

CABIG[®] CLINICAL TRIALS SUITE 1.1

End User Guide



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v.2

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Chapter 1 Using the End User's Guide

This chapter introduces you to the *caBIG® Clinical Trials Suite 1.1 End User's Guide*. Topics in this section include:

- Overview of the Guide
- Audience
- Organization of this Guide
- Additional References
- *User's Guide Text Conventions*
- *Credits and Resources*

Introduction to the End User's Guide

Overview of the Guide

The End User's Guide covers the general use and operation of the Suite. Included here are brief instructions for using the Suite to perform common tasks, such as creating a study, registering a subject, loading lab results to a clinical data management repository, or submitting a possible adverse event-triggered schedule change.

This guide does not provide detailed instructions on the use of each of the component applications. For additional information about how to use specific applications within the Suite, refer to that application's end user or administration guide. See the Additional References section for more information on how to obtain a copy of these application guides.

Audience

The *caBIG® Clinical Trials Suite 1.1 Installation Guide* is intended for use by clinical study personnel who want to learn about operating the Suite.

Technical personnel are referred to the architecture, integration, interface and installation documentation listed in the Additional References section.

Please note that this guide assumes that a trial site is adopting the full Suite (that is, all the applications in the Suite) as opposed to adapting part of the Suite to an existing set of local systems. For sites adapting the Suite to supplement and integrate with existing local systems, support is available. Refer to the *Support* section on page 6 for information on how to request additional support.

Organization of this Guide

The End User's Guide contains the following chapters:

- **Chapter 1 Using the End User's Guide**—This chapter introduces you to the *End User's Guide* and suggests ways you can maximize its use.
- **Chapter 2 Overview of the caBIG® Clinical Trials Suite**—This chapter introduces you to the applications that comprise the Suite.
- **Chapter 3 Using the Suite**—This chapter introduces you to concepts that will aid in your use of the Suite.
- **Chapter 4 Getting Started in the Suite**—This chapter covers the basics for getting started with use of the Suite.
- **Chapter 5 Creating Studies**—This chapter provides an overview of creating in the Suite.
- **Chapter 6 Registering Subjects**—This chapter provides an overview of how to register subjects to studies in the Suite.
- **Chapter 7 Lab Data**—This chapter provides an overview of the different ways for handling and loading lab data in the Suite.
- **Chapter 8 Adverse Event Triggered Schedule Changes**—This chapter provides an overview of the interactions between the Adverse Events Reporting module and the Patient Study Calendar.
- **Glossary**—This section provides a glossary for commonly used terms.
- **Index**—This section of the guide provides a complete index.

Additional References

For more information about the caBIG Clinical Trials Suite 1.1, see the following references:

- caBIG® Clinical Trials Suite 1.1 Release Notes
- caBIG® Clinical Trials Suite 1.1 Administration Guide
- caBIG® Clinical Trials Suite 1.1 Installation Guide
- caBIG® Clinical Trials Suite 1.1 Architecture Guide
- caBIG® Clinical Trials Suite 1.1 Interface Specification Document

For more information, refer also to the End User and Administration Guides covering the individual modules within the Suite:

- Cancer Central Clinical Participant Registry (C3PR)
- Patient Study Calendar (PSC)
- Cancer Adverse Event Reporting System (caAERS)
- Clinical Trials Object Database Systems (CTODS) Lab Viewer
- Cancer Central Clinical Database (C3D) Connector

- Clinical Data Exchange (caXchange)

Text Conventions Used

This section explains conventions used in this guide. The various typefaces represent interface components, keyboard shortcuts, toolbar buttons, dialog box options, and text that you type.

Convention	Description	Example
Bold	Highlights names of option buttons, check boxes, drop-down menus, menu commands, command buttons, or icons.	Click Search .
<u>URL</u>	Indicates a Web address.	http://domain.com
text in SMALL CAPS	Indicates a keyboard shortcut.	Press ENTER.
text in SMALL CAPS + text in SMALL CAPS	Indicates keys that are pressed simultaneously.	Press SHIFT + CTRL.
<i>Italics</i>	Highlights references to other documents, sections, figures, and tables.	See <i>Figure 4.5</i> .
<i>Italic boldface monospace type</i>	Represents text that you type.	In the New Subset text box, enter <i>Proprietary Proteins</i> .
Note:	Highlights information of particular importance.	Note: This concept is used throughout this document.
{ }	Surrounds replaceable items.	Replace {last name, first name} with the Principal Investigator's name.

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NU = Northwestern University, SB = SemanticBits, S = SAIC		

Support

Contacts and Support	
Knowledge Center	https://cabig-kc.nci.nih.gov/CTMS/KC/index.php/CCTS
NCICB Application Support	Website: https://ncicbsupport.nci.nih.gov/sw/ Telephone: 301-451-4384 Toll Free: 888-478-4423 Email: ncicb@pop.nci.nih.gov
CCTS Users Mailing List	CCTS_USERS-L@LIST.NIH.GOV

Chapter 2 Overview of the caBIG[®] Clinical Trials Suite Software

This chapter introduces you to the applications that comprise the Suite. Topics in this chapter include:

- Overview of the Suite
- What is New in CCTS 1.1?
- Cancer Central Clinical Participant Registry
- Patient Study Calendar
- Cancer Adverse Events Reporting System
- caXchange
- Lab Viewer
- Cancer Central Clinical Database Connector

Overview of the Suite

The caBIG[®] Clinical Trials Suite is an enterprise-level clinical trials software application system. The Suite is designed for use primarily at trial sites and provides support for common clinical trials activities, such as the following:

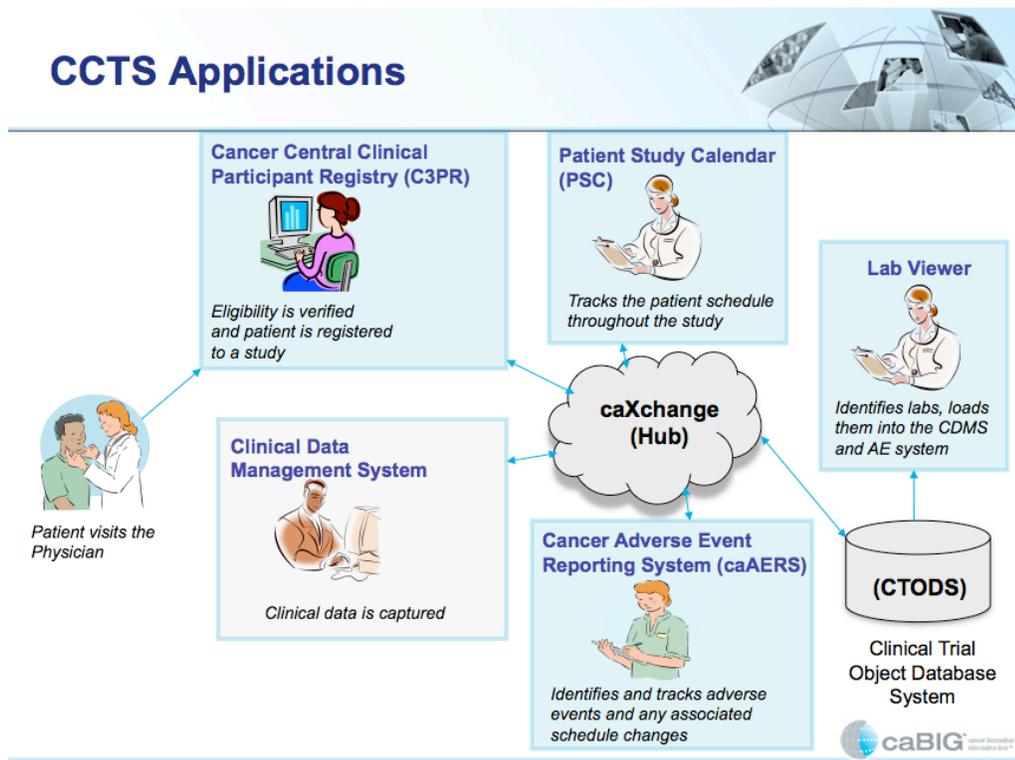
- Registering and tracking patients,
- Managing patient activities and calendars,
- Reporting and tracking adverse events,
- Reviewing laboratory data,
- Transferring data to between applications,
- Capturing and cleaning the clinical data, and
- Analyzing and reporting on the collected data.

The caBIG[®] Clinical Trials Suite is comprised of the following collection of interoperable modules:

- **Clinical Participant Registry (C3PR)** (version 2.5) - A tool for managing clinical trial patient enrollment data across multiple clinical trials, organizations and sites. For more information, go here: <https://cabig.nci.nih.gov/tools/c3pr>.
- **Patient Study Calendar (PSC)** (version 2.3) – A tool for creating and editing study calendar templates, generating and viewing prospective calendars of patient activities, tracking activities as they occur, and managing patient calendars as they change during a study. For more information, go here: <https://cabig.nci.nih.gov/tools/PatientStudyCalendar>

- **Adverse Event Reporting System (caAERS)** (version 1.5) - A tool for collecting, managing, processing and reporting routine and serious adverse events that occur during clinical trials. For more information, go here: <https://cabig.nci.nih.gov/tools/caAERS>.
- **Clinical Data Exchange (caXchange)** (version 1.5) - A configurable hub for exchanging clinical trial information between applications and systems. For more information, go here: <https://cabig.nci.nih.gov/tools/LabIntegrationHub>.
- **Clinical Trials Object Database Systems (CTODS) Lab Viewer** (version 1.5) - A lab viewing tool that works in combination with CTODS (v.1.0), a clinical trial information repository. This release includes data loading scripts and a client side application (CCHC) for loading lab data into CTODS. For more information, go here: <https://cabig.nci.nih.gov/inventory/infrastructure/CTODS>.
- **Cancer Central Clinical Database (C3D) Connector** (version 1.2) – A BRIDG-based adapter that allows applications in the Suite to connect with the C3D. (Note: C3D is not included as part of the caBIG® Clinical Trials Suite 1.1 bundle.)
- **caGrid** (version 1.2) – caGrid is a service-oriented architecture and federation that connects caBIG®-compatible systems together. For more information about caGrid, go here: <https://cabig.nci.nih.gov/workspaces/Architecture/caGrid/>

The applications included in the Suite are designed to work in concert to cover a broad range of key areas in cancer clinical trials management, as shown in the figure below.



What is New in CCTS 1.1?

caBIG® Clinical Trials Suite 1.1 includes a number of key enhancements. One of the most notable improvements is that this version of the Suite now includes the latest versions of each of the component modules. These upgraded versions are listed below in the table.

