

CCTS 1.1

caBIG Clinical Trials Suite
Release Notes CCTS 1.1

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1.0 Introduction
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The caBIG Clinical Trials Suite is an open-source, enterprise-level clinical trials software application system. The Suite is comprised of a collection of robust, feature-rich modules covering a broad range of key areas in cancer clinical trials management, including those listed here:

- Patient Registration
- Patient Scheduling
- Lab Analysis
- Adverse Events Reporting
- Clinical Data Management

The Suite aims to meet the following interoperability standards:

- caBIG Silver Level Certification
- BRIDG Model Harmonization

1.1 Background

This is the second official public release of the caBIG Clinical Trials Suite.

This release includes the following caBIG applications:

Application -----	Version -----
Cancer Central Clinical Participant Registry (C3PR)	2.5.2
Patient Study Calendar (PSC)	2.3.3
Lab Viewer/Clinical Trials Object Database System	1.5.0
Cancer Adverse Event Reporting System (caAERS)	1.5.1
Cancer Centralized Clinical Database (C3D) Connector	1.2.0
caXchange	1.5.0
caGrid	1.2

Note: caGrid 1.2 is not included as part of the CCTS 1.1 distribution package. It can be downloaded from the caGrid website.

1.2 Release History

- November 7, 2008: CCTS 1.1 (This release)
- March 14, 2008: CCTS 1.0.1
- February 28, 2008: CCTS 1.0

1.3 Resources

For additional information about CCTS 1.1, refer to the following sites and documents:

Web Sites:

<http://ncicb.nci.nih.gov/tools/ccts>
<http://gforge.nci.nih.gov/projects/ccts/>

User Guides:

- CCTS 1.1 End User Guide

- C3PR User Guide
- PSC User Guide
- Lab Viewer User Guide
- caAERS User Guide
- caXchange Administration Guide

Installation Guide:

- CCTS 1.1 Installation Guide

Technical Reference Documents:

- CCTS 1.1 Architecture Document
- CCTS 1.1 Interface Specification Document

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2.0 New Features for this Release

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CCTS 1.1:

Suite-Level Features:

- Integration Smoke Tests: The caBIG Clinical Trials Suite include integration smoke tests that verify the installation using tests for key integration scenarios. Additionally each application provides a web happy.jsp that gives a user an ability to verify the application installation. These tests verify caGrid security infrastructure setup and connectivity to key resources such as databases and mail server.
- Hot Links: Standardized the links between application to provide for easier navigation across the caBIG Clinical Trials Suite.
- caGrid 1.2 Upgrade: The suite applications and services have been upgraded to be compatible with caGrid 1.2.
- New interoperability scenario to load AE labs from LabViewer to caAERS.
- Very detailed and validated Installation Guide that includes screen shots to installation.

Application-Specific Features:

- Patient Registration:

- * Dashboard-style UI
- * Flexible event-driven email notifications
- * Companion protocols (embedded and non-required)
- * Enhanced security (site-level, password policy)
- * Additional data elements (e.g. method of payment)
- * BRIDG study structure harmonization

-- Patient Scheduling:

Fixes some minor issues also has feature enhancement to existing Use Cases
Some key enhancements include:

- * Use protocol ID as name of template XML export
- * Add labels to planned activities.
- * Sort scheduled activities on subject's schedule page
- * Custom reports and ability to export them in CSV or Excel file formats.
- * Notifications of amendments, reconsents, or the end of activities on coordinator's dashboard.
- * New activity management interface enables manually creating/editing/deleting activities and sources
- * Edit and delete sites.
- * Improved user interface.
- * Show cycle numbers and days in the patient's schedule.

-- Adverse Event Reporting:

This release of caAERS v1.5.1 is a period production release to address high priority bugs and issues significantly impacting the usage of the new features and functionality deployed in caAERS v1.5.

