

CABIG™ CLINICAL TRIALS SUITE 1.0

End User's Guide



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LISTSERV Facilities Pertinent to Software Teams		
LISTSERV	URL	Name
CCTS--General	ccts-general@gforge.nci.nih.gov	CCTS General Forum
CCTS--Support	ccts-support@gforge.nci.nih.gov	CCTS Support Forum
CCTS--Technical	ccts-technical@gforge.nci.nih.gov	CCTS Technical Forum

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USING THE END USER'S GUIDE

This chapter introduces you to the *caBIG Clinical Trials Suite End User's Guide* and suggests ways you can maximize its use.

Topics in this chapter include:

- *Introduction to the End User's Guide* on this page
- *Organization of this Guide* on page 2
- *Relevant Documents* on page 2
- *User's Guide Text Conventions* on page 3

Introduction to the End User's Guide

Overview of the Guide

The End User's Guide covers the general use and operation of the caBIG Clinical Trials Suite (CTS) application (hereafter referred to as "the Suite"). Included here are brief instructions for using the Suite to create a study, register a subject, load lab results to a clinical data management repository, and handle a possible adverse event-triggered schedule change.

For detailed information about installing the Suite, refer to the caBIG Clinical Trials Suite Installation Guide. For detailed information about a specific application within the Suite, refer to that application's installation or administration guide.

Audience

This *End User's Guide* is intended for use by clinical study personnel using the Suite. It is not intended to be a comprehensive guide for all aspects of the component applications, but rather it provides high level instructions for non-technical personnel in the use of the Suite to manage clinical trials. For detailed information about the functionality and use of the component applications, users should reference the documentation for the individual applications. Technical personnel are referred to the architecture, integration, interface and installation documentation listed in *Relevant Documents* on page 2.

This guide and other Suite documentation assumes that a trial site adopts the full Suite, that is, all applications in the Suite, as opposed to adapting part of the Suite to an existing set of local systems. Support is available for sites adapting the Suite to

supplement and integrate with existing local systems. For such assistance, refer to the *Credits and Resources* on page iii of this document.

Organization of this Guide

The *End User's Guide* contains the following chapters:

Using the End User's Guide—This chapter introduces you to the *End User's Guide* and suggests ways you can maximize its use.

Chapter 1 Overview of the caBIG™ Clinical Trials Suite—This chapter introduces you to the applications that comprise the Suite.

Chapter 2 Using the Suite—This chapter introduces you to concepts that will aid in your use of the Suite.

Chapter 3 Suite Workflows—This chapter introduces you to four scenarios that illustrate how you can use the Suite.

Chapter 4 Troubleshooting—This chapter briefly describes how you can address troubleshooting issues in the Suite.

Appendix A—Glossary

Index—This section of the guide provides a complete index.

Relevant Documents

The following documents may be useful to technical staff implementing the Suite.

Document Title	URL
CCTS 1.0 Scope Document (product specification)	https://gforge.nci.nih.gov/plugins/scm cvs/cvsweb.php/ccts/documentation/requirements/CCTS%20Software%20Product%20Spec%2020070727.doc?cvsroot=ccts
CCTS 1.0 Interoperability Scenarios and Activity Diagrams	https://gforge.nci.nih.gov/plugins/scm cvs/cvsweb.php/ccts/documentation/requirements/CCTS%201.0%20Interoperability%20Scenarios%20and%20Activity%20Diagrams.doc?cvsroot=ccts
Information Modeling and Messaging Specifications as a Foundation to the caBIG CCTS	https://gforge.nci.nih.gov/plugins/scm cvs/cvsweb.php/ccts/documentation/design/ccts_messaging_and_information_models.doc?cvsroot=ccts
CCTS 1.0 Architecture Document	https://gforge.nci.nih.gov/plugins/scm cvs/cvsweb.php/ccts/documentation/design/ccts_architecture.doc?cvsroot=ccts
CCTS Integration Guide	https://gforge.nci.nih.gov/plugins/scm cvs/cvsweb.php/ccts/documentation/design/ccts_integration_guide.doc?cvsroot=ccts
CCTS Interface Specification	https://gforge.nci.nih.gov/plugins/scm cvs/cvsweb.php/ccts/documentation/design/ccts_interface_specification.doc?cvsroot=ccts

Table 1 Additional Suite resources

Document Title	URL
CCTS 1.0 Installation Guide	https://gforge.nci.nih.gov/plugins/scmcs/cvsweb.php/ccts/documentation/installation/ccts_installation_guide.doc?cvsroot=ccts
CCTS 1.0 Release Notes	https://gforge.nci.nih.gov/plugins/scmcs/cvsweb.php/ccts/documentation/installation/ccts_release_notes.txt?cvsroot=ccts

Table 1 Additional Suite resources

User's Guide Text Conventions

Table 2.1 illustrates how text conventions are represented in this guide. The various typefaces differentiate between regular text and menu commands, keyboard keys, toolbar buttons, dialog box options and text that you type.

