Oracle® Study, Subject, and Visit Synchronization Integration Pack for Siebel Clinical and Oracle® Clinical 3.1 - Release Notes

Release 3.1

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Contents

Value Proposition for Oracle Study, Subject and Visit Synchronization Integration Pack for Siebel Clinical and Oracle Clinical for Application Integration Architecture (AIA) Service Pack 3.1

Oracle Study, Subject, and Visit Synchronization Integration Pack for Siebel Clinical and Oracle Clinical for Application Integration Architecture (AIA) Service Pack 3.1 provides integration between two complementary clinical technology applications.

The PIP includes processes that enhance the value of your existing Oracle Clinical and Siebel Clinical implementations. It establishes a source data location for several key study data and metadata components and streamlines the associated workflow processes thereby enabling you to realize a significant value in clinical operations, data management, and regulatory compliance.

The specific areas that are enhanced by the Study, Subject and Visit Synch: Siebel Clinical - Oracle Clinical PIP are:

- Study Site Coordination (including address, investigator, and so on.)

- Study Subject Coordination

- Activity Completion Integration

The PIP enables the timely exchange of data between Oracle Clinical and Siebel Clinical. Investigator and site details sent from Siebel Clinical facilitate the automatic creation of a study site in Oracle Clinical. The integration of such study metadata across both applications increases data quality, enhances operational efficiency, and establishes a single source of these study components.

The PIP also aids in tracking patient screening and enrollment. When patient data is entered in Oracle Clinical without an enrollment date, a screening subject is created in Siebel Clinical and the subject is screened against the subject visit template. When an enrollment date is entered for a patient in Oracle Clinical, the subject is created in Siebel Clinical, if it does not already exist, and is enrolled against the Subject Visit Template. This facilitates more efficient and accurate patient counts.

Investigators are paid based upon activities completed during a trial. Currently these activities are manually marked as completed by a CRA or Medical Monitor. The PIP lets the customer define which data collected in Oracle Clinical Remote Data Capture (OC RDC) constitutes the completion of an activity in Siebel Clinical thereby facilitating timely and accurate payments.

Product Enhancements for Oracle Study, Subject and Visit Synchronization Integration Pack for Siebel Clinical and Oracle Clinical for Application Integration Architecture (AIA) Service Pack 3.1

This section provides an overview of the features of the Study, Subject, and Visit Synch: Siebel Clinical - Oracle Clinical PIP. The features fall into three areas:

- Create/Update Study Sites

- Create/Update Study Subjects

- Update Visit or Activity Completion Date and Status

Create/Update Study Sites

During the Study setup process, protocols are created in Siebel Clinical and clinical studies are defined under a Program and Project in Oracle Clinical. To utilize this integration, the user must manually enter the 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 checkbox 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 who has been 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 as a site in Oracle Clinical. If this combination does not exist in Oracle Clinical, a new site will be created. If the primary address for a protocol site is changed in Siebel Clinical, the address of the site will be updated in Oracle Clinical.

Create/Update Study Subjects

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. Entering an enrollment date for a patient position indicates that 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 enrolled against the active Subject Visit template.

In Oracle Clinical or Oracle Clinical Remote Data Capture (OC RDC), if data is entered for a patient position 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 is recognizable as an invalid date. The correct data can be manually entered in Siebel Clinical, if desired.

If the screening date or enrollment date for a subject is changed in Oracle Clinical, the subject will not be re-screened or re-enrolled against the subject visit template in Siebel Clinical. This will have to be done manually by the Siebel Clinical user.

When a subject is enrolled against the active subject visit template, an informed consent date is used. If this date is entered in Oracle Clinical, the date entered is used. If not, a default date of Jan 1, 1900 is used.

Update Visit or Activity Completion Date and Status

The goal of this flow is to update the completed date of Subject visits and Subject visit activities based on data entered into Oracle Clinical or OC RDC. For this to happen, the Study Manager and Data Manager should collaborate and determine what data must be completed for a visit in OC RDC or an activity in Siebel Clinical for the entry to be considered complete, as well as how to determine what the visit completion date is 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 enable the definition of 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 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 will be analyzed.