Adverse Event Entry

- * Supports a single point of entry for adverse events.
- * Support of solicited adverse events.
- * Support of evaluation period types.
- * Support of cycle/course annotation.
- * Support of evaluation periods.
- * Support of assigning seriousness reasons to individual adverse events.
- * Support for adverse event grading with CTCv2.0.
- * Support of MedDRA configuration for "Other, specify" adverse event termin

Reporting

- * Hardened the caAERS-to-AdEERS submission
- * Updated the "DCP SAE Report" template.
- * Update the caAERS data model and user interface.
- * Implemented an exportable PDF version of MedWatch 3500A form.
- * Added fields for MedWatch report completion.
- * Implemented data elements to populate the MedWatch 3500A form.
- * Updating of the rules to support FDA, DCP, and CTEP reporting.
- * Streamlined user interface.

Data Sharing

- * Support for creating & updating subjects via messaging and web services.
- * Support for updating subjects via xml import.
- * Support for creating & updating studies via messaging and web services.

CCTS_Release_Notes

- * Support for updating studies via xml import.
- * Support for creating & updating research staff via messaging and web serv
- * Support for creating & updating research staff via xml import.
- * Support for creating & updating investigators via messaging and web servi
- * Support for creating & updating investigators via xml import.
- * Implementation of a lab message consumer.
- * Implementation of an adverse event query API.
- * Support for multiple concurrent versions of MedDRA.
- * Support for CTCv2.0 adverse event grading descriptions.

Installation / Configuration

- * Support for changing the SYSTEM_ADMIN password during installation.
- * Addition of "user id" to support changing users' email addresses.
- * Installer agnostic of version changes to caaers-core jar.

General Usability

- * Updated and redesigned user interface.

-- Lab Analysis:

- * Export of user viewable clinical trial data to caAERS
- * Download user viewable clinical trial data in .CSV format to the desktop
- * Integrated with PostGRES v8.2.9 database

-- Clinical Data Management:

- * Provides service for registering Patients into C3D Studies. Enhanced with options for loading patient enrollment information is now configurable.
- * Provides service for loading Laboratory Test Data to C3D Studies.
- * Replicates patient identifying data elements to C3D by way of Common Data Element Identifiers (CDE Ids). Patient Id (MRN) and NCI Institution Code are currently loadable.
- * Leverages Oracle Clinical Data Capture APIs for study data loading.
- * Configurable e-mail alerts sent to support personnel when asynchronous processing encounters problems.

-- caXchange:

- * caXchange routing configuration externalized. Giving caXchange administrat an ability to add or remove target services.
- * caXchange can now be configured to define routing for new service payload
- * caXchange now validates service payloads against schemas published in GlobalModelExchange (GME).
- * caXchange is now pre-configured for routing lab based adverse event messag to caAERS.
- * caXchange installation is now streamlined using ant scripts.

CCTS 1.0.1:

Minor updates, includes

- Additions and corrections to User Guides and other documents.

CCTS 1.0:

The caBIG Clinical Trials Suite contains a rich set of features designed to support the management of cancer clinical trials. The key features included as part of Version 1.0 are listed below.

Suite-Level Features:

- Single Sign-On (SSO): A user of the Suite is prompted to log in only once per session. Once logged in, a user can move securely from one application to another without being forced to repeatedly enter a username and password.
- Hot Links: To support certain common workflows across the Suite, CCTS 1.0 includes a set of smart links which allow a user to move from a page in one application to a related page in another application. For example, after setting up a study in C3PR and then broadcasting the newly created study to all the other applications in the Suite, the user can hot link to PSC and to caAERS to complete any remaining study setup details required by those applications. Similarly, while entering an expedited AE report in caAERS, a user can link from the Labs section in the report to the Lab Viewer application. From here, the user can view the patients labs and consider them for inclusion as part of the expedited AE report.
- Security: The Suite includes state-of-the art security features to safeguard sensitive data and to ensure compliance with HIPAA and 21 CFR Part 11 regulations. The Suite supports SSL for encryption of data across the internet and fully leverages all the advanced security components in caGrid 1.1.
- Reliable Messaging: The Suite includes logic to ensure that data sent from one application to another is successfully delivered.
- Transaction Control: The Suite includes logic to ensure that transactions across applications are completed successfully. Each task is monitored and confirmed. If the task cannot be completed properly in each application, the transaction is rolled back to ensure the integrity of the data across the Suite.
- Semantic and Computational Interoperability: Each application in the Suite is aligned with caBIG Silver Level compatibility and some common concepts have been harmonized with BRIDG 1.0.