Convention	Description	Example
Bold & Capitalized Command Capitalized command > Capitalized command	Indicates a Menu command Indicates Sequential Menu commands	Admin > Refresh
TEXT IN SMALL CAPS	Keyboard key that you press	Press ENTER
TEXT IN SMALL CAPS + TEXT IN SMALL CAPS	Keyboard keys that you press simultaneously	Press SHIFT + CTRL and then release both.
Monospace type	Used for filenames, directory names, commands, file listings, and anything that would appear in a Java program, such as methods, variables, and classes.	URL_definition ::= url_string
Icon	A toolbar button that you click	Click the Paste button () to paste the copied text.
Boldface type	Options that you select in dialog boxes or drop-down menus. Buttons or icons that you click.	In the Open dialog box, select the file and click the Open button.
<i>Italics</i>	Used to reference other documents, sections, figures, and tables.	<i>caCORE Software Development Kit 1.0 Programmer's Guide</i>
<i>Italic boldface monospace type</i>	Text that you type	In the New Subset text box, enter Proprietary Proteins .
Note:	Highlights a concept of particular interest	Note: This concept is used throughout the installation manual.

Table 2.1 caArray Guide Text Conventions

Convention	Description	Example
Warning!	Highlights information of which you should be particularly aware.	Warning! Deleting an object will permanently delete it from the database.
{ }	Curly brackets are used for replaceable items.	Replace {root directory} with its proper value, such as c:\cabio

Table 2.1 caArray Guide Text Conventions (Continued)

CHAPTER 1

OVERVIEW OF THE CABIG™ CLINICAL TRIALS SUITE SOFTWARE

This chapter introduces you to the applications that comprise the Suite.

- [Overview of the Suite](#) on this page
- [Cancer Central Clinical Participant Registry](#) on page 6
- [Patient Study Calendar](#) on page 7
- [Lab Viewer](#) on page 9
- [Cancer Adverse Event Reporting System](#) on page 7
- [caXchange](#) on page 8
- [Cancer Centralized Clinical Database Connector](#) on page 10

Overview of the Suite

The caBIG™ Clinical Trials Suite is an enterprise-level clinical trials software application system, designed primarily for use in trial sites. The Suite is comprised of a collection of interoperable modules covering a broad range of key areas in cancer clinical trials management, including those listed in [Table 1.1](#):

Key Areas	CTMS Applications	Referred to in This Document
Patient Registration	Cancer Central Clinical Participant Registry (C3PR)	Participant Registry
Patient Scheduling	Patient Study Calendar (PSC)	Study Calendar
Adverse Events Reporting	Cancer Adverse Event Reporting System (caAERS)	AE Reporting System
Lab Analysis	Lab Viewer	Lab Viewer

Table 1.1 Key functional areas and corresponding applications

Key Areas	CTMS Applications	Referred to in This Document
Clinical Data Management System	Cancer Centralized Clinical Database (C3D) Connector	

Table 1.1 Key functional areas and corresponding applications

Integration between these applications is centered around four key scenarios common in the workflow of clinical trials:

- Study Creation
- Register Subject
- Load Labs in Clinical Data Management System (CDMS)
- Adverse Event (AE)-Triggered Schedule Change

The Suite aims to meet the following interoperability standards:

- caBIG Silver Level Certification
- Biomedical Research Integrated Domain Group (BRIDG) Model Harmonization

Cancer Central Clinical Participant Registry

Overview of the Cancer Central Clinical Participant Registry (C3PR)

The Cancer Central Participant Registry (C3PR) Release 2 (hereafter 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 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. 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.

Role of the Participant Registry in the Suite

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

For More Info on the Participant Registry

The Participant Registry Installation Guide can be found at this location: https://gforge.nci.nih.gov/plugins/scm cvs/cvsweb.php/ccts/documentation/installation/C3PRv2_Installation_Guidev2.doc?cvsroot=ccts

Additional Participant Registry released documentation can be found in the documentation tab of the C3PRV2 GForge project: http://gforge.nci.nih.gov/docman/?group_id=214

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.