CTMS Application	Version of Application Included in CCTS 1.1	Version of Application Included in CCTS 1.0
Cancer Central Clinical Participant Registry (C3PR)	C3PR 2.5.2	C3PR 2.0
Patient Study Calendar (PSC)	PSC 2.3.3	PSC 2.0
Cancer Adverse Event Reporting System (caAERS)	caAERS 1.5.1	caAERS 1.0
Lab Viewer	Lab Viewer 1.5	Lab Viewer 1.0
Cancer Central Clinical Database (C3D) Connector	C3D Connector 1.2	C3D Connector 1.0
caXchange	caXchange 1.5	caXchange 1.0
caGrid	caGrid 1.2	caGrid 1.1

Additional information about the enhancements introduced with each of the new module releases is provided in the remaining sections of this chapter.

Cancer Central Clinical Participant Registry

Overview of the Cancer Central Clinical Participant Registry (C3PR)

The Cancer Central Clinical Participant Registry (C3PR, hereafter also referred to as the Participant Registry) is a web-based application used for end-to-end registration of patients to clinical trials. This includes capturing the consent signed date, eligibility criteria, stratification, randomization, and screening. Clinical workflows are enabled by both subject- and study-centric views into the registration process.

The Participant Registry also enables multi-site clinical trials where registration information is entered locally at affiliate sites and the registration is completed by call-out to the coordinating site.

C3PR can be run in a stand-alone mode where study definitions, investigators, study personnel, and sites are entered into the system, or it can be run in an integrated mode with the Suite.

New features in C3PR

The Participant Registry includes a number of enhancements, including the following:

- 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

Role of the Participant Registry in the Suite

The Participant Registry provides two key use cases in the Suite: study creation and subject registration. After a study is created and activated in the Participant Registry, a user can propagate that study to the other applications. Once a subject is registered to a propagated study, the registration information (demographics, arm, etc.) can be sent to the other applications. This enables further workflow because key information, such as study and subject identifiers, is programmatically synchronized between the applications.

For More Info on the Participant Registry

The C3PR End User Guide can be found at this location:

https://gforge.nci.nih.gov/docman/view.php/368/14920/C3PRv2_5_End_User_Guide.doc

The C3PR Administration Guide can be found at this location:

https://gforge.nci.nih.gov/docman/view.php/368/14923/C3PRv2_5_Admin_Guide.doc

The C3PR Release Notes can be found at this location:

https://gforge.nci.nih.gov/docman/view.php/368/14919/C3PRv2_5_CCTS_Release_Notes.txt

For additional information about Cancer Central Clinical Participant Registry, go here: <http://cabig.nci.nih.gov/tools/c3pr>

Patient Study Calendar

Overview of Patient Study Calendar (PSC)

The Patient Study Calendar (PSC, hereafter referred to as the Study Calendar) is an open source, standards-compliant, web-based application that assists with the

management of the activities of subjects on clinical trials. The Study Calendar provides the ability to create and edit a standard template to represent the activities defined by a study protocol, use this template to generate and view prospective calendars of subject activities, track the state of activities as a subject progresses through the study, and manage subject calendars as they change during a study. It also provides interfaces for managing access to data across a multi-site environment and balancing the workload of Subject Coordinators.

New features in the Study Calendar

The Study Calendar has been upgraded and includes the following new features:

- Activity management tab
- Flexible report generation interface (including reports by activity state)
- Event-driven notifications
- Template node reuse
- Define templates in terms of cycles
- Create mandatory and/or optional amendments
- Track history of changes to a template
- Manage activities for special patient populations
- Import and export templates in XML format
- Store the most recent date of activities that have been missed or canceled
- Apply labels to activities to generate custom reports
- Numerous interface and performance enhancements

Role of the Study Calendar in the Suite

The Study Calendar receives study creation and patient registration information from the Participant Registry via caXchange. The Study Calendar also receives and displays on a subject's schedule Adverse Event notifications from the Cancer Adverse Event Reporting System. Finally, the Study Calendar provides links from a subject's calendar to the Cancer Adverse Event Reporting System and Lab Viewer so that the coordinator can quickly access additional information about the subject.

For More Info on the Study Calendar

The Study Calendar End User Guide can be found here:

https://gforge.nci.nih.gov/docman/view.php/368/14914/PSC_2-3_End_User_Guide.doc

The Study Calendar Administration Guide can be found here:

https://gforge.nci.nih.gov/docman/view.php/368/14924/PSC_2-3_Admin_Guide.doc

The Study Calendar Release Notes can be found here:

https://gforge.nci.nih.gov/docman/view.php/368/14913/PSC_2-3_Release_Notes.txt

For additional information about the Patient Study Calendar, go here:
<https://cabig.nci.nih.gov/tools/PatientStudyCalendar>

Cancer Adverse Event Reporting System

Overview of Cancer Adverse Event Reporting System (caAERS)

The Cancer Adverse Event Reporting System (caAERS, hereafter also referred to as the AE Reporting System) is an open source, web-based application for documenting, managing, reporting, and analyzing adverse events (AEs). The system operates both as a repository for capturing and tracking routine and serious AEs (SAEs) and as a tool for preparing and submitting expedited AE reports to regulatory agencies. Currently, caAERS works with cancer prevention and therapeutic trials and can accommodate a range of intervention types, including investigational and commercial agents, radiation, surgery, and medical devices. Adverse events can be coded in the AE Reporting System using either CTCAE or MedDRA.

To help organizations stay in compliance with AE reporting regulations, the AE Reporting System application comes loaded with a full complement of industry-standard AE reports, including the FDA MedWatch 3500A form, the CTEP AdEERS reports, and the NCI-DCP SAE form. In addition, the AE Reporting System features a powerful, state-of-the-art rules engine, which can capture a range of sponsor, institution, and protocol-level reporting requirements. Using these rules, the AE Reporting System can automatically determine if an adverse event requires expedited reporting and when and to whom the report must be submitted – for any of an organization’s trials. The business rules used by the AE Reporting System can be authored within the application itself or imported from a library of approved rule sets.

The AE Reporting System also features an advanced email-based alert system that can be customized along a number of dimensions (message content, recipients, delivery times) to ensure that notifications and reminders are sent out as needed. Also included as part of the AE Reporting System is an easy-to-use report template generator, which allows users to build and customize reports.

The AE Reporting System can be deployed as a stand-alone application or as an integrated module within the Suite.

New Features in caAERS

The Adverse Event Reporting System has been upgraded and includes the following new features:

- New User Interface, improved usability, streamlined data entry
- Alerts panel functionality to display lab data sent by Lab Viewer

- Enhanced support of adverse event reporting (MedWatch 3500A, DCP SAE report)
- Support concept of evaluation period type in AE capture and definition
- Support concepts of course, cycle, and reporting period in AE capture and reporting
- Support study defined solicited AE's
- Support of follow-up adverse events
- Support entry of baseline symptoms
- Enhanced AE search capabilities
- Support of multiple versions of MedDRA terminology (v9.0-v11.0)
- Ability to create and update investigators and research staff from local systems via xml import
- Ability to update study and participant data from local systems via xml import
- Support of real-time data updates from local systems via services and messaging

Role of the AE Reporting System in the Suite

The AE Reporting System serves as the adverse event repository and reporting system within the Suite. It is closely integrated with the other modules in the suite, including the Participant Registry and the Study Calendar. The AE Reporting System supports three key use cases in the Suite:

- Study Creation – Studies defined in the Participant Registry can be automatically created in the AE Reporting System.
- Subject Registration – Enrollment of patients onto trials in the Participant Registry can be transmitted to the AE Reporting System.
- AE-Triggered Schedule Change – Notifications of adverse events can be sent from the AE Reporting System to the Study Calendar for review and possible schedule or treatment changes.

For More Info on the AE Reporting System

The caAERS End User Guide can be found at this location:

https://gforge.nci.nih.gov/docman/view.php/368/14910/caAERS_1.5_End_User_Guide.pdf

The caAERS Administration Guide can be found at this location:

https://gforge.nci.nih.gov/docman/view.php/368/14911/caAERS_1.5_Admin_Guide.pdf

The caAERS Release Notes can be found at this location:

https://gforge.nci.nih.gov/docman/view.php/368/14912/caAERS_1.5_Release_Notes.pdf

For more information about the Cancer Adverse Events Reporting System, go here:
<https://cabig.nci.nih.gov/tools/caAERS>

caXchange

Overview of caXchange

caXchange is a powerful software tool that works behind the scenes to exchange all types of clinical trial data and messages between application systems and software services to perform simple or complex workflows. caXchange supports tasks such as routing lab data from a lab information system to a software service that converts the data into HL7 v3 messages and then stores the data in a database from which the Lab Viewer could query lab results. It allows a system administrator to add other software services to perform any kind of task required in a workflow, and provides numerous other technical features such as a graphical user interface for configuring the tool and auditing services for diagnosing workflow design problems. caXchange routes and exchanges clinical trial messages and data for all Suite applications and all Suite workflows over caGrid.

New Features in caXchange

caXchange has been upgraded and includes the following new features:

- Enhanced integration with existing local systems
- Enhanced logging and diagnostics
- Ability to specify modules to include/not include as part of the Suite
- Input validation
- Ability to configure caXchange to receive additional message types

Role of caXchange in the Suite

The Suite needs to be able to exchange information between all component applications in an audited and controlled manner. caXchange provides the capability to send, receive and log messages and data between applications. Specifically, caXchange routes messages in each of the four workflows identified in Chapter 3, CCTS Workflows, on page 17.

Study creation messages from the Participant Registry to the other applications
Subject registration messages from the Participant Registry to the other applications
Labs selected in Lab Viewer to the Clinical Data Management System for loading
Notification of an adverse event from the AE Reporting System to the Study Calendar.

For More Info on caXchange

The caXchange Administration Guide can be found at this location:
https://gforge.nci.nih.gov/docman/view.php/368/14917/caXchange-1-5_Admin_Guide.doc

The caXchange Release Notes can be found at this location:
https://gforge.nci.nih.gov/docman/view.php/368/14918/caXchange-1-5_Release_Notes.doc

For more information about caXchange, go here:
<https://cabig.nci.nih.gov/tools/LabIntegrationHub>

Lab Viewer

Overview of Lab Viewer

The Clinical Trials Object Data System (CTODS) Lab Viewer is a web based application developed by leveraging the SDK generated APIs of the CTODS Lab Domain UML model. The CTODS Lab Viewer allows users to view laboratory activities that are stored in the CTODS Lab Domain database. Users are allowed to search the laboratory activity records by Patient ID, Study ID, Lab Start Date, and Lab End Date. When the search results are displayed, numeric results that are outside the high and low reference ranges of the lab tests are highlighted to alert the user. This visual alert/trigger allows the user to focus in and act on those specific lab test results. Additionally, the CTODS Lab Viewer allows users to send lab data in the form of XML messages via caXchange. The message that can be sent is a Load Lab Data message to the local CDMS application (C3D) and caAERS. CTODS Lab Viewer interface allows the user to select which labs should be loaded into CDMS or caAERS.

