

Clinical Connector Release Notes

Document Change History

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| --- | --- | --- | --- |
| **Version Number** | **Date** | **Contributor** | **Description** |
| 1.0 | December 9, 2009 | Patrick Conrad | Release Notes for release 2.0 |
| 1.1 | February 24, 2010 | Patrick Conrad | Release Notes for release 2.1 |
| 1.2 | July 1, 2010 | Patrick Conrad | Moved release notes from v2.1 to existing features.; added release notes for v2.2 |
| 1.3 | August 20, 2010 | Patrick Conrad | Finalized v2.2 Release Notes |
| 1.4 | December 6, 2010 | Patrick Conrad | Added Release Notes for v2.3 Clinical Connector Admin UI. |
| 1.5 | January 3, 2011 | Patrick Conrad | Added notes concerning the new outbound services GetStudyCRFs and GetStudyCRFData and their attributes. |
| 1.6 | January 31, 2011 | Patrick Conrad | Added notes concerning Study Translation and BDA alterations for Database Object installation and upgrade. |

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# Background/Summary

The caBIG® Clinical Connector, formally known as the C3D Connector, provides services that allow patients to be enrolled in to C3D Studies and to load laboratory test result data into the C3D CDMS.

The Enroll Patient service accepts a request to enroll a patient into an existing study in C3D. The service will acquire a C3D Patient Position for the requested Study and Site, assign values to the C3D Questions related to Patient ID and NCI Institution Code, if available, and return the C3D Patient Position back through the received message.

The Load Lab service accepts requests to load patient laboratory results and loads them into C3D. This service will accepts groups of records in a single request, validates the data for completeness, prepares the data for processing, and submits the data to the C3D Lab Loader for final processing and loading. This service runs asynchronously.

Installation of the caBIG® Clinical Connector is covered in Chapter 13 of the caBIG® Clinical Trials Suite Installation Guide.

# Introduction

## Overview

The caBIG® Clinical Connector Release Notes relate the current condition and any known issues impeding the usability of the Clinical Connector for this specific release.

## Related Documentation

Additional information on the C3D Connector can be found in the following documents:

* caBIG® Clinical Connector Installation Guide
* caBIG® Clinical Connector Administrator's Guide

## Software Compatibility

The Clinical Connector, v2.1 has been tested and compatible with the following:

* Oracle 9.2.0.7
* Oracle Client 8.0.6
* Oracle Clinical (CDMS) 4.5.1 or higher
* TomCat 5.5.27
* JDK v1.5.0\_10
* caGrid v1.3

## Installation and Configuration Notes

For the latest information related to installation and configuration, please refer to the “Clinical Connector Installation Guide” and “Clinical Connector Administrator's Guide”.

# Software Details

## Existing Features

* Provides grid service for registering Patients into C3D Studies.
* Provides grid service for loading Laboratory Test Results to C3D Studies.
* Leverages Oracle Clinical Data Capture APIs for patient data loading.
* Configurable e-mail alerts sent to support personnel when asynchronous processing encounters problems.
* Installation is BDA compliant.
* Processing errors during patient data replication are handled, logged and cleared.
* caGrid Authentication security supported.
* Clinical Connector Service methods have been divided into two separate groups to distinguish between general Clinical Services and specific C3D Services. They are divided as follows:
  + Clinical Connector Services
    - Load Labs
    - RegisterSubject
  + C3D Grid Services
    - Get Study CDEs
    - Get Study CDE Data
    - Is Valid Study
* Clinical Connector Services have been enhanced to use the BRIDG 2.1 data model.
* Suite Level Security for (CSM Authorization) implemented.
* Public/Private Study designation supported for Get Study CDE Data Service.
* Redaction of Private data elements implemented for Get Study CDE Data Service.
* JSP for collecting C3D User Ids and associating them to Grid Ids. This is being implemented to support C3D Study Level security for “Private” studies.
* The following data elements from the Subject Registration message are now being loaded to C3D CRF based on the CDE Id / Version loading mechanism:
  + Patient Consent Signed Date
  + Patient Initials
  + Patient Birth Date
  + Patient Gender
  + Patient Registration Date
* The following data elements are no longer be loaded to C3D:
  + Patient Last Name
  + Patient First Name

## NEW FEATURES THIS RELEASE v2.3

* Clinical Connector Administrator UI – Provides User Interface to manage the following control tables used to manage the Clinical Connector:
  + Service Properties
  + DCAPI Credentials
  + Registration CDEs
  + Private Data CDEs
  + Study Security
* Service properties are now maintained within a database table that can be access and changed via the Clinical Connector Admin UI.
* The Encryption mechanism has been altered from java based to Oracle based.
* C3D Grid Service enhanced to include the following two methods:
  + GetStudyCRFs
    - This will return all of the eCRF names for the specified study.
  + GetStudyCRFData
    - This will return all of the study data for the specified study and eCRF for every patient in the study. The result set will include every data point of the eCRF.
* The two new methods of the C3D Grid Service also include:
  + Study Level Security
    - PRIVATE – User must have a C3D UserId associated to their Grid Id, and the C3D UserId must be authorized to access the study.
    - PUBLIC – User must have a valid Grid Id to access the study data.
  + Private Data CDEs
    - Those CDEs that have been identified as private for the study, or for every study, will be redacted (i.e. set to the value “####”).
* Installation/upgrade of both the base database objects and C3D Support Tools has been incorporated into the BDA Installation. Support for both LOCAL and UNIVERSAL installation of the C3D Support Tools has been included.
* Study Translation has been incorporated into both the RegisterSubject and LoadLabs services. Study translation is used to support Study Identifiers that do not conform to the C3D Standard of study naming.

## Release Information

Software Version: v2.3pre1\_rc1

Release Date: January 31, 2010

# Known Issues

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| ***GFORGE ID*** | ***DESCRIPTION*** |
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The following table contains the major known issues identified during testing. These issues have been logged into GForge along with other minor ones.

# Known Limitations

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| --- | --- |
| Number | Description |
| 1 | Patient Id (MRN) that are not numeric will need additional processing by the AutoLoader in order for it to be loaded in the CDMS. |
| 2 | Studies designed using multiple occurrences of a data element (CDE Id) within the study will cause the data to not load.  This is a known limitation of the DCAPIs, due to the need for addition context data that is not provided via the Patient Registration Service. |
| 3 | Patient data will not load to data collection instruments (DCI) within C3D where there exists a mandatory data element on the DCI.  The data load transaction will be ignored. |