestones with Indicators (Single Study-Site) - Recruitment Detail View (Report CDA-CO-203C)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Original Planned Dates	[Planned 1st Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject 1st Visit Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study-Site Metrics	1st Subject 1st Visit Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject 1st Visit Date" as char(40)))
- Study-Site Original Planned Dates	[Planned 1st Subject Screened Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Screened Date]")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Screened Date" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject Screened Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Screened Date]")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Screened Date" as char(40)))

Table A–153 (Cont.) Study-Site Milestones with Indicators (Single Study-Site) - Recruitment Detail View (Report CDA-CO-203C)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	1st Subject Screened Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Screened Date]")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Screened Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Screened Date" as char(40)))
- Study-Site Original Planned Dates	Planned Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Latest Estimated Dates	Planned LE Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	Latest Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))

Table A–153 (Cont.) Study-Site Milestones with Indicators (Single Study-Site) - Recruitment Detail View (Report CDA-CO-203C)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))

Table A–153 (Cont.) Study-Site Milestones with Indicators (Single Study-Site) - Recruitment Detail View (Report CDA-CO-203C)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	Latest Subject Randomized Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Metrics	[Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))

Table A–153 (Cont.) Study-Site Milestones with Indicators (Single Study-Site) - Recruitment Detail View (Report CDA-CO-203C)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study-Site Metrics	Latest Subject 1st Visit Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))
- Study-Site Metrics	[Last Subject 1st Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject 1st Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject 1st Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject 1st Visit Date]" as char(40)))

Table A–153 (Cont.) Study-Site Milestones with Indicators (Single Study-Site) - Recruitment Detail View (Report CDA-CO-203C)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Original Planned Dates	[Planned Last Subject Last Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Last Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Site Metrics	Latest Subject Latest Visit Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))

Table A–153 (Cont.) Study-Site Milestones with Indicators (Single Study-Site) - Recruitment Detail View (Report CDA-CO-203C)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	[Last Subject Last Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))

Study-Site Milestones with Indicators (Single Study-Site) - Retention Detail View (Report CDA-CO-203D)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study-Site Overview** dashboard, **Study-Site Overview** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Study-Site Milestones with Indicators (Single Study-Site) - Retention Detail View report.

Table A–154 Study-Site Milestones with Indicators (Single Study-Site) - Retention Detail View (Report CDA-CO-203D)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	Retention Flag	"- Study-Site Metrics"."Retention Flag"
- Study-Site Metrics	Retention High Level Reason	"- Study-Site Metrics"."Retention High Level Reason"
- Study-Site Metrics	Milestone Flag	"- Study-Site Metrics"."Milestone Flag"
- Study-Site Metrics	Milestone Detail Reason	"- Study-Site Metrics"."Milestone Detail Reason"
- Study-Site Study-Site Targets	Expected Early Termination Rate	CONCAT('Expected:',cast(MAX("- Study-Site Study-Site Targets"."Expected Early Termination Rate") as char(40)))||' '||CONCAT(' Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site",2)as char(40)))
- Study-Site Metrics	% Subjects Early Terminated for Study-Site	CONCAT('Expected:',cast(MAX("- Study-Site Study-Site Targets"."Expected Early Termination Rate") as char(40)))||' '||CONCAT(' Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site",2)as char(40)))
- Study-Site Original Planned Dates	Planned 1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Latest Estimated Dates	Planned LE 1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))

Table A–154 (Cont.) Study-Site Milestones with Indicators (Single Study-Site) - Retention Detail View (Report CDA-CO-203D)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Original Planned Dates	[Planned 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE 1st Subject Randomized Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))
- Study-Site Metrics	1st Subject Randomized Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE 1st Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Randomized Date" as char(40)))

Table A–154 (Cont.) Study-Site Milestones with Indicators (Single Study-Site) - Retention Detail View (Report CDA-CO-203D)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Original Planned Dates	Planned Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Latest Estimated Dates	Planned LE Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	Latest Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))

Table A–154 (Cont.) Study-Site Milestones with Indicators (Single Study-Site) - Retention Detail View (Report CDA-CO-203D)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Original Planned Dates	[Planned Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Metrics	Latest Subject Randomized Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))

Table A–154 (Cont.) Study-Site Milestones with Indicators (Single Study-Site) - Retention Detail View (Report CDA-CO-203D)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	[Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT('LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT('Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT('Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))

Study-Site Milestones with Indicators (Single Study-Site) - Site Start Up Detail View (Report CDA-CO-203E)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study-Site Overview** dashboard, **Study-Site Overview** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Study-Site Milestones with Indicators (Single Study-Site) - Site Start Up Detail View report.

Table A–155 Study-Site Milestones with Indicators (Single Study-Site) - Site Start Up Detail View (Report CDA-CO-203E)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	Milestone Flag	"- Study-Site Metrics"."Milestone Flag"
- Study-Site Metrics	Milestone Detail Reason	"- Study-Site Metrics"."Milestone Detail Reason"
- Document Metrics	# Documents Outstanding	"- Document Metrics"."# Documents Outstanding"
- Study-Site Original Planned Dates	[Planned Site Initiated Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."Site Initiated Date") as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Site Initiated Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."Site Initiated Date") as char(40)))
- Study-Site Key Dates	Site Initiated Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."Site Initiated Date") as char(40)))

Table A–155 (Cont.) Study-Site Milestones with Indicators (Single Study-Site) - Site Start Up Detail View (Report CDA-CO-203E)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Original Planned Dates	[Planned IRB/EC Submission Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MIN("- Study-Site Key Dates"."[Initial IRB/EC Submission Date]") as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE IRB/EC Submission Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MIN("- Study-Site Key Dates"."[Initial IRB/EC Submission Date]") as char(40)))
- Study-Site Key Dates	[Initial IRB/EC Submission Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MIN("- Study-Site Key Dates"."[Initial IRB/EC Submission Date]") as char(40)))
- Study-Site Original Planned Dates	[Planned Initial IRB/EC Approval Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Key Dates"."Initial IRB/EC Approval Date"as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Initial IRB/EC Approval Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Key Dates"."Initial IRB/EC Approval Date"as char(40)))

Table A–155 (Cont.) Study-Site Milestones with Indicators (Single Study-Site) - Site Start Up Detail View (Report CDA-CO-203E)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Key Dates	Initial IRB/EC Approval Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Key Dates"."Initial IRB/EC Approval Date"as char(40)))
- Study-Site Original Planned Dates	[Planned Critical Document Package Completed Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."[Critical Document Package Completed Date]") as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Critical Document Package Completed Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."[Critical Document Package Completed Date]") as char(40)))
- Study-Site Key Dates	[Critical Document Package Completed Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."[Critical Document Package Completed Date]") as char(40)))

Study-Site Milestones with Indicators (Single Study-Site) - Study Close Detail View (Report CDA-CO-203F)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study-Site Overview** dashboard, **Study-Site Overview** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Study-Site Milestones with Indicators (Single Study-Site) - Study Close Detail View report.

Table A–156 Study-Site Milestones with Indicators (Single Study-Site) - Study Close Detail View (Report CDA-CO-203F)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	Milestone Flag	"- Study-Site Metrics"."Milestone Flag"
- Study-Site Metrics	Milestone Detail Reason	"- Study-Site Metrics"."Milestone Detail Reason"

Table A–156 (Cont.) Study-Site Milestones with Indicators (Single Study-Site) - Study Close Detail View (Report CDA-CO-203F)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	% Enrolled to Total Planned at Study-Site	CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Enrolled to Total Planned at Study-Site",2) as char(40)))
- Study-Site Study-Site Targets	Expected Early Termination Rate	CONCAT('Expected:',cast(MAX(" - Study-Site Study-Site Targets"."Expected Early Termination Rate") as char(40)))||' '||CONCAT(' Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site",2)as char(40)))
- Study-Site Metrics	% Subjects Early Terminated for Study-Site	CONCAT('Expected:',cast(MAX(" - Study-Site Study-Site Targets"."Expected Early Termination Rate") as char(40)))||' '||CONCAT(' Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site",2)as char(40)))
- Study-Site Original Planned Dates	Planned Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Latest Estimated Dates	Planned LE Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))

Table A–156 (Cont.) Study-Site Milestones with Indicators (Single Study-Site) - Study Close Detail View (Report CDA-CO-203F)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	Latest Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))

Table A–156 (Cont.) Study-Site Milestones with Indicators (Single Study-Site) - Study Close Detail View (Report CDA-CO-203F)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	Latest Subject Randomized Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Metrics	[Last Subject Randomized Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Randomized Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Randomized Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Randomized Date]"as char(40)))
- Study-Site Original Planned Dates	[Planned Last Subject Last Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))

Table A–156 (Cont.) Study-Site Milestones with Indicators (Single Study-Site) - Study Close Detail View (Report CDA-CO-203F)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE Last Subject Last Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Site Metrics	Latest Subject Latest Visit Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Study-Site Metrics	[Last Subject Last Visit Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Last Subject Last Visit Date]") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Latest Visit Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."[Last Subject Last Visit Date]" as char(40)))
- Received CRFs	# CRFs Awaiting Entry Completion	"- Received CRFs"."# CRFs Awaiting Entry Completion"
- Received CRFs	# eCRFs To Be Approved	"- Received CRFs"."# eCRFs To Be Approved"
- Received CRFs	# eCRFs To be Verified	"- Received CRFs"."# eCRFs To be Verified"
- Received CRFs	# CRFs Soft- Locked	"- Received CRFs"."# CRFs Soft-Locked"
- Received CRFs	% CRFs Soft Locked / Entry Complete	"- Received CRFs"."% CRFs Soft Locked / Entry Complete"

Table A–156 (Cont.) Study-Site Milestones with Indicators (Single Study-Site) - Study Close Detail View (Report CDA-CO-203F)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Received CRFs	# CRFs Hard-Locked	"- Received CRFs"."# CRFs Hard-Locked"
- Received CRFs	% CRFs Hard Locked / Entry Complete	"- Received CRFs"."% CRFs Hard Locked / Entry Complete"
- Study Original Planned Dates	[Planned Database Lock Date]	CONCAT('Planned:',cast(MAX("- Study Original Planned Dates"."[Planned Database Lock Date]")as char(40))) || ' ' ||CONCAT('LE:',cast(MAX("- Study Latest Estimated Dates"."[Planned LE Database Lock Date]") as char(40))) || ' ' ||CONCAT('Actual:',cast(MAX(" - Study Key Dates"."Database Lock Date") as char(40)))
- Study Latest Estimated Dates	[Planned LE Database Lock Date]	CONCAT('Planned:',cast(MAX("- Study Original Planned Dates"."[Planned Database Lock Date]")as char(40))) || ' ' ||CONCAT('LE:',cast(MAX("- Study Latest Estimated Dates"."[Planned LE Database Lock Date]") as char(40))) || ' ' ||CONCAT('Actual:',cast(MAX(" - Study Key Dates"."Database Lock Date") as char(40)))
- Study Key Dates	Database Lock Date	CONCAT('Planned:',cast(MAX("- Study Original Planned Dates"."[Planned Database Lock Date]")as char(40))) || ' ' ||CONCAT('LE:',cast(MAX("- Study Latest Estimated Dates"."[Planned LE Database Lock Date]") as char(40))) || ' ' ||CONCAT('Actual:',cast(MAX(" - Study Key Dates"."Database Lock Date") as char(40)))
- Study Original Planned Dates	[Planned Clinical Study Report Date]	CONCAT('Planned:',cast(MAX("- Study Original Planned Dates"."[Planned Clinical Study Report Date]")as char(40))) || ' ' ||CONCAT('LE:',cast(MAX("- Study Latest Estimated Dates"."[Planned LE Clinical Study Report Date]") as char(40))) || ' ' ||CONCAT('Actual:',cast(MAX(" - Study Key Dates"."[Clinical Study Report Date]") as char(40)))

Table A–156 (Cont.) Study-Site Milestones with Indicators (Single Study-Site) - Study Close Detail View (Report CDA-CO-203F)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study Latest Estimated Dates	[Planned LE Clinical Study Report Date]	CONCAT('Planned:',cast(MAX("- Study Original Planned Dates"."[Planned Clinical Study Report Date]")as char(40))) || ' ' ||CONCAT('LE:',cast(MAX("- Study Latest Estimated Dates"."[Planned LE Clinical Study Report Date]") as char(40))) || ' ' ||CONCAT('Actual:',cast(MAX(" - Study Key Dates"."[Clinical Study Report Date]") as char(40)))
- Study Key Dates	[Clinical Study Report Date]	CONCAT('Planned:',cast(MAX("- Study Original Planned Dates"."[Planned Clinical Study Report Date]")as char(40))) || ' ' ||CONCAT('LE:',cast(MAX("- Study Latest Estimated Dates"."[Planned LE Clinical Study Report Date]") as char(40))) || ' ' ||CONCAT('Actual:',cast(MAX(" - Study Key Dates"."[Clinical Study Report Date]") as char(40)))

Study-Site Milestones with Indicators (Single Study-Site) - Summary View (Report CDA-CO-203G)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study-Site Overview** dashboard, **Study-Site Overview** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Study-Site Milestones with Indicators (Single Study-Site) - Summary View report.

Table A–157 Study-Site Milestones with Indicators (Single Study-Site) - Summary View (Report CDA-CO-203G)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	Recruitment Flag	"- Study-Site Metrics"."Recruitment Flag"
- Study-Site Metrics	Recruitment High Level Reason	"- Study-Site Metrics"."Recruitment High Level Reason"
- Study-Site Metrics	Retention Flag	"- Study-Site Metrics"."Retention Flag"
- Study-Site Metrics	Retention High Level Reason	"- Study-Site Metrics"."Retention High Level Reason"
- Study-Site Metrics	Milestone Flag	"- Study-Site Metrics"."Milestone Flag"
- Study-Site Metrics	Milestone High Level Reason	"- Study-Site Metrics"."Milestone High Level Reason"
- Study Targets	[Expected Screen Failure Rate]	CONCAT('Expected:',cast(MAX("- Study Targets"."[Expected Screen Failure Rate]") as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."Screen Failure Rate",2) as char(40)))
- Study-Site Metrics	Screen Failure Rate	CONCAT('Expected:',cast(MAX("- Study Targets"."[Expected Screen Failure Rate]") as char(40)))||' '||CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."Screen Failure Rate",2) as char(40)))
- Study-Site Metrics	% Enrolled to Total Planned at Study-Site	CONCAT('Actual:' , cast(ROUND("- Study-Site Metrics"."% Enrolled to Total Planned at Study-Site",2) as char(40)))

Table A–157 (Cont.) Study-Site Milestones with Indicators (Single Study-Site) - Summary View (Report CDA-CO-203G)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Study-Site Targets	Expected Early Termination Rate	CONCAT('Expected:',cast(MAX("- Study-Site Study-Site Targets"."Expected Early Termination Rate") as char(40)))||' '||CONCAT(' Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site",2)as char(40)))
- Study-Site Metrics	% Subjects Early Terminated for Study-Site	CONCAT('Expected:',cast(MAX("- Study-Site Study-Site Targets"."Expected Early Termination Rate") as char(40)))||' '||CONCAT(' Actual:' , cast(ROUND("- Study-Site Metrics"."% Subjects Early Terminated for Study-Site",2)as char(40)))
- Study-Site Metrics	Next Site Visit Date	"- Study-Site Metrics"."Next Site Visit Date"
- Study-Site Metrics	Next Site Visit Type	"- Study-Site Metrics"."Next Site Visit Type"
- Study-Site Original Planned Dates	Planned 1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Latest Estimated Dates	Planned LE 1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))
- Study-Site Metrics	1st Subject Enrolled Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."Planned 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE 1st Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Metrics"."1st Subject Enrolled Date" as char(40)))

Table A–157 (Cont.) Study-Site Milestones with Indicators (Single Study-Site) - Summary View (Report CDA-CO-203G)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Original Planned Dates	Planned Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Latest Estimated Dates	Planned LE Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	Latest Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))
- Study-Site Metrics	Last Subject Enrolled Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."Planned Last Subject Enrolled Date")as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."Planned LE Last Subject Enrolled Date") as char(40)))||' '||CONCAT(' Actual(Latest):',cast("- Study-Site Metrics"."Latest Subject Enrolled Date" as char(40)))||' '||CONCAT(' Actual(Last):',cast("- Study-Site Metrics"."Last Subject Enrolled Date" as char(40)))

Table A–157 (Cont.) Study-Site Milestones with Indicators (Single Study-Site) - Summary View (Report CDA-CO-203G)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
- Study-Site Metrics	# Days Since Last Enrolllment for Study-Site	TRUNCATE("- Study-Site Metrics"."# Days Since Last Enrolllment for Study-Site",0)
- Study-Site Original Planned Dates	[Planned Site Initiated Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."Site Initiated Date") as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Site Initiated Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."Site Initiated Date") as char(40)))
- Study-Site Key Dates	Site Initiated Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."Site Initiated Date") as char(40)))

Study-Site Subject Recruitment Narrative (Report CDA-CO-405)

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.

Audience

- Study Manager
- CRA

Report Type

- Narrative

Location

- **Study-Site Overview** dashboard, **Study-Site Overview** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Study-Site Subject Recruitment Narrative report.

Table A–158 Study-Site Subject Recruitment Narrative (Report CDA-CO-405)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
For Study:	# Planned	Study Metrics.# Subjects Planned for Study
For Study-Site:	# Planned	Study-site Metrics.# Subjects Planned for Study-Site
For Study-Site:	# Screened	Study-site Metrics.# Screened
NA	# Subjects Enrolled	Study-site Metrics.# Subjects Enrolled
NA	% of Planned Site Enrollment Completed	Study-site Metrics.% of Planned Site Enrollment Completed
NA	% of Total Enrolled in Study	Study-site Metrics.% of Total Enrolled in Study
NA	# Randomized	Study-site Metrics.# Randomized
NA	% Randomized vs. Planned - Study	Study Metrics.% Randomized vs. Planned - Study
NA	% of Total Randomized in Study	Study-site Metrics.% of Total Randomized in Study

Study-Site Subject Retention (Report CDA-CO-500)

Displays a summary of retention information for a study-site. This report indicates planned recruitment vs. actual retention information for a single study-site.

Audience

- Study Manager
- CRA

Report Type

- Narrative

Location

- **Study-Site Overview** dashboard, **Study-Site Overview** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Study-Site Subject Retention report.

Table A–159 Study-Site Subject Retention (Report CDA-CO-500)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
For Study:	# Planned	Study Metrics.# Subjects Planned for Study
For Study:	% Early Terminated	Study-site Metrics.% Subjects Early Terminated for Study
For Study-Site:	# Planned	Study-site Metrics.# Subjects Planned for Study-Site
For Study-Site:	# Enrolled (to date)	Study-Site Metrics.# Enrolled
For Study-Site:	# Subjects - Current Status Enrolled	Study-site Metrics.# Subjects - Current Status Enrolled
NA	# Completed	Study-site Metrics.# Subjects who have completed Study
NA	# Early Terminations	Study-site Metrics.# Early Terminations
NA	% Early Terminated	Study-site Metrics.% Subjects Early Terminated for Study-site

Study-Site Team Member List (Report CDA-CO-201)

Lists all of the team members for a study-site.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **Study-Site Overview** dashboard, **Study-Site Team** page

Dimensions

- Study-Site Team Member

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

- Study-Sites with Red or Yellow Performance Flag (Report CDA-CO-204)
- Uninitiated Sites (Report CDA-CO-304)
- Initiated Study-Sites with Recruitment Counts (Report CDA-CO-412)

Column Descriptions

The table describes the columns in the Study-Site Team Member List report.

Table A–160 Study-Site Team Member List (Report CDA-CO-201)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Last Name	Study-Site Team Member.Last Name
NA	First Name	Study-Site Team Member.First Name
NA	Role	Study-Site Team Member.Role
NA	Start Date	Study-Site Team Member.Start Date

Table A–160 (Cont.) Study-Site Team Member List (Report CDA-CO-201)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	End Date	Study-Site Team Member.End Date
NA	Email	Study-Site Team Member.Email
NA	Team Member Active	Study-Site Team Member.Team Member Active
NA	Team Member Comment	Study-Site Team Member.Team Member Comment

Study-Sites with Red or Yellow Performance Flag (Report CDA-CO-204)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **CRA** dashboard, **CRA Overview** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following report from this report:

- Study-Site Team Member List (Report CDA-CO-201)

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Study-Sites with Red or Yellow Performance Flag report.

Table A–161 Study-Sites with Red or Yellow Performance Flag (Report CDA-CO-204)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Site	Program	Study-Site.Program
Study-Site	Study	Study-Site.Study
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Site Name	Study-Site.Site Name
Study-Site	Status	Study-Site.Study-Site Status
NA	Navigate to detail	NA
- Study-Site Metrics	Recruitment Flag	"- Study-Site Metrics"."Recruitment Flag"
- Study-Site Metrics	Recruitment Detail Reason	"- Study-Site Metrics"."Recruitment Detail Reason"
- Study-Site Metrics	Retention Flag	"- Study-Site Metrics"."Retention Flag"
- Study-Site Metrics	Retention Detail Reason	"- Study-Site Metrics"."Retention Detail Reason"
- Study-Site Metrics	Milestone Flag	"- Study-Site Metrics"."Milestone Flag"
- Study-Site Metrics	Milestone Detail Reason	"- Study-Site Metrics"."Milestone Detail Reason"

Subject Enrollment by Region (Report CDA-CO-414)

Shows the distribution of subject enrollment by region. This report indicates which regions are contributing the most to recruitment.

Audience

- Study Manager
- CRA

Report Type

- Graph, Table (optional)

Location

- **Study Overview** dashboard, **Study Region Performance** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Subject Enrollment by Region report.

Table A–162 Subject Enrollment by Region (Report CDA-CO-414)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Study Region	Study-Site.Study Region
NA	# Enrolled	- Study-site Metrics.# Subjects Enrolled

Subject Recruitment (Report CDA-CO-419)

Displays a summary of recruitment information for a study. This report indicates planned recruitment versus actual screening, enrollment and randomization information for a single study.

Audience

- Study Manager
- CRA

Report Type

- Narrative

Location

- **Study Overview** dashboard, **Study Overview** page

Dimensions

None

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Subject Recruitment report.

Table A–163 Subject Recruitment (Report CDA-CO-419)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	# Planned	Study Metrics.# Subjects Planned for Study
NA	# Screened	Study-site Metrics.# Screened
NA	# Enrolled	Study-site Metrics.# Subjects Enrolled
NA	# Randomized	Study-site Metrics.# Randomized
NA	% Enrolled / Planned	Study Metrics.% Enrolled / Planned in Study
NA	% Randomized / Planned	Study Metrics.% Randomized vs. Planned Study

Subject Recruitment (Study Region) (Report CDA-CO-1114)

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.

Audience

- Region Manager
- Study Manager
- Executive Manager
- Program Manager

Report Type

- Narrative

Location

- **Study-Region Overview** dashboard, **Overview** page

Dimensions

- Study-Region

Supplementary Prompts

- NA

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–164 describes the columns in the Subject Recruitment (Study Region) analysis

Table A–164 Subject Recruitment (Study Region) (Report CDA-CO-1114)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Region	Study-Region Name	"Study-Region"."Study-Region Name"
- Study Metrics	# Subjects Planned for Study	"- Study Metrics"."# Subjects Planned for Study"
- Study Region Metrics	# Subjects Planned for Study-Region	"- Study Region Metrics"."# Subjects Planned for Study-Region"
- Study-Site Metrics	# Screened	"- Study-site Metrics"."# Screened"
- Study-Site Metrics	# Enrolled	"- Study-site Metrics"."# Enrolled"
- Study Region Metrics	% Enrolled to Total Planned at Study Region	"- Study Region Metrics"."% Enrolled to Total Planned at Study Region"
- Study-Site Metrics	% of Total Enrolled in Study	"- Study-site Metrics"."% of Total Enrolled in Study"
- Study-Site Metrics	# Randomized	"- Study-site Metrics"."# Randomized"
- Study Region Metrics	% Planned Subjects Randomized	"- Study Region Metrics"."% Planned Subjects Randomized"
- Study-Site Metrics	% of Total Randomized in Study	"- Study-site Metrics"."% of Total Randomized in Study"
Study-Region	Study	"Study-Region"."Study"

Subject Retention (Report CDA-CO-504)

Displays a summary of retention information for a study. This report indicates planned recruitment vs. actual retention information for a single study.

Audience

- Study Manager
- CRA

Report Type

- Narrative

Location

- **Study Overview** dashboard, **Study Overview** page

Dimensions

None

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Subject Retention report.

Table A–165 Subject Retention (Report CDA-CO-504)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	# Planned for Study	Study Metrics.# Subjects Planned for Study
NA	# Current Active	Study-site Metrics.# Current Active Subjects
NA	# Completed Study	Study-site Metrics.# Subjects who have completed Study
NA	# Early Terminations	Study-site Metrics.# Early Terminations
NA	% Early Term / Planned	CAST(- Study-site Metrics.# Early Terminations*100 /- Study Metrics.# Subjects Planned for Study AS FLOAT)

Subject Retention (Study Level) (Report CDA-CO-503)

Displays a summary of retention information for a study. This report indicates planned recruitment vs. actual retention information for a single study.

Audience

- Study Manager
- CRA

Report Type

- Narrative

Location

- **Study Overview** dashboard, **Retention Overview** page

Dimensions

None

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Subject Retention (Study Level) report.

Table A–166 Subject Retention (Study Level) (Report CDA-CO-503)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	# Planned	Study Metrics.# Subjects Planned for Study
NA	# Enrolled	Study-site Metrics.# Subjects Enrolled
NA	# Completed Study	Study-site Metrics.# Subjects who have completed Study
NA	# Early Terminations	Study-site Metrics.# Early Terminations
NA	# Early Term / Planned	Study-site Metrics.# Early Terminations/- Study Metrics.# Subjects Planned for Study

Subject Retention (Study Region) (Report CDA-CO-1115)

Displays a summary of retention information for a study-region. This report indicates planned recruitment vs. actual retention information for a single study-region.

Audience

- Region Manager
- Study Manager
- Executive Manager

- Program Manager

Report Type

- Narrative

Location

- **Study-Region Overview** dashboard, **Overview Retention Overview** page

Dimensions

- Study-Region

Supplementary Prompts

- NA

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–167 describes the columns in the Subject Retention (Study Region) analysis.

Table A–167 Subject Retention (Study Region) (Report CDA-CO-1115)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
Study-Region	Study	"Study-Region"."Study"
- Study Metrics	# Subjects Planned for Study	"- Study Metrics"."# Subjects Planned for Study"
- Study Metrics	% Subjects Early Terminated for Study	"- Study Metrics"."% Subjects Early Terminated for Study"
Study-Region	Study-Region Name	"Study-Region"."Study-Region Name"
- Study Region Metrics	# Subjects Planned for Study-Region	"- Study Region Metrics"."# Subjects Planned for Study-Region"
- Study-Site Metrics	# Enrolled	"- Study-Site Metrics"."# Enrolled"
- Study-Site Metrics	# Subjects - Current Status Enrolled	"- Study-Site Metrics"."# Subjects - Current Status Enrolled"
- Study-Site Metrics	# Subjects - Current Status Completed	"- Study-Site Metrics"."# Subjects - Current Status Completed"
- Study-Site Metrics	# Early Terminations	"- Study-Site Metrics"."# Early Terminations"

Table A–167 (Cont.) Subject Retention (Study Region) (Report CDA-CO-1115)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study Region Metrics	% Subjects Early Terminated for Study-Region	"- Study Region Metrics"."% Subjects Early Terminated for Study-Region"

Subject Retention (Study-Site Level) (Report CDA-CO-502)

Displays a summary of retention information for a study-site. This report indicates planned recruitment vs. actual retention information for a single study-site.

Audience

- Study Manager
- CRA

Report Type

- Narrative

Location

- **Study-Site Overview** dashboard, **Retention Overview** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Subject Retention (Study-Site Level) report.

Table A–168 Subject Retention (Study-Site Level) (Report CDA-CO-502)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
For Study:	# Planned	Study Metrics.# Subjects Planned for Study

Table A–168 (Cont.) Subject Retention (Study-Site Level) (Report CDA-CO-502)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
For Study-Site:	# Planned	Study-site Metrics.# Subjects Planned for Study-Site
NA	# Enrolled	Study-site Metrics.# Subjects Enrolled
NA	# Completed	Study-site Metrics.# Subjects who have completed Study
NA	# Early Terminated	Study-site Metrics.# Early Terminations
NA	% Early Terminated	Study-site Metrics.# Early Terminations/- Study Metrics.# Subjects Planned for Study

Subject Retention Over Time (Study Level) (Report CDA-CO-501)

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.

Audience

- Study Manager
- CRA

Report Type

- Graph, Table (optional)

Location

- **Study Overview** dashboard, **Retention Overview** page

Dimensions

- Study-Site
- All-Purpose Date

Supplementary Prompts

Year Prompt

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Subject Retention Over Time (Study Level) report.

Table A–169 Subject Retention Over Time (Study Level) (Report CDA-CO-501)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Year and Month	All Purpose Date.Year and Month
NA	Study	Study-Site.Study
NA	Study-Site ID #	Study-Site.Study-Site ID #
NA	1	MAX(SUM(CASE WHEN - Study Metrics.# Subjects Planned for Study>0 THEN - Study Metrics.# Subjects Planned for Study ELSE 0 END))
NA	0.9	MAX(SUM(CASE WHEN - Study Metrics.# Subjects Planned for Study>0 THEN - Study Metrics.# Subjects Planned for Study ELSE 0 END) * .9)
NA	0.75	MAX(SUM(CASE WHEN - Study Metrics.# Subjects Planned for Study>0 THEN - Study Metrics.# Subjects Planned for Study ELSE 0 END) * .75)
NA	0.5	MAX(SUM(CASE WHEN - Study Metrics.# Subjects Planned for Study>0 THEN - Study Metrics.# Subjects Planned for Study ELSE 0 END) * .5)
NA	# Subjects Completed	RSUM(- Study-site Metrics.# Subjects who have completed Study)

Subject Retention Over Time (Study-Site Level) (Report CDA-CO-510)

Displays cumulative subjects off study over time, compared to static planned subjects enrolled (50%, 75%, 90% and 100%) for a study-site. This report indicates the progress of subject retention.

Audience

- Study Manager
- CRA

Report Type

- Graph, Table (optional)

Location

- **Study-Site Overview** dashboard, **Retention Overview** page

Dimensions

- Study-Site All-Purpose Date

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

- Cumulative Enrollment and Early Term (Study-Site) (Report CDA-CO-418)

Column Descriptions

The table describes the columns in the Subject Retention Over Time (Study-Site Level) report

Table A–170 Subject Retention Over Time (Study-Site Level) (Report CDA-CO-510)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	Year and Month	All Purpose Date.Year and Month
NA	Study	Study-Site.Study
NA	Study-Site ID #	Study-Site.Study-Site ID #
NA	1	MAX(SUM(CASE WHEN - Study Metrics.# Subjects Planned for Study>0 THEN - Study Metrics.# Subjects Planned for Study ELSE 0 END))
NA	0.9	MAX(SUM(CASE WHEN - Study Metrics.# Subjects Planned for Study>0 THEN - Study Metrics.# Subjects Planned for Study ELSE 0 END) * .9)
NA	0.75	MAX(SUM(CASE WHEN - Study Metrics.# Subjects Planned for Study>0 THEN - Study Metrics.# Subjects Planned for Study ELSE 0 END) * .75)
NA	0.5	MAX(SUM(CASE WHEN - Study Metrics.# Subjects Planned for Study>0 THEN - Study Metrics.# Subjects Planned for Study ELSE 0 END) * .5)
NA	# Subjects Completed	RSUM(- Study-site Metrics.# Subjects who have completed Study)

Subject Retention Over Time Chart (Study-Region Level) (Report CDA-CO-511)

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.

Audience

- Region Manager
- Study Manager
- CRA

Report Type

- View Selector (2 Charts, Table)

Location

- **Study-Region Overview** dashboard, **Overview Retention Overview** page

Dimensions

- Study-Region

Supplementary Prompts

- Year and Month Prompt

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A–171 describes the columns in the Subject Retention Over Time Chart (Study-Region Level) analysis

Table A–171 Subject Retention Over Time Chart (Study-Region Level) (Report CDA-CO-511)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- All Purpose Date	Year and Month	"- All Purpose Date"."Year and Month"
Study-Region	Study	"Study-Region"."Study"
Study-Region	Region Name	"Study-Region"."Region Name"
- Study-Site Metrics	# Subjects who have completed Study	IFNULL(RSUM("- Study-Site Metrics"."# Subjects who have completed Study"), 0) + @{pv_ subjects_completed_stdy_reg}
- Study-Site Metrics	# Early Terminations	IFNULL(RSUM("- Study-Site Metrics"."# Early Terminations"), 0) + @{pv_early_term_stdy_ region}

Subjects Enrolled per Month, Over Time (Report CDA-CO-403)

Displays the number of subjects enrolled per month. This report indicates the pattern of enrollment over time at a study-site.

Audience

- Study Manager
- CRA

Report Type

- Graph, Table (optional)

Location

- **Study-Site Overview** dashboard, **Monitoring Metrics** page

Dimensions

- Study-Site

Supplementary Prompts

Year Prompt

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Subjects Enrolled per Month, Over Time report

Table A–172 Subjects Enrolled per Month, Over Time (Report CDA-CO-403)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	# Enrolled	Study-site Metrics.# Subjects Enrolled
NA	Year and Month	All Purpose Date.Year and Month

Subjects who Failed Screening (Report CDA-CO-428)

Lists (by program, study, and site) all subjects who have failed screening, including screen failure reason and subject comments. This report indicates which screen failure reasons account for the most screen failures.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

None

Dimensions

- Study-Site
- Subject

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

You can navigate to this report from the following reports:

- Screen Failure Reason (Report CDA-CO-425)
- Screen Failure Reason by Site (Report CDA-CO-300)
- Screen Failure Reason (Report CDA-CO-420)

Column Descriptions

The table describes the columns in the Subjects who Failed Screening report.

Table A–173 Subjects who Failed Screening (Report CDA-CO-428)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Study-Site	Study, Site, and Investigator	Study-Site.Study, Site, and Investigator
Study-Site	Study-Site Status	Study-Site.Study-Site Status
Subject	Screening #	Subject.Screening #
Subject	Screen Failure Reason	Subject.Screen Failure Reason
Subject	Subject Comments	Subject.Subject Comments
NA	Subject Status	Subject Metrics.Subject Status

Table A–173 (Cont.) Subjects who Failed Screening (Report CDA-CO-428)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	Status Comment	Subject Metrics.Status Comment

Subjects Withdrawn List (Report CDA-CO-509)

Lists (by program, study, region, and site) all subjects who terminated the study early, including withdrawn reason and subject comments. This report indicates which withdrawn reasons account for the most early terminations.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

None

Dimensions

- Study-Site
- Subject

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

You can navigate to this report from the following reports:

- Withdrawn Reason (Report CDA-CO-505)
- Withdrawn Reason Overview (Report CDA-CO-508)

Column Descriptions

The table describes the columns in the Subjects Withdrawn List report.

Table A–174 Subjects Withdrawn List (Report CDA-CO-509)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
Product	Product Name	Study-Site.Product
Region	Region Status	Study-Site.Study Region Status
Study	Study Status	Study-Site.Study Status
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Program	Study-Site.Program
Study-Site	Site Name	Study-Site.Site Name
Study-Site	Study	Study-Site.Study
Study-Site	Study Region	Study-Site.Study Region
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Study-Site Status	Study-Site.Study-Site Status
Subject	Enrollment Id	Subject.Enrollment Id
Subject	Withdrawn Reason	Subject.Withdrawn Reason
Subject	Subject Comments	Subject.Subject Comments
NA	Subject Status	Subject Metrics.Subject Status
NA	Status Comment	Subject Metrics.Status Comment

Summary of Subjects Awaiting EDC Processing (Report CDA-DM-320)

Identifies specific subjects who have eCRFs awaiting processing. This report indicates those subjects which require processing, and the number of eCRFs to be processed. This information can be used as a summary work log to take to a site visit to drive activity.

Audience

- Data Manager

Report Type

- Table

Location

- **Data Manager - EDC** dashboard, **Study Processing Summary** page

Dimensions

- Study-Site
- Subject

Supplementary Prompts

- Study

- Study-Site

Reports Referenced

You can navigate to the following reports from this report:

- Listing of Subject-Pages, Awaiting EDC Processing (Report CDA-DM-310)

Reports Referencing This Report

The following reports reference this report:

- Key EDC Processing Volumes (Report CDA-DM-305)

Column Descriptions

The table describes the columns in the Summary of Subjects Awaiting EDC Processing report.

Table A–175 Summary of Subjects Awaiting EDC Processing (Report CDA-DM-320)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	NA	Study-Site.Program
NA	NA	Study-Site.Study Name
Subject	Subject ID	Subject.Subject ID
# eCRFs	Entry Complete	Received CRFs.# eCRFs Entry Complete
# eCRFs	Not Verified	Received CRFs.# eCRFs Never Verified
# eCRFs	Awaiting Re-Verification	Received CRFs.# eCRFs Awaiting Re-Verification
# eCRFs	Not Approved	Received CRFs.# eCRFs Not Approved
# eCRFs	Awaiting Re-Approval	Received CRFs.# eCRFs Awaiting Re-Approval

Summary of Subjects Awaiting Paper Processing (Report CDA-DM-420)

Identifies specific CRFs, and the process steps they are awaiting. This report lists, for a subject, the pages which are awaiting processing. This information can be used to drive activity.

Audience

- Data Entry Manager
- Data Manager

Report Type

- Table

Location

- **Data Manager - Paper** dashboard, **Study Processing Summary** page

Dimensions

- Study-Site
- Subject

Supplementary Prompts

- Study
- Study-Site

Reports Referenced

You can navigate to the following reports from this report:

- Listing of Subject-Pages, Awaiting Paper Processing (Report CDA-DM-410)

Reports Referencing This Report

The following reports reference this report:

- Key Paper processing volumes (Report CDA-DM-405)

Column Descriptions

The table describes the columns in the Summary of Subjects Awaiting Paper Processing report

Table A–176 Summary of Subjects Awaiting Paper Processing (Report CDA-DM-420)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	NA	Study-Site.Program
NA	NA	Study-Site.Study Name
Subject	Subject ID	Subject.Subject ID
# CRFs	Present	Received CRFs.# pCRFs Present
# CRFs	Awaiting First Entry Completion	Received CRFs.# pCRFs Awaiting Pass 1 Entry Completion
# CRFs	Awaiting Second Entry Completion	Received CRFs.# pCRFs Awaiting Pass 2 Entry Completion

Top Investigators Compared to All Investigators for Study, Total Enrollment (Report CDA-CO-702)

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.

Audience

- Executive
- Study Manager

- Region Manager
- CRA

Report Type

- Graph, Table (optional)

Location

- **Study Manager** dashboard, **Top Investigators** page
- **CRA** dashboard, **Top Investigators** page
- **Study Overview** dashboard, **Top Investigators** page
- **Executive** dashboard, **Top Investigators** page
- **Region Manager** dashboard, **Top Investigators** page
- **Study-Region Overview** dashboard, **Top Investigators** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Top Investigators Compared to All Investigators for Study, Total Enrollment report.

Table A–177 Top Investigators Compared to All Investigators for Study, Total Enrollment (Report CDA-CO-702)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Study-Site ID #	Study-Site.Study-Site ID #
NA	Study-Site ID #	TBD
NA	Principal Investigator	TBD
NA	# Subjects Enrolled	Study-site Metrics.# Subjects Enrolled
NA	Rank	TBD

Top Investigators, % Planned Enrollment Completed (Report CDA-CO-700)

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.

Audience

- Executive
- Study Manager
- Region Manager
- CRA

Report Type

- Table

Location

- **Study Manager** dashboard, **Top Investigators** page
- **CRA** dashboard, **Top Investigators** page
- **Study Overview** dashboard, **Top Investigators** page
- **Executive** dashboard, **Top Investigators** page
- **Region Manager** dashboard, **Top Investigators** page
- **Study-Region Overview** dashboard, **Top Investigators** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Investigator Contact and Studies List (Report CDA-CO-202)

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Top Investigators, % Planned Enrollment Completed report.

Table A–178 Top Investigators, % Planned Enrollment Completed (Report CDA-CO-700)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Principal Investigator	Study-Site.Principal Investigator
NA	Study	Study-Site.Study
NA	Study-Site ID #	Study-Site.Study-Site ID #
NA	% Enrolled to Total Planned at Study-Site	Study-site Metrics.% Enrolled to Total Planned at Study-Site
NA	Rank	rank (- Study-site Metrics.% Enrolled to Total Planned at Study-Site)

Top Investigators, Total Enrollment (Report CDA-CO-701)

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.

Audience

- Executive
- Study Manager
- Region Manager
- CRA

Report Type

- Table

Location

- **Study Manager** dashboard, **Top Investigators** page
- **CRA** dashboard, **Top Investigators** page
- **Study Overview** dashboard, **Top Investigators** page
- **Executive** dashboard, **Top Investigators** page
- **Region Manager** dashboard, **Top Investigators** page
- **Study-Region Overview** dashboard, **Top Investigators** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Investigator Contact and Studies List (Report CDA-CO-202)

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Top Investigators, Total Enrollment report.

Table A–179 Top Investigators, Total Enrollment (Report CDA-CO-701)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Principal Investigator	Study-Site.Principal Investigator
NA	Study	Study-Site.Study
NA	Study-Site ID #	Study-Site.Study-Site ID #
NA	# Enrolled	- Study-site Metrics.# Subjects Enrolled
NA	Rank	Rank (- Study-site Metrics.# Subjects Enrolled)

Total Subject Enrollment by Region (Report CDA-CO-410)

Shows cumulative actual enrollment by region. This report indicates which regions are contributing the most to recruitment.

Audience

- Study Manager CRA

Report Type

- Graph, Table (optional)

Location

- **Study Overview** dashboard, **Study Region Performance** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Site Detail (Report CDA-CO-209)

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Total Subject Enrollment by Region report.

Table A–180 Total Subject Enrollment by Region (Report CDA-CO-410)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Study Region	Study-Site.Study Region
NA	Site Name	OCDA.Study-Site.Site Name
NA	# Enrolled	Study-site Metrics.# Subjects Enrolled

Uninitiated Sites (Report CDA-CO-304)

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.

Audience

- Study Manager
- CRA

Report Type

- Table

Location

- **CRA** dashboard, **Initiating and Recruiting Study-Sites** page

Dimensions

- Study-Site

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Study-Site Team Member List (Report CDA-CO-201)
- Outstanding Documents List (Report CDA-CO-602)

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Uninitiated Sites report.

Table A–181 Uninitiated Sites (Report CDA-CO-304)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Study	Study-Site.Study
Study-Site	Study Region	"Study-Site"."Study Region"
NA	Study-Site ID #	Study-Site.Study-Site ID #
NA	Principal Investigator	Study-Site.Principal Investigator
NA	Site Name	Study-Site.Site Name
NA	Study-Site Status	Study-Site.Study-Site Status
NA	Initial IRB/EC Approval Date	Study-Site.Initial IRB/EC Approval Date
- Study-Site Original Planned Dates	[Planned IRB/EC Submission Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."[Initial IRB/EC Submission Date]") as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE IRB/EC Submission Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."[Initial IRB/EC Submission Date]") as char(40)))
- Study-Site Key Dates	[Initial IRB/EC Submission Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE IRB/EC Submission Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."[Initial IRB/EC Submission Date]") as char(40)))

Table A–181 (Cont.) Uninitiated Sites (Report CDA-CO-304)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Metrics	Milestone Flag	"- Study-Site Metrics"."Milestone Flag"
- Study-Site Metrics	Milestone Detail Reason	"- Study-Site Metrics"."Milestone Detail Reason"
- Study-Site Original Planned Dates	[Planned Initial IRB/EC Approval Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Key Dates"."Initial IRB/EC Approval Date" as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Initial IRB/EC Approval Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Key Dates"."Initial IRB/EC Approval Date" as char(40)))
- Study-Site Key Dates	Initial IRB/EC Approval Date	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Initial IRB/EC Approval Date]") as char(40)))||' '||CONCAT(' Actual:',cast("- Study-Site Key Dates"."Initial IRB/EC Approval Date" as char(40)))
- Study-Site Original Planned Dates	[Planned Site Initiated Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."Site Initiated Date") as char(40)))

Table A–181 (Cont.) Uninitiated Sites (Report CDA-CO-304)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Latest Estimated Dates	[Planned LE Site Initiated Date]	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."Site Initiated Date") as char(40)))
- Study-Site Key Dates	Site Initiated Date	CONCAT('Planned:',cast(MAX("- Study-Site Original Planned Dates"."[Planned Site Initiated Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Site Initiated Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."Site Initiated Date") as char(40)))
Study-Site	Site Name	"Study-Site"."Site Name"
- Study-Site Original Planned Dates	[Planned Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."[Critical Document Package Completed Date]") as char(40)))
- Study-Site Latest Estimated Dates	[Planned LE Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Critical Document Package Completed Date]") as char(40)))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."[Critical Document Package Completed Date]") as char(40)))

Table A–181 (Cont.) Uninitiated Sites (Report CDA-CO-304)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
- Study-Site Key Dates	[Critical Document Package Completed Date]	CONCAT('Planned:',cast(MIN("- Study-Site Original Planned Dates"."[Planned Critical Document Package Completed Date]") as char(40))||' '||CONCAT(' LE:' , cast(MAX("- Study-Site Latest Estimated Dates"."[Planned LE Critical Document Package Completed Date]") as char(40))||' '||CONCAT(' Actual:',cast(MAX("- Study-Site Key Dates"."[Critical Document Package Completed Date]") as char(40)))
NA	# Documents Outstanding	Document Metrics.# Documents Outstanding
NA	Navigate to Detail	NA

Visit Frequency Compared to Subject Enrollment (Report CDA-CO-819)

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.

Audience

- Study Manager
- Region Manager
- CRA

Report Type

- Graph, Table (optional)

Location

- **Study Overview** dashboard, **Monitoring Metrics** page
- **Study Overview** dashboard, **Monitoring Metrics** page
- **Region Manager** dashboard, **Monitoring Metrics** page

Dimensions

- All Purpose Date

Supplementary Prompts

Year Prompt

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Visit Frequency Compared to Subject Enrollment report.

Table A–182 Visit Frequency Compared to Subject Enrollment (Report CDA-CO-819)

Table Heading	Column Heading	Measure or Dimension in Presentation Layer
NA	Year and Month	All Purpose Date.Year and Month
NA	# Enrolled	Study-site Metrics.# Subjects Enrolled
NA	# Site Visits	Study-site Metrics.# Site Visits

Withdrawn Reason (Report CDA-CO-505)

Displays (by withdrawn reason) the number of subjects who terminated early. This report indicates which withdrawn reasons account for the most early terminations.