Role of Lab Viewer in the Suite

Lab Viewer is involved in three of the four workflows that are the focus of the Suite. In the first two workflows, it receives the Trials study creation message and the subject registration message, both from the Participant Registry, and saves the study, subject, and registration data to the database. It is also featured in the Load Labs in CDMS workflow where the user can query and view the lab data collected during the execution of a clinical trial. It allows you to select laboratory results to send via caXchange to a caBIG™-compatible Clinical Data Management System (CDMS).

New Features in the Lab Viewer

The Lab Viewer has been upgraded and includes the following new features:

- Support for PostgreSQL (in addition to Oracle)

- Export of labs to caAERS
- Export of labs to CSV file
- Enhanced hotlink capabilities and window titles

For More Info on Lab Viewer

The Lab Viewer End User Guide can be found at this location:

<https://qforge.nci.nih.gov/docman/view.php/368/14916/CTODS%20Lab%20Viewer%20End%20User%20Guide.doc>

The Lab Viewer Release Notes can be found here:

<https://qforge.nci.nih.gov/docman/view.php/368/14915/CTODS%20Lab%20Viewer%20Release%20Notes.doc>

For more information about the CTODS Lab Viewer, go here:

<https://cabig.nci.nih.gov/tools/LabViewer>

Cancer Central Clinical Database Connector

Overview of C3D Connector and Cancer Central Clinical Database (C3D)

The C3D Connector is an example of a component that allows a legacy Clinical Data Management System (CDMS), or any other kind of legacy system, to exchange data with the component applications in the Suite. The C3D Connector is a component of the Suite, however the C3D is not. For a basic understanding, both C3D Connector (a Suite application) and Cancer Central Clinical Database (a vendor-provided solution resident at NCI-CBIIT) are reviewed here.

C3D Connector (a Suite Component)

The C3D Connector provides the Suite users the ability to enroll patients and load labs into the CDMS, the Cancer Central Clinical Database in this case. It provides the ability to enroll patients into studies maintained by the Cancer Central Clinical Database, without having to interact with the normal user interface. It also provides a mechanism that allows for the automatic processing and loading of laboratory test result data into the database for specific patients on studies maintained by the Cancer Central Clinical Database using all of the required data qualification and validation procedures

Cancer Central Clinical Database (a Vendor-Supplied Solution)

Cancer Central Clinical Database (C3D) is a clinical trials data management system. C3D collects clinical trial data using standard case report forms (CRFs) based on common data elements (CDEs). C3D utilizes security procedures to protect patient

confidentiality and maintain an audit trail as required by FDA regulations. C3D currently supports electronic submission of clinical trials data to the National Cancer Institutes (NCI) Clinical Data System and the Clinical Trials Monitoring Service (CTMS/Theradex). C3D consists of three web-based components: Oracle Clinical, for protocol building; Remote Data Capture, for data entry and management; and Integrated Review / Java Review, for real-time access to clinical data within and across clinical studies to authorized users.

Role of C3D Connector in the Suite

The role of the C3D Connector in the Suite is to receive authoritative information from the other components of the Suite and save them to the database. Patient Registration information is received from the Participant Registry and used to create Patient Positions with the C3D CTMS. Laboratory Test Results available in the Lab Viewer component can be passed to the C3D Connector which then analyzes and loads the data to the appropriate Study/Patient.

For More Info on C3D Connector

The C3D Connector Administration Guide can be found at this location:

https://gforge.nci.nih.gov/docman/view.php/368/14922/C3D%20Connector_1.2_Admin_Guide.doc

The C3D Connector Release Notes can be found here:

https://gforge.nci.nih.gov/docman/view.php/368/14921/C3D%20Connector_1.2_Release_Notes.doc

Additional information about C3D can be found here:

<https://caiq.nci.nih.gov/tools/c3d>

Chapter 3 Using the Suite

This chapter introduces you to concepts that will aid in your use of the Suite. Topics in this chapter include:

- System Requirements
- Setting up Users
- User Interface
- Minimizing Redundant Data Entry
- Error Handling and Rollback Features

System Requirements

The following are the minimum requirements of a computer that is going to access the Suite:

- Internet connection: speed of 56K or faster (broadband) recommended
- Browser: Firefox 2.0, Internet Explorer 7.0 is recommended, 6.0 is supported
- Display: resolution of 1024 x 768 or better is recommended, 800 x 600 is supported

Setting up Users

Users must be set up and managed at both the Suite level and the individual application level. Each user must first be set up as a CCTS user and then set up as a user within any of the modules to which that user is being granted access. Within each application, users can be assigned to specific roles and studies.

User provisioning and management is not covered in detail in this guide. For detailed instructions on setting up users please refer to the *caBIG® Clinical Trials Suite 1.1 Administration Guide*. Additional information about setting up users within a module and assigning roles can also be found in the administration guides for each application.

Note: Passwords for Suite level user accounts cannot be changed at this time.

User Interface

All of the component applications in the Suite have some look and feel characteristics in common and some unique features. Along with a common tab-based user interface to present user tasks, several of the components have a Google-like search, a common color scheme and a common naming convention for high level data elements. For details about navigation and the look and feel of each application, refer to the user guides for each tool.

Minimizing Redundant Data Entry

For any given component applications in the Suite, many of the data items used are common to one or more other component applications. The Suite minimizes redundant data entry and improves data consistency by providing a mechanism to propagate data from a “source of truth” application to one or more other applications. After entering the data in the “source of truth” application, The Suite provides a link or a button that a user may click to send a message containing the common data to the other applications. This allows the user to determine when the data is complete, accurate, and ready to be disseminated. The other applications automatically receive the message and load the data. The next time the user enters the receiving application, they may view the propagated data.

Data elements related to the following concepts appear on more than one application:

Application	Study	Site	Subject	Lab Data	Users/Security
C3D	Y	Y	Y	Y	
C3PR	Y*	Y	Y*		Y
caAERS	Y	Y	Y	Y	Y
Lab Viewer	Y	Y	Y	Y*	
PSC	Y	Y	Y		Y

* Indicates source of truth for version 1.1 of the Suite

Error Handling and Rollback Features

If an error is returned to an application, the system administrator of the application should be contacted; they will be able to diagnose the problem using system log files. If an error occurs during the transfer of data from one application to one or more other applications, data will not be saved into any of the receiving applications – this is called “rollback”.

Chapter 4 Getting Started in the Suite

This chapter covers topics related to getting started with using the Suite:

- Launching the Suite
- Exiting the Suite
- Application Roles and Workflows
- Hotlinking

Launching the Suite

To enter the Suite, log into any of the individual applications. Because of the single-sign-on (SSO) feature, you can access any of the other applications using the hotlinks without logging in again. See the individual application user guides for specific instructions on logging in.

The Participant Registry is the recommended starting point for creating studies and registering subjects. The Study Calendar is the recommended starting point for reviewing lab activities. The AE Reporting System is the recommended starting point for reviewing adverse events for impact upon subject study schedules.

To launch the Suite:

1. Open your browser and enter the address for the application you want to open. For example, enter the web address for the C3PR application.
2. If you are not already signed in, a Single Sign-On (SSO) page will appear and will prompt you to enter your username and password.

Central Authentication Service (CAS)

Enter Your NetID And Password And Select The Authentication Service To Use For Authentication.

NetID:

Password:

Authentication Service:

Warn me before logging me into other sites.

[clear](#)

For security reasons, please Log Out and Exit your web browser when you are done accessing services that require authentication!

Languages: [English](#)

After entering your username and password, you will be automatically routed to the CCTS application you were trying to open. For example, if you were

trying to open C3PR, you will now be taken to the C3PR home page, as shown below.

C3PR Cancer Clinical Central Participant Registry
National Cancer Institute Clinical Research Branch

Welcome org2 admin | Admin Help | Change skin | Log out

Registration Studies Person & Organization Administration Advanced Search

C3PR » Home Page » Dashboard

Frequently Used Shortcuts

- Search Study
- Create Registration
- Create Study
- Search Registration

C3PR Notifications [My Inbox](#)

You don't have any notifications.

C3PR Development Notes

[C3PR Wiki](#)
[C3PR User Guide](#)
[Check Deployment Status](#)
 Build Number: C3PR v. 2.5

Incomplete Registrations - Most Recent

Subject Name	Subject Medical Record #	Study Short Title	Registration Status
John Lock	6703	Study July 9	Unregistered
Johnny Lee	111	Test C3D study Dec 4th	Unregistered
Test CCTS Part last	asdcdsvsdvscfvcv	Test C3D study Dec 4th	Unregistered
Peter Smith	GSH-43	Test C3D study Dec 4th	Unregistered
Robert Wilson	AC-295	Test C3D study Dec 4th	Unregistered

Pending Studies - Most Recent

Most Active Studies

Short Title	Primary Identifier	Coordinating Center	Accrual w/in Last Week
Sample Study - ABC	NCI-0001	National Cancer Institute	0
test study 24th oct2	nci3	National Cancer Institute	0
test study 24th oct	NCI2	National Cancer Institute	0
Test CCTS Study Coo	Study_CO_test	National Cancer Institute	1
Test Site Coo CCTS	CCTS_SITE_CO_Test	National Cancer Institute	1

Once you have logged into the Suite, you can move freely between any of modules in the Suite in which you are an authorized user without having to re-enter your username and password.

Each module will appear in its own tab or window (once you have linked to each application):

C3PR Dashboard Page | caAERS | Welcome to caAERS | PSC - Subject Coordinator Das... | CTODS Lab Viewer

C3PR Cancer Clinical Central Participant Registry
National Cancer Institute Clinical Research Branch

Welcome org2 admin | Admin Help | Change skin | Log out

Registration Studies Person & Organization Administration Advanced Search

C3PR » Home Page » Dashboard

Frequently Used Shortcuts

- Search Study
- Create Registration
- Create Study
- Search Registration

Incomplete Registrations - Most Recent

Subject Name	Subject Medical Record #	Study Short Title	Registration Status
John Lock	6703	Study July 9	Unregistered

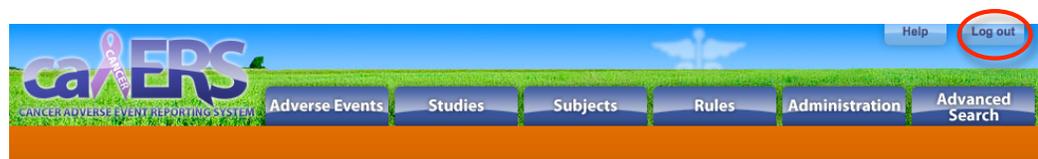
Exiting the Suite

To exit the Suite, you must log out of each application or close each window individually.