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

Oracle Study, Subject and Visit Synchronization Integration Pack for Siebel Clinical and Oracle Clinical for Application Integration Architecture (AIA) Service Pack 3.1: Solution Assumptions and Constraints

Assumptions

1. To enroll a subject in Siebel Clinical, the enrollment date must be populated for the patient position in Oracle Clinical. This can be done through the Patient Positions form by loading enrollment dates in the Oracle Clinical data entry, batch loading enrollment dates or using Patient Synchronization in a validation or 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. When a protocol site is deleted in Siebel Clinical, deletion of a study site in Oracle Clinical may not be desired and therefore 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.

5. The date on which the subject signed the Informed Consent form is a critical date in Siebel Clinical. To gain maximum benefit from the integration, Informed Consent Date should be populated for the patient position in Oracle Clinical. You can populate the Informed Consent Date from a CRF either through the Patient Positions form, or the Patient Enrollment form or using Patient Synchronization in a validation or derivation procedure.

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 investigator address 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 whether an unplanned activity had been completed.

4. Due to size limitations of 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.

Participating Application Enhancements for 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 Clinical Enhancements

This section describes the enhancements to Oracle Clinical 4.6 that were provided for this PIP. The Oracle Clinical iPatch 4.6.0.52 is required to use this PIP. Check My Oracle Support at https://myoraclesupport.oracle.com at the time of installation for any updates or patches that may obsolete this patch.

New Web services have been added to Oracle Clinical that enable the PIP to create and update investigators, sites and study sites.

Oracle Clinical has been enhanced to write a message to a queue whenever data is entered for the first time for a patient position that does not have an enrollment date (screening patient) or when an enrollment date is entered /changed for a patient. This queue is read by the PIP to facilitate the creation of subjects in Siebel Clinical.

A new form has been created to define the completion criteria for visits and activities in the Siebel Clinical Subject Visit template. A new form has also been added to provide the option of the enabling the integration at the Patient level or the activity level.

A new batch job has been provided that can be scheduled to run periodically. This job will analyze the patient data to check if any activities or visits have been completed and write a message to a queue when an activity completion date or status changes. This queue is read by the PIP to update the completion status and dates in Siebel Clinical.

A new field, Informed Consent Signature Date has been added to the Patient Positions and Patient Enrollment forms to store the date when the Informed Consent form was signed by the patient. Oracle recommends that customers populate this field either through the User Interface (UI) or through a validation or derivation procedure.

Siebel Clinical Enhancements

Siebel Clinical 8.1.1.3 is required to use this PIP. It provides the following enhancements to Siebel Clinical:

A new category, Integration, has been added to the More Info tab of the Administration-Clinical Protocols List screen. This category contains a new field, CDMS Study ID, where you enter the study code of the study in Oracle Clinical that is the same as this Protocol. A new check box, Synchronize Active Study Sites, was added to indicate that this Protocol is enabled for the integration.

A new category, Integration, has been added to the More Info tab of the Site Management - Protocol Sites List screen. This category contains a new picklist, Primary Site Address. This picklist enables the user to indicate which address defined for the Protocol Site should be used for the site in Oracle Clinical. A new check box, Activate for Synchronization, has been added as well. Selecting this box will send a message to a JMS queue on the SOA server thereby sending information to Oracle Clinical. Once this check box is selected, any updates to the Protocol Site will come over as well. Updates are not sent for 2 minutes in order to combine updates into one message.

A new Web service has been created to enable the following in Siebel Clinical:

- New subjects created and screened/enrolled against the active subject visit template

- Subject information to be updated

- Completion dates and status to be updated for Subject Visits and Activities.

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Additional Resources

There are additional resources that can help your organization learn more about this release.

Resource	Navigation
Process Integration Pack Implementation Guides	Oracle Technology Network: http://www.oracle.com/technetwork/index.html
Foundation Pack Guides	Oracle Technology Network: http://www.oracle.com/technetwork/index.html
Installation and Upgrade Guide	Oracle Technology Network: http://www.oracle.com/technetwork/index.html

Visit the My Oracle Support at https://myoraclesupport.oracle.com frequently to keep apprised of ongoing changes.

For other sources of documentation, visit Oracle Technology Network: Oracle Documentation at http://www.oracle.com/technetwork/index.html.

For training opportunities, visit Oracle University at http://education.oracle.com/web_prod-plq-dad/plsql/show_desc.redirect?redir_type=3.