Audience

- Study Manager
- Region Manager
- CRA

Report Type

- Graph, table (optional)

Location

- **Study Overview** dashboard, **Retention Overview** page
- **Study-Site Overview** dashboard, **Retention Overview** page
- **Study-Region Overview** dashboard, **Retention Overview** page

Dimensions

- Subject

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Subjects Withdrawn List (Report CDA-CO-509)

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Withdrawn Reason report.

Table A–183 Withdrawn Reason (Report CDA-CO-505)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	Count of Early Terms	COUNT(CASE WHEN - Subject Metrics.Subject Status='EARLY TERM' OR - Subject Metrics.Subject Status='Early Terminated' THEN - Subject Metrics.Subject Status END)
NA	Withdrawn Reason	Subject.Withdrawn Reason

Withdrawn Reason Overview (Report CDA-CO-508)

Displays (by site) the number of early terminations. This report indicates which withdrawn reasons account for the most early terminations.

Audience

- Study Manager
- Region Manager
- CRA

Report Type

- Graph, table (optional)

Location

- **Study Overview** dashboard, **Retention Overview** page
- **Study-Region Overview** dashboard, **Retention Overview** page

Dimensions

- Subject.Withdrawn Reason
- Study-Site.Study, Site, and Investigator

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Subjects Withdrawn List (Report CDA-CO-509)

Reports Referencing This Report

None

Column Descriptions

The table describes the columns in the Withdrawn Reason Overview report.

Table A–184 Withdrawn Reason Overview (Report CDA-CO-508)

Table Heading	Column Heading	Measure/Dimension in Presentation Layer
NA	# Early Terminations	Study-site Metrics.# Early Terminations
Subject	Withdrawn Reason	Subject.Withdrawn Reason
Study-Site	Study, Site, and Investigator	Study-Site.Study, Site, and Investigator

B

Oracle Health Sciences Clinical Development Analytics Presentation Catalog

The OHSCDA Presentation Catalog displays columns that you can use to create requests.

This appendix contains the following topics:

- Dimensions in OHSCDA Presentation Catalog on page B-1
- Facts in OHSCDA Presentation Catalog on page B-1
- Oracle Clinical Sources for OHSCDA Presentation Catalog on page B-59
- Oracle's Siebel Clinical Sources for OHSCDA Presentation Catalog on page B-91

Dimensions in OHSCDA Presentation Catalog

Table B-1 describes the Dimensions displayed in the OHSCDA Presentation Catalog. For each column, it shows the name of the Column, its description, and the Dimension containing the column. The table is sorted by Dimension, and by Column within Dimension. This corresponds to how the Dimension columns are organized in the Presentation Catalog. Each Dimension column has an ID number, which is provided for cross-reference to other tables in this appendix.

Please note that some columns have been de-normalized, so that they appear in more than one Dimension. This de-normalization speeds query execution by eliminating the need for a join to that column in another Dimension. It also supports the ability to constrain columns in a Prompt, so that when you select a value in one column, the other columns are constrained to those related to your selection. When you select a de-normalized column from a Dimension, your results will be limited to the grain of the Dimension.

Table B–1 Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD02	Time - All purpose Date	-	Time series based on Subject Status Date, Document Received Date, Site Visit Completed Date, Follow Up Item Completed Date, Discrepancy Creation Date, CRF Entry Date
AD02-07	Time - All purpose Date	Date	Calendar Date
AD02-02	Time - All purpose Date	Julian Day	Julian Day
AD02-08	Time - All purpose Date	Julian Month	Julian Month
AD02-09	Time - All purpose Date	Julian Week	Julian Week

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD02-03	Time - All purpose Date	Month	Month within calendar year
AD02-10	Time - All purpose Date	Month Name	Full name of the month
AD02-04	Time - All purpose Date	Quarter	Quarter within calendar year
AD02-06	Time - All purpose Date	Week	Week within calendar year
AD02-05	Time - All purpose Date	Year	Calendar year
AD02-11	Time - All purpose Date	Year and Month	Year and month (ex. 1994 / 02)
AD02-13	Time - All purpose Date	Year and Quarter	Year and quarter (ex. 1994 Q1)
AD02-12	Time - All purpose Date	Year and Week	Year and week (ex. 1994 Week10)
-	Time - 1st Site Initiated Date	-	Time series based on 1st Site Initiated Date
AD02-134	Time - 1st Site Initiated Date	Date	Calendar Date
AD02-135	Time - 1st Site Initiated Date	Julian Day	Julian Day
AD02-136	Time - 1st Site Initiated Date	Julian Month	Julian Month
AD02-137	Time - 1st Site Initiated Date	Julian Week	Julian Week
AD02-138	Time - 1st Site Initiated Date	Month	Month within calendar year
AD02-139	Time - 1st Site Initiated Date	Month Name	Full name of the month
AD02-140	Time - 1st Site Initiated Date	Quarter	Quarter within calendar year
AD02-141	Time - 1st Site Initiated Date	Week	Week within calendar year
AD02-142	Time - 1st Site Initiated Date	Year	Calendar year
AD02-143	Time - 1st Site Initiated Date	Year and Month	Year and month (ex. 1994 / 02)
AD02-144	Time - 1st Site Initiated Date	Year and Quarter	Year and quarter (ex. 1994 Q1)
-	Time - 1st Site Initiated Date	-	-
AD02-145	Time - 1st Site Initiated Date	Year and Week	Year and week (ex. 1994 Week10)
AD02-146	Time - 1st Subject Enrolled Date	Date	Calendar Date
AD02-147	Time - 1st Subject Enrolled Date	Julian Day	Julian Day
AD02-148	Time - 1st Subject Enrolled Date	Julian Month	Julian Month
AD02-149	Time - 1st Subject Enrolled Date	Julian Week	Julian Week

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD02-150	Time - 1st Subject Enrolled Date	Month	Month within calendar year
AD02-151	Time - 1st Subject Enrolled Date	Month Name	Full name of the month
AD02-152	Time - 1st Subject Enrolled Date	Quarter	Quarter within calendar year
AD02-153	Time - 1st Subject Enrolled Date	Week	Week within calendar year
AD02-154	Time - 1st Subject Enrolled Date	Year	Calendar year
AD02-155	Time - 1st Subject Enrolled Date	Year and Month	Year and month (ex. 1994 / 02)
AD02-156	Time - 1st Subject Enrolled Date	Year and Quarter	Year and quarter (ex. 1994 Q1)
AD02-157	Time - 1st Subject Enrolled Date	Year and Week	Year and week (ex. 1994 Week10)
-	Time - Discrepancy Close Date	-	Time series based on Discrepancy Close Date
AD02-79	Time - Discrepancy Close Date	Date	Calendar Date
AD02-74	Time - Discrepancy Close Date	Julian Day	Julian Day
AD02-80	Time - Discrepancy Close Date	Julian Month	Julian Month
AD02-81	Time - Discrepancy Close Date	Julian Week	Julian Week
AD02-75	Time - Discrepancy Close Date	Month	Month within calendar year
AD02-82	Time - Discrepancy Close Date	Month Name	Full name of the month
AD02-76	Time - Discrepancy Close Date	Quarter	Quarter within calendar year
AD02-78	Time - Discrepancy Close Date	Week	Week within calendar year
AD02-77	Time - Discrepancy Close Date	Year	Calendar year
AD02-83	Time - Discrepancy Close Date	Year and Month	Year and month (ex. 1994 / 02)
AD02-85	Time - Discrepancy Close Date	Year and Quarter	Year and quarter (ex. 1994 Q1)
AD02-84	Time - Discrepancy Close Date	Year and Week	Year and week (ex. 1994 Week10)
-	Time - Document Expiration Date	-	Time series based on Document Expiration Date
AD02-19	Time - Document Expiration Date	Date	Calendar Date

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD02-14	Time - Document Expiration Date	Julian Day	Julian Day
AD02-20	Time - Document Expiration Date	Julian Month	Julian Month
AD02-21	Time - Document Expiration Date	Julian Week	Julian Week
AD02-15	Time - Document Expiration Date	Month	Month within calendar year
AD02-22	Time - Document Expiration Date	Month Name	Full name of the month
AD02-16	Time - Document Expiration Date	Quarter	Quarter within calendar year
AD02-18	Time - Document Expiration Date	Week	Week within calendar year
AD02-17	Time - Document Expiration Date	Year	Calendar year
AD02-23	Time - Document Expiration Date	Year and Month	Year and month (ex. 1994 / 02)
AD02-25	Time - Document Expiration Date	Year and Quarter	Year and quarter (ex. 1994 Q1)
AD02-24	Time - Document Expiration Date	Year and Week	Year and week (ex. 1994 Week10)
-	Time - Document Sent Date	-	Time series based on Document Sent Date
AD02-31	Time - Document Sent Date	Date	Calendar Date
AD02-26	Time - Document Sent Date	Julian Day	Julian Day
AD02-32	Time - Document Sent Date	Julian Month	Julian Month
AD02-33	Time - Document Sent Date	Julian Week	Julian Week
AD02-27	Time - Document Sent Date	Month	Month within calendar year
AD02-34	Time - Document Sent Date	Month Name	Full name of the month
AD02-28	Time - Document Sent Date	Quarter	Quarter within calendar year
AD02-30	Time - Document Sent Date	Week	Week within calendar year
AD02-29	Time - Document Sent Date	Year	Calendar year
AD02-35	Time - Document Sent Date	Year and Month	Year and month (ex. 1994 / 02)
AD02-37	Time - Document Sent Date	Year and Quarter	Year and quarter (ex. 1994 Q1)

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD02-36	Time - Document Sent Date	Year and Week	Year and week (ex. 1994 Week10)
-	Time - Most Recent Approved Date	-	Time series based on Most Recent Approved Date
AD02-91	Time - Most Recent Approved Date	Date	Calendar Date
AD02-86	Time - Most Recent Approved Date	Julian Day	Julian Day
AD02-92	Time - Most Recent Approved Date	Julian Month	Julian Month
AD02-93	Time - Most Recent Approved Date	Julian Week	Julian Week
AD02-87	Time - Most Recent Approved Date	Month	Month within calendar year
AD02-94	Time - Most Recent Approved Date	Month Name	Full name of the month
AD02-88	Time - Most Recent Approved Date	Quarter	Quarter within calendar year
AD02-90	Time - Most Recent Approved Date	Week	Week within calendar year
AD02-89	Time - Most Recent Approved Date	Year	Calendar year
AD02-95	Time - Most Recent Approved Date	Year and Month	Year and month (ex. 1994 / 02)
AD02-97	Time - Most Recent Approved Date	Year and Quarter	Year and quarter (ex. 1994 Q1)
AD02-96	Time - Most Recent Approved Date	Year and Week	Year and week (ex. 1994 Week10)
-	Time - Most Recent Source Verification Date	-	Time series based on Most Recent Source Verification Date
AD02-103	Time - Most Recent Source Verification Date	Date	Calendar Date
AD02-98	Time - Most Recent Source Verification Date	Julian Day	Julian Day
AD02-104	Time - Most Recent Source Verification Date	Julian Month	Julian Month
AD02-105	Time - Most Recent Source Verification Date	Julian Week	Julian Week
AD02-99	Time - Most Recent Source Verification Date	Month	Month within calendar year
AD02-106	Time - Most Recent Source Verification Date	Month Name	Full name of the month
AD02-100	Time - Most Recent Source Verification Date	Quarter	Quarter within calendar year
AD02-102	Time - Most Recent Source Verification Date	Week	Week within calendar year

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD02-101	Time - Most Recent Source Verification Date	Year	Calendar year
AD02-107	Time - Most Recent Source Verification Date	Year and Month	Year and month (ex. 1994 / 02)
AD02-109	Time - Most Recent Source Verification Date	Year and Quarter	Year and quarter (ex. 1994 Q1)
AD02-108	Time - Most Recent Source Verification Date	Year and Week	Year and week (ex. 1994 Week10)
-	Time - Pass 1 Completion Date	-	Time series based on Pass 1 Completion Date
AD02-115	Time - Pass 1 Completion Date	Date	Calendar Date
AD02-110	Time - Pass 1 Completion Date	Julian Day	Julian Day
AD02-116	Time - Pass 1 Completion Date	Julian Month	Julian Month
AD02-117	Time - Pass 1 Completion Date	Julian Week	Julian Week
AD02-111	Time - Pass 1 Completion Date	Month	Month within calendar year
AD02-118	Time - Pass 1 Completion Date	Month Name	Full name of the month
AD02-112	Time - Pass 1 Completion Date	Quarter	Quarter within calendar year
AD02-114	Time - Pass 1 Completion Date	Week	Week within calendar year
AD02-113	Time - Pass 1 Completion Date	Year	Calendar year
AD02-119	Time - Pass 1 Completion Date	Year and Month	Year and month (ex. 1994 / 02)
AD02-121	Time - Pass 1 Completion Date	Year and Quarter	Year and quarter (ex. 1994 Q1)
AD02-120	Time - Pass 1 Completion Date	Year and Week	Year and week (ex. 1994 Week10)
-	Time - Pass 2 Completion Date	-	Time series based on Pass 2 Completion Date
AD02-127	Time - Pass 2 Completion Date	Date	Calendar Date
AD02-122	Time - Pass 2 Completion Date	Julian Day	Julian Day
AD02-128	Time - Pass 2 Completion Date	Julian Month	Julian Month
AD02-129	Time - Pass 2 Completion Date	Julian Week	Julian Week
AD02-123	Time - Pass 2 Completion Date	Month	Month within calendar year

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD02-130	Time - Pass 2 Completion Date	Month Name	Full name of the month
AD02-124	Time - Pass 2 Completion Date	Quarter	Quarter within calendar year
AD02-126	Time - Pass 2 Completion Date	Week	Week within calendar year
AD02-125	Time - Pass 2 Completion Date	Year	Calendar year
AD02-131	Time - Pass 2 Completion Date	Year and Month	Year and month (ex. 1994 / 02)
AD02-133	Time - Pass 2 Completion Date	Year and Quarter	Year and quarter (ex. 1994 Q1)
AD02-132	Time - Pass 2 Completion Date	Year and Week	Year and week (ex. 1994 Week10)
-	Time - Site Visit Start Date	-	Time series based on Site Visit Start Date
AD02-43	Time - Site Visit Start Date	Date	Calendar Date
AD02-38	Time - Site Visit Start Date	Julian Day	Julian Day
AD02-44	Time - Site Visit Start Date	Julian Month	Julian Month
AD02-45	Time - Site Visit Start Date	Julian Week	Julian Week
AD02-39	Time - Site Visit Start Date	Month	Month within calendar year
AD02-46	Time - Site Visit Start Date	Month Name	Full name of the month
AD02-40	Time - Site Visit Start Date	Quarter	Quarter within calendar year
AD02-42	Time - Site Visit Start Date	Week	Week within calendar year
AD02-41	Time - Site Visit Start Date	Year	Calendar year
AD02-47	Time - Site Visit Start Date	Year and Month	Year and month (ex. 1994 / 02)
AD02-49	Time - Site Visit Start Date	Year and Quarter	Year and quarter (ex. 1994 Q1)
AD02-48	Time - Site Visit Start Date	Year and Week	Year and week (ex. 1994 Week10)
-	Time - Visit Report Approved Date	-	Time series based on Visit Report Approved Date
AD02-67	Time - Visit Report Approved Date	Date	Calendar Date
AD02-62	Time - Visit Report Approved Date	Julian Day	Julian Day

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD02-68	Time - Visit Report Approved Date	Julian Month	Julian Month
AD02-69	Time - Visit Report Approved Date	Julian Week	Julian Week
AD02-63	Time - Visit Report Approved Date	Month	Month within calendar year
AD02-70	Time - Visit Report Approved Date	Month Name	Full name of the month
AD02-64	Time - Visit Report Approved Date	Quarter	Quarter within calendar year
AD02-66	Time - Visit Report Approved Date	Week	Week within calendar year
AD02-65	Time - Visit Report Approved Date	Year	Calendar year
AD02-71	Time - Visit Report Approved Date	Year and Month	Year and month (ex. 1994 / 02)
AD02-73	Time - Visit Report Approved Date	Year and Quarter	Year and quarter (ex. 1994 Q1)
AD02-72	Time - Visit Report Approved Date	Year and Week	Year and week (ex. 1994 Week10)
-	Time - Visit Report Completed Date	-	Time series based on Visit Report Completed Date
AD02-55	Time - Visit Report Completed Date	Date	Calendar Date
AD02-50	Time - Visit Report Completed Date	Julian Day	Julian Day
AD02-56	Time - Visit Report Completed Date	Julian Month	Julian Month
AD02-57	Time - Visit Report Completed Date	Julian Week	Julian Week
AD02-51	Time - Visit Report Completed Date	Month	Month within calendar year
AD02-58	Time - Visit Report Completed Date	Month Name	Full name of the month
AD02-52	Time - Visit Report Completed Date	Quarter	Quarter within calendar year
AD02-54	Time - Visit Report Completed Date	Week	Week within calendar year
AD02-53	Time - Visit Report Completed Date	Year	Calendar year
AD02-59	Time - Visit Report Completed Date	Year and Month	Year and month (ex. 1994 / 02)
AD02-61	Time - Visit Report Completed Date	Year and Quarter	Year and quarter (ex. 1994 Q1)
AD02-60	Time - Visit Report Completed Date	Year and Week	Year and week (ex. 1994 Week10)

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD11	CRF	-	A Case Report Form. This is the form itself, as defined in a study, and which is assigned to be collected at various subject visits during a study.
AD11-02	CRF	CRF Name	Name of the form.
AD11-04	CRF	CRF Short Name	Short name of the form
AD11-05	CRF	DCI_ID	Oracle Clinical ID for the form.
AD11-03	CRF	Description	Free text description of the particular CRF
AD11-01	CRF	Study	Study in which the form is specified.
AD12	CRF Book	-	A specification of which CRFs are to be collected at what subject visits
AD12-01	CRF Book	CRF Book Name	Case Report Form Book (a set of forms to be collected, organized by visit): name of the book
AD12-02	CRF Book	Study	Case Report Form Book (a set of forms to be collected, organized by visit): study in which the book is to be used
AD4	Geography	-	Location of a site, in terms of a fixed hierarchy. State >- Country >- Continent.
AD04-06	Geography	City	City
AD04-01	Geography	Continent	Continent
AD04-03	Geography	Country	Country
AD04-05	Geography	County or District	County or District
AD04-07	Geography	Postal Code	Postal Code
AD04-04	Geography	State or Province	State or Province
AD5	Investigator	-	Attributes of an Investigator, who may participate in multiple studies.
AD05-19	Investigator	Investigator Action Link	Action Link for Siebel Clinical Contacts. Can be used to link back to Contact record in Siebel Clinical
AD05-11	Investigator	Investigator Business Unit	Organizational business unit
AD05-05	Investigator	Investigator City	The city where the investigator is located.
AD05-09	Investigator	Investigator Continent	Continent where the investigator is located
AD05-08	Investigator	Investigator Country	Country where the investigator is located
AD05-13	Investigator	Investigator Email Address	Investigator email address
AD05-14	Investigator	Investigator Fax/Phone #	Investigator fax/phone number
AD05-02	Investigator	Investigator First Name	Investigator's given name
AD05-03	Investigator	Investigator Full Name	Last name, then first name

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD05-01	Investigator	Investigator Last Name	Investigator's surname
AD05-15	Investigator	Investigator Middle Name	Investigator middle name
AD05-12	Investigator	Investigator Mobile #	Investigator mobile number
AD05-06	Investigator	Investigator Postal code	Postal code
AD05-07	Investigator	Investigator State	The state where the investigator is located
AD05-04	Investigator	Investigator Street Address	Investigator's street address
AD05-17	Investigator	Investigator Street Address 2	Investigator's street address - 2nd line
AD05-18	Investigator	Investigator Street Address 3	Investigator's street address - 3rd line
AD05-16	Investigator	Investigator Type	Investigator type
AD05-10	Investigator	Investigator Work Phone	Investigator's work telephone
-	Overall Level Targets	-	-
AD18-01	Overall Level Targets	[Expected % Sites Recruiting 0 Subjects]	The Expected % Sites Recruiting 0 Subjects for all studies.
AD18-10	Overall Level Targets	[Target Critical Document Package Complete to Site Initiated (# Days)]	The Target Critical Document Package Complete to Site Initiated (# Days) for all studies.
AD18-02	Overall Level Targets	[Target Last Subject Last Visit to Database Lock (# Days)]	The Target Last Subject Last Visit to Database Lock (# Days) for all studies.
AD18-03	Overall Level Targets	[Target Protocol Approved to 1st Site Initiated (# Days)]	The Target Protocol Approved to 1st Site Initiated (# Days) for all studies.
AD18-04	Overall Level Targets	[Target Protocol Approved to 1st Subject Enrolled (# Days)]	The Target Protocol Approved to 1st Subject Enrolled (# Days) for all studies.
AD18-11	Overall Level Targets	[Target Protocol Approved to 1st Subject Randomized (# Days)]	The Target Protocol Approved to 1st Subject Randomized (# Days) for all studies.
AD18-12	Overall Level Targets	[Target Protocol Approved to 1st Subject Screened (# Days)]	The Target Protocol Approved to 1st Subject Screened (# Days) for all studies.
AD18-05	Overall Level Targets	[Target Site Visit Completed to Follow Up Item Completed (# Days)]	The Target Site Visit Completed to Follow Up Item Completed (# Days) for all studies.

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD18-06	Overall Level Targets	[Target Site Visit Completed to Visit Report Approved (# Days)]	The Target Site Visit Completed to Visit Report Approved (# Days) for all studies.
AD18-07	Overall Level Targets	[Target Site Visit Completed to Visit Report Completed (# Days)]	The Target Site Visit Completed to Visit Report Completed (# Days) for all studies.
AD18-09	Overall Level Targets	[Target Site Visit Start to Site Visit Completed (# Days)]	The Target Site Visit Start to Site Visit Completed (# Days) for all studies.
AD18-08	Overall Level Targets	[Target Visit Report Completed to Visit Report Approved (# Days)]	The Target Visit Report Completed to Visit Report Approved (# Days) for all studies.
AD7	Product	-	Product dimension
AD07-04	Product	Description	Product Description
AD07-09	Product	Product Action Link	Action Link for Siebel Clinical Product to link back to Product record in Siebel Clinical
AD07-01	Product	Product Name	Name of the product
AD07-07	Product	Product Number	Product #
AD07-08	Product	Product Status	Product Status
AD07-02	Product	Product Type	Type of the product
AD07-03	Product	Product Type Code	Organization's type code for the product
AD16	Program	-	Program
AD16-05	Program	[Expected % Sites Recruiting 0 Subjects]	The Expected % Sites Recruiting 0 Subjects for the Program.
AD16-02	Program	Program	Program Name
AD16-04	Program	Program Action Link	Action Link for Siebel Clinical Program. Can be used to link back to Program record in Siebel Clinical
AD16-01	Program	Program Description	Program Description
AD16-03	Program	Program Mechanism	Program Mechanism
AD16-06	Program	[Target Critical Document Package Complete to Site Initiated (# Days)]	The Target Critical Document Package Complete to Site Initiated (# Days) for the Program.
AD16-07	Program	[Target Last Subject Last Visit to Database Lock (# Days)]	The Target Last Subject Last Visit to Database Lock (# Days) for the Program.
AD16-08	Program	[Target Protocol Approved to 1st Site Initiated (# Days)]	The Target Protocol Approved to 1st Site Initiated (# Days) for the Program.
AD16-09	Program	[Target Protocol Approved to 1st Subject Enrolled (# Days)]	The Target Protocol Approved to 1st Subject Enrolled (# Days) for the Program.

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD16-10	Program	[Target Protocol Approved to 1st Subject Randomized (# Days)]	The Target Protocol Approved to 1st Subject Randomized (# Days) for the Program.
AD16-11	Program	[Target Protocol Approved to 1st Subject Screened (# Days)]	The Target Protocol Approved to 1st Subject Screened (# Days) for the Program.
AD16-12	Program	[Target Site Visit Completed to Follow Up Item Completed (# Days)]	The Target Site Visit Completed to Follow Up Item Completed (# Days) for the Program.
AD16-13	Program	[Target Site Visit Completed to Visit Report Approved (# Days)]	The Target Site Visit Completed to Visit Report Approved (# Days) for the Program.
AD16-14	Program	[Target Site Visit Completed to Visit Report Completed (# Days)]	The Target Site Visit Completed to Visit Report Completed (# Days) for the Program.
AD16-15	Program	[Target Site Visit Start to Site Visit Completed (# Days)]	The Target Site Visit Start to Site Visit Completed (# Days) for the Program.
AD16-16	Program	[Target Visit Report Completed to Visit Report Approved (# Days)]	The Target Visit Report Completed to Visit Report Approved (# Days) for the Program.
AD17	Study-Region	-	Study Region
AD20-05	Region	[Expected % Sites Recruiting 0 Subjects]	The Expected % Sites Recruiting 0 Subjects for the Region.
AD20-06	Region	[Target Critical Document Package Complete to Site Initiated (# Days)]	The Target Critical Document Package Complete to Site Initiated (# Days) for the Region.
AD20-01	Region	[Target Site Visit Completed to Follow Up Item Completed (# Days)]	The Target Site Visit Completed to Follow Up Item Completed (# Days) for the Region.
AD20-03	Region	[Target Site Visit Completed to Visit Report Approved (# Days)]	The Target Site Visit Completed to Visit Report Approved (# Days) for the Region.
AD20-02	Region	[Target Site Visit Completed to Visit Report Completed (# Days)]	The Target Site Visit Completed to Visit Report Completed (# Days) for the Region.
AD20-08	Region	[Target Site Visit Start to Site Visit Completed (# Days)]	The Target Site Visit Start to Site Visit Completed (# Days) for the Region.
AD20-04	Region	[Target Visit Report Completed to Visit Report Approved (# Days)]	The Target Visit Report Completed to Visit Report Approved (# Days) for the Region.

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD20-07	Region	Region Name	The Region name.
AD08	Site	-	Site attributes
AD08-05	Site	Business Unit	Business Unit to which this Site belongs
AD08-12	Site	City	Site City
AD08-04	Site	Continent	Continent in which the Site is located
AD08-03	Site	Country	Country in which the Site is located
AD08-11	Site	County	Site County
AD08-10	Site	Postal Code	Site Postal Code
AD08-06	Site	Site Action Link	Action Link for Siebel Clinical Accounts. Can be used to link back to Account record in Siebel Clinical
AD08-01	Site	Site Name	Name of the Site
AD08-02	Site	State	State in which the Site is located
AD08-07	Site	Street Address	Site address line 1
AD08-08	Site	Street Address 2	Site address line 2
AD08-09	Site	Street Address 3	Site address line 3
TA-SIV	Site Visit	-	Site Visit attributes
TA-SIV11	Site Visit	Site Visit Action Link	Action Link for Siebel Clinical Site Visits. Can be used to link back to Site Visit record in Siebel Clinical
TA-SIV01	Site Visit	Site Visit Comments	Comments about the Site Visit
TA-SIV02	Site Visit	Site Visit Completed Date	Site Visit Completed Date field
TA-SIV03	Site Visit	Site Visit Name	The visit name field in the source system.
TA-SIV04	Site Visit	[Site Visit Report Approved Date]	Site Visit Report Approved Date field
TA-SIV05	Site Visit	Site Visit Report Completed Date	Visit Report Completed Date field
TA-SIV06	Site Visit	Site Visit Report Status	Visit Report Status field
TA-SIV10	Site Visit	Site Visit Report Template	The template selected to create a site visit report in the source system.
TA-SIV07	Site Visit	Site Visit Start Date	Site Visit Start Date field
TA-SIV08	Site Visit	Site Visit Status	Site Visit Status field
TA-SIV09	Site Visit	Site Visit Type	Site Visit Type field
AD9	Study	-	A description of the study
AD09-26	Study	[Clinical Study Report Date]	The Clinical Study Report Date for the Study.
AD09-07	Study	Comparative Agent	Comparative Agent
AD09-06	Study	Data Capture Mode	The mode of doing data entry in this study. Possible values are {'EDC' | 'Paper' | 'Paper and EDC' | 'Unknown'}

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD09-14	Study	Database Lock Date	Database lock date
AD09-08	Study	Diagnosis	Diagnosis
AD09-09	Study	EUDRA Number	EUDRA Number
AD09-35	Study	[Expected % Sites Recruiting 0 Subjects]	The Expected % Sites Recruiting 0 Subjects for the Study.
AD09-73	Study	[Expected Early Termination Rate]	The expected early termination rate for the Study.
AD09-45	Study	[Expected Retention Rate]	The Expected Retention Rate for the Study.
AD09-24	Study	[Expected Screen Failure Rate]	The Expected Screen Failure Rate for the Study.
AD09-19	Study	[Protocol Approved Date]	The Protocol Approved Date for the Study.
AD09-69	Study	[Planned LE 1st Critical Document Package Completed Date]	The Planned LE 1st Critical Document Package Completed Date for the Study.
AD09-52	Study	[Planned LE 1st Initial IRB/EC Approval Date]	The latest estimate of the Planned 1st Initial IRB/EC Approval Date for the Study.
AD09-53	Study	[Planned LE 1st IRB/EC Submission Date]	The latest estimate of the Planned 1st IRB Submission Date for the Study.
AD09-54	Study	[Planned LE 1st Site Initiated Date]	The latest estimate of the Planned 1st Site Initiated Date for the Study.
AD09-55	Study	[Planned LE 1st Subject 1st Visit Date]	The latest estimate of the Planned 1st Subject 1st Visit Date for the Study.
AD09-56	Study	[Planned LE 1st Subject Enrolled Date]	The latest estimate of the Planned 1st Subject Enrolled Date for the Study.
AD09-57	Study	[Planned LE 1st Subject Randomized Date]	The latest estimate of the Planned 1st Subject Randomized Date for the Study.
AD09-58	Study	[Planned LE 1st Subject Screened Date]	The latest estimate of the Planned 1st Subject Screened Date for the Study.
AD09-59	Study	[Planned LE Clinical Study Report Date]	The latest estimate of the Planned Clinical Study Report Date for the Study.
AD09-60	Study	[Planned LE Database Lock Date]	The latest estimate of the Planned Database Lock Date for the Study.
AD09-61	Study	[Planned LE Last Critical Document Package Completed Date]	The latest estimate of the Planned Last Critical Document Package Completed Date for the Study.
AD09-62	Study	[Planned LE Last Site Initiated Date]	The latest estimate of the Planned Last Site Initiated Date for the Study.
AD09-63	Study	[Planned LE Last Subject 1st Visit Date]	The latest estimate of the Planned Last Subject 1st Visit Date for the Study.

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD09-64	Study	[Planned LE Last Subject Enrolled Date]	The latest estimate of the Planned Last Subject Enrolled Date for the Study.
AD09-65	Study	[Planned LE Last Subject Last Visit Date]	The latest estimate of the Planned Last Subject Last Visit Date for the Study.
AD09-66	Study	[Planned LE Last Subject Randomized Date]	The latest estimate of the Planned Last Subject Randomized Date for the Study.
AD09-67	Study	[Planned LE Protocol Approval Date]	The latest estimate of the Planned Protocol Approval Date for the Study.
AD09-48	Study	[Planned 1st Critical Document Package Completed Date]	The Planned 1st Critical Document Package Completed Date for the Study.
AD09-36	Study	[Planned 1st Initial IRB/EC Approval Date]	The Planned 1st Initial IRB/EC Approval Date for the Study.
AD09-50	Study	[Planned 1st IRB/EC Submission Date]	The Planned 1st IRB Submission Date for the Study.
AD09-49	Study	[Planned 1st Site Initiated Date]	The Planned 1st Site Initiated Date for the Study.
AD09-40	Study	[Planned 1st Subject 1st Visit Date]	The Planned 1st Subject 1st Visit Date for the Study.
AD09-46	Study	[Planned 1st Subject Enrolled Date]	The Planned 1st Subject Enrolled Date for the Study.
AD09-38	Study	[Planned 1st Subject Randomized Date]	The Planned 1st Subject Randomized Date for the Study.
AD09-39	Study	[Planned 1st Subject Screened Date]	The Planned 1st Subject Screened Date for the Study.
AD09-25	Study	[Planned Clinical Study Report Date]	The Planned Clinical Study Report Date for the Study.
AD09-20	Study	[Planned Database Lock Date]	The Planned Database Lock Date for the Study.
AD09-51	Study	[Planned Last Critical Document Package Completed Date]	The Planned Last Critical Document Package Completed Date for the Study.
AD09-41	Study	[Planned Last Site Initiated Date]	The Planned Last Site Initiated Date for the Study.
AD09-44	Study	[Planned Last Subject 1st Visit Date]	The Planned Last Subject 1st Visit Date for the Study.
AD09-42	Study	[Planned Last Subject Enrolled Date]	The Planned Last Subject Enrolled Date for the Study.
AD09-43	Study	[Planned Last Subject Last Visit Date]	The Planned Last Subject Last Visit Date for the Study.
AD09-68	Study	[Planned Last Subject Randomized Date]	The Planned Last Subject Randomized Date for the Study.
AD09-18	Study	[Planned Protocol Approval Date]	The Planned Protocol Approval Date for the Study.

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD09-17	Study	Product	The Product specified for the study
AD09-03	Study	Program	Name of the Program that owns the Study
AD09-04	Study	Project	OC Project containing the Study
AD09-01	Study	Study	Unique identifier for the Study
AD09-15	Study	Study Action Link	Action Link for Siebel Clinical Studies. Can be used to link back to Study record in Siebel Clinical
AD09-16	Study	Study Manager	The name of the primary person responsible for the study.
AD09-10	Study	Study Phase	Phase
AD09-02	Study	Study Short Title	A unique short title for the Study
AD09-05	Study	Study Sponsor	Name of the Sponsor company for which this study is being conducted
AD09-11	Study	Study Status	Protocol Status
AD09-12	Study	Study Title	Title
AD09-13	Study	Study Type	Type
AD09-29	Study	[Target 1st Site Initiated to 1st Subject Enrolled (# Days)]	The Target 1st Site Initiated to 1st Subject Enrolled (# Days) for the Study.
AD09-27	Study	[Target 1st Site Initiated to Last Site Initiated (# Days)]	The Target 1st Site Initiated to Last Site Initiated (# Days) for the Study.
AD09-28	Study	[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.
AD09-47	Study	[Target 1st Subject Enrolled to Last Subject Enrolled (# Days)]	The Target 1st Subject Enrolled to Last Subject Enrolled (# Days) for the Study.
AD09-70	Study	[Target Critical Document Package Complete to Site Initiated (# Days)]	The Target Critical Document Package Complete to Site Initiated (# Days) for the Study.
M-STD14	Study	[Target Last Subject Last Visit to Database Lock (# Days)]	The Target Last Subject Last Visit to Database Lock (# Days) for the Study.
AD09-22	Study	[Target Protocol Approved to 1st Site Initiated (# Days)]	The Target Protocol Approved to 1st Site Initiated (# Days) for the Study.
AD09-23	Study	[Target Protocol Approved to 1st Subject Enrolled (# Days)]	The Target Protocol Approved to 1st Subject Enrolled (# Days) for the Study.
AD09-71	Study	[Target Protocol Approved to 1st Subject Randomized (# Days)]	The Target Protocol Approved to 1st Subject Randomized (# Days) for the Study.

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD09-72	Study	[Target Protocol Approved to 1st Subject Screened (# Days)]	The Target Protocol Approved to 1st Subject Screened (# Days) for the Study.
AD09-30	Study	[Target Site Visit Completed to Follow Up Item Completed (# Days)]	The Target Site Visit Completed to Follow Up Item Completed (# Days) for the Study.
AD09-31	Study	[Target Site Visit Completed to Visit Report Approved (# Days)]	The Target Site Visit Completed to Visit Report Approved (# Days) for the Study.
AD09-32	Study	[Target Site Visit Completed to Visit Report Completed (# Days)]	The Target Site Visit Completed to Visit Report Completed (# Days) for the Study.
AD09-34	Study	[Target Site Visit Start to Site Visit Completed (# Days)]	The Target Site Visit Start to Site Visit Completed (# Days) for the Study.
AD09-33	Study	[Target Visit Report Completed to Visit Report Approved (# Days)]	The Target Visit Report Completed to Visit Report Approved (# Days) for the Study.
AD09-74	Study	[Therapeutic Area]	The name of the Therapeutic Area.
-	Study Team Member	-	Study Team Member attributes
AD19-07	Study Team Member	Email	Team member email address.
AD19-06	Study Team Member	End Date	Study Team Member End Date field.
AD19-01	Study Team Member	First Name	Study Team Member First Name field.
AD19-03	Study Team Member	Full Name	Study Team Member Full Name field.
AD19-02	Study Team Member	Last Name	Study Team Member Last Name field.
AD19-04	Study Team Member	Role	Study Team Member Role field.
AD19-05	Study Team Member	Start Date	Study Team Member Start Date field.
AD19-09	Study Team Member	Team Member Active	If the team member's end date is null, indicate that the team member is active.
AD19-08	Study Team Member	Team Member Comment	Study Team Member Comment field.
-	Study-Region	-	-
AD17-04	Study-Region	Region Action Link	Action Link for Siebel Clinical Regions. Can be used to link back to Region record in Siebel Clinical
AD17-03	Study-Region	Region CRO	CRO for a Region
AD17-01	Study-Region	Region Name	Protocol Region
AD17-02	Study-Region	Region Status	Status of Region
AD17-46	Study-Region	[Clinical Study Report Date]	The Clinical Study Report Date for the Study.

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD17-47	Study-Region	[Protocol Approved Date]	The Protocol Approved Date for the Study.
AD17-22	Study-Region	[Planned LE 1st Critical Document Package Completed Date]	The latest estimate of the Planned 1st Critical Document Package Completed Date for the Study-Region.
AD17-23	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.
AD17-24	Study-Region	[Planned LE 1st IRB/EC Submission Date]	The latest estimate of the Planned 1st IRB Submission Date for the Study-Region.
AD17-25	Study-Region	[Planned LE 1st Site Initiated Date]	The latest estimate of the Planned 1st Site Initiated Date for the Study-Region.
AD17-26	Study-Region	[Planned LE 1st Subject 1st Visit Date]	The latest estimate of the Planned 1st Subject 1st Visit Date for the Study-Region.
AD17-27	Study-Region	[Planned LE 1st Subject Enrolled Date]	The latest estimate of the Planned 1st Subject Enrolled Date for the Study-Region.
AD17-28	Study-Region	[Planned LE 1st Subject Randomized Date]	The latest estimate of the Planned 1st Subject Randomized Date for the Study-Region.
AD17-29	Study-Region	[Planned LE 1st Subject Screened Date]	The latest estimate of the Planned 1st Subject Screened Date for the Study-Region.
AD17-30	Study-Region	[Planned LE Last Critical Document Package Completed Date]	The latest estimate of the Planned Last Critical Document Package Completed Date for the Study-Region.
AD17-31	Study-Region	[Planned LE Last Site Initiated Date]	The latest estimate of the Planned Last Site Initiated Date for the Study-Region.
AD17-32	Study-Region	[Planned LE Last Subject 1st Visit Date]	The latest estimate of the Planned Last Subject 1st Visit Date for the Study-Region.
AD17-33	Study-Region	[Planned LE Last Subject Enrolled Date]	The latest estimate of the Planned Last Subject Enrolled Date for the Study-Region.
AD17-34	Study-Region	[Planned LE Last Subject Last Visit Date]	The latest estimate of the Planned Last Subject Last Visit Date for the Study-Region.
AD17-35	Study-Region	[Planned LE Last Subject Randomized Date]	The latest estimate of the Planned Last Subject Randomized Date for the Study-Region.
AD17-19	Study-Region	[Planned 1st Critical Document Package Completed Date]	The Planned 1st Critical Document Package Completed Date for the Study-Region.
AD17-09	Study-Region	[Planned 1st Initial IRB/EC Approval Date]	The Planned 1st Initial IRB/EC Approval Date for the Study-Region.
AD17-20	Study-Region	[Planned 1st IRB/EC Submission Date]	The Planned 1st IRB Submission Date for the Study-Region.

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD17-05	Study-Region	[Planned 1st Site Initiated Date]	The Planned 1st Site Initiated Date for the Study-Region.
AD17-13	Study-Region	[Planned 1st Subject 1st Visit Date]	The Planned 1st Subject 1st Visit Date for the Study-Region.
AD17-10	Study-Region	[Planned 1st Subject Enrolled Date]	The Planned 1st Subject Enrolled Date for the Study-Region.
AD17-11	Study-Region	[Planned 1st Subject Randomized Date]	The Planned 1st Subject Randomized Date for the Study-Region.
AD17-12	Study-Region	[Planned 1st Subject Screened Date]	The Planned 1st Subject Screened Date for the Study-Region.
AD17-21	Study-Region	[Planned Last Critical Document Package Completed Date]	The Planned Last Critical Document Package Completed Date for the Study-Region.
AD17-07	Study-Region	[Planned Last Site Initiated Date]	The Planned Last Site Initiated Date for the Study-Region.
AD17-15	Study-Region	[Planned Last Subject 1st Visit Date]	The Planned Last Subject 1st Visit Date for the Study-Region.
AD17-14	Study-Region	[Planned Last Subject Enrolled Date]	The Planned Last Subject Enrolled Date for the Study-Region.
AD17-16	Study-Region	[Planned Last Subject Last Visit Date]	The Planned Last Subject Last Visit Date for the Study-Region.
AD17-36	Study-Region	[Planned Last Subject Randomized Date]	The Planned Last Subject Randomized Date for the Study-Region.
AD17-06	Study-Region	[Expected % Sites Recruiting 0 Subjects]	The Expected % Sites Recruiting 0 Subjects for the Study-Region.
AD17-42	Study-Region	[Expected Early Termination Rate]	The expected early termination rate for the Study-Region.
AD17-37	Study-Region	[Expected Retention Rate]	The Expected Retention Rate for the Study-Region.
AD17-38	Study-Region	[Expected Screen Failure Rate]	The Expected Screen Failure Rate for the Study-Region.
AD17-39	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.
AD17-08	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.
AD17-40	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.
AD17-18	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.
AD17-41	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.
AD17-43	Study-Region	Region Name	The Region name.

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD17-17	Study-Region	Study-Region Manager	The manager for the Study-Region.
AD17-44	Study-Region	Study-Region Name	The name of the Study-Region
AD17-45	Study-Region	[Therapeutic Area]	The name of the Therapeutic Area.
-	Study-Region Team Member	-	-
AD21-07	Study-Region Team Member	Email	Team member email address.
AD21-06	Study-Region Team Member	End Date	Study-Region Team Member End Date field.
AD21-01	Study-Region Team Member	First Name	Study-Region Team Member First Name field.
AD21-03	Study-Region Team Member	Full Name	Study-Region Team Member Full Name field.
AD21-02	Study-Region Team Member	Last Name	Study-Region Team Member Last Name field.
AD21-04	Study-Region Team Member	Role	Study-Region Team Member Role field.
AD21-05	Study-Region Team Member	Start Date	Study-Region Team Member Start Date field.
AD21-09	Study-Region Team Member	Team Member Active	If the team member's end date is null, indicate that the team member is active.
AD21-08	Study-Region Team Member	Team Member Comment	Study-Region Team Member Comment field.
AD8	Study-Site	-	A physical setting at which one or more studies are conducted.
AD10-10	Study-Site	1st Subject Enrolled Date	Date on which first subject was enrolled at the study-site.
AD10-32	Study-Site	City	Site City
AD10-44	Study-Site	Country	Site Country
AD10-31	Study-Site	County	Site County
AD10-42	Study-Site	CRA	The name of the primary person responsible for the study-site.
AD10-24	Study-Site	CRO	CRO conducting the study at this site
AD10-25	Study-Site	Data Capture Mode	The mode of doing data entry at this study-site. Possible values are {'EDC' | 'Paper' | 'Paper and EDC' | 'Unknown'}
TA-SITE01	Study-Site	Initial IRB/EC Approval Date	Earliest IRB Approval date for a Site
AD10-08	Study-Site	Planned Enrollment Completion Date	Date on which enrollment is (or was) planned to be complete
AD10-07	Study-Site	Planned Enrollment Start Date	Date on which enrollment is (or was) expected to start. This is the date at which subjects start being sought, not the date of the enrollment of the first subject.
AD10-33	Study-Site	Postal Code	Site Postal Code

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD10-22	Study-Site	Principal Investigator	Full name of Investigator currently responsible for the study at the site
AD10-43	Study-Site	Product	The Product specified for the study
AD10-05	Study-Site	Program	Name of the OC Program that owns the Study
AD10-06	Study-Site	Project	Name of the Project that owns the Study
AD10-51	Study-Site	[Critical Document Package Completed Date]	The Critical Document Package Completed Date for the Study-Site.
AD10-56	Study-Site	[Initial IRB/EC Submission Date]	The Initial IRB Submission Date for the Study-Site.
AD10-74	Study-Site	Site Terminated Date	The Site Terminated Date for the Study-Site.
AD10-58	Study-Site	[Planned LE 1st Subject 1st Visit Date]	The latest estimate of the Planned 1st Subject 1st Visit Date for the Study-Site.
AD10-59	Study-Site	[Planned LE 1st Subject Enrolled Date]	The latest estimate of the Planned 1st Subject Enrolled Date for the Study-Site.
AD10-60	Study-Site	[Planned LE 1st Subject Randomized Date]	The latest estimate of the Planned 1st Subject Randomized Date for the Study-Site.
AD10-61	Study-Site	[Planned LE 1st Subject Screened Date]	The latest estimate of the Planned 1st Subject Screened Date for the Study-Site.
AD10-62	Study-Site	[Planned LE Critical Document Package Completed Date]	The latest estimate of the Planned Critical Document Package Completed Date for the Study-Site.
AD10-63	Study-Site	[Planned LE Initial IRB/EC Approval Date]	The latest estimate of the Planned Initial IRB/EC Approval Date for the Study-Site.
AD10-64	Study-Site	[Planned LE IRB/EC Submission Date]	The latest estimate of the Planned IRB Submission Date for the Study-Site.
AD10-65	Study-Site	[Planned LE Last Subject 1st Visit Date]	The latest estimate of the Planned Last Subject 1st Visit Date for the Study-Site.
AD10-66	Study-Site	[Planned LE Last Subject Enrolled Date]	The latest estimate of the Planned Last Subject Enrolled Date for the Study-Site.
AD10-67	Study-Site	[Planned LE Last Subject Last Visit Date]	The latest estimate of the Planned Last Subject Last Visit Date for the Study-Site.
AD10-68	Study-Site	[Planned LE Last Subject Randomized Date]	The latest estimate of the Planned Last Subject Randomized Date for the Study-Site.
AD10-69	Study-Site	[Planned LE Site Initiated Date]	The latest estimate of the Planned Site Initiated Date for the Study-Site.
AD10-73	Study-Site	[Planned 1st Subject 1st Visit Date]	The Planned 1st Subject 1st Visit Date for the Study-Site.
AD10-47	Study-Site	[Planned 1st Subject Enrolled Date]	The Planned 1st Subject Enrolled Date for the Study-Site.