Role of the Study Calendar in the Suite

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

For More Info on the Study Calendar

The Study Calendar installation guide can be found at this location: https://gforge.nci.nih.gov/plugins/scmcvs/cvsweb.php/ccts/documentation/installation/PSC_Install_Guide.doc?cvsroot=ccts

Additional Study Calendar released documentation can be found in the documentation tab of the PSC GForge project:

<http://gforge.nci.nih.gov/plugins/scmcvs/cvsweb.php/studycalendar/PhaseII/Construction/Iteration3/?cvsroot=studycalendar>

Cancer Adverse Event Reporting System

Overview of Cancer Adverse Event Reporting System (caAERS)

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

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

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

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

Role of the AE Reporting System in the Suite

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

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

For More Info on the AE Reporting System

The caAERS Installation Guide can be found at this location: https://gforge.nci.nih.gov/plugins/scm cvs/cvsweb.php/ccts/documentation/installation/caaers_installation_guide_V_ccts.doc?cvsroot=ccts

Additional information about the AE Reporting System can be obtained at the caAERS GForge project site:

<https://gforge.nci.nih.gov/projects/caaersappdev/>

caXchange

Overview of caXchange

caXchange is a generic software tool that works behind the scenes to exchange all types of clinical trial data and messages between application systems and software services to perform simple or complex workflows. caXchange supports tasks such as

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

Role of caXchange in the Suite

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

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

For More Info on caXchange

The caXchange Installation Guide can be found at this location:

<https://gforge.nci.nih.gov/plugins/scm cvs/cvsweb.php/caxchange/Documentation/installation/caXchange%20Installation%20Guide.doc?cvsroot=caxchange>

Additional information about caXchange can be obtained at the caXchange GForge project site:

<https://gforge.nci.nih.gov/plugins/scm cvs/cvsweb.php/caxchange/?cvsroot=caxchange#dirlist>

Lab Viewer

Overview of Lab Viewer

The Lab Viewer allows users to query and view laboratory data retrieved by caXchange. It presents patient id, date and time of the lab, the lab test name, the result value and limits. It also allows the user to select labs to send to a Clinical Data Management System.

Role of Lab Viewer in the Suite

Lab Viewer is involved in three of the four workflows that are the focus of the Suite. In the first two workflows, it receives the Trialsstudy creation message and the subject registration message, both from the Participant Registry, and saves the study, subject, and registration data to the database. It is also featured in the Load Labs in CDMS

workflow where the user can query and view the lab data collected during the execution of a clinical trial. It allows you to select laboratory results to send via caXchange to a caBIG™-compatible Clinical Data Management System (CDMS).

For More Info on Lab Viewer

The Lab Viewer Installation guide can be found at this location:

<https://gforge.nci.nih.gov/plugins/scmcs/cvsweb.php/caxchange/Documentation/installation/CTODS%20Lab%20Viewer%20Installation%20Guide%201.0.doc?cvsroot=caxchange>

Additional documentation on Lab Viewer can be found in the caXchange GForge project:

<https://gforge.nci.nih.gov/plugins/scmcs/cvsweb.php/caxchange/?cvsroot=caxchange#dirlist>

Cancer Centralized Clinical Database Connector

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

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

C3D Connector (a Suite Component)

The C3D Connector provides the Suite users the ability to enroll patients and load labs into the CDMS, the Cancer Centralized Clinical Database in this case. It provides the ability to enroll patients into studies maintained by the Cancer Centralized 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 Centralized Clinical Database using all of the required data qualification and validation procedures

Cancer Central Clinical Database (a Vendor-Supplied Solution)

Cancer Central Clinical Database (C3D) is a clinical trials data management system. C3D collects clinical trial data using standard case report forms (CRFs) based on common data elements (CDEs). C3D utilizes security procedures to protect patient confidentiality and maintain an audit trail as required by FDA regulations. C3D currently supports electronic submission of clinical trials data to the National Cancer Institutes (NCI) Clinical Data System and the Clinical Trials Monitoring Service (CTMS/ Theradex). C3D consists of three web-based components: Oracle Clinical, for protocol building; Remote Data Capture, for data entry and management; and Integrated Review / Java Review, for real-time access to clinical data within and across clinical studies to authorized users.

Role of C3D Connector in the Suite

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

For More Info on C3D Connector

More information on C3D Connector can be found at this location:

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

CHAPTER 2 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 this page
- *User Interface* on this page
- *Hotlinking* on this page
- *Error Handling and Rollback Features* on page 16

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

User Names and Passwords

Users are managed at both the Suite level and the application level. The Suite level user name must be the email address of the user. Users are managed by the system administrator who can refer to the Dorian User Guide (http://www.cagrid.org/mwiki/index.php?title=Dorian:1.1:Users_Guide) for more information.

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 individually.