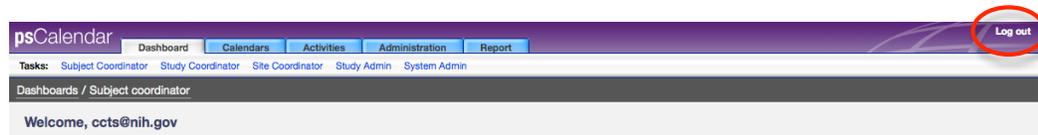
Logging out of C3PR:



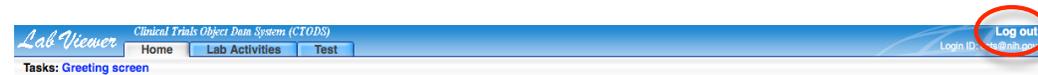
Logging out of caAERS:



Logging out of PSC:



Logging out of Lab Viewer:



Application Roles and Workflows

To use the Suite effectively, users must be set up in each application and granted the appropriate roles.

Roles in C3PR

The likely users of C3PR are people with the job responsibilities listed below. The role(s) granted to each user in the application will depend on the specific responsibilities of the person's job and other institutional rules under which they

execute their responsibilities. Users can be assigned to any one or more of the following four roles:

- C3PR Admin – Is a "super-user" who manages the application; is able to assign users to roles within the application
- Study Coordinator – Manages studies across the site; approves and manages user registration process; grants users to a role within the application; creates new studies in the system
- Registrar – Enrolls Participants to Studies for which approval has been granted
- Site Coordinator – Enters Study definitions in the system; reviews completed Study definitions to determine if they are complete and correct

The screenshot shows the 'Research Staff' form in the C3PR system. The form is divided into several sections:

- Organization:** A text input field with a placeholder '(Begin typing here)' and a search icon.
- Basic Details:**
 - First Name: [Text Input]
 - Last Name: [Text Input]
 - Middle Name: [Text Input]
 - Maiden Name: [Text Input]
 - NCI Identifier: [Text Input]
 - Email (Username): [Text Input]
 - Phone: [Text Input] e.g. 7035600296 or 703-560-0296
 - Fax: [Text Input] e.g. 7035600296 or 703-560-0296
- * User Role (Atleast One - Check all that apply):** This section is circled in red and contains four checkboxes:
 - C3pr admin:
 - Study coordinator:
 - Registrar:
 - Site coordinator:

Refer to the *caBIG® Clinical Trials Suite 1.1 Administration Guide* or to the *C3PR End User's Guide* for more information about these roles.

Roles in caAERS

Access to the different areas of caAERS is controlled by the user roles. User can be assigned to one or more of the following four roles:

- Subject Coordinator – Provides access to the Adverse Events, Studies, and Subjects tabs; the user can document AEs and create reports, studies, and subjects
- Study Coordinator – Provides access to the Studies tab; the user can review studies, AEs, and expedited reports

- Adverse Event Coordinator – Provides access to the Adverse Events tab; the user can view and report AEs for studies they are assigned to
- Site Coordinator – Provides access to the Adverse Events, Studies, Rules, and Administration tabs; the user can report AEs, create studies, set up rules, and have access to administrative features of the application.

Note: The only tasks the site coordinator doesn't have access to is documenting AEs.

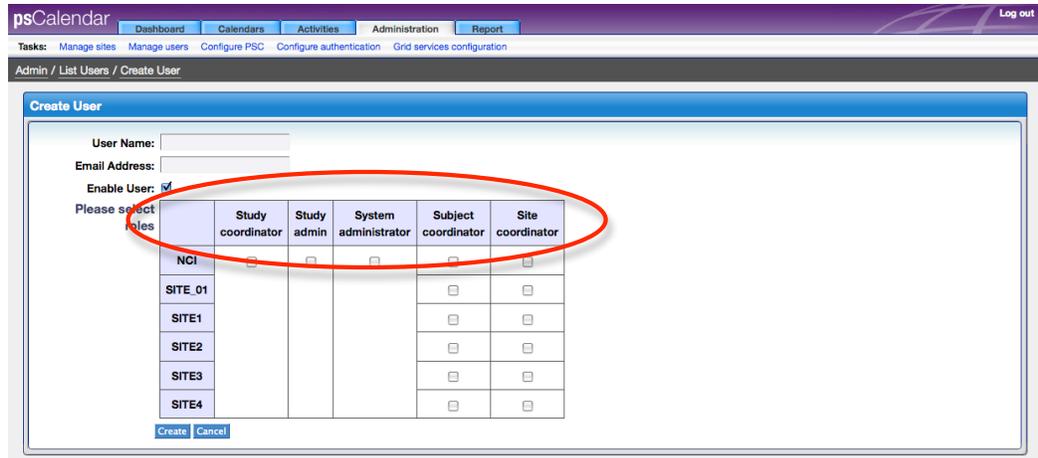
A screenshot of the 'Details' form for creating a Research Staff member. The form is titled 'Details' and includes an 'Instructions' section stating that all caAERS users need accounts and that users should enter organization and contact information. The 'Site' section has a required 'Organization' field with a search prompt. The 'Details' section contains fields for 'First name', 'Middle name', 'Last name', 'Researcher ID' (with a help icon), 'Email address', 'Phone' (with a mask '###-###-####'), 'Fax' (with a mask '###-###-####'), and 'Grid identity'. The 'User Role (Check all that apply)' section is circled in red and lists four roles: 'Subject coordinator', 'Study coordinator', 'Adverse event coordinator', and 'Site coordinator', each with an unchecked checkbox. A green 'Save' button is located at the bottom right of the form.

Refer to the *caBIG® Clinical Trials Suite 1.1 Administration Guide* or to the *caAERS End User's Guide* for more information about these roles.

Roles in PSC

In the PSC application, users can be assigned to one or more of the following four roles:

- Study Coordinator
- Study Admin
- System Administrator
- Subject Coordinator
- Site Coordinator



Refer to the *caBIG® Clinical Trials Suite 1.1 Administration Guide* or to the PSC End User’s Guide for more information about these roles.

Roles in Lab Viewer

Currently, Lab Viewer has one role - authorized to use Lab Viewer or not. After a user has been authenticated via WebSSO Dorian and authorized via CSM, they are allowed to use Lab Viewer.

Refer to the *caBIG® Clinical Trials Suite 1.1 Administration Guide* or to the Lab Viewer Administration for more information about roles in this application.

User Management Across the Suite

The following table describes the application-specific users/roles that should be defined for each application in order to operate all of the caBIG® Clinical Trials Suite functionality.

Role / Application	Site Coordinator	Study Coordinator	Subject Coordinator
C3PR	Site Coordinator: creates new study	Study Coordinator: opens studies and sends them to other applications	Registrar: registers subjects and sends them to other applications
PSC	N/A	Study Coordinator: receives sent studies (automatically), approves templates	Subject Coordinator: receives registrations (automatically), views subject calendars, receives calendar notifications
caAERS	N/A	Study Coordinator: receives sent studies (automatically), completes study definition, assign AE Coordinator to study	Subject Coordinator: receives sent registrations (automatically), receives sent labs (automatically), creates AEs, sends

			calendar notifications
Lab Viewer	N/A	Study Coordinator: receives sent studies (automatically)	Subject Coordinator: receives sent registratons (automatically), sends labs

The following table describes the roles/users necessary to handle the specific caBIG® Clinical Trials Suite messaging scenarios. These users must be created across all applications and be common across the applications for the messaging functionality to work.

Scenario / Application	Create Study	Register Subject	Send Lab to AE System	Send Lab to CDMS	Schedule Notification
C3PR	Site Coordinator (create study), Study Coordinator (open/send study)	Registrar			
PSC	Study Coordinator	Subject Coordinator			Subject Coordinator
caAERS	Study Coordinator	Subject Coordinator	Subject Coordinator		Subject Coordinator
Lab Viewer	Study Coordinator	Subject Coordinator	Subject Coordinator	Subject Coordinator	Subject Coordinator

Table 2.1 User roles assigned to user accounts

Notes:

- N/A = not applicable since that application is not involved in that workflow.
- caXchange routes messages between other applications and just accepts the user's credentials from the sending application.
- Administrative roles usually provide the same privileges as the roles above but are omitted as they are not generally given to end users.
- Detailed information about the user roles and the access privileges they provide is documented in the user guide of each individual application.

Hotlinking

Each of the Suite applications support “hotlinking.” This provides the user with the ability to navigate between the Suite applications without having to log in again. Each link takes the user to a particular page in the target application; the target location is based on the context of where the user was in the source application. By default, hotlinking to an application opens a new window. This default behavior can be changed by a Suite administrator.

The table below lists the hotlinks available in each suite component application:

Component Application	Hotlink Name	Hotlink Location
C3PR	PSC	Bottom, below Registration
C3PR	C3D*	Bottom, below Registration
C3PR	caAERS	Bottom, below Registration
PSC	Lab Viewer	Middle, under subject details
PSC	caAERS	Middle, under subject details
Lab Viewer	caAERS	Top
caAERS	PSC	Towards top, above AEs
caAERS	Lab Viewer	Middle, under Labs heading

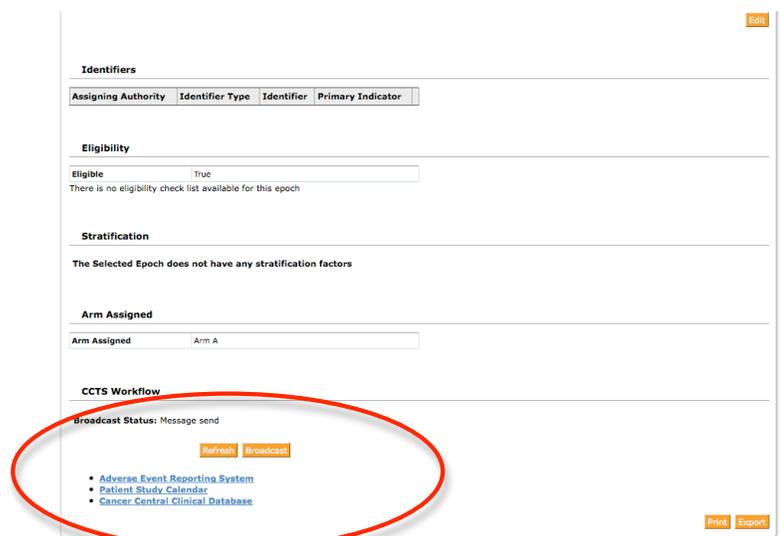
**Note: hotlinks to C3D require users to login with a C3D user name and password.*

Hotlinks Available in C3PR

In C3PR, there are hotlinks to the following modules:

- caAERS
- PSC
- C3D (Users will need to login separately to C3D)

These hotlinks are available from the Manage Registration page.