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD10-53	Study-Site	[Planned 1st Subject Randomized Date]	The Planned 1st Subject Randomized Date for the Study-Site.
AD10-52	Study-Site	[Planned 1st Subject Screened Date]	The Planned 1st Subject Screened Date for the Study-Site.
AD10-55	Study-Site	[Planned Critical Document Package Completed Date]	The Planned Critical Document Package Completed Date for the Study-Site.
AD10-50	Study-Site	[Planned Initial IRB/EC Approval Date]	The Planned Initial IRB/EC Approval Date for the Study-Site.
AD10-57	Study-Site	[Planned IRB/EC Submission Date]	The Planned IRB Submission Date for the Study-Site.
AD10-46	Study-Site	[Planned Last Subject 1st Visit Date]	The Planned Last Subject 1st Visit Date for the Study-Site.
AD10-54	Study-Site	[Planned Last Subject Enrolled Date]	The Planned Last Subject Enrolled Date for the Study-Site.
AD10-48	Study-Site	[Planned Last Subject Last Visit Date]	The Planned Last Subject Last Visit Date for the Study-Site.
AD10-70	Study-Site	[Planned Last Subject Randomized Date]	The Planned Last Subject Randomized Date for the Study-Site.
AD10-49	Study-Site	[Planned Site Initiated Date]	The Planned Site Initiated Date for the Study-Site.
AD10-72	Study-Site	[Expected Early Termination Rate]	The expected early termination rate for the Study-Site.
AD10-71	Study-Site	[Expected Retention Rate]	The expected retention rate for the Study-Site.
AD10-76	Study-Site	Latitude	The latitude of the address for the Study-Site.
AD10-77	Study-Site	Longitude	The longitude of the address for the Study-Site
AD10-75	Study-Site	[Therapeutic Area]	The name of the Therapeutic Area.
AD10-41	Study-Site	Site Initiated Date	Site initiation date.
AD10-01	Study-Site	Site Name	Name of the Site being used for this Study Site.
AD10-45	Study-Site	State	Site State
AD10-34	Study-Site	Street Address	Study-Site address line 1
AD10-35	Study-Site	Street Address 2	Study-Site address line 2
AD10-36	Study-Site	Street Address 3	Study-Site address line 3
AD10-04	Study-Site	Study	Unique identifier for the Study
AD10-03	Study-Site	Study Region	Name of the study-specific region in which the study site is located
AD10-38	Study-Site	Study Region Status	Status of the Study Region (denormalized from Study.Region Status)
AD10-26	Study-Site	Study Sponsor	Sponsor of the research being done at the study-site. This is meaningful only if the user is a CRO. Will be defaulted with a value of "Not Specified"

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD10-40	Study-Site	Study Status	Status of the Study (denormalized from Study.Status)
AD10-37	Study-Site	Study, Site, and Investigator	In Business Model only - concatenation of Study #, Site #, P Investigator Last Name
AD10-39	Study-Site	Study-Site Action Link	Action Link for Siebel Clinical Site. Can be used to link back to Site record in Siebel Clinical
AD10-02	Study-Site	Study-Site ID #	Unique name given the site in the context of the Study.
AD10-29	Study-Site	Study-Site Status	Site Status
AD15	Study-Site Contacts	-	Study-Site Contact attributes
AD15-01	Study-Site Contacts	City	Study-Site contact city
AD15-19	Study-Site Contacts	Contact Action Link	Action Link for Siebel Clinical Contacts. Can be used to link back to Contact record in Siebel Clinical
AD15-02	Study-Site Contacts	Country	Study-Site contact country
AD15-03	Study-Site Contacts	County	Study-Site contact county
AD15-04	Study-Site Contacts	Email Address	Study-Site contact email address
AD15-05	Study-Site Contacts	Employee Flag	Study-Site Contact Employee Flag
AD15-06	Study-Site Contacts	Fax #	Study-Site contact fax number
AD15-07	Study-Site Contacts	First Name	Contact First Name
AD15-08	Study-Site Contacts	Full Name	Last name, then first name
AD15-09	Study-Site Contacts	Last Name	Contact Last Name
AD15-10	Study-Site Contacts	Middle Name	Contact Middle Name
AD15-11	Study-Site Contacts	Mobile #	Study-Site contact mobile number
AD15-12	Study-Site Contacts	Phone #	Study-Site contact phone number
AD15-13	Study-Site Contacts	Postal Code	Study-Site contact postal code
AD15-15	Study-Site Contacts	State	Study-Site contact state
AD15-16	Study-Site Contacts	Street Address	Study-Site contact street address
AD15-17	Study-Site Contacts	Street Address 2	Study-Site Contact Address Line 2
AD15-18	Study-Site Contacts	Street Address 3	Study-Site Contact Address Line 3
AD14	Study-Site Team Member	-	Study-Site Team Member attributes
AD14-10	Study-Site Team Member	Email	Team member Email address
AD14-06	Study-Site Team Member	End Date	End Date in the Team History view
AD14-01	Study-Site Team Member	First Name	Team member first name
AD14-03	Study-Site Team Member	Full Name	Last Name, First Name

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD14-02	Study-Site Team Member	Last Name	Team member last name
AD14-04	Study-Site Team Member	Role	Role in the Team History view
AD14-05	Study-Site Team Member	Start Date	Start Date in the Team History view
AD14-08	Study-Site Team Member	Team Member Action Link	Action Link for Siebel Clinical Employee. Can be used to link back to Employee record in Siebel Clinical
AD14-09	Study-Site Team Member	Team Member Active	Indicates that the team member does not have an end date and is still actively on the team
AD14-07	Study-Site Team Member	Team Member Comment	Comment in the Team History view
TD01	Subject	-	A person taking part in a study. While a person may participate in multiple studies, each participation corresponds to a unique subject
TD01-09	Subject	Birth Date	The subject's date of birth.
TD01-03	Subject	CRF Book	The ID of the DCI book to be used for this subject.
TD01-10	Subject	Death Date	The date that the subject was reported to have died.
TD01-18	Subject	Eligible Flag	Subject Eligible Flag
TD01-06	Subject	Enrollment Date	Date and time when this subject was enrolled in this study.
TD01-20	Subject	Enrollment ID	Enrollment ID
TD01-16	Subject	Gender	The subject's gender. Values are M for male and F for female.
TD01-07	Subject	Is Active	Is the subject one about whom CRFs are to be expected? This is to differentiate between two classes of people who may be given Subject IDs: (1) people who have not yet been screened or enrolled, and thus about whom no clinical trial data is to be expected, (2) people about who clinical trial data is to be expected. Setting for this will have to be user-dependent, since it hinges on when the user assigns a subject ID, and what that signifies with respect to expectation of clinical trial data. Defaults to 'Y'.
TD01-05	Subject	Is Early Terminated	A flag to show if the subject was terminated early from the study. VARCHAR2(1)
TD01-04	Subject	Is Hard Locked	A flag to show if the system prevents any changes to the data for this subject.
TD01-25	Subject	Protocol Deviation Flag	Subject Protocol Deviation Flag
TD01-22	Subject	Protocol Violation Flag	Subject Protocol Violation Flag
TD01-29	Subject	Randomization Date	Date on which the Subject was randomized
TD01-21	Subject	Randomization ID	Randomization ID

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
TD01-23	Subject	Screen Failure Reason	Screen Failure Reason
TD01-24	Subject	Screening #	Screening #
TD01-17	Subject	Screening Date	Date on which subject passed screening.
TD01-01	Subject	Study	Name of the clinical study in which this subject is a participant
TD01-30	Subject	Subject Action Link	Action Link for Siebel Clinical Subjects. Can be used to link back to Subject record in Siebel Clinical
TD01-27	Subject	Subject Age	Current date minus subject Birth Date
TD01-19	Subject	Subject Comments	Subject comment
TD01-28	Subject	Subject Current Status Date	Date of subject's current status
TD01-02	Subject	Subject ID	A unique code for the subject position within the clinical study.
TD01-08	Subject	Subject Initials	The subject's initials, in mixed case.
TD01-11	Subject	Subject Status	Subject's current status
TD01-12	Subject	Subject Termination Date	Date on which the Subject ended participation in the study.
TD01-26	Subject	Withdrawn Reason	Withdrawn reason
AD22-10	Therapeutic Area	[Expected % Sites Recruiting 0 Subjects]	The Expected % Sites Recruiting 0 Subjects for the Therapeutic Area.
AD22-11	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.
AD22-02	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.
AD22-03	Therapeutic Area	[Target Protocol Approved to 1st Site Initiated (# Days)]	The Target Protocol Approved to 1st Site Initiated (# Days) for the Therapeutic Area.
AD22-04	Therapeutic Area	[Target Protocol Approved to 1st Subject Enrolled (# Days)]	The Target Protocol Approved to 1st Subject Enrolled (# Days) for the Therapeutic Area.
AD22-12	Therapeutic Area	[Target Protocol Approved to 1st Subject Randomized (# Days)]	The Target Protocol Approved to 1st Subject Randomized (# Days) for the Therapeutic Area.
AD22-13	Therapeutic Area	[Target Protocol Approved to 1st Subject Screened (# Days)]	The Target Protocol Approved to 1st Subject Screened (# Days) for the Therapeutic Area.
AD22-05	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.

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD22-06	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.
AD22-07	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.
AD22-09	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.
AD22-08	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.
AD22-01	Therapeutic Area	[Therapeutic Area]	The name of the Therapeutic Area.
AD13	Validation Procedure	-	A specification of a rule that validates a particular aspect of collected data
AD13-01	Validation Procedure	Study	Study in which the Procedure is specified.
AD13-03	Validation Procedure	Validation Procedure Description	Description of the validation procedure
AD13-02	Validation Procedure	Validation Procedure Name	Name of the Validation Procedure
AD13-04	Validation Procedure	Validation Procedure Scope	Scope of data used in the Procedure: 1-EVENT 1-DCM 1-EVENT M-DCM M-EVENT 1-DCM M-EVENT M-DCM THES_DERIVATION

Facts in OHSCDA Presentation Catalog

Table B-2 describes the Facts displayed in the OHSCDA Presentation Catalog, and their Columns. For each Column, it shows the name of the Column, its description, and the Fact and Group within the Fact that contain the Column. The table is sorted by Group and Column, within Fact. This corresponds to how the Fact columns are organized in the Presentation Catalog, within the Fact folder. Each Fact Column has an ID number, which is provided for cross-reference to other tables in this Appendix.

Table B–2 Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-DSC03	Discrepancies	Counts	# Closed Discrepancies	Number of discrepancies that have either been obsolete or have been marked irresolvable.
M-DSC12	Discrepancies	Counts	# Days Current Discrepancies Open	For currently open discrepancies, number of days since creation
M-DSC11	Discrepancies	Counts	# Days Discrepancy Open	Days from creation of discrepancy to: - today, if discrepancy still open - date closed, if discrepancy closed.
M-DSC15	Discrepancies	Counts	# Days to Close Discrepancy	NULL if open; Days from creation of discrepancy to: date closed, if discrepancy closed
M-DSC09	Discrepancies	Counts	# Discrepancies Irresolvable	Number of discrepancies that have been marked irresolvable
M-DSC04	Discrepancies	Counts	# Discrepancies sent in DCFs	Number of discrepancies that have been included in one or more DCFs.
M-DSC02	Discrepancies	Counts	# Open Discrepancies	Number of discrepancies awaiting either being resolved or being marked irresolvable.
M-DSC01	Discrepancies	Counts	# Total Discrepancies	Number of discrepancies, both open and closed
TA-DISC09	Discrepancies	Transactional Data	Complete Visit Number	Planned event number || . || subevent number
TA-DISC13	Discrepancies	Transactional Data	CRF Book Page	Page within subject's CRF book where the question giving rise to the discrepancy is located
TA-DISC11	Discrepancies	Transactional Data	CRF Entry Date	Date on which the CRF containing the discrepant value was entered.
TA-DISC12	Discrepancies	Transactional Data	CRF Name	Name of the CRF (e.g. Demog) containing the discrepancy
TA-DISC14	Discrepancies	Transactional Data	CRF Page Section	Within the Page containing the discrepancy, the Section containing the discrepancy
TA-DISC15	Discrepancies	Transactional Data	CRF Question Group	Within the Page and Section, the Question Group containing the discrepancy
TA-DISC16	Discrepancies	Transactional Data	CRF Question Name	Within the Page and Section containing the discrepancy, the Question giving rise to the discrepancy
TA-DISC17	Discrepancies	Transactional Data	CRF Question Occurrence	For the Question giving rise to the discrepancy, the Occurrence Sequence Number of Question. Has value of zero if there is only one occurrence; has value in 1..n, where number of occurrences, n, is greater than zero.

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
TA-DISC21	Discrepancies	Transactional Data	Current Review Status	The current review status of the discrepancy. This tells where the discrepancy is in its movement through a processing workflow. The status values are initially defined by Oracle Clinical, with extensions allowed by customer.
TA-DISC26.1	Discrepancies	Transactional Data	Discrepancy Answered Date	Date when a query about the discrepancy was answered
TA-DISC26	Discrepancies	Transactional Data	Discrepancy Close Date	Date when the discrepancy was closed (i.e. closed, made obsolete, or marked irresolvable).
TA-DISC30	Discrepancies	Transactional Data	Discrepancy Comment Text	Text associated with the discrepancy
TA-DISC25	Discrepancies	Transactional Data	Discrepancy Creation Date	Date when the discrepancy was created
TA-DISC01	Discrepancies	Transactional Data	Discrepancy ID	Unique ID of the discrepancy
TA-DISC22.1	Discrepancies	Transactional Data	Discrepancy State	Open', 'Answered', 'Closed', possibly others.
TA-DISC22	Discrepancies	Transactional Data	Discrepancy Status	OC Discrepancy Status. Takes value of CURRENT, OBSOLETE
TA-DISC23	Discrepancies	Transactional Data	Discrepancy Type	How the discrepancy came into existence: Values are UNIVARIATE, MULTIVARIATE, MANUAL, and INDICATOR
TA-DISC04	Discrepancies	Transactional Data	Investigator	Study-Site Investigator
TA-DISC19	Discrepancies	Transactional Data	Is Irresolvable	True if the discrepancy review status has a long value of IRRESOLVABLE, which is OC's way of saying the review status is Irresolvable.
TA-DISC32	Discrepancies	Transactional Data	Origin	The origin of the discrepancy. Takes one of these values: {System; Non-system}
TA-DISC24	Discrepancies	Transactional Data	Resolution Type	How the discrepancy was resolved. NULL if not currently resolved. The possible values are initially defined by Oracle Clinical, with extensions allowed by customer.
TA-DISC31	Discrepancies	Transactional Data	Sent in DCF	Flag to indicate whether a discrepancy was sent in DCF
TA-DISC03	Discrepancies	Transactional Data	Site	Site at which the discrepancy was created
TA-DISC02	Discrepancies	Transactional Data	Study	Study in which the discrepancy was created
TA-DISC33	Discrepancies	Transactional Data	Study-Site	Name of the Study-Site at which the discrepancy was created

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
TA-DISC08	Discrepancies	Transactional Data	Sub-event Number	Sub-event number of the visit at which the value causing the discrepancy was collected
TA-DISC05	Discrepancies	Transactional Data	Subject ID	ID for the subject about whom the data were collected.
TA-DISC10	Discrepancies	Transactional Data	Subject Visit Date	Date of the subject visit when the value causing the discrepancy was collected
TA-DISC06	Discrepancies	Transactional Data	Subject Visit Name	Name of the subject visit at which the value causing the discrepancy was collected
TA-DISC07	Discrepancies	Transactional Data	Subject Visit Number	Number of the subject visit at which the value causing the discrepancy was collected
TA-DISC20	Discrepancies	Transactional Data	Validation Procedure Name	If the discrepancy arose from execution of a validation procedure, the name of that procedure. Null otherwise.
M-DRS02	Discrepancy Review Statuses	Transactional Data	# Days Discrepancy Ever in Review Status	Number of days a discrepancy ever occupied a particular discrepancy review status.
M-DRS03	Discrepancy Review Statuses	Statistics	Avg # Days Discrepancy Ever in Review Status	Number of days a discrepancy ever occupied a particular discrepancy review status, divided by the number of discrepancies ever in that review status
M-DRS04	Discrepancy Review Statuses	Statistics	Avg # Days Open Discrepancy Ever in Review Status	Number of days a currently open discrepancy ever occupied a discrepancy review status, divided by the number of discrepancies ever in that review status
M-DRS01	Discrepancy Review Statuses	Transactional Data	Discrepancy Review Status	A review status occupied by a discrepancy over the life of the discrepancy.
M-SST51	Document Metrics	Counts	# Days Document Outstanding	Number of days between Document Sent date and today's date, when Document Received date is null
M-SST50	Document Metrics	Counts	# Days from Document Sent to Document Received	Number of days between Document Sent date and Document Received Date
M-DOC02	Document Metrics	Intervals	# Days Until Document Expiration	The number of days between Document Expiration Date and today's date.
M-DOC01	Document Metrics	Counts	# Documents	Count of all Activities where Activity is Document or Site-Initiation
M-DOC03	Document Metrics	Counts	# Documents Outstanding	The number of documents with a Sent Date and no Received Date.
M-DOC04	Document Metrics	Counts	# Documents Received	The number of documents with a Received Date.

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
TA-DOC01	Document Metrics	Transactional Data	Activity	Document Activity
TA-DOC04	Document Metrics	Transactional Data	Activity Type	Activity Type
TA-DOC02	Document Metrics	Transactional Data	Document Comments	Document Comments
TA-DOC09	Document Metrics	Transactional Data	Document Domain	The domain of the document, such as study, region, study-site, contact, or account.
TA-DOC05	Document Metrics	Transactional Data	Document Expected Date	Document Expected Date
TA-DOC08	Document Metrics	Transactional Data	Document Expiration Date	Document Expiration Date
TA-DOC03	Document Metrics	Transactional Data	Document Name	Document Name
TA-DOC06	Document Metrics	Transactional Data	Document Received Date	Document Received Date
TA-DOC07	Document Metrics	Transactional Data	Document Sent Date	Document Sent Date
M-FUI02	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.
M-FUI03	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.
M-FUI01	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.
TA-FUI07	Follow Up Item Metrics	Transactional Data	Follow Up Item Action Link	Action Link for Siebel Clinical Follow Up Item. Can be used to link back to Follow Up Item record in Siebel Clinical
TA-FUI01	Follow Up Item Metrics	Transactional Data	Follow Up Item Comments	Follow Up Item Comments field
TA-FUI02	Follow Up Item Metrics	Transactional Data	Follow Up item Completed Date	Follow Up Item Resolved Date field
TA-FUI03	Follow Up Item Metrics	Transactional Data	Follow Up Item Created Date	Date Follow Up Item record was created
TA-FUI04	Follow Up Item Metrics	Transactional Data	Follow Up Item Description	Follow Up Item Description field
TA-FUI05	Follow Up Item Metrics	Transactional Data	Follow Up item Due Date	Follow Up Item Due Date field
TA-FUI06	Follow Up Item Metrics	Transactional Data	Follow Up Item Status	Follow Up Item Status field

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
TA-FUI07	Follow Up Item Metrics	Transactional Data	Follow Up Item Type	Follow Up Item Type field
M-ALL10	Overall Metrics	Counts	# Studies	The number of study records.
M-ALL09	Overall Metrics	Medians	[Median # Protocol Amendments per Study]	The median of the number of protocol amendments that occurred for all studies.
M-ALL20	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.
M-ALL13	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.
M-ALL14	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.
M-ALL02	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.
M-ALL15	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.
M-ALL21	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.
M-ALL03	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.
M-ALL04	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.
M-ALL05	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.
M-ALL06	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.
M-ALL07	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.

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-ALL16	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.
M-ALL17	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.
M-ALL18	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.
M-ALL08	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.
M-ALL19	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.
M-ALL01	Overall Metrics	Ratios	% Sites Recruiting 0 Subjects	The percentage of initiated sites that have not enrolled any subjects, across all studies.
M-ALL11	Overall Metrics	Ratios	% Sites Recruiting 1 or More Subjects	The percentage of Study-Sites that have at least one subject enrolled.
M-ALL12	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.
M-PRG16	Program Metrics	Counts	# Studies	The number of study records.
M-PRG24	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.
M-PRG14	Program Metrics	Medians	[Median # Protocol Amendments per Study]	The median of the number of protocol amendments that occurred for all studies in a Program.
M-PRG22	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.
M-PRG01	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.
M-PRG19	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.

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-PRG03	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.
M-PRG04	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.
M-PRG23	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.
M-PRG06	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.
M-PRG07	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.
M-PRG21	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.
M-PRG20	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.
M-PRG08	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.
M-PRG09	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.
M-PRG10	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.
M-PRG11	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.
M-PRG12	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.

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-PRG13	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.
M-PRG15	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.
M-PRG17	Program Metrics	Ratios	% Sites Recruiting 1 or More Subjects	The percentage of Study-Sites that have at least one subject enrolled.
M-PRG18	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.
M-RCF18	Received CRFs	Counts	# CRFs Awaiting Entry Completion	Count of CRFs that meet the criteria for Incomplete
M-RCF09	Received CRFs	Counts	# CRFs Blank	Count of Blank CRFs. This is the Total number of CRFs where a user has opened and marked the CRF as blank intentionally.
M-RCF19	Received CRFs	Counts	# CRFs Electronically Loaded	Number of CRFs that were electronically, i.e. batch, loaded
M-RCF01	Received CRFs	Counts	# CRFs Entry Complete	Total number of CRFs for which entry has been completed
M-RCF29.1	Received CRFs	Counts	# CRFs Hard Locked	Number of Hard Locked CRFs
M-RCF10	Received CRFs	Counts	# CRFs Present	Count of Present CRFs.
M-RCF29	Received CRFs	Counts	# CRFs Soft Locked	Number of Soft Locked CRFs
M-RCF37	Received CRFs	Intervals	# Days from CRF Entry Complete to Soft Locked	Interval between CRF Entry Complete and Soft Locked
M-RCF34	Received CRFs	Intervals	# Days from CRF Visit to Entry Complete	Interval between CRF visit date and (1) for eCRF: date on which first data entry completed; (2) for pCRF: date on which second data entry completed, if required for study, else first entry completed.
M-RCF35	Received CRFs	Intervals	# Days from eCRF Complete to Initial Verified	Interval between eCRF entry date and date of Initial Verification
M-RCF40	Received CRFs	Intervals	# Days from eCRF Complete to Soft Locked	# Days from date of eCRF Complete to Date when eCRF was Soft Locked.
M-RCF36	Received CRFs	Intervals	# Days from eCRF Entry Complete to Initially Approved	Number of days from eCRF entry completion to date when initially approved.
M-RCF38	Received CRFs	Intervals	# Days from eCRF Final Approval to Soft Locked	Number of days from most recent eCRF Approved to Soft Locked.

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-RCF30	Received CRFs	Intervals	# Days from eCRF Initially Verified to Finally Approved	For an eCRF currently both Verified and Approved, the interval, in days, between those initial verification and final approval, calculated as date(final approval) - date(initial verification)
M-RCF39	Received CRFs	Intervals	# Days from eCRF Visit to eCRF Complete	# Days from date of eCRF Visit to Date when entry complete
M-RCF76	Received CRFs	Intervals	# Days from pCRF Entry Complete to Soft Locked	Total # Days from pCRF Entry Complete to Soft Locked
M-RCF32	Received CRFs	Intervals	# Days from pCRF Pass 1 Entry to Pass 2 Entry Complete	Interval between pCRF first entry and second entry
M-RCF31.1	Received CRFs	Intervals	# Days from pCRF Visit to Entry Complete	Interval between pCRF visit date and completion of all required entry passes.
M-RCF31	Received CRFs	Intervals	# Days from pCRF Visit to Pass 1 Entry	Interval between pCRF visit date and date of first entry
M-RCF11	Received CRFs	Intervals	# Days pCRF Awaiting Pass 1 Entry	Number of days pCRF received in house, awaiting first entry, to today's date
M-RCF33	Received CRFs	Intervals	# Days pCRF Awaiting Pass 2 Entry from Pass 1 Entry	Number of days pCRF achieved first entry completion, to today's date, where pCRF status is still Pass 1 complete, and second pass is required
M-RCF24	Received CRFs	Counts	# eCRFs Approved	Number of eCRFs which have been approved by Investigator
M-RCF86	Received CRFs	Counts	# eCRFs Awaiting Entry Completion	Count of eCRFs that meet the criteria for Incomplete
M-RCF26	Received CRFs	Counts	# eCRFs Awaiting Re-Approval	Number of eCRFs requiring Re-Approval by Investigator
M-RCF22	Received CRFs	Counts	# eCRFs Awaiting Re-Verification	Number of eCRFs which require source-data Verification to be redone by the CRA/Monitor, after a change by the Investigator
M-RCF81	Received CRFs	Counts	# eCRFs Blank	Count of Blank eCRFs. This is the Total number of eCRFs where a user has opened and marked the eCRF as blank intentionally.
M-RCF68	Received CRFs	Counts	# eCRFs Entry Complete	Total number of eCRFs for which entry has been completed
M-RCF71.1	Received CRFs	Counts	# eCRFs Hard Locked	Total # of Hard Locked eCRFs
M-RCF70	Received CRFs	Counts	# eCRFs Initially Approved	Total number of eCRFs there were approved at least once
M-RCF69	Received CRFs	Counts	# eCRFs Initially Verified	Total number of eCRFs that were verified at least once
M-RCF25	Received CRFs	Counts	# eCRFs Not Approved	Number of eCRFs which require initial Approval by Investigator

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-RCF23	Received CRFs	Counts	# eCRFs Not Verified	Number of entry-complete eCRFs that have never been verified.
M-RCF75	Received CRFs	Counts	# eCRFs Present	Total # of Present # eCRFs
M-RCF72	Received CRFs	Counts	# eCRFs Soft Locked	Total number of Soft Locked eCRFs
M-RCF21.1	Received CRFs	Counts	# eCRFs To Be Approved	Number of eCRFs that either have never been approved or that are awaiting re-approval.
M-RCF21	Received CRFs	Counts	# eCRFs To be Verified	Number of eCRFs that either have never been verified or that are awaiting re-verification.
M-RCF84	Received CRFs	Counts	# eCRFs Unplanned	Number of eCRFs that are Present but collected at an unplanned event
M-RCF20	Received CRFs	Counts	# eCRFs Verified	Number of eCRFs which have been source-data verified by the CRA/Monitor
M-RCF15	Received CRFs	Counts	# pCRFs Awaiting Double Entry Reconciliation	Number of pCRFs awaiting double-entry reconciliation
M-RCF17	Received CRFs	Counts	# pCRFs Awaiting Entry Completion	Number of pCRFs awaiting completion of either first or second data entry
M-RCF08	Received CRFs	Counts	# pCRFs Awaiting Pass 1 Entry Completion	Number of pCRFs awaiting completion of first data entry, including those at Received status
M-RCF73	Received CRFs	Counts	# pCRFs Awaiting Pass 2 Entry	Total number of pCRFs Awaiting Pass 2 Entry
M-RCF16	Received CRFs	Counts	# pCRFs Awaiting Pass 2 Entry Completion	Number of pCRFs awaiting completion of second data entry
M-RCF82	Received CRFs	Counts	# pCRFs Blank	Count of Blank pCRFs. This is the Total number of pCRFs where a user has opened and marked the pCRF as blank intentionally.
M-RCF78	Received CRFs	Counts	# pCRFs Entry Complete	Total number of pCRFs for which entry has been completed
M-RCF74.1	Received CRFs	Counts	# pCRFs Hard Locked	Total # of Hard Locked pCRFs
M-RCF06	Received CRFs	Counts	# pCRFs Pass 1 Entry Started, but Incomplete	Number of pCRFs at Pass 1 Started
M-RCF07	Received CRFs	Counts	# pCRFs Pass 1 Entry Complete	Number of pCRFs at Pass 1 Complete
M-RCF14	Received CRFs	Counts	# pCRFs Pass 2 Entry Complete	Number of pCRFs completed second entry
M-RCF13	Received CRFs	Counts	# pCRFs Pass 2 Entry Started, but Incomplete	Number of pCRFs at Pass 2 Started or Pass 2 Pending
M-RCF83	Received CRFs	Counts	# pCRFs Present	Count of Present pCRFs
M-RCF05	Received CRFs	Counts	# pCRFs Received, Not Entered	Number of pCRFs at Received

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-RCF74	Received CRFs	Counts	# pCRFs Soft Locked	Total # of Soft Locked pCRFs
M-RCF85	Received CRFs	Counts	# pCRFs Unplanned	Number of pCRFs that are Present but collected at an unplanned event
M-RCF64.2	Received CRFs	Ratios	% CRFs Hard Locked / Entry Complete	100 * # CRFs Hard Locked/# CRFs Entry Complete
M-RCF62	Received CRFs	Ratios	% CRFs Soft Locked / Entry Complete	The ratio of CRFs Soft Locked to number of CRFs with Entry Complete, expressed as a percentage
M-RCF64.1	Received CRFs	Ratios	% CRFs Soft Locked / Present	% CRF Soft Locked/#CRFs Present
M-RCF55.1	Received CRFs	Ratios	% eCRFs Approved / Entry Complete	% #eCRFs Approved / # eCRFs Entry Complete
M-RCF52.1	Received CRFs	Ratios	% eCRFs Approved / Present	% # eCRFs Verified / # eCRFs Entry Complete
M-RCF64.3	Received CRFs	Ratios	% eCRFs Hard Locked / Entry Complete	100 * # eCRFs Hard Locked/# eCRFs Entry Complete
M-RCF62.1	Received CRFs	Ratios	% eCRFs Soft Locked / Entry Complete	The ratio of eCRFs Soft Locked to number of eCRFs with Entry Complete, expressed as a percentage
M-RCF58	Received CRFs	Ratios	% eCRFs Soft Locked / Present	% # eCRFs Soft Locked / # eCRFs Present
M-RCF55.2	Received CRFs	Ratios	% eCRFs Verified / Entry Complete	% #eCRFs Verified / # eCRFs Entry Complete
M-RCF52	Received CRFs	Ratios	% eCRFs Verified / Present	% # eCRFs Verified / # eCRFs Present
M-RCF64.4	Received CRFs	Ratios	% pCRFs Hard Locked / Entry Complete	100 * # pCRFs Hard Locked/# pCRFs Entry Complete
M-RCF62.2	Received CRFs	Ratios	% pCRFs Soft Locked / Entry Complete	The ratio of pCRFs Soft Locked to number of pCRFs with Entry Complete, expressed as a percentage
M-RCF65	Received CRFs	Ratios	% Processed / Present	% CRF completely entered / #CRFs Present
M-RCF64	Received CRFs	Ratios	% Re-Approval / Approved	The ratio of number of eCRFs requiring re-approval to the number currently approved expressed as a percentage.
M-RCF63	Received CRFs	Ratios	% Re-Verification / Verified	The ratio of number of eCRFs awaiting re-verification to the number currently verified, expressed as a percentage.
M-RCF49.2	Received CRFs	Statistics	Avg # Days from CRF Entry Complete to Soft Locked	For all Soft Locked CRFs, the average number of Days from date of CRF Complete to Date when CRF was Soft Locked.

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-RCF45	Received CRFs	Statistics	Avg # Days from CRF Visit to Entry Complete	Average interval between CRF visit date and (1) for eCRF: date on which first data entry completed; (2) for pCRF: date on which second data entry completed, if required for study, else first entry completed.
M-RCF46	Received CRFs	Statistics	Avg # Days from eCRF Complete to Initially Verified	Across all eCRFs that have every been set to Verified at the current level of analysis, the average number of days in the interval between eCRF entry date and date of Initial Verification
M-RCF49	Received CRFs	Statistics	Avg # Days from eCRF Complete to Soft Locked	For all Soft Locked eCRFs, the average number of Days from date of eCRF Complete to Date when eCRF was Soft Locked.
M-RCF47	Received CRFs	Statistics	Avg # Days from eCRF Entry Complete to Initially Approved	Across all eCRFs that have every been set to Approved at the current level of analysis, the average number of days in the interval between eCRF entry completion to date when initially approved.
M-RCF50	Received CRFs	Statistics	Avg # Days from eCRF Final Approval to Soft Locked	For all Soft Locked eCRFs, the average number of days from most recent eCRF Approved to Soft Locked.
M-RCF48	Received CRFs	Statistics	Avg # Days from eCRF Initially Verified to Finally Approved	For all eCRFs currently both Verified and Approved, the average interval between initial verification and final approval dates.
M-RCF41	Received CRFs	Statistics	Avg # Days from eCRF Visit to eCRF Complete	Across all eCRFs that are complete at the current level of analysis, the average number of days between the date of the visit when the CRF was collected and the date when it was Complete.
M-RCF49.1	Received CRFs	Statistics	Avg # Days from pCRF Entry Complete to Soft Locked	For all Soft Locked pCRFs, the average number of Days from date of pCRF Complete to Date when pCRF was Soft Locked.
M-RCF43	Received CRFs	Statistics	Avg # Days from pCRF First Entry to Second Entry Complete	Average interval between pCRF first entry and second entry
M-RCF45.1	Received CRFs	Statistics	Avg # Days from pCRF Visit to Entry Complete	Average interval between pCRF visit date and date on which second data entry completed, if required for study, else first entry completed.
M-RCF42	Received CRFs	Statistics	Avg # Days from pCRF Visit to First Entry	Average interval between pCRF visit date and date of first entry
M-RCF77	Received CRFs	Statistics	Avg # Days pCRF Awaiting Pass 1 Entry	Average # of Days pCRF Awaiting First Entry

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-RCF44	Received CRFs	Statistics	Avg # Days pCRF Awaiting Pass 2 Entry from Pass 1 Entry	Average number of days pCRF achieved first entry completion, to today's date, where pCRF status is still Pass 1 complete, and second pass is required
TA-RCRF09	Received CRFs	Transactional Data	Complete Visit Number	Planned event number ||.|| subevent number
TA-RCRF12	Received CRFs	Transactional Data	CRF Book Name	Name of the CRF Book used to organize collected pages
TA-RCRF11	Received CRFs	Transactional Data	CRF Name	Name of the CRF (e.g. Demog)
TA-RCRF35	Received CRFs	Transactional Data	Data Capture Mode	Mode in which this CRF was capture. Values = {Paper, EDC}
TA-RCRF01	Received CRFs	Transactional Data	Document ID	External identifier for the CRF
TA-RCRF14	Received CRFs	Transactional Data	Entry Date	Date on which the CRF was entered.
TA-RCRF34	Received CRFs	Transactional Data	Hard Lock Date	Date when last Hard Locked
TA-RCRF32	Received CRFs	Transactional Data	Initial Approval Date	Initial date on which the CRF was approved by the Investigator
TA-RCRF30	Received CRFs	Transactional Data	Initial Source Verification Date	Date on which the CRF was initially source-verified
TA-RCRF04	Received CRFs	Transactional Data	Investigator	Study-Site Investigator
TA-RCRF24	Received CRFs	Transactional Data	Is Awaiting First Entry completion	Flag indicating that a CRF is awaiting first entry completion
TA-RCRF20	Received CRFs	Transactional Data	Is Awaiting Re-Approval	Flag indicating whether a received CRF is awaiting re-approval
TA-RCRF17	Received CRFs	Transactional Data	Is Awaiting Re-Verification	Flag indicating whether a received CRF is awaiting re-verification
TA-RCRF25	Received CRFs	Transactional Data	Is Awaiting Second entry completion	Flag indicating that a CRF is awaiting second entry completion
TA-RCRF22	Received CRFs	Transactional Data	Is Blank	Flag indicating whether there is any data for this received DCI.
TA-RCRF26	Received CRFs	Transactional Data	Is Entry Complete	Flag indicating that a CRF is completely entered
TA-RCRF28	Received CRFs	Transactional Data	Is Hard Locked	If a Received CRF is Hard Locked, data in the cry is prevented from being modified. This can only be reversed by extraordinary means.
TA-RCRF19	Received CRFs	Transactional Data	Is not in Approved state	Flag indicating whether an eCRF has not yet ever been approved. "Y' means "not approved", else "N".
TA-RCRF16	Received CRFs	Transactional Data	Is not in Verified state	Flag indicating whether a an eCRF has not yet ever been verified. "Y' means "not verified, else "N".

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
TA-RCRF23	Received CRFs	Transactional Data	Is Soft Locked	If a Received CRF is Soft Locked, data in the cry is prevented from being modified. However, a soft-lock can be reversed, if it is necessary to modify data, without extraordinary measures.
TA-RCRF33	Received CRFs	Transactional Data	Most Recent Approval Date	Most recent date on which the CRF was approved by the Investigator
TA-RCRF31	Received CRFs	Transactional Data	Most Recent Source Verification Date	Most recent date on which the CRF was source-verified
TA-RCRF13	Received CRFs	Transactional Data	Page in CRF Book	Page number within subject's CRF book on which this CRF is located.
TA-RCRF15	Received CRFs	Transactional Data	Received CRF Status	Current status of the received CRF
TA-RCRF03	Received CRFs	Transactional Data	Site	Site at which the CRF was created
TA-RCRF29	Received CRFs	Transactional Data	Soft Lock Date	Date when last soft locked
TA-RCRF02	Received CRFs	Transactional Data	Study	Study in which the CRF was created
TA-RCRF08	Received CRFs	Transactional Data	Sub-event Number	Sub-event number of the visit at which the CRF was collected
TA-RCRF05	Received CRFs	Transactional Data	Subject ID	ID for the Subject about whom the data were collected.
TA-RCRF10	Received CRFs	Transactional Data	Subject Visit Date	Date of the subject visit when the CRF was collected
TA-RCRF06	Received CRFs	Transactional Data	Subject Visit Name	Name of the subject visit at which the CRF was collected
TA-RCRF07	Received CRFs	Transactional Data	Subject Visit Number	Number of the subject visit at which CRF was collected
M-REG14	Region Metrics	Counts	# Study-Regions	The number of Study-Region records.
M-REG16	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 Region: Critical Document Package Completed Date to Site Initiated Date.
M-REG11	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 Region: Initial IRB/EC Approval Date to 1st Subject 1st Visit Date.
M-REG12	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 Region: Initial IRB/EC Approval Date to Site Initiated Date.
M-REG10	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 Region: Site Initiated for Study-Site to 1st Subject 1st Visit Date for Study-Site.

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-REG15	Region Metrics	Medians	Median Site Initiated to 1st Subject Enrolled (# Days)	The median of the following cycle time across all Study-Sites in a Region: Site Initiated for Study-Site to 1st Subject Enrolled Date for Study-Site.
M-REG17	Region 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 Region: Site Visit Completed Date to Follow Up Item Completed Date.
M-REG18	Region 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 Region: Site Visit Completed Date to Visit Report Approved Date.
M-REG19	Region 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 Region: Site Visit Completed Date to Visit Report Completed Date.
M-REG20	Region 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 Region: Visit Report Completed Date to Visit Report Approved Date.
M-REG05	Region Metrics	Ratios	% Sites Recruiting 0 Subjects	The percentage of initiated sites that have not enrolled any subjects, for all Study-Sites in a Region.
M-REG07	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.
M-REG09	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.
M-SIV01	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.
M-SIV02	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.
M-SIV03	Site Visit Metrics	Intervals	# Days from Site Visit Start to Site Visit Completed	Site Visit Completed Date - Site Visit Start Date
M-SIV04	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.
M-SIV05	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.
M-SIV06	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.

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-SIV07	Site Visit Metrics	Counts	# Follow Up Items	The number of Follow Up Item records.
M-SIV08	Site Visit Metrics	Counts	# Follow Up Items Completed	The number of follow up items with a Follow Up Item Completed Date.
M-SIV10	Site Visit Metrics	Counts	# Outstanding Follow Up Items	The number of unresolved Follow Up Items.
M-STD45	Study Metrics	Actual Milestones	[1st Critical Document Package Completed Date]	The earliest Critical Document Package Completed Date for all Study-Sites in the Study.
M-STD32	Study Metrics	Actual Milestones	1st Initial IRB/EC Approval Date	The first Initial IRB/EC Approval Date for all Study-Sites in the Study.
M-STD46	Study Metrics	Actual Milestones	[1st IRB/EC Submission Date]	The first IRB/EC Submission Date for all Study-Sites in the Study.
M-STD11	Study Metrics	Actual Milestones	1st Site Initiated Date	The earliest of site initiated dates for a study.
M-STD84	Study Metrics	Actual Milestones	1st Subject 1st Visit Date	The date of the first visit across all subjects for the Study.
M-STD85	Study Metrics	Actual Milestones	1st Subject Enrolled Date	First Subject Enrolled
M-STD86	Study Metrics	Actual Milestones	1st Subject Randomized Date	First Subject Randomized
M-STD87	Study Metrics	Actual Milestones	1st Subject Screened Date	First Subject Screened
M-STD57	Study Metrics	Actual Milestones	[Last Critical Document Package Completed Date]	The Last Critical Document Package Completed Date for the Study.
M-STD58	Study Metrics	Actual Milestones	[Last Site Initiated Date]	The Last Site Initiated Date for the Study.
M-STD59	Study Metrics	Actual Milestones	[Last Subject 1st Visit Date]	The Last Subject 1st Visit Date for the Study.
M-STD70	Study Metrics	Actual Milestones	[Last Subject Enrolled Date]	The Last Subject Enrolled Date for the Study.
M-STD68	Study Metrics	Actual Milestones	[Last Subject Last Visit Date]	The Last Subject Last Visit Date for the Study.
M-STD69	Study Metrics	Actual Milestones	[Last Subject Randomized Date]	The Last Subject Randomized Date for the Study.
M-STD47	Study Metrics	Actual Milestones	[Latest Critical Document Package Completed Date]	The Latest Critical Document Package Completed Date for the Study.
M-STD12	Study Metrics	Actual Milestones	Latest Site Initiated Date	The date of the most recent site initiated
M-STD88	Study Metrics	Actual Milestones	Latest Subject 1st Visit Date	The Latest 1st Visit Date across all subjects for the Study.
M-STD89	Study Metrics	Actual Milestones	Latest Subject Enrolled Date	Most recent date on which a subject enrolled in the study

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-STD90	Study Metrics	Actual Milestones	Latest Subject Latest Visit Date	The Latest Visit Date across all subjects for the Study.
M-STD91	Study Metrics	Actual Milestones	Latest Subject Randomized Date	Most recent date on which a subject was randomized
M-STD16	Study Metrics	Counts	[# Protocol Amendments]	The number of amendments to the protocol.
M-STD40	Study Metrics	Counts	# Sites Recruiting 0 Subjects	The number of initiated Study-Sites with 0 subjects enrolled.
M-STD42	Study Metrics	Counts	# Sites Recruiting at Least 90% of Planned Subjects	The number of initiated Study-Sites that have enrolled at least 90% of their planned subjects.
M-SST49	Study Metrics	Counts	# Sites with 1 or More Subjects Screened	Number of study-sites with 1 or more subjects screened
M-STD48	Study Metrics	Counts	# Study-Regions	The number of Study-Region records.
M-STD07	Study Metrics	Counts	# Study-Sites	# of protocol sites created for the study
M-STD13	Study Metrics	Counts	# Study-Sites Initiated	The number of initiated Study-Sites.
M-STD01	Study Metrics	Counts	# Study-Sites Planned for Study	Number of sites planned to execute the study
M-STD08	Study Metrics	Counts	# Study-Sites with 1 or more Subjects Enrolled	Number of sites with a value in the first subject enrolled date
M-STD02	Study Metrics	Counts	# Subjects Planned for Study	Total number of subjects planned to be enrolled for the Study
M-STD55	Study 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 and 1st Site Initiated Date for the Study.
M-STD56	Study 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 the Study to 1st Site Initiated Date for the Study.
M-STD27	Study 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 the Study to 1st Subject 1st Visit Date for the Study.
M-STD24	Study Metrics	Cycle Times	1st Site Initiated to 1st Subject Enrolled (# Days)	The number of days between 1st Site Initated Date for a Study and 1st Subject Enrolled Date for a Study.
M-STD65	Study 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.
M-STD25	Study 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.

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-STD66	Study 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 to Last Subject 1st Visit Date for a Study.
M-STD26	Study 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 to Latest Subject 1st Visit Date for a Study.
M-STD64	Study Metrics	Cycle Times	[1st Subject Enrolled to Last Subject Enrolled (# Days)]	The number of days from 1st Subject Enrolled Date for a Study and Last Subject Enrolled Date for a Study.
M-STD61	Study Metrics	Cycle Times	1st Subject Enrolled to Latest Subject Enrolled (# Days)	The number of days from 1st Subject Enrolled Date for a Study and Latest Subject Enrolled Date for a Study.
M-STD67	Study Metrics	Cycle Times	[Last Subject Last Visit to Database Lock (# Days)]	The number of days from Last Subject Last Visit Date for a Study to Database Lock Date for a Study.
M-STD15	Study Metrics	Cycle Times	Latest Subject Latest Visit to Database Lock (# Days)	The number of days from Latest Subject Latest Visit Date for a Study to Database Lock Date for a Study.
M-STD17	Study Metrics	Cycle Times	[Protocol Approved to 1st Site Initiated (# Days)]	The number of days from Protocol Approved Date for a Study to 1st Site Initiated Date for a Study.
M-STD18	Study Metrics	Cycle Times	[Protocol Approved to 1st Subject Enrolled (# Days)]	The number of days from Protocol Approved Date for a Study to 1st Subject Enrolled Date for a Study.
M-STD62	Study Metrics	Cycle Times	[Protocol Approved to 1st Subject Randomized (# Days)]	The number of days from Protocol Approved Date for a Study to 1st Subject Randomized Date for a Study.
M-STD44	Study Metrics	Cycle Times	[Protocol Approved to 1st Subject Screened (# Days)]	The number of days from Protocol Approved Date for a Study to 1st Subject Screened Date for a Study.
M-STD82	Study Metrics	Flags	KPI Detail Reason	Detail reason for the Study KPI Flag
M-STD80	Study Metrics	Flags	KPI Flag	KPI Flag for the Study.
M-STD81	Study Metrics	Flags	KPI High Level Reason	High level reason for the Study KPI Flag
M-STD79	Study Metrics	Flags	Milestone Detail Reason	Detail reason for the Study Milestone Flag
M-STD77	Study Metrics	Flags	Milestone Flag	Milestone Flag for the Study.
M-STD78	Study Metrics	Flags	Milestone High Level Reason	High level reason for the Study Milestone Flag
M-STD76	Study Metrics	Flags	Recruitment Detail Reason	Detail reason for the Study Recruitment Flag
M-STD74	Study Metrics	Flags	Recruitment Flag	Recrutiment Flag for the Study.
M-STD75	Study Metrics	Flags	Recruitment High Level Reason	High level reason for the Study Recruitment Flag

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-STD73	Study Metrics	Flags	Retention Detail Reason	Detail reason for the Study Retention Flag
M-STD71	Study Metrics	Flags	Retention Flag	Retention Flag for the Study.
M-STD72	Study Metrics	Flags	Retention High Level Reason	High level reason for the Study Retention Flag
M-STD49	Study Metrics	Medians	Median # Days Between Site Visits	The median of the following cycle time across all site visits for a Study: number of days between consecutive Site Visit Start Dates for completed site visits.
M-STD50	Study 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.
M-STD51	Study 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: Critical Document Package Completed Date to Site Initiated Date.
M-STD21	Study 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: Initial IRB/EC Approval Date to 1st Subject 1st Visit Date.
M-STD22	Study 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: Initial IRB/EC Approval Date to Site Initiated Date.
M-STD20	Study 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: Site Initiated for Study-Site to 1st Subject 1st Visit Date for Study-Site.
M-STD60	Study Metrics	Medians	Median Site Initiated to 1st Subject Enrolled (# Days)	The median of the following cycle time across all Study-Sites in a Study: Site Initiated for Study-Site to 1st Subject Enrolled Date for Study-Site.
M-STD52	Study 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 Study: Site Visit Completed Date to Follow Up Item Completed Date.
M-STD53	Study 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 Study: Site Visit Completed Date to Visit Report Approved Date.
M-STD54	Study 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 Study: Site Visit Completed Date to Visit Report Completed Date.

