

CABIG® CLINICAL TRIALS SUITE 2.0

User's Guide



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v.2

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Chapter 1 About the User's Guide

This chapter introduces you to the *caBIG® Clinical Trials Suite 2.0 Installation Guide*. Topics in this section include:

- *Introduction to the User's Guide* on this page
- *Organization of this Guide* on page 2
- *Additional References* on page 2
- *Text Conventions Used* on page 3
- *Credits and Resources* on page 4
- *Support* on page 8

Introduction to the User's Guide

Overview of the Guide

This guide covers the general use and operation of the *caBIG® Clinical Trials Suite* (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 each application's user's 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 2.0 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 8 for information on how to request additional support.

Organization of this Guide

This guide contains the following chapters:

- ***Chapter 1 About the User’s Guide***—This chapter introduces you to this 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 2.0*, see the following references:

- *caBIG® Clinical Trials Suite 2.0 Release Notes*
- *caBIG® Clinical Trials Suite 2.0 Administration Guide*
- [caBIG® Clinical Trials Suite 2.0 Installation Guide](#)
- *caBIG® Clinical Trials Suite 2.0 Architecture Guide*
- *caBIG® Clinical Trials Suite 2.0 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)
- Lab Viewer
- Cancer Central Clinical Database (C3D) Connector

- caBIG® Integration Hub)

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</i> <i>boldface</i> <i>monospace</i> type | 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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| Charlie Mead | Chief Technology Officer, NCI CBIIT |
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NCI = NCI-CBTT, S = SAIC, SB = SemanticBits, E = Ekagra, P = Pyramed Research, SP = ScenPro, Mayo = Mayo Clinic, DF = Dana Farber, DU = Duke Comprehensive Cancer Center; L=Lockheed Martin Management System Designers

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| E = Ekagra, NCI = NCI-CBIIT | | |

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| SB = SemanticBits, NCI = NCI-CBIIT, S = SAIC | | |

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E = Ekagra

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SP = ScenPro

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| Gaurav Gupta (SB) | | Warren Kibbe (NU) |
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| John Dzak (NU) | | Sean Whitaker (NU) |
| Jalpa Patel (NU) | | Peter Yan (S) |
| Nataliya Shurupova (NU) | | |
| | | Adopters |
| Patient Advocate | Analysts | Mayo Clinic |
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| | Sean Whitaker (NU) | Thomas Jefferson University |

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 |

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* on page 10
- *What is New in CCTS 2.0?* on page 12
- *Cancer Central Clinical Participant Registry* on page 13
- *Patient Study Calendar* on page 14
- *Cancer Adverse Event Reporting System* on page 15
- *caBIG® Integration Hub (formerly caXchange)* on page 18
- *Lab Viewer* on page 17
- *Clinical Connector*
- *Overview of Clinical Connector and Cancer Central Clinical Database (C3D)*

The Clinical 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 Clinical Connector is a component of the Suite, however C3D is not. For a basic understanding, both Clinical Connector (a Suite application) and Cancer Central Clinical Database (a vendor-provided solution resident at NCI CBIIT) are reviewed here.

Clinical Connector (a Suite Component)

The Clinical Connector provides the Suite users the ability to enroll patients and load labs into the CDMS, the Cancer Central Clinical Database (C3D) 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 Institute's (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 Clinical Connector in the Suite

The role of the Clinical 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 within the C3D CTMS. Laboratory Test Results available in the Lab Viewer component can be passed to the Clinical Connector which then analyzes and loads the data to the appropriate Study/Patient.

For More Info on Clinical Connector

The *Clinical Connector Administration Guide* can be found at this location:

http://gforge.nci.nih.gov/docman/view.php/365/20092/Clinical%20Connector_2.0_Admin_Guide.doc

The Clinical Connector Release Notes can be found here:

http://gforge.nci.nih.gov/docman/view.php/365/20093/Clinical%20Connector_2.0_Release_Notes.docx

The Clinical Connector Tools page can be found here:

<https://cabig.nci.nih.gov/tools/C3DClinicalConnector~v~2>

Additional information about C3D can be found here:

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

- on page 20

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 2.8) - 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 2.6) – 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 2.0) - 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>.

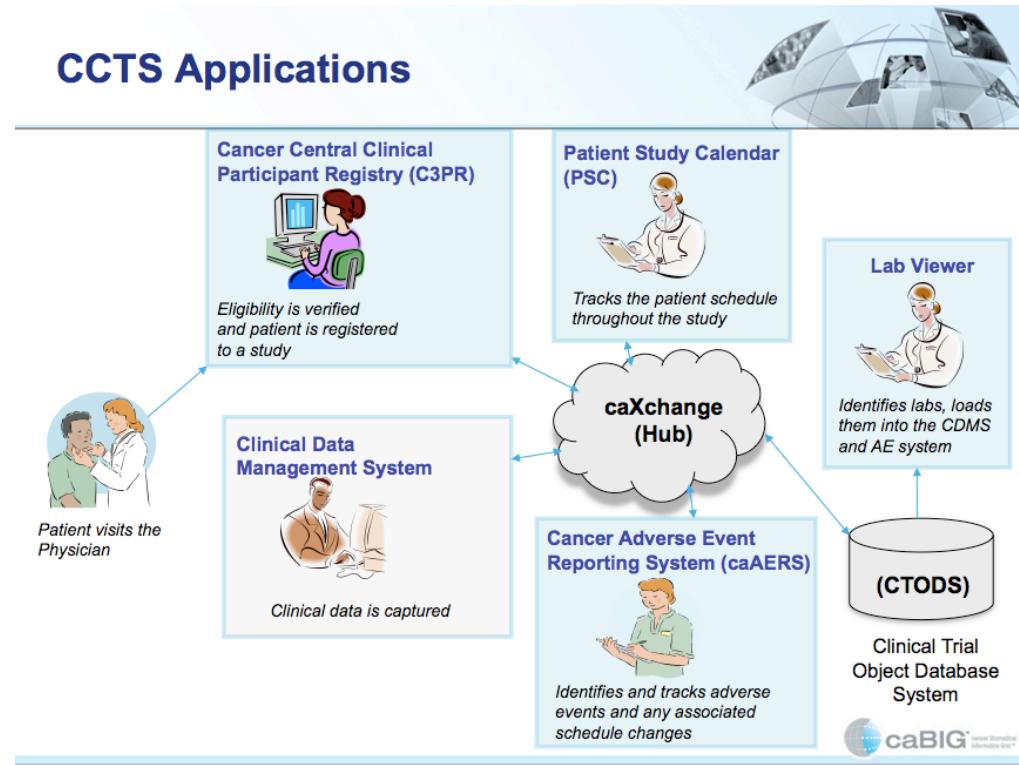
Clinical Data Exchange (caBIG Integration Hub) (version 2.0) - A configurable hub for exchanging clinical trial information between applications and systems. For more information, go here: <https://cabig.nci.nih.gov/tools/LabIntegrationHub>.

Lab Viewer (version 2.0) - A web-based application that provides users with the ability to view laboratory data in the Clinical Trials Object Data System (CTODS) Laboratory Database, a clinical trial information repository. This release includes integration with the CTRP/COPPA services, enhanced search capabilities and a client side application (CCHC) for loading lab data into the CTODS database. For more information, go here: <https://cabig.kc.nci.nih.gov/CTMS/KC/index.php/LabViewer>.

Cancer Central Clinical Database (C3D) Connector (version 2.0) – 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 2.0 bundle.)

caGrid (version 1.3) – 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 2.0?

caBIG® Clinical Trials Suite 2.0 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 2.0 | Version of Application Included in CCTS 1.1 |
|---|---|---|
| Cancer Central Clinical Participant Registry (C3PR) | C3PR 2.8 | C3PR 2.5.2 |
| Patient Study Calendar (PSC) | PSC 2.6 | PSC 2.3.3 |
| Cancer Adverse Event Reporting System (caAERS) | caAERS 2.0 | caAERS 1.5.1 |
| Lab Viewer | Lab Viewer 2.0 | Lab Viewer 1.5 |
| Cancer Central Clinical Database (C3D) Connector | C3D Connector 2.0 | C3D Connector 1.2 |

| CTMS Application | Version of Application Included in CCTS 2.0 | Version of Application Included in CCTS 1.1 |
|-------------------------|--|--|
| caXchange | caXchange 2.0 | caXchange 1.5 |
| caGrid | caGrid 1.3 | caGrid 1.2 |

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

Another key feature in the caBIG® Clinical Trials Suite 2.0 release is integration with NCI Enterprise Services (NES). Most notably, the suite integrates with the Person (i.e. Research Staff and Investigators), Organization (i.e. trial sites, sponsors, etc.), Protocol Abstraction (i.e. study definition), and the Correlation (i.e. relationships amongst the aforementioned entities) NCI Enterprise Services. This means that each of these entities within the Suite applications is automatically synchronized in real-time. As soon as the source data is changed at NCI, it is automatically reflected within each application. This is accomplished through the use of the grid and a set of services that are invoked by each application.

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)
- Biomedical Research Integrated Domain Group (BRIDG) study structure harmonization
- Supports searching Clinical Trials Research Program (CTR) databases using NCI Enterprise Services
- Build and Deployment Automation (BDA) Certified
- Ability to amend a study (new protocol version)
- Export of accrual data in Summary 3 format

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.) may 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 Information on the Participant Registry

The *C3PR End User Guide* can be found at this location: https://cabig-kc.nci.nih.gov/CTMS/KC/index.php/C3PR_End_User_Guide_2.5.5

The *C3PR Administration Guide* can be found at this location: https://cabig-kc.nci.nih.gov/CTMS/KC/index.php/C3PR_Administration_GuideThe_C3PR_Release

Notes can be found at this location: https://cabig-kc.nci.nih.gov/CTMS/KC/index.php/C3PR_Release_Notes

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:

- Import activities in CSV format or XML format
- Change cycle length with amendments to the template
- Produce reports based upon activity labels
- Configurable activity types
- Duplicate existing templates
- Assign URIs to activities
- Replaceable logo image
- Populations are now amendable
- Subject-centric, timeline-based schedule provides a single view for all studies in which a subject is enrolled
- Display names of users and edit user details
- Enter weights for activities to determine display order
- Palette-based editing system for adding activities
- iCalendar export and subscription support

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 Information on the Study Calendar

The *Study Calendar End User Guide* can be found here:

https://cabig-kc.nci.nih.gov/CTMS/KC/index.php/PSC_End_User_Guide

The *Study Calendar Template Creation Guide* can be found here:

https://cabig-kc.nci.nih.gov/CTMS/KC/index.php/PSC_Template_Creation

The *Study Calendar Administration Guide* can be found here:

https://cabig-kc.nci.nih.gov/CTMS/KC/index.php/PSC_Administration_Guide

The Study Calendar Release Notes can be found here:

https://cabig-kc.nci.nih.gov/CTMS/KC/index.php/PSC_Release_Notes

For additional information about the Patient Study Calendar, go here:
<https://cabig-kc.nci.nih.gov/CTMS/KC/index.php/PSC>

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, and 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:

- Improved user interface, improved usability, streamlined data entry
- Streamlined expedited adverse event report generation.

- Introduction of powerful workflow management feature, which facilitates routing adverse event reports to the appropriate personnel for review, comment, and approval prior to submission
- Enhanced support of adverse event recording and reporting (MedWatch 3500A, DCP SAE report)
- Support for any version of MedDRA
- Support of the CTCAE v4.0
- Support study defined expected AE's
- An advanced search and data extraction interface
- An API for programmatically adding adverse events
- Support re-running of rules when changes occur to AEs
- Support searching NCI Enterprise Services
- Support association of Research Staff to multiple organizations

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 Information on the AE Reporting System

The *caAERS End User Guide* can be found at this location: https://cabig-kc.nci.nih.gov/CTMS/KC/index.php/caAERSv2.0_End_User_Guide

The *caAERS Administration Guide* can be found at this location: https://cabig-kc.nci.nih.gov/CTMS/KC/index.php/caAERSv2.0_Administration_Guide

The *caAERS Release Notes* can be found at this location: https://cabig-kc.nci.nih.gov/CTMS/KC/index.php/caAERSv2.0_Release_Notes

See the following page for more information about the Cancer Adverse Events Reporting System: <https://cabig.nci.nih.gov/tools/caAERS>

caBIG® Integration Hub (formerly caXchange)

Overview of the caBIG® Integration Hub

The caBIG® Integration Hub 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. caBIG® Integration Hub 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 auditing services for diagnosing workflow design problems. caBIG® Integration Hub routes and exchanges clinical trial messages and data for all Suite applications and all Suite workflows in caGrid. caBIG Integration Hub facilitates CCTS integration with the COPPA services.

