Oracle® Study, Subject, and Visit Synchronization Integration Pack for Siebel Clinical and Oracle® Clinical 3.1 - Implementation Guide

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Contents

Preface

Welcome to the Oracle Study, Subject and Visit Synchronization Integration Pack for Siebel Clinical and Oracle Clinical for Application Integration Architecture (AIA) Service Pack 3.1

Oracle Application Integration Architecture (AIA) provides the following guides and resources for this release:

Oracle AIA Guides

- Oracle Fusion Middleware Infrastructure Components and Utilities User's Guide for Oracle Application Integration Architecture Foundation Pack 11*g* Release 1 (11.1.1.4.0)
- Oracle Fusion Middleware Installation and Upgrade Guide for Oracle Application Integration Architecture Foundation Pack 11*g* Release 1 (11.1.1.4.0)
- Oracle Fusion Middleware Concepts and Technologies Guide for Oracle Application Integration Architecture Foundation Pack 11*g* Release 1 (11.1.1.4.0)
- Oracle Fusion Middleware Reference Process Models User's Guide for Oracle Application Integration Architecture Foundation Pack 11*g* Release 1 (11.1.1.4.0)
- Oracle Fusion Middleware Migration Guide for Oracle Application Integration Architecture 11*g* Release 1 (11.1.1.4.0)
- Oracle Fusion Middleware Developer's Guide for Oracle Application Integration Architecture Foundation Pack 11*g* Release 1 (11.1.1.4.0)

Additional Resources

The following resources are also available:

Resource	Location
Oracle Application Integration Architecture: Product-to-Guide Index	Oracle Technology Network: http://www.oracle.com/technetwork/index.html
Known Issues and Workarounds	My Oracle Support: https://support.oracle.com/
Release Notes	Oracle Technology Network: http://www.oracle.com/technetwork/index.html
Documentation updates	My Oracle Support: https://support.oracle.com/

Part 1: Understanding the Delivered Integrations

Chapter 1: Understanding the Oracle Study, Subject and Visit Synchronization Integration Pack for Siebel Clinical and Oracle Clinical

This chapter discusses:

Key Benefits of the PIP

The Study, Subject and Visit Synch: Siebel Clinical - Oracle Clinical PIP integrates two complementary clinical technology applications.

This integration includes the following processes:

- Study Site Coordination (including address, investigator, and so on.)
- Study Subject Coordination
- Activity Completion Integration

The Study, Subject and Visit Synch: Siebel Clinical - Oracle Clinical PIP enables timely exchange of data between Oracle Clinical and Siebel Clinical. Information sent from Siebel Clinical, (for example, investigator and site details) that automates the creation of a study site and eliminates the manual creation of a Site, Investigator, and Study Site. The information sent from Oracle Clinical, such as patient numbers and information related to the completion of Oracle Clinical items (Visits, DCIs, DCMs, Questions), facilitates efficient and accurate patient counts and activity completion tracking in Siebel Clinical. The automation of these processes ultimately provides the means to effect timely and accurate Investigator payments. It also aids accurate tracking and response to issues related to site performance and protocol adherence.

General Business Process

- In Siebel Clinical sites are created at a protocol level. Siebel Clinical sends protocol site information to Oracle Clinical, including address, investigator name, and site number. This information is used to automatically create or update Investigators, Sites and Study Sites in Oracle Clinical.
- When a patient has enrolled in a study or commences the screening visit process, Oracle Clinical sends information to Siebel Clinical about the patient so that a subject may be created for the appropriate Protocol Site in Siebel Clinical. Subsequent updates to the patient are transmitted to Siebel Clinical, which then updates the patient in that system.

- Siebel Clinical can schedule activities to be completed during patient visits, including the designation of a patient visit as an individual activity. Certain data collection tasks in Oracle Clinical may correspond to completion of Activities in Siebel Clinical. For example an ECG DCI in Oracle Clinical will correspond to a visit activity in Siebel Clinical. The collection/completion of a visit or specific sets of data within a visit in Oracle Clinical can be used to update the status of an activity in Siebel Clinical.

Common Terms Used in this Guide

Siebel Clinical Term	Oracle Clinical Term	Definition
Protocol	Study	A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. Within Siebel Clinical, Protocol is synonymous with Study.
Account Address	Site	The organization with which the investigator on the study is associated. This entity is not associated with a Study. An account is not equivalent to a site in Oracle Clinical. In Siebel Clinical, the account includes all the locations of an organization. In Oracle Clinical, a site is a particular location where a clinical study can be conducted. However, in Oracle Clinical, you cannot include the same site in the study with different principal investigators. In Siebel Clinical, an account can belong to multiple protocol sites in a protocol with a different principal investigator assigned to each one.
Principal Investigator(PI)	Investigator	The physician or clinician responsible for conducting the trial.
None	Patient Position	An identifier in Oracle Clinical that is a placeholder for a real participant in a clinical study. Patient Positions are created, based on the target enrollment in a study and assigned to a study site. As each subject is enrolled or data is collected for that subject, a Patient Position will be assigned.
Subject	Patient	Persons recruited by investigators that participate in the trial at a study site.
Subject Visit Template	DCI Book	The expected events (visit and activities or procedures) that are conducted throughout the course of the trial as specified in the study protocol.
Subject Visit Schedule		The planned schedule of events for a particular subject at a Site based upon the Subject Visit Template. Once the actual events occur the information in the Schedule is updated.
None	Completion Criteria	A set of parameters, defined in Oracle Clinical and based on Visit, Clinical Planned Event, received DCI, received DCM, or question(s) response(s), which can be used to assign a completion date to a Siebel Clinical activity.
Activity	None	Required procedures or tasks in the Visit schedule in Siebel Clinical.

Business Process Flows

This section provides an overview and discusses these process flows:

- Create/Update Study Sites
- Create/Update Study Subjects
- Update Visit or Activity Completion Date and Status

Create/Update Study Sites

Overview

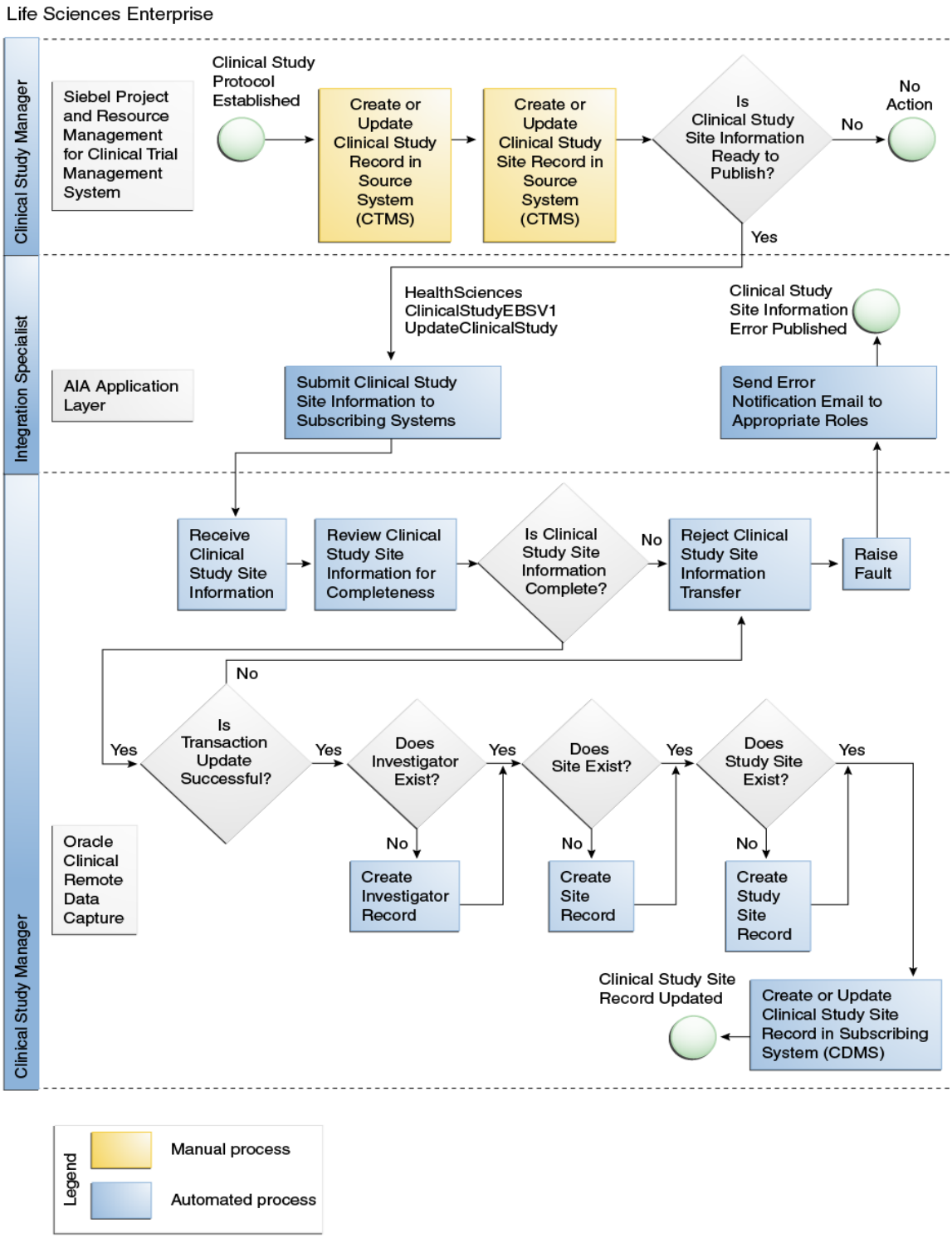
During the Study set up process Protocols are created in Siebel Clinical under a Program. Clinical Studies are defined in Oracle Clinical under a Program and Project. To utilize this integration, the user must manually enter Study code from Oracle Clinical into the CDMS Study ID field of the corresponding Protocol in Siebel Clinical. Once the CDMS study id is entered, the Synchronize Activities Sites flag must be selected.

When a protocol site is created in Siebel Clinical and the Study manager feels it is ready to be shared with Oracle Clinical, the Activate for Synchronization check box is selected, which creates a study site in Oracle Clinical. All future updates to the Protocol Site will be sent to Oracle Clinical. If the principal investigator for the Protocol Site does not exist in Oracle Clinical, the system will create one.

The combination of the primary address and account assigned for the protocol site are considered as a site in Oracle Clinical. If this combination does not exist in Oracle Clinical, a new site will be created.

Flow Diagram

The following diagram shows the Create/Update Study Sites flow:



Create/Update Study Sites Flow Diagram

Create/Update Study Subjects

Overview

In Oracle Clinical, Patient Positions are created for the target enrollment for a study and assigned to study sites based on the target enrollment for the study site. The enrollment date for a patient position indicates that a patient has been enrolled in the study and assigned this Enrollment ID. This creates a subject for the appropriate Protocol Site in Siebel Clinical and the subject will be screened and enrolled against the active Subject Visit Template.

In Oracle Clinical or Oracle Clinical Remote Data Capture (OCRDC), if data is entered for a patient position and no enrollment date has been specified, it is assumed that the patient is undergoing the screening process assigned to this Screening ID. This creates a subject for the appropriate Protocol Site in Siebel Clinical and the subject will be screened against the active Subject Visit Template.

