

**Oracle® Study, Subject, and Visit
Synchronization Integration Pack for Siebel
Clinical and Oracle® Clinical 2.5 - Implementation
Guide**

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Oracle Study, Subject, and Visit Synchronization Integration Pack for Siebel Clinical and Oracle Clinical 2.5 -
Implementation Guide

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Study Subject and Visit Sync: Siebel Clinical – Oracle Clinical Process Integration Pack for AIA Service Pack 2.5 – Implementation Guide Preface

This preface discusses:

- Oracle Application Integration Architecture - Foundation Pack: Core Infrastructure Components Guide
- The Oracle Application Integration Architecture - Foundation Pack: Concepts and Technologies Guide
- Oracle Application Integration Architecture - Foundation Pack: Integration Developer's Guide
- Oracle Application Integration Architecture Process Integration Packs
- Additional resources

Oracle Application Integration Architecture - Foundation Pack: Core Infrastructure Components Guide

The *Oracle Application Integration Architecture - Foundation Pack: Core Infrastructure Components Guide* provides conceptual, setup, and usage information for the following Core Infrastructure Components:

- The Business Service Repository (BSR)
- The Composite Application Validation System (CAVS)
- Error handling and logging
- The Diagnostics Framework

Oracle Application Integration Architecture Foundation Pack Concepts and Technologies Guide

The *Oracle Application Integration Architecture - Foundation Pack: Concepts and Technologies Guide* is a companion volume to the *Oracle Application Integration Architecture - Foundation Pack: Core Infrastructure Components Guide* and *Oracle Application Integration Architecture - Foundation Pack: Integration Developer's Guide*. The *Oracle Application Integration Architecture - Foundation Pack: Concepts and Technologies Guide* provides definitions of fundamental Oracle Application Integration Architecture (AIA) concepts and discusses:

- Oracle AIA
- Enterprise business objects and enterprise business messages
- Enterprise business services
- Application business connector services
- Interaction patterns
- Extensibility
- Versioning
- Business processes
- Batch processing
- Infrastructure services
- Security

Oracle Application Integration Architecture - Foundation Pack: Integration Developer's Guide

The *Oracle Application Integration Architecture - Foundation Pack: Integration Developer's Guide* is a companion volume to *Oracle Application Integration Architecture - Foundation Pack: Concepts and Technologies Guide* and *Oracle Application Integration Architecture - Foundation Pack: Core Infrastructure Components Guide*.

The *Oracle Application Integration Architecture - Foundation Pack: Integration Developer's Guide* discusses how to:

- Create an integration scenario.
- Define business service patterns.
- Design and develop enterprise business services.
- Design and develop enterprise business flows.
- Design and construct application business connector services.
- Work with message transformation, enrichment, and configuration.

- Develop custom xpath functions.
- Design and construct JMS Adapter services.
- Work with enterprise message headers.
- Work with message routing.
- Work with transactions.
- Develop Oracle AIA services to work with the Composite Application Validation System (CAVS).
- Configure Oracle AIA processes to be eligible for error handling and logging.
- Extend enterprise business objects.

In addition, this book provides, Application Integration Architecture naming standards.

Oracle Application Integration Architecture Process Integration Packs

A process integration pack (PIP) is a prebuilt set of integrated orchestration flows, application integration logic, and extensible enterprise business objects and services required to manage the state and execution of a defined set of activities or tasks between specific Oracle applications associated with a given process. A PIP provides everything you need to deploy a selected integrated business process area. The PIP product offering is suited to customers seeking to rapidly implement a discreet business process.

Additional Resources

The following resources are available:

Resource	Location
Installation Guide	My Oracle Support https://metalink.oracle.com/
Documentation updates	My Oracle Support https://metalink.oracle.com/
Release Notes	Oracle Technology Network http://www.oracle.com/technology/
Known issues, workarounds, and most current list of patches	My Oracle Support https://metalink.oracle.com/
Siebel Life Sciences Guide, Version 8.1, Rev. C	My Oracle Support https://metalink.oracle.com/

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

This chapter provides an overview of the Study, Subject and Visit Synchronization Integration Pack and discusses the:

- Key Benefits of the PIP
- Participating Applications
- Business Process Flows
- Solution Assumptions and Constraints

Key Benefits of the PIP

The Oracle Study, Subject, and Visit Synchronization Process Integration Pack for Siebel Clinical and Oracle Clinical (OC-SC PIP) provides integration between two complementary clinical technology applications.

The Oracle Clinical-Siebel Clinical PIP includes these processes:

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

The OC-SC PIP enables the timely exchange of data between Oracle Clinical and Siebel Clinical. Information sent from Siebel Clinical, including investigator and site details to facilitate the automatic creation of a study site, removes necessity of a manual Site, Investigator, and Study Site creation process. 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 more 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 provides a means to more accurately track and respond to issues around site performance and protocol adherence.

General Business Process

- In Siebel Clinical sites are created at a protocol level. Siebel Clinical sends information to Oracle Clinical about the protocol site, including address, investigator name, and site #. This information is used to automatically create or update Investigators, Sites and Study Sites in Oracle Clinical.
- When a patient is enrolled in a study or begins 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.

- In Siebel Clinical, activities can be scheduled 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.

Terminology and Key Concepts

Coordinating Terminology

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 the investigator on the study is associated with. 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. In Oracle Clinical the same site cannot be included 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	In Oracle Clinical, an identifier 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, the subject is assigned to a Patient Position.
Subject	Patient	Persons recruited by investigators that participate on 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.

Siebel Clinical Term	Oracle Clinical Term	Definition
Subject Visit Schedule		Based upon the Subject Visit Template, the planned schedule of events for a particular subject at a Site. 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) that can be used to assign a completion date to a Siebel Clinical activity.
Activity	None	In Siebel Clinical, required procedures or tasks in the Visit schedule