Application-Specific Features:

- Patient Registration:

- * Create Studies
 - * create Subjects
 - * Register subjects on studies
 - * Eligibility
 - * Randomization
 - * Stratification
 - * Multi-site registration
 - * Accrual ceiling
 - * 2-step registration
 - * Reports
 - * Broadcast study and registration data to PSC, Lab Viewer, caAERS, and C3D
 - * Hot Link to PSC, Lab Viewer, and caAERS
 - * Dashboard-style UI
 - * Flexible event-driven email notifications
 - * Companion protocols (embedded and non-required)
 - * Enhanced security (site-level, password policy)
 - * Additional data elements (e.g. method of payment)
 - * BRIDG study structure harmonization
- Patient Scheduling:
- * Create Study Templates
 - * Generate Patient Calendars
 - * Manage events on Patient Calendars
 - * Handle study amendments and versions
 - * Generate reports
 - * Export data to standard calendar and mail programs
 - * Display notification of Adverse Events
 - * Hot Link to Lab Viewer and caAERS
- Adverse Event Reporting:
- * Document routine AEs and serious AEs
 - * Create and submit Expedited AE Reports
 - * Use CTCv2, CTCAEv3, or MedDRA
 - * Submit reports directly to AdEERS
 - * Submit reports to DCP, FDA, and other agencies
 - * Generate MedWatch 3500A, CIOMS, NCI SAE Form, AdEERS 5 Calendar Day and 10 Calendar Day reports
 - * Generate reports as PDFs
 - * Support for investigational and commercial agents
 - * Support for a range of study therapies -- including Drug Agent, Radiation, Surgery, and Medical Devices
 - * Import/Export AE data
 - * Hot Link to PSC and Lab Viewer
- Lab Analysis:
- * Management and analysis of lab data
 - * Search for labs based on subject, study, and date
 - * Load labs into C3D

- * Search for out-of-range labs
- * Hot Link to caAERS

-- Clinical Data Management:

- * The Suite includes a plug-in connector that integrates C3D with the other applications.
- * Using this Connector, one can automate some of the advanced features and functions in C3D.

-- caXchange:

- * Provides the ability for Cancer Centers to send patient laboratory data to the caXchange and route it appropriately to the recipient applications.
- * Follows JBI specifications, which makes all the developed components reusable and prevent vendor lock.
- * Provides facilities for auditing the messages.
- * Provides the clustering support for failover and reliable messaging.

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3.0 Known Issues and Limitations
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CCTS 1.1:

For the most recent list of open issues, refer to the project defect tracking database at the following URL:

http://gforge.nci.nih.gov/tracker/?group_id=368

Listed here are the known issues and limitations at the time of release of this version of the caBIG Clinical Trials Suite.

Known issues and limitations specific to each module are listed below:

CCTS suite level:

1. If study is created in C3PR that have a Non-Treatment Epoch with Arms, the Registration of the Subject on such studies is not supported by CCTS. This that PSC does not retain the ARMs on Non-Treating Epochs in a study causing scenario to fail on such studies.
2. Must ensure Organizations and OrgIDs are in sync across all CCTS application
3. Must ensure investigators are defined the same across all CCTS application. The investigator name and ID must be same in each of the other application
4. Users should be added to the system using an email address for their user and must be added to all systems with the same username.

5. Each user defined in CCTS must have credentials defined in Dorian (use GAA server to create the user) and the the username must match the username defined in the applications.
6. Time Synchronization for Servers/Virtual Machines: If components of CCTS are on different physical servers or virtual machines, then the system date and time must be synchronized between all of them and kept in constant sync. This is for the caGrid infrastructure which uses time based digital certificates as user authentication. For more information about synchronizing your computer clock, including setup instructions, can be found at <http://tf.nist.gov/service/its.htm>
7. Scalability and performance: Limited load and performance testing has been done on this version of the Suite. Users may run into issues under certain circumstances or data intense operations.
8. Error handling and messages: This version of the Suite has limited error handling. Enhanced error handling will be added to a future version of the Suite.
9. C3D does not support grid based single sign-on requiring user to login again.