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-STD09	Study 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 Study: Site Visit Start Date to Site Visit Completed Date.
M-STD63	Study 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 Study: Visit Report Completed Date to Visit Report Approved Date.
M-STD43	Study Metrics	Rates	# Subjects Enrolled per Month Study Active	For a Study that has not achieved database lock, the number of subjects enrolled per month since the first site was Initiated. For a Study that has achieved database lock, the number of subjects enrolled per month for the period between First Site Initiation and Latest Subject Enrolled at Study.
M-STD28	Study Metrics	Ratios	% of Planned Sites Initiated	The percentage of Study-Sites planned for the Study that have been initiated.
M-STD23	Study Metrics	Ratios	% Over/Under Enrolled	The percentage of planned subjects over (+) or under (-) enrolled for the Study.
M-STD06	Study Metrics	Ratios	% Planned Subjects Enrolled (Study)	Ratio of number of enrolled subjects to total planned number of subjects for the study
M-STD10	Study Metrics	Ratios	% Planned Subjects Randomized (Study)	The % of planned subjects randomized.
M-STD29	Study Metrics	Ratios	% Sites Recruiting 0 Subjects	The percentage of initiated sites that have not enrolled any subjects, for all Study-Sites in a Study.
M-STD30	Study Metrics	Ratios	% Sites Recruiting 1 or More Subjects	the number of sites recruiting one or more Subjects divided by the number of Sites Initiated.
M-STD31	Study 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.
M-STD83	Study Metrics	Ratios	Screen Failure Rate	The number of subjects who failed screening divided by the number of subjects screened for the Study.
M-STR10	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.
M-SRG07	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.
M-SRG33	Study-Region Metrics	Actual Milestones	[1st IRB/EC Submission Date]	The first IRB/EC Submission Date for all Study-Sites in the Study-Region.
M-SRG03	Study-Region Metrics	Actual Milestones	1st Site Initiated Date	The first Site Initiated Date for all Study-Sites in the Study-Region.

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-STR31	Study-Region Metrics	Actual Milestones	1st Subject 1st Visit Date	The date of the first visit across all subjects for the Study-Region.
M-STR32	Study-Region Metrics	Actual Milestones	1st Subject Enrolled Date	First Subject Enrolled
M-STR33	Study-Region Metrics	Actual Milestones	1st Subject Randomized Date	First Subject Randomized
M-STR34	Study-Region Metrics	Actual Milestones	1st Subject Screened Date	First Subject Screened
M-STR03	Study-Region Metrics	Actual Milestones	Date Achieved 90% Planned Enrollment	The date on which the Study-Region achieved 90% of planned subject enrollment.
M-STR04	Study-Region Metrics	Actual Milestones	[Last Critical Document Package Completed Date]	The Last Critical Document Package Completed Date for the Study-Region.
M-STR05	Study-Region Metrics	Actual Milestones	[Last Site Initiated Date]	The Last Site Initiated Date for the Study-Region.
M-STR06	Study-Region Metrics	Actual Milestones	[Last Subject 1st Visit Date]	The Last Subject 1st Visit Date for the Study-Region.
M-STR20	Study-Region Metrics	Actual Milestones	[Last Subject Enrolled Date]	The Last Subject Enrolled Date for the Study-Region.
M-STR18	Study-Region Metrics	Actual Milestones	[Last Subject Last Visit Date]	The Last Subject Last Visit Date for the Study-Region.
M-STR19	Study-Region Metrics	Actual Milestones	[Last Subject Randomized Date]	The Last Subject Randomized Date for the Study-Region.
M-SRG34	Study-Region Metrics	Actual Milestones	[Latest Critical Document Package Completed Date]	The Latest Critical Document Package Completed Date for the Study-Region.
M-SRG05	Study-Region Metrics	Actual Milestones	Latest Site Initiated Date	The Latest Site Initiated Date for the Study-Region.
M-STR35	Study-Region Metrics	Actual Milestones	Latest Subject 1st Visit Date	The Latest 1st Visit Date across all subjects for the Study-Region.
M-STR36	Study-Region Metrics	Actual Milestones	Latest Subject Enrolled Date	Most recent date on which a subject enrolled in the study
M-STR37	Study-Region Metrics	Actual Milestones	Latest Subject Latest Visit Date	The Latest Visit Date across all subjects for the Study-Region.
M-STR38	Study-Region Metrics	Actual Milestones	Latest Subject Randomized Date	Most recent date on which a subject was randomized
M-SRG27	Study-Region Metrics	Counts	# Sites Recruiting 0 Subjects	The number of initiated Study-Sites with 0 subjects enrolled.
M-SRG28	Study-Region Metrics	Counts	# Sites Recruiting 1 or More Subjects	The number of initiated Study-Sites with one or more subjects enrolled.
M-SRG29	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%.
M-STR30	Study-Region Metrics	Counts	# Sites with 1 or More Subjects Screened	Number of study-sites with 1 or more subjects screened

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-SRG26	Study-Region Metrics	Counts	# Study-Sites	The number of Study-Site records.
M-SRG16	Study-Region Metrics	Counts	# Study-Sites Initiated	The number of initiated Study-Sites.
M-SRG01	Study-Region Metrics	Counts	# Study-Sites Planned for Study-Region	# Planned Sites for the study-region
M-SRG02	Study-Region Metrics	Counts	# Subjects Planned for Study-Region	# Planned Subjects for the study-region
M-STR09	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.
M-SRG14	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.
M-SRG13	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.
M-SRG08	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.
M-STR14	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.
M-SRG06	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.
M-STR15	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.
M-SRG12	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.
M-STR13	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.
M-STR02	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.
M-STR29	Study-Region Metrics	Flags	Milestone Detail Reason	Detail reason for the Study-Region Milestone Flag

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-STR27	Study-Region Metrics	Flags	Milestone Flag	Milestone Flag for the Study-Region.
M-STR28	Study-Region Metrics	Flags	Milestone High Level Reason	High level reason for the Study-Region Milestone Flag
M-STR26	Study-Region Metrics	Flags	Recruitment Detail Reason	Detail reason for the Study-Region Recruitment Flag
M-STR24	Study-Region Metrics	Flags	Recruitment Flag	Recruitment Flag for the Study-Region.
M-STR25	Study-Region Metrics	Flags	Recruitment High Level Reason	High level reason for the Study-Region Recruitment Flag
M-STR23	Study-Region Metrics	Flags	Retention Detail Reason	Detail reason for the Study-Region Retention Flag
M-STR21	Study-Region Metrics	Flags	Retention Flag	Retention Flag for the Study-Region.
M-STR22	Study-Region Metrics	Flags	Retention High Level Reason	High level reason for the Study-Region Retention Flag
M-STR11	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.
M-SRG09	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.
M-STR12	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.
M-SRG23	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.
M-SRG24	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.
M-SRG25	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.
M-STR08	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.

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-STR16	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.
M-STR17	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.
M-SRG04	Study-Region Metrics	Ratios	% of Planned Sites Initiated	The percentage of Study-Sites planned for the Study-Region that have been initiated.
M-SRG11	Study-Region Metrics	Ratios	% Over/Under Enrolled	The percentage of planned subjects over (+) or under (-) enrolled for the Study-Region.
M-SRG10	Study-Region Metrics	Ratios	% Planned Subjects Randomized	The percentage of planned subjects randomized minus 100.
M-SRG30	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.
M-SRG31	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.
M-SRG32	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.
M-STR01	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
M-STR07	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.
M-SST96	Study-Site Metrics	Actual Milestones	1st Subject 1st Visit Date	The date of the first visit across all subjects for the Study-Site.
M-SST42	Study-Site Metrics	Actual Milestones	1st Subject Enrolled Date	First Subject Enrolled
M-SST43	Study-Site Metrics	Actual Milestones	1st Subject Randomized Date	First Subject Randomized
M-SST44	Study-Site Metrics	Actual Milestones	1st Subject Screened Date	First Subject Screened
M-SST88	Study-Site Metrics	Actual Milestones	Date Achieved 90% Planned Enrollment	The date on which the Study-Site achieved 90% of planned subject enrollment.
M-SST89	Study-Site Metrics	Actual Milestones	[Last Subject 1st Visit Date]	The Last Subject 1st Visit Date for the Study-Site.
M-SST90	Study-Site Metrics	Actual Milestones	[Last Subject Enrolled Date]	The Last Subject Enrolled Date for the Study-Site.
M-SST91	Study-Site Metrics	Actual Milestones	[Last Subject Last Visit Date]	The Last Subject Last Visit Date for the Study-Site.

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-SST92	Study-Site Metrics	Actual Milestones	[Last Subject Randomized Date]	The Last Subject Randomized Date for the Study-Site.
M-SST79	Study-Site Metrics	Actual Milestones	Latest Subject 1st Visit Date	The Latest 1st Visit Date across all subjects for the Study-Site.
M-SST46	Study-Site Metrics	Actual Milestones	Latest Subject Enrolled Date	Most recent date on which a subject enrolled in the study
M-SST81	Study-Site Metrics	Actual Milestones	Latest Subject Latest Visit Date	The Latest Visit Date across all subjects for the Study-Site.
M-SST47	Study-Site Metrics	Actual Milestones	Latest Subject Randomized Date	Most recent date on which a subject was randomized
M-SST48	Study-Site Metrics	Actual Milestones	Latest Subject Screened Date	Most recent date on which a subject was screened
M-SST61	Study-Site Metrics	Counts	# Completed Site Visits	The number of Site Visit records with a Site Visit Completed Date
M-SST62	Study-Site Metrics	Counts	# Completed Visit Reports	The number of Visit Reports where Completed Date is not null.
M-SST04	Study-Site Metrics	Counts	# Current Active Subjects	Total number of Subjects currently conducting Study
M-SST03	Study-Site Metrics	Counts	# Currently Enrolled plus # Normally Terminated	The total number of subjects who are either currently enrolled or who have normally completed the study protocol
M-SST39	Study-Site Metrics	Counts	# Days Since Initiation	Number of days from current date to Site Initiation Date
M-SST06	Study-Site Metrics	Counts	# Early Terminations	# Subjects who have ever had a status of Early Terminated
M-SST02	Study-Site Metrics	Counts	# Enrolled	# Subjects who have ever had a status of Enrolled
M-SST08	Study-Site Metrics	Counts	# Planned Subject Visits Completed	Number of planned Subject visits which have occurred. This is the count, across all CRFs received for all subjects at the site, of distinct planned visits at which the CRFs were collected. Planned visits are those for which sub-event number is zero.
M-SST32	Study-Site Metrics	Counts	# Randomized	# Subjects who have ever had a status of Randomized
M-SST33	Study-Site Metrics	Counts	# Re-Screened	# Subjects who have ever had a status of Re-screened
M-SST34	Study-Site Metrics	Counts	# Screen Failure	# Subjects who have ever had a status of Screen Failure
M-SST35	Study-Site Metrics	Counts	# Screened	# Subjects who have ever had a status of Screened
M-SST65	Study-Site Metrics	Counts	# Site Visits	The number of Site Visit records
M-SST36	Study-Site Metrics	Counts	# Subjects	Count of the number of subject records returned

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-SST05C	Study-Site Metrics	Counts	# Subjects - Current Status Completed	# Subjects with a current status of Completed
M-SST06C	Study-Site Metrics	Counts	# Subjects - Current Status Early Terminated	Number of Subjects whose current status is Early Terminated
M-SST02C	Study-Site Metrics	Counts	# Subjects - Current Status Enrolled	# Subjects with a current status of Enrolled
M-SST32C	Study-Site Metrics	Counts	# Subjects - Current Status Randomized	# Subjects with a current status of Randomized
M-SST33C	Study-Site Metrics	Counts	# Subjects - Current Status Re-Screened	# Subjects with a current status of Re-screened
M-SST34C	Study-Site Metrics	Counts	# Subjects - Current Status Screen Failure	# Subjects with a current status of Screen failure
M-SST35C	Study-Site Metrics	Counts	# Subjects - Current Status Screened	# Subjects with a current status of Screened
M-SST37	Study-Site Metrics	Counts	# Subjects Deviation	Number of subjects with the Protocol Deviation flag checked
M-SST66	Study-Site Metrics	Counts	# Subjects Enrolled Since Latest Site Visit	The number of subjects that have been enrolled since the most recent Site Visit End date.
M-SST01	Study-Site Metrics	Counts	# Subjects Planned for Study-Site	Total number of subjects planned to be enrolled at the Study-Site.
M-SST67	Study-Site Metrics	Counts	# Subjects Randomized Since Latest Site Visit	The number of subjects that have been randomized since the most recent Site Visit End date.
M-SST68	Study-Site Metrics	Counts	# Subjects Screened Since Latest Site Visit	The number of subjects that have been screened since the most recent Site Visit End date.
M-SST38	Study-Site Metrics	Counts	# Subjects Violation	Number of subjects with the Protocol Violation flag checked
M-SST05	Study-Site Metrics	Counts	# Subjects who have Completed Study	# Subjects who have ever had a status of Completed
M-SST09	Study-Site Metrics	Counts	# Unplanned Subject Visits Completed	Number of unplanned Subject visits which have occurred. This is the count, across all CRFs received for all subjects at the site, of distinct unplanned visits at which the CRFs were collected. Unplanned visits are those for which sub-event number is greater than zero.
M-SST69	Study-Site Metrics	Counts	# Visit Reports	The number of visit report records
M-SST70	Study-Site Metrics	Counts	[# Visit Reports Awaiting Approval]	The number of visit reports where Completed Date is not null and Approved Date is null
M-SST71	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

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-SST95	Study-Site 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-Site to Last Subject 1st Visit Date for a Study-Site.
M-SST80	Study-Site 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-Site to Latest Subject 1st Visit Date for a Study-Site.
M-SST85	Study-Site Metrics	Cycle Times	[Critical Document Package Complete to Site Initiated (# Days)]	The number of days from Critical Document Package Completed for a Study-Site to Site Initiated Date.
M-SST83	Study-Site Metrics	Cycle Times	Initial IRB/EC Approval to 1st Subject 1st Visit (# Days)	The number of days from Initial IRB/EC Approval Date for a Study-Site and 1st Subject 1st Visit for a Study-Site.
M-SST84	Study-Site Metrics	Cycle Times	Initial IRB/EC Approval to Site Initiated (# Days)	The number of days from Initial IRB/EC Approval Date for a Study-Site and Site Initiated Date for a Study-Site.
M-SST82	Study-Site Metrics	Cycle Times	Site Initiated to 1st Subject 1st Visit (# Days)	The number of days from Site Initiated Date for a Study-Site to 1st Subject 1st Visit Date for a Study-Site.
M-SST93	Study-Site Metrics	Cycle Times	Site Initiated to 1st Subject Enrolled (# Days)	The number of days from Site Initiated Date for a Study-Site to 1st Subject Enrolled Date for a Study-Site.
M-SST105	Study-Site Metrics	Flags	Milestone Detail Reason	Detail reason for the Study-Site Milestone Flag
M-SST103	Study-Site Metrics	Flags	Milestone Flag	Milestone Flag for the Study-Site.
M-SST104	Study-Site Metrics	Flags	Milestone High Level Reason	High level reason for the Study-Site Milestone Flag
M-SST102	Study-Site Metrics	Flags	Recruitment Detail Reason	Detail reason for the Study-Site Recruitment Flag
M-SST100	Study-Site Metrics	Flags	Recruitment Flag	Recruitment Flag for the Study-Region.
M-SST101	Study-Site Metrics	Flags	Recruitment High Level Reason	High level reason for the Study-Site Recruitment Flag
M-SST99	Study-Site Metrics	Flags	Retention Detail Reason	Detail reason for the Study-Site Retention Flag
M-SST97	Study-Site Metrics	Flags	Retention Flag	Retention Flag for the Study-Site.
M-SST98	Study-Site Metrics	Flags	Retention High Level Reason	High level reason for the Study-Site Retention Flag
M-SST52	Study-Site Metrics	Intervals	# Days Since Last Enrollment for Study-Site	Number of days between today's date and the most recent enrollment date at the study-site
M-SST63	Study-Site Metrics	Intervals	# Days Since Latest Site Visit	The number of dates since the most recent completed site visit.

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-SST76	Study-Site Metrics	Medians	Median # Days Between Site Visits	The median of the following cycle time across all site visits for a Study-Site: number of days between consecutive Site Visit Start Dates for completed site visits.
M-SST77	Study-Site 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-Site.
M-SST86	Study-Site Metrics	Rates	# Subjects Enrolled per Site per Month Site Active	For a Study-Site that does not have a terminated date, the number of subjects enrolled since the Study-Site was initiated. For a Study-Site that has a terminated date, the number of subjects enrolled per month for the period between Study-Site initiation and latest subject enrolled at Study-Site
M-SST15.1	Study-Site Metrics	Ratios	% Enrolled to Total Planned at Study-Site	Ratio of number of enrolled subjects to total planned number of subjects for the study site.
M-SST54	Study-Site Metrics	Ratios	% of Total Enrolled in Study	The number of subjects enrolled at study-site divided by the number of subjects enrolled in the study
M-SST55	Study-Site Metrics	Ratios	% of Total Randomized in Study	The number of subjects randomized at study-site divided by the number of subjects randomized in study
M-SST56	Study-Site Metrics	Ratios	% of Total Screened in Study	The number of subjects screened at study-site divided by the number of subjects screened in study
M-SST94	Study-Site Metrics	Ratios	% Over/Under Enrolled	The percentage of planned subjects over (+) or under (-) enrolled for the Study-Site.
M-SST72	Study-Site Metrics	Ratios	% Randomized vs. Planned for Study-Site	The % of planned subjects randomized.
M-SST58	Study-Site Metrics	Ratios	% Subjects Early Terminated for Study	The number of subjects early terminated in study divided by the number of subjects enrolled in study
M-SST57	Study-Site Metrics	Ratios	% Subjects Early Terminated for Study-Site	The number of subjects early terminated at study-site divided by the number of subjects enrolled at study-site
M-SST19	Study-Site Metrics	Ratios	Closed Discrepancies per CRF	Number of Closed Discrepancies per CRF currently Present
M-SST23	Study-Site Metrics	Ratios	Closed Discrepancies per Enrolled Subject	Number of closed discrepancies per currently enrolled Subject
M-SST17	Study-Site Metrics	Ratios	Open Discrepancies per CRF	Number of Open Discrepancies per CRF currently Present
M-SST20	Study-Site Metrics	Ratios	Open Discrepancies per Enrolled Subject	Number of Open Discrepancies per currently enrolled Subject

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-SST87	Study-Site Metrics	Ratios	Screen Failure Rate	The number of subjects who failed screening divided by the number of subjects screened for the Study-Site.
M-SST18	Study-Site Metrics	Ratios	Total Discrepancies per CRF	Number of all Discrepancies (Open or Closed) per CRF currently Present
M-SST21	Study-Site Metrics	Ratios	Total Discrepancies per Enrolled Subject	Number of all Discrepancies (Open or Closed) per currently enrolled Subject
M-SST73	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.
M-SST41	Study-Site Metrics	Statistics	1st Subject Completed Date	Earliest date on which a subject completed the study
M-SST40	Study-Site Metrics	Statistics	1st Subject Withdrawn Date	Earliest date on which a subject withdrew (Status is Early Terminated) from the study
M-SST59	Study-Site Metrics	Statistics	Avg # Days Document Outstanding	Average number of days between Document Sent date and today's date,
M-SST60	Study-Site Metrics	Statistics	Avg # Days from Document Sent to Document Received	Average number of days between Document Sent date and Document Received Date
M-SST24.1	Study-Site Metrics	Statistics	Avg Duration of All Discrepancies	For all discrepancies ever open at a study-site, the average number of days they were open.
M-SST29	Study-Site Metrics	Statistics	Avg Duration of Closed Discrepancies	For those discrepancies that are closed, the average number of days from creation to Closed.
M-SST24	Study-Site Metrics	Statistics	Avg Duration of Currently Open Discrepancies	For all open discrepancies at a study-site, the average number of days open
TA-SUBJ02	Study-Site Metrics	Statistics	Initial Informed Consent Date	Earliest Informed Consent date for a subject
M-SST74	Study-Site Metrics	Statistics	Latest Site Visit Completed Date	Most recent of all Site Visit Completed Dates for a Site
M-SST75	Study-Site Metrics	Statistics	Latest Site Visit Start Date	Most recent of all Site Visit Completed Dates for a Site
M-SST101	Study-Site Metrics	Statistics	Latest Site Visit Type	Visit type of the most recent of all Site Visit Completed Dates for a Site
M-SST45	Study-Site Metrics	Statistics	Latest Subject Completed Date	Most recent date on which a subject completed the study
M-SST24.3	Study-Site Metrics	Statistics	Max Duration of All Discrepancies	For all discrepancies ever open at a study-site, the maximum number of days they were open.
M-SST31	Study-Site Metrics	Statistics	Max Duration of Closed Discrepancies	For all closed discrepancies at a study-site, the maximum number of days it took to close them.

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-SST28	Study-Site Metrics	Statistics	Max Duration of Currently Open Discrepancies	For all discrepancies currently open, the maximum number of days any of them has been open.
M-SST24.2	Study-Site Metrics	Statistics	Min Duration of All Discrepancies	For all discrepancies ever open at a study-site, the minimum number of days they were open.
M-SST30	Study-Site Metrics	Statistics	Min Duration of Closed Discrepancies	For all closed discrepancies at a study-site, the minimum number of days it took to close them.
M-SST27	Study-Site Metrics	Statistics	Min Duration of Currently Open Discrepancies	For all open discrepancies at a study-site, the minimum number of days open
M-SST78	Study-Site Metrics	Statistics	Next Site Visit Date	Earliest Site Visit with Start Visit after today.
M-SST100	Study-Site Metrics	Statistics	Next Site Visit Type	Visit type of the Earliest Site Visit with Start Visit after today.
TA-SUBJ04	Subject Metrics	Actual Milestones	1st Visit Date	The date of the first post-enrollment visit for the subject.
TA-SUBJ09	Subject Metrics	Actual Milestones	[Last Visit Date]	The Last Visit Date for the Subject.
TA-SUBJ05	Subject Metrics	Actual Milestones	Latest Visit Date	The Latest Visit Date for the Subject.
TA-SUBJ06	Subject Metrics	Subject Visits	# Subject Visits Completed	The number of subject visits that have been completed.
TA-SUBJ07	Subject Metrics	Subject Visits	# Subject Visits Overdue	The number of subject visits that have been planned up to today's date but have not been completed.
TA-SUBJ08	Subject Metrics	Subject Visits	# Subject Visits Planned	The number of subject visits planned after today's date.
TA-SUBJ03	Subject Metrics	Transactional Data	Current Status Comment	Subject Status Comments
TA-SUBJ01	Subject Metrics	Transactional Data	Current Subject Status	Subject Status
M-SBVT03	Subject Visit	Subject Visits	Subject Visit Completed Date	The Subject Visit Completed Date.
M-SBVT04	Subject Visit	Subject Visits	Subject Visit Completed Flag	Indicates whether the Subject Visit was completed.
M-SBVT05	Subject Visit	Subject Visits	Subject Visit Description	The Subject Visit Description.
M-SBVT06	Subject Visit	Subject Visits	Subject Visit Due Date	The Subject Visit Due Date.
M-SBVT07	Subject Visit	Subject Visits	Subject Visit Max Due Date	The maximum date on which the subject visit would be due.
M-SBVT08	Subject Visit	Subject Visits	Subject Visit Min Due Date	The minimum date on which the subject visit would be due.
M-SBVT09	Subject Visit	Subject Visits	Subject Visit Planned Date	The Subject Visit Planned Date
M-SBVT10	Subject Visit	Subject Visits	Subject Visit Protocol Deviation	Indicates whether there is a protocol deviation on the subject visit.

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-SBVT11	Subject Visit	Subject Visits	Subject Visit Protocol Violation	Indicates whether there is a protocol violation on the subject visit.
M-SBVT12	Subject Visit	Subject Visits	Subject Visit Sequence	The Subject Visit Sequence.
M-SBVT13	Subject Visit	Subject Visits	Subject Visit Template Version	The Subject Visit Template Version.
M-SBVT14	Subject Visit	Subject Visits	Subject Visit Type	The Subject Visit Type.
M-TA10	Therapeutic Area Metrics	Counts	# Studies	The number of study records.
M-TA27	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.
M-TA16	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.
M-TA25	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.
M-TA03	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.
M-TA22	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.
M-TA05	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.
M-TA06	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.
M-TA26	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.
M-TA07	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.

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-TA08	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.
M-TA24	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.
M-TA23	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.
M-TA09	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.
M-TA11	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.
M-TA12	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.
M-TA13	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.
M-TA14	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.
M-TA15	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.

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-TA20	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.
M-TA21	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.
M-TA01	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.

Oracle Clinical Sources for OHSCDA Presentation Catalog

There are two tables in this section:

- Table B–3, Presentation Catalog - Oracle Clinical Sourceslists Oracle Clinical sources for presentation catalog.
- Table B–4, Aliases for Table Names lists the aliases used for table names in Table B-3.

Oracle Clinical Sources

Table B-3 describes how OHSCDA populates each column from an Oracle Clinical database. Each Measure has an ID number, which is provided for cross-reference to other tables in this Appendix. To display the information compactly, Table B-3 uses aliases for table names. Refer to Table B-4 for the correspondence between aliases and table names.

Table B–3 Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD02-02	-	Not sourced from OC
AD02-03	-	Not sourced from OC
AD02-04	-	Not sourced from OC
AD02-05	-	Not sourced from OC
AD02-06	-	Not sourced from OC
AD02-07	-	Not sourced from OC
AD02-08	-	Not sourced from OC
AD02-09	-	Not sourced from OC
AD02-10	-	Not sourced from OC
AD02-11	-	Not sourced from OC
AD02-12	-	Not sourced from OC
AD02-13	-	Not sourced from OC
AD02-14	-	Not sourced from OC
AD02-15	-	Not sourced from OC
AD02-16	-	Not sourced from OC

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD02-17	-	Not sourced from OC
AD02-18	-	Not sourced from OC
AD02-19	-	Not sourced from OC
AD02-20	-	Not sourced from OC
AD02-21	-	Not sourced from OC
AD02-22	-	Not sourced from OC
AD02-23	-	Not sourced from OC
AD02-24	-	Not sourced from OC
AD02-25	-	Not sourced from OC
AD02-26	-	Not sourced from OC
AD02-27	-	Not sourced from OC
AD02-28	-	Not sourced from OC
AD02-29	-	Not sourced from OC
AD02-30	-	Not sourced from OC
AD02-31	-	Not sourced from OC
AD02-32	-	Not sourced from OC
AD02-33	-	Not sourced from OC
AD02-34	-	Not sourced from OC
AD02-35	-	Not sourced from OC
AD02-36	-	Not sourced from OC
AD02-37	-	Not sourced from OC
AD02-38	-	Not sourced from OC
AD02-39	-	Not sourced from OC
AD02-40	-	Not sourced from OC
AD02-41	-	Not sourced from OC
AD02-42	-	Not sourced from OC
AD02-43	-	Not sourced from OC
AD02-44	-	Not sourced from OC
AD02-45	-	Not sourced from OC
AD02-46	-	Not sourced from OC
AD02-47	-	Not sourced from OC
AD02-48	-	Not sourced from OC
AD02-49	-	Not sourced from OC
AD02-50	-	Not sourced from OC
AD02-51	-	Not sourced from OC
AD02-52	-	Not sourced from OC
AD02-53	-	Not sourced from OC

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD02-54	-	Not sourced from OC
AD02-55	-	Not sourced from OC
AD02-56	-	Not sourced from OC
AD02-57	-	Not sourced from OC
AD02-58	-	Not sourced from OC
AD02-59	-	Not sourced from OC
AD02-60	-	Not sourced from OC
AD02-61	-	Not sourced from OC
AD02-62	-	Not sourced from OC
AD02-63	-	Not sourced from OC
AD02-64	-	Not sourced from OC
AD02-65	-	Not sourced from OC
AD02-66	-	Not sourced from OC
AD02-67	-	Not sourced from OC
AD02-68	-	Not sourced from OC
AD02-69	-	Not sourced from OC
AD02-70	-	Not sourced from OC
AD02-71	-	Not sourced from OC
AD02-72	-	Not sourced from OC
AD02-73	-	Not sourced from OC
AD02-74	-	Not sourced from OC
AD02-75	-	Not sourced from OC
AD02-76	-	Not sourced from OC
AD02-77	-	Not sourced from OC
AD02-78	-	Not sourced from OC
AD02-79	-	Not sourced from OC
AD02-80	-	Not sourced from OC
AD02-81	-	Not sourced from OC
AD02-82	-	Not sourced from OC
AD02-83	-	Not sourced from OC
AD02-84	-	Not sourced from OC
AD02-85	-	Not sourced from OC
AD02-86	-	Not sourced from OC
AD02-87	-	Not sourced from OC
AD02-88	-	Not sourced from OC
AD02-89	-	Not sourced from OC
AD02-90	-	Not sourced from OC

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD02-91	-	Not sourced from OC
AD02-92	-	Not sourced from OC
AD02-93	-	Not sourced from OC
AD02-94	-	Not sourced from OC
AD02-95	-	Not sourced from OC
AD02-96	-	Not sourced from OC
AD02-97	-	Not sourced from OC
AD02-98	-	Not sourced from OC
AD02-99	-	Not sourced from OC
AD02-100	-	Not sourced from OC
AD02-101	-	Not sourced from OC
AD02-102	-	Not sourced from OC
AD02-103	-	Not sourced from OC
AD02-104	-	Not sourced from OC
AD02-105	-	Not sourced from OC
AD02-106	-	Not sourced from OC
AD02-107	-	Not sourced from OC
AD02-108	-	Not sourced from OC
AD02-109	-	Not sourced from OC
AD02-110	-	Not sourced from OC
AD02-111	-	Not sourced from OC
AD02-112	-	Not sourced from OC
AD02-113	-	Not sourced from OC
AD02-114	-	Not sourced from OC
AD02-115	-	Not sourced from OC
AD02-116	-	Not sourced from OC
AD02-117	-	Not sourced from OC
AD02-118	-	Not sourced from OC
AD02-119	-	Not sourced from OC
AD02-120	-	Not sourced from OC
AD02-121	-	Not sourced from OC
AD02-122	-	Not sourced from OC
AD02-123	-	Not sourced from OC
AD02-124	-	Not sourced from OC
AD02-125	-	Not sourced from OC
AD02-126	-	Not sourced from OC
AD02-127	-	Not sourced from OC

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD02-128	-	Not sourced from OC
AD02-129	-	Not sourced from OC
AD02-130	-	Not sourced from OC
AD02-131	-	Not sourced from OC
AD02-132	-	Not sourced from OC
AD02-133	-	Not sourced from OC
AD02-134	-	Not sourced from OC
AD02-135	-	Not sourced from OC
AD02-136	-	Not sourced from OC
AD02-137	-	Not sourced from OC
AD02-138	-	Not sourced from OC
AD02-139	-	Not sourced from OC
AD02-140	-	Not sourced from OC
AD02-141	-	Not sourced from OC
AD02-142	-	Not sourced from OC
AD02-143	-	Not sourced from OC
AD02-144	-	Not sourced from OC
AD02-145	-	Not sourced from OC
AD02-146	-	Not sourced from OC
AD02-147	-	Not sourced from OC
AD02-148	-	Not sourced from OC
AD02-149	-	Not sourced from OC
AD02-150	-	Not sourced from OC
AD02-151	-	Not sourced from OC
AD02-152	-	Not sourced from OC
AD02-153	-	Not sourced from OC
AD02-154	-	Not sourced from OC
AD02-155	-	Not sourced from OC
AD02-156	-	Not sourced from OC
AD02-157	-	Not sourced from OC
AD04-01	ocl_regions.continent	where the continent is composed of country, and the country has only one continent. Else null.
AD04-03	os.country and inv.country	-
AD04-04	os.state and inv.country	-
AD04-05	-	Not sourced from OC
AD04-06	os.city and inv.city	-
AD04-07	os.postal_code and inv.postal_code	-

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD05-01	inv.last_name	-
AD05-02	inv.first_name	-
AD05-03	inv.first_name ||' '|| inv.last_name	-
AD05-04	inv.address _line%	catenation of 3 lines
AD05-05	inv.city	-
AD05-06	inv.postal_code	-
AD05-07	inv.state	-
AD05-08	inv.country	-
AD05-09	inv.continent	-
AD05-10	-	Not sourced from OC
AD05-11	-	Not sourced from OC
AD05-12	-	Not sourced from OC
AD05-13	-	Not sourced from OC
AD05-14	-	Not sourced from OC
AD05-15	-	Not sourced from OC
AD05-16	-	Not sourced from OC
AD05-17	-	Not sourced from OC
AD05-18	-	Not sourced from OC
AD05-19	-	Not sourced from OC
AD07-01	pm.product_name	-
AD07-02	-	Not sourced from OC
AD07-03	pm.pm_type_code	-
AD07-04	-	Not sourced from OC
AD07-07	-	Not sourced from OC
AD07-08	-	Not sourced from OC
AD07-09	-	Not sourced from OC
AD08-01	site.name	-
AD08-02	site.state	-
AD08-03	site.country	-
AD08-04	region_components.part_of_region_code	Continent, given country
AD08-05	-	Not sourced from OC
AD08-06	-	Not sourced from OC
AD08-07	site.address_line_1	-
AD08-08	site.address_line_2	-
AD08-09	site.address_line_3	-
AD08-10	site.postal_code	-

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD08-11	-	Not sourced from OC
AD08-12	site.city	-
AD09-01	os.study	-
AD09-02	cs.short_title	-
AD09-03	os.program_code	-
AD09-04	os.project_code	-
AD09-05	-	Not sourced from OC
AD09-06	os.project_code	If all received CRFs have a single Data Capture mode, that is the mode of the study. If mixed, the 'Paper and EDC'; If no data collected, mode is 'Unknown'.
AD09-07	-	Not sourced from OC
AD09-08	-	Not sourced from OC
AD09-09	-	Not sourced from OC
AD09-10	-	Not sourced from OC
AD09-11	-	Not sourced from OC
AD09-12	-	Not sourced from OC
AD09-13	-	Not sourced from OC
AD09-14	-	Not sourced from OC
AD09-15	-	Not sourced from OC
AD09-16	-	Not sourced from OC
AD09-17	-	Not sourced from OC
AD09-18	-	Not sourced from OC
AD09-19	-	Not sourced from OC
AD09-20	-	Not sourced from OC
AD09-22	-	Not sourced from OC
AD09-23	-	Not sourced from OC
AD09-24	-	Not sourced from OC
AD09-25	-	Not sourced from OC
AD09-26	-	Not sourced from OC
AD09-27	-	Not sourced from OC
AD09-28	-	Not sourced from OC
AD09-29	-	Not sourced from OC
AD09-30	-	Not sourced from OC
AD09-31	-	Not sourced from OC
AD09-32	-	Not sourced from OC
AD09-33	-	Not sourced from OC
AD09-34	-	Not sourced from OC

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD09-35	-	Not sourced from OC
AD09-36	-	Not sourced from OC
AD09-38	-	Not sourced from OC
AD09-39	-	Not sourced from OC
AD09-40	-	Not sourced from OC
AD09-41	-	Not sourced from OC
AD09-42	-	Not sourced from OC
AD09-43	-	Not sourced from OC
AD09-44	-	Not sourced from OC
AD09-45	-	Not sourced from OC
AD09-46	-	Not sourced from OC
AD09-47	-	Not sourced from OC
AD09-48	-	Not sourced from OC
AD09-49	-	Not sourced from OC
AD09-50	-	Not sourced from OC
AD09-51	-	Not sourced from OC
AD09-52	-	Not sourced from OC
AD09-53	-	Not sourced from OC
AD09-54	-	Not sourced from OC
AD09-55	-	Not sourced from OC
AD09-56	-	Not sourced from OC
AD09-57	-	Not sourced from OC
AD09-58	-	Not sourced from OC
AD09-59	-	Not sourced from OC
AD09-60	-	Not sourced from OC
AD09-61	-	Not sourced from OC
AD09-62	-	Not sourced from OC
AD09-63	-	Not sourced from OC
AD09-64	-	Not sourced from OC
AD09-65	-	Not sourced from OC
AD09-66	-	Not sourced from OC
AD09-67	-	Not sourced from OC
AD09-68	-	Not sourced from OC
AD09-69	-	Not sourced from OC
AD09-70	-	Not sourced from OC
AD09-71	-	Not sourced from OC
AD09-72	-	Not sourced from OC

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD09-73	-	Not sourced from OC
AD09-74	-	Not sourced from OC
AD10-01	site.name	-
AD10-02	ss.study_site	-
AD10-03	-	Not sourced from OC
AD10-04	cs.study	-
AD10-05	os.program_code	-
AD10-06	os.project_code	-
AD10-07	ep.planned_start_date	-
AD10-08	ep.planned_target_date	-
AD10-10	min(pp.patient_enrollment_date)	-
AD10-22	inv.first_name ||' '|| inv.last_name	-
AD10-24	-	Not sourced from OC
AD10-25	-	If all received CRFs have a single Data Capture mode, that is the mode of the study. If mixed, the 'Paper and EDC'; If no data collected, mode is 'Unknown'.
AD10-26	-	Not sourced from OC
AD10-29	sites.active_flag	Not sourced from OC
AD10-31	-	Not sourced from OC
AD10-32	sites.city	Not sourced from OC
AD10-33	sites.postal_code	Not sourced from OC
AD10-34	sites.address_line_1	Not sourced from OC
AD10-35	sites.address_line_2	Not sourced from OC
AD10-36	sites.address_line_3	Not sourced from OC
AD10-37	-	In Business Model only - concatenation of Study #, Site #, P Investigator Last Name
AD10-38	-	Not sourced from OC
AD10-39	-	Not sourced from OC
AD10-40	cs.study_status_type_code	-
AD10-41	-	Not sourced from OC
AD10-42	-	Not sourced from OC
AD10-43	-	Not sourced from OC
AD10-44	-	Not sourced from OC
AD10-45	-	Not sourced from OC
AD10-46	-	Not sourced from OC
AD10-47	-	Not sourced from OC
AD10-48	-	Not sourced from OC
AD10-49	-	Not sourced from OC

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD10-50	-	Not sourced from OC
AD10-51	-	Not sourced from OC
AD10-52	-	Not sourced from OC
AD10-53	-	Not sourced from OC
AD10-54	-	Not sourced from OC
AD10-55	-	Not sourced from OC
AD10-56	-	Not sourced from OC
AD10-57	-	Not sourced from OC
AD10-58	-	Not sourced from OC
AD10-59	-	Not sourced from OC
AD10-60	-	Not sourced from OC
AD10-61	-	Not sourced from OC
AD10-62	-	Not sourced from OC
AD10-63	-	Not sourced from OC
AD10-64	-	Not sourced from OC
AD10-65	-	Not sourced from OC
AD10-66	-	Not sourced from OC
AD10-67	-	Not sourced from OC
AD10-68	-	Not sourced from OC
AD10-69	-	Not sourced from OC
AD10-70	-	Not sourced from OC
AD10-71	-	Not sourced from OC
AD10-72	-	Not sourced from OC
AD10-73	-	Not sourced from OC
AD10-74	-	Not sourced from OC
AD10-75	-	Not sourced from OC
AD10-76	-	Not sourced from OC
AD10-77	-	Not sourced from OC
AD11-01	cs.study	exclude GLIB
AD11-02	dci.name	-
AD11-03	dci.help_text	-
AD11-04	dci.short_name	-
AD11-05	dcis.dci_id	-
AD12-01	book.name	-
AD12-02	cs.study	exclude GLIB
AD13-01	cs.study	exclude GLIB
AD13-02	proc.name	-

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD13-03	proc.description	-
AD13-04	proc.procedure_type_code	-
AD14-01	-	Not sourced from OC
AD14-02	-	Not sourced from OC
AD14-03	-	Not sourced from OC
AD14-04	-	Not sourced from OC
AD14-05	-	Not sourced from OC
AD14-06	-	Not sourced from OC
AD14-07	-	Not sourced from OC
AD14-08	-	Not sourced from OC
AD14-09	-	Not sourced from OC
AD14-10	-	Not sourced from OC
AD15-01	-	Not sourced from OC
AD15-02	-	Not sourced from OC
AD15-03	-	Not sourced from OC
AD15-04	-	Not sourced from OC
AD15-05	-	Not sourced from OC
AD15-06	-	Not sourced from OC
AD15-07	-	Not sourced from OC
AD15-08	-	Not sourced from OC
AD15-09	-	Not sourced from OC
AD15-10	-	Not sourced from OC
AD15-11	-	Not sourced from OC
AD15-12	-	Not sourced from OC
AD15-13	-	Not sourced from OC
AD15-15	-	Not sourced from OC
AD15-16	-	Not sourced from OC
AD15-17	-	Not sourced from OC
AD15-18	-	Not sourced from OC
AD15-19	-	Not sourced from OC
AD16-01	-	Not sourced from OC
AD16-02	-	Not sourced from OC
AD16-03	-	Not sourced from OC
AD16-04	-	Not sourced from OC
AD16-05	-	Not sourced from OC
AD16-06	-	Not sourced from OC
AD16-07	-	Not sourced from OC

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD16-08	-	Not sourced from OC
AD16-09	-	Not sourced from OC
AD16-10	-	Not sourced from OC
AD16-11	-	Not sourced from OC
AD16-12	-	Not sourced from OC
AD16-13	-	Not sourced from OC
AD16-14	-	Not sourced from OC
AD16-15	-	Not sourced from OC
AD16-16	-	Not sourced from OC
AD17-01	-	Not sourced from OC
AD17-02	-	Not sourced from OC
AD17-03	-	Not sourced from OC
AD17-04	-	Not sourced from OC
AD17-05	-	Not sourced from OC
AD17-06	-	Not sourced from OC
AD17-07	-	Not sourced from OC
AD17-08	-	Not sourced from OC
AD17-09	-	Not sourced from OC
AD17-10	-	Not sourced from OC
AD17-11	-	Not sourced from OC
AD17-12	-	Not sourced from OC
AD17-13	-	Not sourced from OC
AD17-14	-	Not sourced from OC
AD17-15	-	Not sourced from OC
AD17-16	-	Not sourced from OC
AD17-17	-	Not sourced from OC
AD17-18	-	Not sourced from OC
AD17-19	-	Not sourced from OC
AD17-20	-	Not sourced from OC
AD17-21	-	Not sourced from OC
AD17-22	-	Not sourced from OC
AD17-23	-	Not sourced from OC
AD17-24	-	Not sourced from OC
AD17-25	-	Not sourced from OC
AD17-26	-	Not sourced from OC
AD17-27	-	Not sourced from OC
AD17-28	-	Not sourced from OC

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD17-29	-	Not sourced from OC
AD17-30	-	Not sourced from OC
AD17-31	-	Not sourced from OC
AD17-32	-	Not sourced from OC
AD17-33	-	Not sourced from OC
AD17-34	-	Not sourced from OC
AD17-35	-	Not sourced from OC
AD17-36	-	Not sourced from OC
AD17-37	-	Not sourced from OC
AD17-38	-	Not sourced from OC
AD17-39	-	Not sourced from OC
AD17-40	-	Not sourced from OC
AD17-41	-	Not sourced from OC
AD17-42	-	Not sourced from OC
AD17-43	-	Not sourced from OC
AD17-44	-	Not sourced from OC
AD17-45	-	Not sourced from OC
AD17-46	-	Not sourced from OC
AD17-47	-	Not sourced from OC
AD18-01	-	Not sourced from OC
AD18-02	-	Not sourced from OC
AD18-03	-	Not sourced from OC
AD18-04	-	Not sourced from OC
AD18-05	-	Not sourced from OC
AD18-06	-	Not sourced from OC
AD18-07	-	Not sourced from OC
AD18-08	-	Not sourced from OC
AD18-09	-	Not sourced from OC
AD18-10	-	Not sourced from OC
AD18-11	-	Not sourced from OC
AD18-12	-	Not sourced from OC
AD19-01	-	Not sourced from OC
AD19-02	-	Not sourced from OC
AD19-03	-	Not sourced from OC
AD19-04	-	Not sourced from OC
AD19-05	-	Not sourced from OC
AD19-06	-	Not sourced from OC