Business Process Flows

Create/Update Study Sites

Description

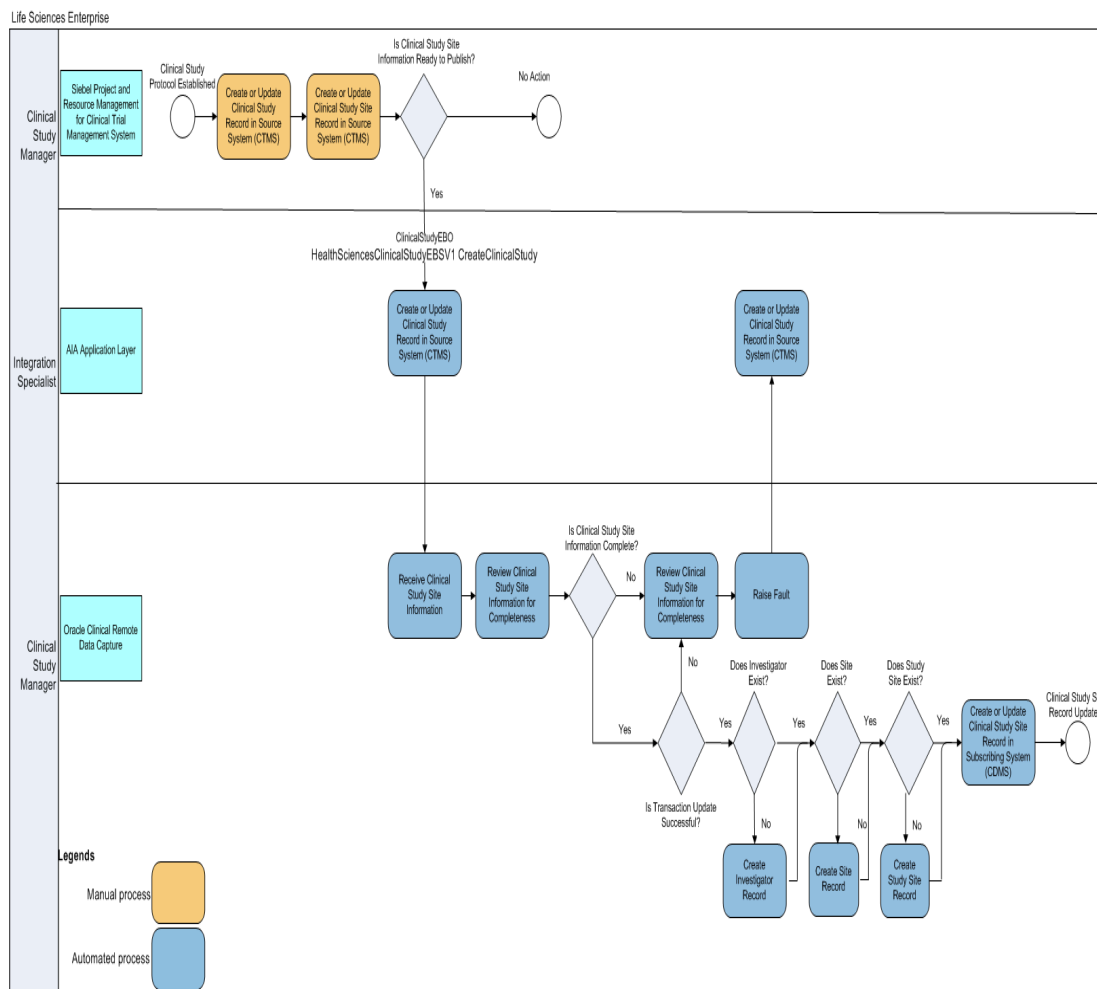
During the Study set up process, Protocols are created in Siebel Clinical under a Program. Clinical Studies are defined in Oracle Clinical under a Program and Project. To utilize this integration, the user must manually enter Study code from Oracle Clinical into the CDMS Study ID field of the Protocol 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 triggers the creation of a study site in Oracle Clinical. All future updates to the Protocol Site will be sent to Oracle Clinical. If the principal investigator assigned responsibility for the Protocol Site does not exist in Oracle Clinical, the system will create it.

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

Flow Diagram

This figure shows the Create/Update Study Sites flow:



Create/Update Study Sites Flow Diagram

Create/Update Study Subjects

Description

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. If the enrollment date is entered for a patient position, this indicates a patient has been enrolled in the study and assigned this Enrollment ID. This triggers a subject to be created for the appropriate Protocol Site in Siebel Clinical and the subject is screened and enrolled against the active Subject Visit Template.

If data is entered for a patient position, in Oracle Clinical or Oracle Clinical Remote Data Capture, and no enrollment date has been specified, this is assumed to be a patient undergoing the screening process assigned this Screening ID. This triggers a subject to be created for the appropriate Protocol Site in Siebel Clinical and the subject is 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 as the Initials in Siebel Clinical. If the date of birth of the patient was not entered in Oracle Clinical, the birth date is set to Jan 1, 1800 in Siebel Clinical. This date of Jan 1, 1800 should be recognized by a user as an invalid date of birth. The correct data can be manually entered in Siebel Clinical, if desired.

When Siebel Clinical assigns an Enrollment Visit Template to a subject, the date the informed consent was signed is required. Informed Consent Signature date is an optional field in Oracle Clinical. If it is not entered in Oracle Clinical, the Informed Consent Date is set to Jan 1, 1900 in Siebel Clinical. This will adversely impact the dates in the Visit Schedule for the subject and should be corrected by the user manually 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 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 should be corrected by the user manually in Siebel Clinical.

Flow Diagram

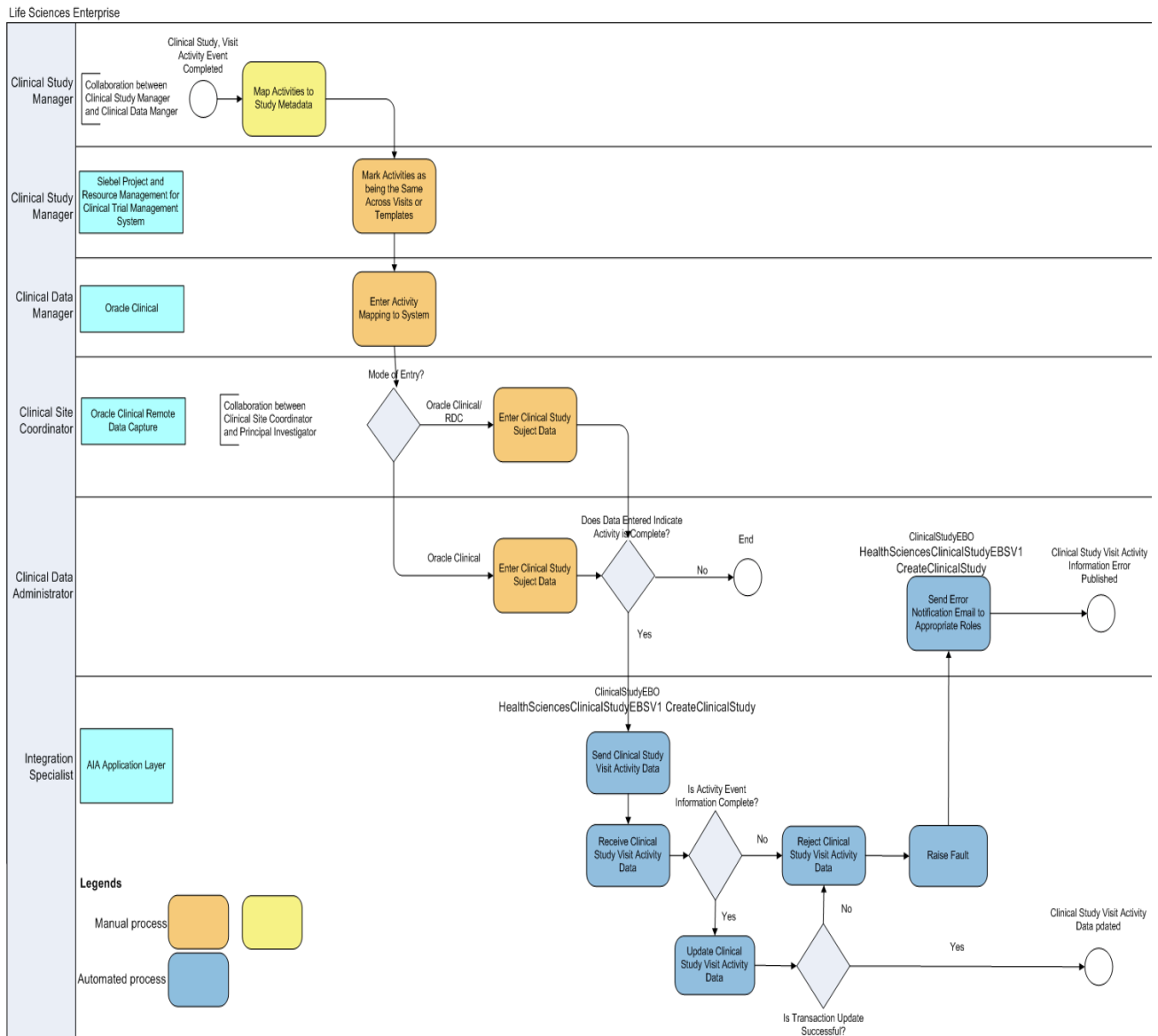
The figure shows the Create/Update Study Subjects flow:

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

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

Flow Diagram

This figure 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

Assumptions

1. For the Clinical Study Subject flow integration to proceed, you must populate the Enrollment date for a patient in Oracle Clinical. This can be done through the Patient Positions form, by loading enrollment dates in Oracle Clinical data entry, 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 re-assignment of the principal investigator for a protocol site will not cause the investigator to be deleted from Oracle Clinical.
3. Deletion of a study site in Oracle Clinical when a protocol site is deleted in Siebel Clinical may not be desired and thus is not currently part of this integration.
4. Since patient data can be deleted and then re-entered in Oracle Clinical, it would not be desirable to remove the subject in Siebel Clinical when enrollment date was blanked out or patient data was removed.

Constraints

1. There is no direct mapping of a Program in Siebel Clinical to a Program or Project in Oracle Clinical. Protocols are created in Siebel Clinical under a Program. Clinical Studies are created in Oracle Clinical under a Program and Project. Therefore, the mapping of a Clinical study to a Protocol is a manual process.
2. The address for an investigator is not required in Oracle Clinical. Since synchronization of investigators would be a separate business process, the address will not be populated for an investigator in Oracle Clinical by this integration.
3. Unplanned visits in Oracle Clinical will not be associated with Siebel Clinical activities. Since no mapping would exist, Oracle Clinical would not be able to determine an unplanned activity had been completed.
4. Due to size limitations in Oracle Clinical for Study Site code, the Protocol Site Number cannot be more than 10 characters long. We recommend that you incorporate this length restriction in your Siebel Clinical environment to avoid errors.
5. The changes to data about an investigator such as last name or phone number do not come over to Oracle Clinical until something else about 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 covers:

- Integration Flows
- Data Requirements
- Siebel Clinical Interface
- Oracle Clinical Interfaces
- Core AIA Components
- Integration Services

Synchronizing Clinical Study Sites Overview

Information about a study site is entered as a Protocol Site in Siebel Clinical and a Study Site in Oracle Clinical. This integration is uni-directional, from Siebel Clinical to 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 as an investigator in Oracle Clinical, an investigator is created in Oracle Clinical for that principal investigator.

The combination of the primary address for the Protocol Site and the Account is considered 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 does not cause deletion of any objects in Oracle Clinical.

Prerequisites

Oracle Clinical requires that the state and country values entered for the address of a site are a valid region defined in Oracle Clinical. 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 DVM before the integration can be used. Refer to the [Describing Domain Value Maps](#) section in Chapter 5 for additional information.

In addition to populating the DVM, there may be states and countries available in Siebel Clinical that do not exist as regions in Oracle Clinical. Scripts have been provided to help identify the missing regions. Run the scripts listed for Oracle Clinical and Siebel Clinical. Compare the output and enter any missing states or countries into Oracle Clinical as regions.

Note: Oracle Clinical allows 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

1. Login to the Fusion Middleware Server and change directory to the following location located under the AIA Home: PIPS/Core/Setup/SiebelClinicalOracleClinical/Install/Utility
2. Login to SQL*PLUS as rxa_des user.
3. SQL*PLUS > start OracleClinicalRegionDataDownload.sql
4. SQL*PLUS > exit

Downloading the Lists of States and Countries in Siebel Clinical

For Oracle Database:

1. Login to the Fusion Middleware Server and change directory to the following location located under the AIA Home: PIPS/Core/Setup/SiebelClinicalOracleClinical/Install/Utility
2. Login to SQL*PLUS as SADMIN user.
3. SQL*PLUS > start SiebelClinicalRegionDataDownload.sql
4. SQL*PLUS > exit

For MS SQL Server:

Perform the following steps to run the script.

1. Make sure 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.
4. Run the SQL script file - SiebelClinicalRegionDataDownload.sql.

Output File Format

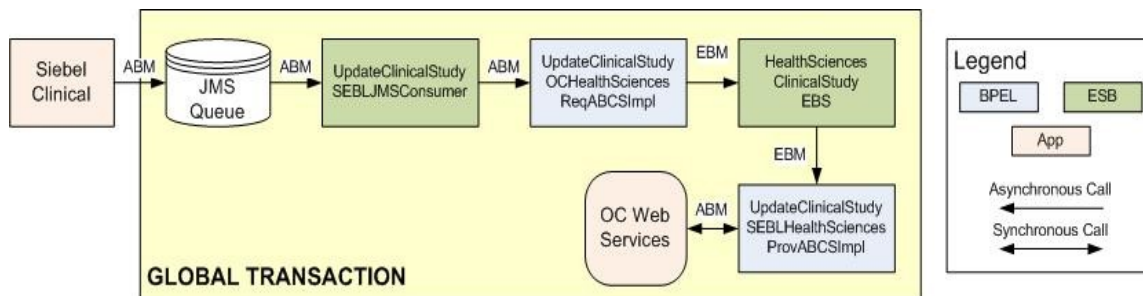
The output file format is as following.

```
Region Code~Name~Description~Region Type Code
ASIA~ASIA~ASIA continent~CONT
EUROPE~Europe~Europe~CONT
DE~Germany~Germany~COUNTRY
IND~INDIA~INDIA~COUNTRY
```