C3PR:

1. Imports: a bug in the C3PR release renders users unable to import subjects. When a large load of subjects will be presented with an error page, and the operation will fail. The fix for this issue is to manually create subjects and their registrations through the Import and Create Registration workflows.
2. Marking a subject as "Off Study" for companion protocols has intermittent failures. An error will be presented with is a "Lazy Initialization Exception". There is currently no fix for this issue should a user run into it. Note that this issue does not effect registrations.
3. Image Url site banner in configuration page cannot be empty.
4. IE 7 Issues:
 - Cannot create Research staff/Investigator from prototype window in study flows.
Note: This information can be entered from the Person & Organization screen.
 - Help icons and Buttons are not rendering accurately on certain screens.
5. Notifications: The notifications can currently only be configured for the organization. i.e: Notifications can be configured for the organization whose NCI code is 1. This can be done on the Configure C3PR screen by the admin.

PSC:

1. If labels are amended during the template amendment process, and subject schedules have already been generated, the schedules will not be updated.
2. When moving activities on the Manage Period page, the 'X' icons will sometimes move to another activity. When this occurs, the 'X' must be deleted and a new one added at the desired location.
3. Large lists of activities (several hundred or more) will not display on the Manage Period tab. The activities are available to be added to templates, however. This only affects users who want to create, edit, or delete activities from within the user interface.

Lab Viewer:

No known issues at this time.

caAERS:

1. Expedited Flow: Device. Expiration date can't be future date.
2. Subject - changing birthdate must also be accompanied by another change in the change will not save.
3. Dose Modified & Administration delay fields are tied when they shouldn't be
4. Some criteria (gender, ethnicity) do not function in Advanced Search>>subj
5. Need to be able to capture partial AE data for an evaluation period
6. Search Study - hitting enter after typing in parameters makes it look like working but nothing happens
7. In Rules flow DELETE button raise the client side validation for empty fie
8. Validation error message displayed twice
9. Rules autocompleter not indicated by color
10. In expedited flow, "Has the participant been retreated" is autopopulating "please select"
11. Medical history isn't being back populated to subject/study assignment, so for new expedited reports
12. Start date of first course not getting copied to expedited report.
13. When creating Prevention studies, requires disease, no way to put 'healthy equivalent
14. During CCTS installation if caAERS is installed after PSC, it will overwrite PSC causing the invalid installation. To avoid this, please install caAERS Alternatively manually add following PSC configuration to csm_jass.config

```
psc {
  gov.nih.nci.security.authentication.loginmodules.RDBMSLoginModule requ
  driver="org.postgresql.Driver"
  url="jdbc:postgresql://<host>:<port>/psc"
  user="<user-id>"
  passwd="<password>"
  encryption-enabled="YES"
  query="SELECT * FROM CSM_USER WHERE LOGIN_NAME=? and PASSWORD=?"
  ;
};
```
15. Electronic submission of reports from caAERS to AdEERS works in this release reports. Amended reports and partially completed reports are not supported to use this feature, prior arrangement with NCI CTEP is required.
16. Currently, if you try to create a routine AE or expedited report without determining SAE reporting assessment criteria for the sponsor or institution the protocol, caAERS will generate an error. See the caAERS Administration on creating, importing, or enabling rules.

C3D Connector:

1. Patient Id (MRN) must be numeric in order for it to be considered for processing. Hyphens are removed from the Patient Id during process and do not effect Load Lab processing. Numeric Patient Id a requirement of the batch Lab Loader Utility provided by C3D.

2. Studies designed using multiple occurrences of a data element (CDE Id) will fail. This is a limitation of the DCAPIs.
3. If C3D is not used with the Suite, the Register Subject task will not work. If the user is broadcasting the registration from C3PR, the user will receive a message that the registration could not be carried out in the other applications.

caXchange:

1. Validation for HL7v3 service payload is not currently implemented.
2. Errors message "Illegal call to send" seen in the servicemix log file when rollbacks are issued, even though rollbacks are processed correctly.([GForge])

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4.0 Bug fixes
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Please refer the GForge bug tracker:

http://gforge.nci.nih.gov/tracker/?group_id=368

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5.0 Bug Reports and Support
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Send email to ccts-support@gforge.nci.nih.gov to request support or report a bug.