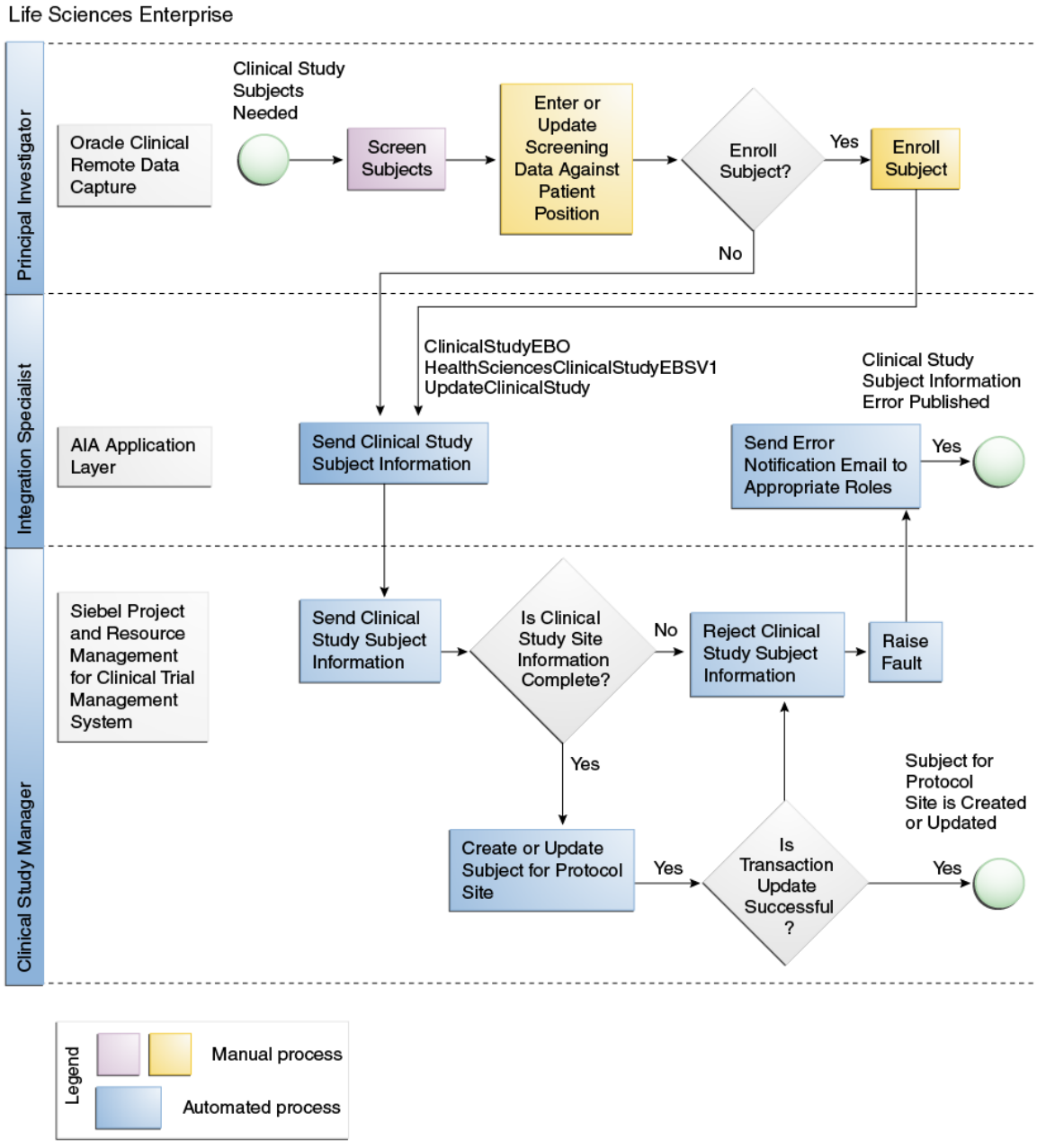
Siebel Clinical requires the subject's initials and date of birth to create a subject. These are not required fields in Oracle Clinical. Therefore, if the patient's initials are not entered in Oracle Clinical, the Enrollment ID is used to populate the Initials in Siebel Clinical. If the date of birth of the patient was not entered in Oracle Clinical, the default value of Jan 1, 1800 will be used in Siebel Clinical. The user should recognize this date as invalid. The correct data can be manually entered in Siebel Clinical, if desired.

To assign an Enrollment Visit Template to a subject in Siebel Clinical, the date the informed consent was signed is required. Informed Consent Signature date is an optional field in Oracle Clinical and if it is not entered Siebel Clinical assigns a default value of Jan 1, 1900. This will adversely impact the dates in the Visit Schedule for the subject and the user should manually correct it in Siebel Clinical.

To assign a Screening Visit Template to a subject in Siebel Clinical, the screen date is required. However, this is not a required field in Oracle Clinical. Therefore, if this date is not entered in Oracle Clinical, the subject's birth date is used. This will adversely impact the dates in the Visit Schedule for the subject and the user should manually correct it in Siebel Clinical.

Flow Diagram

The following diagram shows the Create/Update Study Subjects flow:



Create/Update Study Subjects Flow Diagram

Update Visit or Activity Completion Date and Status

Overview

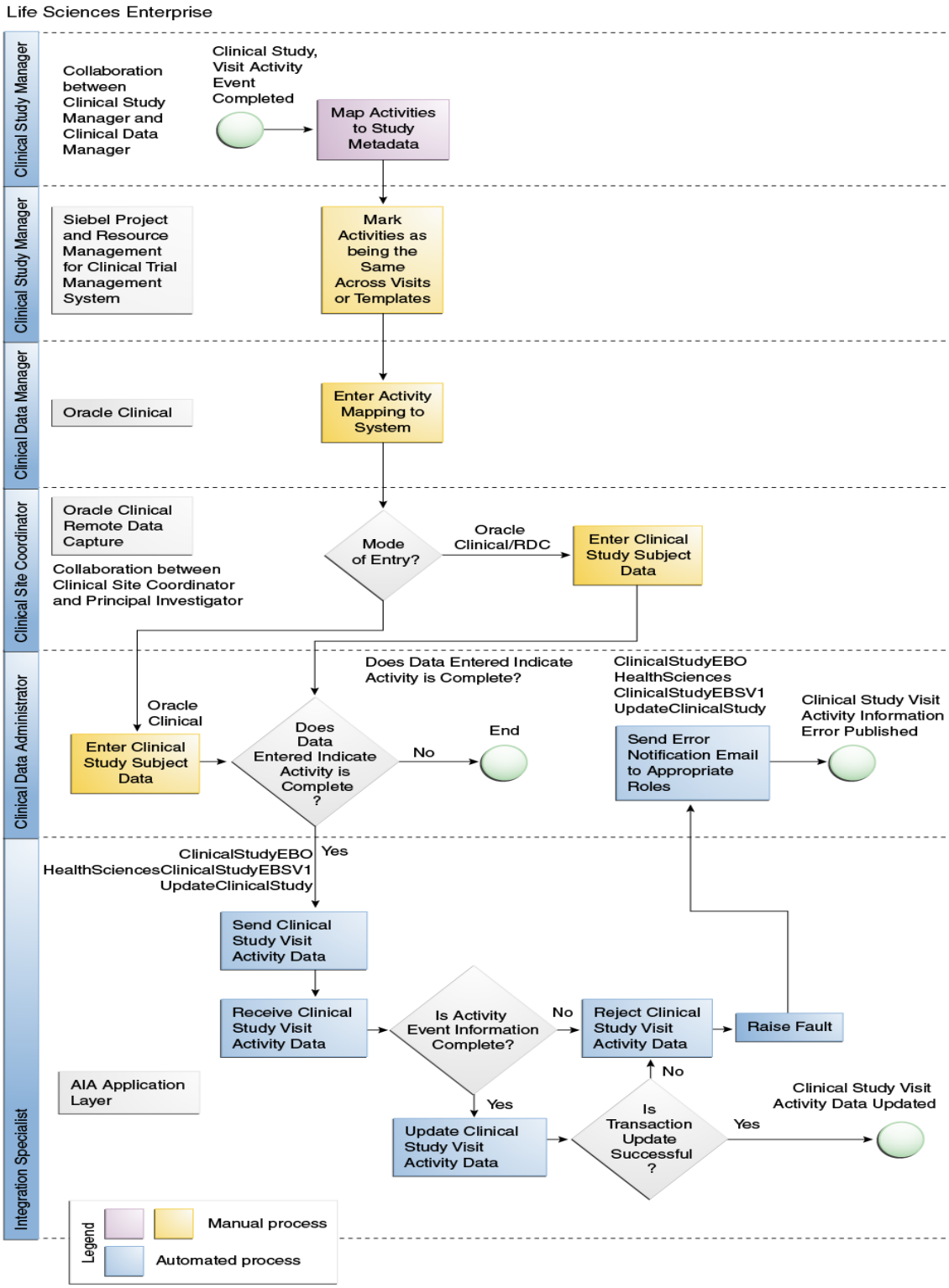
This workflow updates the completion date of Subject visits and Subject visit activities based on data entered into Oracle Clinical or OC RDC. To initiate this, Study Manager and Data Manager should collaborate and determine what data must be completed in OC RDC for a visit or activity to be considered complete in Siebel Clinical. They must also decide how to determine the visit completion date in Oracle Clinical. Enhancements have been made to Siebel Clinical to indicate that multiple activities or visits share the same completion criteria. Enhancements have been made to Oracle Clinical to define the activity completion criteria in terms of Oracle Clinical data collection objects such as Data Collection Instruments (DCI), Data Collection Modules (DCM) or DCM questions.

After the Activity Completion criteria are defined, you can schedule a batch job to initiate a process that analyzes patient data to evaluate whether any visits or visit activities have been completed since the last time the process ran. If any activity completion criteria has been added or changed, all patient data will be analyzed.

This batch job sends messages regarding the completion date of either activities or visits or both, which updates the completion date and status of the associated activities, or visits for the appropriate Subject Visit schedule in Siebel Clinical.

Flow Diagram

The following diagram shows the Update Visit or Activity Completion Date and Status flow:



Update Visit or Activity Completion Date and Status Flow Diagram

Solution Assumptions and Constraints

These are the solution, assumptions, and constraints:

Assumptions

1. For the Clinical Study Subject workflow integration to proceed, you must populate the Enrollment date for a patient in Oracle Clinical. This can be done in various ways through the Patient Positions form. The enrollment dates can be loaded in Oracle Clinical data entry, by batch loading enrollment dates or using Patient Synchronization in a derivation procedure to populate the date from a CRF.
2. Investigators defined in Oracle Clinical may be used on any Clinical Study. Therefore the integration assumes that reassigning the principal investigator for a protocol site will not cause the investigator to be deleted from Oracle Clinical.
3. When a protocol site is deleted in Siebel Clinical, you may not want to delete the corresponding study site in Oracle Clinical. Hence, this is not currently part of the integration.
4. Since patient data can be deleted and re-entered in Oracle Clinical, it will not be desirable to remove the subject in Siebel Clinical when the enrollment date was left blank or patient data was removed.

Constraints

1. Protocols are created in Siebel Clinical under a Program and Clinical Studies are created in Oracle Clinical under a Program and Project. Therefore, mapping a Clinical study to a Protocol is not an automatic process and must be done manually.
2. The investigator address is not required in Oracle Clinical. The synchronization of investigators is a separate business process and the investigator address will not be populated in Oracle Clinical by this integration.
3. Unplanned visits in Oracle Clinical will not be associated with Siebel Clinical activities. Since no mapping will exist, Oracle Clinical will not be able to determine whether an unplanned activity has been completed or not.
4. Due to size limitations for Study Site code in Oracle Clinical, the Protocol Site Number cannot be longer than 10 characters. Oracle recommends that you incorporate this length restriction in your Siebel Clinical environment to avoid errors.
5. The changes to investigator data (for example last name or phone number)will not be propagated to Oracle Clinical until something other data in the protocol site is changed or the investigator is assigned to another protocol site that is synchronized.

Chapter 2: Synchronizing Clinical Study Sites

This chapter provides an overview of the synchronization of Clinical Study Sites between Siebel Clinical and Oracle Clinical and discusses:

Overview

Study site information is entered as a Protocol Site in Siebel Clinical and a Study Site in Oracle Clinical. This integration is uni-directional and happens from Siebel Clinical to Oracle Clinical. Updates to the investigator, site or study site in Siebel Clinical are synchronized to Oracle Clinical. Updates made in Oracle Clinical for investigator, site or study site are not synchronized back to Siebel Clinical.

When the Activate for Synchronization flag is selected for a protocol site in Siebel Clinical, a corresponding study site will be created in Oracle Clinical. If the principal investigator responsible for the protocol site does not exist in Oracle Clinical, one will be created. The combination of the Account and the primary address for the Protocol Site is considered as a Site in Oracle Clinical. If this combination does not exist, a new site is created.

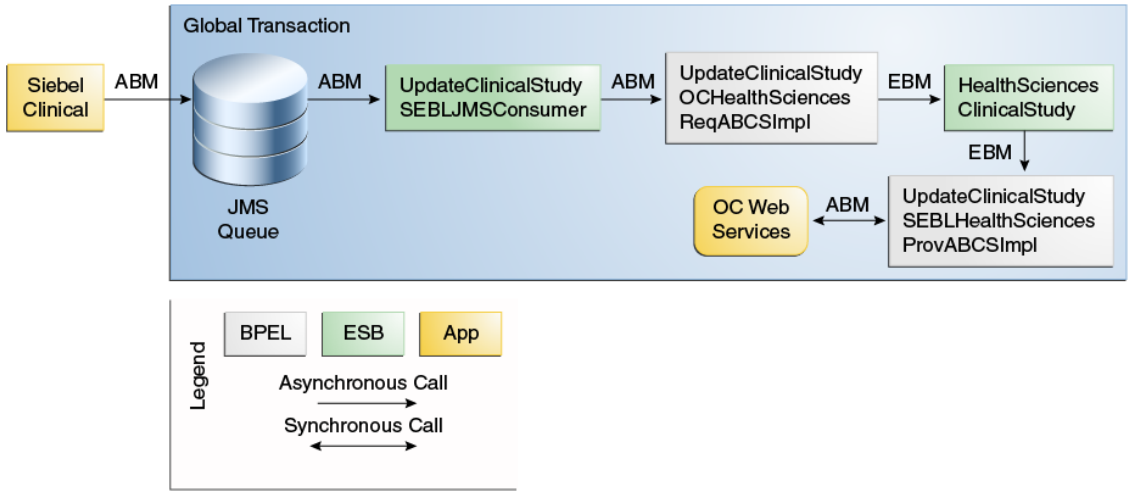
Deleting a principal investigator, account or protocol site in Siebel Clinical will not cause deletion of any objects in Oracle Clinical.