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD19-07	-	Not sourced from OC
AD19-08	-	Not sourced from OC
AD19-09	-	Not sourced from OC
AD20-01	-	Not sourced from OC
AD20-02	-	Not sourced from OC
AD20-03	-	Not sourced from OC
AD20-04	-	Not sourced from OC
AD20-05	-	Not sourced from OC
AD20-06	-	Not sourced from OC
AD20-07	-	Not sourced from OC
AD20-08	-	Not sourced from OC
AD21-01	-	Not sourced from OC
AD21-02	-	Not sourced from OC
AD21-03	-	Not sourced from OC
AD21-04	-	Not sourced from OC
AD21-05	-	Not sourced from OC
AD21-06	-	Not sourced from OC
AD21-07	-	Not sourced from OC
AD21-08	-	Not sourced from OC
AD21-09	-	Not sourced from OC
AD22-01	-	Not sourced from OC
AD22-02	-	Not sourced from OC
AD22-03	-	Not sourced from OC
AD22-04	-	Not sourced from OC
AD22-05	-	Not sourced from OC
AD22-06	-	Not sourced from OC
AD22-07	-	Not sourced from OC
AD22-08	-	Not sourced from OC
AD22-09	-	Not sourced from OC
AD22-10	-	Not sourced from OC
AD22-11	-	Not sourced from OC
AD22-12	-	Not sourced from OC
AD22-13	-	Not sourced from OC
M-ALL01	-	Not sourced from OC
M-ALL02	-	Not sourced from OC
M-ALL03	-	Not sourced from OC
M-ALL04	-	Not sourced from OC

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-ALL05	-	Not sourced from OC
M-ALL06	-	Not sourced from OC
M-ALL07	-	Not sourced from OC
M-ALL08	-	Not sourced from OC
M-ALL09	-	Not sourced from OC
M-ALL10	-	Not sourced from OC
M-ALL11	-	Not sourced from OC
M-ALL12	-	Not sourced from OC
M-ALL13	-	Not sourced from OC
M-ALL14	-	Not sourced from OC
M-ALL15	-	Not sourced from OC
M-ALL16	-	Not sourced from OC
M-ALL17	-	Not sourced from OC
M-ALL18	-	Not sourced from OC
M-ALL19	-	Not sourced from OC
M-ALL20	-	Not sourced from OC
M-ALL21	-	Not sourced from OC
M-DOC01	-	Not sourced from OC
M-DOC02	-	Not sourced from OC
M-DOC03	-	Not sourced from OC
M-DOC04	-	Not sourced from OC
M-DRS01	derh.discrepancy_rev_status_code	-
M-DRS02	sum(derh.next_status_ts - derh.creation_ts)	For each particular review status (the summation is needed in case the discrepancy enters the review status more than once)
M-DRS03	M-DRS02/(number of discrepancies that occupied a given review status)	-
M-DRS04	(M-DRS02/(number of discrepancies that occupied a given review status)) given currently open discrepancies only	-
M-DSC01	disc	count
M-DSC02	disc	count where not OBSOLETE and not irresolvable
M-DSC03	disc	count where discrepancy_status_code = OBSOLETE or irresolvable
M-DSC04	disc	count where disc.dcf_id is not null
M-DSC09	disc	count where irresolvable
M-DSC11	disc	close date - creation date given State = CLOSED; last ETL date - creation date given State = OPEN
M-DSC12	disc	last ETL date - creation date given State = OPEN

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-DSC15	close date - creation date	where State = CLOSED
M-FUI01	-	Not sourced from OC
M-FUI02	-	Not sourced from OC
M-FUI03	-	Not sourced from OC
M-PRG01	-	Not sourced from OC
M-PRG03	-	Not sourced from OC
M-PRG04	-	Not sourced from OC
M-PRG06	-	Not sourced from OC
M-PRG07	-	Not sourced from OC
M-PRG08	-	Not sourced from OC
M-PRG09	-	Not sourced from OC
M-PRG10	-	Not sourced from OC
M-PRG11	-	Not sourced from OC
M-PRG12	-	Not sourced from OC
M-PRG13	-	Not sourced from OC
M-PRG14	-	Not sourced from OC
M-PRG15	-	Not sourced from OC
M-PRG16	-	Not sourced from OC
M-PRG17	-	Not sourced from OC
M-PRG18	-	Not sourced from OC
M-PRG19	-	Not sourced from OC
M-PRG20	-	Not sourced from OC
M-PRG21	-	Not sourced from OC
M-PRG22	-	Not sourced from OC
M-PRG23	-	Not sourced from OC
M-PRG24	-	Not sourced from OC
M-RCF01	rdci.received_dcis	count where required entry passes are complete. For eCRF, this is Pass 1. For pCRF, it is Pass 1 unless second pass is required for the study.
M-RCF05	rdci	where received_dci_status_code = 'RECEIVED'
M-RCF06	rdci	where received_dci_status_code = 'PASS 1 STARTED
M-RCF07	rdci	count where PASS 1 COMPLETE
M-RCF08	rdci	where RECEIVED or PASS 1 STARTED
M-RCF09	rdci	where BLANK_FLAG = 'Y'
M-RCF10	rdci	count
M-RCF11	rdci	last ETL - log_in_ts, where RECEIVED
M-RCF13	rdci	count where rdci.received_dci_status_code in ('PASS 2 STARTED', 'PASS 2 PENDING')

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-RCF14	rdci	count where rdci.received_dci_status_code = 'PASS 2 COMPLETE'
M-RCF15	rdci	count where rdci.received_dci_status_code = 'PASS 2 PENDING'
M-RCF16	rdci	count where rdci.received_dci_status_code in ('PASS 1 COMPLETE', 'PASS 2 STARTED', 'PASS 2 PENDING')
M-RCF17	rdci	count where: rdci is paper (i.e. substr(rdci.document_number, 1,1) != 'R') and either received_dci_status_code = 'PASS 1 STARTED', if PASS 2 not required, or received_ dci_status_code in ('PASS 1 COMPLETE', 'PASS 2 STARTED', 'PASS 2 PENDING')
M-RCF18	rdci	count where: (rdci is paper (i.e. substr(rdci.document_number, 1,1) != 'R') and either received_dci_status_code = 'PASS 1 STARTED', if PASS 2 not required, or received_ dci_status_code in ('PASS 1 COMPLETE', 'PASS 2 STARTED', 'PASS 2 PENDING')) or /* eCRF */ received_dci_status_code = 'PASS 1 STARTED')
M-RCF19	rdci	count where received_dci_status_code = 'BATCH'
M-RCF20	rh	count where trans_type = 'SYS VER YES'
M-RCF21	rh	count where trans_type in ('SYS VER NO', 'SYS VER UNDONE', 'SYS VER DATACHG)
M-RCF21.1	rh	count where trans_type in ('SYS APP NO', 'SYS APP UNDONE', 'SYS APP DATACHG')
M-RCF22	rh	count where trans_type = 'SYS VER DATACHG'
M-RCF23	rh	count where trans_type = 'SYS VER NO', ' SYS VER UNDONE'
M-RCF24	rh	count where trans_type = 'SYS APP YES'
M-RCF25	rh	count where trans_type = ('SYS APP NO', 'SYS APP UNDONE')
M-RCF26	rh	count where trans_type = 'SYS APP DATACHG'
M-RCF29	rdci	count all received DCIs that are locked (data_ lock_flag = 'Y') but not yet frozen (freeze_flag = 'N')
M-RCF29.1	rdci	count where TA-RCRF28 is 'Y'
M-RCF30	rh	interval from first verification to latest approval, using trans_type
M-RCF31	rdci	-
M-RCF31.1	rdci	ENTRY_COMPLETE_DT - ACTL_SUBJ_VIST_ DT
M-RCF32	rdci	pass2_compltn_dt - pass1_compltn_dt
M-RCF33	rdci	for pCRFs in studies requiring pass 2 entry only. If pass 2 complete, then pass2_compltn_dt - pass1_compltn_dt; else LAST_ETL_DT - pass1_ compltn_dt.

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-RCF34	rdci	ENTRY_COMPLETE_DT - ACTL_SUBJ_VIST_ DT
M-RCF35	rh	for eCRFs only: Date of first verification that is not undone - PASS1_COMPLTN_DT
M-RCF36	rh	for eCRFs only: Date of first approval that is not undone - PASS1_COMPLTN_DT
M-RCF37	rdci	data_lock_ts - ENTRY_COMPLETE_DT
M-RCF38	rh	for eCRFs only: data_lock_ts - Date of latest approval
M-RCF39	rdci	for eCRFs only: pass1_compltn_dt - ACTL_SUBJ_ VIST_DT
M-RCF40	rh	for eCRFs only: data_lock_dt - actl_subj_vist_dt
M-RCF41	rdci	avg(M-RCF39)
M-RCF42	rdci	avg(M-RCF31)
M-RCF43	rdci	avg(M-RCF32)
M-RCF44	rdci	avg(M-RCF33)
M-RCF45	rdci	avg(M-RCF34) for eCRFs
M-RCF45.1	rdci	avg(M-RCF34) for pCRFs
M-RCF46	rdci	avg(M-RCF35)
M-RCF47	rdci	avg(M-RCF36)
M-RCF48	rdci	M-RCF30/M-RCF71
M-RCF49	rdci	avg(M-RCF40)
M-RCF49.1	rdci	avg(M-RCF76)
M-RCF49.2	rdci	avg(M-RCF37)
M-RCF50	rdci	avg(M-RCF38)
M-RCF52	rdci	100 * M-RCF20/M-RCF75
M-RCF52.1	rdci	100 * M-RCF24/M-RCF75
M-RCF55.1	rdci	100 * M-RCF24/M-RCF01
M-RCF55.2	rdci	100 * M-RCF20/M-RCF01
M-RCF58	rdci	100 * M-RCF72 /M-RCF75
M-RCF62	rdci	100 * M-RCF29/M-RCF1
M-RCF62.1	rdci	100 * M-RCF72/M-RCF64.3
M-RCF62.2	rdci	100 * M-RCF74/M-RCF78
M-RCF63	rdci	100 * M-RCF22/M-RCF20
M-RCF64	rdci	100 * M-RCF26l/M-RCF24
M-RCF64.1	rdci	100 * M-RCF29/M-RCF75
M-RCF64.2	rdci	100 * (M-RCF74 + M-RCRF74.1)/M-RCF64.3
M-RCF64.3	rdci	100 * M-RCF71.1/M-RCF64.3
M-RCF64.4	rdci	100 * M-RCF74.1/M-RCF78

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-RCF65	rdci	100 * M-RCF1/M-RCF10
M-RCF68	rdci	count where eCRF and received_dci_status_code = 'PASS 1 COMPLETE'
M-RCF69	rdci	count where at least one non-undone verification has occurred.
M-RCF70	rdci	count where at least one non-undone approval has occurred.
M-RCF71.1	-	-
M-RCF72	rdci	count all DCIs received via RDC that are locked (data_lock_flag = 'Y') but not yet frozen (freeze_ flag = 'N')
M-RCF73	rdci	pCRFs requiring pass 2 entry only: count where received_dci_status_code = 'PASS 1 COMPLETE'
M-RCF74	rdci	count all received paper DCIs that are locked (data_lock_flag = 'Y') but not yet frozen (freeze_ flag = 'N')
M-RCF74.1	rdci	pCRFs only: count where TA-RCRF28 is 'Y'
M-RCF75	rdci	eCRFs only: count *
M-RCF76	rdci	For pCRFs:data_lock_ts - ENTRY_COMPLETE_ DT
M-RCF77	rdci	Avg(Pass 1 complete dt - ACTL_SUBJ_VIST_DT)
M-RCF78	rdci	for pCRFs: count where ENTRY-COMPLETE
M-RCF81	rdci	eCRFs only: count where blank_flag = 'Y'
M-RCF82	rdci	pCRFs only: count where blank_flag = 'Y'
M-RCF83	rdci	-
M-RCF84	rdci	eCRFs only: count where subevent_number > 0
M-RCF85	rdci	pCRFs only: count where subevent_number > 0
M-RCF86	rdci	eCRFs only: count where received_dci_status_ code = 'PASS 1 STARTED'
M-REG05	-	Not sourced from OC
M-REG07	-	Not sourced from OC
M-REG09	-	Not sourced from OC
M-REG10	-	Not sourced from OC
M-REG11	-	Not sourced from OC
M-REG12	-	Not sourced from OC
M-REG14	-	Not sourced from OC
M-REG15	-	Not sourced from OC
M-REG16	-	Not sourced from OC
M-REG17	-	Not sourced from OC
M-REG18	-	Not sourced from OC
M-REG19	-	Not sourced from OC

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-REG20	-	Not sourced from OC
M-SBVT03	-	Not sourced from OC
M-SBVT04	-	Not sourced from OC
M-SBVT05	-	Not sourced from OC
M-SBVT06	-	Not sourced from OC
M-SBVT07	-	Not sourced from OC
M-SBVT08	-	Not sourced from OC
M-SBVT09	-	Not sourced from OC
M-SBVT10	-	Not sourced from OC
M-SBVT11	-	Not sourced from OC
M-SBVT12	-	Not sourced from OC
M-SBVT13	-	Not sourced from OC
M-SBVT14	-	Not sourced from OC
M-SIV01	-	Not sourced from OC
M-SIV02	-	Not sourced from OC
M-SIV03	-	Not sourced from OC
M-SIV04	-	Not sourced from OC
M-SIV05	-	Not sourced from OC
M-SIV06	-	Not sourced from OC
M-SIV07	-	Not sourced from OC
M-SIV08	-	Not sourced from OC
M-SIV10	-	Not sourced from OC
M-SRG01	-	Not sourced from OC
M-SRG02	-	Not sourced from OC
M-SRG03	-	Not sourced from OC
M-SRG04	-	Not sourced from OC
M-SRG05	-	Not sourced from OC
M-SRG06	-	Not sourced from OC
M-SRG07	-	Not sourced from OC
M-SRG08	-	Not sourced from OC
M-SRG09	-	Not sourced from OC
M-SRG10	-	Not sourced from OC
M-SRG11	-	Not sourced from OC
M-SRG12	-	Not sourced from OC
M-SRG13	-	Not sourced from OC
M-SRG14	-	Not sourced from OC
M-SRG16	-	Not sourced from OC

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-SRG23	-	Not sourced from OC
M-SRG24	-	Not sourced from OC
M-SRG25	-	Not sourced from OC
M-SRG26	-	Not sourced from OC
M-SRG27	-	Not sourced from OC
M-SRG28	-	Not sourced from OC
M-SRG29	-	Not sourced from OC
M-SRG30	-	Not sourced from OC
M-SRG31	-	Not sourced from OC
M-SRG32	-	Not sourced from OC
M-SRG33	-	Not sourced from OC
M-SRG34	-	Not sourced from OC
M-SST01	ep.planned_patient_enrollment	-
M-SST02	pp	count(*) where .patient_enrollment_date is not null and screening_position_flag = 'N'
M-SST02C	-	-
M-SST03	pp	Calculate as # Subjects Enrolled - (# Early Terminations + # Subjects Lost to Follow up)
M-SST04	pp	Calculate as # Subjects Enrolled - (# Early Terminations + # Subjects Lost to Follow up + # Subjects Completed)
M-SST05	pp	A subject who has completed the study is one with an entry in patient_statuses with status of "COMPLETE"
M-SST05C	-	-
M-SST06	pp	An early terminator is one with an entry in patient_statuses with status of "EARLY TERM"
M-SST06C	-	-
M-SST08	ae	count actual events where sub-event number is 0.
M-SST09	ae	count actual events where sub-event number > 0.
M-SST15.1	-	100* (M-SST2/M-SST1)
M-SST17	-	M-DSC2/M-RCF10
M-SST18	-	M-DSC1/M-RCF10
M-SST19	-	M-DSC3/M-RCF10
M-SST20	-	M-DSC2/M-SST2
M-SST21	-	M-DSC1/M-SST2
M-SST23	-	M-DSC3/M-RCF10
M-SST24	-	M-DSC11/M-DSC2
M-SST24.1	-	(M-DSC11+M-DSC15)/(M-DSC2+M-DSC3)
M-SST24.2	-	min(min(M-DSC11), min(M-DSC15))

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-SST24.3	-	max(max(M-DSC11), max(M-DSC15))
M-SST27	-	min(M-DSC11)
M-SST28	-	max(M-DSC11)
M-SST29	-	M-DSC15/M-DSC3
M-SST30	-	min(M-DSC15)
M-SST31	-	max(M-DSC15)
M-SST32	-	Not sourced from OC
M-SST32C	-	Not sourced from OC
M-SST33	-	Not sourced from OC
M-SST33C	-	Not sourced from OC
M-SST34	-	Not sourced from OC
M-SST34C	-	Not sourced from OC
M-SST35	-	Not sourced from OC
M-SST35C	-	Not sourced from OC
M-SST36	-	Not sourced from OC
M-SST37	-	Not sourced from OC
M-SST38	-	Not sourced from OC
M-SST39	-	Not sourced from OC
M-SST40	-	Not sourced from OC
M-SST41	-	Not sourced from OC
M-SST42	-	Not sourced from OC
M-SST43	-	Not sourced from OC
M-SST44	-	Not sourced from OC
M-SST45	-	Not sourced from OC
M-SST46	-	Not sourced from OC
M-SST47	-	Not sourced from OC
M-SST48	-	Not sourced from OC
M-SST49	-	Not sourced from OC
M-SST50	-	Not sourced from OC
M-SST51	-	Not sourced from OC
M-SST52	-	Not sourced from OC
M-SST54	-	Not sourced from OC
M-SST55	-	Not sourced from OC
M-SST56	-	Not sourced from OC
M-SST57	-	Not sourced from OC
M-SST58	-	Not sourced from OC
M-SST59	-	Not sourced from OC

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-SST60	-	Not sourced from OC
M-SST61	-	Not sourced from OC
M-SST62	-	Not sourced from OC
M-SST63	-	Not sourced from OC
M-SST65	-	Not sourced from OC
M-SST66	-	Not sourced from OC
M-SST67	-	Not sourced from OC
M-SST68	-	Not sourced from OC
M-SST69	-	Not sourced from OC
M-SST70	-	Not sourced from OC
M-SST71	-	Not sourced from OC
M-SST72	-	Not sourced from OC
M-SST73	-	Not sourced from OC
M-SST74	-	Not sourced from OC
M-SST75	-	Not sourced from OC
M-SST76	-	Not sourced from OC
M-SST77	-	Not sourced from OC
M-SST78	-	Not sourced from OC
M-SST79	-	Not sourced from OC
M-SST80	-	Not sourced from OC
M-SST81	-	Not sourced from OC
M-SST82	-	Not sourced from OC
M-SST83	-	Not sourced from OC
M-SST84	-	Not sourced from OC
M-SST85	-	Not sourced from OC
M-SST86	-	Not sourced from OC
M-SST87	-	Not sourced from OC
M-SST88	-	Not sourced from OC
M-SST89	-	Not sourced from OC
M-SST90	-	Not sourced from OC
M-SST91	-	Not sourced from OC
M-SST92	-	Not sourced from OC
M-SST93	-	Not sourced from OC
M-SST94	-	Not sourced from OC
M-SST95	-	Not sourced from OC
M-SST96	-	Not sourced from OC
M-SST97	-	Not sourced from OC

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-SST98	-	Not sourced from OC
M-SST99	-	Not sourced from OC
M-SST100	-	Not sourced from OC
M-SST101	-	Not sourced from OC
M-SST102	-	Not sourced from OC
M-SST103	-	Not sourced from OC
M-SST104	-	Not sourced from OC
M-SST105	-	Not sourced from OC
M-SST106	-	Not sourced from OC
M-SST107	-	Not sourced from OC
M-STD01	ep	count (*) where plan_sub_type_code = 'SITE'
M-STD02	csv, ep	For a given study, first look at the number of patients to enroll in the live study version to determine planned enrollment for that study. If that is null, use study enrollment plan
M-STD06	-	100 * # Enrolled/# Enrollments Planned
M-STD07	-	Not sourced from OC
M-STD08	-	Not sourced from OC
M-STD09	-	Not sourced from OC
M-STD10	-	Not sourced from OC
M-STD11	-	Not sourced from OC
M-STD12	-	Not sourced from OC
M-STD13	-	Not sourced from OC
M-STD14	-	Not sourced from OC
M-STD15	-	Not sourced from OC
M-STD16	-	Not sourced from OC
M-STD17	-	Not sourced from OC
M-STD18	-	Not sourced from OC
M-STD20	-	Not sourced from OC
M-STD21	-	Not sourced from OC
M-STD22	-	Not sourced from OC
M-STD23	-	Not sourced from OC
M-STD24	-	Not sourced from OC
M-STD25	-	Not sourced from OC
M-STD26	-	Not sourced from OC
M-STD27	-	Not sourced from OC
M-STD28	-	Not sourced from OC
M-STD29	-	Not sourced from OC

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-STD30	-	Not sourced from OC
M-STD31	-	Not sourced from OC
M-STD32	-	Not sourced from OC
M-STD40	-	Not sourced from OC
M-STD42	-	Not sourced from OC
M-STD43	-	Not sourced from OC
M-STD44	-	Not sourced from OC
M-STD45	-	Not sourced from OC
M-STD46	-	Not sourced from OC
M-STD47	-	Not sourced from OC
M-STD48	-	Not sourced from OC
M-STD49	-	Not sourced from OC
M-STD50	-	Not sourced from OC
M-STD51	-	Not sourced from OC
M-STD52	-	Not sourced from OC
M-STD53	-	Not sourced from OC
M-STD54	-	Not sourced from OC
M-STD55	-	Not sourced from OC
M-STD56	-	Not sourced from OC
M-STD57	-	Not sourced from OC
M-STD58	-	Not sourced from OC
M-STD59	-	Not sourced from OC
M-STD60	-	Not sourced from OC
M-STD61	-	Not sourced from OC
M-STD62	-	Not sourced from OC
M-STD63	-	Not sourced from OC
M-STD64	-	Not sourced from OC
M-STD65	-	Not sourced from OC
M-STD66	-	Not sourced from OC
M-STD67	-	Not sourced from OC
M-STD68	-	Not sourced from OC
M-STD69	-	Not sourced from OC
M-STD70	-	Not sourced from OC
M-STD71	-	Not sourced from OC
M-STD72	-	Not sourced from OC
M-STD73	-	Not sourced from OC
M-STD74	-	Not sourced from OC

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-STD75	-	Not sourced from OC
M-STD76	-	Not sourced from OC
M-STD77	-	Not sourced from OC
M-STD78	-	Not sourced from OC
M-STD79	-	Not sourced from OC
M-STD80	-	Not sourced from OC
M-STD81	-	Not sourced from OC
M-STD82	-	Not sourced from OC
M-STD83	-	Not sourced from OC
M-STD84	-	Not sourced from OC
M-STD85	-	Not sourced from OC
M-STD86	-	Not sourced from OC
M-STD87	-	Not sourced from OC
M-STD88	-	Not sourced from OC
M-STD89	-	Not sourced from OC
M-STD90	-	Not sourced from OC
M-STD91	-	Not sourced from OC
M-STR01	-	Not sourced from OC
M-STR02	-	Not sourced from OC
M-STR03	-	Not sourced from OC
M-STR04	-	Not sourced from OC
M-STR05	-	Not sourced from OC
M-STR06	-	Not sourced from OC
M-STR07	-	Not sourced from OC
M-STR08	-	Not sourced from OC
M-STR09	-	Not sourced from OC
M-STR10	-	Not sourced from OC
M-STR11	-	Not sourced from OC
M-STR12	-	Not sourced from OC
M-STR13	-	Not sourced from OC
M-STR14	-	Not sourced from OC
M-STR15	-	Not sourced from OC
M-STR16	-	Not sourced from OC
M-STR17	-	Not sourced from OC
M-STR18	-	Not sourced from OC
M-STR19	-	Not sourced from OC
M-STR20	-	Not sourced from OC

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-STR21	-	Not sourced from OC
M-STR22	-	Not sourced from OC
M-STR23	-	Not sourced from OC
M-STR24	-	Not sourced from OC
M-STR25	-	Not sourced from OC
M-STR26	-	Not sourced from OC
M-STR27	-	Not sourced from OC
M-STR28	-	Not sourced from OC
M-STR29	-	Not sourced from OC
M-STR30	-	Not sourced from OC
M-STR31	-	Not sourced from OC
M-STR32	-	Not sourced from OC
M-STR33	-	Not sourced from OC
M-STR34	-	Not sourced from OC
M-STR35	-	Not sourced from OC
M-STR36	-	Not sourced from OC
M-STR37	-	Not sourced from OC
M-STR38	-	Not sourced from OC
M-TA01	-	Not sourced from OC
M-TA03	-	Not sourced from OC
M-TA05	-	Not sourced from OC
M-TA06	-	Not sourced from OC
M-TA07	-	Not sourced from OC
M-TA08	-	Not sourced from OC
M-TA09	-	Not sourced from OC
M-TA10	-	Not sourced from OC
M-TA11	-	Not sourced from OC
M-TA12	-	Not sourced from OC
M-TA13	-	Not sourced from OC
M-TA14	-	Not sourced from OC
M-TA15	-	Not sourced from OC
M-TA16	-	Not sourced from OC
M-TA20	-	Not sourced from OC
M-TA21	-	Not sourced from OC
M-TA22	-	Not sourced from OC
M-TA23	-	Not sourced from OC
M-TA24	-	Not sourced from OC

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-TA25	-	Not sourced from OC
M-TA26	-	Not sourced from OC
M-TA27	-	Not sourced from OC
TA-DISC01	disc.discrepancy_entry_id	-
TA-DISC02	cs.study	where cs.clinical_study_id = disc.clinical_study_ id
TA-DISC03	os.name	where os.site_id = disc.site_id
TA-DISC04	inv	inv.last_name, inv.first_name where inv.investigator_id = disc.investigator_id
TA-DISC05	pp.patient	-
TA-DISC06	cpe.name	-
TA-DISC07	cpe.visit_number	-
TA-DISC08	disc.subevent_number	-
TA-DISC09	cpe.visit_number || '.' || disc.subevent_number where cpe.clin_plan_eve_id = disc.clin_ plan_eve_id	-
TA-DISC10	rcdi.dci_date	-
TA-DISC11	rcdi.log_in_ts	-
TA-DISC12	dci.dci_id	-
TA-DISC13	disc.CRF_PAGE_NUMBER	-
TA-DISC14	dcm.name	-
TA-DISC15	dqg.name	-
TA-DISC16	dq.question_name	-
TA-DISC17	dq.occurrence_sn	-
TA-DISC19	disc.discrepancy_rev_status_code	where DISC_IRRESOLVABLE
TA-DISC20	proc.name	-
TA-DISC21	disc.DISCREPANCY_REV_STATUS_ CODE	-
TA-DISC22	disc.discrepancy_rev_status_code	-
TA-DISC22.1	disc.discrepancy_rev_status_code	where STATE = 'CLOSED'
TA-DISC23	disc.DE_SUB_TYPE_CODE	-
TA-DISC24	discrepancy_entries.discrepancy_ resolu_type_code	-
TA-DISC25	disc.creation_ts	-
TA-DISC26	disc	Date discrepancy STATE became CLOSED.
TA-DISC26.1	disc.DE_SUB_TYPE_CODE	Not sourced from OC
TA-DISC30	disc.comment_text	-
TA-DISC31	disc	Y' if disc.discrepancy_entry_id in (select discrepancy_id from dcf_discrepancies)

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
TA-DISC32	-	case disc.de_sub_type_code in ('MANUAL','MANUAL HEADER') then 'Non-System' else 'System' end origin
TA-DISC33	ss.study_site	where ss.SITE_ID = disc.site_id and ss.CLINICAL_STUDY_ID = disc.CLINICAL_ STUDY_ID
TA-DOC01	-	Not sourced from OC
TA-DOC02	-	Not sourced from OC
TA-DOC03	-	Not sourced from OC
TA-DOC04	-	Not sourced from OC
TA-DOC05	-	Not sourced from OC
TA-DOC06	-	Not sourced from OC
TA-DOC07	-	Not sourced from OC
TA-DOC08	-	Not sourced from OC
TA-DOC09	-	Not sourced from OC
TA-FUI01	-	Not sourced from OC
TA-FUI02	-	Not sourced from OC
TA-FUI03	-	Not sourced from OC
TA-FUI04	-	Not sourced from OC
TA-FUI05	-	Not sourced from OC
TA-FUI06	-	Not sourced from OC
TA-FUI07	-	Not sourced from OC
TA-FUI08	-	Not sourced from OC
TA-RCRF01	rdci.document_id	-
TA-RCRF02	cs.study	where cs.clinical_study_id = rdci.clinical_study_ id
TA-RCRF03	os.name	where os.site_id = rdci.site_id
TA-RCRF04	inv	first_name || ' ' || last_name
TA-RCRF05	pp.patient	-
TA-RCRF06	rdci.clin_plan_eve_name	-
TA-RCRF07	cpe.visit_number	-
TA-RCRF08	rdci.subevent_number	-
TA-RCRF09	rdci.visit_number, subevent_number	-
TA-RCRF10	rdci.dci_date	-
TA-RCRF11	rdci.dci_id	-
TA-RCRF12	book.name	-
TA-RCRF13	page.start_page_number	-
TA-RCRF14	rdci.received_dci_login_ts	-
TA-RCRF15	rdci.received_dci_status_code	-

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
TA-RCRF16	rdci.received_dci_id	case when rdcih.trans_type in 'SYS VER NO', 'SYS VER UNDONE') then 'Y' else 'N'
TA-RCRF17	rdci.received_dci_id	case when rdcih.trans_type ='SYS VER DATACHG' then 'Y' else 'N'
TA-RCRF19	rdci.received_dci_id	case when rdcih.trans_type in 'SYS APP NO', 'SYS APP UNDONE') then 'Y' else 'N'
TA-RCRF20	select rdci.received_dci_id,	case when rdcih.trans_type ='SYS APP DATACHG' then 'Y' else 'N'
TA-RCRF22	rdci.blank_flag	-
TA-RCRF23	rdci.data_lock_flag	-
TA-RCRF24	rdci	when rdci.received_dci_status_code in 'RECEIVED', 'PASS 1 STARTED') then 'Y' else 'N' end
TA-RCRF25	rdci	case when rdci.received_dci_status_code in 'PASS 1 COMPLETE', 'PASS 2 STARTED', 'PASS 2 PENDING') then 'Y' else 'N' end
TA-RCRF26	-	ENTRY_COMPLETE
TA-RCRF28	book.name	A received DCI is hard locked if the patient position for which that received DCI is collected has been frozen. Freezing the patient position means all of that patient position's received dcis are hard-locked. So we use pp.freeze_flag as hard-lock flag
TA-RCRF29	rdci.data_lock_ts	-
TA-RCRF30	rdci	Date of first non-undone verification, using rh.
TA-RCRF31	rdci.received_dci_status_code	Date of most recent non-undone verification, using rh.
TA-RCRF32	rdci	Date of first non-undone approval using rh.
TA-RCRF33	rdci	Date of most recent non-undone approval using rh.
TA-RCRF34	-	-
TA-RCRF35	-	see eCRF, pCRF
TA-SITE01	-	Not sourced from OC
TA-SIV01	-	Not sourced from OC
TA-SIV02	-	Not sourced from OC
TA-SIV03	-	Not sourced from OC
TA-SIV04	-	Not sourced from OC
TA-SIV05	-	Not sourced from OC
TA-SIV06	-	Not sourced from OC
TA-SIV07	-	Not sourced from OC
TA-SIV08	-	Not sourced from OC
TA-SIV09	-	Not sourced from OC
TA-SIV10	-	Not sourced from OC

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
TA-SIV11	-	Not sourced from OC
TA-SUBJ01	-	Not sourced from OC
TA-SUBJ02	-	Not sourced from OC
TA-SUBJ03	-	Not sourced from OC
TA-SUBJ04	-	Not sourced from OC
TA-SUBJ05	-	Not sourced from OC
TA-SUBJ06	-	Not sourced from OC
TA-SUBJ07	-	Not sourced from OC
TA-SUBJ08	-	Not sourced from OC
TA-SUBJ09	-	Not sourced from OC
TD01-01	pp.clinical_study_id	-
TD01-02	pp.patient	-
TD01-03	pp.dci_book_id	-
TD01-04	pp.freeze_flag	-
TD01-05	pp.early_termination_flag	-
TD01-06	ps, pp	icase when ps.patient_status_code ='ENROLLED' then ps.status_date when pp.patient_enrollment_ date is not null then pp.patient_enrollment_date else null end
TD01-07	pp	Case when <TD01-06> is not null then 'Y' else 'N' end
TD01-08	pp.reported_initials	-
TD01-09	pp.reported_birth_date	-
TD01-10	pp.reported_death_date	-
TD01-11	ps	Use the latest status code for the subject
TD01-12	ps,pp	case when ps.patient_status_code ='COMPLETE' then ps.status_date when pp.termination_date is not null and pp.early_termination_flag != 'Y' then pp.termination_date else null end
TD01-16	pp.reported_sex	-
TD01-17	-	Not sourced from OC
TD01-18	-	Not sourced from OC
TD01-19	-	Not sourced from OC
TD01-20	-	Not sourced from OC
TD01-21	-	Not sourced from OC
TD01-22	-	Not sourced from OC
TD01-23	-	Not sourced from OC
TD01-24	-	Not sourced from OC
TD01-25	-	Not sourced from OC
TD01-26	-	Not sourced from OC

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
TD01-27	-	Not sourced from OC
TD01-28	-	Not sourced from OC
TD01-29	-	Not sourced from OC
TD01-30	-	Not sourced from OC

Aliases

To display the information compactly, Table B-3 uses aliases for table names. Table B-4 lists these aliases:

Table B–4 Aliases for Table Names

Alias	Table Name
book	rxc.dci_books
cpe	rxa_des.clinical_planned_events
cs	rxa_des.clinical_studies
dci	rxc.dcis
derh	rxc.discrepancy_review_hist
disc	rxc.discrepancy_entries
dq	rxc.dcm_questions
dqg	rxc.dcm_question_groups
ep	rxa_des.enrollment_plans
inv	rxa_des.ocl_investigators
os	rxa_des.ocl_studies
page	rxc.dci_book_pages
pp	rxa_des.patient_positions
pm	rxa_des.ocl_product_masters
proc	rxc.procedures
ps	rxa_des.patient_statuses
rcv	rxc.reference_codelist_values
rdci	rxc.received_dcis
rdcm	rxc.received_dcms
site	rxa_des.ocl_sites
ss	rxa_des.ocl_study_sites

Caution: Where source location is described in snippets of SQL code, it should be read as an indication of how the information is to be extracted. This is typically not the actual code used in the OC-specific ETL programs. Consult the ETL for actual extraction queries.

Note that:

- eCRF is distinguished from pCRF by the first character in the document ID. If this is 'R', the document is assumed to be entered through RDC, and therefore an eCRF. Otherwise, it is considered to be an eCRF.
- ACTL_SUBJ_VIST_DT is the date when the RDCI was collected. This is taken to be the first non-null of these: rdci.visit_date; min(rdcm.visit_date) for the rdci; min(rdci.visit_date) for the rdci's visit; min(rdcm.visit_date) for the rdci's visit.
- ENTRY_COMPLETE: an eCRF is entry complete if it is pass 1 complete; a pCRF is entry complete if either (a) pass 2 is required and it is pass 2 complete, or (b) it is pass 1 complete.
- ENTRY_COMPLETE_DT is the date when RDCI became ENTRY_COMPLETE.
- LAST_ETL_DT is the date when the ETL was last executed.
- All queries on received_dcis look only at records where end_ts = to_date(3000000, 'J')
- A discrepancy is DISC_IRRESOLVABLE if disc.discrepancy_rev_status_code in (select rcv.ref_codelist_value_short_val from reference_codelist_values rcv where rcv.ref_codelist_name = 'DISCREPANCY REV STATUS CODE' and rcv.long_value = 'IRRESOLVABLE');
- A discrepancy's STATE is CLOSED {DISCREPANCY_REV_STATUS_CODE is 'CLOSED', or DISCREPANCY_STATUS_CODE = 'OBSOLETE', or DISC_ IRRESOLVABLE). OPEN otherwise.

Oracle's Siebel Clinical Sources for OHSCDA Presentation Catalog

Table B-5 describes how OHSCDA populates each column from an Siebel Clinical (SC) database. Each Measure has an ID number, which is provided for cross-reference to other tables in this Appendix.

Table B–5 Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD02-02	-	Not sourced from SC
AD02-03	-	Not sourced from SC
AD02-04	-	Not sourced from SC
AD02-05	-	Not sourced from SC
AD02-06	-	Not sourced from SC
AD02-07	-	Not sourced from SC
AD02-08	-	Not sourced from SC
AD02-09	-	Not sourced from SC
AD02-10	-	Not sourced from SC
AD02-11	-	Not sourced from SC
AD02-12	-	Not sourced from SC
AD02-13	-	Not sourced from SC
AD02-14	-	Not sourced from SC
AD02-15	-	Not sourced from SC
AD02-16	-	Not sourced from SC

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD02-17	-	Not sourced from SC
AD02-18	-	Not sourced from SC
AD02-19	-	Not sourced from SC
AD02-20	-	Not sourced from SC
AD02-21	-	Not sourced from SC
AD02-22	-	Not sourced from SC
AD02-23	-	Not sourced from SC
AD02-24	-	Not sourced from SC
AD02-25	-	Not sourced from SC
AD02-26	-	Not sourced from SC
AD02-27	-	Not sourced from SC
AD02-28	-	Not sourced from SC
AD02-29	-	Not sourced from SC
AD02-30	-	Not sourced from SC
AD02-31	-	Not sourced from SC
AD02-32	-	Not sourced from SC
AD02-33	-	Not sourced from SC
AD02-34	-	Not sourced from SC
AD02-35	-	Not sourced from SC
AD02-36	-	Not sourced from SC
AD02-37	-	Not sourced from SC
AD02-38	-	Not sourced from SC
AD02-39	-	Not sourced from SC
AD02-40	-	Not sourced from SC
AD02-41	-	Not sourced from SC
AD02-42	-	Not sourced from SC
AD02-43	-	Not sourced from SC
AD02-44	-	Not sourced from SC
AD02-45	-	Not sourced from SC
AD02-46	-	Not sourced from SC
AD02-47	-	Not sourced from SC
AD02-48	-	Not sourced from SC
AD02-49	-	Not sourced from SC
AD02-50	-	Not sourced from SC
AD02-51	-	Not sourced from SC
AD02-52	-	Not sourced from SC
AD02-53	-	Not sourced from SC

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD02-54	-	Not sourced from SC
AD02-55	-	Not sourced from SC
AD02-56	-	Not sourced from SC
AD02-57	-	Not sourced from SC
AD02-58	-	Not sourced from SC
AD02-59	-	Not sourced from SC
AD02-60	-	Not sourced from SC
AD02-61	-	Not sourced from SC
AD02-62	-	Not sourced from SC
AD02-63	-	Not sourced from SC
AD02-64	-	Not sourced from SC
AD02-65	-	Not sourced from SC
AD02-66	-	Not sourced from SC
AD02-67	-	Not sourced from SC
AD02-68	-	Not sourced from SC
AD02-69	-	Not sourced from SC
AD02-70	-	Not sourced from SC
AD02-71	-	Not sourced from SC
AD02-72	-	Not sourced from SC
AD02-73	-	Not sourced from SC
AD02-74	-	Not sourced from SC
AD02-75	-	Not sourced from SC
AD02-76	-	Not sourced from SC
AD02-77	-	Not sourced from SC
AD02-78	-	Not sourced from SC
AD02-79	-	Not sourced from SC
AD02-80	-	Not sourced from SC
AD02-81	-	Not sourced from SC
AD02-82	-	Not sourced from SC
AD02-83	-	Not sourced from SC
AD02-84	-	Not sourced from SC
AD02-85	-	Not sourced from SC
AD02-86	-	Not sourced from SC
AD02-87	-	Not sourced from SC
AD02-88	-	Not sourced from SC
AD02-89	-	Not sourced from SC
AD02-90	-	Not sourced from SC

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD02-91	-	Not sourced from SC
AD02-92	-	Not sourced from SC
AD02-93	-	Not sourced from SC
AD02-94	-	Not sourced from SC
AD02-95	-	Not sourced from SC
AD02-96	-	Not sourced from SC
AD02-97	-	Not sourced from SC
AD02-98	-	Not sourced from SC
AD02-99	-	Not sourced from SC
AD02-100	-	Not sourced from SC
AD02-101	-	Not sourced from SC
AD02-102	-	Not sourced from SC
AD02-103	-	Not sourced from SC
AD02-104	-	Not sourced from SC
AD02-105	-	Not sourced from SC
AD02-106	-	Not sourced from SC
AD02-107	-	Not sourced from SC
AD02-108	-	Not sourced from SC
AD02-109	-	Not sourced from SC
AD02-110	-	Not sourced from SC
AD02-111	-	Not sourced from SC
AD02-112	-	Not sourced from SC
AD02-113	-	Not sourced from SC
AD02-114	-	Not sourced from SC
AD02-115	-	Not sourced from SC
AD02-116	-	Not sourced from SC
AD02-117	-	Not sourced from SC
AD02-118	-	Not sourced from SC
AD02-119	-	Not sourced from SC
AD02-120	-	Not sourced from SC
AD02-121	-	Not sourced from SC
AD02-122	-	Not sourced from SC
AD02-123	-	Not sourced from SC
AD02-124	-	Not sourced from SC
AD02-125	-	Not sourced from SC
AD02-126	-	Not sourced from SC
AD02-127	-	Not sourced from SC

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD02-128	-	Not sourced from SC
AD02-129	-	Not sourced from SC
AD02-130	-	Not sourced from SC
AD02-131	-	Not sourced from SC
AD02-132	-	Not sourced from SC
AD02-133	-	Not sourced from SC
AD02-134	-	Not sourced from SC
AD02-135	-	Not sourced from SC
AD02-136	-	Not sourced from SC
AD02-137	-	Not sourced from SC
AD02-138	-	Not sourced from SC
AD02-139	-	Not sourced from SC
AD02-140	-	Not sourced from SC
AD02-141	-	Not sourced from SC
AD02-142	-	Not sourced from SC
AD02-143	-	Not sourced from SC
AD02-144	-	Not sourced from SC
AD02-145	-	Not sourced from SC
AD02-146	-	Not sourced from SC
AD02-147	-	Not sourced from SC
AD02-148	-	Not sourced from SC
AD02-149	-	Not sourced from SC
AD02-150	-	Not sourced from SC
AD02-151	-	Not sourced from SC
AD02-152	-	Not sourced from SC
AD02-153	-	Not sourced from SC
AD02-154	-	Not sourced from SC
AD02-155	-	Not sourced from SC
AD02-156	-	Not sourced from SC
AD02-157	-	Not sourced from SC
AD04-01	-	Not sourced from SC
AD04-03	-	Not sourced from SC
AD04-04	-	Not sourced from SC
AD04-05	-	Not sourced from SC
AD04-06	-	Not sourced from SC
AD04-07	-	Not sourced from SC
AD05-01	S_CONTACT.LAST_NAME	-

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD05-02	S_CONTACT.FST_NAME	-
AD05-03	S_CONTACT.LAST_NAME + S_CONTACT.FST_NAME	-
AD05-04	S_ADDR_PER.ADDR	-
AD05-05	S_ADDR_PER.CITY	-
AD05-06	S_ADDR_PER.ZIPCODE	-
AD05-07	S_ADDR_PER.STATE	-
AD05-08	S_ADDR_PER.COUNTRY	-
AD05-09	-	Not sourced from SC
AD05-10	S_CONTACT.WORK_PH_ NUM	-
AD05-11	-	Not sourced from SC
AD05-12	S_CONTACT.CELL_PH_NUM	-
AD05-13	S_CONTACT.EMAIL_ADDR	-
AD05-14	S_CONTACT.FAX_PH_NUM	-
AD05-15	S_CONTACT.MID_NAME	-
AD05-16	S_CONTACT.CON_CD	-
AD05-17	S_ADDR_PER.ADDR_LINE_2	-
AD05-18	S_ADDR_PER.ADDR_LINE_3	-
AD05-19	S_CONTACT_ROW_ID	-
AD07-01	S_PROD_INT.NAME	-
AD07-02	S_PROD_INT.TYPE	-
AD07-03	-	Not sourced from SC
AD07-04	S_PROD_INT.DESC_TEXT	-
AD07-07	S_PROD_INT.PART_NUM	-
AD07-08	S_PROD_INT.STATUS_CD	-
AD07-09	S_PROD_INT.ROW_ID	-
AD08-01	S_ORG_EXT.NAME	-
AD08-02	S_ADDR_PER.STATE	S_ORG_EXT.PR_ADDR_ID = S_ADDR_PER.ROW_ID
AD08-03	S_ADDR_PER.COUNTRY	S_ORG_EXT.PR_ADDR_ID = S_ADDR_PER.ROW_ID
AD08-04	-	Not sourced from SC
AD08-05	S_BU.NAME	S_ORG_EXT.BU_ID = S_BU.PAR_ROW_ID
AD08-06	S_ORG_EXT.ID	-
AD08-07	S_ADDR_PER.ADDR	S_ORG_EXT.PR_ADDR_ID = S_ADDR_PER.ROW_ID
AD08-08	S_ADDR_PER.ADDR_LINE_2	S_ORG_EXT.PR_ADDR_ID = S_ADDR_PER.ROW_ID
AD08-09	S_ADDR_PER.ADDR_LINE_3	S_ORG_EXT.PR_ADDR_ID = S_ADDR_PER.ROW_ID
AD08-10	S_ADDR_PER.ZIPCODE	S_ORG_EXT.PR_ADDR_ID = S_ADDR_PER.ROW_ID
AD08-11	S_ADDR_PER.COUNTY	S_ORG_EXT.PR_ADDR_ID = S_ADDR_PER.ROW_ID

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD08-12	S_ADDR_PER.CITY	S_ORG_EXT.PR_ADDR_ID = S_ADDR_PER.ROW_ID
AD09-01	S_CL_PTCL_LS.PTCL_NUM	-
AD09-02	S_CL_PTCL_LS.PTCL_ABBR_TL	-
AD09-03	S_CL_PGM_LS.NAME	-
AD09-04	-	Not sourced from SC
AD09-05	-	Not sourced from SC
AD09-06	-	Not sourced from SC
AD09-07	S_CL_PTCL_LS.PTCL_COMP_AGNT	-
AD09-08	S_CL_PTCL_LS.PTCL_DIAGNOSIS	-
AD09-09	S_CL_PTCL_LS.EUDRA_NUM	-
AD09-10	S_CL_PTCL_LS.PTCL_PHASE	-
AD09-11	S_CL_PTCL_LS.PTCL_STAT_CD	-
AD09-12	S_CL_PTCL_LS.PTCL_TITLE	-
AD09-13	S_CL_PTCL_LS.PTCL_TYPE_CD	-
AD09-14	S_CL_PTCL_LS.DB_LOCK_DT	-
AD09-15	S_CL_PTCL_LS.ROW_ID	-
AD09-16	S_CONTACT.S_CONTACT.LAST_NAME & ', ' & S_CONTACT.FST_NAME	where S_PT_POS_HST_LS.ROLE_CD = "Study Manager'
AD09-17	S_PROD_INT.NAME	-
AD09-18	-	Not sourced from SC
AD09-19	-	Not sourced from SC
AD09-20	-	Not sourced from SC
AD09-22	-	Not sourced from SC
AD09-23	-	Not sourced from SC
AD09-24	-	Not sourced from SC
AD09-25	-	Not sourced from SC
AD09-26	-	Not sourced from SC
AD09-27	-	Not sourced from SC
AD09-28	-	Not sourced from SC
AD09-29	-	Not sourced from SC
AD09-30	-	Not sourced from SC
AD09-31	-	Not sourced from SC
AD09-32	-	Not sourced from SC
AD09-33	-	Not sourced from SC