Getting Started in the Suite

Launching the Suite

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

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

Exiting the Suite

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

Application Roles and Workflows

To perform the four basic Suite workflows described in the next section, users need to following roles assigned to their user accounts ([Table 2.1](#)):

Workflows				
Application Name	Create Study	Register Subject	Load Labs in CDMS	Lab-Based AE-Triggered Schedule Change
Cancer Central Clinical Participant Registry	Study Coordinator	Registrar	N/A	N/A
Cancer Adverse Event Reporting System	Site Coordinator	Site Coordinator or Participant Coordinator	N/A	Site Coordinator or Participant Coordinator or AE Coordinator
Lab Viewer	User	User	User	N/A
Patient Study Calendar	Study Coordinator	Subject Coordinator	Subject Coordinator	Subject Coordinator

Table 2.1 User roles assigned to user accounts

Workflows				
Application Name	Create Study	Register Subject	Load Labs in CDMS	Lab-Based AE-Triggered Schedule Change
Cancer Centralized Clinical Database	Protocol Builder	Reviewer	Reviewer or Nurse or Data Manager	N/A

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 login 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. Hotlinking to an application always opens a new window.

Table 2.2 lists the hotlinks available in each suite component application:

Component Application	Hotlink Name	Hotlink Location
Cancer Central Clinical Participant Registry	PSC	Bottom, below Registration
Cancer Central Clinical Participant Registry	C3D	Bottom, below Registration
Cancer Central Clinical Participant Registry	caAERS	Bottom, below Registration
Patient Study Calendar	Lab Viewer	Middle, under subject details
Patient Study Calendar	caAERS	Middle, under subject details
Lab Viewer	caAERS	Top
Cancer Adverse Event Reporting System	PSC	Towards top, above AEs
Cancer Adverse Event Reporting System	LabViewer	Middle, under Labs heading

Table 2.2 Hotlinks available in the Suite applications

Minimizing Redundant Data Entry

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

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

Application	Study	Site	Subject	Lab Data	Users/ Security
Cancer Centralized Clinical Database	Y	Y	Y	Y	
Cancer Central Clinical Participant Registry	Y*	Y	Y*		Y
Cancer Adverse Event Reporting System	Y	Y	Y		Y
Lab Viewer	Y	Y	Y	Y*	Y
Patient Study Calendar	Y	Y	Y		Y
* Indicates source of truth for version 1.0 of the Suite only					

Table 2.3 Data elements included in more than one Suite application

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 3

SUITE WORKFLOWS

This chapter introduces you to four scenarios that illustrate how a user can use the Suite.

Topics in this chapter include:

- *Create Study Scenario* on this page
- *Register Subject Scenario* on page 20
- *Load Labs in CDMS Scenario* on page 22
- *Lab-Based Adverse Event-Triggered Schedule Change Scenario* on page 25

Create Study Scenario

Narrative

A new study must be defined in the system. The Protocol Coordinator enters the required information into the Suite via the Participant Registry application and the data is saved to the database. Once the information is complete and correct, the Protocol Coordinator initiates a process to route the Create Study message to the other Suite component applications which then record the study in their systems.

Walk-Through

This scenario begins with the Protocol Coordinator entering the study data into the Participant Registry (*Figure 3.1*). For detailed instruction on how to create a study in the application, in the Participant Registry application, see the user guide located here: https://gforge.nci.nih.gov/docman/view.php/214/10369/c3prv2_end_user_guide.doc.

Figure 3.1 Study Data Entered in the Participant Registry

Once the data is completed and saved in the Participant Registry, the Protocol Coordinator initiates the replication of the data to the other applications by clicking the **Broadcast** button in the CCTS Workflow area at the bottom of the Manage Study screen. *Figure 3.2* shows that the broadcast message has been sent.

Figure 3.2 Create Study Message Broadcast to Other Applications

The data is received by the AE Reporting System, Lab Viewer and the Study Calendar. [Figure 3.3](#) illustrates the same study appearing in the AE Reporting System.

The screenshot shows the 'caAERS' interface for 'Create Study: Overview'. The main content area is divided into several sections:

- Overview:**
 - Primary identifier: 04_C_0121
 - Short title: Test C3D study Dec 4th
 - Long Title: Test C3D study Dec 4th
 - Precis: (empty)
 - Description: (empty)
 - Primary sponsor: Cancer Therapy Evaluation Program
 - Coordinating center: Cancer and Leukemia Group B
 - Phase code: Phase I Trial
 - Status: Active - Trial is open to accrual
 - Terminology: CTC
 - Terminology Version: CTCAE v3.0
 - Multi institutional: Yes
 - AdEERS reporting: Yes
- Therapies:**
 - Therapy name: (empty)
 - Drug Administration: (empty)
 - Device: (empty)
- Agents:**

Agent name	Agent NSC number	IND indicator	IND #	Investigational new drug?	Part of lead IND?
(V166A) VHL14 Peptide	721380	CTEP IND	CTEP IND	Cancer Therapy Evaluation Program	Yes
- Treatment Assignments:**

Code	Dose level order	Description	Comments
TAC1	3	Trial I needs no tac.	
- Sites:** (empty)

Figure 3.3 Study Data Received by the AE Reporting System

Additional study-related data may be entered in other applications if needed ([Table 3.1](#)):

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

Table 3.1 Additional study-related data in Suite applications

For CCTS 1.0, the Protocol Coordinator must also enter the study data into the C3D ([Figure 3.4](#)). Though the C3D application is not part of the Suite, it is used as the CDMS in this example of the Create Study workflow. For this and the other workflows to be successfully completed, the study must be created in C3D. For detailed

instruction on how to create a study in C3D, see the C3D user documents, located here: <http://ncicbsupport.nci.nih.gov/sw/content/C3D.html>.