Study Site Integration Flow

Flow Diagram

This figure 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 will write a message (ABM) to the AIA_CLINICALSTUDYQ JMS Queue.
2. The ABM is picked up by the Adpater_UpdateClinicalStudySEBLJMSr consumer service and passed to the UpdateClinicalStudySEBLHealthSciencesReqABCSImpl (requestor ABCS).
3. The requestor ABCS will transform the ABM into an UpdateClinicalStudyEBM, populating the ClinicalStudyInvestigator, ClinicalStudySite and ClinicalStudyStudySite cross-reference tables as it does so. It will retrieve State and Country information for the Site Address from the State and Country domain value map tables.
4. The EBM is then passed onto the HealthSciencesClinicalStudyEBS (EBS).
5. The EBS will pass the EBM to the UpdateClinicalStudyOCHHealthSciencesProvABCSImpl (provider ABCS) based on the routing rules with which it has been configured.
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 length of the value specified for investigator in the CreateInvestigator ABM is greater than 10 characters, the value of investigator 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 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 State and Country domain value map tables.
10. The ABM is then passed to the appropriate Oracle Clinical Web service.
11. If the length of the value specified for site in the CreateSite ABM is greater than 10 characters, the value of site 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 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; the ID of the newly created StudySite is returned, which can then be added to the ClinicalStudyStudySite cross-reference table.

Update Study Site Flow

1. When a Protocol Site has Activate for Synchronization check box selected and any information about Protocol Site is updated, for example, Address of Protocol Site, Siebel will write a message (ABM) to the AIA_CLINICALSTUDYQ JMS Queue.
2. The message is picked up by the Adapter_UpdateClinicalStudySEBLJMS consumer service and passed to the UpdateClinicalStudySEBLHealthSciencesReqABCSImpl (requestor ABCS).
3. The requestor ABCS will transform the ABM into an UpdateClinicalStudy EBM.
4. The EBM will contain integration IDs for the Investigator, Site and StudySite, which are retrieved from the corresponding cross-reference tables. The values for state and country in the site address are retrieved from the State and Country domain value maps.
5. The EBM is then passed onto the HealthSciencesClinicalStudyEBS (EBS).
6. The EBS passes the EBM to the UpdateClinicalStudyOCHHealthSciencesProvABCSImpl (provider ABCS), based on the routing rules with which it has been configured.
7. 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.
8. If the length of the value specified for investigator in the CreateInvestigator ABM is greater than 10 characters, the value of investigator is replaced with the sequence number used for the investigator_id field in the ocl_investigators table.
9. If a new Investigator has been created, the ClinicalStudyInvestigator cross-reference table is updated.
10. The provider 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 state and country for the site address are retrieved from the State and Country domain value map tables.
11. The ABM is then passed to the appropriate Oracle Clinical Web service.
12. If the length of the value specified for site in the CreateSite ABM is greater than 10 characters, the value of site is replaced with the sequence number used for the site_id field in the ocl_sites table.
13. If a new Site has been created the ClinicalStudySite cross-reference table is updated.
14. The provider then transforms the EBM into either an “Update StudySite” ABM, which includes Oracle Clinical identifiers for the Site and Investigator (from the corresponding cross reference tables).
15. A synchronous call to the Oracle Clinical Web service is made.

Data Requirements

The following information must be entered for a Protocol Site for the integration to successfully create/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

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.

Core AIA Components

The integration flow uses the following components:

- ClinicalStudy EBO
- HealthSciencesClinicalStudyEBSV1
- UpdateClinicalStudyEBM

The core EBO and EBM XSD files can be located by EBO within this parent folder:
[http://\[HOST:PORT\]/AIAComponents/EnterpriseObjectLibrary/Core/EBO/](http://[HOST:PORT]/AIAComponents/EnterpriseObjectLibrary/Core/EBO/).

The core Oracle Clinical WSDL files can be located by EBO within this parent folder:
[http://\[HOST:PORT\]/AIAComponents/EnterpriseBusinessServiceLibrary/Core/EBO/](http://[HOST:PORT]/AIAComponents/EnterpriseBusinessServiceLibrary/Core/EBO/).

For detailed documentation of individual EBOs, click the EBO Name link on the Integration Scenario Summary page in the Oracle AIA Console. You can also use the Integration Scenario Summary page to search for and view integration scenarios that utilize a particular EBO or Oracle Clinical.

For more information, see Oracle Application Integration Architecture - Foundation Pack: Core Infrastructure Components Guide, “Using the BSR,” Using the BSR UI to View Integration Scenarios.

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 Application Integration Architecture – Foundation Pack: Integration Developer’s Guide, “Extensibility for AIA Artifacts.”

Integration Services

These are the services delivered with this integration:

- Adapter_UpdateClinicalStudySEBLJMS

This is a JMS consumer service that reads a JMS message from the AIA_ClinicalStudyQ in the Fusion Middleware database.

- Adapter_UpdateClinicalStudySEBLJMS_RS

This service routes the ABM to the Requestor ABCS, UpdateClinicalStudySEBLHealthSciencesReqABCSEBImpl

- UpdateClinicalStudySEBLHealthSciencesReqABCSEBImpl

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

- HealthSciencesClinicalStudyEBSV1

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

- `UpdateClinicalStudyOCHealthSciencesProvABCImpl`

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. It covers:

- Integration Flows
- Data Requirements
- Siebel Clinical Interface
- Oracle Clinical Interfaces
- Core AIA Components
- Integration Services

Synchronizing Clinical Study Subject Information Overview

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 for 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, this indicates a patient has been enrolled in the study and assigned an Enrollment ID. This triggers a subject to be created 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 Oracle Clinical Remote Data Capture, 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 triggers a subject to be created for the appropriate Protocol Site in Siebel Clinical and the subject is screened against the active Subject Visit Template.

Siebel Clinical requires the subject's initials and birth date to create a subject. Because these are not required fields 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 you can use to identify subjects who may require updated information. You can manually update with the correct data in Siebel Clinical, if desired.

When Siebel Clinical assigns an Enrollment Visit Template to a subject, the date the informed consent was signed is required. The Informed Consent Signature date is optional in Oracle Clinical. If it is not entered, the Informed Consent Date is set to Jan 1, 1900 in Siebel Clinical.

This will alter the dates in the Visit Schedule for the subject and you may want to correct this manually 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 entered in Oracle Clinical, the subject's birth date is used. This adversely impacts the dates in the Visit Schedule for the subject and should manually correct this field 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. The information that Oracle Clinical transfers is the Study ID and Patient ID, which identify the patient, and 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 that does not have an enrollment date
- Updating information in any of the fields listed for an enrolled patient or a patient with collected data.