Study Site Integration Flow

This section provides the activity diagrams and functional descriptions for the Study Site Integration Flow.

Flow Diagram

The following diagram shows the Study Site Integration flow:



Study Site Integration Flow

Create Study Site Flow

1. When the Activate for Synchronization check box is selected for a Protocol Site, Siebel Clinical will write a message Application Business Message (ABM) to the AIA_SiebelClinical_ClinicalStudyJMSQueue Queue.
2. The ABM is picked up by the UpdateClinicalStudySEBLJMSConsumer consumer service and passed to the UpdateClinicalStudySEBLHealthSciencesReqABCSImpl (requester Application Business Connector Service (ABCS)).
3. The requester ABCS will transform the ABM into an UpdateClinicalStudyEBM, populating the ClinicalStudyInvestigator, ClinicalStudySite and ClinicalStudyStudySite cross-reference tables. It will retrieve State and Country information for the Site Address from the corresponding DVM tables.
4. The Enterprise Business Message (EBM) is then passed onto the HealthSciencesClinicalStudyEBS (EBS).
5. The EBS will pass the EBM to the UpdateClinicalStudyOCHealthSciencesProvABCSImpl (provider ABCS) based on the configuration routing rules.
6. The provider ABCS receives the EBM and transforms it into either a Create Investigator ABM (if the Investigator is new) or an Update Investigator ABM (if the Investigator already exists). The ABM is then passed to the appropriate Oracle Clinical web service.
7. If the investigator value in the CreateInvestigator ABM is longer than 10 characters, it is replaced with the sequence number used for the investigator_id field in the ocl_investigators table.
8. If a new Investigator has been created the ClinicalStudyInvestigator cross-reference table is updated.
9. The provider ABCS then transforms the EBM into either a Create Site ABM (if the Site is new) or an Update Site ABM (if the Site already exists). The Oracle Clinical state and country values are retrieved from the corresponding DVM tables.

10. The ABM is then passed to the appropriate Oracle Clinical web service.
11. If the site value in the CreateSite ABM is longer than 10 characters, it is replaced with the sequence number used for the site_id field in the ocl_sites table.
12. If a new Site has been created the ClinicalStudySite cross-reference table is updated.
13. The provider ABCS then transforms the EBM into a “Create StudySite” ABM, which includes Oracle Clinical identifiers for the Site and Investigator (from the corresponding cross-reference tables).
14. A synchronous call to the Oracle Clinical web service is made and the ID of the newly created StudySite is returned. This can then be added to the ClinicalStudyStudySite cross-reference table.

Update Study Site Flow

1. When the Activate for Synchronization check box is selected for a Protocol Site and its information is updated (for example Address of Protocol Site), Siebel Clinical will write a message (ABM) to the AIA_SiebelClinical_ClinicalStudyJMSQueue Queue.
2. The message is picked up by the UpdateClinicalStudySEBLJMSConsumer consumer service and passed to the UpdateClinicalStudySEBLHealthSciencesReqABCSImpl (requester ABCS).
3. The requester ABCS will transform the ABM into an UpdateClinicalStudy EBM. This EBM will contain integration IDs for the Investigator, Site, and StudySite, which are retrieved from the corresponding cross-reference tables. The state and country values in the site address are retrieved from the corresponding DVMs.
4. The EBM is then passed onto the HealthSciencesClinicalStudyEBS (EBS).
5. The EBS passes the EBM to the UpdateClinicalStudyOCHealthSciencesProvABCSImpl (provider ABCS), based on the configuration routing rules.
6. The provider ABCS receives the EBM and transforms it into either a Create Investigator ABM (if the Investigator is new) or an Update Investigator ABM (if the Investigator already exists). The ABM is then passed to the appropriate Oracle Clinical web service.
7. If the investigator value in the CreateInvestigator ABM is longer than 10 characters, it is replaced with the sequence number used for the investigator_id field in the ocl_investigators table.
8. If a new Investigator has been created, the ClinicalStudyInvestigator cross-reference table is updated.
9. The provider ABCS then transforms the EBM into either a Create Site ABM (if the Site is new) or an Update Site ABM (if the Site already exists). The Oracle Clinical values for the site address state and country are retrieved from the corresponding DVM tables.
10. The ABM is then passed to the appropriate Oracle Clinical web service.
11. If the site value in the CreateSite ABM is longer than 10 characters, it is replaced with the sequence number used for the site_id field in the ocl_sites table.
12. If a new Site has been created the ClinicalStudySite cross-reference table is updated.
13. The provider ABCS then transforms the EBM into an “Update StudySite” ABM, which includes Oracle Clinical identifiers for the Site and Investigator (from the corresponding cross-reference tables).

14. A synchronous call to the Oracle Clinical web service is made.

Siebel Clinical Interfaces

Siebel Outbound Web Services:

Name	Schema
LS ClinicalProtocolSite	Clinical Protocol Site Business Object

Oracle Clinical Interfaces

The following Oracle Clinical artifacts are used by this integration.

Inbound to Oracle Clinical Web Services:

SiteService – This service allows the integration to create, query, and update Sites in Oracle Clinical.

InvestigatorService – This service allows the integration to create, query and update investigators in Oracle Clinical.

StudySiteService – This service allows the integration to create and update Study Sites in Oracle Clinical.

Industry AIA Components

The integration flow uses the following components:

- ClinicalStudy Enterprise Business Object (EBO)
- HealthSciencesClinicalStudyEBSV1
- UpdateClinicalStudyEBM

The industry EBO and EBM XML Schema Definition (XSD) files can be located by EBO within the $AIA_HOME/AIAMetaData/AIAComponents/EnterpriseObjectLibrary/Industry/HealthSciences/EBO/ parent folder.

The industry EBS Web Services Description Language (WSDL) files can be located by EBO within the $AIA_HOME/AIAMetaData/AIAComponents/EnterpriseBusinessServiceLibrary/Industry/HealthSciences/EBO/ parent folder.

For detailed documentation of individual EBOs and EBMs, click the AIA Reference Doc link on EBO and EBM detail pages in Oracle Enterprise Repository or Oracle Clinical.

For more information about using the Oracle Enterprise Repository and configuring it to provide the AIA Reference Doc link, see *Oracle Fusion Middleware Developer's Guide for Oracle Application Integration Architecture Foundation Pack 11g Release 1, "Configuring and Using Oracle Enterprise Repository as the Oracle AIA SOA Repository."*

EBOs can be extended, for instance, to add new data elements. These extensions are protected, and will remain intact after a patch or an upgrade.

For more information, see *Oracle Fusion Middleware Developer's Guide for Oracle Application Integration Architecture Foundation Pack 11g R1*, "Extensibility for AIA Artifacts."

Integration Services

These are the services delivered with this integration:

- UpdateClinicalStudySEBLJMSConsumer

  This is a Java Message Service (JMS) consumer service that reads a JMS message from the AIA_SiebelClinical_ClinicalStudyJMSQueue in the Fusion Middleware database.

- UpdateClinicalStudySEBLHealthSciencesReqABCSImpl

  The requester ABCS is responsible for transforming the Siebel Protocol Site ABM into an UpdateClinicalStudy EBM.

- HealthSciencesClinicalStudyEBS

  The EBS service is responsible for passing the message from the Requester ABCS to the Provider ABCS.

- UpdateClinicalStudyOCHealthSciencesProvABCSImpl

  The Provider ABCS is responsible for transforming the UpdateClinicalStudyEBM into the appropriate ABMs to call the appropriate Oracle Clinical web services.

Chapter 3: Synchronizing Clinical Study Subject Information

This chapter provides an overview of the synchronization of Clinical Study Subject information between Oracle Clinical and Siebel Clinical and discusses:

Overview

After enabling Patient Integration for an Oracle Clinical study, the synchronization process can be initiated. In Oracle Clinical, Patient Positions are created for the target enrollment of a study and assigned to study sites based on the target enrollment for it. The enrollment date for a patient position indicates that a patient has been enrolled in the study and assigned an Enrollment ID. This creates a subject for the appropriate Protocol Site in Siebel Clinical and the subject is screened and enrolled against the active Subject Visit Template.

If data is collected for a patient position in Oracle Clinical or OC RDC and no enrollment date has been specified, the system assumes this to be a patient undergoing the screening process and assigns a Screening ID. This creates a subject for the appropriate Protocol Site in Siebel Clinical and will be screened against the active Subject Visit Template.

To create a subject in Siebel Clinical, the subject's initials and birth date are required. However, these are not required fields in Oracle Clinical and if the patient's initials are not available in Oracle Clinical, the Enrollment ID is used as the initials in Siebel Clinical. If the patient's birth date is not available in Oracle Clinical, it is set to Jan 1, 1800 in Siebel Clinical. This is an invalid date that can be used to identify subjects whose information has to be updated. You can manually enter the correct data in Siebel Clinical, if desired.

To assign an Enrollment Visit Template to a subject in Siebel Clinical, the date the informed consent was signed on is required. This date is optional in Oracle Clinical and if it is not entered a default value of Jan 1, 1900 is entered in Siebel Clinical. This will alter the dates in the Visit Schedule for the subject and you may want to manually correct this in Siebel Clinical.

To assign a Screening Visit Template to a subject in Siebel Clinical the screen date is required. This is not a mandatory field in Oracle Clinical and if this date is not available the subject's birth date is used in Siebel Clinical. This adversely impacts the dates in the subject's Visit Schedule and should be manually corrected in Siebel Clinical.

When a patient is enrolled in a study or begins the screening visit process, Oracle Clinical sends patient information to Siebel Clinical so that a subject may be created for the appropriate Protocol Site in Siebel Clinical. Oracle Clinical transfers the Study ID and Patient ID, which identify the patient, and along with the following information:

- Patient_Position_id

- Initials
- Sex
- Birth Date
- Informed Consent Signature Date
- Death Date
- StudySite the patient is assigned to
- Start Date of the patient assignment
- DCI Book assigned to the patient
- Frozen Flag
- Include in Efficacy Flag
- Include in Safety Analysis Flag
- Position Type (Screening, Enrollment, Replacement)
- Patient Dropped Flag
- Early Termination Flag
- Enrollment Date
- Exclude from Efficacy Reason
- Inclusion/Exclusion Date
- Exclude from Safety Reason
- Patient Reference
- Randomization Date
- Last Pregnancy Date
- First Screening Date
- Termination Date
- Patient Status History

This process flow is triggered by one of the following events:

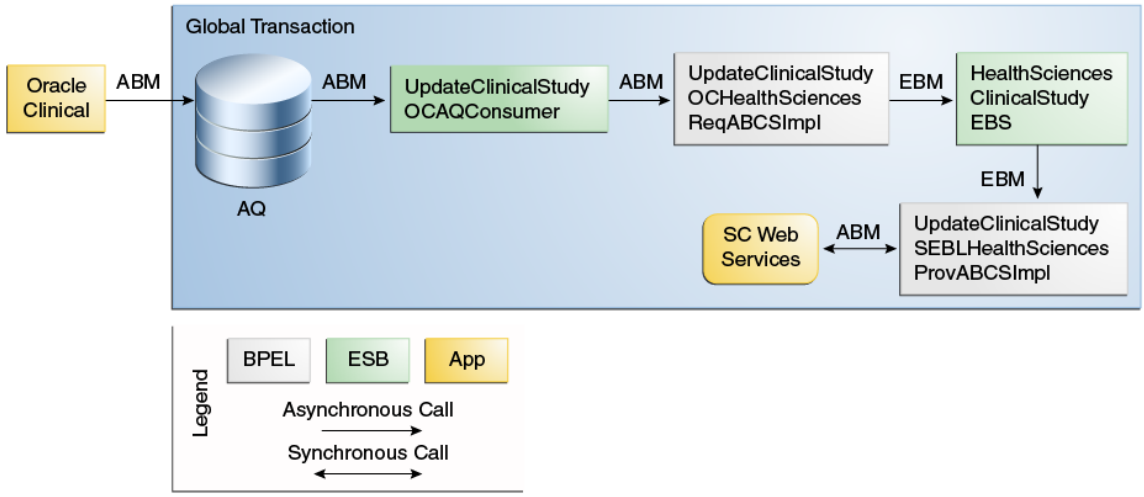
- Specifying an enrollment date for a patient position in Oracle Clinical
- Entering the first CRF for a patient who does not have an enrollment date
- Updating information in any of the fields listed for an enrolled patient or a patient with collected data.