New Features in the caBIG® Integration Hub

The caBIG® Integration Hub 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 caBIG Integration Hub to receive additional message types
- Ability to integrate with NCI CBIIT COPPA Grid Services
- Ability to transform messages to facilitate integration across different domain versions
- Ability to send mail notifications
- Provides a non-caGrid interface to integrate with

Role of caBIG® Integration Hub in the Suite

The Suite needs to be able to exchange information between all component applications in an audited and controlled manner. caBIG® Integration Hub provides the capability to send, receive and log messages and data between applications. Specifically, caBIG® Integration Hub routes messages for the following CCTS workflows:

- Study creation

- Subject registration
- Lab-based adverse event notification
- Adverse event-based patient schedule modification
- Loading lab data to CDMS

In addition to these CCTS workflows, caBIG® Integration Hub facilitates suite integration with the COPPA services. For the Lab Viewer CCTS application it implements business services enabling retrieval of Person and Organization objects based on CTEP Identifier. caBIG® Integration Hub provides a single suite level configurable integration point for the COPPA services.

For More Info on caBIG® Integration Hub

The caBIG® Integration Hub v2.0 fact sheet can be found at this location:

<https://ncisvn.nci.nih.gov/svn/cabigintegrationhub/trunk/docs/Overview/caBIG%20Integration%20Hub%20Tool%20Fact%20Sheet.doc>

The caBIG® Integration Hub Administration Guide can be found at this location:

<https://ncisvn.nci.nih.gov/svn/cabigintegrationhub/trunk/docs/admin/caXchange%20Administration%20Guide.doc>

The caXchange Release Notes can be found at this location:

https://qforge.nci.nih.gov/docman/view.php/368/14918/caXchange-1-5_Release_Notes.doc^[HM2]

For more information about caXchange, go here:

<https://cabig.nci.nih.gov/tools/LabIntegrationHub>^[HM3]

Lab Viewer

Overview of Lab Viewer

Lab Viewer is a web based application that allows users to view laboratory activities that are stored in the Clinical Trials Object Data System (CTODS) Laboratory Database. Users may search for laboratory activity records by Study, Participant, and Lab Start and End Dates. 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. LabViewer also allows users to select and send lab data (as an HL7 v3 message) to other applications in the Clinical Trial Compatibility Framework (CTCF) using the caBIG® Integration Hub. LabViewer supports messages to the local CDMS application, C3D, and the local adverse event reporting system, 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 Study Creation Message and the Subject Registration Message, both from the Participant Registry. Study, subject, and registration data are persisted in the CTODS database. LabViewer 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. LabViewer allows you to select and send CDMS compatible laboratory results through the caBIG® Integration Hub-to other applications in the CTCF.

New Features in the Lab Viewer

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

- Enhanced Search and Laboratory Results Filtering Capabilities
- Download laboratory data in .CSV, .XLS and .XML format
- Enhanced administrative link / user account management
- Integration with the Person/Organization services in CTRP/COPPA
- Upgraded to caGrid 1.3

For More Information on Lab Viewer

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

<https://qforge.nci.nih.gov/docman/view.php/614/19901/CTODS%20Lab%20Viewer%20End%20User%20Guide.doc>

The Lab Viewer Release Notes can be found here:

<https://qforge.nci.nih.gov/docman/view.php/614/19903/CTODS%20Lab%20Viewer%20Release%20Notes%20v2.0.doc>

For more information about the CTODS Lab Viewer, go here: <https://cabig-kc.nci.nih.gov/CTMS/KC/index.php/LabViewer>

Clinical Connector

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

The Clinical 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 Clinical Connector is a component of the Suite, however C3D is not. For a basic understanding, both Clinical Connector (a Suite application) and Cancer Central Clinical Database (a vendor-provided solution resident at NCI CBIIT) are reviewed here.

Clinical Connector (a Suite Component)

The Clinical Connector provides the Suite users the ability to enroll patients and load labs into the CDMS, the Cancer Central Clinical Database (C3D) 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 Institute's (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 Clinical Connector in the Suite

The role of the Clinical 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 within the C3D CTMS. Laboratory Test Results available in the Lab Viewer component can be passed to the Clinical Connector which then analyzes and loads the data to the appropriate Study/Patient.

For More Info on Clinical Connector

The *Clinical Connector Administration Guide* can be found at this location:

http://qforge.nci.nih.gov/docman/view.php/365/20092/Clinical%20Connector_2.0_Admin_Guide.doc

The Clinical Connector Release Notes can be found here:

http://qforge.nci.nih.gov/docman/view.php/365/20093/Clinical%20Connector_2.0_Release_Notes.docx

The Clinical Connector Tools page can be found here:

<https://cabig.nci.nih.gov/tools/C3DClinicalConnector-v~2>

Additional information about C3D can be found here:

<https://cabig.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* on page 23
- *Setting Up Users* on page 23
- *User Interface* on page 23
- *Minimizing Redundant Data Entry* on page 24
- *Error Handling and Rollback Features* on page 24

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 lease refer to the *caBIG® Clinical Trials Suite 2.0 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 the “source of record” to one or more other applications. After entering the data in the “source of record” 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 NCI Enterprise Services provide the data.

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* on page 25
- *Exiting the Suite* on page 26
- *Application Roles and Workflows* on page 27
- *Hotlinking* on page 32

Launching the Suite

To enter the Suite, log into any of its component 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 component 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. If you are not already signed in, a Single Sign-On (SSO) page appears.
2. Enter your username and password.

Central Authentication Service (CAS)

The screenshot shows a login form titled "Central Authentication Service (CAS)". The form has a light gray background and a dark blue header bar. The header bar contains the text "Central Authentication Service (CAS)" in white. Below the header, there is a message: "Enter Your NetID And Password And Select The Authentication Service To Use For Authentication." On the left side of the form, there are input fields for "NetID" and "Password". Below these fields is a dropdown menu labeled "Authentication Service" with the option "-- Please Select". There is also a checkbox labeled "Warn me before logging me into other sites." At the bottom of the form are two buttons: "LOGIN" and "clear". On the right side of the form, there is a note: "For security reasons, please Log Out and Exit your web browser when you are done accessing services that require authentication!" and a language selection section labeled "Languages: English".

You are automatically routed to the CCTS application you were trying to open. For example, if you were trying to open C3PR, the C3PR home page appears, as shown below.

Frequently Used Shortcuts

- Manage Study
- Create Registration
- Create Study
- Manage Registration

Notifications [My Inbox](#)

You don't have any notifications.

C3PR Development Notes

- C3PR Wiki
- C3PR User Guide

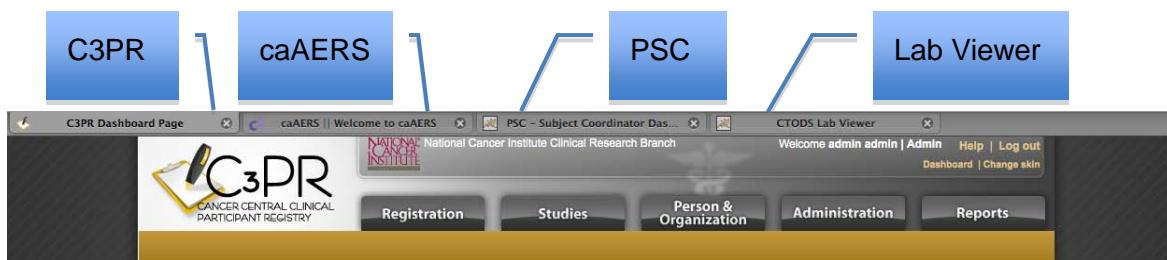
Build Number: c3pr v. 2.8rc3

| Subject name | Primary identifier | Short title | Registration status |
|---------------|--------------------|----------------|---------------------|
| 99 99 | g-subject1 | AdvilStudy | Pending |
| Allan Jackson | ALLAN-J-MRN | Adjuvant Chemo | Pending |
| Jane Subject | JS-03232 | Adjuvant Chemo | Pending |

| Short title | Primary identifier | Coordinating center | Phase |
|-------------------------------------|--------------------|--|--------------------|
| | NCI-2009-00006 | Saint Francis Hospital and Medical Center | Phase III Trial |
| | NCI-2009-00005 | AIDS-Associated Malignancies Clinical Trials Consortium | Phase II Trial |
| Mandatory at Abstraction Validation | | Abramson Cancer Center of The University of Pennsylvania | Phase II/III Trial |
| | NCI-2009-00002 | Suburban Hospital | Phase I/II Trial |
| | | Test Org | Phase II/III Trial |

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):



Exiting the Suite

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

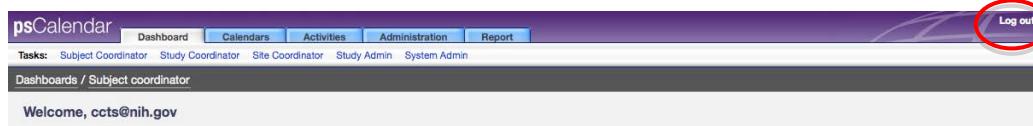
Logging Out of C3PR:

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

Logging Out of caAERS:



Logging Out of PSC:



Logging Out of Lab Viewer:



Application Roles and Workflows

To use the Suite effective, 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
 - A "super-user" who manages the application
 - 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 C3PR interface with a red oval highlighting the 'User Role' section. The 'User Role' section contains the following checkboxes:

- C3PR admin
- Study coordinator
- Registrar
- Site coordinator

Refer to the *caBIG® Clinical Trials Suite 2.0 Administration Guide* or to the *C3PR End User's Guide* for more information about these roles.

Roles in caAERS (Paul)

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, Subjects, and Advanced Search tabs; the user can add subjects to the system, associate subjects to studies, document AEs and create adverse event reports.
- Study Coordinator – Provides access to all tabs except Administration; the user can create and edit studies, assign subjects to studies, and view AEs, and expedited reports.
- Adverse Event Coordinator – Provides access to the Adverse Events, Subjects, Studies, and Advanced Search tabs; the user can enter and report AEs , and view study and subject information.
- Site Coordinator – Provides access to all tabs; the user can perform all actions in the system with the exception of adverse event entry and reporting.
- Central Office Report Reviewer – Provides read-only access to adverse events and adverse event reports. Typically used as a coordinating center role.

- Data Coordinator – Provides read-only access to adverse events. Typically used as a coordinating center role.

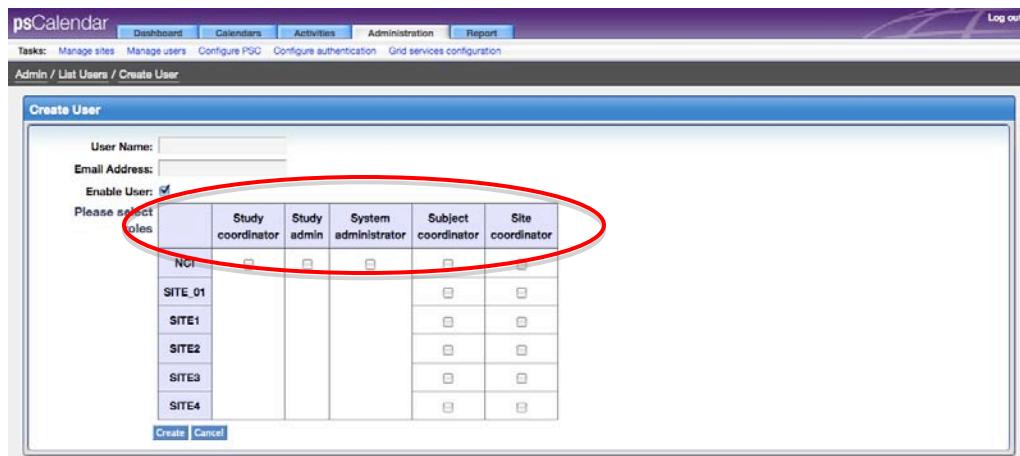
The screenshot shows the 'Research Staff Details' form. At the top, there are fields for First name, Middle name, Last name, Primary email, and Login ID. Below these is a button labeled 'Add Organization'. The next section is for 'Organization' information, including Email address, Phone, Fax, Street, City, State, Postal code, and Country. A large red circle highlights the 'Associate to all studies:' section, which contains a checkbox labeled 'Role name'. Underneath are checkboxes for Study coordinator, Subject coordinator, Adverse event coordinator, Site coordinator, Central office report reviewer, and Data coordinator. To the right of this section is a 'Start date' table with six rows, each with a date input field in the format '(mm/dd/yyyy)'.

Refer the *caAERS v2.0 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 five roles:

| | |
|-----------------------------|---|
| System Administrator | <ul style="list-style-type: none"> Creates user accounts Grants users to role(s) and site(s) within the application Configures the application |
| Study Administrator | <ul style="list-style-type: none"> Reviews completed study templates and approves them Imports and exports study templates Makes studies available to each site |
| Study Coordinator | <ul style="list-style-type: none"> Creates new study templates Marks templates as being ready for review by Study Administrator |
| Site Coordinator | <ul style="list-style-type: none"> Accepts study templates and amendments for use at a site Determines which study templates are accessible by each Subject Coordinator at a site Reassigns subject calendars to appropriate Subject Coordinator |
| Subject Coordinator | <ul style="list-style-type: none"> Assigns subjects to studies Generates and manages calendars for subjects |



Refer to the *caBIG® Clinical Trials Suite 2.0 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. View existing users or add new users by accessing the Administration Tab → User Configuration link.