Prerequisites

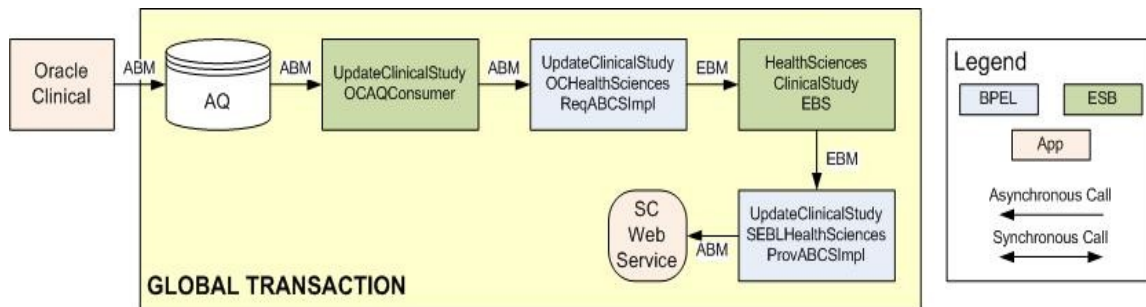
You must populate the ClinicalStudySubjectStatus DVM. Refer to the [Describing Domain Value Maps](#) section in Chapter 5.

Clinical Study Subject Information Flow

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

Flow Diagram

This figure shows the Clinical Study Subject Information flow:



Clinical Study Subject Information Flow

Create Study Subject

1. If 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 Queue (AQ).
2. The message is picked up by the Adapter_UpdateClinicalStudyOCAQ consumer service and passed to the UpdateClinicalStudyOCHealthSciencesReqABCSImpl (requestor 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 domain value map table.

4. The UpdateClinicalStudyEBM is passed onto the HealthSciencesClinicalStudyEBSV1 (EBS).
5. The EBS will use routing rules to pass the EBM onto the UpdateClinicalStudySEBLHealthSciencesProvABCImpl (provider ABCS) based on the routing rules with which it has been configured.
6. The provider ABCS will transform the EBM into an ABM for the Siebel Clinical ClinicalSubject Web service retrieving 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 domain value map table.
7. A synchronous call to the Siebel Clinical ClinicalSubject Web service is made; 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. If the 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 changes, this will trigger a Clinical Study ABM to be written to the Clinical_Study_Queue AQ.
2. The message is picked up by the Adapter_UpdateClinicalStudyOCAQ adapter service and passed to the UpdateClinicalStudyOCHealthSciencesReqABCImpl (requestor ABCS).
3. The requestor ABCS will retrieve the following for populating in 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 domain value map.
4. The message will then be transformed into an UpdateClinicalStudy EBM and passed onto the HealthSciencesClinicalStudyEBSV1 (EBS).
5. The EBS will follow routing rules to pass the EBM onto the UpdateClinicalStudySEBLHealthSciencesProvABCImpl (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. If an error occurs at any point that prevents the process from completing, compensating steps are taken.

Data Requirements

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

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. C. All changes for ACR 539 are listed in the What's New chapter.

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.

Core AIA Components

The integration flow uses the following components:

- ClinicalStudy EBO
- HealthSciencesClinicalStudyEBSV1
- UpdateClinicalStudyEBM

The core EBO and EBM XSD files can be located by EBO within this parent folder:
[http://\[HOST:PORT\]/AIAComponents/EnterpriseObjectLibrary/Core/EBO/](http://[HOST:PORT]/AIAComponents/EnterpriseObjectLibrary/Core/EBO/).

The core Oracle Clinical WSDL files can be located by EBO within this parent folder:
[http://\[HOST:PORT\]/AIAComponents/EnterpriseBusinessServiceLibrary/Core/EBO/](http://[HOST:PORT]/AIAComponents/EnterpriseBusinessServiceLibrary/Core/EBO/).

For detailed documentation of individual EBOs, click the EBO Name link on the Integration Scenario Summary page in the Oracle AIA Console. You can also use the Integration Scenario Summary page to search for and view integration scenarios that utilize a particular EBO or Oracle Clinical.

For more information, see Oracle Application Integration Architecture - Foundation Pack: Core Infrastructure Components Guide, “Using the BSR,” Using the BSR UI to View Integration Scenarios.

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 Application Integration Architecture – Foundation Pack: Integration Developer’s Guide, “Extensibility for AIA Artifacts.”

Integration Services

These are the services delivered with this integration:

- Adapter_UpdateClinicalStudyOCAQ

This is an AQ adapter consumer service that reads an XML message from the AIA_ClinicalStudyQ in the Oracle Clinical database.

- Adapter_UpdateClinicalStudyOCAQ_RS

This service routes the ABM to the Requestor ABCS, UpdateClinicalStudyOCHealthSciencesReqABCSEImpl

- UpdateClinicalStudyOCHealthSciencesReqABCSEImpl

The requestor ABCS is responsible for transforming the Oracle Clinical ClinicalStudy ABM into an UpdateClinicalStudyEBM.

- HealthSciencesClinicalStudyEBSV1

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

- UpdateClinicalStudySEBLHealthSciencesProvABCSEImpl

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

You can use the Integration Scenario Summary page in the Oracle AIA Console to search for and view integration scenarios that utilize a particular ABC service.

For more information, see Oracle Application Integration Architecture – Foundation Pack: Core Infrastructure Components Guide, “Using the BSR,” Using the BSR UI to View Integration Scenario

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. It covers:

- Integration Flows
- Data Requirements
- Siebel Clinical Interface
- Oracle Clinical Interfaces
- Core AIA Components
- Integration Services

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 information about the status of an activity to Siebel Clinical. For this to happen, 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 that was entered since the previous run of the batch job to see if the completion criteria for any activities has been met or changed. The process can be configured to run periodically on a schedule that you define.

- When the Track Activities menu item is selected, if the study in context is not enabled for Subject Activity integration, an error is returned and you are prompted to select a new study from a list of studies you have access to.
- If the study context does not exist when the Track Activities menu is selected, you are prompted to select a new study from a list of studies you have access to.
- You can change the study context while in the Track Activities form by choosing Special > Click Study or Change study button.
- When the process runs, the system will evaluate patient data that has been modified since the last time the process ran to determine if any activities have been completed or are no longer complete. 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.

Refer to the [Setting Up the Participating Applications](#) section in Chapter 5 for additional information.

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

Prerequisites

Clinical Items need to be defined for each activity and visit in the active Subject Visit Templates in Siebel Clinical. For information about defining clinical items in Siebel Clinical, refer to the Siebel Life Sciences Guide, Version 8.1, Rev.C. All changes for ACR 539 are listed in the What's New chapter. .

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

Each clinical item must be entered as any Activity in the Maintain Activity Completion Criteria form and the completion criteria defined for it.