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD09-34	-	Not sourced from SC
AD09-35	-	Not sourced from SC
AD09-36	-	Not sourced from SC
AD09-38	-	Not sourced from SC
AD09-39	-	Not sourced from SC
AD09-40	-	Not sourced from SC
AD09-41	-	Not sourced from SC
AD09-42	-	Not sourced from SC
AD09-43	-	Not sourced from SC
AD09-44	-	Not sourced from SC
AD09-45	-	Not sourced from SC
AD09-46	-	Not sourced from SC
AD09-47	-	Not sourced from SC
AD09-48	-	Not sourced from SC
AD09-49	-	Not sourced from SC
AD09-50	-	Not sourced from SC
AD09-51	-	Not sourced from SC
AD09-52	-	Not sourced from SC
AD09-53	-	Not sourced from SC
AD09-54	-	Not sourced from SC
AD09-55	-	Not sourced from SC
AD09-56	-	Not sourced from SC
AD09-57	-	Not sourced from SC
AD09-58	-	Not sourced from SC
AD09-59	-	Not sourced from SC
AD09-60	-	Not sourced from SC
AD09-61	-	Not sourced from SC
AD09-62	-	Not sourced from SC
AD09-63	-	Not sourced from SC
AD09-64	-	Not sourced from SC
AD09-65	-	Not sourced from SC
AD09-66	-	Not sourced from SC
AD09-67	-	Not sourced from SC
AD09-68	-	Not sourced from SC
AD09-69	-	Not sourced from SC
AD09-70	-	Not sourced from SC
AD09-71	-	Not sourced from SC

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD09-72	-	Not sourced from SC
AD09-73	-	Not sourced from SC
AD09-74	-	Not sourced from SC
AD10-01	S_ORG_EXT.NAME	-
AD10-02	S_PTCL_SITE_LS.SITE_NUM	-
AD10-03	S_CL_PTCL_LS.REGION_CD	-
AD10-04	S_CL_PTCL_LS.PTCL_NUM	-
AD10-05	S_CL_PGM_LS.NAME	-
AD10-06	-	Not sourced from SC
AD10-07	-	Not sourced from SC
AD10-08	-	Not sourced from SC
AD10-10	S_PTCL_SITE_LS.FST_SUBJ_ ENRL_DT	-
AD10-22	S_CONTACT.LAST_ NAME+FST_NAME	S_PTL_ST_CON_LS.AFFL_CON_ID=S_CONTACT.PAR_ ROW_ID AND RELATION_TYPE_CD ='Principal Investigator'
AD10-24	S_ORG_EXT.NAME	-
AD10-25	-	Not sourced from SC
AD10-26	-	Not sourced from SC
AD10-29	S_PTCL_SITE_LS.STATUS_CD	-
AD10-31	-	Not sourced from SC
AD10-32	S_ADDR_PER.CITY	-
AD10-33	S_ADDR_PER.ZIPCODE	-
AD10-34	S_ADDR_PER.ADDR	-
AD10-35	S_ADDR_PER.ADDR_LINE_2	-
AD10-36	S_ADDR_PER.ADDR_LINE_3	-
AD10-37	-	In Business Model only - concatenation of Study #, Site #, P Investigator Last Name
AD10-38	S_CL_PTCL_LS.PTCL_STAT_ CD	REGION_CD NOT NULL
AD10-39	S_PTCL_SITE_LS.ROW_ID	-
AD10-40	S_CL_PTCL_LS.PTCL_STAT_ CD	-
AD10-41	S_PTCL_SITE_LS.ST_INITN_ CMPL_DT	-
AD10-42	S_CONTACT.S_ CONTACT.LAST_NAME & ', ' & S_CONTACT.FST_NAME	where S_ST_POS_HST_LS.ROLE_CD = "CRA"
AD10-43	S_PROD_INT.NAME	-
AD10-44	S_ADDR_PER.COUNTRY	-
AD10-45	S_ADDR_PER.STATE	-

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD10-46	-	Not sourced from SC
AD10-47	-	Not sourced from SC
AD10-48	-	Not sourced from SC
AD10-49	-	Not sourced from SC
AD10-50	-	Not sourced from SC
AD10-51	-	Not sourced from SC
AD10-52	-	Not sourced from SC
AD10-53	-	Not sourced from SC
AD10-54	-	Not sourced from SC
AD10-55	-	Not sourced from SC
AD10-56	-	Not sourced from SC
AD10-57	-	Not sourced from SC
AD10-58	-	Not sourced from SC
AD10-59	-	Not sourced from SC
AD10-60	-	Not sourced from SC
AD10-61	-	Not sourced from SC
AD10-62	-	Not sourced from SC
AD10-63	-	Not sourced from SC
AD10-64	-	Not sourced from SC
AD10-65	-	Not sourced from SC
AD10-66	-	Not sourced from SC
AD10-67	-	Not sourced from SC
AD10-68	-	Not sourced from SC
AD10-69	-	Not sourced from SC
AD10-70	-	Not sourced from SC
AD10-71	-	Not sourced from SC
AD10-72	-	Not sourced from SC
AD10-73	-	Not sourced from SC
AD10-74	S_PTCL_SITE_LS.SITE_TERM_DT	-
AD10-75	-	Not sourced from SC
AD10-76	S_ADDR_PER.LATITUDE	-
AD10-77	S_ADDR_PER.LONGITUDE	-
AD11-01	-	Not sourced from SC
AD11-02	-	Not sourced from SC
AD11-03	-	Not sourced from SC
AD11-04	-	Not sourced from SC

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD11-05	-	Not sourced from SC
AD12-01	-	Not sourced from SC
AD12-02	-	Not sourced from SC
AD13-01	-	Not sourced from SC
AD13-02	-	Not sourced from SC
AD13-03	-	Not sourced from SC
AD13-04	-	Not sourced from SC
AD14-01	S_CONTACT.FST_NAME	-
AD14-02	S_CONTACT.LAST_NAME	-
AD14-03	S_CONTACT.FULL_NAME	-
AD14-04	S_ST_HST_POS_LS.ROLE_CD	-
AD14-05	S_ST_HST_POS_LS.START_DT	-
AD14-06	S_ST_HST_POS_LS.END_DT	-
AD14-07	S_ST_HST_POS_ LS.COMMENTS	-
AD14-08	S_CONTACT.ROW_ID	-
AD14-09	-	S_ST_HST_POS_LS.END_DT is null or > today
AD14-10	S_CONTACT.EMAIL_ADDR	-
AD15-01	S_ADDR_PER.CITY	-
AD15-02	S_ADDR_PER.COUNTRY	-
AD15-03	-	Not sourced from SC
AD15-04	S_CONTACT.EMAIL_ADDR	-
AD15-05	S_CONTACT.EMP_FLG	-
AD15-06	S_CONTACT.FAX_PH_NUM	-
AD15-07	S_CONTACT.FST_NAME	-
AD15-08	S_CONTACT.FULL_NAME	-
AD15-09	S_CONTACT.LAST_NAME	-
AD15-10	S_CONTACT.MID_NAME	-
AD15-11	S_CONTACT.CELL_PH_NUM	-
AD15-12	S_CONTACT.WORK_PHONE	-
AD15-13	S_ADDR_PER.ZIPCODE	-
AD15-15	S_ADDR_PER.STATE	-
AD15-16	S_ADDR_PER.ST_ADDRESS	-
AD15-17	S_ADDR_PER.ADDR_LINE_2	-
AD15-18	S_ADDR_PER.ADDR_LINE_3	-
AD15-19	S_CONTACT_ROW_ID	-
AD16-01	S_CL_PGM_LS.DESC_TEXT	-

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD16-02	S_CL_PGM_LS.NAME	-
AD16-03	S_CL_PGM_LS.PROG_ MCHNSM_CD	-
AD16-04	S_CL_PGM_LS.ROW_ID	-
AD16-05	-	Not sourced from SC
AD16-06	-	Not sourced from SC
AD16-07	-	Not sourced from SC
AD16-08	-	Not sourced from SC
AD16-09	-	Not sourced from SC
AD16-10	-	Not sourced from SC
AD16-11	-	Not sourced from SC
AD16-12	-	Not sourced from SC
AD16-13	-	Not sourced from SC
AD16-14	-	Not sourced from SC
AD16-15	-	Not sourced from SC
AD16-16	-	Not sourced from SC
AD17-01	S_CL_PTCL_LS.REGION_CD	-
AD17-02	S_CL_PTCL_LS.PTCL_STAT_ CD	REGION_CD NOT NULL
AD17-03	S_ORG_EXT.NAME	-
AD17-04	S_CL_PTCL_LS_ROW_ID	-
AD17-05	-	Not sourced from SC
AD17-06	-	Not sourced from SC
AD17-07	-	Not sourced from SC
AD17-08	-	Not sourced from SC
AD17-09	-	Not sourced from SC
AD17-10	-	Not sourced from SC
AD17-11	-	Not sourced from SC
AD17-12	-	Not sourced from SC
AD17-13	-	Not sourced from SC
AD17-14	-	Not sourced from SC
AD17-15	-	Not sourced from SC
AD17-16	-	Not sourced from SC
AD17-17	S_CONTACT	LAST_NAME, FST_NAME where S_PT_POS_HST_ LS.ROLE_CD = "Region Manager'
AD17-18	-	Not sourced from SC
AD17-19	-	Not sourced from SC
AD17-20	-	Not sourced from SC

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD17-21	-	Not sourced from SC
AD17-22	-	Not sourced from SC
AD17-23	-	Not sourced from SC
AD17-24	-	Not sourced from SC
AD17-25	-	Not sourced from SC
AD17-26	-	Not sourced from SC
AD17-27	-	Not sourced from SC
AD17-28	-	Not sourced from SC
AD17-29	-	Not sourced from SC
AD17-30	-	Not sourced from SC
AD17-31	-	Not sourced from SC
AD17-32	-	Not sourced from SC
AD17-33	-	Not sourced from SC
AD17-34	-	Not sourced from SC
AD17-35	-	Not sourced from SC
AD17-36	-	Not sourced from SC
AD17-37	-	Not sourced from SC
AD17-38	-	Not sourced from SC
AD17-39	-	Not sourced from SC
AD17-40	-	Not sourced from SC
AD17-41	-	Not sourced from SC
AD17-42	-	Not sourced from SC
AD17-43	S_CL_PTCL_LS	REGION_CD
AD17-44	S_CL_PTCL_LS	PTCL_NUM+ "/ " + REGION_CD
AD17-45	-	Not sourced from SC
AD17-46	-	Not sourced from SC
AD17-47	-	Not sourced from SC
AD18-01	-	Not sourced from SC
AD18-02	-	Not sourced from SC
AD18-03	-	Not sourced from SC
AD18-04	-	Not sourced from SC
AD18-05	-	Not sourced from SC
AD18-06	-	Not sourced from SC
AD18-07	-	Not sourced from SC
AD18-08	-	Not sourced from SC
AD18-09	-	Not sourced from SC
AD18-10	-	Not sourced from SC

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD18-11	-	Not sourced from SC
AD18-12	-	Not sourced from SC
AD19-01	S_PT_POS_HST_LS	FST_NAME
AD19-02	S_PT_POS_HST_LS	LAST_NAME
AD19-03	S_PT_POS_HST_LS	[LAST_NAME]+", "+[FST_NAME]
AD19-04	S_PT_POS_HST_LS	ROLE_CD
AD19-05	S_PT_POS_HST_LS	START_DT
AD19-06	S_PT_POS_HST_LS	END_DT
AD19-07	S_PT_POS_HST_LS	EMAIL_ADDR
AD19-08	S_PT_POS_HST_LS	COMMENTS
AD19-09	S_PT_POS_HST_LS	END_DT
AD20-01	-	Not sourced from SC
AD20-02	-	Not sourced from SC
AD20-03	-	Not sourced from SC
AD20-04	-	Not sourced from SC
AD20-05	-	Not sourced from SC
AD20-06	-	Not sourced from SC
AD20-07	S_CL_PTCL_LS	REGION_CD
AD20-08	-	Not sourced from SC
AD21-01	S_PT_POS_HST_LS	FST_NAME
AD21-02	S_PT_POS_HST_LS	LAST_NAME
AD21-03	S_PT_POS_HST_LS	[LAST_NAME]+", "+[FST_NAME]
AD21-04	S_PT_POS_HST_LS	ROLE_CD
AD21-05	S_PT_POS_HST_LS	START_DT
AD21-06	S_PT_POS_HST_LS	END_DT
AD21-07	S_PT_POS_HST_LS	EMAIL_ADDR
AD21-08	S_PT_POS_HST_LS	COMMENTS
AD21-09	S_PT_POS_HST_LS	END_DT
AD22-01	-	Not sourced from SC
AD22-02	-	Not sourced from SC
AD22-03	-	Not sourced from SC
AD22-04	-	Not sourced from SC
AD22-05	-	Not sourced from SC
AD22-06	-	Not sourced from SC
AD22-07	-	Not sourced from SC
AD22-08	-	Not sourced from SC
AD22-09	-	Not sourced from SC

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD22-10	-	Not sourced from SC
AD22-11	-	Not sourced from SC
AD22-12	-	Not sourced from SC
AD22-13	-	Not sourced from SC
M-ALL01	S_CL_SUBJ_ST_LS	select ptcl_num, count(*) from s_ptcl_site_ls, s_cl_ptcl_ls where cl_ptcl_id = s_cl_ptcl_ls.row_id and count (S_CL_SUBJ_ST_LS.STATUS_CD = Enrolled) =0 and st_initn_cmpl_dt is not null group by ptcl_num order by 1
M-ALL02	S_PS_STMPVER_LS	select site_num, irb_apprv_dt "IRB_Approval_Date" from S_PS_STMPVER_LS, s_ptcl_site_ls where s_ptcl_site_ls.row_id = S_PS_STMPVER_LS.ptcl_site_id order by 1 From S_CL_SUBJ_LS, we have to find out the first subject (ROW_ID) using min(CREATED) in a particular protocol site. S_CL_SUBJ_LS.ROW_ID is the subject id (CL_SUBJ_ID in S_EVT_ACT)Using the CL_SUBJ_ID, get min(TODO_ACTL_END_DT) from S_EVT_ACT & SITE_NUM from S_PTCL_SITE_LS Join Condition between tables: s_evt_act.cl_subj_id is not null and s_cl_subj_ls.row_id = s_Evt_act.CL_SUBJ_ID and s_ptcl_site_ls.site_uid = s_cl_subj_ls.ptcl_site_id and s_evt_act.TODO_ACTL_END_DT is not null and S_EVT_ACT.TEMPLATE_FLG = 'V'
M-ALL03	S_CL_PTCL_LS	Protocol Approved Date cannot be sourced. min (S_PTCL_SITE_LS.ST_INITN_CMPL_DT)
M-ALL04	S_CL_PTCL_LS	select ptcl_num, min(status_date) "First_Subj_Enrolled_Date" from s_cl_subj_ls, s_cl_ptcl_ls, S_PTCL_SITE_LS, S_CL_SUBJ_ST_LS where s_cl_subj_ls.PTCL_SITE_ID = S_PTCL_SITE_LS.row_id and S_PTCL_SITE_LS.cl_ptcl_id = s_cl_ptcl_ls.row_id and S_CL_SUBJ_ST_LS.par_subj_id = s_cl_subj_ls.row_id and S_CL_SUBJ_ST_LS.status_cd = 'Enrolled' group by ptcl_num order by 1 Protocol Approved Date cannot be sourced.
M-ALL05	S_CL_SUBJ_ST_LS	STATUS_DATE select ptcl_num, min(status_date) "First_Subj_Randomized_Date" from s_cl_subj_ls, s_cl_ptcl_ls, S_PTCL_SITE_LS, S_CL_SUBJ_ST_LS where s_cl_subj_ls.PTCL_SITE_ID = S_PTCL_SITE_LS.row_id and S_PTCL_SITE_LS.cl_ptcl_id = s_cl_ptcl_ls.row_id and S_CL_SUBJ_ST_LS.par_subj_id = s_cl_subj_ls.row_id and S_CL_SUBJ_ST_LS.status_cd = 'Randomized' group by ptcl_num order by 1 Protocol Approved Date cannot be sourced.
M-ALL06	S_CL_SUBJ_ST_LS	STATUS_DATE select ptcl_num, min(status_date) "First_Screen_Date" from s_cl_subj_ls, s_cl_ptcl_ls, S_PTCL_SITE_LS, S_CL_SUBJ_ST_LS where s_cl_subj_ls.PTCL_SITE_ID = S_PTCL_SITE_LS.row_id and S_PTCL_SITE_LS.cl_ptcl_id = s_cl_ptcl_ls.row_id and S_CL_SUBJ_ST_LS.par_subj_id = s_cl_subj_ls.row_id and S_CL_SUBJ_ST_LS.status_cd = 'Screened' group by ptcl_num order by 1 Protocol Approved Date cannot be sourced.

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-ALL07	-	"select site_num, st_initn_cmpl_dt ""Site_Initiation_Date"" from s_ptcl_site_ls order by 1 1st Subject 1st Visit can get from: From S_CL_SUBJ_LS, we have to find out the first subject (ROW_ID) using min(CREATED) in a particular protocol site.S_CL_SUBJ_LS.ROW_ID is the subject id (CL_SUBJ_ID in S_EVT_ACT) Using the CL_SUBJ_ID, get min(TODO_ACTL_END_DT) from S_EVT_ACT & SITE_NUM from S_PTCL_SITE_LS Join Condition between tables: s_evt_act.cl_subj_id is not null and s_cl_subj_ls.row_id = s_Evt_act.CL_SUBJ_ID and s_ptcl_site_ls.site_uid = s_cl_subj_ls.ptcl_site_id and s_evt_act.TODO_ACTL_END_DT is not null and S_EVT_ACT.TEMPLATE_FLG = 'V'"
M-ALL08	S_EVT_ACT	select cl_ptcl_st_id, TODO_PLAN_START_DT "site_Visit_Start_Date", TODO_ACTL_END_DT "Site_Visit_Cmpl_Dt" from s_Evt_act where TODO_ACTL_END_DT is not null and subtype_cd = 'Site Visit'
M-ALL09	S_CL_PTCL_LS	select ptcl_num, count(*) from s_cl_ptcl_ls, S_PTCL_VER_LS where s_cl_ptcl_ls.row_id = cl_ptcl_id group by ptcl_num
M-ALL10	S_CL_PTCL_LS	select count(ptcl_num) from s_cl_ptcl_ls
M-ALL11	S_CL_PTCL_LS	Number of sites recruiting one or more subjects in a protocol: select ptcl_num, count(*) from s_ptcl_site_ls, s_cl_ptcl_ls where s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and count (S_CL_SUBJ_ST_LS.STATUS_CD = Enrolled) >=1 group by ptcl_num
M-ALL12	S_CL_SUBJ_ST_LS	Number of sites which enrolled atleast 90% of planned subjects in a protocol: select ptcl_num, count(*) from s_ptcl_site_ls, s_cl_ptcl_ls where cl_ptcl_id = s_cl_ptcl_ls.row_id and s_ptcl_site_ls.NUM_PLAN_SUBJ > 0 and (NUM_ENROLLED/s_ptcl_site_ls.NUM_PLAN_SUBJ*100 >= 90) group by ptcl_num order by 1 Get NUM_ENROLLED by: count (S_CL_SUBJ_ST_LS.STATUS_CD = Enrolled)
M-ALL13	S_CL_PTCL_LS	1st Site Initiate can get from min (S_PTCL_SITE_LS.ST_INITN_CMPL_DT) To get LATEST Site Initiated Date, we have to use different table, column: max(S_PTCL_SITE_LS.ST_INITN_CMPL_DT) Ex: select max(ST_INITN_CMPL_DT) from S_PTCL_SITE_LS where CL_PTCL_ID = '1-4LOA'
M-ALL14	S_PTCL_SITE_LS.ST_INITN_CMPL_DT	1st site initiated can get from S_PTCL_SITE_LS.ST_INITN_CMPL_DT Ex: select max(ST_INITN_CMPL_DT) from S_PTCL_SITE_LS "Critical Document Package Completed Date" cannot be sourced.
M-ALL15	S_PS_STMPVER_LS S_CL_PTCL_LS	IRB_APPRV_DT select site_num, irb_apprv_dt "IRB_Approval_Date", st_initn_cmpl_dt "Site_Initiation_Date" from S_PS_STMPVER_LS, s_ptcl_site_ls where S_PS_STMPVER_LS.ptcl_site_id = s_ptcl_site_ls.row_id order by 1

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-ALL16	S_EVT_ACT	TODO_ACTL_END_DT select a.cl_ptcl_st_id, b.TODO_ACTL_END_DT "Site_Visit_Cmpl_Dt", a.TODO_ACTL_END_DT "Follow_Up_Item_Cmpl_Dt" from s_Evt_act a, s_evt_act b where a.par_evt_id = b.activity_uid and a.subtype_cd = 'Follow-Up' and b.subtype_cd = 'Site Visit' and b.TODO_ACTL_END_DT is not null and a.TODO_ACTL_END_DT is not null
M-ALL17	S_EVT_ACT	TODO_ACTL_END_DT Site visit completed date can get from: select cl_ptcl_st_id, TODO_ACTL_END_DT "Visit_Completed_Date" from s_evt_act where subtype_cd = 'Site Visit' and TODO_ACTL_END_DT is not null Visit report approved date cannot be sourced.
M-ALL18	S_EVT_ACT	Site visit completed date can get from: select cl_ptcl_st_id, TODO_ACTL_END_DT "Site_Visit_Completed_Date", APPT_END_DT "Visit_Rep_Completed_Date" from s_evt_act where subtype_cd = 'Site Visit' and TODO_ACTL_END_DT is not null
M-ALL19	S_EVT_ACT	APPT_END_DT Visit Report Approved date cannot be sourced.
M-ALL20	S_CL_PTCL_LS	1st Site Initiate can get from min (S_PTCL_SITE_LS.ST_INITN_CMPL_DT) Last cannot be determined, so this cannot be sourced.
M-ALL21	S_CL_PTCL_LS	DB_LOCK_DT Last subject last visit date cannot be sourced. Database Lock date for the protocol can get from: S_CL_PTCL_LS.DB_LOCK_DT
M-DOC01	S_EVT_ACT.ROW_ID	SUBTYPE_CD='Document'
M-DOC02	-	Calculated in RPD based on W_ACTIVITY_F.DOC_EXPIRATION_DT
M-DOC03	-	Calculated in RPD based on W_ACTIVITY_F.DOC_RECEIVED_DT and W_ACTIVITY_F.DOC_SENT_DT
M-DOC04	-	Calculated in RPD based on W_ACTIVITY_F.DOC_RECEIVED_DT
M-DRS01	-	Not sourced from SC
M-DRS02	-	Not sourced from SC
M-DRS03	-	Not sourced from SC
M-DRS04	-	Not sourced from SC
M-DSC01	-	Not sourced from SC
M-DSC02	-	Not sourced from SC
M-DSC03	-	Not sourced from SC
M-DSC04	-	Not sourced from SC
M-DSC09	-	Not sourced from SC
M-DSC11	-	Not sourced from SC
M-DSC12	-	Not sourced from SC
M-DSC15	-	Not sourced from SC
M-FUI01	-	Calculated in RPD based on W_RXI_FOLLOWUP_ITEM_F.FOLLOWUP_ITEM_CMPLT_DT and W_RXI_SITE_VISIT_D.SITE_VISIT_CMPLT_DT

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-FUI02	-	Calculated in RPD based on W_RXI_FOLLOWUP_ITEM_F.FOLLOWUP_ITEM_CMPLT_DT and W_RXI_SITE_VISIT_D.SITE_VISIT_CMPLT_DT
M-FUI03	-	Calculated in RPD based on W_RXI_FOLLOWUP_ITEM_F.FOLLOWUP_ITEM_CMPLT_DT
M-PRG01	S_CL_PTCL_LS	select s_cl_pgm_ls.name "Program_Name", min(S_PTCL_SITE_LS.ST_INITN_CMPL_DT) "1st_Site_Initiated_Date", max(S_PTCL_SITE_LS.ST_INITN_CMPL_DT) "Latest_Site_Initiated_Date" from s_cl_pgm_ls, s_cl_ptcl_ls where s_cl_ptcl_ls.cl_pgm_id = s_cl_pgm_ls.row_id group by s_cl_pgm_ls.name
M-PRG03	-	select s_cl_pgm_ls.name "Program_Name", irb_apprv_dt "IRB_Approval_Date" from s_cl_pgm_ls, s_cl_ptcl_ls, s_ptcl_site_ls, S_PS_STMPVER_LS where s_ptcl_site_ls.row_id = S_PS_STMPVER_LS.ptcl_site_id and s_cl_ptcl_ls.cl_pgm_id = s_cl_pgm_ls.row_id and s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id order by 1 1st Subject 1st Visit can get from: From S_CL_SUBJ_LS, we have to find out the first subject (ROW_ID) using min(CREATED) in a particular protocol site. S_CL_SUBJ_LS.ROW_ID is the subject id (CL_SUBJ_ID in S_EVT_ACT) Using the CL_SUBJ_ID, get min(TODO_ACTL_END_DT) from S_EVT_A CT & SITE_NUM from S_PTCL_SITE_LS Join Condition between tables: s_evt_act.cl_subj_id is not null and s_cl_subj_ls.row_id = s_Evt_act.CL_SUBJ_ID and s_ptcl_site_ls.site_uid = s_cl_subj_ls.ptcl_site_id and s_evt_act.TODO_ACTL_END_DT is not null and S_EVT_ACT.TEMPLATE_FLG = 'V'
M-PRG04	S_PS_STMPVER_LS S_PTCL_SITE_LS	IRB_APPRV_DT ST_INITN_CMPL_DT
M-PRG06	-	select s_cl_pgm_ls.name "Program_Name", ptcl_num, min (S_PTCL_SITE_LS.ST_INITN_CMPL_DT) "1st_Site_Initiated_Date" from s_cl_pgm_ls, s_cl_ptcl_ls where s_cl_ptcl_ls.cl_pgm_id = s_cl_pgm_ls.row_id order by 1,2 Protocol Approved Date cannot be sourced.
M-PRG07	-	select s_cl_pgm_ls.name "Program_Name", ptcl_num, min (s_cl_subj_st_ls.status_date) "First Subject Enrolled Date" from s_cl_pgm_ls, s_cl_ptcl_ls where s_cl_pgm_ls.row_id = s_cl_ptcl_ls.cl_pgm_id and s_cl_subj_st_ls.status_cd = 'Enrolled' and s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and s_ptcl_site_ls.row_id = s_cl_subj_ls.ptcl_site_id and s_cl_subj_ls.row_id = s_cl_subj_st_ls.par_subj_id group by s_cl_ptcl_ls.ptcl_num order by 1,2 Protocol Approved Date cannot be sourced.

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-PRG08	-	select s_cl_pgm_ls.name "Program_Name", site_num "Site_Number", st_initn_cmpl_dt "Site_Initiation_Date" from s_ptcl_site_ls, s_cl_ptcl_ls, s_cl_pgm_ls where s_cl_ptcl_ls.cl_pgm_id = s_cl_pgm_ls.row_id and s_ptcl_site_ls.cl_ptcl_id = s_cl_ptcl_ls.row_id 1st Subject 1st Visit can get from: From S_CL_SUBJ_LS, we have to find out the first subject (ROW_ID) using min(CREATED) in a particular protocol site. S_CL_SUBJ_LS.ROW_ID is the subject id (CL_SUBJ_ID in S_EVT_ACT) Using the CL_SUBJ_ID, get min(TODO_ACTL_END_DT) from S_EVT_ACT & SITE_NUM from S_PTCL_SITE_LS Join Condition between tables: s_evt_act.cl_subj_id is not null and s_cl_subj_ls.row_id = s_Evt_act.CL_SUBJ_ID and s_ptcl_site_ls.site_uid = s_cl_subj_ls.ptcl_site_id and s_evt_act.TODO_ACTL_END_DT is not null and S_EVT_ACT.TEMPLATE_FLG = 'V'
M-PRG09	-	select a.cl_ptcl_st_id, b.TODO_ACTL_END_DT "Site_Visit_Cmpl_Dt", a.TODO_ACTL_END_DT "Follow_Up_Item_Cmpl_Dt" from s_Evt_act a, s_evt_act b where a.par_evt_id = b.activity_uid and a.subtype_cd = 'Follow-Up' and b.subtype_cd = 'Site Visit' and b.TODO_ACTL_END_DT is not null and a.TODO_ACTL_END_DT is not null and b.cl_ptcl_st_id in (select row_id from s_ptcl_site_ls where cl_ptcl_id in (select row_id from s_cl_ptcl_ls where cl_pgm_id in (select row_id from s_cl_pgm_ls where name = 'Anemia')))
M-PRG10	-	Site visit completed date in a program can get from: select s_cl_pgm_ls.name "Program_Name", site_num, TODO_ACTL_END_DT "Site_Visit_Completed_Date" from s_cl_pgm_ls,s_cl_ptcl_ls,s_ptcl_site_ls,s_evt_act where s_cl_pgm_ls.row_id = s_cl_ptcl_ls.cl_pgm_id and s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and s_ptcl_site_ls.row_id = s_evt_act.cl_ptcl_st_id and TODO_ACTL_END_DT is not null and subtype_cd = 'Site Visit' Visit report approved date cannot be sourced.
M-PRG11	-	select s_cl_pgm_ls.name "Program_Name", TODO_ACTL_END_DT "Site_Visit_Completed_Date", appt_end_dt "Visit_Rep_Completed_Date" from s_cl_pgm_ls,s_cl_ptcl_ls,s_ptcl_site_ls,s_evt_act where s_cl_pgm_ls.row_id = s_cl_ptcl_ls.cl_pgm_id and s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and s_ptcl_site_ls.row_id = s_evt_act.cl_ptcl_st_id and TODO_ACTL_END_DT is not null
M-PRG12	-	select s_cl_pgm_ls.name "Program_Name", ptcl_num, site_num, TODO_PLAN_START_DT "Site_Visit_Start_Date", TODO_ACTL_END_DT "Site_Visit_Completed_Date" from s_cl_pgm_ls,s_cl_ptcl_ls,s_ptcl_site_ls,s_evt_act where s_cl_pgm_ls.row_id = s_cl_ptcl_ls.cl_pgm_id and s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and s_ptcl_site_ls.row_id = s_evt_act.cl_ptcl_st_id and TODO_ACTL_END_DT is not null

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-PRG13	-	select s_cl_pgm_ls.name "Program_Name", ptcl_num, site_num, appt_end_dt "Visit_Rep_Completed_Date" from s_cl_pgm_ls,s_cl_ptcl_ls,s_ptcl_site_ls,s_evt_act where s_cl_pgm_ls.row_id = s_cl_ptcl_ls.cl_pgm_id and s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and s_ptcl_site_ls.row_id = s_evt_act.cl_ptcl_st_id and TODO_ACTL_END_DT is not null Visit Report Approved Date cannot be sourced.
M-PRG14	-	select ptcl_num, count(*) from s_cl_ptcl_ls, S_PTCL_VER_LS where s_cl_ptcl_ls.row_id = cl_ptcl_id group by ptcl_num
M-PRG15	-	select ptcl_num, count(*) from s_ptcl_site_ls, s_cl_ptcl_ls where cl_ptcl_id = s_cl_ptcl_ls.row_id and count (S_CL_SUBJ_ST_LS.STATUS_CD = Enrolled) =0 group by ptcl_num order by 1
M-PRG16	-	select count(ptcl_num) from s_cl_ptcl_ls
M-PRG17	-	Number of sites recruiting one or more subjects in a protocol: select ptcl_num, count(*) from s_ptcl_site_ls, s_cl_ptcl_ls where s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and count (S_CL_SUBJ_ST_LS.STATUS_CD = Enrolled) >= 1 group by ptcl_num
M-PRG18	-	Number of sites which enrolled atleast 90% of planned subjects in a protocol: select ptcl_num, count(*) from s_ptcl_site_ls, s_cl_ptcl_ls where cl_ptcl_id = s_cl_ptcl_ls.row_id and NUM_ENROLLED > 0 and (NUM_ENROLLED/s_ptcl_site_ls.NUM_PLAN_SUBJ*100 >= 90) group by ptcl_num order by 1 Get NUM_ENROLLED by: count (S_CL_SUBJ_ST_LS.STATUS_CD = Enrolled)
M-PRG19	S_PTCL_SITE_LS	ST_INITN_CMPL_DT Critical Document package Completed Date cannot be sourced
M-PRG20	-	SELECT s_cl_pgm_ls.name "Program_Name", ptcl_num, min(s_cl_subj_st_ls.status_date) "First_Subj_Screened_Date" from s_cl_pgm_ls, s_cl_ptcl_ls, s_ptcl_site_ls, s_cl_subj_ls, s_cl_subj_st_ls where s_cl_subj_st_ls.status_cd = 'Screened' and s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and s_ptcl_site_ls.row_id = s_cl_subj_ls.ptcl_site_id and s_cl_subj_ls.row_id = s_cl_subj_st_ls.par_subj_id and s_cl_pgm_ls.row_id = s_cl_ptcl_ls.cl_pgm_id group by s_cl_pgm_ls.name, ptcl_num Protocol approved date cannot be sourced.
M-PRG21	-	SELECT s_cl_pgm_ls.name "Program_Name", ptcl_num, min(s_cl_subj_st_ls.status_date) "First_Subj_Randomized_Date" from s_cl_pgm_ls, s_cl_ptcl_ls, s_ptcl_site_ls, s_cl_subj_ls, s_cl_subj_st_ls where s_cl_subj_st_ls.status_cd = 'Randomized' and s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and s_ptcl_site_ls.row_id = s_cl_subj_ls.ptcl_site_id and s_cl_subj_ls.row_id = s_cl_subj_st_ls.par_subj_id and s_cl_pgm_ls.row_id = s_cl_ptcl_ls.cl_pgm_id group by s_cl_pgm_ls.name, ptcl_num Protocol approved date cannot be sourced.
M-PRG22	-	select s_cl_pgm_ls.name "Program_Name", min(S_PTCL_SITE_LS.ST_INITN_CMPL_DT) "1st_Site_Initiated_Date" from s_cl_pgm_ls, s_cl_ptcl_ls where s_cl_ptcl_ls.cl_pgm_id = s_cl_pgm_ls.row_id group by s_cl_pgm_ls.name Last site initiated date cannot be sourced.

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-PRG23	S_CL_PTCL_DT	DB_LOCK_DT Last subject last visit date cannot be sourced. Database Lock date for the protocol can get from: S_CL_PTCL_LS.DB_LOCK_DT
M-PRG24	S_EVT_ACT.APPT_START_DT	-
M-RCF01	-	Not sourced from SC
M-RCF05	-	Not sourced from SC
M-RCF06	-	Not sourced from SC
M-RCF07	-	Not sourced from SC
M-RCF08	-	Not sourced from SC
M-RCF09	-	Not sourced from SC
M-RCF10	-	Not sourced from SC
M-RCF11	-	Not sourced from SC
M-RCF13	-	Not sourced from SC
M-RCF14	-	Not sourced from SC
M-RCF15	-	Not sourced from SC
M-RCF16	-	Not sourced from SC
M-RCF17	-	Not sourced from SC
M-RCF18	-	Not sourced from SC
M-RCF19	-	Not sourced from SC
M-RCF20	-	Not sourced from SC
M-RCF21	-	Not sourced from SC
M-RCF21.1	-	Not sourced from SC
M-RCF22	-	Not sourced from SC
M-RCF23	-	Not sourced from SC
M-RCF24	-	Not sourced from SC
M-RCF25	-	Not sourced from SC
M-RCF26	-	Not sourced from SC
M-RCF29	-	Not sourced from SC
M-RCF29.1	-	Not sourced from SC
M-RCF30	-	Not sourced from SC
M-RCF31	-	Not sourced from SC
M-RCF31.1	-	Not sourced from SC
M-RCF32	-	Not sourced from SC
M-RCF33	-	Not sourced from SC
M-RCF34	-	Not sourced from SC
M-RCF35	-	Not sourced from SC
M-RCF36	-	Not sourced from SC
M-RCF37	-	Not sourced from SC

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-RCF38	-	Not sourced from SC
M-RCF39	-	Not sourced from SC
M-RCF40	-	Not sourced from SC
M-RCF41	-	Not sourced from SC
M-RCF42	-	Not sourced from SC
M-RCF43	-	Not sourced from SC
M-RCF44	-	Not sourced from SC
M-RCF45	-	Not sourced from SC
M-RCF45.1	-	Not sourced from SC
M-RCF46	-	Not sourced from SC
M-RCF47	-	Not sourced from SC
M-RCF48	-	Not sourced from SC
M-RCF49	-	Not sourced from SC
M-RCF49.1	-	Not sourced from SC
M-RCF49.2	-	Not sourced from SC
M-RCF50	-	Not sourced from SC
M-RCF52	-	Not sourced from SC
M-RCF52.1	-	Not sourced from SC
M-RCF55.1	-	Not sourced from SC
M-RCF55.2	-	Not sourced from SC
M-RCF58	-	Not sourced from SC
M-RCF62	-	Not sourced from SC
M-RCF62.1	-	Not sourced from SC
M-RCF62.2	-	Not sourced from SC
M-RCF63	-	Not sourced from SC
M-RCF64	-	Not sourced from SC
M-RCF64.1	-	Not sourced from SC
M-RCF64.2	-	Not sourced from SC
M-RCF64.3	-	Not sourced from SC
M-RCF64.4	-	Not sourced from SC
M-RCF65	-	Not sourced from SC
M-RCF68	-	Not sourced from SC
M-RCF69	-	Not sourced from SC
M-RCF70	-	Not sourced from SC
M-RCF71.1	-	Not sourced from SC
M-RCF72	-	Not sourced from SC
M-RCF73	-	Not sourced from SC

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-RCF74	-	Not sourced from SC
M-RCF74.1	-	Not sourced from SC
M-RCF75	-	Not sourced from SC
M-RCF76	-	Not sourced from SC
M-RCF77	-	Not sourced from SC
M-RCF78	-	Not sourced from SC
M-RCF81	-	Not sourced from SC
M-RCF82	-	Not sourced from SC
M-RCF83	-	Not sourced from SC
M-RCF84	-	Not sourced from SC
M-RCF85	-	Not sourced from SC
M-RCF86	-	Not sourced from SC
M-REG05	-	select ptcl_num, count(*) from s_ptcl_site_ls, s_cl_ptcl_ls where cl_ptcl_id = s_cl_ptcl_ls.row_id and s_ptcl_site_ls.ST_INITN_CMPL_DT is not null and count (S_CL_SUBJ_ST_LS.STATUS_CD = Enrolled) =0 group by ptcl_num order by 1
M-REG07	-	Number of initiated sites recruiting one or more subjects in a protocol: select ptcl_num, count(*) from s_ptcl_site_ls, s_cl_ptcl_ls where s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and ST_INITN_CMPL_DT is not null and count (S_CL_SUBJ_ST_LS.STATUS_CD = Enrolled) >= 1 group by ptcl_num Number of sites initiated against each protocol: select ptcl_num, count(*) from s_ptcl_site_ls, s_cl_ptcl_ls where s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and ST_INITN_CMPL_DT is not null and count (S_CL_SUBJ_ST_LS.STATUS_CD = Enrolled) >= 1 group by ptcl_num
M-REG09	-	Number of sites which enrolled atleast 90% of planned subjects in a protocol: select ptcl_num, count(*) from s_ptcl_site_ls, s_cl_ptcl_ls where cl_ptcl_id = s_cl_ptcl_ls.row_id and NUM_ENROLLED> 0 and (NUM_ENROLLED/s_ptcl_site_ls.NUM_PLAN_SUBJ*100 >= 90) group by ptcl_num order by 1 Get NUM_ENROLLED by: count (S_CL_SUBJ_ST_LS.STATUS_CD = Enrolled) Number of sites initiated against each protocol: select ptcl_num, count(*) from s_ptcl_site_ls, s_cl_ptcl_ls where s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and ST_INITN_CMPL_DT is not null and NUM_ENROLLED >= 1 group by ptcl_num

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-REG10	-	select region_cd "Region", ptcl_num, site_num, min(st_ initn_cmpl_dt) "Site_Initiated_Date" from s_cl_ptcl_ls, s_ptcl_site_ls, S_PS_STMPVER_LS where s_ptcl_site_ls.row_id = S_PS_STMPVER_LS.ptcl_ site_id and s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id group by region_cd,ptcl_num, site_num order by 1,2,3 1st Subject 1st Visit can get from: From S_CL_SUBJ_LS, we have to find out the first subject (ROW_ID) using min(CREATED) in a particular protocol site. S_CL_SUBJ_LS.ROW_ID is the subject id (CL_SUBJ_ID in S_EVT_ACT) Using the CL_SUBJ_ID, get min(TODO_ACTL_END_DT) from S_EVT_ACT & SITE_NUM from S_PTCL_SITE_LS Join Condition between tables: s_evt_act.cl_subj_id is not null and s_cl_subj_ls.row_id = s_Evt_act.CL_SUBJ_ID and s_ptcl_site_ls.site_uid = s_cl_subj_ls.ptcl_site_id and s_evt_ act.TODO_ACTL_END_DT is not null and S_EVT_ ACT.TEMPLATE_FLG = 'V'
M-REG11	-	select region_cd "Region", ptcl_num, site_num, irb_apprv_ dt "IRB_Approval_Date" from s_cl_ptcl_ls, s_ptcl_site_ls, S_PS_STMPVER_LS where s_ptcl_site_ls.row_id = S_PS_STMPVER_LS.ptcl_ site_id and s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id order by 1,2 1st Subject 1st Visit can get from: From S_CL_SUBJ_LS, we have to find out the first subject (ROW_ID) using min(CREATED) in a particular protocol site. S_CL_SUBJ_LS.ROW_ID is the subject id (CL_SUBJ_ID in S_EVT_ACT) Using the CL_SUBJ_ID, get min(TODO_ACTL_END_DT) from S_EVT_ACT & SITE_NUM from S_PTCL_SITE_LS Join Condition between tables: s_evt_act.cl_subj_id is not null and s_cl_subj_ls.row_id = s_Evt_act.CL_SUBJ_ID and s_ptcl_site_ls.site_uid = s_cl_subj_ls.ptcl_site_id and s_evt_ act.TODO_ACTL_END_DT is not null and S_EVT_ ACT.TEMPLATE_FLG = 'V'
M-REG12	-	select region_cd "Region",ptcl_num,site_num, irb_apprv_ dt "IRB_Approval_Date", st_initn_cmpl_dt "Site_Initiation_ Date" from S_PS_STMPVER_LS, s_cl_ptcl_ls, s_ptcl_site_ls where S_PS_STMPVER_LS.ptcl_site_id = s_ptcl_site_ ls.row_id and s_cl_ptcl_ls.row_id = cl_ptcl_id order by 1
M-REG14	-	select count(ptcl_num) from s_cl_ptcl_ls

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-REG15	-	select s_cl_pgm_ls.name "Program_Name", region_cd "Region", ptcl_num, site_num, min(st_initn_cmpl_dt) "Site_ Initiated_Date", min(status_date) "First_Subj_Enrolled_ Date" from s_cl_pgm_ls, s_cl_ptcl_ls, s_ptcl_site_ls, s_cl_ subj_st_ls, s_cl_subj_ls where s_cl_pgm_ls.row_id = s_cl_ ptcl_ls.cl_pgm_id and s_cl_ptcl_ls.row_id = s_ptcl_site_ ls.cl_ptcl_id and s_ptcl_site_ls.row_id = s_cl_subj_ls.ptcl_ site_id and s_cl_subj_ls.row_id = s_cl_subj_st_ls.par_subj_ id and s_cl_subj_st_ls.status_cd = 'Enrolled' group by s_cl_ pgm_ls.name, region_cd, ptcl_num, site_num order by 1,2,3
M-REG16	-	select s_cl_pgm_ls.name "Program_Name", region_cd "Region",ptcl_num, site_num, ST_INITN_CMPL_DT "Site_ Initiation_Date" from s_cl_pgm_ls,s_cl_ptcl_ls,s_ptcl_site_ ls where s_cl_pgm_ls.row_id = s_cl_ptcl_ls.cl_pgm_id and s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id Critical Document package Completed Date cannot be sourced
M-REG17	-	select a.cl_ptcl_st_id, b.TODO_ACTL_END_DT "Site_Visit_ Cmpl_Dt", a.TODO_ACTL_END_DT "Follow_Up_Item_ Cmpl_Dt" from s_Evt_act a, s_evt_act b where a.par_evt_id = b.activity_uid and a.subtype_cd = 'Follow-Up' and b.subtype_cd = 'Site Visit' and b.TODO_ACTL_END_DT is not null and a.TODO_ACTL_END_DT is not null and b.cl_ ptcl_st_id in (select row_id from s_ptcl_site_ls where cl_ ptcl_id in (select row_id from s_cl_ptcl_ls where region_cd = 'USA'))
M-REG18	-	Site visit completed date in a program can get from: select s_cl_pgm_ls.name "Program_Name", region_cd "Region", ptcl_num, site_num, TODO_ACTL_END_DT "Site_Visit_ Completed_Date" from s_cl_pgm_ls,s_cl_ptcl_ls,s_ptcl_ site_ls,s_evt_act where s_cl_pgm_ls.row_id = s_cl_ptcl_ ls.cl_pgm_id and s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ ptcl_id and s_ptcl_site_ls.row_id = s_evt_act.cl_ptcl_st_id and TODO_ACTL_END_DT is not null and subtype_cd = 'Site Visit' order by 1,2,3,4 Visit report approved date cannot be sourced.
M-REG19	-	select s_cl_pgm_ls.name "Program_Name", region_cd "Region", ptcl_num, site_num, TODO_ACTL_END_DT "Site_Visit_Completed_Date", appt_end_dt "Visit_Rep_ Completed_Date" from s_cl_pgm_ls,s_cl_ptcl_ls,s_ptcl_ site_ls,s_evt_act where s_cl_pgm_ls.row_id = s_cl_ptcl_ ls.cl_pgm_id and s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ ptcl_id and s_ptcl_site_ls.row_id = s_evt_act.cl_ptcl_st_id and TODO_ACTL_END_DT is not null and subtype_cd = 'Site Visit' order by 1,2,3,4 Visit Report Completed date cannot be sourced.
M-REG20	-	select s_cl_pgm_ls.name "Program_Name", region_cd "Region", ptcl_num, site_num, appt_end_dt "Visit_Rep_ Completed_Date" from s_cl_pgm_ls,s_cl_ptcl_ls,s_ptcl_ site_ls,s_evt_act where s_cl_pgm_ls.row_id = s_cl_ptcl_ ls.cl_pgm_id and s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ ptcl_id and s_ptcl_site_ls.row_id = s_evt_act.cl_ptcl_st_id and TODO_ACTL_END_DT is not null and subtype_cd = 'Site Visit' order by 1,2,3,4 Visit Report Approved Date cannot be sourced.
M-SBVT03	S_EVT_ACT	TODO_ACTL_END_DT
M-SBVT04	S_EVT_ACT	CMPLTD_FLG