User Management Across the Suite (Ram)

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 Administrator | 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 | Site Coordinator: accepts study template for use at a site and assigns Subject Coordinator to study | Determines which sites will be able to perform the study | Study Coordinator: receives sent studies (automatically), approves templates | Subject Coordinator: receives registrations (automatically), views subject calendars, receives calendar notifications |

| Role / Application | Site Coordinator | Study Administrator | Study Coordinator | Subject Coordinator |
|---------------------------|-------------------------|----------------------------|--|---|
| 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 registrations (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 | Patient schedule, “Interapplication links” |
| PSC | caAERS | Patient schedule, “Interapplication links” |
| Lab Viewer | caAERS | Top |
| caAERS | PSC | Towards top, above AEs |
| caAERS | Lab Viewer | Middle, under Labs heading |

***Note:** Hotlinks to C3D require users to log in 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 (after selecting a subject).

The screenshot shows the 'Enrollment Details' section of the C3PR interface. Under 'CCTS Applications', there is a list of three links: 'Adverse Event Reporting System', 'Patient Study Calendar', and 'Cancer Central Clinical Database'. The 'Patient Study Calendar' link is circled in red.

Hotlinks Available in caAERS

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

The screenshot shows the caAERS interface with the 'Manage Reports' tab selected. In the instructions section, there is a link to the 'study calendar'. A blue callout box with the text 'Link to Study Calendar application from the Manage Reports page in caAERS' points to this link. Below the instructions, there is a table listing various study cycles with their details and report submission status.

| Course | # of Reports | # of AEs | Data Entry Status | Report Submission Status | Options |
|----------------------------------|--------------|----------|-------------------|--------------------------|----------------|
| Cycle #: 4; Start Date: 11/02/09 | 1 | 2 | In-progress | Reports Due | Please selec ▾ |
| Cycle #: 3; Start Date: 10/23/09 | 1 | 1 | In-progress | Reports Completed | Please selec ▾ |
| Start Date: 10/15/09 | 1 | 1 | In-progress | Reports Completed | Please selec ▾ |
| Start Date: 10/08/09 | 1 | 1 | In-progress | Reports Due | Please selec ▾ |
| Cycle #: 1; Start Date: 10/01/09 | 1 | 1 | In-progress | Reports Due | Please selec ▾ |

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

Subject (mm-pt-003) sam smith
Study (7351) A Phase II Trial of 17-N-Allylaminoo-17-Demethoxygeldanamycin (17-AAG) in Combination with Gemcitabine in Patients with Metastatic Pancreatic Adenocarcinoma
Course Cycle #: 4; Start Date: 11/02/09
Report(s) CTEP 10 Calendar Day SAE Report
[Apply Now](#)

Labs

Instructions Enter any labs that are relevant for describing the event(s) in this report.
View this person's details in the [lab viewer](#).

[Add a lab](#)

[Save & Back](#) [Save](#) [Save & Continue](#)

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.

psCalendar Dashboard Calendars Activities Administration Report Log out

Comprehensive schedule for Boo Radley

Timeline (0 days)

| | | | | | | | |
|--------|---------------------------|-------|--------|--------|--------|-------|-------|
| 2008 | 2009 | 2010 | 2011 | | | | |
| | WeeklongStudy / Treatment | | | | | | |
| Sep 21 | Sep 28 | Oct 5 | Oct 12 | Oct 19 | Oct 26 | Nov 2 | Nov 9 |

Schedule details

- 2009-09-29 [WeeklongStudy / Treatment / CBC](#) [Added details](#)
- 2009-09-30 [WeeklongStudy / Treatment / CBC](#)

Opens the AE application to display any documented adverse events.

Modify schedule

- Display
- Notifications
- Amendments
- Delay or advance
- Select and modify
- Next segment
- Population
- Export
- Inter-study inclusion links

View this subject's [adverse events](#) [lab results](#)

Template links

Opens Lab Viewer application to display current patient's labs

Hotlinks Available in Lab Viewer

Lab Activities - Search Results [26 record(s) found]

[View this patient in caAERS](#)

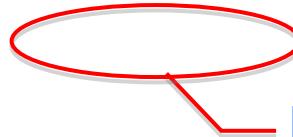
| <input checked="" type="checkbox"/> | Patient ID | Site | Date / Time | Lab Test | Text Result | Numeric Result | Unit Of Measure | Lower Limit | Upper Limit | Sent to CDMS | Sent to caAERS |
|-------------------------------------|------------|------|------------------|-----------------|-------------|----------------|-----------------|-------------|-------------|--------------|----------------|
| <input type="checkbox"/> | 69-98-14-2 | | 5/7/08 10:28 PM | ALK_PHOS | | 102.0 | U/L | 37.0 | 116.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 5/7/08 10:28 PM | ANC | | 3.728 | mm3 | 1.0 | 7.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 4/29/08 10:28 PM | BANDS | with Polys | | | 0.0 | 4.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 5/7/08 10:28 PM | BASO | | 0.1 | % | 0.0 | 3.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 4/29/08 10:28 PM | BASO | | 0.1 | % | 0.0 | 3.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 5/7/08 10:28 PM | BASO_ABS | | 0.004 | mm3 | 0.0 | 0.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 5/7/08 10:28 PM | BILIRUBIN_TOTAL | | 0.8 | mg/dL | 0.0 | 1.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 5/7/08 10:28 PM | BUN | | 11.0 | mg/dL | 8.0 | 22.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 5/7/08 10:28 PM | EOSIN_ABS | | 0.014 | mm3 | 0.0 | 0.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 5/7/08 10:28 PM | GLUC_NONFASTING | | 110.0 | mg/dL | 70.0 | 115.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 5/7/08 10:28 PM | HEMATOCRIT | | 32.5 | % | 31.0 | 43.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 4/29/08 10:28 PM | HEMATOCRIT | | 32.5 | % | 31.0 | 43.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 5/7/08 10:28 PM | INORG_PHOS | | 3.8 | mg/dL | 2.0 | 4.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 5/7/08 10:28 PM | LDH | | 179.0 | U/L | 113.0 | 226.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 5/7/08 10:28 PM | LYMPHOCYTES_ABS | | 3.62 | mm3 | 0.0 | 4.0 | false | false |

26 Lab Results found, displaying 1 to 15 [First/Prev] 1..2 [Next/Last]
Export options: [CSV](#) | [Excel](#) [PDF](#)

[Cancel](#) [Load Labs to caAERS](#) [Load Labs to CDMS](#)

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

[RC7]



Opens the Adverse Events application and displays any documented AEs for the patient on the current study.

Chapter 5 Creating Studies

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

- Overview on page 36
- *Steps for Creating a Study* on page 36

Overview

In caBIG® Clinical Trials Suite, there are a variety of ways to enter studies into the suite. One primary method is to fetch the study from the NCI Enterprise Service in each application. This will mean that, as study details change over time, they will be immediately reflected within each application. However, you can also send a study definition from C3PR to the other applications. This can either be a manually entered study or a study fetched from the Enterprise Services. Once the information is complete and correct in C3PR, 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. This is a necessary step if you are using Lab Viewer, which does not directly fetch study definitions from the Enterprise Services.

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:

| Application | Role |
|--------------------|--|
| C3PR | Site Coordinator (to create the study), Study Coordinator (to open and broadcast the study to the other modules) |
| PSC | Study Coordinator, Site Coordinator |
| caAERS | Study Coordinator |
| Lab Viewer | Study Coordinator |

Additional Prerequisites

Before creating a study in the Suite, it is necessary to ensure that Investigators and organizations associated with a study being broadcast are already created in each of the modules, that the assigned identifier (typically, the CTEP identifier) is not null, and that the assigned identifier is identical between the modules. . This restriction applies especially to caAERS and to PSC. See the *caBIG® Clinical Trials Suite 2.0 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 application interface. At the top, there's a navigation bar with tabs for Registration, Studies, Person & Organization, Administration, and Reports. The 'Studies' tab is active. On the left, there's a sidebar with sections for 'Frequently Used Shortcuts' (containing 'Manage Study', 'Create Study', 'Create Registration', and 'Manage Registration'), 'Notifications' (showing 'You don't have any notifications.'), and 'C3PR Development Notes' (containing links to 'C3PR Wiki' and 'C3PR User Guide'). The main content area has two tables. The first table, 'Incomplete Registrations - Most Recent', lists three entries: 'gg gg' (Primary identifier: g-subject1, Short title: AdvilStudy, Status: Pending), 'Allan Jackson' (Primary identifier: ALLAN-J-MRN, Short title: Adjuvant Chemo, Status: Pending), and 'Jane Subject' (Primary identifier: JS-03232, Short title: Adjuvant Chemo, Status: Pending). The second table, 'Pending Studies - Most Recent', lists four entries: 'Saint Francis Hospital and Medical Center' (Short title: AIDS-Associated Malignancies Clinical Trials Consortium, Primary identifier: NCI-2009-00006, Phase: Phase II Trial), 'Abramson Cancer Center of The University of Pennsylvania' (Short title: Mandatory at Abstraction Validation, Primary identifier: NCI-2009-00005, Phase: Phase II/III Trial), 'Suburban Hospital' (Short title: NCI-2009-00002, Primary identifier: Test Org, Phase: Phase II/III Trial), and another entry for 'Saint Francis Hospital and Medical Center' (Phase: Phase III Trial).

| Subject name | Primary identifier | Short title | Registration status |
|---------------|--------------------|----------------|---------------------|
| gg gg | g-subject1 | AdvilStudy | Pending |
| Allan Jackson | ALLAN-J-MRN | Adjuvant Chemo | Pending |
| Jane Subject | JS-03232 | Adjuvant Chemo | Pending |

| Short title | Primary identifier | Coordinating center | Phase |
|---|--------------------|--|--------------------|
| Saint Francis Hospital and Medical Center | | Saint Francis Hospital and Medical Center | Phase III Trial |
| AIDS-Associated Malignancies Clinical Trials Consortium | NCI-2009-00006 | AIDS-Associated Malignancies Clinical Trials Consortium | Phase II Trial |
| Mandatory at Abstraction Validation | NCI-2009-00005 | Abramson Cancer Center of The University of Pennsylvania | Phase II/III Trial |
| | NCI-2009-00002 | Suburban Hospital | Phase I/II Trial |
| | | Test Org | Phase II/III Trial |

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

Step 2: Broadcast the Study

Once you have completed and saved the study data, a Study Coordinator in C3PR initiates the replication of the data to the other applications. The Study Coordinator opens the study by selecting **Manage Study** and then clicking the **Broadcast Study** link at the top of the Summary page.

The status of the broadcast is 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. |

Status Messages Resulting from Broadcasting a Study

Note: If one of the modules is unable to successfully process the create study message, it displays an error message. The create study transaction is then terminated and rolled back in all the modules. The Suite is designed with a one-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: Add Study Details As Needed (Sean/Paul)

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, assign Study to sites, approve Study at site, assign Subject Coordinator for Study |
| Cancer Adverse Event Reporting System | Enter adverse event terminology, disease terminology, agents, therapies, treatment assignments, study diseases, and other related data such as study sites, investigators and personnel. Additionally, a user must click the “Study Set-up Complete” button. |

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 2.0 Administration Guide* and in the *PSC End User’s Guide*.

The screenshot shows the psCalendar application interface. At the top, there is a navigation bar with tabs: Dashboard, Calendars, Activities, Administration, and Report. Below the navigation bar, a sub-navigation menu lists Tasks: Subject Coordinator, Study Coordinator, Site Coordinator, Study Admin, and System Admin. A breadcrumb trail indicates the user is at Dashboards / Site coordinator. The main content area displays a "Please note" section with a bullet point: "Initial template of NCI-0001 needs to be [approved](#) for NCI." Another section titled "Manage subject coordinators" contains the text: "As a site coordinator, you can [manage](#) the visibility of studies to individual subject coordinators. You can also [change](#) the primary subject coordinator for individual subjects."

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 2.0 Administration Guide* and in the *caAERS 2.0 End User's Guide*.

The screenshot shows the caAERS study setup interface. The top navigation bar includes links for Adverse Events, Studies, Subjects, Rules, Administration, and Advanced Search. Below the navigation bar, a breadcrumb trail shows the current path: 1. Overview > 2. Details > 3. Therapies > 4. Agents > 5. Treatment Assignments > 6. Disease > 7. Solicited AEs > 8. Expected AEs > 9. Sites > 10. Investigators > 11. Personnel > 12. Identifiers. A message box at the top says: "Instructions: Review the study information below to verify completeness and correctness. To make changes, click "Back" or select the page you need to edit. Click "Save" when you are ready to save the study." An "Export Study XML" button is available. The main content area is titled "Overview" and displays study details such as Primary identifier 6789, Short title Smoke Test, Long Title Smoke Test long title, Precis, Description, Primary sponsor Cancer Therapy Evaluation Program, and Coordinating center Mayo Clinic Rochester. A callout bubble points to the "Phase code Phase I Trial" field, which is highlighted in red. The callout text reads: "Click this button after completing study data entry in caAERS. This will allow subjects to be associated to studies in caAERS." At the bottom right of the page, a green button says "✓ Study Setup Complete!"