The screenshot shows the Oracle Clinical Studies application interface. The window title is "Maintain Clinical Studies" and the application name is "ORACLE". The main form is titled "Clinical Studies" and contains the following fields and controls:

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

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

Figure 3.4 Study Data entered in C3D

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

Register Subject Scenario

Narrative

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

Walk-Through

The CRA checks eligibility data and registers the patient to the study in the Participant Registry (*Figure 3.5*). For detailed information on how to register a participant to a

study, see the C3PR User Guide at this location: https://gforge.nci.nih.gov/docman/view.php/214/10369/c3prv2_end_user_guide.doc.

The screenshot shows the 'Review & Submit' screen for creating a registration. It includes a navigation bar with tabs for Registration, Studies, Subjects, Administration, and Advanced Search. Below the navigation bar is a progress indicator with steps: 1. Select Subject & Study, 2. Enrollment Details, 3. Check Eligibility, 4. Stratify, 5. Select Arm, and 6. Review & Submit. The main content area is titled 'Create Registration: Review & Submit' and contains two tables of information.

Subject	
First Name	George
Last Name	Allen
Gender	Male
MRN	59-60-003
Assigning Authority	SITE_01 (SITE_01)
Birth Date	01/01/1965
Ethnicity	Non Hispanic or Latino
Race	White

Study	
Status	Active
Short Title	Test C3D study Dec 4th
Long Title	Test C3D study Dec 4th
Randomized	Yes
Multi Institutional	Yes
Phase	Phase I Trial
Coordinating Center Identifier	04_C_0121

Figure 3.5 Subject registration in the Participant Registry

Once the data is complete and saved in the Participant Registry, the Clinical Research Associate initiates 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. Figure 3.6 shows that the broadcast message has been sent.

The screenshot shows the 'Eligibility' screen in the CCTS Workflow area. It includes sections for Eligibility, Inclusion Criteria, Exclusion Criteria, Stratification, and Arm Assigned. The 'Broadcast Status' section is highlighted with a red circle, showing a message that has been sent and buttons for 'Refresh' and 'Broadcast'.

Eligible	
Eligible	True

Inclusion Criteria	
Question	Answer
Does subject have cancer?	Yes

Exclusion Criteria	
Question	Answer
Is subject's age < 18?	No

Stratification	
Strata	Answer
Question 1	2
Question 2	A

Arm Assigned	
Arm Assigned	Arm A

Broadcast Status: Message send confirmed [Refresh](#) [Broadcast](#)

[Adverse Event Reporting](#)
[Study Calendar](#)
[Clinical Database](#)

[Print](#) [Export](#)

Figure 3.6 Register subject message broadcast to other applications

The Study Calendar receives the registration, for example, and furthermore it automatically generates a study calendar for the subject and the CRA views the schedule of activities (*Figure 3.7*).