Hotlinks Available in caAERS

In caAERS, there is a hotlink to the Study Calendar (PSC).

The screenshot shows the 'Manage reports' page in caAERS. A blue callout box points to a link that says 'View this person's schedule in the [study calendar](#).'

Evaluation Period	# of Reports	# of AEs	Data Entry Status	Report Status	Options
▼ 10/01/08 - 10/31/08	1	1	In-progress	Report(s) Due	

Report Type	Report Version	# of AEs	Data Entry Status	Submission Status	Options
▶ test-1	0	1	Complete	Due on 10/29/2008	None notify PSC Submit Withdraw

All Adverse Events for this Reporting Period

▶ AE Term	Grade	AE Start Date	Requires Expedited Reporting?

In addition, there is a hotlink to Lab Viewer from the Labs page in caAERS.

The screenshot shows the 'Labs' page in caAERS. A red circle highlights a link that says 'View this person's details in the [lab viewer](#).'

Instructions: Enter any labs that are relevant for describing the event(s) in this report.

Lab A

Lab category: Any

Lab test name: Please select

Units: Please select

Baseline value: _____ date: _____

Worst value: _____ date: _____

Recovery value: _____ date: _____

A blue callout box states: 'Opens Lab Viewer application to allow user to view additional lab data that may need to be included in an expedited AE report.'

Hotlinks Available in Study Calendar (PSC)

In PSC, users can hotlink to the Adverse Events Reporting System (caAERS) or to the Lab Viewer.

The screenshot shows the psCalendar interface with a navigation bar (Dashboard, Calendars, Activities, Administration, Report) and a 'Log out' link. Below the navigation bar, there are tabs for 'Existing templates' and 'New template'. The main content area displays 'Studies / SMOKE_TEST (Treatment: Arm A) / Schedule for John Smith'. A sidebar on the left shows 'Schedule' for 'John Smith' with fields for 'Study S', 'Site N', and 'Current amendment I'. On the right, there are buttons for 'Take subject off study', 'Export ICS', 'View schedule for current subject' (with a dropdown for 'Smith, John' and a 'Go' button), and 'View this subject's' followed by 'adverse events' and 'lab results' buttons. A blue callout box points to the 'adverse events' button with the text: 'Opens the AE application to display any documented adverse events.' Another blue callout box points to the 'lab results' button with the text: 'Opens Lab Viewer application to display current patient's labs'.

Hotlinks Available in Lab Viewer

In Lab Viewer, users can hotlink to the Adverse Events Reporting System (caAERS).

The screenshot shows the Lab Viewer interface with a navigation bar (Home, Lab Activities, Test) and a 'Login ID: c' link. Below the navigation bar, there are tabs for 'Greeting screen' and 'Lab Activities - Search Results'. A table of lab activities is displayed with columns: Patient Id, Date / Time, Lab Test, Text Result, Numeric Result, Unit Of Measure, Lower Limit, Upper Limit, Sent to CDMS, and Sent to caAERS. A blue callout box points to a link above the table that says 'View this patient in caAERS' with the text: 'Opens the Adverse Events application and displays any documented AEs for the patient on the current study.' The table contains the following data:

	Patient Id	Date / Time	Lab Test	Text Result	Numeric Result	Unit Of Measure	Lower Limit	Upper Limit	Sent to CDMS	Sent to caAERS
<input checked="" type="checkbox"/>	00-00-00-0	5/7/08 10:28 PM	BUN		11.0	mg/dL	8.0	20.0		
<input type="checkbox"/>	00-00-00-0	5/7/08 10:28 PM	URIC_ACID		3.3	mg/dL	2.0	7.0		
<input type="checkbox"/>	00-00-00-0	5/7/08 10:28 PM	BILIRUBIN_TOTAL		0.8	mg/dL	0.0	1.2		
<input type="checkbox"/>	00-00-00-0	5/7/08 10:28 PM	ALK_PHOS		102.0	U/L	37	135		
<input type="checkbox"/>	00-00-00-0	5/7/08 10:28 PM	SGOT_AST		180.0	U/L	9.0	37		
<input type="checkbox"/>	00-00-00-0	5/7/08 10:28 PM	SGPT_ALT		40.0	U/L	6.0	37		

Chapter 5 Creating Studies

This chapter describes the steps required to create a studying the Suite. Topics in this chapter include:

- Overview
- Steps for Creating a Study

Overview

In caBIG[®] Clinical Trials Suite, studies are first created in the Participant Registry (C3PR). Once the information is complete and correct, a Create Study message is then broadcasted to the other modules in the Suite. A record of the study is kept in each module, where it can be viewed, augmented, or updated, as needed.

The Create Study feature works for the following modules: C3PR, PSC, caAERS, and Lab Viewer. At this time studies cannot be created in C3D using this feature. See the caBIG[®] Clinical Trials Suite Admin Guide for further details on setting up a study in C3D or refer to the C3D documentation set.

Steps for Creating a Study

There are a number of prerequisites that must be met before one can successfully create a study in the Suite.

Roles Required for Creating A Study

To create a study in the Suite, a user or set of users will need to have the following roles assigned in each of the modules:

<i>Application</i>	<i>Role</i>
<i>C3PR</i>	Site Coordinator (to create the study), Study Coordinator (to open and broadcast the study to the other modules)
<i>PSC</i>	Study Coordinator
<i>caAERS</i>	Study Coordinator
<i>Lab Viewer</i>	Study Coordinator

Additional Prerequisites

Before creating a study in the Suite, it is necessary to ensure that Investigators and Organizations are set up correctly in each module. This restriction applies especially to caAERS and to PSC. See the caBIG[®] *Clinical Trials Suite 1.1 Administration Guide* for detailed information on this requirement.

Step 1: Create the Study in C3PR

To create a study, first launch the C3PR module. From here, select the Create Study option.

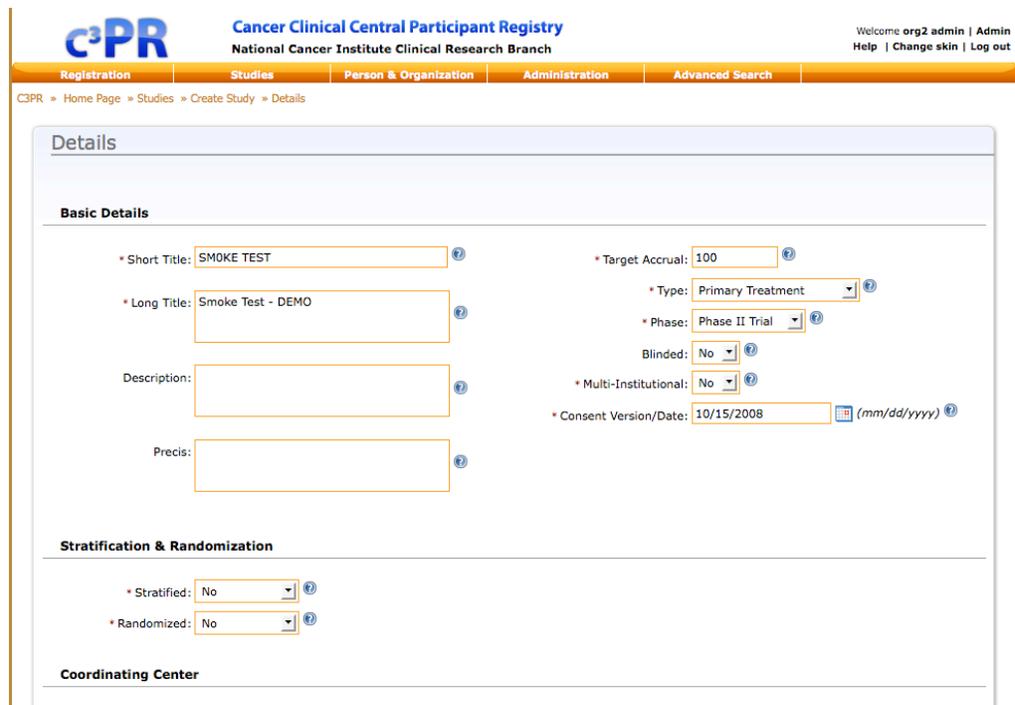


The screenshot shows the C3PR dashboard with the following elements:

- Navigation Bar:** Registration, Studies, Person & Organization, Administration, Advanced Search.
- Header:** Cancer Clinical Central Participant Registry, National Cancer Institute Clinical Research Branch. Welcome org2 admin | Admin Help | Change skin | Log out.
- Shortcuts:** A red circle highlights the 'Frequently Used Shortcuts' section, which includes links for Search Study, Create Registration, Create Study, and Search Registration.
- Table:** 'Incomplete Registrations - Most Recent' table with columns: Subject Name, Subject Medical Record #, Study Short Title, and Registration Status.

Subject Name	Subject Medical Record #	Study Short Title	Registration Status
John Lock	6703	Study July 9	Unregistered
Johnny Lee	111	Test C3D study Dec 4th	Unregistered
Test CCTS Part last	asdcasdcvasdvcasfcv	Test C3D study Dec 4th	Unregistered
Peter Smith	GSH-43	Test C3D study Dec 4th	Unregistered
Robert Wilson	AC-295	Test C3D study Dec 4th	Unregistered
- Notifications:** C3PR Notifications - my Inbox. You don't have any notifications.

Complete all the steps and required fields for setting up the trial. For detailed instruction on how to create a study in the Participant Registry application, see the *C3PR End User Guide*.



The screenshot shows the 'Details' page for creating a study in C3PR. The page is titled 'Details' and has a breadcrumb trail: C3PR > Home Page > Studies > Create Study > Details.

Basic Details

- Short Title: SMOKE TEST
- Long Title: Smoke Test - DEMO
- Description: (empty field)
- Precis: (empty field)
- Target Accrual: 100
- Type: Primary Treatment
- Phase: Phase II Trial
- Blinded: No
- Multi-Institutional: No
- Consent Version/Date: 10/15/2008 (mm/dd/yyyy)

Stratification & Randomization

- Stratified: No
- Randomized: No

Coordinating Center

Step 2: Broadcast the Study

Once the data is completed and saved, a Study Coordinator in C3PR initiates the replication of the data to the other applications by clicking the **Broadcast** button in the CCTS Workflow area at the bottom of the Manage Study screen.