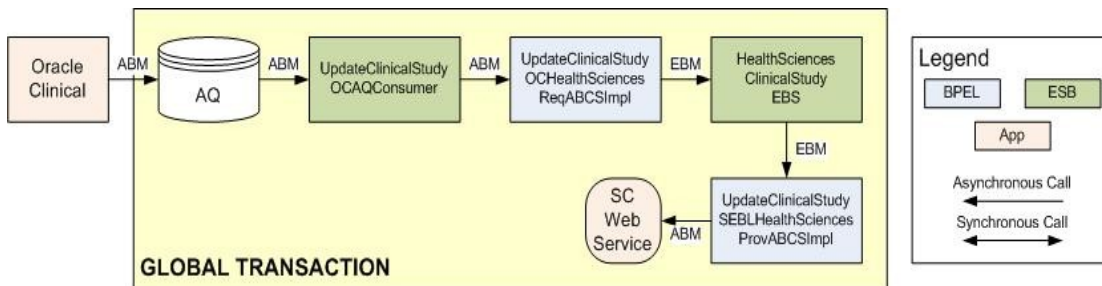
The Track Activities batch job must be scheduled to run on a regular basis. Refer to the [Setting Up Participating Applications](#) section in Chapter 5 for information on these Oracle Clinical prerequisites.

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 instead 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 figure shows the Clinical Study Subject Activity flow:



Clinical Study Subject Activity Flow

Update Subject Visit/Activity Completion

1. If Subject Activity Integration is enabled for a study in Oracle clinical and activity completion criteria have been defined, when the Track Activity batch job is run, Oracle Clinical will write a ClinicalStudy (ABM) to the Clinical_Study_Queue Advanced Queue (AQ) when the completion date of an activity has changed. Refer to [participating applications](#) section for more detail.
2. The message will be picked up by the Adapter_UpdateClinicalStudyOCAQ adapter service and passed to the UpdateClinicalStudyOCHealthSciencesReqABCSImpl (requestor ABCS).

3. The message will then be transformed into an UpdateClinicalStudy EBM and the ClinicalStudySubject Identification is retrieved from the ClinicalStudy_ClinicalStudySubjectId cross-reference table.
4. The UpdateClinicalStudyEBM is passed onto the HealthSciencesClinicalStudyEBSV1 (EBS).
5. The EBS will follow routing rules to pass the EBM onto the UpdateClinicalStudySEBLHealthSciencesProvABCSEBImpl (provider ABCS).
6. The provider ABCS will transform the EBM into an ABM for the Siebel Clinical Web service retrieving the following information during the transformation the Siebel Clinical row id for the Subject from the ClinicalStudy_ClinicalStudySubjectId cross-reference table
7. A synchronous call to the Siebel Clinical, Clinical Subject Web service is made.

These processes are part of a global transaction. If an error occurs at any point that prevents the process from completing, compensating steps are taken.

Data Requirements

For more information about defining clinical items in Siebel Clinical, Refer to the Siebel Life Sciences Guide, Version 8.1, Rev. C. All changes for ACR 539 are listed in the What's New chapter.

For more information about mapping activity completion criteria in Oracle Clinical, refer to the [Defining Completion Criteria](#) section in Chapter 5.

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.

Core AIA Components

The integration flow uses the following components:

- ClinicalStudy EBO

- HealthSciencesClinicalStudyEBSV1
- UpdateClinicalStudyEBM

The core EBO and EBM XSD files can be located by EBO within this parent folder:
http://[HOST:PORT]/AIAComponents/EnterpriseObjectLibrary/Core/EBO/.

The core Oracle Clinical WSDL files can be located by EBO within this parent folder:
http://[HOST:PORT]/AIAComponents/EnterpriseBusinessServiceLibrary/Core/EBO/.

For detailed documentation of individual EBOs, click the EBO Name link on the Integration Scenario Summary page in the Oracle AIA Console. You can also use the Integration Scenario Summary page to search for and view integration scenarios that utilize a particular EBO or Oracle Clinical.

For more information, see Oracle Application Integration Architecture - Foundation Pack: Core Infrastructure Components Guide, “Using the BSR,” Using the BSR UI to View Integration Scenarios.

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 Application Integration Architecture – Foundation Pack: Integration Developer’s Guide, “Extensibility for AIA Artifacts.”

Integration Services

These are the services delivered with this integration:

- Adapter_UpdateClinicalStudyOCAQ

This is an AQ adapter consumer service that reads an XML message from the AIA_ClinicalStudyQ in Oracle Clinical database.

- Adapter_UpdateClinicalStudyOCAQ_RS

This service routes the ABM to the Requestor ABCS, UpdateClinicalStudyOCHealthSciencesReqABCSImpl

- UpdateClinicalStudyOCHealthSciencesReqABCSImpl

The requestor ABCS is responsible for transforming the Oracle Clinical ClinicalStudy ABM into an UpdateClinicalStudyEBM.

- HealthSciencesClinicalStudyEBSV1

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

- UpdateClinicalStudySEBLHealthSciencesProvABCSImpl

The Provider ABCS is responsible for transforming the UpdateClinicalStudyEBM into the appropriate ABMs to call the appropriate Siebel Clinical Web service.

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

This chapter discusses the steps you must complete to integrate data in Siebel Clinical and Oracle Clinical. It covers:

- Participating Applications
- Cross-References
- Domain Value Maps
- Errors
- EBO Implementation Maps (EIMs)

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 enable integration of a Siebel Clinical protocol with an Oracle Clinical study.

For more information on configuring Siebel Clinical for integration with Oracle Clinical, see Siebel Life Sciences Guide, Version 8.1, Rev. C. All changes for ACR 539 are listed in the What's New chapter.

Synchronizing Clinical Study Sites

Information about a study site 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 create 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 as an investigator in Oracle Clinical, an investigator is created in Oracle Clinical for that principal investigator.

The combination of the primary address for the Protocol Site and the Account are considered 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 does not cause deletion of any objects in Oracle Clinical.

For more information, see Chapter 2: [Synchronizing Clinical Study Sites](#) for a technical description of the relevant integration components.

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 for 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, this indicates a patient has been enrolled in the study and assigned an Enrollment ID. This triggers a subject to be created 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 Oracle Clinical Remote Data Capture, 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 triggers a subject to be created for the appropriate Protocol Site in Siebel Clinical and the active Screening Visit Template to be assigned to the subject.

Although Siebel Clinical requires the subject's initials and birth date to create a subject, these fields are not required fields 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 you can use to identify subjects who may require updated information. You can manually update with the correct 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 you should update this manually 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 value of Jan 1, 1900. This will impact the dates in the Visit Schedule for the subject and you should manually correct this field in Siebel Clinical.