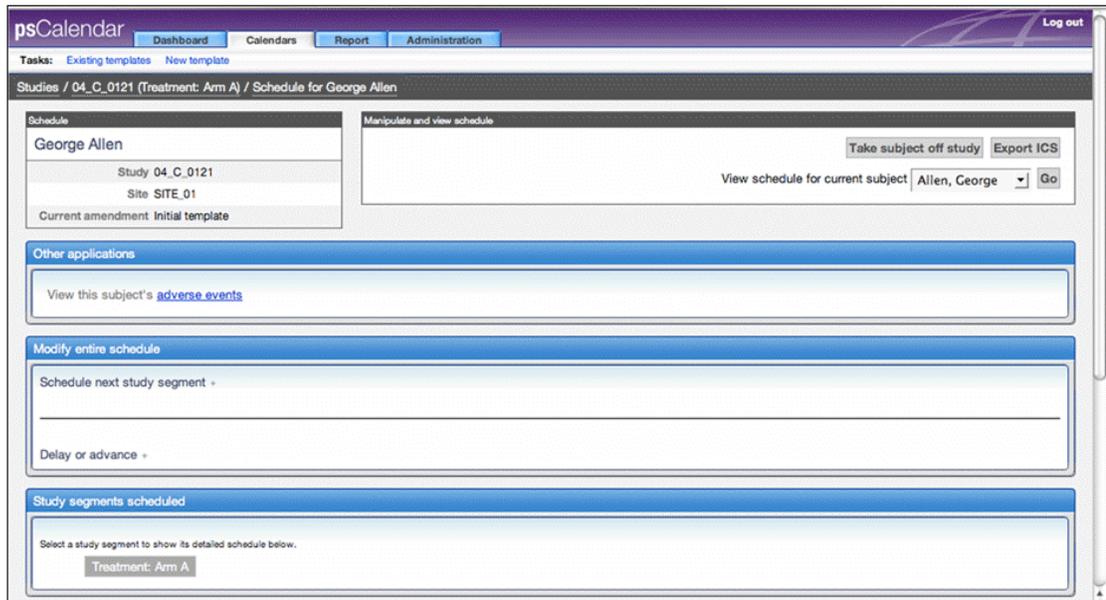


Figure 3.7 Study Calendar for newly registered subject

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

Load Labs in CDMS Scenario

Narrative

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

Walk-Through

The CRA queries a patient's schedule in the Study Calendar (*Figure 3.8*).

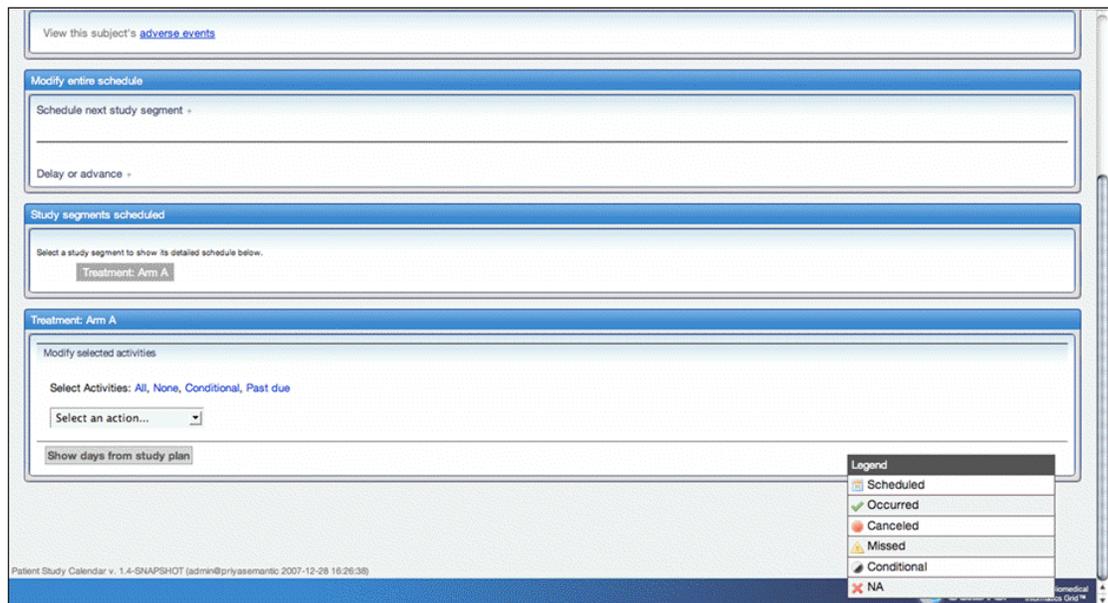


Figure 3.8 Patient schedule query in the Study Calendar

The CRA switches to Lab Viewer and reviews the list and requests lab results since the last visit (*Figure 3.9*).

Select	Patient Id	Date / Time	Lab Test	Text Result	Numeric Result	Unit Of Measure	Lower Limit	Upper Limit
<input type="checkbox"/>	59-60-00-3	2/7/07 7:30 AM	SGPT_ALT		40.0	U/L	6.0	41.0
<input type="checkbox"/>	59-60-00-3	2/7/07 7:30 AM	SGOT_AST		190.0	U/L	9.0	34.0
<input type="checkbox"/>	59-60-00-3	2/7/07 7:30 AM	ALK_PHOS		102.0	U/L	37.0	116.0
<input type="checkbox"/>	59-60-00-3	2/7/07 7:30 AM	BILRUBIN_TOTAL		0.8	mg/dL	0.1	1.0
<input type="checkbox"/>	59-60-00-3	2/7/07 7:30 AM	GLUC_NONFASTING		110.0	mg/dL	70.0	115.0
<input type="checkbox"/>	59-60-00-3	2/7/07 7:30 AM	LDH		179.0	U/L	113.0	226.0
<input type="checkbox"/>	59-60-00-3	2/7/07 7:30 AM	INORG_PHOS		3.8	mg/dL	2.5	4.8
<input type="checkbox"/>	59-60-00-3	2/7/07 7:30 AM	POTASSIUM		4.0	mmoVL	3.3	5.1
<input type="checkbox"/>	59-60-00-3	2/7/07 7:30 AM	TOT_PROT		6.0	g/dL	6.0	7.6
<input type="checkbox"/>	59-60-00-3	2/7/07 7:30 AM	BUN		11.0	mg/dL	8.0	22.0

Figure 3.9 Subject's labs queried in Lab Viewer

The CRA selects which lab results are relevant to the study by clicking the checkbox on the left and sends them to the Participant Registry for loading in the repository by

clicking **Load Labs to CDMS** in the CDMS button in the lower right corner of the screen (Figure 3.10).