Details

Instructions Enter the general details of the study.

| | |
|-----------------------------|-----------------------------------|
| * Short title | Smoke Test |
| * Long title | Smoke Test long title |
| Precis | |
| Description | |
| * Phase | Phase II Trial |
| * Status | Active - Trial is open to accrual |
| * Multi Institutional | No |
| * AdEERS reporting required | Yes |

Adverse event coding terminology

| | |
|------------------------|------------|
| * Terminology | CTC |
| * CTC version | CTCAE v3.0 |
| * Other MedDRA Version | MedDRA v9 |

Disease coding terminology

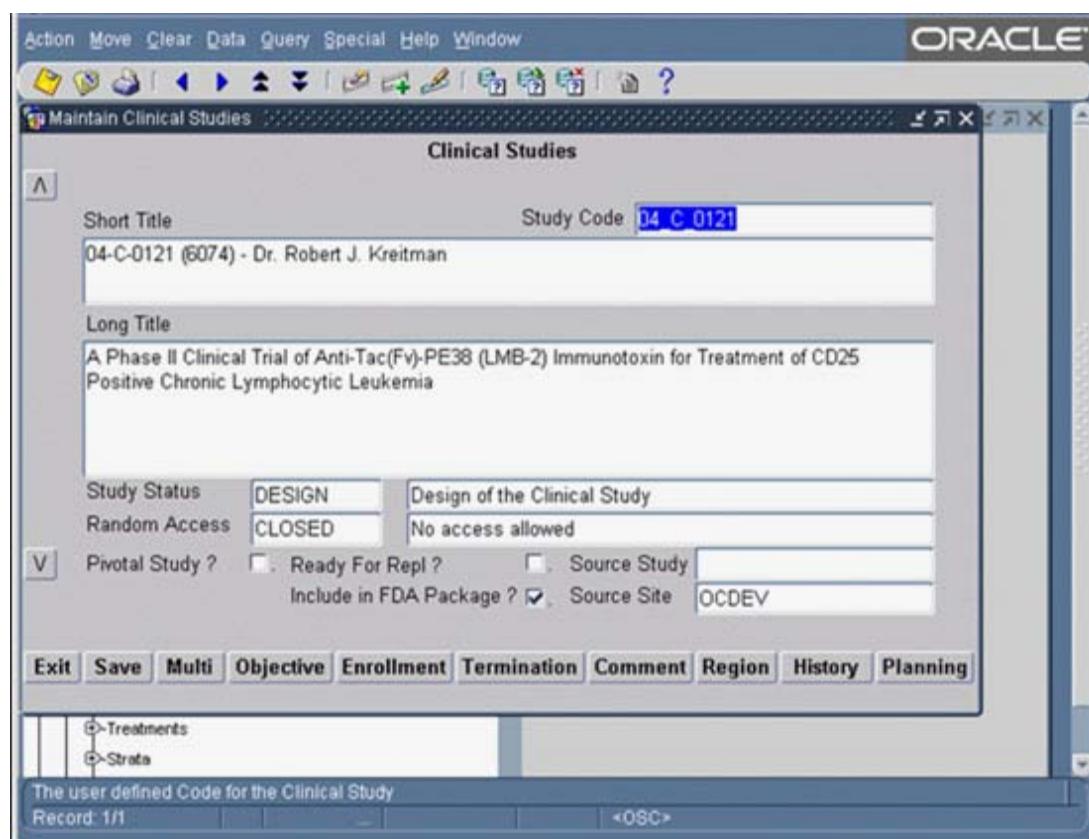
| | |
|---------------|------|
| * Terminology | CTEP |
|---------------|------|

Study method details

| | |
|--------------|--------------|
| Study design | Open/Unblind |
|--------------|--------------|

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>.



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* on page 42
- *Steps for Registering a Subject* on page 42

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 are 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. The user who is registering the subject must be authorized to assign subjects to the study.

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.

The image consists of two vertically stacked screenshots of the C3PR (Cancer Central Clinical Participant Registry) application. Both screenshots show a dark-themed interface with a navigation bar at the top containing links for Registration, Studies, Person & Organization, Administration, and Reports. The 'Registration' link is highlighted in yellow, indicating the current module. A sub-navigation bar below shows steps 1 through 7: Subject & Study, Enrollment Details, Eligibility, Stratification, Arm, Companion Registrations, and Review & Submit. Step 2, 'Enrollment Details', is currently selected and highlighted in yellow.

Screenshot 1 (Top): Selected Study and Subject Information

This screenshot shows the 'Selected Study' section with the text 'Selected Study: Adjuvant Chemo (NXT0000130) at National Cancer Institute'. Below it is the 'Select Epoch' section, which lists a single entry: 'Treatment' under 'Name', 'Description' is blank, and 'Enrolling' status is 'Yes'. At the bottom, the text 'Selected Subject: Jane Subject (MRN - JS-03232)' is displayed. Action buttons include 'Save' and 'Save & Continue'.

Screenshot 2 (Bottom): Enrollment Details Form

This screenshot shows the 'Enrollment Details' form. It includes fields for 'Name' (Jane Subject), 'Subject MRN' (JS-03232), 'Study' (Adjuvant Chemo), 'Epoch' (Treatment), 'Consent date', 'Consent signed date', 'Enrolling physician' (dropdown menu 'Please select...'), 'Primary disease' (dropdown menu 'Please select...'), 'Primary disease site' (text input field '(Begin typing here)' with a dropdown menu 'Select Disease Site'), and 'Payment method' (dropdown menu 'Please select...'). Action buttons at the bottom include 'Save & Back', 'Save', and 'Save & Continue'.

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 are 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.

The screenshot shows the C3PR interface with the following details:

- Header:** National Cancer Institute Clinical Research Branch, Welcome admin admin | Admin, Help | Log out, Dashboard | Change skin.
- Navigation Bar:** Registration, Studies, Person & Organization, Administration, Reports.
- Sub-navigation:** Manage Study, Create Study, Create Companion Study.
- Workflow:** 1. Summary > 2. Sites > 3. Identifiers > 4. Investigators > 5. Personnel > 6. Notifications > 7. Registrations > 8. Amendments.
- Buttons:** Close Study, Edit Study, Amend Study, Edit Accrual, Broadcast Study (highlighted with a red oval), Export XML, Print.
- Study Details Section:**
 - Short title: Adjuvant Chemo
 - Primary Identifier: NXT0000130
 - Target accrual: 100
 - Phase: Phase I/II Trial
 - Status: Open
 - Type: Interventional
 - Blinded: Yes
 - Stratified: No
 - Randomized: Yes
 - Randomization type: Phone Call
 - Open date: 11/20/2009
- Principal Investigator Section:** Organization: National Cancer Institute (NCI), Principal Investigator: Johnny Dune.
- Identifiers Section:**

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 backed 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.

The screenshot displays the psCalendar application interface. At the top, there is a navigation bar with tabs: Dashboard, Calendars, Activities, Administration, and Report. On the far right of the header is a "Log out" link. Below the header, a title bar reads "Comprehensive schedule for Boo Radley".

The main area features a horizontal timeline from September 2008 to November 2009. A specific event, "WeeklongStudy / Treatment", is highlighted in yellow across the timeline. Below the timeline, dates are listed: Sep 21, Sep 28, Oct 5, Oct 12, Oct 19, Oct 26, Nov 2, and Nov 9. To the left of the timeline, there is a vertical "Timeline" indicator.

On the left side, under "Schedule details", two entries are shown:

- 2009-09-29 WeeklongStudy / Treatment / [CBC](#) [Added details](#)
- 2009-09-30 WeeklongStudy / Treatment / [CBC](#)

On the right side, under "Modify schedule", there is a sidebar with various options: Display, Notifications, Amendments, Delay or advance, Select and modify, Next segment, Population, Export, Interapplication links (with links to adverse events and lab results), and Template links.

At the bottom left of the main content area, the text "Patient Study Calendar v. 2.6.0.RC1postdev" is visible.

Chapter 7 Lab Data

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

- *Loading Labs Into the CTODS Lab Database* on page 46
- *Loading Lab Data from LabViewer to C3D* on page 46
- *Sending Lab Data Alerts to the AE System* on page 48

Loading Labs Into the CTODS Lab Database

There are a number of ways to load labs into the CTODS database. The Cancer Center Hub Client (CCHC) is one method. Refer to the *caBIG® Clinical Trials Suite 2.0 Administration Guide* and the *Lab Viewer Administration Guide* for more information on this tool or on loading labs in general.

Loading Lab Data from LabViewer 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 LabViewer 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 |
| LabViewer | Subject Coordinator |

Prerequisites

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

Step 1: Search for Labs in LabViewer

To load labs, open the LabViewer application and search by either Study or Patient to retrieve the lab results.

The screenshot shows the 'Study Search' interface of the Lab Viewer application. At the top, there is a search bar with a 'Search' button. Below it, instructions say: '* Please enter one or more search terms above and select the "Search" button.
** Search will perform search in Study Title and Identifier.' The main area is titled 'Search Results:' and contains a table with columns: ID, Short Title, Sponsor code, Phase code, Status, HealthCare Site, and Principal Investigator. The table lists four studies:

| ID | Short Title | Sponsor code | Phase code | Status | HealthCare Site | Principal Investigator |
|------------|-------------|--------------|------------|--------|-------------------------|-------------------------|
| 04_C_0121 | | | | | Details | Details |
| 04_C_0122 | | | | | Details | Details |
| SMOKE_TEST | Smoke Test | | | ACTIVE | Details | Details |
| 04_C_0135 | short title | | | | Details | Details |

Below the table, it says '4 Studies found, displaying all Studies.1' and provides export options: CSV | Excel | XML.

Step 2: Send Labs to C3D

Lab results appear in the Lab Activities screen.

The screenshot shows the 'Lab Activities - Search Results [26 record(s) found]' screen. It displays a table of lab results with columns: Patient.Id, Site, Date / Time, Lab.Test, Text.Result, Numeric.Result, Unit.Of.Measure, Lower.Limit, Upper.Limit, Sent.to.CDMS, and Sent.to.caAERS. Each row has a checkbox in the first column. A red arrow points to the first column of checkboxes. Another red arrow points to the 'Load Labs to CDMS' button at the bottom right of the screen.

| Patient.Id | Site | Date / Time | Lab.Test | Text.Result | Numeric.Result | Unit.Of.Measure | Lower.Limit | Upper.Limit | Sent.to.CDMS | Sent.to.caAERS |
|------------|------|------------------|-----------------|-------------|----------------|-----------------|-------------|-------------|--------------|----------------|
| 69-98-14-2 | | 5/7/08 10:28 PM | ALK_PHOS | | 102.0 | U/L | 37.0 | 116.0 | false | false |
| 69-98-14-2 | | 5/7/08 10:28 PM | ANC | | 3.728 | mm3 | 1.0 | 7.0 | false | false |
| 69-98-14-2 | | 4/29/08 10:28 PM | BANDS | with Polys | | | 0.0 | 4.0 | false | false |
| 69-98-14-2 | | 5/7/08 10:28 PM | BASEO | | 0.1 | % | 0.0 | 3.0 | false | false |
| 69-98-14-2 | | 4/29/08 10:28 PM | BASEO | | 0.1 | % | 0.0 | 3.0 | false | false |
| 69-98-14-2 | | 5/7/08 10:28 PM | BASEO_ABS | | 0.034 | mm3 | 0.0 | 0.0 | false | false |
| 69-98-14-2 | | 5/7/08 10:28 PM | BILIRUBIN_TOTAL | | 0.8 | mg/dL | 0.0 | 1.0 | false | false |
| 69-98-14-2 | | 5/7/08 10:28 PM | BUN | | 11.0 | mg/dL | 8.0 | 22.0 | false | false |
| 69-98-14-2 | | 5/7/08 10:28 PM | EOSIN_ABS | | 0.074 | mm3 | 0.0 | 0.0 | false | false |
| 69-98-14-2 | | 5/7/08 10:28 PM | GLUC_NONFASTING | | 110.0 | mg/dL | 70.0 | 115.0 | false | false |
| 69-98-14-2 | | 5/7/08 10:28 PM | HEMATOCRIT | | 32.5 | % | 31.0 | 43.0 | false | false |
| 69-98-14-2 | | 4/29/08 10:28 PM | HEMATOCRIT | | 32.5 | % | 31.0 | 43.0 | false | false |
| 69-98-14-2 | | 5/7/08 10:28 PM | INORG_PHOS | | 3.8 | mg/dL | 2.0 | 4.0 | false | false |
| 69-98-14-2 | | 5/7/08 10:28 PM | LDH | | 179.0 | U/L | 113.0 | 226.0 | false | false |
| 69-98-14-2 | | 5/7/08 10:28 PM | LYMPHOCYTES_ABS | | 3.62 | mm3 | 0.0 | 4.0 | false | false |