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6.0 Installation
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CCTS 1.1:

The CCTS 1.1 installation guide can be found at:

http://gforge.nci.nih.gov/docman/?group_id=368

or withing the CCTS 1.1 distribution at:

[ccts-1-1/documentation/ccts_installation_guide.doc](#)

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1.0 Introduction
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The caBIG Clinical Trials Suite is an open-source, enterprise-level clinical trials software application system. The Suite is comprised of a collection of robust, feature-rich modules covering a broad range of key areas in cancer clinical trials management, including those listed here:

- Patient Registration
- Patient Scheduling
- Lab Analysis
- Adverse Events Reporting
- Clinical Data Management

The Suite aims to meet the following interoperability standards:

- caBIG Silver Level Certification
- BRIDG Model Harmonization

1.1 Background

This is the first official public release of the caBIG Clinical Trials Suite. Additional major releases are planned for the second half of 2008 and the first quarter of 2009.

This release includes the following caBIG applications:

Application -----	Version -----
Cancer Central Clinical Participant Registry (C3PR)	2.0
Patient Study Calendar (PSC)	1.4
Lab Viewer/Clinical Trials Object Database System	1.0
Cancer Adverse Event Reporting System (caAERS)	1.0
Cancer Centralized Clinical Database (C3D) Connector	1.0
caXchange	1.0
caGrid	1.1

1.2 Release History

February 28, 2008: CCTS 1.0 (this release)

1.3 Resources

For additional information about CCTS 1.0, refer to the following sites and documents:

CCTS Project Web Site:

<http://gforge.nci.nih.gov/projects/ccts/>

User Guides:

- CCTS 1.0 End User Guide
- C3PR User Guide
- PSC User Guide
- Lab Viewer User Guide
- caAERS User Guide

Technical Reference Documents:

- CCTS 1.0 Architecture Document
- CCTS 1.0 Interface Specification Document
- CCTS 1.0 Interoperability Scenarios and Activity Diagrams

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2.0 New Features for this Release
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The caBIG Clinical Trials Suite contains a rich set of features designed to support the management of cancer clinical trials. The key features included as part of Version 1.0 are listed below.

Suite-Level Features:

- Single Sign-On (SSO): A user of the Suite is prompted to log in only once per session. Once logged in, a user can move securely from one application to another without being forced to repeatedly enter a username and password.
- Hot Links: To support certain common workflows across the Suite, CCTS 1.0 includes a set of smart links which allow a user to move from a page in one application to a related page in another application. For example, after setting up a study in C3PR and then broadcasting the newly created study to all the other applications in the Suite, the user can hot link to PSC and to caAERS to complete any remaining study setup details required by those applications. Similarly, while entering an expedited AE report in caAERS, a user can link from the Labs section in the report to the Lab Viewer application. From here, the user can view the patients labs and consider them for inclusion as part of the expedited AE report.
- Security: The Suite includes state-of-the art security features to safeguard sensitive data and to ensure compliance with HIPAA and 21 CFR Part 11 regulations. The Suite supports SSL for encryption of data across the internet and fully leverages all the advanced security components in caGrid 1.1.
- Reliable Messaging: The Suite includes logic to ensure that data sent from one application to another is successfully delivered.
- Transaction Control: The Suite includes logic to ensure that transactions across applications are completed successfully. Each task is monitored and confirmed. If the task cannot be completed properly in each application, the transaction is rolled back to ensure the integrity of the data across the Suite.

- Semantic and Computational Interoperability: Each application in the Suite is aligned with caBIG Silver Level compatibility and some common concepts have been harmonized with BRIDG 1.0.