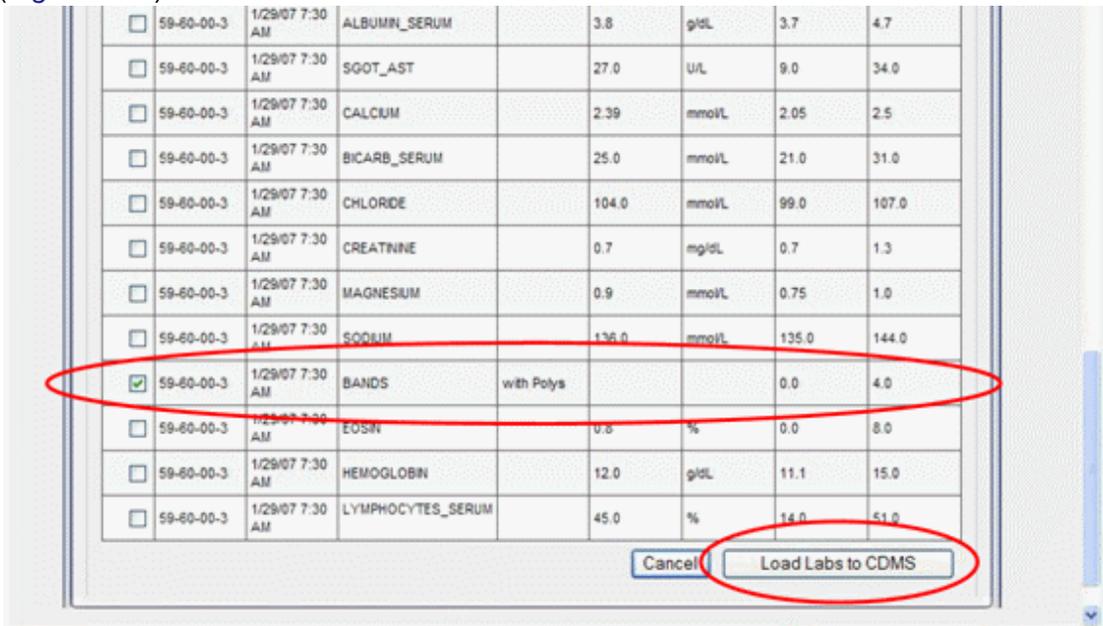


Figure 3.10 Selecting and sending labs to CDMS

Once the data validation and loading process is complete, the lab data is available in the CDMS (C3D, in this instance) for future reference (Figure 3.11).