26 Lab Results found, displaying 1 to 15. [First/Prev] 1, 2 [Next/Last]
Export options: CSV | Excel | XML

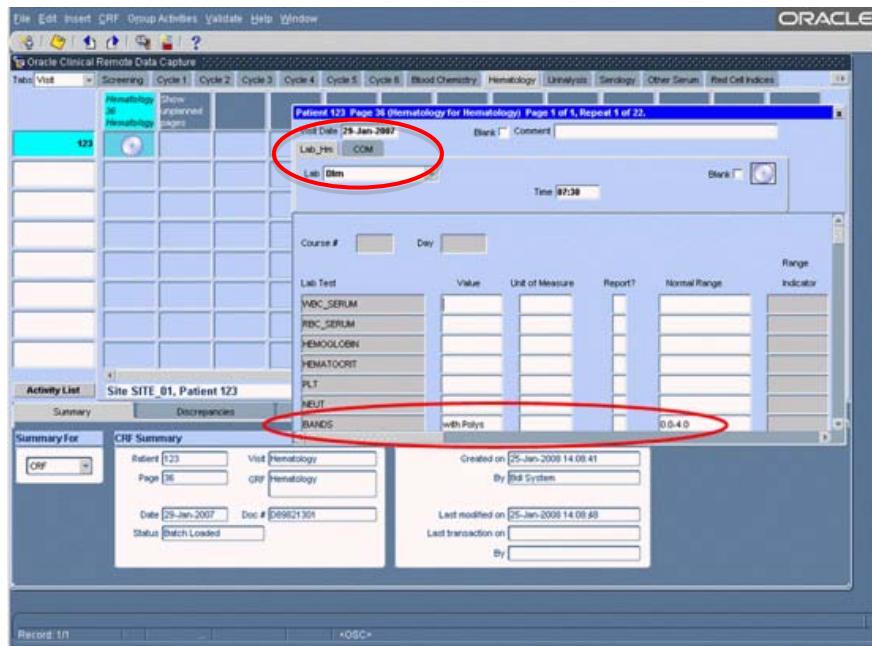
Cancel Load Labs to caAERS **Load Labs to CDMS**

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.

Note A status message appears 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.



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 LabViewer 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 |
| LabViewer | 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 LabViewer and caAERS
- The subject must already be registered to the study in both LabViewer and caAERS

Step 1: Search for Labs in LabViewer

To load labs, open the LabViewer 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 LabViewer 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 Activities - Search Results [26 record(s) found] | | | | | | | | | | | |
|--|------------|------|------------------|-----------------|-------------|----------------|-----------------|-------------|-------------|--------------|----------------|
| View this patient in caAERS | | | | | | | | | | | |
| <input checked="" type="checkbox"/> | Patient Id | Site | Date / Time | Lab Test | Text Result | Numeric Result | Unit Of Measure | Lower Limit | Upper Limit | Sent to CDMS | Sent to caAERS |
| <input type="checkbox"/> | 69-98-14-2 | | 5/7/08 10:28 PM | ALK_PHOS | | 102.0 | U/L | 37.0 | 116.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 5/7/08 10:28 PM | ANC | | 3.728 | mm3 | 1.0 | 7.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 4/29/08 10:28 PM | BANDS | with Polys | | | 0.0 | 4.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 5/7/08 10:28 PM | BASEO | | 0.1 | % | 0.0 | 3.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 4/29/08 10:28 PM | BASEO | | 0.1 | % | 0.0 | 3.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 5/7/08 10:28 PM | BASEO_ABS | | 0.014 | mm3 | 0.0 | 0.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 5/7/08 10:28 PM | BILIRUBIN_TOTAL | | 0.8 | mg/dL | 0.0 | 1.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 5/7/08 10:28 PM | BUN | | 11.0 | mg/dL | 8.0 | 22.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 5/7/08 10:28 PM | EOSIN_ABS | | 0.074 | mm3 | 0.0 | 0.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 5/7/08 10:28 PM | GLUC_NONFASTING | | 110.0 | mg/dL | 70.0 | 115.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 5/7/08 10:28 PM | HEMATOCRIT | | 32.5 | % | 31.0 | 43.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 4/29/08 10:28 PM | HEMATOCRIT | | 32.5 | % | 31.0 | 43.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 5/7/08 10:28 PM | INORG_PHOS | | 3.8 | mg/dL | 2.0 | 4.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 5/7/08 10:28 PM | LDH | | 179.0 | U/L | 113.0 | 226.0 | false | false |
| <input type="checkbox"/> | 69-98-14-2 | | 5/7/08 10:28 PM | LYMPHOCYTES_ABS | | 3.62 | mm3 | 0.0 | 4.0 | false | false |

26 Lab Results found, displaying 1 to 15. [First/Prev] 1 2 [Next/Last]
Export options: [CSV](#) | [Excel](#) | [XML](#)

[Cancel](#) [Load Labs to caAERS](#) [Load Labs to CDMS](#)

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

| | | | | | | | | | |
|-------------------------------------|------------|-----------------|----------|-------|-----|-----|------|-------|--|
| <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 | <div style="border: 1px solid red; padding: 2px;">Wed Oct 29 14:57:46 EDT 2008</div> |
|-------------------------------------|------------|-----------------|----------|-------|-----|-----|------|-------|--|

Step 3: Within caAERS, View or Process Alert

In the caAERS application, the lab data sent from Lab Viewer appears as an alert. A user in caAERS can then view the alert and elect to act on the alert or dismiss the alert, as appropriate.

The screenshot shows the caAERS application interface. At the top, there is a navigation bar with links for Adverse Events, Studies, Subjects, Rules, Administration, and Advanced Search. Below the navigation bar, there are three main buttons: Report Adverse Events, Manage Reports, and Routing and Review. The Routing and Review button is highlighted with a green checkmark icon. The main content area displays study information: Study (SMOKE_TEST) SMOKE TEST and Subject (GM-001) George Mathew. Below this, instructions provide details about viewing adverse events and reports for each course. A link to the study calendar is also present. A table summarizes the adverse events and reports for the study, showing 1 report, 1 AE, and an In-progress status. A dropdown menu labeled 'Please select' is open, showing options like 'Please select', 'Export caAERS XLS', 'Export caAERS PDF', 'Export caAERS CSV', and 'Notify'. A red arrow points from a callout box to the 'Notify' option in the dropdown menu. A blue callout box contains the text: 'Click the notify link to send an alert message to the Study Calendar.'

| Course | # of Reports | # of AEs | Data Entry Status | Report Submission Status | Options | |
|----------------------------------|----------------------|-------------|-------------------|--------------------------|--------------------------|----------------|
| Cycle #: 1; Start Date: 11/01/09 | 1 | 1 | In-progress | Reports Due | Please select | |
| | Report Type | Amendment # | # of AEs | Data Entry Status | Report Submission Status | Options |
| | + NCI AdAEERS Report | | 0 | 1 | In-progress | Due in 10 days |

caAERS v. 2.0-RC3

Click the notify link to send an alert message to the Study Calendar.

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

Study (SMOKE_TEST) SMOKE TEST
Subject (GM-001) George Mathew

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

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

| Course | # of Reports | # of AEs | Data Entry Status | Report Submission Status | Options | |
|----------------------------------|---------------------|-------------|-------------------|--------------------------|--------------------------|-----------------------------|
| Cycle #: 1; Start Date: 11/01/09 | 1 | 1 | In-progress | Reports Due | Please select ▾ | |
| | Report Type | Amendment # | # of AEs | Data Entry Status | Report Submission Status | Options |
| | + NCI AdEERS Report | | 0 | 1 In-progress | Due in 10 days | Notify Person ▾ Notified |

caAERS v. 2.0-RC3

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

1. Reporter > 2. Adverse Events > 3. Describe Event > 4. Course > 5. Study Interventions > 6. Subject Details >
7. Other Causes > 8. Labs > 9. Attribution > 10. Additional Info > 11. Review & Submit

| Labs |
|---------------------------|
| Lab Date Value Unit |
| BUN 2008-04-29 11.0 mg/dL |

Comments/Alerts

Subject (GM-001) George Mathew
Study (SMOKE_TEST) SMOKE TEST
Course Cycle #: 1; Start Date: 11/01/09
Report(s) NCI AdEERS Report [Apply Help](#)

Reporter

Instructions Enter contact information for the person reporting the adverse event and the treating physician. You can select the person from the drop down list or enter the details.

Note: To prepare and submit an expedited report anyway, enter contact information for yourself and the treating physician. Make sure you have entered all the adverse events you want to include in the expedited reports you want to create.

Reporter Details

Reporter
 * First name: Monish
 Middle name:
 * Last name: D
 * E-mail address: monish.dombla@semanticbits.com
 * Phone: 1234567890 #####

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.

The screenshot shows the caAERS interface with the following details:

- Header:** Welcome ects dev1, Help, Log out
- Top Navigation:** Adverse Events, Studies, Subjects, Rules, Administration, Advanced Search, Report Adverse Events, Manage Reports, Routing and Review
- Breadcrumb:** 1. Reporter > 2. Adverse Events > 3. Describe Event > 4. Course > 5. Study Interventions > 6. Subject Details > 7. Other Causes > 8. Labs > 9. Attribution > 10. Additional Info > 11. Review & Submit
- Labs Section:** Displays a table with one row:

| Lab | Date | Value | Unit |
|-----|------------|-------|-------|
| BUN | 2008-04-29 | 11.0 | mg/dL |
- Comments / Alerts:** A red vertical bar on the left containing the text "Report(s) NCI AdEERS Report" and a "Copy Now" button.
- Instructions:** Enter any labs that are relevant for describing the event(s) in this report.
- Buttons:** Add a lab, Save & Back, Save, Save & Continue
- Footer:** caAERS v. 2.0-RC1

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* on page 53
- *Steps for Sending a Schedule Change Notification* on page 53

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 LabViewer to the AE System, 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> |
|---------------------------|---------------------|
| C3PR | N/A |
| PSC | Subject Coordinator |
| caAERS | Subject Coordinator |
| LabViewer | 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

The screenshot shows the caAERS web application. At the top, there's a navigation bar with links for Help, Log out, Adverse Events, Studies, Subjects, Rules, Administration, and Advanced Search. Below the navigation is a toolbar with Manage reports and Enter AEs buttons. The main content area displays a table of adverse events. A tooltip is overlaid on the 'Options' column of the first row, which contains a link labeled 'Click the notify link to send an alert message to the Study Calendar.' A red arrow points from the text in the tooltip to the 'notify' link in the table. The table has columns for Evaluation Period, # of Reports, # of AEs, Data Entry Status, Report Status, and Options.

| Evaluation Period | # of Reports | # of AEs | Data Entry Status | Report Status | Options |
|--|--------------|----------|-------------------|-------------------------------|--|
| ▼ 10/01/08 - 10/31/08 | 1 | | In-progress | Report(s) Due | Status Options 10/29/2008 notify PSC Submit Withdraw |
| All Adverse Events for this Reporting Period | | | | | |
| ▶ AE Term | | Grade | AE Start Date | Requires Expedited Reporting? | |

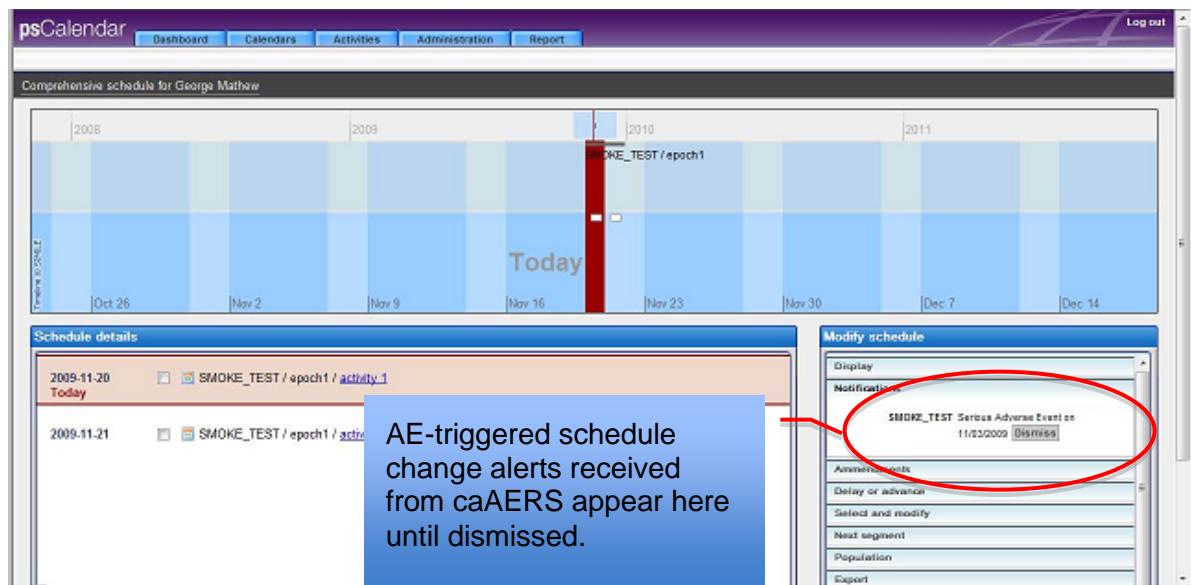
After the notification is sent, the link text is updated to reflect that the message was sent successfully to the Study Calendar.