Clinical Study Subject Information Flow

This section provides the activity diagrams and functional descriptions for the Clinical Study Subject Information Flow.

Flow Diagram

The following diagram shows the Clinical Study Subject information flow:



Clinical Study Subject Information Flow

Create Study Subject

1. When Patient Integration is enabled for a study and either the enrolment date is entered for a patient position or the first CRF is entered for a patient position with no enrolment date, Oracle Clinical write a message (ABM) to the Clinical_Study_Queue Advanced Queuing (AQ).
2. The message is picked up by the UpdateClinicalStudyOCAQConsumer consumer service and passed to the UpdateClinicalStudyOCHealthSciencesReqABCSImpl (requester ABCS).
3. The message will then be transformed into an UpdateClinicalStudy EBM and:
    a. The ClinicalStudySubject ID value is updated in the CLINICALSTUDY_CLINICALSTUDYSUBJECTID cross-reference table.
    b. The ClinicalStudySite identification is retrieved from the CLINICALSTUDYSTUDYSITE cross-reference table.
    c. The Clinical Subject status is retrieved from the ClinicalStudySubject_Status DVM table.
4. The UpdateClinicalStudyEBM is passed to the HealthSciencesClinicalStudyEBS (EBS).
5. The EBS will use the configuration routing rules to pass the EBM onto the UpdateClinicalStudySEBLHealthSciencesProvABCSImpl (provider ABCS).
6. The provider ABCS will transform the EBM into an ABM for the Siebel Clinical ClinicalSubject web service and retrieves the following information during the transformation:

a. The Siebel Clinical ID for the Protocol Site from the ClinicalStudyStudySite cross-reference table

b. The Siebel Clinical ID for the Subject from the ClinicalStudy_ClinicalStudySubjectId cross-reference table

c. The Clinical Subject status from the ClinicalStudySubject_Status DVM table.

7. A synchronous call is made to the Siebel Clinical ClinicalSubject web service; the ID of the newly created Subject is returned, which will then be added to the ClinicalStudy_ClinicalStudySubjectId cross-reference table.

Update Study Subject

1. When Patient Integration is enabled for a study in Oracle Clinical and information from the patient positions table, patient_statuses table is changed or the patient position assignment to a study site is changed, a Clinical Study ABM is written to the Clinical_Study_Queue AQ.
2. The message is picked up by the UpdateClinicalStudyOCAQConsumer adapter service and passed to the UpdateClinicalStudyOCHealthSciencesReqABCSImpl (requester ABCS).
3. The requester ABCS will retrieve the following for populating the UpdateClinicalStudyEBM:

   a. Clinical Study Subject identification from the ClinicalStudy_ClinicalStudySubjectId cross-reference table

   b. Clinical Study Site identification from the ClinicalStudyStudySite cross-reference table.

   c. ClinicalStudySubject Status from the ClinicalStudySubject_Status DVM.

4. The message will then be transformed into an UpdateClinicalStudy EBM and passed to the HealthSciencesClinicalStudyEBS (EBS).
5. The EBS will follow routing rules to pass the EBM to the UpdateClinicalStudySEBLHealthSciencesProvABCSImpl (provider ABCS).
6. The provider ABCS will retrieve the following before transforming the EBM into an ABM for the Siebel Clinical web service:

   a. Siebel Clinical ID for the Protocol Site from the ClinicalStudyStudySite cross-reference table

   b. Siebel Clinical Row ID for the Subject from the ClinicalStudy_ClinicalStudySubjectId cross-reference table.

7. A synchronous call to the Siebel Clinical ClinicalSubject web service is made.

These processes are part of a global transaction. Compensating steps will be taken if an error occurs at any point, which prevents the process completion.

Siebel Clinical Interfaces

The following Siebel artifacts are used by this integration:

Siebel Inbound Web Services:

Name	Schema
ClinicalSubject	Clinical Subject Internal Integration Object

For more information about Siebel web services, see the *Siebel Life Sciences Guide*, Version 8.1, Rev. D.

Oracle Clinical Interfaces

The following Oracle Clinical artifacts are used by this integration.

Outbound from Oracle Clinical event interfaces:

Oracle Clinical writes ClinicalStudy ABM to the CLINICAL_STUDY_QUEUE AQ.

Industry AIA Components

The integration workflow uses the following components:

- ClinicalStudy EBO
- HealthSciencesClinicalStudyEBSV1
- UpdateClinicalStudyEBM

The industry EBO and EBM XML Schema Definition (XSD) files can be located by EBO within the $AIA_HOME/AIAMetaData/AIAComponents/EnterpriseObjectLibrary/Industry/HealthSciences/EBO/ parent folder.

The industry EBS Web Services Description Language (WSDL) files can be located by EBO within the $AIA_HOME/AIAMetaData/AIAComponents/EnterpriseBusinessServiceLibrary/Industry/HealthSciences/EBO/ parent folder.

For detailed documentation of individual EBOs and EBMs, click the AIA Reference Doc link on EBO and EBM detail pages in Oracle Enterprise Repository or Oracle Clinical.

For more information about using the Oracle Enterprise Repository and configuring it to provide the AIA Reference Doc link, see *Oracle Fusion Middleware Developer's Guide for Oracle Application Integration Architecture Foundation Pack 11g Release 1*, "Configuring and Using Oracle Enterprise Repository as the Oracle AIA SOA Repository."

EBOs can be extended, for instance, to add new data elements. These extensions are protected, and will remain intact after a patch or an upgrade.

For more information, see *Oracle Fusion Middleware Concepts and Technologies Guide for Oracle Application Integration Architecture Foundation Pack 11g Release 1, "Understanding Extensibility".*

Integration Services

These are the services delivered with this integration:

- UpdateClinicalStudyOCAQConsumer

This is an AQ adapter consumer service that reads an XML message from the AIA_ClinicalStudyQ in the Oracle Clinical database. This service routes the ABM to the Requester ABCS, UpdateClinicalStudyOCHealthSciencesReqABCSImpl.

- UpdateClinicalStudyOCHealthSciencesReqABCSImpl

  This requester ABCS is responsible for transforming the Oracle Clinical ClinicalStudy ABM into an UpdateClinicalStudyEBM.

- HealthSciencesClinicalStudyEBS

  This EBS service is responsible for passing the message from the Requester ABCS to the Provider ABCS.

- UpdateClinicalStudySEBLHealthSciencesProvABCSImpl

  This Provider ABCS is responsible for transforming the UpdateClinicalStudyEBM into the appropriate ABMs to call the Siebel Clinical ClinicalSubject web service.

For more information about using the Oracle Enterprise Repository and configuring it to provide the AIA Reference Doc link, see *Oracle Fusion Middleware Developer's Guide for Oracle Application Integration Architecture Foundation Pack 11g Release 1*, "Configuring and Using Oracle Enterprise Repository as the Oracle AIA SOA Repository."

Chapter 4: Automating the Update of Activity Completion Date and Status Based on Data Entered in Oracle Clinical or Oracle Clinical Remote Data Capture (OCRDC)

This chapter provides an overview of automating the update of activity completion date and status based on data that is collected in Oracle Clinical or RDC and discusses:

Overview

In Siebel Clinical, activities are scheduled to happen at patient visits. The patient visit itself is also considered an activity. The data in Oracle Clinical can be used to send activity status information to Siebel Clinical. For this to happen, the completion criteria for an activity or visit must be defined. The completion criteria is defined by indicating which visit, DCIs, DCMs or DCM questions in Oracle Clinical must be completed for the activity or visit to be considered complete. An activity may be specific to a visit or could occur at multiple visits.

You can schedule a new batch job in Oracle Clinical that analyzes the patient data entered since the last time the batch job was run to see if the completion criteria have been met or changed. The process can be configured to run periodically on a custom schedule.

- When the Track Activities menu item selected and the study in context is not enabled for Subject Activity integration, an error occurs and you are prompted to select a new study.
- If the study context does not exist when the Track Activities menu is selected, you are prompted to select a new study.
- You can change the study context while in the Track Activities form by selecting **Special** > **Click Study** or **Change Study**.
- During the process the system will evaluate new patient data that has been modified since the last time the process ran to determine if activities are complete or not. If any activity completion criteria has been made active since the last time the process ran, all patient data is checked to see if any activities have been completed.

For more information about participating applications, see Setting Up the Participating Applications.

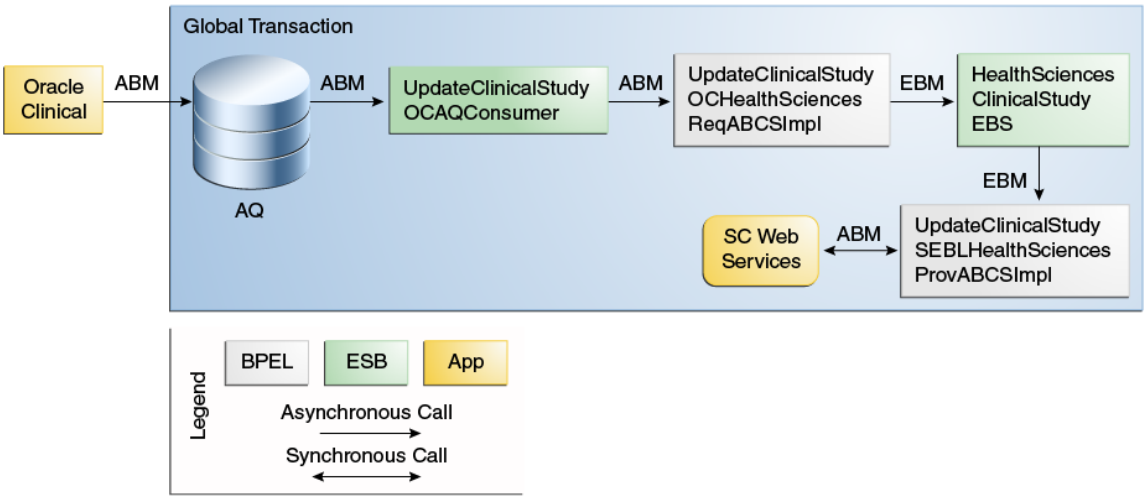
- The integration will send a message to Siebel Clinical to update the completed date and status of the activity or visit.

Clinical Study Subject Activity Flow

This section provides the activity diagrams and functional descriptions for Clinical Study Subject Activity Flow. This is not a synchronization flow but data from Oracle Clinical is used to update the completion date and status of a Subject activity or visit in Siebel Clinical.

Flow Diagram

The following diagram shows the Clinical Study Subject Activity flow:



Clinical Study Subject Activity flow

Update Subject Visit/Activity Completion

1. When Subject Activity Integration is enabled for a study in Oracle clinical and activity completion criteria have been defined, running the Track Activity batch job in Oracle Clinical will write a ClinicalStudy (ABM) to the Clinical_Study_Queue Advanced Queue (AQ) when the completion date of an activity has changed.

For more information about Oracle Clinical prerequisites, see Setting Up the Participating Applications.

2. The message will be picked up by the UpdateClinicalStudyOCAQConsumer adapter service and passed to the UpdateClinicalStudyOCHealthSciencesReqABCSImpl (requester ABCS).
3. The message will then be transformed into an UpdateClinicalStudy EBM and the ClinicalStudySubject Identification is retrieved from the ClincialStudy_ClinicalStudySubjectId cross-reference table.
4. The UpdateClinicalStudyEBM is passed onto the HealthSciencesClinicalStudyEBS (EBS).

5. The EBS will follow routing rules to pass the EBM onto the UpdateClinicalStudySEBLHealthSciencesProvABCSImpl (provider ABCS).
6. The provider ABCS will transform the EBM into an ABM for the Siebel Clinical web service. During this process the Siebel Clinical row id for the Subject from the ClinicalStudy_ClinicalStudySubjectId cross-reference table is retrieved.
7. A synchronous call is made to the Clinical Subject web service in Siebel Clinical.

These processes are part of a global transaction. Compensating steps will be taken if an error occurs at any point that prevents the process completion.