The screenshot shows the 'Manage Study' interface. At the top, there is a table with columns 'Companion Study Short Title', 'Status', and 'Mandatory'. Below this is an 'Amendments' section with a table for 'Version #', 'Amendment Date', and 'Comments'. The 'CCTS Workflow' section shows a 'Broadcast Status: Message send confirmed' message. At the bottom of this section, the 'Refresh' and 'Broadcast' buttons are circled in red. To the right of the workflow section are buttons for 'Export Study', 'Edit Study', and 'Amend Study'. At the very bottom right is a 'Print' button.

The status of the broadcast will be updated on the screen. If the status message does not change, click the **Refresh** button to recheck the status. The following status messages may appear:

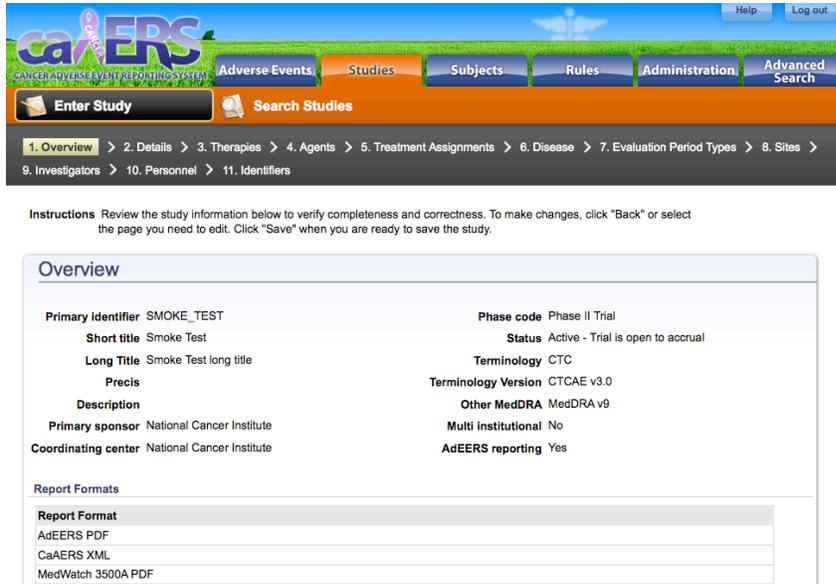
Status	Meaning
Message Send	The study message has been sent to the other modules. Confirmation not yet received.
Message Send Confirmed	The study message has been sent and confirmed. The study has been set up in each module.
Message Send Failed	The message failed. The study was not set up in any of the other modules.

Note: If one of the modules is unable to successfully process the create study message, it will send a message back to this effect and the create study transaction will be terminated and will be rolled back in all the modules. The Suite is designed with a 1 minute timeout threshold. If no rollback request is received within this threshold, the message will be regarded as successful and the study will be created in the modules that can process it. Because of this rollback feature and the timeout threshold, we recommend that the study be viewed in each module to confirm that it was set up correctly.

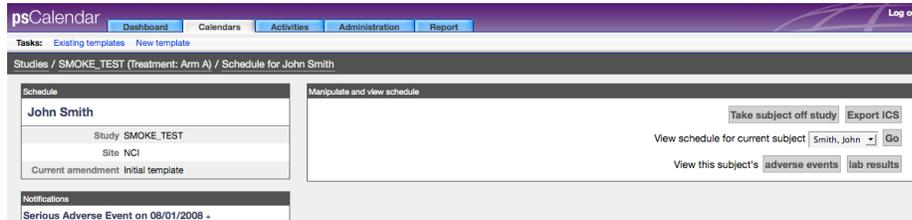
Step 3: Confirm the Study in Each Module

Confirm that the study was created correctly in each module.

The screens below shows the same study appearing in the AE Reporting System.



And the same study as it appears in the Study Calendar.

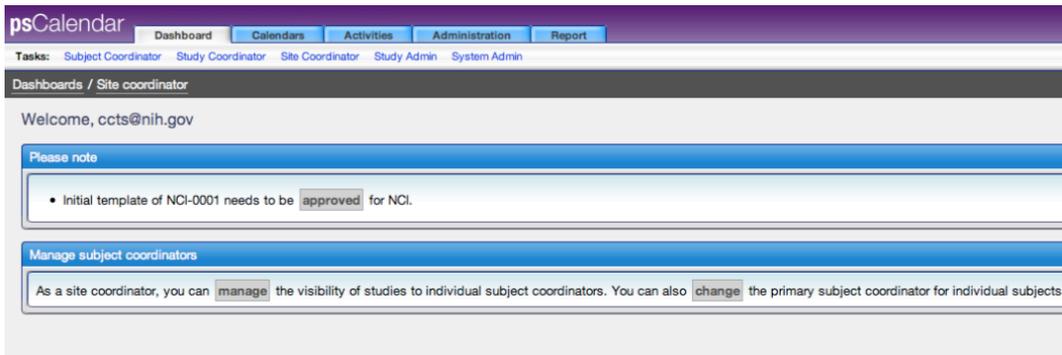


Step 4: Add Additional Study Details As Needed

Additional study-related data may be entered in other applications if needed. In PSC and caAERS, additional steps or data elements are required before the study can be used in these applications.

Application	Additional Study-Related Data Items
Patient Study Calendar	Create template for Study, approve Study at site, assign Subject Coordinator for Study
Cancer Adverse Event Reporting System	Study basics and details such as phase, CTC version, agents and therapies, treatment assignments, study diseases, and other related data such as study sites, investigators and personnel

In PSC, a number of steps are required to set up a study template and release it. These steps are covered in detail in the *caBIG® Clinical Trials Suite 1.1 Administration Guide* and in the *PSC End User's Guide*.



In caAERS, additional data elements may need to be specified for the study. Usually, one will want to specify the AE coding terminology associated with the study and may also want to add additional study details. These steps are covered in detail in the *caBIG® Clinical Trials Suite 1.1 Administration Guide* and in the *caAERS End User's Guide*.

Details

Instructions Enter the general details of the study.

* **Short title** ?

* **Long title** ?

Precis ?

Description ?

* **Phase** ?

* **Status** ?

* **Multi institutional**

* **AdEERS reporting required**

Adverse event coding terminology

* **Terminology**

* **CTC version**

* **Other MedDRA Version**

Disease coding terminology

* **Terminology**

Study method details

Study design ?

Expedited report formats

If C3D is being used with the Suite, the study will need to be created in C3D. For detailed instruction on how to create a study in C3D, see the C3D user documents, located here: <http://ncicbsupport.nci.nih.gov/sw/content/C3D.html>.

The screenshot shows the Oracle Clinical Studies application window. The title bar reads "Maintain Clinical Studies" and "Clinical Studies". The menu bar includes "Action", "Move", "Clear", "Data", "Query", "Special", "Help", and "Window". The toolbar contains various icons for navigation and editing. The main form area is titled "Clinical Studies" and contains the following fields:

- Short Title: 04-C-0121 (6074) - Dr. Robert J. Kreitman
- Study Code: 04 C 0121
- Long Title: A Phase II Clinical Trial of Anti-Tac(Fv)-PE38 (LMB-2) Immunotoxin for Treatment of CD25 Positive Chronic Lymphocytic Leukemia
- Study Status: DESIGN (Design of the Clinical Study)
- Random Access: CLOSED (No access allowed)
- Pivotal Study?: Ready For Repl? Source Study
- Include in FDA Package?: Source Site: OCDEV

At the bottom of the form, there are buttons for "Exit", "Save", "Multi", "Objective", "Enrollment", "Termination", "Comment", "Region", "History", and "Planning". Below the form, there are expandable sections for "Treatments" and "Strata". The status bar at the bottom indicates "The user defined Code for the Clinical Study" and "Record: 1/1".

For further details about any of these applications, see the respective product documentation set.

Chapter 6 Registering Subjects

This chapter describes the steps required to register subjects to studies in the Suite. Topics in this chapter include:

- Typical Scenario
- Steps for Registering a Subject

Typical Scenario

A new patient must be registered to the study in the system. The Clinical Research Associate (CRA) verifies that the subject meets the eligibility criteria and enters the required information into the Suite via the Patient Registry application and the data is saved to the database. Once the patient has been assigned to an epoch, the CRA initiates a process to route the Register Subject message, including epoch start date and name, to the other Suite component applications (Study Calendar, CDMS, AE Reporting, Lab Viewer) which then record the participant information, including epoch, in their system. The message to the Study Calendar triggers the generation of the study calendar for that subject. The CRA views the schedule of upcoming visits and the associated activities for that subject.

Steps for Registering a Subject

Roles Required for Registration

To register a subject to a study in the Suite, a user or set of users will need to have the following roles assigned in each of the modules:

Application	Role
C3PR	Registrar
PSC	Subject Coordinator
caAERS	Subject Coordinator
Lab Viewer	Subject Coordinator

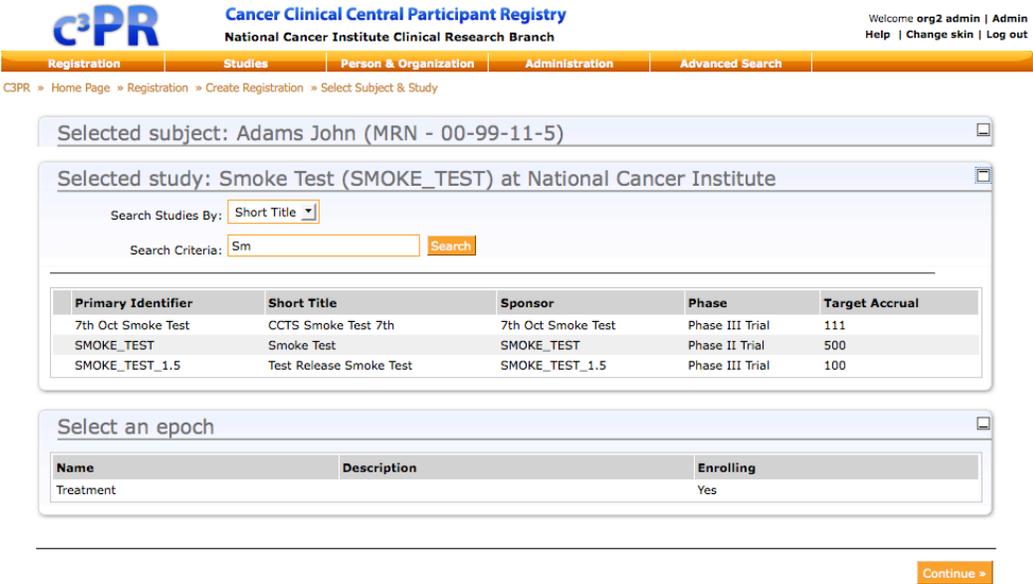
Additional Prerequisites

Before registrations can be successfully broadcasted from C3PR to the other modules in the Suite, a number of prerequisites must be met. These include the following:

- The study must be already be created in each module
- In PSC, the study template must be created and released.