This screenshot shows the same caAERS interface after the alert has been sent. The 'Options' column for the first row now displays the text 'Notified' instead of 'notify'. A red circle highlights this change. The rest of the table structure remains the same as in the previous screenshot.

| 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 | Notified Status Options 10/29/2008 None Notified Submit Withdraw |
| All Adverse Events for this Reporting Period | | | | | |
| ▶ AE Term | | Grade | AE Start Date | Requires Expedited Reporting? | |

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.

Chapter 9 Integration with COPPA

Topics covered in this chapter include the following:

- *C3PR Integration with COPPA* on page 56
- *caAERS Integration with COPPA* on page 62
- *PSC Integration with COPPA* on page 73
- *LabViewer Integration with COPPA* on page 75

C3PR Integration with COPPA

Overview

C3PR supports searching the NCI Enterprise Services for data related to protocol abstraction, persons, organizations, and their correlations (also known as the "COPPA" services). The source of these data is Clinical Trials Research Program (CTRP) databases. C3PR will save references to the data from these services and will call the services each time the data are used to ensure currency. In the event the services are unreachable, saved local data will be used until the connection to the services is restored at which time it will be refreshed. Data elements obtained using the services are noted in the user interface with the  icon.

Calling the Services

The general sequence of events that occur when searching the NCI Enterprise Services is as follows:

1. C3PR searches the local database and retrieves results matching the search criteria.
2. C3PR searches the NCI Enterprise Services and retrieves results matching the search criteria.
3. C3PR saves a reference to these records in the C3PR local database as remote records.
4. C3PR then merges the local results and the NCI Enterprise Service results and takes the union of the two search results.
5. C3PR removes duplicates from the search results based on the CTEP ID for organizations and persons. C3PR does not remove duplicates from study search results.
6. If a result is contained in both the local and NCI Enterprise Service results, the data from the local database is returned to the user.
7. C3PR displays the search results to the user.

Remote and Local Attributes

Each of the attributes returned by the NCI Enterprise Services is identified as either local or remote attributes. A local attribute is an attribute for which the local data takes precedence and will not be over-written by data obtained from the NCI Enterprise Services. Inversely, a remote attribute is one for which the data obtained from the NCI Enterprise Services will take precedence and over-write information saved in the local database.

Important Tips

- C3PR must be configured by your system administrator to use NCI Enterprise Services.
- The usage of caBIG Integration Hub is required in order to use the NCI Enterprise Services.
- Once a remote record has been returned by a search and saved in the local database (per 2.1 above) it will be able to be searched and used as if it were a local record.
- In the event that the services are unavailable, C3PR will use data from the local database.
 - This includes all remote records that have been returned by a previous search and saved in the local database (per 2.1 above).
 - Once access to the NCI Enterprise Services is restored, the remote record data will be refreshed.
- Autocompleter searches do not search the NCI Enterprise Services. However, all remote records for which references are saved locally will be searched and any records satisfying the search criteria will be refreshed from the NCI Enterprise Services.
- Wildcard searches are not supported when using the NCI Enterprise Services. However, all remote records for which references are saved locally will be searched and any records satisfying the search criteria will be refreshed from the NCI Enterprise Services.

Protocol Abstraction

C3PR supports searching the NCI Protocol Abstraction Service. Users can search this service in the **Study >> Search Studies** page. The NCI Protocol Abstraction Service will be searched during the following search scenarios:

- A study title search on any part of the official study title.

Note: This is a case sensitive sub-string search.

- A study ID search on an exact match of the NCI Protocol Abstraction Service study ID.

Note: This is a case sensitive exact search.

- Searches not conforming to these constraints will only search the local database, however, any remote records will invoke the appropriate NCI Enterprise Services and the data will be refreshed.
- **For example:** Study ID: XYZ is a local study where the coordinating center is a remote organization. A search on study ID for "X" will return Study XYZ and the NCI Enterprise Organization Service will be invoked to refresh the data for the coordinating center.

The screenshot shows the C3PR web application. At the top, there is a navigation bar with the C3PR logo, the National Cancer Institute Clinical Research Branch logo, and user information (Welcome admin admin | Admin, Help | Log out, Dashboard | Change skin). Below the navigation bar is a main menu with tabs: Registration, Studies, Person & Organization, Administration, and Reports. Under the Studies tab, there are three buttons: Manage Study, Create Study, and Create Companion Study. The main content area is titled 'Search' and contains instructions: 'To search for a study, first select an Identifier, Short Title or Status as the search type. Next, enter text in the "Search criteria" field (e.g. study status) and then click 'Search'. Leave the "Search criteria" field blank to get a list of all studies in the local database.' It also includes a disclaimer: 'Searching based on status is not supported when using NCI Enterprise Services (COPPA). Short title searches using NCI Enterprise Services (COPPA) could take several minutes to process.' Below these instructions are search input fields: 'Search by' dropdown set to 'Identifier', 'Search criteria' input field containing 'NCI-2009-00004', and a 'Search' button.

Example results for a search by 'Identifier'. Note the NCI icon next to the identifier. The same icon will also appear for research staff, investigators and organizations retrieved from the CTRP database using the NCI Enterprise Services.

The screenshot shows the 'Search Results' page. The search results table has two columns: 'Short Title' and 'Primary Id'. There is one result listed: 'Evaluation of Efficacy and Mechanisms of an Antiinflammatory Intervention for Chemotherapy Related Mucosal Injury' and 'NCI-2009-000'. To the right of the table is a blue circular icon.

| Short Title | Primary Id |
|---|--------------|
| Evaluation of Efficacy and Mechanisms of an Antiinflammatory Intervention for Chemotherapy Related Mucosal Injury | NCI-2009-000 |

The search results will return and save any/all of the following elements, when available:

Study Details

- Study short title
- Study long title
- Study description

- Study type
- Study target accrual number

Study Phase

- Study status
- Study coordinating center study ID
- Study sponsor study ID

Click on the study in the search results to view study details. You may then edit the study within C3PR.

Note: Currently, you may not upload updated studies via the NCI Enterprise Services. Changes made to a study retrieved from the CTRP database will be saved locally.

| Study Details | | |
|--|--------------------------------------|------------|
| Short title: Evaluation of Efficacy and Mechanisms of an Antiinflammatory Intervention for Chemotherapy Related Mucosal Injury | Type: N/A | |
| Primary identifier: NCI-2009-00004 | Blinded: Yes | |
| Target accrual: | Stratified: No | |
| Phase: Phase II Trial | Randomized: Yes | |
| Status: Pending | Randomization type: Phone Call | |
| | Open date: 12/08/2009 | |
| Principal Investigator | | |
| Organization: National Institute of Nursing Research (3583078) | Principal investigator: robert frank | |
| Identifiers | | |
| Assigning authority | Identifier type | Identifier |
| Consents | | |
| Consents | | |
| Epochs & Arms | | |
| No Epoch for this study. | | |
| Eligibility Criteria | | |
| Diseases | | |
| No disease associated with this study. | | |
| Companion Studies | | |
| No companion study associated with this study | | |

Study Organizations

Searches of the Protocol Abstraction service will return the following correlated organizations, if available. **Note:** Any organizations associated to the study will automatically invoke the NCI Enterprise Organization Service to retrieve the current information for each organization.

- Study coordinating center organization / lead organization (with the CTEP Id, which if missing results in Study Rejection)
- Study sponsor organization
- Study participating organizations / study sites

Note: Any organizations associated to the study will automatically invoke the NCI Enterprise Organization Service to retrieve the current information for each organization.

The screenshot shows the C3PR (Cancer Central Clinical Participant Registry) interface. At the top, there's a navigation bar with tabs for Registration, Studies, Person & Organization, Administration, and Reports. Below this is a secondary navigation bar with Subject, Investigator, Research Staff, and Organization tabs. The 'Organization' tab is currently selected. A sub-menu below it shows 'Manage Organization' and 'Create Organization'. The main content area is titled 'Search' and contains instructions: 'To search for an organization, first enter the name or NCI Identifier and then click 'Search'. Leave the "Search criteria" field blank to return a list of all organizations in the local database.' It also includes a 'Disclaimer' note about COPPA mode. There are input fields for 'Name' (containing 'Mayo Phase 2 Consortium') and 'CTEP identifier', along with a 'Search' button.

Example results using a 'Name' search for an organization.

The screenshot shows the 'Search Results' page for organizations. The title is 'Search Results' under 'Organizations'. It displays a table with one result: 'Mayo Phase 2 Consortium' with a small NCI logo, 'MPC' as the CTEP identifier, and '136319' as the NCI identifier. There are 'FILTER' and 'CLEAR' buttons at the top right of the search results table.

Study Persons

Searches of the Protocol Abstraction service will return the following correlated persons, if available.

Note: Any persons associated to the study will automatically invoke the NCI Enterprise Person Services to retrieve the current information for each person.

- Study principle investigator (with the CTEP Id, which if missing results in study rejection)
- Study site investigators

Note: Any persons associated to the study will automatically invoke the NCI Enterprise Person Services to retrieve the current information for each person.

Person

C3PR supports searching the NCI Person service and saving the following elements:

- Person name (First Name, Last Name, Middle Name)
- Person contact information (phone, fax and email address)
- Person NCI ID
- Organizations to which the person is associated

Note: This will also invoke the Organization service to ensure the data for the organization is up-to-date. In C3PR, a staff member may belong to only one organization. C3PR will associate a research staff member with the first organization fetched during a search. An investigator may belong to multiple organizations, so all of those associations are made in C3PR during a search. C3PR rejects organizations with no CTEP ID, so those organizations will be excluded from the search results.

- For Person Name searches, any portion of a name can be searched.
- For Person CTEP ID searches, any portion of the ID can be searched.
- For Person Organization searches, the organization selected in the autocomplete will be searched.

Remote Attributes

The below attributes will be refreshed with data from the NCI Enterprise Services every time the person is referenced by C3PR.

Note: Any edits made by a user to the below fields will be overwritten when the data are refreshed.

- External ID - This is the unique identifier for this person in the NCI Enterprise Service.
- First name
- Last name
- Middle name

All Attributes

Organization

C3PR supports searching the NCI Organization service and saving the following elements:

- Organization name
- Organization NCI ID
- Organization CTEP ID
- Organization address(Street address, city, state, zip, country)
- For Organization CTEP ID searches, any portion of the ID can be searched.
- For Organization name searches, only an exact match to the sub-string of the name will be searched.

caAERS Integration with COPPA

Using the NCI Enterprise Services

Overview

caAERS supports searching the NCI Enterprise Services for protocol abstraction, persons, organizations, and the correlations (i.e. the associations) between them (also known as the "COPPA" services). caAERS will save references to the data from these services and will call the services each time the data is used to ensure the data is current. In the event the services are not able to be reached, the data that is saved locally will be used until the connection to the services is restored, at which time it will be refreshed. Data that is obtained using the services is noted in the user interface with the  icon.

Calling the Services

The general sequence of events that occur when searching the NCI Enterprise Services is as follows:

1. caAERS searches the local database and retrieves results matching the search criteria.
2. caAERS searches the NCI Enterprise Services and retrieves results matching the search criteria
 - caAERS saves a reference to these records in the caAERS local database as remote records.
3. caAERS then merges the local results and the NCI Enterprise Service results and takes the union of the two search results.
 - caAERS removes duplicates from the search results based on the CTEP ID for organizations and persons. caAERS does not remove duplicates from study search results.
 - If a result is contained in both the local and NCI Enterprise Service results, the data from the local database is returned to the user.
4. caAERS displays the search results to the user

Remote and Local Attributes

Each attribute returned by the NCI Enterprise Services is either local or remote. A local attribute is an attribute for which the local data takes precedence and will not be overwritten by data obtained from the NCI Enterprise Services. Inversely, a remote attribute is one for which the data obtained from the NCI Enterprise Services will take precedence and over-write information saved in the local database. In most cases, remote attributes are not editable for remote records.

Important Tips

- caAERS must be configured by your system administrator to use the NCI Enterprise Services.
- The usage of caBIG Integration Hub is required in order to use the NCI Enterprise Services.
- Once a remote record has been returned by a search and saved in the local database (per 2.1 above) it will be able to be searched and used as if it were a local record.
- In the event that the NCI Enterprise Services are unavailable, caAERS will use data from the local database.
 - This includes all remote records that have been returned by a previous search and saved in the local database (per 2.1 above).
 - Once access to the NCI Enterprise Services is restored, the remote record data will be refreshed.
- Autocompleter searches do not search the NCI Enterprise Services. However, all remote records for which references are saved locally will be searched and any records satisfying the search criteria will be refreshed from the NCI Enterprise Services.
- Wildcard searches do not search the NCI Enterprise Services. However, all remote records for which references are saved locally will be searched and any records satisfying the search criteria will be refreshed from the NCI Enterprise Services.