Application-Specific Features:

- Patient Registration:
 - * Create Studies
 - * create Subjects
 - * Register subjects on studies
 - * Eligibility
 - * Randomization
 - * Stratification
 - * Multi-site registration
 - * Accrual ceiling
 - * 2-step registration
 - * Reports
 - * Broadcast study and registration data to PSC, Lab Viewer, caAERS, and C3D
 - * Hot Link to PSC, Lab Viewer, and caAERS
- Patient Scheduling:
 - * Create Study Templates
 - * Generate Patient Calendars
 - * Manage events on Patient Calendars
 - * Handle study amendments and versions
 - * Generate reports
 - * Export data to standard calendar and mail programs
 - * Display notification of Adverse Events
 - * Hot Link to Lab Viewer and caAERS
- Adverse Event Reporting:
 - * Document routine AEs and serious AEs
 - * Create and submit Expedited AE Reports
 - * Use CTCv2, CTCAEv3, or MedDRA
 - * Submit reports directly to AdEERS
 - * Submit reports to DCP, FDA, and other agencies
 - * Generate MedWatch 3500A, CIOMS, NCI SAE Form, AdEERS 5 Calendar Day and 10 Calendar Day reports
 - * Generate reports as PDFs
 - * Support for investigational and commercial agents
 - * Support for a range of study therapies -- including Drug Agent, Radiation, Surgery, and Medical Devices
 - * Import/Export AE data
 - * Hot Link to PSC and Lab Viewer

- Lab Analysis:
 - * Management and analysis of lab data
 - * Search for labs based on subject, study, and date
 - * Load labs into C3D
 - * Search for out-of-range labs
 - * Hot Link to caAERS

- Clinical Data Management:
 - * The Suite includes a plug-in connector that integrates C3D with the other applications.
 - * Using this Connector, one can automate some of the advanced features and functions in C3D.

- caXchange:
 - * Provides the ability for Cancer Centers to send patient laboratory data to the caXchange and route it appropriately to the recipient applications.
 - * Follows JBI specifications, which makes all the developed components reusable and prevent vendor lock.
 - * Provides facilities for auditing the messages.
 - * Provides the clustering support for failover and reliable messaging.

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3.0 Known Issues and Limitations
=====

For the most recent list of open issues, refer to the project defect tracking database at the following URL:

http://gforge.nci.nih.gov/tracker/?group_id=368

Listed here are the known issues and limitations at the time of release of this version of the caBIG Clinical Trials Suite.

Issue 1: Installation.

CCTS 1.0 is an enterprise-level application and requires a high level of technical expertise to install. In future releases of CCTS, we will include additional utilities and tools designed to simplify the installation process.

Issue 2: Time Synchronization for Servers/Virtual Machines: If components of CCTS are installed across different physical servers or virtual machines, then the system date and time has to be synchronized between all of them and kept in

constant sync. This is for the proper running of caGrid infrastructure which uses time based digital certificates as user identities. Information about synchronizing your computer clock, including setup instructions, can be found at <http://tf.nist.gov/service/its.htm>

- Issue 3: A CDMS application is not included with CCTS 1.0. CCTS 1.0 includes a connector that allows an existing C3D instance to be integrated into CCTS. However, the C3D application itself is not included as part of this Suite. C3D is based on Oracle Clinical and is not an open source application.
- Issue 4: If C3D is not used with the Suite, the Register Subject task will not work successfully. Upon broadcasting the registration from C3PR, the user will receive a message onscreen indicating that the registration could not be carried out in the other applications.
- Issue 5: Limitations to Create Study and Register Subject tasks. The Suite includes functionality to permit a study to be created in C3PR and then broadcasted to the other applications. Currently, there are a number of limits to this functionality.
- To create a study or register a subject using the broadcast feature, one must first make sure that
 - * the Organization (or Site) name and identifier already exists in all applications.
 - * the Investigator names and identifiers associated with the study must already exist in all applications.
 - Additional steps are required in PSC and caAERS to complete the set up the study. This must be done before the study can be used in those applications.
 - The Study will not be created in C3D. Studies must be created as a separate and independent step in C3D.
- Issue 6: Restrictions with User Management when using SSO. The following limitations and issues apply:
- SSO User Accounts must be created and administered in Dorian.
 - A User's username must be a unique, valid email address.
 - The user management features in the individual

applications do not work when using the Single Sign-On feature.