Step 1: Register Patient to the Study in C3PR

The first step is to open the C3PR application and register the subject to the study in this module.



Note: For detailed, step-by-step instructions on registering subjects in C3PR, refer to the *C3PR End User's Guide*. This guide covers eligibility, consents, and other important topics related to registration.

Step 2: Broadcast the Registration

Once the data is complete and saved in the Participant Registry, the Registrar can then initiate replication of the subject's registration to the other applications by clicking the **Broadcast** button in the CCTS Workflow area at the bottom of the screen.

Arm Assigned

Arm Assigned

CCTS Workflow

Broadcast Status: Message send

Refresh
Broadcast

- [Adverse Event Reporting System](#)
- [Patient Study Calendar](#)
- [Cancer Central Clinical Database](#)

The status of the broadcast will be updated. If the message does not change, click the refresh button to check on the status. The following status messages may appear:

Status	Meaning
Message Send	The registration message has been sent to the other modules. Confirmation not yet received.
Message Send Confirmed	The registration message has been sent and confirmed. The registration has been processed in each module.
Message Send Failed	The message failed. The registration was not completed in any of the other modules.

Note: If one of the modules is unable to successfully process the register subject message, it will send a message back to this effect and the register subject transaction will be terminated and will be rolled back in all the modules.

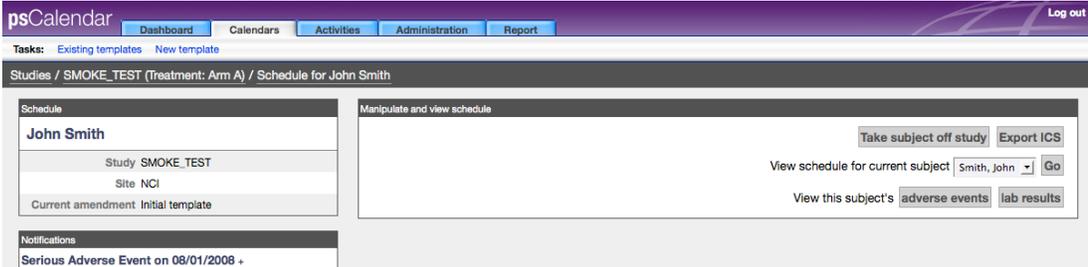
Step 3: Hotlink to the other Modules to Confirm the Registration

After the registration message has been broadcasted, use the hotlinks in C3PR to open the other modules to view the patient registration in these other applications.

Refresh
Broadcast

- [Adverse Event Reporting System](#)
- [Patient Study Calendar](#)
- [Cancer Central Clinical Database](#)

The screen below shows an example of what to expect when hotlinking from C3PR to the Study Calendar. In this example, the Study Calendar has received the registration and automatically generates a study calendar for the subject based on the study template.



Chapter 7 Lab Data

In this chapter, we cover the following tasks associated with lab data:

- Loading Lab data into CTODS
- Loading labs from the Lab Viewer to C3D
- Sending lab data alerts to the AE System

Loading Labs into CTODS

There are a number of ways to load labs into the CTODS repository. The Cancer Center Hub Client (CCHC), which is included as part of the caBIG® Clinical Trials Suite, provides one method. Refer to the *caBIG® Clinical Trials Suite 1.1 Administration Guide* and the *Lab Viewer Administration Guide* for more information on this tool or on loading labs in general.

Loading Labs from Lab Viewer to C3D

Typical Scenario

The Clinical Research Associate (CRA) looks at the scheduled study-specific visit for a given patient in the Study Calendar. The CRA identifies all the lab tests that should have been scheduled and completed for that visit date. The CRA needs all the lab values that would fall within the timeframe of the identified and previous visit dates. The CRA then reviews the lab tests actually conducted during this timeframe in the Lab Viewer and identifies study-relevant test results to be loaded into the Clinical Data Management System (CDMS). (For example, a diabetic patient may have also had an A1C done as part of standard care – in this case, this value would not be stored in the CDMS). The CRA initiates a process to send the selected labs to the CDMS which then loads them into the database.

Roles Required for Loading Labs to C3D

To send labs from Lab Viewer to C3D, a user will need to have the following roles assigned in each of the modules:

Application	Role
C3PR	N/A
PSC	N/A
caAERS	N/A
Lab Viewer	Subject Coordinator

Prerequisites

A number of prerequisites must be met before labs can be successfully loaded from Lab Viewer to C3D.

Step 1: Search for Labs in Lab Viewer

To load labs, open the Lab Viewer application and enter the study and patient and date ranges of interest.

The screenshot shows the 'Lab Viewer' application interface. The title bar reads 'Clinical Trials Object Data System (CTODS)'. The navigation menu includes 'Home', 'Lab Activities', and 'Test'. The current task is 'Greeting screen'. The main content area is titled 'Enter The Lab Activity Search Criteria'. It contains the following text: 'Search for an existing Lab Activity by entering the Study Id, Patient Id, Begin Date, and End Date.' Below this are four input fields: '* Study Identifier' (containing 'SMOKE_TEST'), '* Patient Identifier' (containing '00-00-00-0'), '* Begin Date (MM/DD/YYYY)', and '* End Date (MM/DD/YYYY)'. There are 'Reset' and 'Search' buttons. A note at the bottom states '* indicates the fields required'.

Step 2: Send Labs to C3D

If there are any labs, they will appear in the Lab Activities screen.

The screenshot shows the 'Lab Viewer' application interface. The title bar reads 'Clinical Trials Object Data System (CTODS)'. The navigation menu includes 'Home' and 'Lab Activities'. The current task is 'Search lab activities'. The main content area is titled 'Lab Activities - Search Results'. It contains a table with the following data:

Select	Patient Id	Date / Time	Lab Test	Text Result	Numeric Result	Unit Of Measure	Lower Limit	Upper Limit
<input type="checkbox"/>	59-60-00-3	2/7/07 7:30 AM	SGPT_ALT		40.0	U/L	6.0	41.0
<input type="checkbox"/>	59-60-00-3	2/7/07 7:30 AM	SGOT_AST		93.0	U/L	9.0	34.0
<input type="checkbox"/>	59-60-00-3	2/7/07 7:30 AM	ALK_PHOS		102.0	U/L	37.0	116.0
<input type="checkbox"/>	59-60-00-3	2/7/07 7:30 AM	BILRUBN_TOTAL		0.8	mg/dL	0.1	1.0
<input type="checkbox"/>	59-60-00-3	2/7/07 7:30 AM	GLUC_NONFASTING		110.0	mg/dL	70.0	115.0
<input type="checkbox"/>	59-60-00-3	2/7/07 7:30 AM	LDH		179.0	U/L	113.0	226.0
<input type="checkbox"/>	59-60-00-3	2/7/07 7:30 AM	INORG_PHOS		3.8	mg/dL	2.5	4.8
<input type="checkbox"/>	59-60-00-3	2/7/07 7:30 AM	POTASSIUM		4.0	mmol/L	3.3	5.1
<input type="checkbox"/>	59-60-00-3	2/7/07 7:30 AM	TOT_PROT		6.0	g/dL	6.0	7.6
<input type="checkbox"/>	59-60-00-3	2/7/07 7:30 AM	BUN		11.0	mg/dL	8.0	22.0

Select the labs that should be loading into the CDMS and click the **Load Labs to CDMS** button in the lower right corner of the screen.

<input type="checkbox"/>	00-00-00-0	4/29/08 10:28 PM	SODIUM		136.0	mmol/L	135.0	144.0	false	false
<input checked="" type="checkbox"/>	00-00-00-0	4/29/08 10:28 PM	POTASSIUM		4.0	mmol/L	3.0	5.0	false	false
<input checked="" type="checkbox"/>	00-00-00-0	4/29/08 10:28 PM	CHLORIDE		104.0	mmol/L	99.0	107.0	false	false
<input checked="" type="checkbox"/>	00-00-00-0	4/29/08 10:28 PM	MAGNESIUM		0.9	mmol/L	0.0	1.0	false	false
<input checked="" type="checkbox"/>	00-00-00-0	4/29/08 10:28 PM	BICARB_SERUM		25.0	mmol/L	21.0	31.0	false	false
<input checked="" type="checkbox"/>	00-00-00-0	4/29/08 10:28 PM	URIC_ACID		3.3	mg/dL	2.0	5.0	false	false
<input checked="" type="checkbox"/>	00-00-00-0	4/29/08 10:28 PM	BILIRUBIN_TOTAL		0.8	mg/dL	0.0	1.0	false	false
<input checked="" type="checkbox"/>	00-00-00-0	4/29/08 10:28 PM	BUN		11.0	mg/dL	8.0	22.0	false	false
<input type="checkbox"/>	00-00-00-0	4/29/08 10:28 PM	BUN		11.0	mg/dL	8.0	22.0	false	false

Note: A status message will appear at the top of the screen indicating whether the labs were successfully submitted to C3D.

Step 3: Confirm Lab Loads in C3D

Once the data validation and loading process is complete, the lab data is available in the CDMS (C3D, in this instance) for future reference.

The screenshot shows the Oracle Clinical Remote Data Capture interface. A patient's lab results are displayed in a table. The 'BANDS' row is circled in red. The table has columns for Lab Test, Value, Unit of Measure, Report?, Normal Range, and Range Indicator.

Lab Test	Value	Unit of Measure	Report?	Normal Range	Range Indicator
WBC_SERUM					
RBC_SERUM					
HEMOGLOBIN					
HEMATOCRIT					
PLT					
NEUT					
BANDS	with Polys			0.0-4.0	

Note: We recommend that, whenever possible, the user confirm the loading of the labs by opening the C3D application and reviewing the results.