Protocol Abstraction

caAERS supports searching the NCI Enterprise Protocol Abstraction Service. Users can search this service in the **Study >> Search Studies** page. The NCI Enterprise Protocol Abstraction Service will be searched for the following searches:

- A study title search on any part of the public study title.
Note: This is a case sensitive search.
- A study ID search on an exact match of the NCI Protocol Abstraction Service study ID.

Searches not conforming to these constraints will only search the local database, however, any remote records with references saved in the local database will invoke the appropriate NCI Enterprise Services and the data will be refreshed.

For example: Study ID: XYZ is a local study where the coordinating center is a remote organization. A search on study ID for "X" will return Study XYZ and the NCI Enterprise Organization Service will be invoked to refresh the data for the coordinating center.

| Study ID | Short Title | Funding Sponsor | Phase | Status |
|-------------|---|-----------------------------------|-----------|-----------------------------------|
| E48099 | Intensified Methotrexate, Nalarabine (Compound 506U78, IND# 52611) and Augmented BFM Therapy for Children and Young Adults with Newly Diagnosed T-Cell Acute Lymphoblastic Leukemia (ALL) | Cancer Therapy Evaluation Program | Phase III | Active - Trial is open to accrual |
| E48 | Intensified Methotrexate, Nalarabine (Compound 506U78, IND# 52611) and Augmented BFM Therapy for Children and Young Adults with Newly Diagnosed T-Cell Acute Lymphoblastic Leukemia (ALL) | Cancer Therapy Evaluation Program | Phase I | Active - Trial is open to accrual |
| NCT00075725 | Phase III Randomized Study of Dexamethasone Versus Prednisone During Induction and High-Dose Methotrexate With Leucovorin Rescue Versus Escalating-Dose Methotrexate Without Leucovorin Rescue During Interim Maintenance I in Patients With Newly Diagnosed High-Risk Acute Lymphoblastic Leukemia | Children's Oncology Group | Phase III | In Review |

The search results will return and save any of the following elements, when available:

Study Details

- Study short title
- Study long title
- Study description
- Study phase
- Study status
- Study coordinating center study ID
- Study sponsor study ID
- Study therapies

Study Organizations Searches of the Protocol Abstraction service will return the following correlated organizations, if available.

Note: Any organizations associated to the study will automatically invoke the NCI Enterprise Organization Service to retrieve the current information for each organization.

- Study coordinating center organization / lead organization
- Study sponsor organization
- Study participating organizations / study sites

Primary identifier E48099
 Short title Intensified Methotrexate, Nalarabine (Compound 506U78; IND# 52611) and Augmented BFM Therapy for Children and Young Adults with Newly Diagnosed T-Cell Acute Lymphoblastic Leukemia (ALL)
 Long Title A Trial of Extracorporeal Photopheresis, Pentostatin, and Total Body Irradiation in Patients Undergoing Reduced Intensity Allogeneic Stem Cell Transplantation for the Treatment of Malignancies
 Precis
 Description This is a study to explore the use of a reduced intensity transplant conditioning regimen. A conditioning regimen is the treatment that is given to prepare a body for the new bone marrow that will be received from a donor. Reduced intensity conditioning uses lower doses of chemotherapy than conventional conditioning regimens. The use of lower doses of drugs and radiation cause fewer side effects. Reduced intensity regimens have been offered to older patients or patients at increased risk for transplant-related side effects and have been shown to be safe and effective. Reduced intensity conditioning regimens are now considered for many patients who are undergoing transplant.
 Funding sponsor NCI Cancer Therapy Evaluation Program
 Coordinating center Biometric Research Branch
 Phase code Phase III Trial

Study Persons Searches of the Protocol Abstraction service will return the following correlated persons, if available.

Note: Any persons associated to the study will automatically invoke the NCI Enterprise Person Services to retrieve the current information for each person.

- Study principle investigator
- Study site investigators
- Study site principle investigator

| Investigator | Organization | Role | Status |
|--------------------|--|-----------------------------|--------|
| Janet Meller | Biometric Research Branch | Principal Investigator | Active |
| George Lewandowski | Cancer and Blood Institute Medical Group at The Lucy Curci Cancer Center | Site Principal Investigator | Active |

Person

caAERS supports searching the NCI Enterprise Person Services. Users can search these services in the **Administration >> Investigator >> Search Investigator** page or in the **Administration >> Research Staff >> Search Research Staff** page. The NCI Enterprise Person Services will be searched for the following searches:

- A search on any part of the person's first name.
- A search on any part of the person's last name.

- A search on an exact match of the investigator's CTEP ID (investigator searches only).
- A search on an exact match of the person's associated organization(s).

Note: These are case insensitive searches.

Welcome Dev1 GridID1 Help Log out

caAERS CANCER ADVERSE EVENT REPORTING SYSTEM

Adverse Events Studies Subjects Rules Administration Advanced Search

Configure caAERS IND# Create/Edit Investigator Search Investigator

Investigator Organization Research Staff Track Reports Import Configure Password Policy

Search Criteria

Instructions Search for an investigator by name or investigator number.

First name rich

Last name

Investigator number

Organization Begin typing here...

Search

This search may take few minutes as caAERS is accessing NCI Enterprise Services (COPPA)

Searches not conforming to these constraints will only search the local database, however, any remote records with references saved in the local database will invoke the appropriate NCI Enterprise Services and the data will be refreshed.

Welcome Dev1 GridID1 Help Log out

caAERS CANCER ADVERSE EVENT REPORTING SYSTEM

Adverse Events Studies Subjects Rules Administration Advanced Search

Configure caAERS IND# Create/Edit Investigator Search Investigator

Investigator Organization Research Staff Track Reports Import Configure Password Policy

Search Criteria

Instructions Search for an investigator by name or investigator number.

First name rich

Last name

Investigator number

Organization Begin typing here...

Search

+ Add Investigator

Search Results

121 results found, displaying 1 to 121

| First name | Middle name | Last name | Investigator number | Status |
|------------|-------------|------------|---------------------|--------|
| Richard | Alan | Lopchinsky | 50260 | Active |
| Richard | | Pazdur | 74 | Active |
| Richard | Scott | Foster | 217 | Active |

The search results will return and save any of the following attributes, when available:

- Person first name (remote attribute)
- Person middle name (remote attribute)
- Person last name (remote attribute)
- Person email address
- Person phone number
- Person fax number
- Person CTEP ID (remote attribute)
- All organizations to which the person is associated

Note: This will invoke the NCI Enterprise Organization Service to ensure the data for the organization is up-to-date.

The screenshot shows the caAERS web application. At the top, there's a navigation bar with links for Adverse Events, Studies, Subjects, Rules, Administration, and Advanced Search. Below that is a secondary navigation bar with links for Configure caAERS, IND#, Investigator, Organization, Research Staff (which is selected), Track Reports, Import, and Configure Password Policy. The main content area has tabs for 'Create/Edit Research Staff' and 'Search Research Staff'. The 'Basic Details' tab is active, displaying fields for First name, Middle name, Last name, Primary email address (john.grecola@osumc.edu), Username (highlighted in red), and Active Date. A note next to the Username field says 'Username is required to save edits and add the person as a caAERS user.' The 'Associate Organizations' tab is also visible, listing 'Highlands Oncology Group, P.A. - Fayetteville' and 'AIDS-Associated Malignancies Clinical Trials Consortium' with their respective contact information.

Important: As shown above, if you wish to add a person as a user in caAERS, you will be required to provide a username.

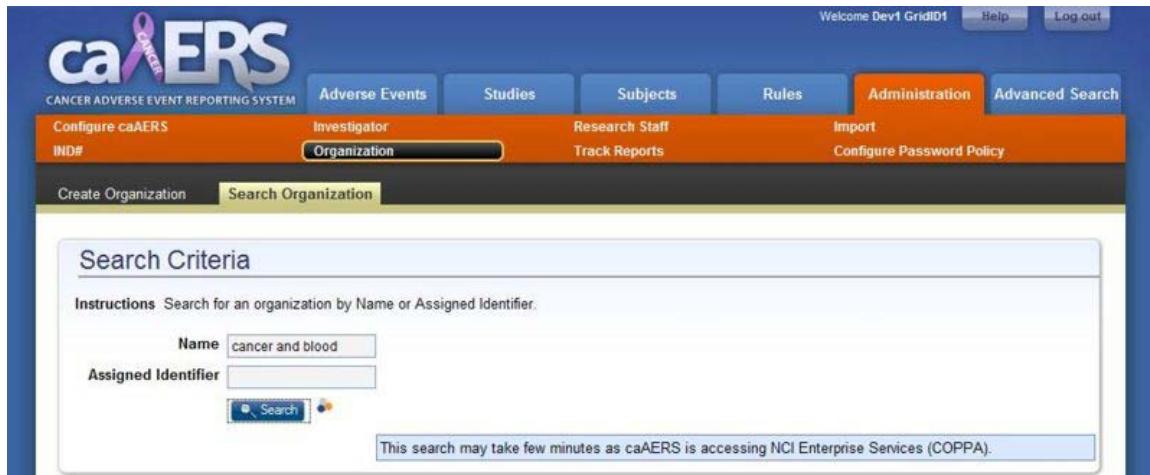
Organization

caAERS supports searching the NCI Enterprise Organization Service. Users can search this service in the **Administration >> Organization >> Search Organization** page. The NCI Enterprise Organization Service will be searched for the following searches:

- A search on any part of the organization name.

- A search on any part of the organization CTEP identifier.

Note: These are case insensitive searches.



Welcome Dev1 GridID1 Help Log out

caAERS CANCER ADVERSE EVENT REPORTING SYSTEM

Adverse Events Studies Subjects Rules Administration Advanced Search

Configure caAERS IND# Investigator Research Staff Import

IND# Organization Track Reports Configure Password Policy

Create Organization Search Organization

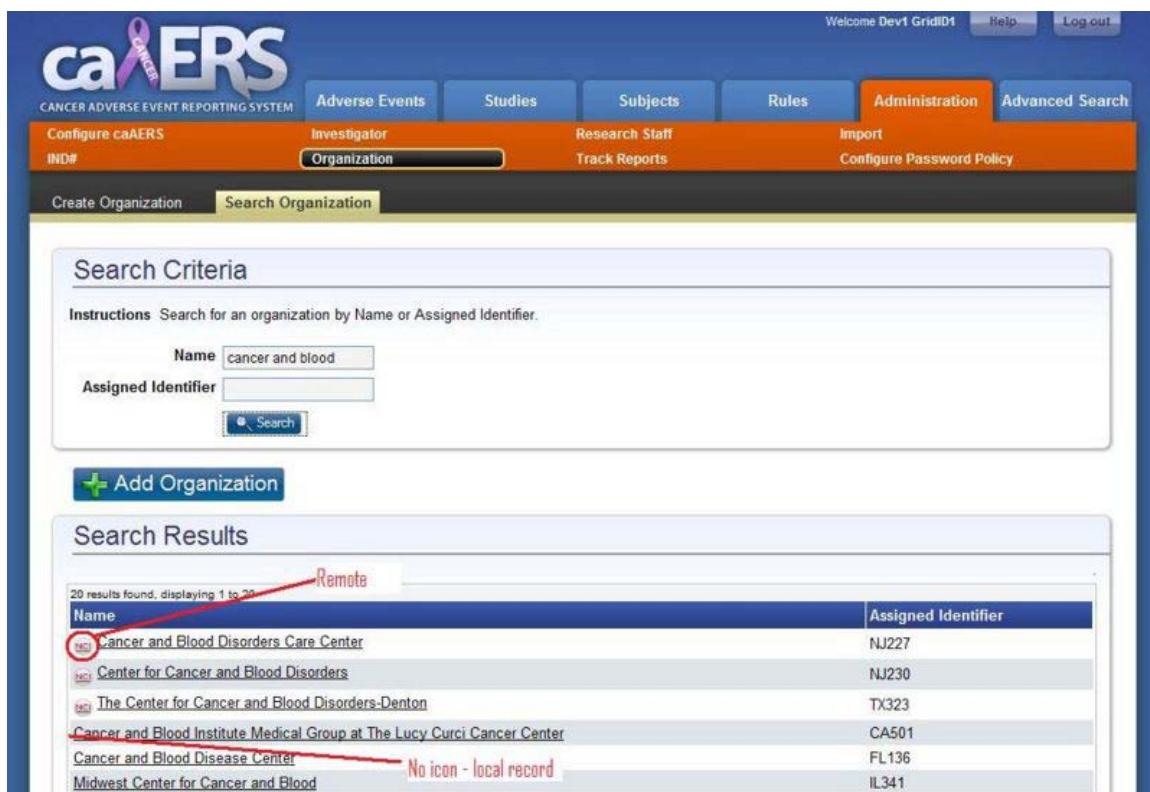
Search Criteria

Instructions Search for an organization by Name or Assigned Identifier.