Siebel Clinical Interfaces

Siebel Inbound Web Services:

Name	Schema
ClinicalSubject	Clinical Subject Internal Integration Object

Oracle Clinical Interfaces

Outbound from Oracle Clinical event interfaces:

Oracle Clinical writes ClinicalStudy ABM to the CLINICAL_STUDY_QUEUE AQ.

Industry AIA Components

The integration flow uses the following components:

- ClinicalStudy EBO
- HealthSciencesClinicalStudyEBSV1
- UpdateClinicalStudyEBM

The industry EBO and EBM XML Schema Definition (XSD) files can be located by EBO within the $AIA_HOME/AIAMetaData/AIAComponents/EnterpriseObjectLibrary/Industry/HealthSciences/EBO/ parent folder.

The industry EBS Web Services Description Language (WSDL) files can be located by EBO within the $AIA_HOME/AIAMetaData/AIAComponents/EnterpriseBusinessServiceLibrary/Industry/HealthSciences/EBO/ parent folder.

For detailed documentation of individual EBOs and EBMs, click the AIA Reference Doc link on EBO and EBM detail pages in Oracle Enterprise Repository or Oracle Clinical.

For more information about using the Oracle Enterprise Repository and configuring it to provide the AIA Reference Doc link, see *Oracle Fusion Middleware Developer's Guide for Oracle Application Integration Architecture Foundation Pack 11g Release 1*, "Configuring and Using Oracle Enterprise Repository as the Oracle AIA SOA Repository."

EBOs can be extended, for instance, to add new data elements. These extensions are protected and will remain intact after a patch or an upgrade.

For more information, see *Oracle Fusion Middleware Concepts and Technologies Guide for Oracle Application Integration Architecture Foundation Pack 11g Release 1, "*Understanding Extensibility*".*

Integration Services

These are the services delivered with this integration:

- UpdateClinicalStudyOCAQConsumer

  This is an AQ adapter consumer service that reads an XML message from the AIA_ClinicalStudyQ in Oracle Clinical database. This service routes the ABM to the Requester ABCS, UpdateClinicalStudyOCHealthSciencesReqABCSImpl.

- UpdateClinicalStudyOCHealthSciencesReqABCSImpl

  This requester ABCS is responsible for transforming the Oracle Clinical ClinicalStudy ABM into an UpdateClinicalStudyEBM.

- HealthSciencesClinicalStudyEBS

  This EBS service is responsible for passing the message from the Requester ABCS to the Provider ABCS.

- UpdateClinicalStudySEBLHealthSciencesProvABCSImpl

  This Provider ABCS is responsible for transforming the UpdateClinicalStudyEBM into the appropriate ABMs that will call the appropriate Siebel Clinical web service.

Part 2: Implementing the Delivered Integrations

Chapter 5: Implementing the Study, Subject and Visit Synch: Siebel Clinical - Oracle Clinical Process Integration Pack

This chapter discusses:

Prerequisites

This section discusses the prerequisites for the following:

- Synchronizing Clinical Study Sites
- Synchronizing Clinical Study Subject Information
- Automating the Update of Activity Completion Date and Status Based on Data Entered in Oracle Clinical or Oracle Clinical Remote Data Capture (OCRDC)

Prerequisites for Synchronizing Clinical Study Sites

In Oracle Clinical the state and country values for the site address should be a valid region defined in the system. Siebel Clinical provides a list of values for states and countries that can be customized by each company. You must populate the State and Country Domain Value Map (DVM) before the integration can be used.

For more information about DVMs, see Describing Domain Value Maps.

In addition to populating the DVM, there may be states and countries available in Siebel Clinical that are not recognized as regions in Oracle Clinical. Scripts have been provided to help you identify the missing regions. Run these scripts and compare the output. Enter any missing states or countries into Oracle Clinical as regions.

Note: While Oracle Clinical permits a hierarchy of regions, Siebel Clinical does not. You can enter countries and then enter the states as regions within the countries.

Downloading the Lists of States and Countries in Oracle Clinical

Perform the following steps to download a list of States and Countries in Oracle Clinical:

1. Log in to the Fusion Middleware Server and change directory to the following location under the AIA Home: $AIA_HOME/data/StudySubjectVisitSyncSCandOC/sql
2. Log in to SQL*PLUS as rxa_des user.
3. SQL*PLUS > start OracleClinicalRegionDataDownload.sql.
4. SQL*PLUS > exit.
5. Verify the list of States and Countries in the OracleClinicalRegionDataDownload.out file.

Downloading the Lists of States and Countries in Siebel Clinical

Perform the following steps to download a list of States and Countries in Siebel Clinical: For Oracle Database:

1. Log in to the Fusion Middleware Server and change directory to the following location under the AIA Home: $AIA_HOME/data/StudySubjectVisitSyncSCandOC/sql
2. Log in to SQL*PLUS as Siebel table owner.
3. SQL*PLUS > start SiebelClinicalRegionDataDownload.sql.
4. SQL*PLUS > exit.
5. Verify the list of States and Countries in the SiebelClinicalRegionDataDownload.out file.

For MS SQL Server:

Perform the following steps to run the script:

1. Ensure that the MS SQL Server client is installed in the user machine.
2. Create a system DSN for the database connection to the Siebel database.
3. Open the MS SQL Server Client and log into the database by using the System DSN created in the previous step.
4. Run the SQL script file - SiebelClinicalRegionDataDownload.sql.

Output File Format

The output file format is as follows:

Region Code~Name~Description~Region Type Code

ASIA~ASIA~ASIA continent~CONT

EUROPE~Europe~Europe~CONT

DE~Germany~Germany~COUNTRY

IND~INDIA~INDIA~COUNTRY

Prerequisites for Synchronizing Clinical Study Sites

You must populate the ClinicalStudySubjectStatus DVM.

For more information about DVMs, see Describing Domain Value Maps.

Prerequisites for Automating the Update of Activity Completion Date and Status Based on Data Entered in Oracle Clinical or Oracle Clinical Remote Data Capture (OCRDC)

You must define Clinical Items for each activity and visit in the active Subject Visit Templates in Siebel Clinical.

For more information about defining clinical items in Siebel Clinical, see the *Siebel Life Sciences Guide*, Version 8.1, Rev. D.

In Oracle Clinical, the study must have the Subject Activity integration enabled.

You must enter each Clinical Item as an Activity in the Maintain Activity Completion Criteria form and the completion criteria defined for it.

You must schedule the Track Activities batch job to run on a regular basis.

For more information about Oracle Clinical prerequisites, see Setting Up the Participating Applications.

Data Requirements

Data requirements indicate the mandatory data that must be provided to make the integration flows successful.

This section discusses the data requirements of the following process integrations:

- Synchronizing Clinical Study Sites
- Synchronizing Clinical Study Subject Information
- Automating the Update of Activity Completion Date and Status Based on Data Entered in Oracle Clinical or Oracle Clinical Remote Data Capture (OCRDC)

Data Requirements for Synchronizing Clinical Study Sites

The following Protocol Site information is required for the integration to successfully create and update a Study Site in Oracle Clinical:

A primary address must be defined for the Protocol Site. The primary address must include these defined values:

- Address Line
- City

- State
- Zip Code
- Country
- Phone

Each principal investigator assigned to a Protocol Site must have these defined values:

- First Name
- Last Name
- Phone Number

Data Requirements for Synchronizing Clinical Study Subject Information

The Patient Position enrollment date in Oracle Clinical must be populated for a subject to be assigned an Enrollment Visit Template in Siebel Clinical.

Data Requirements for Automating the Update of Activity Completion Date and Status Based on Data Entered in Oracle Clinical or Oracle Clinical Remote Data Capture (OCRDC)

For more information about defining clinical items in Siebel Clinical, see the *Siebel Life Sciences Guide*, Version 8.1, Rev. D.

For more information about mapping activity completion criteria in Oracle Clinical, see Defining Completion Criteria.

Setting Up the Participating Applications

This section describes how to set up Siebel Clinical and Oracle Clinical to utilize the integration.

Setting up Siebel Clinical

This section describes the tasks and general procedures that you must complete to integrate a Siebel Clinical protocol with an Oracle Clinical study.

For more information about configuring Siebel Clinical for integration with Oracle Clinical, see the *Siebel Life Sciences Guide*, Version 8.1, Rev. D.

Synchronizing Clinical Study Sites

Study site information is entered as a Protocol Site in Siebel Clinical and is used to create a Study Site in Oracle Clinical. This integration is uni-directional, from Siebel Clinical to Oracle Clinical.

For Study Sites to be synchronized between Siebel Clinical and Oracle Clinical, you must assign the CDMS Study ID for the protocol and select the **Synchronize Active Sites** check box. When the Siebel Clinical Protocol Site is ready to be synchronized with the associated Oracle Clinical study, you must select a primary address from the list of Protocol Site addresses and select the **Activate Synchronization** check box. When this is complete the Oracle Clinical study and the Siebel Clinical protocol are linked and the first Siebel Clinical protocol site is associated with a newly created study site in Oracle Clinical.

When the Activate for Synchronization flag is selected for a Protocol Site in Siebel Clinical, a Study Site is created in Oracle Clinical. If the principal investigator responsible for the protocol site does not exist in Oracle Clinical, one is created.

The combination of the primary address of the Protocol Site and the Account are considered as a Site in Oracle Clinical. If this combination does not exist, a new site is created in Oracle Clinical.

Updates to the investigator, site or study site in Siebel Clinical are synchronized to Oracle Clinical. Updates made in Oracle Clinical for investigator, site or study site are not synchronized back to Siebel Clinical. Deletion of a principal investigator account or protocol site in Siebel Clinical will not result in deletion of any objects in Oracle Clinical.

For more information about configuring Siebel Clinical for integration with Oracle Clinical, see the *Siebel Life Sciences Guide*, Version 8.1, Rev. D.

For more information about configuring relevant integration components, see Synchronizing Clinical Study Sites.

Synchronizing Clinical Study Subject Information

After you have enabled Patient Integration for an Oracle Clinical study, the synchronization process for patient information can be initiated. In Oracle Clinical, Patient Positions are created for the target enrollment of a study and assigned to study sites based on the target enrollment for the study site. If the enrollment date is entered for a patient position, it indicates that a patient has been enrolled in the study and assigned an Enrollment ID. This creates a subject for the appropriate Protocol Site in Siebel Clinical and the active Enrollment Visit Template to be assigned to the subject.

If data is collected for a patient position in Oracle Clinical or OC RDC, and no enrollment date has been specified, the system assumes this to be a patient undergoing the screening process and assigns a Screening ID. This creates a subject for the appropriate Protocol Site in Siebel Clinical and assigns the active Screening Visit Template to it.

Although Siebel Clinical requires the subject's initials and birth date to create a subject, this information is not mandatory in Oracle Clinical. If the patient's initials are not entered in Oracle Clinical, the Enrollment ID is used as the Initials in Siebel Clinical. If the patient's birth date is not entered in Oracle Clinical, the birth date is set to Jan 1, 1800 in Siebel Clinical. This is an invalid date that can be used to identify subjects whose information should be updated. You can then manually correct the data in Siebel Clinical, if desired.

The Informed Consent Date is not collected in Oracle Clinical. Therefore, subjects that are created in Siebel Clinical by the integration will have the Informed Consent Date set to the birth date of the subject. This will alter the dates in the Visit Schedule for the subject and should be manually corrected in Siebel Clinical.

When Siebel Clinical assigns a Screening Visit Template to a subject, the screen date is required. This is not a required field in Oracle Clinical. Therefore, if this date is not collected for a subject in Oracle Clinical, the system will populate a default value of Jan 1, 1900. This will impact the dates in the Visit Schedule for the subject and should be manually corrected in Siebel Clinical.

For more information about synchronization, see Create/Update Study Subjects Business Process Flow and Synchronizing Clinical Study Subject Information.

Automating the Update of Activity Completion Criteria

In Siebel Clinical, activities are scheduled to occur at patient visits. The patient visit itself is also considered an activity. Based on completion criteria you have defined for an activity or visit, the data in Oracle Clinical can be used to send information about the status of an activity to Siebel Clinical. Completion criteria are defined by indicating which visit, DCIs, DCMs or DCM questions in Oracle Clinical must be completed for the associated activity or visit to be considered complete.

Clinical Items

In Siebel Clinical, Subject Visit Templates are defined for screening and enrollment visits. When protocols are amended, new versions of Subject Visit Templates are created and activated. Although the same activity may occur at different visits in a Subject Visit Template or across different versions of a visit template, Siebel Clinical treats each activity as a separate entity.