Sending Lab Data Alerts to the AE System

Roles Required for Sending Labs to caAERS

To send lab data from Lab Viewer to the AE System, a user or set of users will need to have the following roles assigned in each of the modules:

Application	Role
C3PR	N/A
PSC	N/A
caAERS	Subject Coordinator
Lab Viewer	Subject Coordinator

Additional Prerequisites

Before registrations can be successfully broadcasted from C3PR to the other modules in the Suite, a number of prerequisites must be met. These include the following:

- The study must already be set up in both Lab Viewer and caAERS
- The subject must already be registered to the study in both Lab Viewer and caAERS

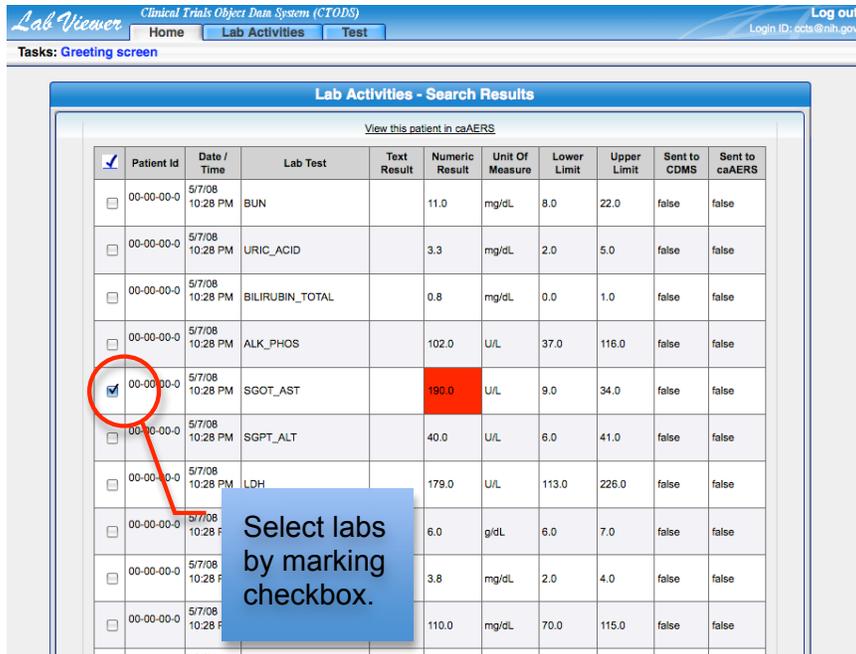
Step 1: Search for Labs in Lab Viewer

To load labs, open the Lab Viewer application and select the study and subject and range of dates that are appropriate.

Note: Labs whose upper or lower limit values are out of range will be highlighted in red in the Lab Viewer search results screen.

Step 2: Send Labs to caAERS

Select the labs to be sent to caAERS and click the **Load Labs to caAERS** button.



Lab Viewer Clinical Trials Object Data System (CTODS) Home Lab Activities Test Log out Login ID: ccts@nih.gov

Tasks: Greeting screen

Lab Activities - Search Results

View this patient in caAERS

<input checked="" type="checkbox"/>	Patient Id	Date / Time	Lab Test	Text Result	Numeric Result	Unit Of Measure	Lower Limit	Upper Limit	Sent to CDMS	Sent to caAERS
<input type="checkbox"/>	00-00-00-0	5/7/08 10:28 PM	BUN		11.0	mg/dL	8.0	22.0	false	false
<input type="checkbox"/>	00-00-00-0	5/7/08 10:28 PM	URIC_ACID		3.3	mg/dL	2.0	5.0	false	false
<input type="checkbox"/>	00-00-00-0	5/7/08 10:28 PM	BILIRUBIN_TOTAL		0.8	mg/dL	0.0	1.0	false	false
<input type="checkbox"/>	00-00-00-0	5/7/08 10:28 PM	ALK_PHOS		102.0	U/L	37.0	116.0	false	false
<input checked="" type="checkbox"/>	00-00-00-0	5/7/08 10:28 PM	SGOT_AST		190.0	U/L	9.0	34.0	false	false
<input type="checkbox"/>	00-00-00-0	5/7/08 10:28 PM	SGPT_ALT		40.0	U/L	6.0	41.0	false	false
<input type="checkbox"/>	00-00-00-0	5/7/08 10:28 PM	LDH		179.0	U/L	113.0	226.0	false	false
<input type="checkbox"/>	00-00-00-0	5/7/08 10:28 PM			6.0	g/dL	6.0	7.0	false	false
<input type="checkbox"/>	00-00-00-0	5/7/08 10:28 PM			3.8	mg/dL	2.0	4.0	false	false
<input type="checkbox"/>	00-00-00-0	5/7/08 10:28 PM			110.0	mg/dL	70.0	115.0	false	false

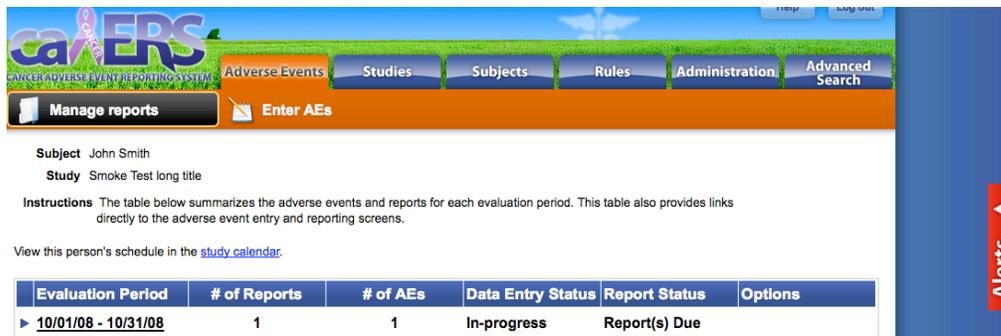
Select labs by marking checkbox.

A status message will appear in the Sent to caAERS column indicating whether the labs were successfully submitted to C3D.

<input type="checkbox"/>	00-00-00-0	5/7/08 10:28 PM	ALK_PHOS		102.0	U/L	37.0	116.0	false	false
<input checked="" type="checkbox"/>	00-00-00-0	5/7/08 10:28 PM	SGOT_AST		190.0	U/L	9.0	34.0	false	Wed Oct 29 14:57:46 EDT 2008
<input type="checkbox"/>	00-00-00-0	5/7/08 10:28 PM	SGPT_ALT		40.0	U/L	6.0	41.0	false	false

Step 3: Within caAERS, View or Process Alert

In the caAERS application, the lab data sent from Lab Viewer appears as an alert. An AE coordinator or reporter in caAERS can then elect to act on the alert or dismiss the alert, as the situation and regulations require.



caAERS CANCER ADVERSE EVENT REPORTING SYSTEM

Adverse Events Studies Subjects Rules Administration Advanced Search

Manage reports Enter AEs

Subject John Smith
Study Smoke Test long title

Instructions The table below summarizes the adverse events and reports for each evaluation period. This table also provides links directly to the adverse event entry and reporting screens.

View this person's schedule in the [study calendar](#).

Evaluation Period	# of Reports	# of AEs	Data Entry Status	Report Status	Options
▶ 10/01/08 - 10/31/08	1	1	In-progress	Report(s) Due	

Alerts

The Alerts panel in caAERS can be expanded or collapsed, as shown in the example screens here.

If an AE is documented for the patient, the alert can be viewed again at any time during the documentation or expedited report creation process.

On the Labs section of the expedited report, a hotlink can be used to open back to the lab viewer so the reporter can search for additional labs or information related to this patient to include in the report.

Chapter 8 Adverse Event-Triggered Schedule Changes

This chapter provides an overview of some of the interactions between caAERS and PSC supported in the Suite. Topics covered here include the following:

- Typical Scenario
- Steps for Sending a Schedule Change Notification

Typical Scenario

A subject has an adverse event (AE) that has already been entered into the AE Reporting system. If the CRA determines that the AE meets the study criteria for dose or schedule change, they send a notification via the AE Reporting System to the Study Calendar that there may be a change in the subject's schedule due to the AE. When this subject's schedule is next queried in the calendar, an AE alert will appear with the schedule. The CRA will then investigate the situation and ensure that the AE alert has been addressed before continuing treatment. Then, if required, the subject's schedule will be modified by the CRA.

Steps for Sending a Schedule Change Notification

In the AE Reporting System, the CRA queries for a list of AEs since the last visit, by providing the patient id.

Roles Required for Sending Schedule Change Notifications

To send lab data from Lab Viewer to the AE System, a user or set of users will need to have the following roles assigned in each of the modules:

Application	Role
C3PR	N/A
PSC	Subject Coordinator
caAERS	Subject Coordinator
Lab Viewer	Subject Coordinator

Additional Prerequisites

Before messages can be exchanged between caAERS and PSC regarding possible AE-Triggered schedule changes, the following prerequisites must be met:

- The study must already be set up in both PSC and caAERS
- The subject must already be registered to the study in both PSC and caAERS

Step 1: View Adverse Events in caAERS

After the notification is sent, the link text is updated to reflect that the message was sent successfully to the Study Calendar.

Step 2: Send Alert to the Study Calendar

In PSC, the alert is received and displayed for viewing and possible action.

For further details about any of these applications, see the respective product documentation set.

Glossary

Term	Definition
AdEERS	Adverse Event Expedited Report System
AE	Adverse Event
API	Application Programming Interface
BRIDG	Biomedical Research Integrated Domain Group
C3D	Cancer Central Clinical Database
C3PR	Cancer Central Clinical Participant Registry
caAERS	Cancer Adverse Event Reporting System
caBIG	Cancer Biomedical Informatics Grid
caCORE	Cancer Common Ontologic Reference Environment
caGrid	The underlying service oriented architecture for caBIG
caXchange	Clinical trials data and message exchange system
CBIIT	Center for Biomedical Informatics and Information Technology
CCTS	caBIG Clinical Trials Suite
CDE	Common Data Element
CDMS	Clinical Data Management System
CRA	Clinical Research Associate
CRF	Case Report Form
CSM	Common Security Module
CTEP	Cancer Therapy Evaluation Program
CTMS	Clinical Trials Management Systems
CTODS	Clinical Trials Object Data System
DCP	Department of Cancer Prevention
ESB	Enterprise Service Bus (open source)
EVS	Enterprise Vocabulary Service
FDA	Food and Drug Administration
GAARDS	Grid Authentication and Authorization with Reliably Distributed Services
GUI	Graphical User Interface
HL7	Health Level Seven
HTTP	Hypertext Transfer Protocol
IND	Investigational New Drug
NCI	National Cancer Institute
NCICB	National Cancer Institute Center for Bioinformatics
PDF	Portable Document Format (Adobe)
PSC	Patient Study Calendar
RDBMS	Relational Database Management System
SAE	Serious Adverse Event
SDK	Software Development Kit
SVN	Subversion (a version control system)
UI	User Interface
UML	Unified Modeling Language
VCDE	Vocabularies & Common Data Elements
XML	eXtensible Markup Language

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