Refer to the [Create/Update Study Subjects Business Process Flow](#) in Chapter 1 and Chapter 3: [Synchronizing Clinical Study Subject Information](#) for further 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. The data in Oracle Clinical can be used to send information about the status of an activity to Siebel Clinical, based on completion criteria you have defined for an activity or visit. 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 protocol amendments occur, new versions of Subject Visit Templates are created and made active. 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 in one version of a Subject Visit Template would have the same completion criteria as a visit in another version of that Subject Visit Template or 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 comprised two visits, Visit 1 and Visit 2. If a protocol amendment is made that 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 the set of activities. For example, a clinical item can be assigned to the set of identical lab tests that are performed at each of a series of visits. This allows 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 Siebel Life Sciences Guide, Version 8.1, Rev. C. All changes for ACR 539 are listed in the What's New chapter.

Setting up Oracle Clinical

When the Activate for Synchronization field is selected in Siebel Clinical for a Protocol Site, a corresponding Study Site is created in Oracle Clinical (Oracle Clinical). Since a study site in Oracle Clinical does not exist without Investigator and Site details, if the Siebel Clinical Investigator and Site details do not exist they are 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

Any updates made in Oracle Clinical 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 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 information about a patient_position once the enrollment date has been entered or data has been entered against a patient position without an enrollment date. The other option allows you to define completion criteria in Oracle Clinical for Siebel Clinical activities and send messages when those activities have been completed.

There are two new settings:

- Enable Patient Integration – If set to Y, messages about patient_positions, patient_status and the study sites assignments for the patient _positions are written to an Advanced Queue. This happens when the enrollment date is entered or data is entered for a patient position with no enrollment date. All subsequent updates to these patient positions are sent to Siebel Clinical.
- Enable Subject Activity Integration – If set to Y, users are 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 means that the integration is turned off. If you wish to enable one or both of these integrations on all new studies, change the applicable settings to Y and all new studies will be created with the integrations enabled.

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

If you wish to enable integration for some studies but not all, proceed to the study level settings described here.

Enabling Integration for a Single Study:

To enable integration for 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 that an enrollment date is specified for enrolled patients. If you do not enter enrollment dates into the Patient Positions form, but instead use CRF data entry 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 with the enrollment date entered on the form. You can also use pat_sync to enter the Informed Consent Date of a patient.

Refer to the Patient Synchronization section in Creating a Study in Oracle Clinical documentation for additional information.

Automating the Update of Activity Completion Criteria

Track Activity Batch Process

The Track Activity process is a PSUB batch job that evaluates all active completion criteria and determines if the patient data entered or updated since the last time the track activity job ran will causes 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 from a list of studies you have access to.
- 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 from a list of studies to which you have access.

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

Refer to the Oracle Clinical documentation for information about running, viewing, and scheduling PSUB jobs. Completion Criteria Processing

Completion Criteria Processing

The following parameters define how the system processes objects that comprise completion criteria.

Completeness Criteria

1. An RDCI or RDCM that is marked as 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

1. If a DCI or DCM that was mapped to an activity is soft deleted, the activity is no longer considered complete.
2. If the blank flag is set to Y for a DCI or DCM that was mapped to an activity, the activity is no longer considered complete.
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, the activity is no longer considered complete.
4. If a response value for a DCM Question that was mapped to an activity is removed leaving the response empty, the activity is no longer considered complete.
5. If the activity is no longer considered complete due to one of the preceding events, the following information about the activity 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 is key changed for a Received DCI (RDCI) or Received DCM (RDCM) that was mapped to an activity, the activity is no longer considered complete for the old patient...
2. If the DCI book for a RDCI, which is either, mapped itself to a DCI Book Visit or contains a RDCM or response mapped to a DCI Book Visit, the activity is no longer considered complete for the mapped visit.

- If the visit for a RDCI, which is either mapped itself to an activity or contains a RDCM or response mapped to an activity, 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 about the activity 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 and create new activities, navigate to Definition->Activity Completion Criteria. The system displays the Maintain Activity Completion Criteria, which provides a summary of all existing activity completion criteria for the study.

Activity	Type	Status	DCI Book	Clinical Planned Event	Completion Date Level	Com Date
SKMTESTNEW1	Visit	R	DCIBOOK1	DOSING	DCM	Spe
SKMTEST2	Visit	R			DCI	Visit
SKMTESTNEW3	Visit	R	DCIBOOK1	DOSING	DCM	Visit
SKMtest30	Visit	R	DCIBOOK1	DOSING	DCI	Spe
skm1	Activity during Visit	P	DCIBOOK1	DOSING	DCM Question	Spe
skm3	Visit	P	DCIBOOK1	DOSING	DCI	Spe
skm4	Visit	P	DCIBOOK1	SCREENING VISIT	DCM Question	Spe
skm5	Visit	P	DCIBOOK1	SCREENING VISIT	DCM Question	Spe
skm6	Visit	P			DCI	Spe
skm9999	Activity during Visit	P	DCIBOOK1	DOSING	DCM Question	Spe
skm7	Visit	P	DCIBOOK1		DCI	Spe
SKMTEST7	Visit	R	DCIBOOK1	SCREENING VISIT	DCM Question	Spe

Activity Completion Criteria Summary Screen

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

Activity Completion Criteria Detail Screen

Updating an Existing Activity

If an existing activity is selected in the Maintain Activity Completion Criteria window when you click the Details button, the system displays the Activity Completion Criteria Details window for that activity.

- The Save button will save changes on this screen to the database.
- The Back button returns to the Maintain Activity Completion Criteria window.
- If changes are pending when you click the Back button, 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 create a new activity by selecting the Data>Insert Record menu item. If you choose 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 there are existing records, click the Add New Activity button to create a new activity from the Activity Completion Criteria Details window.

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

Completion Criteria

Activity

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

Activity Type

The completion criteria for an activity can be defined in the context of 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. When an activity mapping is first entered it will default to a status of P
3. The status can be changed from Provisional to Active if:
 - a. At least one DCI, DCM or DCM question have been mapped and
 - b. The completion date level and completion date function have been filled in.
 - c. If the criteria level is DCI, all DCIs specified are Active.
 - d. If the criteria level is DCM, all DCMs specified are Active.
 - e. If the criteria level is DCM question, all DCMs the DCM questions are part of are Active.
4. You cannot change a mapping that is set to Active.
5. The status may be changed from Active to Provisional. However, any data that is entered in the system while the status is set to P will not be mapped to an activity.
6. Changing the status to P does not affect any previously completed activity mappings.
7. The status can be changed from Active to Retired.
8. Once a mapping is retired, patient data will no longer be mapped to it.
9. 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.
10. The status can be changed from Retired to Active 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 as specific to a particular visit in a DCI Book or to a Clinical Planned Event (CPE) defined for the study.