To minimize the effort involved in defining the same completion criteria for the same activity multiple times, the concept of a clinical item has been introduced in Siebel Clinical. When a new activity is added to a Subject Visit Template, by default, the system sets the clinical item to the activity description.

Visits are also considered activities. When a new visit is added to a Subject Visit Template, the clinical item defaults to the visit name.

If a visit has the same completion criteria as that of a visit in another version or in an entirely different Subject Visit Template, the visits can be assigned to the same Clinical Item. This allows the completion criteria to be specified once in Oracle Clinical. However, the same clinical item cannot be added to more than one visit in the same Subject Visit Template version.

An example of this is a Screening Visit Template comprising two visits, Visit 1 and Visit 2. If a protocol amendment changes Visit 2, a new version of the Screening Visit Template would be created. You could create a clinical item value that is assigned to Visit 1 in both versions of the Screening Visit Template.

If a Subject Visit activity occurs at multiple visits or in multiple Subject Visit Templates or Subject Visit Template versions, the same clinical item can be assigned to that set of activities. For example, a clinical item can be assigned to the set of identical lab tests that are performed at each of the visits. This enables the completion criteria for that activity to be defined once in Oracle Clinical against a single clinical item.

For more information on defining clinical items, see the *Siebel Life Sciences Guide*, Version 8.1, Rev. D.

Setting up Oracle Clinical

In Siebel Clinical, when the Activate for Synchronization field is selected for a Protocol Site a corresponding Study Site is created in Oracle Clinical. A study site in Oracle Clinical cannot exist without Investigator and Site details so if the corresponding information is not available in Siebel Clinical it will be created in Oracle Clinical. These new objects are used to create the Study Site in Oracle Clinical. All sites and investigators transferred by the PIP are created as active.

Synchronizing Clinical Study Sites

In Oracle Clinical any updates made to a site or an investigator associated with an integrated study may be overwritten by updates from Siebel Clinical.

LocalStudySite.ChangeStudySite Procedure

It is recommended that you modify the PL/SQL procedure, LocalStudySite.ChangeStudySite, to prevent study sites created by user, RXA_WS, from being updated. This will prevent someone in Oracle Clinical from breaking the link between Protocol Site in Siebel Clinical and Study Site in Oracle Clinical.

Enabling the Integration

Oracle Clinical has two new options that facilitate the integration with Siebel Clinical. One option enables the transfer of patient_position information once the enrollment date has been entered or data has been entered against a patient position without an enrollment date. The other option permits completion criteria for Siebel Clinical activities to be defined in Oracle Clinical and send messages when those activities have been completed.

There are two new settings:

- Enable Patient Integration – When this is set to Y and the enrollment date is entered or data is entered for a patient position with no enrollment date, messages about patient_positions, patient_status, and the study sites assignments for the patient _positions are written to an Advanced Queue. All subsequent updates to these patient positions are sent to Siebel Clinical.
- Enable Subject Activity Integration – When this is set to Y, users will be able to define completion criteria for visits and activities in Siebel Clinical and schedule jobs to send messages to Siebel Clinical when the activities have been completed.

The following sections describe how to set these integrations at the database or study level:

Enabling Integration for All New Studies:

To enable integration at the database level for all new studies, navigate to **Admin** > **Integration Database Settings**.

The system displays the Integration Database Settings window. There are two integration settings available:

- Enable Patient Integration?
- Enable Subject Activity Integration?

For each setting the default value is N, which indicates that the integration is turned off. If you wish to enable one or both of these integrations on all new studies, change the settings to Y and all new studies will be created with the corresponding integrations enabled.

Note: Changing these settings will not affect any existing studies.

If you wish to enable the integration only for a few studies but not all, proceed to the study level settings described in the following section.

Enabling Integration for a Single Study:

To enable integration at the study level for an individual study, navigate to **Design** > **Integration Study Settings**. The system displays the Integration Study Settings window and specifies the active study. As at the database level, there are two integration settings available:

- Enable Patient Integration?
- Enable Subject Activity Integration?

The default values for these settings are based on the value of the database level setting defined in **Admin** > **Integration Database Settings** form at the time the study was created.

To enable the relevant integration for the study, change the value from N to Y.

Note: Both the Patient Integration and the Subject Activity Integration must be enabled to use the Subject Activity integration.

Synchronizing Clinical Study Subject Information

Enrollment Date and Informed Consent Date

Siebel Clinical requires an enrollment date to be specified for enrolled patients. If you use the CRF data entry instead of the Patient Positions form to capture this value, you can use the pat_sync function in a derivation procedure to populate the enrollment date in the Patient Positions table. You can also use pat_sync to enter the Informed Consent Date of a patient.

For more information about patient synchronization, see Oracle Clinical documentation, “Creating a Study.”

Automating the Update of Activity Completion Criteria

Track Activity Batch Process

The Track Activity process is a PSUB batch job, which evaluates all active completion criteria and determines if the patient data entered or updated since the last time the track activity job ran will cause the completion status or date of an activity or visit to change. If new activity completion criteria have become active since the last time the track activity job was run, all existing patient data for the study is examined.

To set up the Track Activity process, navigate to **Conduct** > **Data Validation** > **Track Activities**. The system displays the Track Activity Completion window.

- If no study context exists when the Track Activities menu is selected, the system will prompt you to select a new study.
- When you select the **Track Activities** menu item, if the study in context is not enabled for Subject Activity integration, the system will display an error and prompt you to select a new study.

If you want to change the study context while in the Track Activities window, select **Special** > **Click Study** or **Change Study**.

For more information about running, viewing, and scheduling PSUB jobs, see Oracle Clinical documentation.

Completion Criteria Processing

The following parameters define how the system will process completion criteria objects.

Completeness Criteria

1. A Received DCI (RDCI) or Received DCM (RDCM) that is marked blank is not considered complete.
2. If the study requires two passes, only an RDCI or RDCM with the status PASS 2 COMPLETE or BATCH LOADED is considered complete.
3. If the study does not require two passes, only a RDCI or RDCM with the status PASS 1 COMPLETE, PASS 2 STARTED, PASS 2 PENDING, PASS 2 COMPLETE or BATCH LOADED is considered complete.

Exception Processing

An activity will no longer be considered as complete:

1. If a DCI or DCM that was mapped to an activity is soft deleted.
2. If the blank flag is set to Y for a DCI or DCM that was mapped to an activity.
3. If a response value for a DCM Question that was mapped to an activity is modified to a value other than the one defined in the mapping.
4. If a response value for a DCM Question that was mapped to an activity is removed leaving the response empty.

   If the activity is no longer considered complete due to one of the preceding events, the following information is written to the database queue:

   a. Activity ID (Note that this is the clinical item that was selected for the Activity name in the Map Activities form)
   b. Study
   c. Study Site Code
   d. Patient
   e. Visit (Note that this will be the clinical item mapped to the Visit)
   f. Activity Code (can be VISIT or ACTIVITY)
   g. Blank value for Completed Date

Key Change Processing

1. If the patient key is changed for a RDCI or RDCM that was mapped to an activity, the activity is no longer considered complete for the old patient.
2. If the DCI book for an RDCI is either mapped to a DCI Book Visit or contains a RDCM or response mapped to a DCI Book Visit then the activity is no longer considered complete for the mapped visit.

3. If the visit for a RDCI is either mapped to an activity or contains a RDCM or response mapped to an activity then the activity is no longer considered complete for the old visit.

Updating Activity Queue

If the completed date for an activity has changed since the last time the process was run, the following information is written to the database queue:

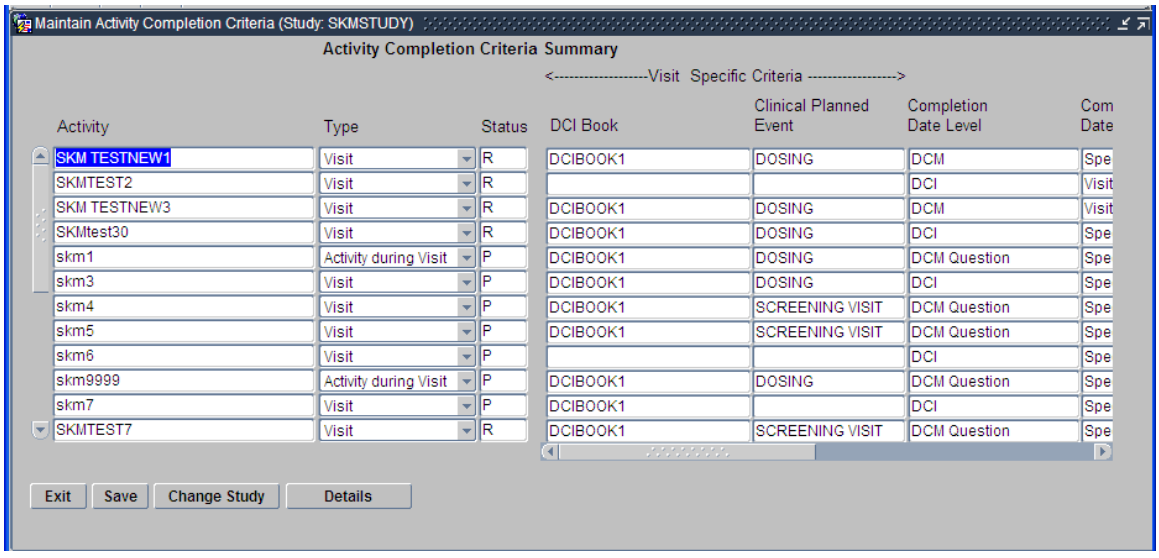
- Activity ID (Note that this is the clinical item that was selected for the Activity name in the Map Activities form)
- Study
- Study Site Code
- Patient
- Visit (Note that this is the clinical item mapped to the Visit)
- Activity Code (can be VISIT or ACTIVITY)
- Completed Date

Defining Completion Criteria

Oracle Clinical provides the means to map Siebel Clinical activities to Oracle Clinical study definition objects. The purpose of this portion of the integration is to allow events in Oracle Clinical – collection of specific data – to trigger the completion of associated activities in Siebel Clinical.

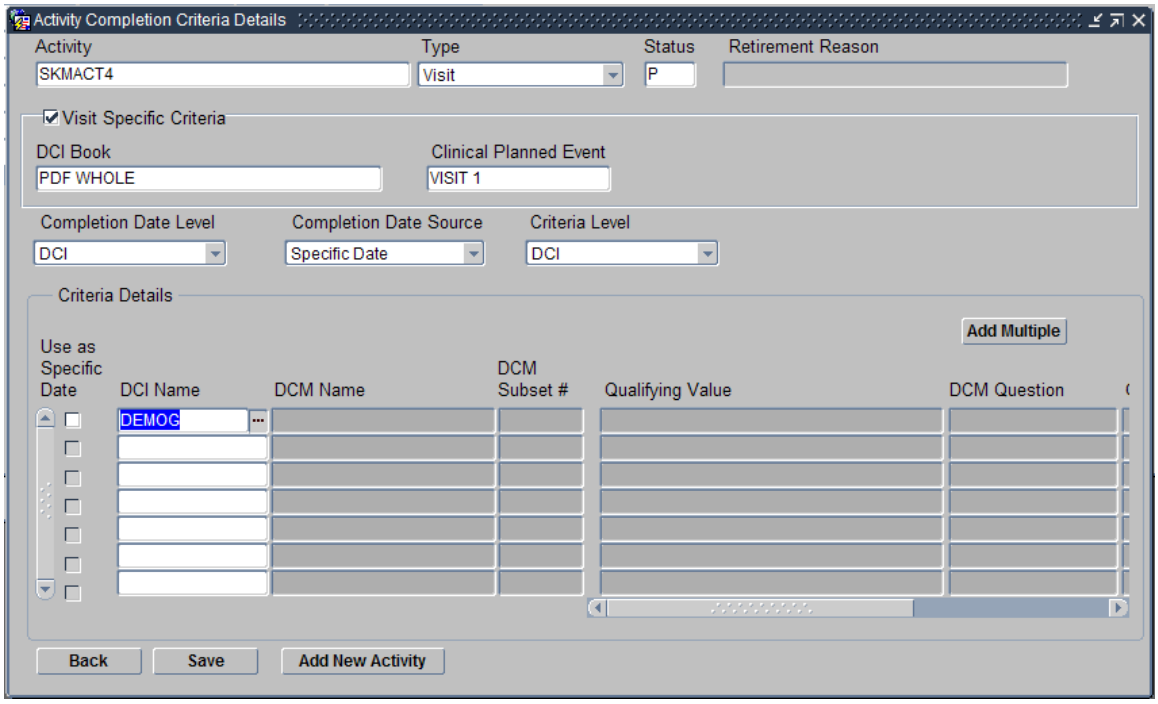
Maintain Activity Completion Criteria

To view or modify existing activities and create new ones, navigate to **Definition** > **Activity Completion Criteria**. The system displays the Maintain Activity Completion Criteria screen, which provides a summary of all existing activity completion criteria for the study.