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-SBVT05	S_EVT_ACT	NAME
M-SBVT06	S_EVT_ACT	APPT_START_DT
M-SBVT07	S_EVT_ACT_LSX	MAX_DUE_DT
M-SBVT08	S_EVT_ACT_LSX	MIN_DUE_DT
M-SBVT09	S_EVT_ACT	TODO_PLAN_START_DT
M-SBVT10	S_CL_CFT_LS	PTCL_DEV_FLG
M-SBVT11	S_CL_CFT_LS	PTCL_VLTN_FLG
M-SBVT12	S_EVT_ACT_LSX	EVT_PRRTY_SEQ
M-SBVT13	S_SBJTMP_VER_LS	NAME
M-SBVT14	S_EVT_ACT	TODO_CD
M-SIV01	-	Calculated in RPD based on W_RXI_SITE_VISIT_D.SITE_VISIT_REPORT_APRVD_DT and W_RXI_SITE_VISIT_D.SITE_VISIT_CMPLT_DT
M-SIV02	-	Calculated in RPD based on W_RXI_SITE_VISIT_D.SITE_VISIT_REPORT_CMPLT_DT and W_RXI_SITE_VISIT_D.SITE_VISIT_CMPLT_DT
M-SIV03	-	Calculated in RPD based on W_RXI_SITE_VISIT_D.SITE_VISIT_START_DT and W_RXI_SITE_VISIT_D.SITE_VISIT_CMPLT_DT
M-SIV04	-	Calculated in RPD based on W_RXI_SITE_VISIT_D.SITE_VISIT_REPORT_CMPLT_DT and W_RXI_SITE_VISIT_D.SITE_VISIT_REPORT_APRVD_DT
M-SIV05	-	Calculated in RPD based on W_RXI_SITE_VISIT_D.SITE_VISIT_REPORT_APRVD_DT
M-SIV06	-	Calculated in RPD based on W_RXI_SITE_VISIT_D.SITE_VISIT_REPORT_CMPLT_DT
M-SIV07	-	-
M-SIV08	-	-
M-SIV10	-	-
M-SRG01	S_CL_PTCL_LS.NUM_PLAN_SITE	-
M-SRG02	S_CL_PTCL_LS.NUM_PLAN_SUBJ	-
M-SRG03	-	select S_CL_pgm_ls.name "Program_Name", ptcl_name, min (S_PTCL_SITE_LS.ST_INITN_CMPL_DT) from s_cl_pgm_ls, s_cl_ptcl_ls where S_CL_pgm_ls.row_id = cl_pgm_id order by S_CL_pgm_ls.name, ptcl_name
M-SRG04	-	Get the number of sites planned for a study from: S_CL_PTCL_LS.NUM_PLAN_SITE. Get the number of sites initiated in a study using below query: select ptcl_num, count(*) from s_ptcl_site_ls, s_cl_ptcl_ls where s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and s_ptcl_site_ls.st_initn_cmpl_dt is not null group by ptcl_num

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-SRG05	-	To get LATEST Site Initiated Date, we have to use different table, column: max(S_PTCL_SITE_LS.ST_INITN_CMPL_DT) Ex: select s_cl_pgm_ls.name "Program_Name",region_cd "Region",ptcl_num, max(ST_INITN_CMPL_DT) "Latest_Site_Initiated_Date" from s_cl_pgm_ls,s_cl_ptcl_ls,S_PTCL_SITE_LS where s_cl_pgm_ls.row_id = cl_pgm_id and s_cl_ptcl_ls.row_id = cl_ptcl_id group by s_cl_pgm_ls.name,region_cd,ptcl_num
M-SRG06	-	First Site Initiated: min (S_PTCL_SITE_LS.ST_INITN_CMPL_DT) Latest site initiated date can get from: select s_cl_pgm_ls.name "Program_Name",region_cd "Region",ptcl_num,max(ST_INITN_CMPL_DT) "Latest_Site_Initiated_Date" from s_cl_pgm_ls,s_cl_ptcl_ls, s_ptcl_site_ls where s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and s_cl_pgm_ls.row_id = cl_pgm_id group by s_cl_pgm_ls.name,region_cd,ptcl_num
M-SRG07	-	select s_cl_pgm_ls.name "Program_Name", region_cd "Region", ptcl_num, site_num, min(irb_apprv_dt) "IRB_Approval_Date" from s_cl_pgm_ls, s_cl_ptcl_ls, s_ptcl_site_ls, S_PS_STMPVER_LS, s_evt_act where s_evt_act.CL_SUBJ_ID is not null and subtype_cd = 'Visit' and s_evt_act.cl_ptcl_st_id = s_ptcl_site_ls.row_id and s_ptcl_site_ls.row_id = S_PS_STMPVER_LS.ptcl_site_id and s_cl_ptcl_ls.cl_pgm_id = s_cl_pgm_ls.row_id and s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id group by s_cl_pgm_ls.name,region_cd,ptcl_num, site_num order by 1,2,3
M-SRG08	-	select s_cl_pgm_ls.name"Program_Name",region_cd "Region",ptcl_num, min (s_cl_subj_st_ls.status_date) -min (S_PTCL_SITE_LS.ST_INITN_CMPL_DT) "No_Of_Days" from s_cl_pgm_ls,s_cl_ptcl_ls where s_cl_pgm_ls.row_id = cl_pgm_id and s_cl_subj_st_ls.status_cd = 'Enrolled' and s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and s_ptcl_site_ls.row_id = s_cl_subj_ls.ptcl_site_id and s_cl_subj_ls.row_id = s_cl_subj_st_ls.par_subj_id group by s_cl_ptcl_ls.ptcl_num
M-SRG09	-	select count(*) from s_evt_act where par_evt_id in (select activity_uid from s_evt_act where TODO_ACTL_END_DT is not null and subtype_cd = 'Site Visit' and cl_ptcl_st_id in (select row_id from s_ptcl_site_ls where cl_ptcl_id in (select row_id from s_cl_ptcl_ls where region_cd = 'USA'))) and subtype_cd = 'Follow-Up'
M-SRG10	-	Get planned subjects of a site from: S_PTCL_SITE_LS.NUM_PLAN_SUBJ. There is no direct column to get the number of subjects randomized. Use below query to get it: select s_cl_pgm_ls.name "Program_Name",region_cd "Region",ptcl_num,site_num, count(*) from s_cl_pgm_ls,s_cl_ptcl_ls,s_ptcl_site_ls, s_cl_subj_ls, S_CL_SUBJ_ST_LS where s_cl_pgm_ls.row_id = s_cl_ptcl_ls.cl_pgm_id and s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and s_cl_subj_ls.PTCL_SITE_ID = s_ptcl_site_ls.row_id and S_CL_SUBJ_ST_LS.par_subj_id = s_cl_subj_ls.row_id and S_CL_SUBJ_ST_LS.status_cd = 'Randomized' group by s_cl_pgm_ls.name,region_cd,ptcl_num,site_num
M-SRG11	S_CL_PTCL_LS.NUM_PLAN_SUBJ S_CL_PTCL_LS.NUM_SUBJ_ENRL	-

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-SRG12	-	1st Subject 1st Visit can get from: From S_CL_SUBJ_LS, we have to find out the first subject (ROW_ID) using min(CREATED) in a particular protocol site. S_CL_SUBJ_LS.ROW_ID is the subject id (CL_SUBJ_ID in S_EVT_ACT) Using the CL_SUBJ_ID, get min(TODO_ACTL_END_DT) from S_EVT_ACT & SITE_NUM from S_PTCL_SITE_LS Join Condition between tables: s_evt_act.cl_subj_id is not null and s_cl_subj_ls.row_id = s_Evt_act.CL_SUBJ_ID and s_ptcl_site_ls.site_uid = s_cl_subj_ls.ptcl_site_id and s_evt_act.TODO_ACTL_END_DT is not null and S_EVT_ACT.TEMPLATE_FLG = 'V' To get Latest Subject 1st Visit: From S_CL_SUBJ_LS, we have to find out the latest subject (ROW_ID) using max(CREATED) in a particular protocol site. S_CL_SUBJ_LS.ROW_ID is the subject id (CL_SUBJ_ID in S_EVT_ACT) Using the CL_SUBJ_ID, get min(TODO_ACTL_END_DT) from S_EVT_ACT & SITE_NUM from S_PTCL_SITE_LS Join Condition between tables: s_evt_act.cl_subj_id is not null and s_cl_subj_ls.row_id = s_Evt_act.CL_SUBJ_ID and s_ptcl_site_ls.site_uid = s_cl_subj_ls.ptcl_site_id and s_evt_act.TODO_ACTL_END_DT is not null
M-SRG13	-	select s_cl_pgm_ls.name "Program_Name",region_cd "Region",ptcl_num, min(TODO_ACTL_END_DT) "1st_Subject_1st_Visit_Date", min(irb_apprv_dt) "1st_IRB_Approved_Date" from s_cl_pgm_ls,s_cl_ptcl_ls, s_ptcl_site_ls, S_PS_STMPVER_LS, s_Evt_act where s_cl_pgm_ls.row_id = cl_pgm_id and s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and s_ptcl_site_ls.row_id = S_PS_STMPVER_LS.ptcl_site_id and subtype_cd = 'Visit' and cl_ptcl_st_id = s_ptcl_site_ls.row_id group by s_cl_pgm_ls.name,region_cd,ptcl_num
M-SRG14	-	select region_cd "Region",ptcl_num, min(S_PTCL_SITE_LS.ST_INITN_CMPL_DT) "1st_Site_Initiated_Date", min(irb_apprv_dt) "1st_IRB_Approved_Date" from s_cl_ptcl_ls, s_ptcl_site_ls, S_PS_STMPVER_LS where s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and s_ptcl_site_ls.row_id = S_PS_STMPVER_LS.ptcl_site_id group by region_cd,ptcl_num
M-SRG16	-	select ptcl_num, count(*) from s_ptcl_site_ls, s_cl_ptcl_ls where s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and s_ptcl_site_ls.st_initn_cmpl_dt is not null group by ptcl_num

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-SRG23	-	select region_cd "Region",ptcl_num,ptcl_site_id, irb_apprv_dt "IRB_Approval_Date" from S_PS_STMPVER_LS, s_ptcl_site_ls, s_cl_ptcl_ls where s_ptcl_site_ls.row_id = S_PS_STMPVER_LS.ptcl_site_id and s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id order by 1,2,3 1st Subject 1st Visit can get from: From S_CL_SUBJ_LS, we have to find out the first subject (ROW_ID) using min(CREATED) in a particular protocol site. S_CL_SUBJ_LS.ROW_ID is the subject id (CL_SUBJ_ID in S_EVT_ACT) Using the CL_SUBJ_ID, get min(TODO_ACTL_END_DT) from S_EVT_ACT & SITE_NUM from S_PTCL_SITE_LS Join Condition between tables: s_evt_act.cl_subj_id is not null and s_cl_subj_ls.row_id = s_Evt_act.CL_SUBJ_ID and s_ptcl_site_ls.site_uid = s_cl_subj_ls.ptcl_site_id and s_evt_act.TODO_ACTL_END_DT is not null and S_EVT_ACT.TEMPLATE_FLG = 'V'
M-SRG24	-	select region_cd "Region",ptcl_num,cl_ptcl_st_id, min(st_initn_cmpl_dt) "Site_Initiation_Date", min(irb_apprv_dt) "IRB_Approval_Date" from S_PS_STMPVER_LS, s_evt_act, s_ptcl_site_ls, s_cl_ptcl_ls where s_evt_act.CL_SUBJ_ID is not null and subtype_cd = 'Visit' and s_evt_act.cl_ptcl_st_id = s_ptcl_site_ls.row_id and s_ptcl_site_ls.row_id = S_PS_STMPVER_LS.ptcl_site_id and s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id group by region_cd,ptcl_num,cl_ptcl_st_id order by 1
M-SRG25	-	select region_cd "Region",ptcl_num,site_num, st_initn_cmpl_dt "Site_Initiation_Date" from s_ptcl_site_ls, s_cl_ptcl_ls where s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id order by 1,2,3 1st Subject 1st Visit can get from: From S_CL_SUBJ_LS, we have to find out the first subject (ROW_ID) using min(CREATED) in a particular protocol site. S_CL_SUBJ_LS.ROW_ID is the subject id (CL_SUBJ_ID in S_EVT_ACT) Using the CL_SUBJ_ID, get min(TODO_ACTL_END_DT) from S_EVT_ACT & SITE_NUM from S_PTCL_SITE_LS Join Condition between tables: s_evt_act.cl_subj_id is not null and s_cl_subj_ls.row_id = s_Evt_act.CL_SUBJ_ID and s_ptcl_site_ls.site_uid = s_cl_subj_ls.ptcl_site_id and s_evt_act.TODO_ACTL_END_DT is not null and S_EVT_ACT.TEMPLATE_FLG = 'V'
M-SRG26	-	select ptcl_num, count(*) from s_ptcl_site_ls, s_cl_ptcl_ls where s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id group by ptcl_num
M-SRG27	-	select ptcl_num, count(*) from s_ptcl_site_ls, s_cl_ptcl_ls where s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and ST_INITN_CMPL_DT is not null and count (S_CL_SUBJ_ST_LS.STATUS_CD = Enrolled) =0 group by ptcl_num

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-SRG28	-	select ptcl_num, count(*) from s_ptcl_site_ls, s_cl_ptcl_ls where s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and ST_INITN_CMPL_DT is not null and count (S_CL_SUBJ_ ST_LS.STATUS_CD = Enrolled) >= 1 group by ptcl_num
M-SRG29	-	Number of sites which enrolled atleast 90% of planned subjects in a protocol: select ptcl_num, count(*) from s_ ptcl_site_ls, s_cl_ptcl_ls where cl_ptcl_id = s_cl_ptcl_ ls.row_id and s_ptcl_site_ls.NUM_PLAN_SUBJ > 0 and (NUM_ENROLLED/s_ptcl_site_ls.NUM_PLAN_SUBJ*100 >= 90) group by ptcl_num order by 1 Get NUM_ ENROLLED by: count (S_CL_SUBJ_ST_LS.STATUS_CD = Enrolled)
M-SRG30	-	select s_cl_pgm_ls.name "Program_Name",region_cd "Region",ptcl_num, count(*) from s_cl_pgm_ls,s_cl_ptcl_ ls,s_ptcl_site_ls where s_cl_pgm_ls.row_id = cl_pgm_id and cl_ptcl_id = s_cl_ptcl_ls.row_id and count (S_CL_ SUBJ_ST_LS.STATUS_CD = Enrolled) =0 and st_initn_ cmpl_dt is not null group by s_cl_pgm_ls.name,region_ cd,ptcl_num order by 1,2,3
M-SRG31	-	select s_cl_pgm_ls.name "Program_Name",region_cd "Region",ptcl_num, count(*) from s_cl_pgm_ls,s_cl_ptcl_ ls,s_ptcl_site_ls where cl_ptcl_id = s_cl_ptcl_ls.row_id and count (S_CL_SUBJ_ST_LS.STATUS_CD = Enrolled) >= 1 and s_cl_pgm_ls.row_id = s_cl_ptcl_ls.cl_pgm_id group by s_cl_pgm_ls.name,region_cd,ptcl_num order by 1 Number of sites initiated against each protocol: select s_cl_pgm_ ls.name "Program_Name",region_cd "Region",ptcl_num, count(*) from s_cl_pgm_ls,s_cl_ptcl_ls,s_ptcl_site_ls where s_cl_pgm_ls.row_id = cl_pgm_id and s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and ST_INITN_CMPL_DT is not null group by s_cl_pgm_ls.name,region_cd,ptcl_num order by 1,2,3
M-SRG32	-	Number of sites which enrolled atleast 90% of planned subjects in a protocol: select s_cl_pgm_ls.name "Program_ Name",region_cd "Region",ptcl_num, count(*) from s_cl_ pgm_ls, s_cl_ptcl_ls, s_ptcl_site_ls where s_cl_pgm_ls.row_ id = cl_pgm_id and cl_ptcl_id = s_cl_ptcl_ls.row_id and s_ ptcl_site_ls.NUM_PLAN_SUBJ > 0 and (NUM_ ENROLLED/s_ptcl_site_ls.NUM_PLAN_SUBJ*100 >= 90) group by s_cl_pgm_ls.name,region_cd,ptcl_num order by 1,2,3 Number of sites initiated against each protocol: select s_cl_pgm_ls.name "Program_Name",region_cd "Region",ptcl_num, count(*) from s_cl_pgm_ls,s_cl_ptcl_ ls,s_ptcl_site_ls where s_cl_pgm_ls.row_id = cl_pgm_id and s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and ST_ INITN_CMPL_DT is not null group by s_cl_pgm_ ls.name,region_cd,ptcl_num Get NUM_ENROLLED by: count (S_CL_SUBJ_ST_LS.STATUS_CD = Enrolled)
M-SRG33	-	Not sourced from SC
M-SRG34	-	Not sourced from SC
M-SST01	S_PTCL_SITE_LS.NUM_ PLAN_SUBJ	-
M-SST02	S_PTCL_SITE_LS.NUM_SUBJ_ ENRL	-

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-SST02C	S_CL_SUBJ_LS.PR_STATUS_ID	Count of S_CL_SUBJ_LS.ROW_ID Where S_CL_SUBJ_LS.PR_STATUS_ID = S_CL_SUBJ_ST_LS.ROW_ID and S_CL_SUBJ_ST_LS.STATUS_CD="Enrolled"
M-SST03	S_PTCL_SITE_LS.NUM_SUBJ_ENRL+S_PTCL_SITE_LS.NUM_COMPLTD	-
M-SST04	S_PTCL_SITE_LS.NUM_SUBJ_ENRL	-
M-SST05	S_PTCL_SITE_LS.NUM_COMPLTD	-
M-SST05C	S_CL_SUBJ_LS.PR_STATUS_ID	Count of S_CL_SUBJ_LS.ROW_ID Where S_CL_SUBJ_LS.PR_STATUS_ID = S_CL_SUBJ_ST_LS.ROW_ID and S_CL_SUBJ_ST_LS.STATUS_CD="Completed"
M-SST06	S_PTCL_SITE_LS.NUM_ERLY_TERM	-
M-SST06C	S_CL_SUBJ_LS.PR_STATUS_ID	Count of S_CL_SUBJ_LS.ROW_ID Where S_CL_SUBJ_LS.PR_STATUS_ID = S_CL_SUBJ_ST_LS.ROW_ID and S_CL_SUBJ_ST_LS.STATUS_CD="Early Terminated"
M-SST08	-	Not sourced from SC
M-SST09	-	Not sourced from SC
M-SST15.1	(S_PTCL_SITE_LS.NUM_SUBJ_ENRL/ S_PTCL_SITE_LS.NUM_PLAN_SUBJ) * 100	-
M-SST17	-	Not sourced from SC
M-SST18	-	Not sourced from SC
M-SST19	-	Not sourced from SC
M-SST20	-	Not sourced from SC
M-SST21	-	Not sourced from SC
M-SST23	-	Not sourced from SC
M-SST24	-	Not sourced from SC
M-SST24.1	-	Not sourced from SC
M-SST24.2	-	Not sourced from SC
M-SST24.3	-	Not sourced from SC
M-SST27	-	Not sourced from SC
M-SST28	-	Not sourced from SC
M-SST29	-	Not sourced from SC
M-SST30	-	Not sourced from SC
M-SST31	-	Not sourced from SC
M-SST32	S_CL_SUBJ_ST_LS.STATUS_CD	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Randomized'
M-SST32C	S_CL_SUBJ_LS.PR_STATUS_ID	Count of S_CL_SUBJ_LS.ROW_ID Where S_CL_SUBJ_LS.PR_STATUS_ID = S_CL_SUBJ_ST_LS.ROW_ID and S_CL_SUBJ_ST_LS.STATUS_CD='Randomized'

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-SST33	S_CL_SUBJ_LS.STATUS_CD	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Re-Screened'
M-SST33C	S_CL_SUBJ_LS.PR_STATUS_ ID	Count of S_CL_SUBJ_LS.ROW_ID Where S_CL_SUBJ_ LS.PR_STATUS_ID = S_CL_SUBJ_ST_LS.ROW_ID and S_ CL_SUBJ_ST_LS.STATUS_CD='Re-Screened'
M-SST34	S_CL_SUBJ_ST_LS.STATUS_ CD	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Screen Failure'
M-SST34C	S_CL_SUBJ_LS.PR_STATUS_ ID	Count of S_CL_SUBJ_LS.ROW_ID Where S_CL_SUBJ_ LS.PR_STATUS_ID = S_CL_SUBJ_ST_LS.ROW_ID and S_ CL_SUBJ_ST_LS.STATUS_CD='Screen Failure'
M-SST35	S_CL_SUBJ_LS.STATUS_CD	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Screened'
M-SST35C	S_CL_SUBJ_LS.PR_STATUS_ ID	Count of S_CL_SUBJ_LS.ROW_ID Where S_CL_SUBJ_ LS.PR_STATUS_ID = S_CL_SUBJ_ST_LS.ROW_ID and S_ CL_SUBJ_ST_LS.STATUS_CD='Screened'
M-SST36	S_CL_SUBJ_ LS.INTEGRATION_ID	-
M-SST37	S_CL_SUBJ_LS.PTCL_DEV_ FLG	-
M-SST38	S_CL_SUBJ_LS.PTCL_VLTN_ FLG	-
M-SST39	S_PTCL_SITE_LS.ST_INITN_ CMPL_DT	-
M-SST40	S_CL_SUBJ_LS.WTHDWN_DT	-
M-SST41	S_CL_SUBJ_ST_LS.STATUS_ DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Completed'
M-SST42	S_CL_SUBJ_ST_LS.STATUS_ DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Enrolled'
M-SST43	S_CL_SUBJ_ST_LS.STATUS_ DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Randomized'
M-SST44	S_CL_SUBJ_ST_LS.STATUS_ DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Screened'
M-SST45	S_CL_SUBJ_ST_LS.STATUS_ DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Completed'
M-SST46	S_CL_SUBJ_ST_LS.STATUS_ DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Enrolled'
M-SST47	S_CL_SUBJ_ST_LS.STATUS_ DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Randomized'
M-SST48	S_CL_SUBJ_ST_LS.STATUS_ DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Screened'
M-SST49	COUNT (S_PTCL_SITE_ LS.ROW_ID)	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Screened'
M-SST50	S_EVT_ACT.DOC_SENT_DT - S_EVT_ACT.DOC_RCVD_DT	-
M-SST51	S_EVT_ACT.DOC_SENT_DT - Current timestamp	Where S_EVT_ACT.DOC_RCVD_DT is null
M-SST52	Current timestamp - M-SST46	-

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-SST54	M-SST02 / # Subjects Enrolled at Study	-
M-SST55	M-SST32 / # Randomized at Study	-
M-SST56	M-SST35 / # Screened at Study	-
M-SST57	M-SST06 / M-SST02	Total for Study-site
M-SST58	M-SST06 / M-SST02	Total for Study
M-SST59	M-SST51 / # Documents	-
M-SST60	Avg (M-SST50)	-
M-SST61	-	-
M-SST62	-	-
M-SST63	-	Current date- latest site visit Completed date
M-SST65	-	Count(W_RXI_SITE_VISIT_F.ROW_WID)
M-SST66	-	Count (S_CL_SUBJ_ST_LS.ROW_ID) from S_CL_SUBJ_ST_LS, S_EVT_ACT SiteVisit, S_CL_SUBJ_LS where S_CL_SUBJ_ST_LS.STATUS_CD = 'Enrolled' and S_CL_SUBJ_ST_LS.STATUS_DATE > (MAX (SiteVisit.TODO_ACTL_END_DT) and SiteVisit.SUBTYPE_CD = "Site Visit" and SiteVisit.CL_PTCL_ST_ID = S_CL_SUBJ_LS.PTCL_SITE_ID and S_CL_SUBJ_ST_LS.PAR_SUBJ_ID = S_CL_SUBJ_LS.ROW_ID
M-SST67	-	Count (S_CL_SUBJ_ST_LS.ROW_ID) from S_CL_SUBJ_ST_LS, S_EVT_ACT SiteVisit, S_CL_SUBJ_LS where S_CL_SUBJ_ST_LS.STATUS_CD = 'Randomized' and S_CL_SUBJ_ST_LS.STATUS_DATE > (MAX (SiteVisit.TODO_ACTL_END_DT) and SiteVisit.SUBTYPE_CD = "Site Visit" and SiteVisit.CL_PTCL_ST_ID = S_CL_SUBJ_LS.PTCL_SITE_ID and S_CL_SUBJ_ST_LS.PAR_SUBJ_ID = S_CL_SUBJ_LS.ROW_ID
M-SST68	-	Count (S_CL_SUBJ_ST_LS.ROW_ID) from S_CL_SUBJ_ST_LS, S_EVT_ACT SiteVisit, S_CL_SUBJ_LS where S_CL_SUBJ_ST_LS.STATUS_CD = 'Screened' and S_CL_SUBJ_ST_LS.STATUS_DATE > (MAX (SiteVisit.TODO_ACTL_END_DT) and SiteVisit.SUBTYPE_CD = "Site Visit" and SiteVisit.CL_PTCL_ST_ID = S_CL_SUBJ_LS.PTCL_SITE_ID and S_CL_SUBJ_ST_LS.PAR_SUBJ_ID = S_CL_SUBJ_LS.ROW_ID
M-SST69	-	When Visit report completed date is NOT null
M-SST70	-	When Visit report completed date is NOT null and visit report approval date is also null then count record
M-SST71	-	when site visit complete date IS NOT NULL and visit report complete date both are IS null then count
M-SST72	-	M-SST32 # Subjects Randomized / M-SST01 # Subjects Planned for Study-Site
M-SST73	-	Min(when site visit start date> AD10-41 Site initiated date, return site visit start date)
M-SST74	-	Max (when site visit complete date <= current date, site visit complete date)

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-SST75	-	Max(when site visit start date <= current date, return site visit start date)
M-SST76	-	select cl_ptcl_st_id, TODO_PLAN_START_DT "Site_Visit_ Start_Date" from s_Evt_act where TODO_ACTL_END_DT is not null and subtype_cd = 'Site Visit' and cl_ptcl_st_id in (select row_id from s_ptcl_site_ls where site_num = 'US-001' and cl_ptcl_id in (select row_id from s_cl_ptcl_ls where ptcl_num = 'AMXN 9374')) order by cl_ptcl_st_id, TODO_PLAN_START_DT
M-SST77	-	select cl_ptcl_st_id, count(*) "No_Of_Follow_Up_Items" from s_evt_act where TODO_ACTL_END_DT is not null and subtype_cd = 'Follow-Up' group by cl_ptcl_st_id
M-SST78	-	Min(when site visit start date> current date , return site visit start date)
M-SST79	S_EVT_ACT.TODO_ACTL_ END_DT	select min(S_EVT_ACT.TODO_ACTL_END_DT) from S_ EVT_ACT where S_EVT_ACT.TEMPLATE_FLG = 'V' and S_EVT_ACT.CL_SUBJ_ID = (Select S_CL_SUBJ_ST_ LS.PAR_SUBJ_ID, MAX(STATUS_DATE) From S_CL_ SUBJ_ST_LS Where S_CL_SUBJ_ST_LS.STATUS_CD = "Enrolled" And S_CL_SUBJ_LS.PTCL_SITE_ID = row_id of the site you are calculating this for)
M-SST80	s_evt_act.TODO_ACTL_END_ DT	-
M-SST81	-	select max (S_EVT_ACT.TODO_ACTL_END_DT) from S_ EVT_ACT where S_EVT_ACT.TEMPLATE_FLG = 'V' and S_EVT_ACT.CL_SUBJ_ID = (Select S_CL_SUBJ_ST_ LS.PAR_SUBJ_ID, MAX (STATUS_DATE) From S_CL_ SUBJ_ST_LS Where S_CL_SUBJ_ST_LS.STATUS_CD = "Enrolled" And S_CL_SUBJ_LS.PTCL_SITE_ID = row_id of the site you are calculating this for)
M-SST82	-	1st Subject 1st Visit can get from: From S_CL_SUBJ_LS, we have to find out the first subject (ROW_ID) using min(CREATED) in a particular protocol site. S_CL_SUBJ_LS.ROW_ID is the subject id (CL_SUBJ_ID in S_EVT_ACT) Using the CL_SUBJ_ID, get min(TODO_ACTL_END_DT) from S_EVT_ACT & SITE_NUM from S_PTCL_SITE_LS Join Condition between tables: s_evt_act.cl_subj_id is not null and s_cl_subj_ls.row_id = s_Evt_act.CL_SUBJ_ID and s_ptcl_site_ls.site_uid = s_cl_subj_ls.ptcl_site_id and s_evt_ act.TODO_ACTL_END_DT is not null and S_EVT_ ACT.TEMPLATE_FLG = 'V' and site initiated date can get from: S_PTCL_SITE_LS.ST_ INITN_CMPL_DT

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-SST83	-	select site_num, irb_apprv_dt "IRB_Approved_Date" from s_cl_ptcl_ls, s_ptcl_site_ls, S_PS_STMPVER_LS where s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and s_ptcl_site_ls.row_id = S_PS_STMPVER_LS.ptcl_site_id order by 1 1st Subject 1st Visit can get from: From S_CL_SUBJ_LS, we have to find out the first subject (ROW_ID) using min(CREATED) in a particular protocol site. S_CL_SUBJ_LS.ROW_ID is the subject id (CL_SUBJ_ID in S_EVT_ACT) Using the CL_SUBJ_ID, get min(TODO_ACTL_END_DT) from S_EVT_ACT & SITE_NUM from S_PTCL_SITE_LS Join Condition between tables: s_evt_act.cl_subj_id is not null and s_cl_subj_ls.row_id = s_Evt_act.CL_SUBJ_ID and s_ptcl_site_ls.site_uid = s_cl_subj_ls.ptcl_site_id and s_evt_act.TODO_ACTL_END_DT is not null and S_EVT_ACT.TEMPLATE_FLG = 'V'
M-SST84	-	SELECT site_num, irb_apprv_dt-ST_INITN_CMPL_DT "No_Of_Days" from s_ptcl_site_ls, S_PS_STMPVER_LS where ptcl_site_id = s_ptcl_site_ls.row_id
M-SST85	-	site initiated date can get from: S_PTCL_SITE_LS.ST_INITN_CMPL_DT Critical document package completed date cannot be sourced.
M-SST86	S_CL_SUBJ_ST_LS	select site_num,to_char(enrl_dt, 'Month'), count(*) from S_cl_subj_ls,s_ptcl_site_ls,s_cl_ptcl_ls where enrl_dt is not null and ptcl_site_id = s_ptcl_site_ls.row_id and s_ptcl_site_ls.cl_ptcl_id = s_cl_ptcl_ls.row_id and s_ptcl_site_ls.SITE_TERM_DT is not null and enrl_dt >= st_initn_cmpl_dt group by site_num,to_char(enrl_dt, 'Month') order by 2
M-SST87	S_CL_SUBJ_ST_LS	The number of subjects screened against each site can get from: select site_num, count(*) from s_cl_subj_ls, s_ptcl_site_ls, S_CL_SUBJ_ST_LS where ptcl_site_id = s_ptcl_site_ls.row_id and s_cl_subj_ls.row_id = S_CL_SUBJ_ST_LS.PAR_SUBJ_ID and s_cl_subj_ls.screen_dt is not null and S_CL_SUBJ_ST_LS.status_cd = 'Screened' group by site_num order by 1 The number of subjects screen failed against each site : select site_num, count(*) from s_cl_subj_ls, s_ptcl_site_ls, S_CL_SUBJ_ST_LS where ptcl_site_id = s_ptcl_site_ls.row_id and s_cl_subj_ls.row_id = S_CL_SUBJ_ST_LS.PAR_SUBJ_ID and s_cl_subj_ls.screen_dt is not null and S_CL_SUBJ_ST_LS.status_cd = 'Screen Failure' group by site_num order by 1
M-SST88	S_CL_PTCL_LS S_CL_SUBJ_LS	site_num enrl_dt num_subj_enrl num_plan_subj
M-SST89	-	Not sourced from SC
M-SST90	-	Not sourced from SC
M-SST91	-	Not sourced from SC
M-SST92	-	Not sourced from SC
M-SST93	S_CL_PTCL_LS	select site_num, fst_subj_enrl_dt-ST_INITN_CMPL_DT "No_Of_Days" from s_ptcl_site_ls

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-SST94	S_CL_PTCL_LS.NUM_PLAN_SUBJ S_CL_PTCL_LS.NUM_SUBJ_ENRL	-
M-SST95	-	Not sourced from SC
M-SST96	S_EVT_ACT	select min(S_EVT_ACT.TODO_ACTL_END_DT) from S_EVT_ACT where S_EVT_ACT.TEMPLATE_FLG = 'V' and S_EVT_ACT.CL_SUBJ_ID = (Select S_CL_SUBJ_ST_LS.PAR_SUBJ_ID, min (STATUS_DATE) From S_CL_SUBJ_ST_LS Where S_CL_SUBJ_ST_LS.STATUS_CD = "Enrolled" And S_CL_SUBJ_LS.PTCL_SITE_ID = row_id of the site you are calculating this for)
M-SST97	-	See Flag section
M-SST98	-	See Flag section
M-SST99	-	See Flag section
M-SST100	-	See Flag section
M-SST101	-	See Flag section
M-SST102	-	See Flag section
M-SST103	-	See Flag section
M-SST104	-	See Flag section
M-SST105	-	See Flag section
M-SST106	-	See Flag section
M-SST107	-	See Flag section
M-STD02	S_CL_PTCL_LS.NUM_PLAN_SUBJ	-
M-STD06	S_CL_PTCL_LS.DB_LOCK_DT	-
M-STD07	COUNT (S_PTCL_SITE_LS.ROW_ID)	-
M-STD08	S_PTCL_SITE_LS.NUM_SUBJ_ENRL	-
M-STD09	S_EVT_ACT.TODO_PLAN_START_DT S_EVT_ACT.	Where TODO_ACTL_END_DT is not null
M-STD10	-	M-SST32 # Subjects Randomized / M-STD02 # Subjects Planned for Study
M-STD11	-	Min(AD10-41 Study site Initiated Date)
M-STD12	-	Max(AD10-41 Study site Initiated Date)
M-STD13	-	select ptcl_num, count(*) from s_ptcl_site_ls, s_cl_ptcl_ls where s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and s_ptcl_site_ls.st_initn_cmpl_dt is not null group by ptcl_num
M-STD14	-	Not sourced from SC

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-STD15	-	From S_CL_SUBJ_LS, we have to find out the latest subject (ROW_ID) using max(CREATED) in a particular protocol site. S_CL_SUBJ_LS.ROW_ID is the subject id (CL_SUBJ_ID in S_EVT_ACT) Using the CL_SUBJ_ID, get max(TODO_ACTL_END_DT) from S_EVT_ACT & SITE_NUM from S_PTCL_SITE_LS Join Condition between tables: s_evt_act.cl_subj_id is not null and s_cl_subj_ls.row_id = s_Evt_act.CL_SUBJ_ID and s_ptcl_site_ls.site_uid = s_cl_subj_ls.ptcl_site_id and s_evt_act.TODO_ACTL_END_DT is not null
M-STD16	-	Not sourced from SC
M-STD17	-	Not sourced from SC
M-STD18	-	Not sourced from SC
M-STD20	-	select ptcl_num, site_num "Site_Number", ST_INITN_CMPL_DT "Site_Initiated_Date" from s_ptcl_site_ls, s_cl_ptcl_ls where s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id order by 1,2 1st Subject 1st Visit can get from: From S_CL_SUBJ_LS, we have to find out the first subject (ROW_ID) using min(CREATED) in a particular protocol site. S_CL_SUBJ_LS.ROW_ID is the subject id (CL_SUBJ_ID in S_EVT_ACT) Using the CL_SUBJ_ID, get min(TODO_ACTL_END_DT) from S_EVT_ACT & SITE_NUM from S_PTCL_SITE_LS Join Condition between tables: s_evt_act.cl_subj_id is not null and s_cl_subj_ls.row_id = s_Evt_act.CL_SUBJ_ID and s_ptcl_site_ls.site_uid = s_cl_subj_ls.ptcl_site_id and s_evt_act.TODO_ACTL_END_DT is not null and S_EVT_ACT.TEMPLATE_FLG = 'V'
M-STD21	-	select ptcl_num, irb_apprv_dt "IRB_Approval_Date" from s_cl_ptcl_ls, s_ptcl_site_ls, S_PS_STMPVER_LS where s_ptcl_site_ls.row_id = S_PS_STMPVER_LS.ptcl_site_id and s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id order by 1 1st Subject 1st Visit can get from: From S_CL_SUBJ_LS, we have to find out the first subject (ROW_ID) using min(CREATED) in a particular protocol site. S_CL_SUBJ_LS.ROW_ID is the subject id (CL_SUBJ_ID in S_EVT_ACT) Using the CL_SUBJ_ID, get min(TODO_ACTL_END_DT) from S_EVT_ACT & SITE_NUM from S_PTCL_SITE_LS Join Condition between tables: s_evt_act.cl_subj_id is not null and s_cl_subj_ls.row_id = s_Evt_act.CL_SUBJ_ID and s_ptcl_site_ls.site_uid = s_cl_subj_ls.ptcl_site_id and s_evt_act.TODO_ACTL_END_DT is not null and S_EVT_ACT.TEMPLATE_FLG = 'V'

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-STD22	-	select ptcl_num, site_num, irb_apprv_dt "IRB_Approval_ Date", st_initn_cmpl_dt "Site_Initiation_Date" from s_cl_ ptcl_ls, s_ptcl_site_ls, S_PS_STMPVER_LS where s_ptcl_ site_ls.row_id = S_PS_STMPVER_LS.ptcl_site_id and s_cl_ ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id order by 1,2
M-STD23	S_CL_PTCL_LS.NUM_PLAN_ SUBJ S_CL_PTCL_LS.NUM_ SUBJ_ENRL	-
M-STD24	-	select ptcl_num, min(S_PTCL_SITE_LS.ST_INITN_CMPL_ DT) "1st_Site_Initiated_Date", min (s_cl_subj_st_ls.status_ date) "1st_Subj_Enroll_Date" from s_cl_ptcl_ls, s_ptcl_site_ ls, S_PS_STMPVER_LS where s_cl_ptcl_ls.row_id = s_ptcl_ site_ls.cl_ptcl_id and s_ptcl_site_ls.row_id = S_PS_ STMPVER_LS.ptcl_site_id and s_cl_subj_st_ls.status_cd = 'Enrolled' and s_ptcl_site_ls.row_id = s_cl_subj_ls.ptcl_ site_id and s_cl_subj_ls.row_id = s_cl_subj_st_ls.par_subj_ id group by s_cl_ptcl_ls.ptcl_num group by ptcl_num
M-STD25	-	select ptcl_num, min(S_PTCL_SITE_LS.ST_INITN_CMPL_ DT) "1st_Site_Initiated_Date", max(st_initn_cmpl_dt) "Latest_Site_Initiated_Date" from s_cl_ptcl_ls, s_ptcl_site_ ls, S_PS_STMPVER_LS where s_cl_ptcl_ls.row_id = s_ptcl_ site_ls.cl_ptcl_id and s_ptcl_site_ls.row_id = S_PS_ STMPVER_LS.ptcl_site_id group by ptcl_num
M-STD26	-	1st Subject 1st Visit can get from: From S_CL_SUBJ_LS, we have to find out the first subject (ROW_ID) using min(CREATED) in a particular protocol site. S_CL_SUBJ_LS.ROW_ID is the subject id (CL_SUBJ_ID in S_EVT_ACT) Using the CL_SUBJ_ID, get min(TODO_ACTL_END_DT) from S_EVT_ACT & SITE_NUM from S_PTCL_SITE_LS Join Condition between tables: s_evt_act.cl_subj_id is not null and s_cl_subj_ls.row_id = s_Evt_act.CL_SUBJ_ID and s_ptcl_site_ls.site_uid = s_cl_subj_ls.ptcl_site_id and s_evt_ act.TODO_ACTL_END_DT is not null and S_EVT_ ACT.TEMPLATE_FLG = 'V' Latest subject 1st visit can get from: From S_CL_SUBJ_LS, we have to find out the latest subject (ROW_ID) using max(CREATED) in a particular protocol site. S_CL_SUBJ_LS.ROW_ID is the subject id (CL_SUBJ_ID in S_EVT_ACT) Using the CL_SUBJ_ID, get min(TODO_ACTL_END_DT) from S_EVT_ACT & SITE_NUM from S_PTCL_S ITE_LS Join Condition between tables: s_evt_act.cl_subj_id is not null and s_cl_subj_ls.row_id = s_Evt_act.CL_SUBJ_ID and s_ptcl_site_ls.site_uid = s_cl_subj_ls.ptcl_site_id and s_evt_ act.TODO_ACTL_END_DT is not null

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-STD27	-	select ptcl_num, irb_apprv_dt "1st_IRB_Approved_Date" from s_cl_ptcl_ls, s_ptcl_site_ls, S_PS_STMPVER_LS where s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and s_ptcl_site_ls.row_id = S_PS_STMPVER_LS.ptcl_site_id order by 1 1st Subject 1st Visit can get from: From S_CL_SUBJ_LS, we have to find out the first subject (ROW_ID) using min(CREATED) in a particular protocol site. S_CL_SUBJ_LS.ROW_ID is the subject id (CL_SUBJ_ID in S_EVT_ACT) Using the CL_SUBJ_ID, get min(TODO_ACTL_END_DT) from S_EVT_ACT & SITE_NUM from S_PTCL_SITE_LS Join Condition between tables: s_evt_act.cl_subj_id is not null and s_cl_subj_ls.row_id = s_Evt_act.CL_SUBJ_ID and s_ptcl_site_ls.site_uid = s_cl_subj_ls.ptcl_site_id and
M-STD28	-	Number of planned sites for a protocol can get from: S_CL_PTCL_LS.NUM_PLAN_SITE Number of sites initiated in a protocol can get from: select ptcl_num, count(*) from s_ptcl_site_ls, s_cl_ptcl_ls where s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and ST_INITN_CMPL_DT is not null group by ptcl_num
M-STD29	-	Number of sites which are initiated recruiting 0 subjects: select ptcl_num, count(*) from s_ptcl_site_ls, s_cl_ptcl_ls where s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and ST_INITN_CMPL_DT is not null and count (S_CL_SUBJ_ST_LS.STATUS_CD = Enrolled) =0 group by ptcl_num
M-STD30	-	Number of sites recruiting one or more subjects in a protocol: select ptcl_num, count(*) from s_ptcl_site_ls, s_cl_ptcl_ls where s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and ST_INITN_CMPL_DT is not null and count (S_CL_SUBJ_ST_LS.STATUS_CD = Enrolled) >= 1 group by ptcl_num Number of sites initiated against each protocol: select ptcl_num, count(*) from s_ptcl_site_ls, s_cl_ptcl_ls where s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and ST_INITN_CMPL_DT is not null and count (S_CL_SUBJ_ST_LS.STATUS_CD = Enrolled) >= 1 group by ptcl_num
M-STD31	-	Number of sites which enrolled atleast 90% of planned subjects in a protocol: select ptcl_num, count(*) from s_ptcl_site_ls, s_cl_ptcl_ls where cl_ptcl_id = s_cl_ptcl_ls.row_id and NUM_ENROLLED > 0 and NUM_ENROLLED/s_ptcl_site_ls.NUM_PLAN_SUBJ*100 >= 90) group by ptcl_num order by 1 Number of sites initiated against each protocol: select ptcl_num, count(*) from s_ptcl_site_ls, s_cl_ptcl_ls where s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and ST_INITN_CMPL_DT is not null and NUM_ENROLLED >= 1 group by ptcl_num Get NUM_ENROLLED by: count (S_CL_SUBJ_ST_LS.STATUS_CD = Enrolled)
M-STD32	-	select site_num,min(irb_apprv_dt) from S_PS_STMPVER_LS, s_ptcl_site_ls where ptcl_site_id = s_ptcl_site_ls.row_id group by site_num order by 1