If you define the activity completion criteria as specific to a particular visit, this 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 being 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 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

For each activity the completion date may be collected in a different manner. This may vary based on your business practices and study requirements. Therefore, when you define activity completion criteria, you must tell Oracle Clinical where to get the completion date to send to Siebel Clinical 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 that contains 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

When 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 the Add Multiple button to select multiple objects.

- Once multiple objects are selected they are displayed on the lower half of the screen.
- If objects are selected and existing objects already existed, the new objects are added to the bottom of the list and will not overwrite the existing selected objects.
- The records are not saved to the database until the user clicks the Save button on the Activity Completion Criteria Details screen.

Activity Completion Criteria Details

Activity: SKMACT4 Type: Visit Status: P Retirement Reason:

☒ Visit Specific Criteria

DCI Book: PDF WHOLE Clinical Planned Event: VISIT 1

Completion Date Level: DCI Completion Date Source: Specific Date Criteria Level: DCI

Criteria Details

Use as Specific Date	DCI Name	DCM Name	DCM Subset #	Qualifying Value	DCM Question
<input checked="" type="checkbox"/>	DEMOG				
<input type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					

Buttons: Back, Save, Add New Activity, Add Multiple

Entering DCIs One-at-a-Time

Specifying DCIs in Completion Criteria

After you have navigated to the Activity Completion Criteria Details window for 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 choose 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 the OK button.
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 the Add Multiple button. The system displays the Multiple Selection DCIs window, which lists each DCI and displays the DCI Name, DCI Type, and Status for each.

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

Specifying DCMs in Completion Criteria

After you have navigated to the Activity Completion Criteria Details window for 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 one at a time in the Criteria Details section:

1. Use the DCM Name LOV to display a list of DCMs.
2. The LOV will display the name, subset, qualifying value, type and description of the DCM.
3. When a DCM subset is selected from the DCM Name LOV, the subset # is filled in on the form.
4. 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.
5. 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.
6. Only the DCM Name, DCM Subset # and Qualifying Value fields are updateable. All other fields are not editable. You can specify DCMs to include in completion criteria either individually, in group of DCMs, or by specifying a DCI.

If you want to add more than one DCM at a time, click the Add Multiple button. The system gives you a choice of method to locate DCMs, 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 the Select All or Clear All buttons, as necessary to make your selection.
3. When you click the OK button, the system displays DCMs you have selected in the Activity Completion Criteria Details screen.
4. If you click the Cancel button, 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, that 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.

Activity Completion Criteria Details

Activity: SKMACT4 Type: Activity during Visit Status: P Retirement Reason:

☒ Visit Specific Criteria

DCI Book: PDF WHOLE Clinical Planned Event: VISIT 1

Completion Date Level: DCI Completion Date Source: Specific Date Criteria Level: DCM

Criteria Details

Use as Specific Date: ☐

DCI Name	DCM Name	DCM Subset #	Qualifying Value	DCM Question
	PE	1		

Buttons: Back, Save, Add New Activity, Add Multiple

Entering DCMs One-at-a-Time

Specifying DCMs that must be completed for a Visit Specific activity

1. If the activity completion criteria was defined as Visit Specific and a DCI Book was entered, you are 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 in the visit more than once, you must select a qualifying value when mapping to the DCM. The system does not save the completion criteria until all required qualifying values are chosen.
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 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 in the visit multiple times, a qualifying value must be specified when mapping to the DCM. If the DCM is not qualified, the completion criteria cannot be saved.

Activity Completion Criteria Details

Activity: SKMACT4 Type: Activity during Visit Status: P Retirement Reason:

☒ Visit Specific Criteria

DCI Book: PDF WHOLE Clinical Planned Event: VISIT 1

Completion Date Level: DCI Completion Date Source: Specific Date Criteria Level: DCM Question

Criteria Details

Use as Specific Date: ☐

Add Multiple

DCI Name	DCM Name	DCM Subset #	Qualifying Value	DCM Question
<input type="checkbox"/>	VITALS	1		DIAS
<input type="checkbox"/>	PE	1		WEIGHT
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				

Back Save Add New Activity

Entering DCM Questions One-at-a-Time

Specifying DCM Questions in Completion Criteria

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

1. Use the DCM Name LOV to 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 # is filled in on the form.
3. The Subset# LOV 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 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 DCM Question Group by the sequence the DCM Question group is defined in the DCM.

If you click the Add Multiple button, you choose whether you want to locate DCM Questions by accessing DCIs and DCMs and drilling down.

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

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

2. Select a DCM Subset and click the DCM Question Groups button to display the list of non-repeating DCM Question Groups collected in the DCM Subset.
3. Select a DCM Question Group and click the DCM questions button to display a list of DCM questions collected in the DCM question group.
4. If you choose to use the DCMs to specify questions, you can select multiple DCM questions from the list, from which you can use the All or Clear All Selections buttons to select the correct set.
5. When you click the OK button, the selected DCM questions are displayed in the Activity Completion Criteria Details window.
6. When you click the Cancel button, 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 the DCM Question Groups button, the system displays the list of non-repeating DCM Question Groups collected in the DCM Subset as well as the DCM Question Group Name and Domain.
2. When you select a DCM Question Group and click the DCM questions button, 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 the specific visit, you can navigate to the DCM Question level for the DCIs planned for the 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 to select 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 for the 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 Application Integration Architecture – Foundation Pack - Integration Developer's Guide and the Oracle Cross Reference User Guide.

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_01	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_01	Concatenation of Investigator ID and Investigator (user identifier) in Oracle Clinical	

XREFTABLENAME	COLUMN NAME	DESCR	USAGE
CLINICALSTUDYSTUDYSITE	COMMON	Concatenation of CDMS_STUDY_ID from Protocol in Siebel Clinical and Protocol Site No	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
CLINICALSTUDYSTUDYSITE	COMMON	Concatenation of CDMS_STUDY_ID from Protocol in Siebel Clinical and Protocol Site No	Used to look up Siebel 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	

Describing 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 additional maps as needed. Transactional business processes never update DVMs—they only read from them. They are stored in XML files and cached in memory at runtime.

DVM types are seeded for the flows, and administrators can extend the list of mapped values by adding more maps. The DVM data should be in sync with what the participating applications use. This sync-up should be done prior to running any initial loads, or initiating any incremental transactional flows.

These are the domain value mappings (DVMs) for this integration:

DVM Type	DVM Column Name	Comments
COUNTRY	COMMON, SEBLCLIN_01, OC_01	This maps the country codes between Siebel Clinical and Oracle Clinical.
STATE	COMMON, SEBLCLIN_01, OC_01	This maps the state codes between Siebel Clinical and Oracle Clinical.
ClinicalStudySubject _Status	COMMON, SEBLCLIN_01, OC_01	This DVM is used to map the patient statuses defined by customers in OC to Subject statuses in Siebel Clinical.

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, refer to the product 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 EBO Implementation Maps (EIMs)

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

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