Activity Completion Criteria Summary Screen

From the summary screen, click **Details** to display the Activity Completion Criteria Details screen, which lets you view or update the activity completion criteria for the selected activity.



Activity Completion Criteria Detail Screen

Updating an Existing Activity

After you select an existing activity in the Maintain Activity Completion Criteria window, click **Details** to view the Activity Completion Criteria Details window for the activity.

- **Save** saves changes on this screen to the database.
- **Back** returns to the Maintain Activity Completion Criteria window.
- If changes are pending when you click **Back**, the system provides the opportunity to cancel and save the changes first.

Adding a New Activity

When there are no existing activities listed in the Maintain Activity Completion Criteria window, you can create a new activity by selecting the **Data** > **Insert Record** menu item. If you select this method, you must enter all required fields in this multi-record window. Once all required fields are complete and you have saved the criteria, you can view it in the Activity Completion Criteria Details window.

When existing records are listed in the Maintain Activity Completion Criteria window, click **Add New Activity** to create a new activity from the Activity Completion Criteria Details window.

The Maintain Activity Completion Criteria window lets you enter an activity name and type. The activity value is the clinical item entered in Siebel Clinical. Activity type can be selected from a list. The activity type values are Visit or Activity during Visit.

Completion Criteria

Activity

Use the Activity field to associate the completion criteria with a clinical item defined in Siebel Clinical.

Activity Type

The completion criteria for an activity can be defined as an entire visit or as an activity that occurs in a visit. Use the Type field to select the appropriate value.

Activity Completion Criteria Status

1. Activity completion criteria can have a status of:
    a. A – Active
    b. P – Provisional
    c. R – Retired
2. The default status for an activity mapping is P.
3. The status can be changed from P to A if:
    a. At least one DCI, DCM or DCM question has been mapped and the completion date level and completion date function have been filled.
    b. If the criteria level is DCI, all DCIs specified are Active.
    c. If the criteria level is DCM, all DCMs specified are Active.
    d. If the criteria level is DCM question, all DCMs that the DCM questions are part of are Active.
4. You cannot change a mapping that is set to A.
5. The status can be changed from A to P. Changing the status to P does not affect any previously completed activity mappings. However, any data that is entered in the system while the status is set to P will not be mapped to an activity.
6. The status can be changed from A to R.
    a. Once a mapping is retired, patient data will no longer be mapped to it.
    b. You must specify a retirement reason when you change the status from A to R. The Retirement Reason field becomes editable when the status field is set to R.
7. The status can be changed from R to A but patient data that was entered while the mapping was retired will not be mapped to the activity.

Visit Specific Criteria

The completion criteria for an activity can be defined specific to a particular visit in a DCI Book or to a Clinical Planned Event (CPE) for the study.

Defining the activity completion criteria specific to a particular visit indicates that the activity is either the visit or CPE itself or that the activity can only occur at that visit or CPE.

If you define an activity as the visit or CPE itself, the list of objects that constitute the visit or CPE as complete must be entered.

This can be one of the following but not a combination of the different levels of objects:

- A List of DCIs
- A List of DCMs
- A DCM Question

Note: You must also follow these requirements when defining completion criteria for activities within visits.

The List of Values (LOV) for DCI Book will contain all Active and Provisional DCI Books defined for the Study.

- If a DCI Book is entered, the LOV for CPE will include the visits defined in the selected DCI Book.
- If a DCI Book is not entered, the LOV for CPE will include all the CPEs defined for the study.

If a visit or CPE is not specified when defining the Activity Completion criteria, the activity can occur at any visit or CPE. However, an activity cannot span visits or CPEs.

Completion Date Level

The completion date for each activity may be collected in a different manner based on your business practices and study requirements. Therefore, while defining activity completion criteria, you must indicate the location of the completion date for the visit or activity. If the completion date for an activity is being collected on the CRF, the level would be DCM Question. If the completion date is considered to be the visit date, you must specify whether you collect the visit date at the DCI level, DCM level or as a response to a DCM question.

Completion Date Source

If the level for completed date is specified as DCI or DCM, then the completion date for the visit or activity is the visit date itself. However, visits can span multiple days. You must choose how to determine the completion date at that level. The valid choices are:

- Visit Start Date – the system uses the earliest of the visit dates for the specified list of DCIs or DCMs.
- Visit End Date – the system uses the most recent of all the visit dates for the specified list of DCIs or DCMs.
- Specific Date – in this case, you must pick a particular DCI or DCM where the visit date and its value are specified.

If the level for completed date is specified as DCM Question then the completion date source will default to Specific Date and cannot be changed. The value of the DCM Question marked as containing the completed date is used as the completed date. Only a DCM question defined as type DATE can be selected as the completion source. A DCM question can only be selected as the completion date source if the criteria level is also a DCM question.

Completion Criteria Level

You may specify the completion criteria for an activity as one of the following but not a combination of the different levels of objects:

1. One or more DCIs or

2. One or more DCMs or
3. A DCM question that is not part of a repeating question group

Activity Completion Criteria Details

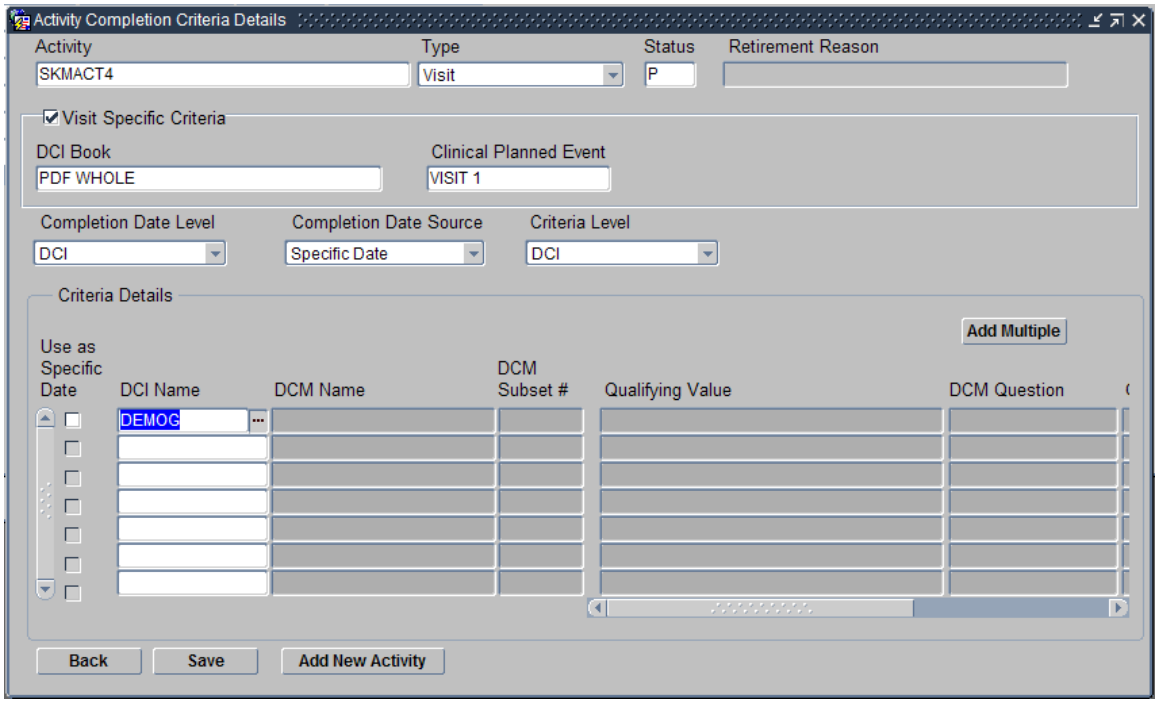
After you have defined the activity completion date level, date source, and the criteria level, there are two methods that you can use to choose data objects:

- The objects can be selected one at a time by using the Criteria Details section of the window.

  or

  You can use Add Multiple to select multiple objects.

- Once multiple objects are selected they are displayed on the lower half of the screen.
- The new objects will be added to the bottom of the list of existing selected objects and will not overwrite them.
- The records are not saved to the database until you click **Save** on the Activity Completion Criteria Details screen.



Entering DCIs One-at-a-Time

Specifying DCIs in Completion Criteria

After you have navigated to the Activity Completion Criteria Details window of the activity for which you want to define completion criteria and set the activity type and visit-specific criteria, you can specify the DCIs to include in completion criteria either individually or as a group.

The list of DCIs that you can select from is based on the study and the choices of the DCI Book and the Clinical Planned Event.

If you choose to select DCIs individually in the Criteria Details section:

1. Use the DCI Name LOV to display a list of DCIs. The DCIs LOV displays the DCI Name, DCI Type, and Status for each.
2. Highlight a DCI and click **OK**.
3. Repeat the process until all required DCIs are displayed in the Criteria Details list.

If you want to add more than one DCI at a time, select **Add Multiple**. The system displays the Multiple Selection DCIs window, which lists each DCI and displays its DCI Name, DCI Type, and Status.

Use the Select check box adjacent to each DCI to include it in the completion criteria. Click **Select All** to select all items in the list and **Clear All** to clear all selections in the list.

Specifying DCMs in Completion Criteria

After you have navigated to the Activity Completion Criteria Details window of the activity for which you want to define completion criteria and set the activity type and visit-specific criteria, you can specify the DCMs to include in completion criteria either individually or as a group. .

If you choose to select DCMs individually in the Criteria Details section:

1. Use the DCM Name LOV to display a list of DCMs.

   The LOV will display the name, subset, qualifying value, type and description of the DCM.

2. When a DCM subset is selected from the DCM Name LOV, the subset # (number) is filled in the form.
3. The Subset# field will have an LOV that displays the available subsets of the DCM populated in the DCM Name field. If no DCM name field is populated, the subset LOV will not pop up.
4. The Qualifying Value field will have an LOV that displays the discrete values of the qualifying question group discrete value group subset defined for the DCM.
5. Only the DCM Name, DCM Subset # (number) and Qualifying Value fields can be updated. All other fields cannot be edited. You can specify DCMs to be included in completion criteria either individually, as a group of DCMs, or by specifying a DCI.

If you want to add more than one DCM at a time, click **Add Multiple**. You can do this either by selecting each DCM or by selecting the parent DCI.

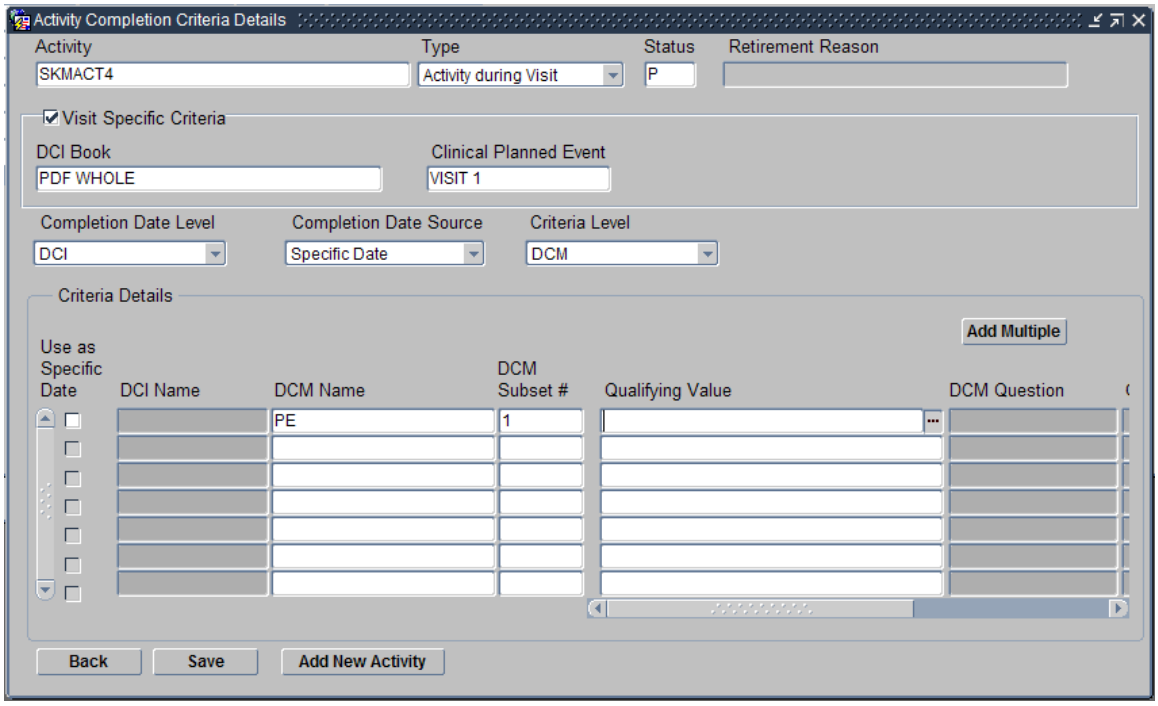
If you choose to select DCMs:

1. The system allows you to select multiple DCMs from the list.
2. Click **Select All** or **Clear All**, as appropriate to your selection.
3. When you click **OK**, the system displays DCMs you have selected in the Activity Completion Criteria Details screen.
4. If you click **Cancel**, the window closes and no selections will be displayed in the Activity Completion Details window.