- In caAERS, the Forgot Password/Reset feature does not work for resetting the password for a user set up in Dorian. Passwords must be reset in Dorian.

Issue 7: In order to Load Labs in C3D from the Lab Viewer, the Medical Record Number or Subject ID must be numeric. C3D does not recognize non-numeric Subject Identifiers when processing Laboratory Test Data.

Issue 8: Scalability and performance. Limited load and performance testing has been conducted on this version of the Suite. Users may run into issues under certain circumstances or with heavy loads or data intense operations.

Issue 9: Error handling and messages. This version of the Suite has limited error handling features. Enhanced error handling will be added to a future version of the Suite.

Issue 10: The Lab Loads UML model in the CCTS Interface Specification document is not correct. A more recent copy of the model is available in the documentation\interface-details\models folder which is included as part of the CCTS 1.0 Distribution Package. Look for the Load lab Message Updated.zip file.

Known issues and limitations specific to each module are listed below:

C3PR:

1. Edit Study Flow: In the edit study flow, the system first shows appropriate error message when adding duplicate values (epoch names, arm names, diseases, investigators, study sites, study personnel) but still doesn't show a user-friendly message even after updating the values.

PSC:

1. Some rendering issues in Internet Explorer
2. No other known issues.

Lab Viewer:

1. No known issues at this time.

caAERS:

1. Electronic submission of reports from caAERS to AdEERS works in this release only for completed reports. Amended reports and partially completed reports are not supported. Also, please note that, to use this feature, prior arrangement with NCI CTEP is required.
2. There are a few known issues with caAERS when used with Internet Explorer version 7.
 - The export rules feature may not work correctly.
 - The download PDF feature from the Submit page may not work correctly. You should be able to download the PDF from the Manage Reports page.

An alternative workaround is to use the Firefox browser.

3. Currently, if you try to create a routine AE or expedited report without enabling a ruleset for determining SAE reporting assessment criteria for the sponsor or institution associated with the protocol, caAERS will generate an error. See the caAERS Administration Guide for instructions on creating, importing, or enabling rules.
4. All required fields for a study must be completed prior to creating an expedited report or routine report. Trying to create an expedited report or routine AE on a study that is missing required fields (such as the CTC version being used for the trial) may cause caAERS to generate an error. This is only an issue when using caAERS as part of the CCTS 1.0 application suite and trying to enter AEs on a study created using the Create Study feature in the C3PR application.
5. Wrapping of tabs. If your browser window is not sized large enough, some of the tabs may wrap and distort the UI. To fix, resize the browser window.
6. As designed, caAERS does not let a user access areas or features disallowed by the user's role. However, unfriendly error message may appear in some limited cases if you try to access an area of the application for which you don't have privileges. We will add a more friendly error message to future release.
7. When creating a study in caAERS using the C3Pr Create Study feature, the organization name and identifier and the

Investigator names and identifies must already exist in caAERS. The names and identifiers must be entered in caAERS exactly as they are in C3Pr.

C3D Connector:

1. Patient Id (MRN) must be numeric in order for it to be considered for Lab Result processing. Hyphens are removed from the Patient Id during processing and do not effect the Load Lab. Numeric Patient Id is a requirement of the Lab Loader Utility
2. Studies designed using multiple occurrences of a data element (CDE Id) will not load data. This is a limitation of the DCAPIs.

caXchange:

1. Aggregator Listener timeout error in wrong part of response message (GForge ID: 10659)

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 4.0 Bug fixes
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Please refer the GForge bug tracker:

http://gforge.nci.nih.gov/tracker/?group_id=368

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 5.0 Bug Reports and Support
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Send email to ccts-support@gforge.nci.nih.gov to request support or report a bug.

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 6.0 Installation
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The CCTS 1.0 installation guide can be found at:

http://gforge.nci.nih.gov/docman/?group_id=368

or withing the CCTS 1.0 distribution at:

ccts-1-0/documentation/ccts_installation_guide.doc