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-STD40	-	select ptcl_num, count(*) from s_ptcl_site_ls, s_cl_ptcl_ls where cl_ptcl_id = s_cl_ptcl_ls.row_id and s_ptcl_site_ ls.ST_INITN_CMPL_DT is not null and count (S_CL_ SUBJ_ST_LS.STATUS_CD = Enrolled) =0 group by ptcl_ num order by 1
M-STD42	-	select ptcl_num, count(*) from s_ptcl_site_ls, s_cl_ptcl_ls where cl_ptcl_id = s_cl_ptcl_ls.row_id and s_ptcl_site_ ls.ST_INITN_CMPL_DT is not null and s_ptcl_site_ ls.NUM_PLAN_SUBJ > 0 and (NUM_ENROLLED/s_ptcl_ site_ls.NUM_PLAN_SUBJ*100 >= 90) group by ptcl_num order by 1 Get NUM_ENROLLED by: count (S_CL_SUBJ_ ST_LS.STATUS_CD = Enrolled)
M-STD43	-	The number of subjects enrolled per month in a protocol which does not have a database lock date: select ptcl_num, to_char(enrl_dt, 'Month'), count(*) from S_cl_subj_ls,s_ ptcl_site_ls,s_cl_ptcl_ls where enrl_dt is not null and ptcl_ site_id = s_ptcl_site_ls.row_id and s_ptcl_site_ls.cl_ptcl_id = s_cl_ptcl_ls.row_id and s_cl_ptcl_ls.db_lock_dt is null group by ptcl_num,to_char(enrl_dt, 'Month') order by 2 The number of subjects enrolled per month in a protocol which have a database lock date: select ptcl_num, to_ char(enrl_dt, 'Month'), count(*) from S_cl_subj_ls,s_ptcl_ site_ls,s_cl_ptcl_ls where enrl_dt is not null and ptcl_site_ id = s_ptcl_site_ls.row_id and s_ptcl_site_ls.cl_ptcl_id = s_ cl_ptcl_ls.row_id and s_cl_ptcl_ls.db_lock_dt is not null group by ptcl_num,to_char(enrl_dt, 'Month') order by 2
M-STD44	-	Not sourced from SC
M-STD45	-	Not sourced from SC
M-STD46	-	Not sourced from SC
M-STD47	-	Not sourced from SC
M-STD48	-	select count(ptcl_num) from s_cl_ptcl_ls
M-STD49	-	select cl_ptcl_st_id, TODO_PLAN_START_DT "Site_Visit_ Start_Date" from s_Evt_act where TODO_ACTL_END_DT is not null and subtype_cd = 'Site Visit' and cl_ptcl_st_id in (select row_id from s_ptcl_site_ls where cl_ptcl_id in (select row_id from s_cl_ptcl_ls where ptcl_num = 'AMXN 9374')) order by cl_ptcl_st_id, TODO_PLAN_START_DT
M-STD50	-	select count(*) from s_evt_act where par_evt_id in (select activity_uid from s_evt_act where TODO_ACTL_END_DT is not null and subtype_cd = 'Site Visit' and cl_ptcl_st_id in (select row_id from s_ptcl_site_ls where cl_ptcl_id in (select row_id from s_cl_ptcl_ls where ptcl_num = 'AMXN 9374'))) and subtype_cd = 'Follow-Up'
M-STD51	-	Not sourced from SC
M-STD52	-	select a.cl_ptcl_st_id, b.TODO_ACTL_END_DT "Site_Visit_ Cmpl_Dt", a.TODO_ACTL_END_DT "Follow_Up_Item_ Cmpl_Dt" from s_Evt_act a, s_evt_act b where a.par_evt_id = b.activity_uid and a.subtype_cd = 'Follow-Up' and b.subtype_cd = 'Site Visit' and b.TODO_ACTL_END_DT is not null and a.TODO_ACTL_END_DT is not null and b.cl_ ptcl_st_id in (select row_id from s_ptcl_site_ls where cl_ ptcl_id in (select row_id from s_cl_ptcl_ls where ptcl_num = 'AMXN 9374'))

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-STD53	-	select ptcl_num,site_num,TODO_ACTL_END_DT "Site_ Visit_Completed_Dt" from s_cl_ptcl_ls, s_ptcl_site_ls, s_ evt_act where s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and TODO_ACTL_END_DT is not null and subtype_Cd = 'Site Visit' and s_evt_act.cl_ptcl_st_id = s_ptcl_site_ls.row_ id order by 1,2 Visit Report Approved Date cannot be sourced.
M-STD54	-	select ptcl_num,site_num,TODO_ACTL_END_DT "Site_ Visit_Completed_Dt", appt_end_dt "Visit_Rep_Completed_ Dt" from s_cl_ptcl_ls, s_ptcl_site_ls, s_evt_act where s_cl_ ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and TODO_ ACTL_END_DT is not null and subtype_Cd = 'Site Visit' and s_evt_act.cl_ptcl_st_id = s_ptcl_site_ls.row_id order by 1,2
M-STD55	-	Not sourced from SC
M-STD56	-	select ptcl_num, min(S_PTCL_SITE_LS.ST_INITN_CMPL_ DT) "1st_Site_Initiated_Date", min(irb_apprv_dt) "1st_IRB_ Approved_Date" from s_cl_ptcl_ls, s_ptcl_site_ls, S_PS_ STMPVER_LS where s_cl_ptcl_ls.row_id = s_ptcl_site_ ls.cl_ptcl_id and s_ptcl_site_ls.row_id = S_PS_STMPVER_ LS.ptcl_site_id group by ptcl_num
M-STD57	-	Not sourced from SC
M-STD58	-	Not sourced from SC
M-STD59	-	Not sourced from SC
M-STD60	-	select ptcl_num, site_num "Site_Number", min(ST_INITN_ CMPL_DT) "Site_Initiated_Date",min (s_cl_subj_st_ ls.status_date)"1st_Subj_Enroll_Dt" from s_ptcl_site_ls, s_ cl_ptcl_ls where s_cl_subj_st_ls.status_cd = 'Enrolled' and s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and s_ptcl_ site_ls.row_id = s_cl_subj_ls.ptcl_site_id and s_cl_subj_ ls.row_id = s_cl_subj_st_ls.par_subj_id group by s_cl_ptcl_ ls.ptcl_num group by ptcl_num,site_num order by 1,2 Get FST_SBJ_ENRL_DT by: select min (s_cl_subj_st_ls.status_ date) where s_cl_subj_st_ls.status_cd = 'Enrolled' and s_cl_ ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and s_ptcl_site_ ls.row_id = s_cl_subj_ls.ptcl_site_id and s_cl_subj_ls.row_ id = s_cl_subj_st_ls.par_subj_id group by s_cl_ptcl_ls.ptcl_ num
M-STD61	-	SELECT s_cl_ptcl_ls.ptcl_num, min (s_cl_subj_st_ls.status_ date) "1st_Subj_Enroll_Date", max(s_cl_subj_st_ls.status_ date) "Latest_Subj_Enroll_Date" from s_cl_ptcl_ls, s_ptcl_ site_ls, s_cl_subj_ls, s_cl_subj_st_ls where s_cl_subj_st_ ls.status_cd = 'Enrolled' and s_cl_ptcl_ls.row_id = s_ptcl_ site_ls.cl_ptcl_id and s_ptcl_site_ls.row_id = s_cl_subj_ ls.ptcl_site_id and s_cl_subj_ls.row_id = s_cl_subj_st_ ls.par_subj_id group by s_cl_ptcl_ls.ptcl_num
M-STD62	-	Not sourced from SC
M-STD63	S_EVT_ACT.APPT_END_DT	-
M-STD64	-	Not sourced from SC
M-STD65	-	Not sourced from SC
M-STD66	-	Not sourced from SC
M-STD67	-	Not sourced from SC

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-STD68	-	Not sourced from SC
M-STD69	-	Not sourced from SC
M-STD70	-	Not sourced from SC
M-STD71	-	See Flag section
M-STD72	-	See Flag section
M-STD73	-	See Flag section
M-STD74	-	See Flag section
M-STD75	-	See Flag section
M-STD76	-	See Flag section
M-STD77	-	See Flag section
M-STD78	-	See Flag section
M-STD79	-	See Flag section
M-STD80	-	See Flag section
M-STD81	-	See Flag section
M-STD82	-	See Flag section
M-STD83	-	Select Count (S_CL_SUBJ_ST_LS.PAR_SUBJ_ID) From S_CL_SUBJ_ST_LS, S_PTCL_SITE_LS Where S_CL_SUBJ_ST_LS.STATUS_CD = "Screen Failure" And S_CL_SUBJ_LS.PTCL_SITE_ID = S_PTCL_SITE_LS.ROW_ID And S_PTCL_SITE_LS.CL_PTCL_ID = row_id of the study you are calculating this for) / Select Count (S_CL_SUBJ_ST_LS.PAR_SUBJ_ID) From S_CL_SUBJ_ST_LS, S_PTCL_SITE_LS Where S_CL_SUBJ_ST_LS.STATUS_CD = "Screened" And S_CL_SUBJ_LS.PTCL_SITE_ID = S_PTCL_SITE_LS.ROW_ID And S_PTCL_SITE_LS.CL_PTCL_ID = row_id of the study you are calculating this for)
M-STD84	-	select min(S_EVT_ACT.TODO_ACTL_END_DT) from S_EVT_ACT where S_EVT_ACT.TEMPLATE_FLG = 'V' and S_EVT_ACT.CL_SUBJ_ID = (Select S_CL_SUBJ_ST_LS.PAR_SUBJ_ID, min (STATUS_DATE) From S_CL_SUBJ_ST_LS, S_PTCL_SITE_LS Where S_CL_SUBJ_ST_LS.STATUS_CD = "Enrolled" And S_CL_SUBJ_LS.PTCL_SITE_ID = S_PTCL_SITE_LS.ROW_ID And S_PTCL_SITE_LS.CL_PTCL_ID = row_id of the study you are calculating this for)
M-STD85	S_CL_SUBJ_ST_LS.STATUS_DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Enrolled'
M-STD86	S_CL_SUBJ_ST_LS.STATUS_DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Randomized'
M-STD87	S_CL_SUBJ_ST_LS.STATUS_DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Screened'
M-STD88	S_EVT_ACT.TODO_ACTL_END_DT	select min (S_EVT_ACT.TODO_ACTL_END_DT) from S_EVT_ACT where S_EVT_ACT.TEMPLATE_FLG = 'V' and S_EVT_ACT.CL_SUBJ_ID = (Select S_CL_SUBJ_ST_LS.PAR_SUBJ_ID, MAX (STATUS_DATE) From S_CL_SUBJ_ST_LS Where S_CL_SUBJ_ST_LS.STATUS_CD = "Enrolled")

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-STD89	-	SELECT max (s_cl_subj_st_ls.status_date) from s_cl_subj_st_ls where s_cl_subj_st_ls.status_cd = 'Enrolled'
M-STD90	S_EVT_ACT.TODO_ACTL_END_DT	select max(S_EVT_ACT.TODO_ACTL_END_DT) from S_EVT_ACT where S_EVT_ACT.TEMPLATE_FLG = 'V'
M-STD91	-	SELECT max (s_cl_subj_st_ls.status_date) from s_cl_subj_st_ls where s_cl_subj_st_ls.status_cd = 'Randomized'
M-STR01	-	count (S_CL_SUBJ_ST_LS.STATUS_CD = "Early Terminated")/ count (S_CL_SUBJ_ST_LS.STATUS_CD = Enrolled)
M-STR02	-	SELECT region_cd "Region",s_cl_ptcl_ls.ptcl_num, min (s_cl_subj_st_ls.status_date) "1st_Sub_Enroll_Date",max(s_cl_subj_st_ls.status_date) "Latest_Subj_Enroll_Date" from s_cl_ptcl_ls, s_ptcl_site_ls, s_cl_subj_ls, s_cl_subj_st_ls where s_cl_subj_st_ls.status_cd = 'Enrolled' and s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and s_ptcl_site_ls.row_id = s_cl_subj_ls.ptcl_site_id and s_cl_subj_ls.row_id = s_cl_subj_st_ls.par_subj_id group by region_cd,s_cl_ptcl_ls.ptcl_num
M-STR03	S_CL_PTCL_LS S_CL_SUBJ_LS	site_num enrl_dt num_subj_enrl num_plan_subj
M-STR04	-	Not sourced from SC
M-STR05	-	Not sourced from SC
M-STR06	-	Not sourced from SC
M-STR07	S_CL_PTCL_LS. S_CL_PTCL_LS.	NUM_SCRN_FAIL NUM_SUBJ_SCRN
M-STR08	-	select region_cd "Region", ptcl_num, site_num, min(st_initn_cmpl_dt) "Site_Initiated_Date", min(status_date) "First_Subj_Enrolled_Date" from s_cl_ptcl_ls, s_ptcl_site_ls, s_cl_subj_st_ls, s_cl_subj_ls where s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and s_ptcl_site_ls.row_id = s_cl_subj_ls.ptcl_site_id and s_cl_subj_ls.row_id = s_cl_subj_st_ls.par_subj_id and s_cl_subj_st_ls.status_cd = 'Enrolled' group by region_cd, ptcl_num, site_num order by 1,2,3
M-STR09	-	Not sourced from SC
M-STR10	-	Not sourced from SC
M-STR11	S_EVT_ACT.TODO_PLAN_START_DT	select cl_ptcl_st_id, TODO_PLAN_START_DT "Site_Visit_Start_Date" from s_Evt_act where TODO_ACTL_END_DT is not null and subtype_cd = 'Site Visit' and cl_ptcl_st_id in (select row_id from s_ptcl_site_ls where cl_ptcl_id in (select row_id from s_cl_ptcl_ls where region_cd = 'USA')) order by cl_ptcl_st_id, TODO_PLAN_START_DT
M-STR12	-	Not sourced from SC
M-STR13	-	Not sourced from SC
M-STR14	-	Not sourced from SC
M-STR15	-	Not sourced from SC

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-STR16	S_EVT_ACT	TODO_PLAN_START_DT TODO_ACTL_END_DT select region_cd "Region",ptcl_num,cl_ptcl_st_id, TODO_PLAN_START_DT "site_Visit_Start_Date", TODO_ACTL_END_DT "Site_Visit_Cmpl_Dt" from s_cl_ptcl_ls,s_ptcl_site_ls,s_Evt_act where TODO_ACTL_END_DT is not null and subtype_cd = 'Site Visit' and s_cl_ptcl_ls.row_id = s_ptcl_site_ls.cl_ptcl_id and s_ptcl_site_ls.row_id = s_Evt_act.cl_ptcl_st_id
M-STR17	-	(S_PTCL_SITE_LS.NUM_SUBJ_ENRL/ S_PTCL_SITE_LS.NUM_PLAN_SUBJ) * 100
M-STR18	-	Not sourced from SC
M-STR19	-	Not sourced from SC
M-STR20	-	Not sourced from SC
M-STR21	-	See Flag section
M-STR22	-	See Flag section
M-STR23	-	See Flag section
M-STR24	-	See Flag section
M-STR25	-	See Flag section
M-STR26	-	See Flag section
M-STR27	-	See Flag section
M-STR28	-	See Flag section
M-STR29	-	See Flag section
M-STR30	S_CL_PTCL_LS	NUM_PLAN_SUBJ NUM_PLAN_SITE NUM_SUBJ_ENRL
M-STR31	S_EVT_ACT.TODO_ACTL_END_DT	select min(S_EVT_ACT.TODO_ACTL_END_DT) from S_EVT_ACT where S_EVT_ACT.TEMPLATE_FLG = 'V'
M-STR32	S_CL_SUBJ_ST_LS.STATUS_DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Enrolled'
M-STR33	S_CL_SUBJ_ST_LS.STATUS_DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Randomized'
M-STR34	S_CL_SUBJ_ST_LS.STATUS_DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Screened'
M-STR35	S_EVT_ACT.TODO_ACTL_END_DT	select min (S_EVT_ACT.TODO_ACTL_END_DT) from S_EVT_ACT where S_EVT_ACT.TEMPLATE_FLG = 'V' and S_EVT_ACT.CL_SUBJ_ID = (Select S_CL_SUBJ_ST_LS.PAR_SUBJ_ID, MAX (STATUS_DATE) From S_CL_SUBJ_ST_LS Where S_CL_SUBJ_ST_LS.STATUS_CD = ""Enrolled"")
M-STR36	-	SELECT max (s_cl_subj_st_ls.status_date) from s_cl_subj_st_ls where s_cl_subj_st_ls.status_cd = 'Enrolled'
M-STR37	S_EVT_ACT.TODO_ACTL_END_DT	select max(S_EVT_ACT.TODO_ACTL_END_DT) from S_EVT_ACT where S_EVT_ACT.TEMPLATE_FLG = 'V'
M-STR38	-	SELECT max (s_cl_subj_st_ls.status_date) from s_cl_subj_st_ls where s_cl_subj_st_ls.status_cd = 'Randomized'

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-TA01	S_CL_PTCL_LS	NUM_PLAN_SUBJ NUM_PLAN_SITE NUM_SUBJ_ENRL SELECT S_CL_PGM_LS.NAME, S_CL_PTCL_LS.PTCL_ NAME, count(*) "Num_Of_Sites_Initiated" FROM S_CL_ PGM_LS, S_PTCL_SITE_LS, S_CL_PTCL_LS WHERE S_ CL_PGM_LS.ROW_ID = S_CL_PTCL_LS.CL_PGM_ID AND S_CL_PTCL_LS.ROW_ID = S_PTCL_SITE_LS.CL_ PTCL_ID AND ST_INITN_CMPL_DT IS NOT NULL GROUP BY S_CL_PGM_LS.NAME, S_CL_PTCL_ LS.PTCL_NAME order by S_CL_PGM_LS.NAME, S_CL_ PTCL_LS.PTCL_NAME
M-TA03	S_CL_PTCL_LS	To get LATEST Site Initiated Date, we have to use different table, column: max(S_PTCL_SITE_LS.ST_INITN_CMPL_ DT) Ex: select max(ST_INITN_CMPL_DT) from S_PTCL_ SITE_LS where CL_PTCL_ID = '1-4LOA' min (S_PTCL_ SITE_LS.ST_INITN_CMPL_DT)
M-TA05	S_PS_STMPVER_LS S_CL_ PTCL_LS	select site_num, irb_apprv_dt "IRB_Approval_Date" from S_PS_STMPVER_LS, s_ptcl_site_ls where s_ptcl_site_ls.row_id = S_PS_STMPVER_LS.ptcl_ site_idorder by 1 From S_CL_SUBJ_LS, we have to find out the first subject (ROW_ID) using min(CREATED) in a particular protocol site. S_CL_SUBJ_LS.ROW_ID is the subject id (CL_SUBJ_ID in S_EVT_ACT) Using the CL_SUBJ_ID, get min(TODO_ACTL_END_DT) from S_EVT_ACT & SITE_NUM from S_PTCL_SITE_LS Join Condition between tables: s_evt_act.cl_subj_id is not null and s_cl_subj_ls.row_id = s_Evt_act.CL_SUBJ_ID and s_ptcl_site_ls.site_uid = s_cl_subj_ls.ptcl_site_id and s_evt_ act.TODO_ACTL_END_DT is not null and S_EVT_ ACT.TEMPLATE_FLG = 'V'
M-TA06	S_PS_STMPVER_LS S_CL_ PTCL_LS	select site_num, irb_apprv_dt "IRB_Approval_Date", st_ initn_cmpl_dt "Site_Initiation_Date" from S_PS_ STMPVER_LS, s_ptcl_site_ls where S_PS_STMPVER_ LS.ptcl_site_id = s_ptcl_site_ls.row_id order by 1
M-TA07	-	Not sourced from SC
M-TA08	-	Not sourced from SC
M-TA09	S_CL_SUBJ_LS	select site_num, st_initn_cmpl_dt "Site_Initiation_Date" from s_ptcl_site_ls order by 1 1st Subject 1st Visit can get from: From S_CL_SUBJ_LS, we have to find out the first subject (ROW_ID) using min(CREATED) in a particular protocol site. S_CL_SUBJ_LS.ROW_ID is the subject id (CL_SUBJ_ID in S_EVT_ACT) Using the CL_SUBJ_ID, get min(TODO_ACTL_END_DT) from S_EVT_ACT & SITE_NUM from S_PTCL_SITE_LS Join Condition between tables: s_evt_act.cl_subj_id is not null and s_cl_subj_ls.row_id = s_Evt_act.CL_SUBJ_ID and s_ptcl_site_ls.site_uid = s_cl_subj_ls.ptcl_site_id and s_evt_ act.TODO_ACTL_END_DT is not null and S_EVT_ ACT.TEMPLATE_FLG = 'V'

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-TA10	S_CL_PGM_LS S_CL_PTCL_LS	NAME select S_CL_PGM_LS.name, count(*) from S_CL_PGM_LS, S_CL_PTCL_LS where S_CL_PTCL_LS.CL_PGM_ID = S_CL_PGM_LS.ROW_ID group by S_CL_PGM_LS.name This query should give the number of protocols against each program/Therapeutic Area.
M-TA11	S_EVT_ACT	select a.cl_ptcl_st_id, b.TODO_ACTL_END_DT "Site_Visit_Cmpl_Dt", a.TODO_ACTL_END_DT "Follow_Up_Item_Cmpl_Dt" from s_Evt_act a, s_evt_act b where a.par_evt_id = b.activity_uid and a.subtype_cd = 'Follow-Up' and b.subtype_cd = 'Site Visit' and b.TODO_ACTL_END_DT is not null and a.TODO_ACTL_END_DT is not null and b.cl_ptcl_st_id in (select row_id from s_ptcl_site_ls where cl_ptcl_id in (select row_id from s_cl_ptcl_ls where cl_pgm_id in (select row_id from s_cl_pgm_ls where name = 'Anemia')))
M-TA12	S_EVT_ACT	TODO_ACTL_END_DT WHERE SUBTYPE_CD = 'Site Visit'
M-TA13	S_EVT_ACT	TODO_ACTL_END_DT WHERE SUBTYPE_CD = 'Site Visit'
M-TA14	S_EVT_ACT	TODO_ACTL_END_DT TODO_PLAN_START_DT WHERE SUBTYPE_CD = 'Site Visit'
M-TA15	-	Not sourced from SC
M-TA16	-	Not sourced from SC
M-TA20	S_PTCL_SITE_LS	SITE_NUM NUM_SUBJ_ENRL select s_cl_pgm_ls.name "Program_Name",Ptcl_num,count(*) from s_cl_pgm_ls,s_cl_ptcl_ls,s_ptcl_site_ls WHERE s_ptcl_site_ls.st_initn_cmpl_dt is not null and count (S_CL_SUBJ_ST_LS.STATUS_CD = Enrolled) =0 group by s_cl_pgm_ls.name,Ptcl_num order by 1,2
M-TA21	S_PTCL_SITE_LS	SITE_NUM NUM_SUBJ_ENRL select count(*) from s_ptcl_site_ls WHERE count (S_CL_SUBJ_ST_LS.STATUS_CD = Enrolled) > 1 To get number of sites initiated: SELECT S_CL_PGM_LS.NAME, S_CL_PTCL_LS.PTCL_NAME, count(*) "Num_Of_Sites_Initiated" FROM S_CL_PGM_LS, S_PTCL_SITE_LS, S_CL_PTCL_LS WHERE S_CL_PGM_LS.ROW_ID = S_CL_PTCL_LS.CL_PGM_ID AND S_CL_PTCL_LS.ROW_ID = S_PTCL_SITE_LS.CL_PTCL_ID AND ST_INITN_CMPL_DT IS NOT NULL GROUP BY S_CL_PGM_LS.NAME, S_CL_PTCL_LS.PTCL_NAME order by S_CL_PGM_LS.NAME, S_CL_PTCL_LS.PTCL_NAME
M-TA22	-	Not sourced from SC
M-TA23	-	Not sourced from SC
M-TA24	-	Not sourced from SC
M-TA25	-	Not sourced from SC
M-TA26	-	Not sourced from SC
M-TA27	S_EVT_ACT	select cl_ptcl_st_id, TODO_PLAN_START_DT "Site_Visit_Start_Date" from s_Evt_act where TODO_ACTL_END_DT is not null and subtype_cd = 'Site Visit' and cl_ptcl_st_id in (select row_id from s_ptcl_site_ls where site_num = 'US-001' and cl_ptcl_id in (select row_id from s_cl_ptcl_ls where ptcl_num = 'AMXN 9374')) order by cl_ptcl_st_id, TODO_PLAN_START_DT

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
TA-DISC01	-	Not sourced from SC
TA-DISC02	-	Not sourced from SC
TA-DISC03	-	Not sourced from SC
TA-DISC04	-	Not sourced from SC
TA-DISC05	-	Not sourced from SC
TA-DISC06	-	Not sourced from SC
TA-DISC07	-	Not sourced from SC
TA-DISC08	-	Not sourced from SC
TA-DISC09	-	Not sourced from SC
TA-DISC10	-	Not sourced from SC
TA-DISC11	-	Not sourced from SC
TA-DISC12	-	Not sourced from SC
TA-DISC13	-	Not sourced from SC
TA-DISC14	-	Not sourced from SC
TA-DISC15	-	Not sourced from SC
TA-DISC16	-	Not sourced from SC
TA-DISC17	-	Not sourced from SC
TA-DISC19	-	Not sourced from SC
TA-DISC20	-	Not sourced from SC
TA-DISC21	-	Not sourced from SC
TA-DISC22	-	Not sourced from SC
TA-DISC22.1	-	Not sourced from SC
TA-DISC23	-	Not sourced from SC
TA-DISC24	-	Not sourced from SC
TA-DISC25	-	Not sourced from SC
TA-DISC26	-	Not sourced from SC
TA-DISC26.1	-	Not sourced from SC
TA-DISC30	-	Not sourced from SC
TA-DISC31	-	Not sourced from SC
TA-DISC32	-	Not sourced from SC
TA-DISC33	-	Not sourced from SC
TA-DOC01	S_EVT_ACT.SUBTYPE_CD	-
TA-DOC02	S_EVT_ACT.COMMENTS_ LONG	-
TA-DOC03	S_EVT_ACT.NAME	-
TA-DOC04	S_EVT_ACT.TODO_CD	-
TA-DOC05	S_EVT_ACT.DOC_EXPCTD_ DT	-

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
TA-DOC06	S_EVT_ACT.DOC_RCVD_DT	-
TA-DOC07	S_EVT_ACT.DOC_SENT_DT	-
TA-DOC08	S_EVT_ACT.APPT_END_DT	-
TA-DOC09	-	""Study Level Document"" WHEN s_evt_act.CL_PTCL_ID is not null AND S_CL_PTCL_LS.REGION_CD is null Join using where s_evt_act.CL_PTCL_ID = S_CL_PTCL_ LS.row_id ""Region Level Document"" WHEN s_evt_ act.CL_PTCL_ID is not null AND S_CL_PTCL_ LS.REGION_CD is NOT null Join using where s_evt_ act.CL_PTCL_ID = S_CL_PTCL_LS.row_id ""Site Level Document"" WHEN s_evt_act.TARGET_OU_ID is not null ""Contact Level Document"" WHEN s_evt_act.TARGET_ PER_ID is not null ""Study-Site Level Document"" WHEN s_evt_act.CL_PTCL_ST_ID is not null
TA-FUI01	S_EVT_ACT.COMMENTS	-
TA-FUI02	S_EVT_ACT.TODO_ACTL_ END_DT	-
TA-FUI03	S_EVT_ACT.CREATED	-
TA-FUI04	S_EVT_ACT.NAME	-
TA-FUI05	S_EVT_ACT.APPT_START_DT	-
TA-FUI06	S_EVT_ACT.EVT_STAT_CD	-
TA-FUI07	S_EVT_ACT.TODO_CD	-
TA-FUI08	S_EVT_ACT.ROW_ID	-
TA-RCRF01	-	Not sourced from SC
TA-RCRF02	-	Not sourced from SC
TA-RCRF03	-	Not sourced from SC
TA-RCRF04	-	Not sourced from SC
TA-RCRF05	-	Not sourced from SC
TA-RCRF06	-	Not sourced from SC
TA-RCRF07	-	Not sourced from SC
TA-RCRF08	-	Not sourced from SC
TA-RCRF09	-	Not sourced from SC
TA-RCRF10	-	Not sourced from SC
TA-RCRF11	-	Not sourced from SC
TA-RCRF12	-	Not sourced from SC
TA-RCRF13	-	Not sourced from SC
TA-RCRF14	-	Not sourced from SC
TA-RCRF15	-	Not sourced from SC
TA-RCRF16	-	Not sourced from SC
TA-RCRF17	-	Not sourced from SC
TA-RCRF19	-	Not sourced from SC
TA-RCRF20	-	Not sourced from SC

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
TA-RCRF22	-	Not sourced from SC
TA-RCRF23	-	Not sourced from SC
TA-RCRF24	-	Not sourced from SC
TA-RCRF25	-	Not sourced from SC
TA-RCRF26	-	Not sourced from SC
TA-RCRF28	-	Not sourced from SC
TA-RCRF29	-	Not sourced from SC
TA-RCRF30	-	Not sourced from SC
TA-RCRF31	-	Not sourced from SC
TA-RCRF32	-	Not sourced from SC
TA-RCRF33	-	Not sourced from SC
TA-RCRF34	-	Not sourced from SC
TA-RCRF35	-	Not sourced from SC
TA-SITE01	S_PS_STMPVER_LS.IRB_ APPRV_DT	-
TA-SIV01	S_EVT_ACT.COMMENTS_ LONG	-
TA-SIV02	S_EVT_ACT.TODO_ACTL_ END_DT	-
TA-SIV03	S_EVT_ACT.NAME	-
TA-SIV04	-	Not sourced from SC
TA-SIV05	S_EVT_ACT.APPT_END_DT	-
TA-SIV06	S_EVT_ACT.SRA_STAT_CD	-
TA-SIV07	S_EVT_ACT.APPT_START_DT	-
TA-SIV08	S_EVT_ACT.EVT_STAT_CD	-
TA-SIV09	S_EVT_ACT.TODO_CD	-
TA-SIV10	S_EVT_ACT.S_TMPL_ PLANITEM.NAME	S_EVT_ACT.TEMPLATE_ID = S_TMPL_ PLANITEM.ROWID
TA-SIV11	S_ECT_ACT.ROW_ID	-
TA-SUBJ01	S_CL_SUBJ_ST_LS.STATUS_ CD	-
TA-SUBJ02	S_CL_SJ_CSNT_LS.INFO_ CONSNT_DT	S_CL_SJ_CSNT_LS.CL_SUBJ_ID = S_CL_SUBJ_LS.ROW_ ID S_CL_SJ_CSNT_LS.SUBJ_TMPL_VER_ID = S_SBJTMP_ VER_LS.ROW_ID
TA-SUBJ03	S_CL_SUBJ_ST_ LS.COMMENTS	-
TA-SUBJ04	S_EVT_ACT	TODO_ACTL_END_DT select min(TODO_ACTL_END_ DT) from S_EVT_ACT where subtype_cd = 'Visit'
TA-SUBJ05	S_EVT_ACT	TODO_ACTL_END_DT select cl_subj_id,max(TODO_ ACTL_END_DT) "Subj_Visit_Cmpl_Dt" from S_EVT_ACT where subtype_cd = 'Visit' and cl_subj_id is not null and TODO_ACTL_END_DT is not null group by cl_subj_id

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
TA-SUBJ06	S_EVT_ACT	select cl_subj_id, count(*) from s_evt_act where TODO_ ACTL_END_DT is not null and subtype_cd = 'Visit' group by cl_subj_id
TA-SUBJ07	S_EVT_ACT	There is no direct column to get this measure. select cl_subj_id, count(*) from s_evt_act where Template_ FLG = 'V' and TODO_PLAN_START_DT is not null and TODO_PLAN_ START_DT < ETL_RUN_DATE and TODO_ACTL_END_ DT is null group by cl_subj_id
TA-SUBJ08	S_EVT_ACT	There is no direct column to get this measure. select cl_subj_id, count(*) from s_evt_act where TODO_ PLAN_START_DT > sysdate and subtype_cd = 'Visit' group by cl_subj_id
TA-SUBJ09	-	Not sourced from SC
TD01-01	S_CL_PTCL_LS.PTCL_NUM	-
TD01-02	S_CL_SUBJ_LS.SUBJ_NUM	-
TD01-03	-	Not sourced from SC
TD01-04	-	Not sourced from SC
TD01-05	S_CL_SUBJ_ST_LS.STATUS_ CD	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Early Terminated'
TD01-06	S_CL_SUBJ_ST_LS.STATUS_ DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Enrolled'
TD01-07	-	Not sourced from SC
TD01-08	S_CL_SUBJ_LS.SUBJ_INITL	-
TD01-09	S_CL_SUBJ_LS.BIRTH_DT	-
TD01-10	-	Not sourced from SC
TD01-11	S_CL_SUBJ_ST_LS.STATUS_ CD	-
TD01-12	S_CL_SUBJ_ST_LS.STATUS_ DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Early Terminated'
TD01-16	-	Not sourced from SC
TD01-17	S_CL_SUBJ_ST_LS.STATUS_ DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Screened'
TD01-18	S_CL_SUBJ_LS.ELGBL_FLG	-
TD01-19	S_CL_SUBJ_LS.COMMENTS	-
TD01-20	S_CL_SUBJ_LS.ENRL_NUM	-
TD01-21	S_CL_SUBJ_LS.RDMZATN_ NUM	-
TD01-22	S_CL_SUBJ_LS.PTCL_VLTN_ FLG	-
TD01-23	S_CL_SUBJ_LS.EXCLD_RSN_ CD	-

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
TD01-24	S_CL_SUBJ_LS.SUBJ_ NUM+BIRTH_DT	-
TD01-25	S_CL_SUBJ_LS.PTCL_DEV_ FLG	-
TD01-26	S_CL_SUBJ_LS.WTHDWN_ RSN_CD	-
TD01-27	.CURRENT_DATE - BIRTH_ DT	-
TD01-28	S_CL_SUBJ_ST_LS.STATUS_ DATE	-
TD01-29	-	Not sourced from SC
TD01-30	S_CL_SUBJ_LS.ROW_ID	-

Glossary

Case Report Form

A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial subject. The CRF is the way the **Clinical Data** for Patients is collected.

CDMS

Clinical Data Management System (For example, Oracle Clinical)

Central Laboratory

A location, under contract to a Clinical Trial sponsor, where samples are sent from multiple sites for analysis.

Clinical Data

Data pertaining to the medical characteristics or status of a patient or subject.

Clinical Research Organization

A company or organization that conducts all or part of a clinical trial under contract to a Clinical Trial sponsor.

Clinical Study

See **Clinical Trial**

Clinical Trial

Before a pharmaceutical or biotech company can initiate testing on humans, it must conduct extensive pre-clinical or laboratory research. This research typically involves years of experiments on animal and human cells. The compounds are also extensively tested on animals. If this stage of testing is successful, a pharmaceutical company provides this data to the Food and Drug Administration (FDA), requesting approval to begin testing the drug on humans. This is called an Investigational New Drug application (IND). A clinical trial is a carefully designed investigation of the effects of drug, medical treatment, or device on a group of patients (also called Subjects).

compound

The product being tested or researched within the Clinical Trial.

CRA

Clinical Research Associate. An employee of the Sponsor, responsible for getting a site prepared to conduct a trial and getting cleaned data back from the site to the Sponsor.

CRF

See **Case Report Form**

CRF Book

A set of paper forms or electronic forms that record the results of the set of assessments performed on a subject taking part in a clinical trial.

CRF Page

A single form within a CRF Book.

CRO

Clinical Research Organization

CTMS

Clinical Trial Management System (For example, Oracle's Siebel Clinical)

discrepancy

Problems found with data reported in the CRF pages by Investigators for specific Patients

eCRF

A single electronic **CRF**.

EDC

Electronic Data Capture system (For example, Oracle Remote Data Capture (RDC))

informed consent

A discussion of all procedures, benefits, risks, and expectations of a clinical trial between clinical investigators and potential patients. The FDA requires all patients to sign an informed consent form before participating in a trial.

investigator

A person responsible for the conduct of the clinical trial at a trial site. When a Clinical Trial is conducted at a Site by a team the Investigator is the responsible leader of the team and may be called Principal Investigator (PI). Other investigators are called Sub-investigators. Investigators are qualified health care professionals, often are MDs, PhDs or Pham Ds.

patient

A person who participates in a **Clinical Study** and is the focus of the Clinical Trial's research.

patient visits

A series of scheduled visits by a Patient to an Investigator based interval specified in the Clinical Trial's Protocol. During the Patient visits the Investigators undertakes the required medical procedures defined in the Clinical Trial Protocol and completes the corresponding CRFs.

phase

Phase of trial, typically 1,2,3 or 4.

program

Groups of Clinical Studies or Clinical Trials for the same compound.

projects

Groups of Studies within a Program (Oracle Clinical Only)

Protocol

A Protocol is a document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. It is a plan that states what will be done in the study and why. It outlines how many people will take part in the study, what types of Subjects may take part, what tests they will receive how often, and the treatment plan. The Sponsor of the Clinical Trial typically designs the Protocol.

Protocol amendment

A written description of a change(s) to or formal clarification of a protocol.

queries

Each query is a request for information, sent to an Investigator, to resolve a Discrepancy detected in data signed for by that Investigator.

randomization

The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.

region

A geographic region in which the Clinical Study or Clinical Trial will be carried out.

Regulatory Authority

An authority such as FDA and EMEA regulating clinical development processes.

site coordinator

The individual who manages the conduct of the clinical trial. Coordinators are often nurses.

site visit

A visit or trip by a CRA to a Site for monitoring and support activities.

sites

Sites are locations where clinical trials are conducted. They are typically a clinic or hospitals where **investigator**s see subjects and perform study procedures, such as medical checks.

Sponsor

The organization funding the clinical trial. This is typically the Pharmaceutical company whose product is being tested with the clinical trial.

study document

A required Document to initiate or start a Clinical Trial at a Site (For example, Investigator Resume.)

study

See **Clinical Trial**

subject

See **patient**

Index

A

accessing
  OCDA, 2-2
action links, 3-4
analyses
  printing, 2-7
  refreshing, 2-11
  viewing descriptions, 2-6
architecture
  OCDA, 1-2

C

cache, definition, 2-11
Catalog, 2-4
CRA
  dashboard, A-1
  dashboard pages, A-2
    CRA Overview, A-2
    eCRF Workload, A-5
    Initiating & Recruiting Sites, A-3
    Monitoring Metrics, A-3
    Performance, A-5
    Site Document List, A-4
    Sites to Monitor, A-2
    Study-Site Milestones, A-2, A-4
    Top Investigators, A-4
CRA Overview
  CRA dashboard page, A-2
custom reports in OCDA, 3-3

D

Dashboard Page & Analysis Index
  Index dashboard page, A-27
dashboard pages
  CRA, A-2
    CRA Overview, A-2
    eCRF Workload, A-5
    Initiating & Recruiting Sites, A-3
    Monitoring Metrics, A-3
    Performance, A-5
    Site Document List, A-4
    Sites to Monitor, A-2
    Study-Site Milestones, A-2, A-4
    Top Investigators, A-4
Data Manager - EDC, A-5
  Discrepancy Workload, A-6
  eCRF Workload, A-6
  Home, A-6
  Key Rates, A-6
  Page Workload, A-8
  Performance, A-7
  Quality, A-6
  Study Discrepancies, A-7
  Study Processing Detail, A-7
  Study Processing Summary, A-7
Data Manager - Paper, A-8
  Discrepancy Workload, A-8
  Home, A-8
  Performance, A-9
  Quality, A-9
  Study Processing Detail, A-9
  Study Processing Summary, A-9
definition, 2-1
Index, A-27
  Dashboard Page & Analysis Index, A-27
Study Manager, A-14
  Initiating & Recruiting Studies, A-14
  Monitoring Metrics, A-14
  Study Manager Overview, A-14
  Top Investigators, A-15
Study Overview, A-15
  Monitoring Metrics, A-18
  Non Performing Investigators, A-18
  Recruitment Overview, A-17
  Retention Overview, A-17
  Screening Overview, A-17
  Site Document List, A-19
  Site Document Metrics, A-19
  Site Performance, A-18
  Site Region Performance, A-18
  Study Overview, A-16
  Study-Site Milestones, A-16
  Study-Site Overview, A-24
  Top Investigators, A-18
Study-Site Overview, A-24
  Monitoring Metrics, A-25
  Retention Overview, A-25
  Screening & Recruitment Overview, A-24
  Site Document List, A-26

Site Document Metrics, A-26
Study-Site Team, A-25
Visit Reports & Follow Up Items, A-26
dashboards
about, A-1
CRA, A-1
Data Manager - EDC, A-5
Data Manager - Paper, A-8
definition, 2-1
Index, A-27
printing, 2-7
refreshing, 2-11
Study Manager, A-13
Study Overview, A-15
Study-Site Overview, A-23
viewing, 2-4
viewing descriptions, 2-6
Data Manager - EDC
dashboard, A-5
dashboard pages, A-5
Discrepancy Workload, A-6
eCRF Workload, A-6
Home, A-6
Key Rates, A-6
Page Workload, A-8
Performance, A-7
Quality, A-6
Study Discrepancies, A-7
Study Processing Detail, A-7
Study Processing Summary, A-7
Data Manager - Paper
dashboard, A-8
dashboard pages, A-8
Discrepancy Workload, A-8
Home, A-8
Performance, A-9
Quality, A-9
Study Processing Detail, A-9
Study Processing Summary, A-9
data tracking
See tracking data
descriptions of dashboards and analyses, viewing, 2-6
dimensions in the presentation catalog, B-1
Discrepancy Workload
Data Manager - EDC dashboard page, A-6
Data Manager - Paper dashboard page, A-8
drilling down results, 2-14

E

eCRF Workload
CRA dashboard page, A-5
Data Manager - EDC dashboard page, A-6
ETL programs
version management, 1-4
exiting, Oracle BI, 2-6

F

facts in the presentation catalog, B-26
filters, definition, 2-2

H

Home
Data Manager - EDC dashboard page, A-6
Data Manager - Paper dashboard page, A-8

I

Index
dashboard, A-27
dashboard pages, A-27
Dashboard Page & Analysis Index, A-27
Initiating & Recruiting Sites
CRA dashboard page, A-3
Initiating & Recruiting Studies
Study Manager dashboard page, A-14
introducing, OCDA, 1-1

K

Key Rates
Data Manager - EDC dashboard page, A-6

L

logging in, OCDA, 2-2
logging out, Oracle BI *See* exiting, Oracle BI

M

managing ETL versions, 1-4
Monitoring Metrics
CRA dashboard page, A-3
Study Manager dashboard page, A-14
Study Overview dashboard page, A-18
Study-Site Overview dashboard page, A-25
Top Investigators dashboard page, A-15
My Account page, using, 2-14

N

navigation in Oracle BI, 2-11
Non Performing Investigators
Study Overview dashboard page, A-18

O

OCDA
accessing, 2-2
architecture, 1-2
custom reports, 3-3
logging in, 2-2
overview, 1-1
predefined reports, 3-1
online help, using, 2-6
Oracle BI
drilling down, 2-14

exiting, 2-6
navigating, 2-11
setting preferences, 2-15
setting time zone, 2-16
sorting table columns, 2-14
using, 2-4
Oracle BI Analysis Editor, 2-5
Oracle BI Delivers, 2-5
Oracle BI features links, using, 2-12
Oracle BI Interactive Dashboards, 2-5
Oracle BI interactive home page, 2-5
Oracle BI Presentation Services, 2-4
Oracle BI Analysis Editor, 2-5
Oracle BI Delivers, 2-5
Oracle BI Interactive Dashboards, 2-5
Oracle BI interactive Home Page, 2-5
Oracle Business Intelligence Catalog, 2-4
overview, OCDA, 1-1
overview, using OCDA, 2-1

P

Page Workload
Data Manager - EDC dashboard page, A-8
pages
See dashboard pages, definition
parameters, definition, 2-2
Performance
CRA dashboard page, A-5
Data Manager - EDC dashboard page, A-7
Data Manager - Paper dashboard page, A-9
predefined
reports, 3-1
presentation catalog
dimensions, B-1
facts, B-26
oracle clinical sources, B-59
siebel clinical sources, B-91
printing dashboards and analyses, 2-7
prompts, definition, 3-1

Q

Quality
Data Manager - EDC dashboard page, A-6
Data Manager - Paper dashboard page, A-9

R

Recruitment Overview
Study Overview dashboard page, A-17
refreshing
dashboards and analyses, 2-11
information in selection pane, 2-11
regulatory compliance, 1-3
data tracking, 1-4
ETL version management, 1-4
security, 1-4
reporting, using OCDA, 1-3
reports
custom, 3-3
defined, 3-1
parameters, 2-2
predefined, 3-1
view, 3-2
view on Apple iPhone, 3-4
results
downloading, downloading results, 2-8
Retention Overview
Study Overview dashboard page, A-17
Study-Site Overview dashboard page, A-25

S

Screening & Recruitment Overview
Study-Site Overview dashboard page, A-24
Screening Overview
Study Overview dashboard page, A-17
security, 1-4
setting preferences, Oracle BI, 2-15
setting time zone, Oracle BI, 2-16
Site Document List
CRA dashboard page, A-4
Study Overview dashboard page, A-19
Site Document Metrics
Study Overview dashboard page, A-19
Study-Site Overview dashboard page, A-26
Site Performance
Study Overview dashboard page, A-18
Site Region Performance
Study Overview dashboard page, A-18
Sites to Monitor
CRA dashboard page, A-2
sorting table columns in Oracle BI, 2-14
Study Discrepancies
Data Manager - EDC dashboard page, A-7
Study Manager
dashboard, A-13
dashboard pages, A-14
Initiating & Recruiting Studies, A-14
Monitoring Metrics, A-14
Study Manager Overview, A-14
Top Investigators, A-15
Study Manager Overview
Study Manager dashboard page, A-14
Study Overview
dashboard, A-15
dashboard pages, A-15
Monitoring Metrics, A-18
Non Performing Investigators, A-18
Recruitment Overview, A-17
Retention Overview, A-17
Screening Overview, A-17
Site Document List, A-19
Site Document Metrics, A-19
Site Performance, A-18
Site Region Performance, A-18
Study Overview, A-16
Study-Site Milestones, A-16
Study-Site Overview, A-24
Top Investigators, A-18

Study Overview dashboard page, A-16
Study-Site Overview dashboard page, A-24
Study Processing Detail
Data Manager - EDC dashboard page, A-7
Data Manager - Paper dashboard page, A-9
Study Processing Summary
Data Manager - EDC dashboard page, A-7
Data Manager - Paper dashboard page, A-9
Study-Site Document List
Study Overview dashboard page, A-26
Study-Site Milestones
CRA dashboard page, A-2, A-4
Study Overview dashboard page, A-16
Study-Site Overview
dashboard, A-23
dashboard pages, A-24
Monitoring Metrics, A-25
Retention Overview, A-25
Screening & Recruitment Overview, A-24
Site Document List, A-26
Site Document Metrics, A-26
Study-Site Team, A-25
Visit Reports & Follow Up Items, A-26
Study-Site Team
Study-Site Overview dashboard page, A-25

T

Top Investigators
CRA dashboard page, A-4
Study Overview dashboard page, A-18
tracking data, 1-4

U

using
My Account Page, 2-14
Oracle BI, 2-4
using OCDA, 2-1
using online help, 2-6
using Oracle BI features links, 2-12

V

viewing
dashboards, 2-4
descriptions of dashboards and analyses, 2-6
predefined reports, 3-2
reports on Apple iPhone, 3-4
saved requests, 3-10
Visit Reports & Follow Up Items
Study-Site Overview dashboard page, A-26

W

what can i do using Oracle Clinical Development Analytics, 1-2
what is available to you after accessing Oracle BI, 2-12