Name Assigned Identifier

This search may take few minutes as caAERS is accessing NCI Enterprise Services (COPPA).

Searches not conforming to these constraints will only search the local database, however, any remote records with references saved in the local database will invoke the appropriate NCI Enterprise Services and the data will be refreshed.



Welcome Dev1 GridID1 Help Log out

caAERS CANCER ADVERSE EVENT REPORTING SYSTEM

Adverse Events Studies Subjects Rules Administration Advanced Search

Configure caAERS IND# Investigator Research Staff Import

IND# Organization Track Reports Configure Password Policy

Create Organization Search Organization

Search Criteria

Instructions Search for an organization by Name or Assigned Identifier.

Name Assigned Identifier

Search Results

20 results found, displaying 1 to 20

| Name | Assigned Identifier |
|--|---------------------|
| Cancer and Blood Disorders Care Center | NJ227 |
| Center for Cancer and Blood Disorders | NJ230 |
| The Center for Cancer and Blood Disorders-Denton | TX323 |
| Cancer and Blood Institute Medical Group at The Lucy Curci Cancer Center | CA501 |
| Cancer and Blood Disease Center | FL136 |
| Midwest Center for Cancer and Blood | IL341 |

The search results will return and save any of the following attributes, when available:

- Organization name (remote attribute)
- Organization identifier
 - This will be the CTEP identifier for the organization, if available.

- If the CTEP identifier is not available, the NCI Enterprise Organization Service identifier will be returned and saved.
- Organization city (remote attribute; not displayed in user interface)
- Organization state (not displayed in user interface)
- Organization country (remote attribute; not displayed in user interface)

The screenshot shows the caAERS web application interface. At the top, there's a navigation bar with links for 'Adverse Events', 'Studies', 'Subjects', 'Rules', 'Administration', and 'Advanced Search'. Below this is a secondary navigation bar with 'Configure caAERS', 'IND#', 'Investigator', 'Organization', 'Research Staff', 'Track Reports', 'Import', and 'Configure Password Policy'. The main content area has tabs for 'Create/Edit Organization' and 'Search Organization'. A large form titled 'Organization Details' is displayed. It contains fields for 'Name' (set to 'Cancer and Blood Institute Medical Group at The Lucy Curci Cancer Center') and 'Assigned Identifier' (set to 'CA501'). A note says 'Organization name is editable for local records.' There's also a 'Description' field with a placeholder and a 'Sync' button. At the bottom right is a green 'Save' button.

Syncing Organizations

The syncing operation changes a local organization record into a remote organization record, and by doing this, the organization information will be refreshed from the NCI Enterprise Services each time the organization is referenced.

Note: Syncing does not work with Internet Explorer.

To sync a local organization to a remote organization:

1. Search for the local organization in the Administration >> Organization >> Search Organization page.
2. Select the local organization you would like to sync by clicking on the name of the organization.

Hint: Only organizations without the icon are local organizations.

Search Criteria

Instructions Search for an organization by Name or Assigned Identifier.

| | |
|---------------------------------------|-------------|
| Name | mayo clinic |
| Assigned Identifier | |
| <input type="button" value="Search"/> | |

[+ Add Organization](#)

Search Results

| Name | Assigned Identifier |
|--------------------------------|---------------------|
| Mayo Clinic Scottsdale-Phoenix | AZ020 |
| Mayo Clinic Hospital | AZ073 |
| Mayo Clinic Jacksonville | FL080 |

- After clicking on the organization name, you will be taken to the organization edit page.

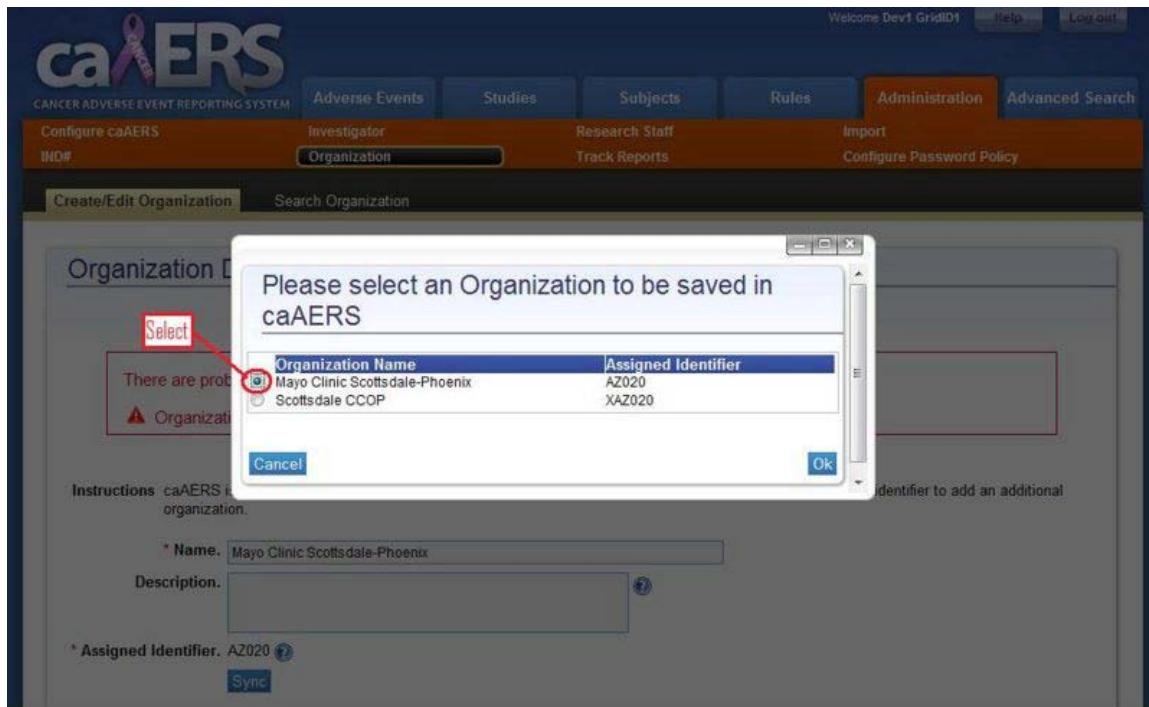
Organization Details

Instructions caAERS is pre-loaded with approximately 5000 organizations. Enter the organization's Name and Assigned identifier to add an additional organization.

| | |
|-------------------------------------|--------------------------------|
| * Name. | Mayo Clinic Scottsdale-Phoenix |
| Description. | <input type="text"/> |
| * Assigned Identifier. | AZ020 ? |
| <input type="button" value="Sync"/> | |

- Click the "Sync" button.
 - The caAERS system will now search the NCI Enterprise Organization Service for any remote organizations that have similar CTEP organization identifiers as the local organization being synced.
 - A pop-up will appear with the results of the search.

4. Click on the radio button next to the organization to which the local organization should be synced.



5. Click "Ok" to save your organization sync, or "Cancel" to cancel the sync operation.

To verify the organization sync, search for the organization you just synced in the **Administration > Organization > Search Organization** page. You should now see the icon next to the organization you synced, indicating that this is now a remote organization.

Search Criteria

Instructions: Search for an organization by Name or Assigned Identifier.

| | |
|---------------------------------------|-------------|
| Name: | mayo clinic |
| Assigned Identifier: | |
| <input type="button" value="Search"/> | |

Add Organization

Search Results

| Name | Assigned Identifier |
|--------------------------------|---------------------|
| Mayo Clinic Scottsdale-Phoenix | AZ020 |
| Mayo Clinic Hospital | AZ073 |
| Mayo Clinic Jacksonville | FL080 |

Note icon - sync
4 results found
successful.

PSC Integration with COPPA

PSC supports searching for Organizations and Protocols from the COPPA services. Organizations may be saved as sites within PSC, and a protocol may be associated with a corresponding template.

Organization (Site)

On the Administration tab, select the “Manage sites” task and then the “Create New Site” link. The site creation page searches COPPA for matches to the value you enter for either “Site name” or “Assigned Identifier”. The results are displayed below the entry boxes. To create a site from one of the found organizations, click the “Create” button to the right of the “Site Name” in the search results. If you prefer to simply save a local site, click the “Save” button.

| Site Name | Assigned Identifier | Provider | Controls |
|----------------------------------|---------------------|----------|------------------------|
| Northwestern University | 14409 | coppa | Create |
| Abbott-Northwestern Hospital | 49621 | coppa | Create |
| Northwestern Memorial Hospital | 113885 | coppa | Create |
| Evanston Northwestern Healthcare | 160539 | coppa | Create |

Note: Notice in the screenshot above, entering “Northwestern” in the “Site name” field searches COPPA for any Organizations that contain the text “Northwestern.”

After clicking “Create,” the list of available Sites within PSC will be updated accordingly, as depicted in the following screenshot.

| Site Name | Manage Blackout Dates | Controls | Provider |
|-------------------------|---------------------------------------|---|----------|
| NMH | Manage Blackout Dates | Edit Delete | |
| NU | Manage Blackout Dates | Edit | |
| Northwestern University | Manage Blackout Dates | Delete | coppa |

Notice that the Site cannot be edited since it was provided to us from COPPA directly.

Protocol Abstraction

As PSC is primarily concerned with the protocol template and generating patient calendars, it captures very little data in terms of protocol abstraction. It captures the various identifiers to ensure that the template is associated with correct study.

From the “Calendars” tab, select “Create new study.” Notice the “Study info” section of the screen contains a button to allow the template to be associated with an external study.

The screenshot shows the 'Study info' section of the COPPA interface. It includes fields for 'Protocol identifier' (ABC 1004), 'Amendment' (Initial template, view all), 'Populations' (Add), and 'Other formats' (PSC XML).

The “Find external study” field is used to search the COPPA database to find the study that should be associated with the template. Click “Associate” when you have found the proper study.

The screenshot shows the 'Study Manipulations' page in psCalendar. A search bar finds the study 'Phase II'. The results table includes columns for Long Title, Assigned Identifier, Provider, and Secondary Identifier. The 'Provider' column shows 'coppa'. The 'Secondary Identifier' column contains detailed study information. An 'Associate' button is visible in the last column.

| Long Title | Assigned Identifier | Provider | Secondary Identifier |
|--|---------------------|----------|--|
| Phase II Trial of Flavopiridol and Cisplatin in Advanced Epithelial Ovarian and Primary Peritoneal C... More | NCI-2009-00010 | coppa | COPPA Identifier : NCI-2009-00010 Extension : 27876 Lead Organization Identifier : MC0260 Official Title : Phase II Trial of Flavopiridol and Cisplatin in Advanced Epithelial Ovarian and Primary Peritoneal Carcinomas Public Title : Cisplatin and Flavopiridol in Treating Patients With Advanced Ovarian Epithelial Cancer or Primary Peritoneal Cancer More |

The assigned identifier for the study will now be associated with the study template.

LabViewer Integration with COPPA

LabViewer provides run-time validation for Person and Organization information against the COPPA database.

Step 1: Select the “Details” Link

After searching for a Study, click the **Details** link in the HealthCare Site or Principal Investigator column.

| ID | Short Title | Sponsor code | Phase code | Status | HealthCare Site | Principal Investigator |
|------------|-------------|--------------|------------|--------|-------------------------|-------------------------|
| 04_C_0121 | | | | | Details | Details |
| 04_C_0122 | | | | | Details | Details |
| SMOKE_TEST | Smoke Test | | | ACTIVE | Details | Details |
| 04_C_0135 | short title | | | | Details | Details |

4 Studies found, displaying all Studies.1
Export options: [CSV](#) | [Excel](#) | [XML](#)

Details about the Name, Address, and contact information for each will be displayed.

| Name | Address | Phone | Email | Updated Date |
|--------------------|------------------------|-------|---|--------------|
| University of Oulu | Pentti Kaiteran Katu 1 | | mailto:ncictcpoppaservices@mail.nih.gov | 2009-05-20 |
| NCI | | | | |

2 HealthCareSites found, displaying all HealthCareSites.1
Export options: [CSV](#) | [Excel](#) | [XML](#)

| Name | Address | Phone | Email | Updated Date |
|------------------|---|---------------------------|----------------------------|--------------|
| Raymond P. Smith | 4921 Parkview Place, Suite 14C Saint Louis MO 63110 USA | x-text-fax:(314)-290-7575 | mailto:unknown@example.com | 2009-05-20 |
| PlaceHolder | | | | |
| John Doe | | | | 2009-04-09 |

3 Principal Investigators found, displaying all Principal Investigators.1
Export options: [CSV](#) | [Excel](#) | [XML](#)

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 Representation 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 | Division of Cancer Prevention |
| ESB | Enterprise Service Bus (open source) |
| EVS | Enterprise Vocabulary Services |
| 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 |

| <i>Term</i> | <i>Definition</i> |
|--------------------|---|
| 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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