If you choose to select DCIs:

1. The system displays a list of DCIs.
   a. Selecting a DCI and choosing DCI Modules displays the list of DCMs defined for that DCI.
   b. If the DCM subset selected has a qualifying value defined for it. This value is populated in the Qualifying Value field in the Activity Completion Criteria Details window.

2. If you choose DCM as the path to select the DCMs, the system displays the DCM multiple selection window.



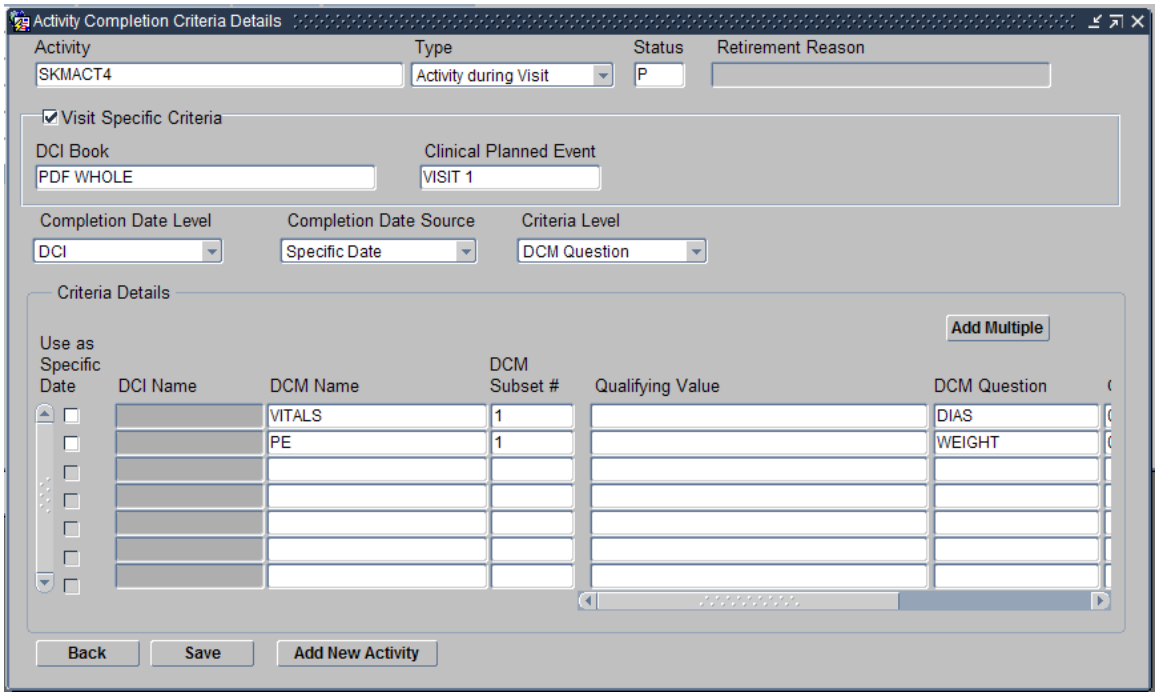
Entering DCMs One-at-a-Time

Specifying DCMs that must be completed for a Visit Specific activity

1. If the activity completion criteria has been defined as Visit Specific and a DCI Book entered, you will be able to navigate to the DCM level from the list of DCIs planned for the specific visit in the DCI book. Selecting the DCMs from the list indicates that the DCMs must be completed before the activity is considered complete.
2. Only DCMs that are planned for the visit can be selected.
3. If the same DCM exists more than once in the visit, you must select a qualifying value when mapping to the DCM. The system will not save the completion criteria until all required qualifying values have been selected.
4. If you did not select a DCI Book in the Specific Visit criteria, you can navigate to the DCM level from a list of all active or provisional DCIs defined for the study.

Specifying DCMs that must be completed for an activity to be considered completed for any visit

1. If you did not define the Activity Completion criteria as Visit Specific, you can select them from the list of Active or Provisional DCMs defined for the study. Selecting DCMs from the list indicates that the DCMs must be completed at a single visit before the activity is considered complete.
2. If the same DCM exists more than once in the visit, a qualifying value must be specified when mapping to the DCM. If qualifying values are not specified for the DCM, the completion criteria cannot be saved.



Entering DCM Questions One-at-a-Time

Specifying DCM Questions in Completion Criteria

You can choose to select DCM questions individually or as a set by selecting DCM Questions in the Activity Completion Criteria Details section.

1. Use the DCM Name LOV to display a DCM's the name, subset, qualifying value, type and description.
2. When a DCM subset is selected from the DCM Name LOV, the subset # (number) is filled in the form.
3. The Subset number LOV is displayed only when the DCM name is populated. It displays the available subsets of the DCM populated in the DCM Name field.
4. The Qualifying Value LOV displays the discrete values of the qualifying question group discrete value group subset defined for the DCM.
5. The DCM Question Name LOV displays the DCM questions that are collected in the DCM Subset that was chosen. It includes:
    a. DCM questions from non-repeating question groups
    b. DCM Question Group Name, the DCM Question Name and the occurrence number
    c. The LOV is sorted by the sequence of the DCM Question Group defined in the DCM.

You can click **Add Multiple** and select whether you want to locate DCM Questions by accessing the DCIs and DCMs and then drilling down them.

If you choose DCI as the method to select the DCM questions, the system displays a list of DCIs.

1. Select a DCI and its DCI Modules to display the list of DCMs defined for it.

2. Select a DCM Subset and click **DCM Question Groups** to display the list of non-repeating DCM Question Groups collected in the DCM Subset.
3. Select a DCM Question Group and click **DCM questions** to display a list of DCM questions collected in the DCM question group.
4. If you have used the DCMs to specify questions you can select multiple DCM questions from the list and then click the All or Clear All Selections buttons to select the correct set.
5. When you click **OK**, the selected DCM questions are displayed in the Activity Completion Criteria Details window.
6. When you click **Cancel**, the window closes and no selections are displayed in the Activity Completion Criteria Details window.

If you choose DCM as the path to select the DCMs, the system displays a list of all active and provisional DCMs in the study.

1. When you select a DCM Subset and click **DCM Question Groups**, the system displays a list of non-repeating DCM Question Groups collected in the DCM Subset along with their name and domain.
2. When you select a DCM Question Group and click **DCM Questions**, the system displays a list of DCM questions collected in the DCM question group.
3. The list of DCM Questions will include DCM Question Name, Occurrence and Type.

Specifying Responses to DCM Questions for Visit Specific Completion Criteria

If the completion criteria are defined as Visit Specific and a DCI Book was included in the definition of that specific visit, you can navigate to the DCM Question level for the DCIs planned for that specific visit.

- A response value can be specified to indicate that only the entered response value will meet the completion criteria for the activity.
- If the question is a DVG question, an LOV is available for selecting the correct Response value. The LOV will list the active values in the DVG Subset defined for the DCM question.
- DCM questions that are part of a repeating question group cannot be defined as completion criteria for an activity.

Specifying Responses to DCM Questions for Completion Criteria at Any Visit

If the activity completion criteria were not defined as Visit Specific, you can navigate to the DCM Question level for the DCMs defined in that study and select the questions you want to include in the criteria.

- You can specify a response value for a question. This will limit the activity to being considered complete when the response is collected.
- If you do not specify a response for a question, any value collected will meet the completion criteria.

Identifying Cross-References

Cross-references map and connect the records within the application network, and enable these applications to communicate in the same language. The integration server stores the relationship in a persistent way so that others can refer to it.

For more information about cross-references, see *Oracle Fusion Middleware Developer's Guide for Oracle SOA Suite*, "Working with Cross References".

These are the cross-references for Siebel Clinical to Oracle Clinical:

XREFTABLENAME	COLUMN NAME	DESCR	USAGE
CLINICALSTUDYSITE	COMMON	Concatenation of rowid of Account and row id of Primary Address for the Protocol Site in Siebel Clinical	Populated when a Site is created in Oracle Clinical during the Study Site integration.
	SEBLCLIN_01	Concatenation of rowid of Account and row id of Primary Address for the Protocol Site in Siebel Clinical	
	OC_O1	Concatenation of Site ID and Site (user identifier) from Oracle Clinical	
CLINICALSTUDYINVESTIGATOR	COMMON	Rowid for Contact in Siebel Clinical	Populated when an Investigator is created in Oracle Clinical during the Study Site integration
	SEBLCLIN_01	Rowid for Contact in Siebel Clinical	
	OC_O1	Concatenation of Investigator ID and Investigator (user identifier) in Oracle Clinical	
CLINICALSTUDYSTUDYSITE	COMMON	Concatenation of CDMS_STUDY_ID from Protocol in Siebel Clinical and Protocol Site Number	Populated when StudySite is created during StudySite integration.
	SEBLCLIN_01	ProtocolSiteId from Protocol Site in Siebel Clinical	
	OC_01	Concatenation of Clinical Study ID and Site ID in Oracle Clinical	

These are the cross-references for Oracle Clinical to Siebel Clinical:

XREFTABLENAME	COLUMN NAME	DESCR	USAGE
CLINICALSTUDYSTUDYSI	COMMON	Concatenation of	Used to look up Siebel

XREFTABLENAME	COLUMN NAME	DESCR	USAGE
TE		CDMS_STUDY_ID from Protocol in Siebel Clinical and Protocol Site Number	Clinical Study Site when subjects are created during the Subject Integration.
	SEBLCLIN_01	ProtocolSiteId from Protocol Site in Siebel Clinical	
	OC_01	Concatenation of Clinical Study ID and Site ID in Oracle Clinical	
CLINICALSTUDY_CLINICALSTUDYSUBJECTID	COMMON	Concatenation of Clinical Study Code (Study) and Patient Position Code (Patient) from Oracle Clinical	Populated when subjects are created during the Subject integration.
	SEBLCLIN_01	Rowid of the Subject in Siebel Clinical	
	OC_01	Patient Position ID for Patient Position in Oracle Clinical	

Working with Domain Value Maps

Domain value maps (DVMs) are a standard feature of the Oracle SOA Suite and enable you to equate lookup codes and other static values across applications. For example, “FOOT” and “FT” or “US” and “USA.”

DVMs are static in nature, though administrators can add and update additional maps as needed. Transactional business processes never update DVMs—they only read from them.

These are the DVMs for Study, Subject and Visit Synch: Siebel Clinical - Oracle Clinical PIP:

DVM Type	DVM Column Name	Comments
COUNTRY	COMMON, SEBLCLIN_01, OC_O1	This maps the country codes between Siebel Clinical and Oracle Clinical.
STATE	COMMON, SEBLCLIN_01, OC_O1	This maps the state codes between Siebel Clinical and Oracle Clinical.
CLINICALSTUDYSUBJECT_STATUS	COMMON, SEBLCLIN_01, OC_01	This maps the patient status defined by customers in Oracle Clinical to the Subject status in Siebel Clinical.

For more information about working with DVMs, see *Oracle Fusion Middleware Developer's Guide for Oracle SOA Suite 11g Release 1,* “Working with Domain Value Maps" and "Using Oracle SOA Composer with Domain Value Maps".

Handling Errors

Based on the roles defined for the services, email notifications are sent if a service errors out. There are no AIA specific errors thrown by the Process Integration for Product Management services.

For more information about Oracle Clinical errors, see the Oracle Clinical documentation.

For more information about AIA error handling, see the Oracle Application Integration Architecture – *Foundation Pack: Core Infrastructure Components Guide,* "Setting Up and Using Error Handling and Logging."

Viewing Enterprise Business Object Implementation Maps

For more information about how services are mapped, see the My Oracle Support document: EBO Implementation Maps (EIMs) 881022.1.

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