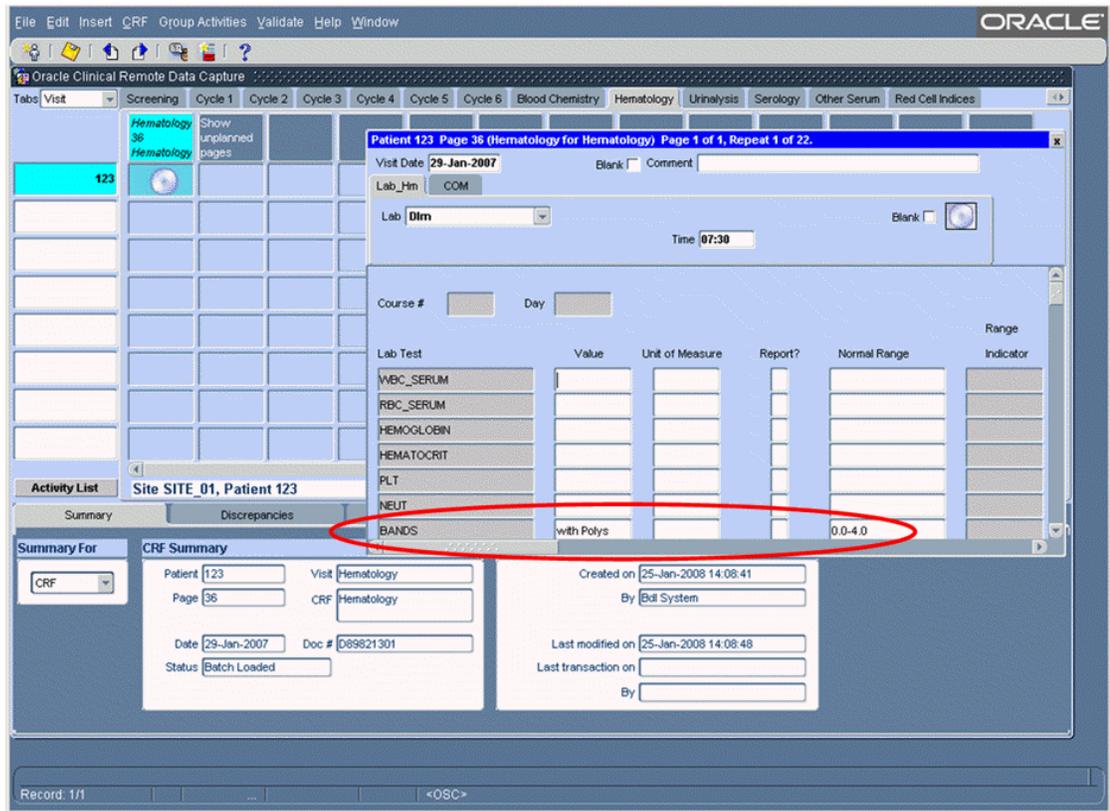


Figure 3.11 Lab Data loaded in CDMS

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

Adverse Event-Triggered Schedule Change Scenario

Narrative

A subject has an adverse event (AE) which 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.

Walk-Through

In the AE Reporting System, the CRA queries for a list of AEs since the last visit, by providing the patient id (*Figure 3.12*).

The screenshot displays the caAERS interface with the following elements:

- Header:** caAERS cancer Adverse Event Reporting System. Navigation tabs: Adverse Events, Studies, Participants, Rules, Administration, Advanced Search. Log out button.
- Tasks:** Create Participant, Search/Edit Participant, Assign Participants to Studies.
- Search Instructions:** Search for Participants by choosing any of the listed Criteria. The result set will show a list of Participants.
- Participant Criteria:**
 - Identifier: 59-60-003
 - First Name: [Empty]
 - Last Name: [Empty]
- Search:** Search button.
- Participant Search Results:**
 - 1 results found, displaying 1 to 1
 - Navigation: First, Prev, Next, Last, Rows Displayed (15), Filter, Clear.
 - Table:

First Name	Last Name	Primary ID
George	Allen	59-60-003

caAERS v. 0.9-SNAPSHOT (2008-01-07 18:12:44) caBIG Cancer Biomedical Informatics Grid

Figure 3.12 Query subject's AEs in the AE Reporting System

The CRA then identifies which AEs may require a schedule change and sends notification to the Study Calendar by clicking the **Notify PSC** link in the Actions column on the right (Figure 3.13).

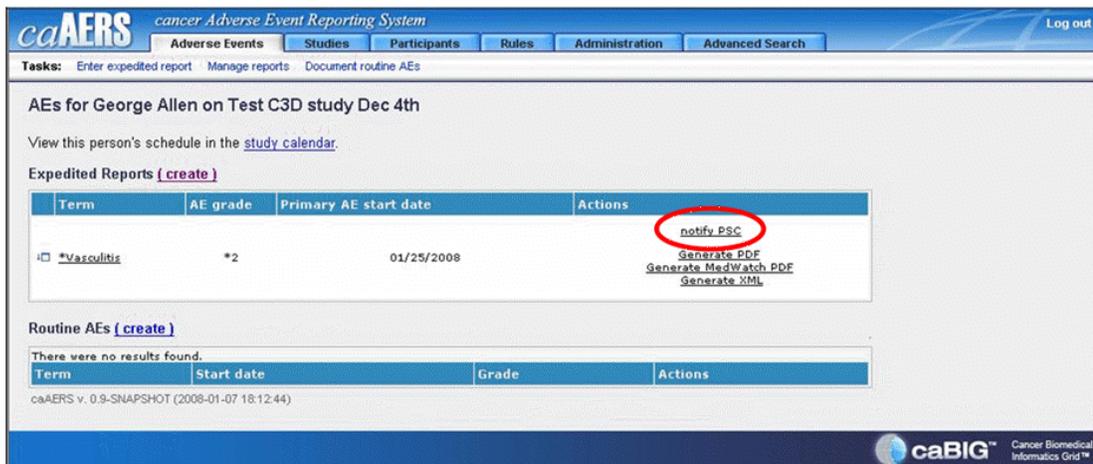


Figure 3.13 Notifying PSC about a possible schedule change

The CRA later queries for a patient's calendar in the Study Calendar and receives both calendar data and notification of any AEs that occurred since the last visit (Figure 3.14).

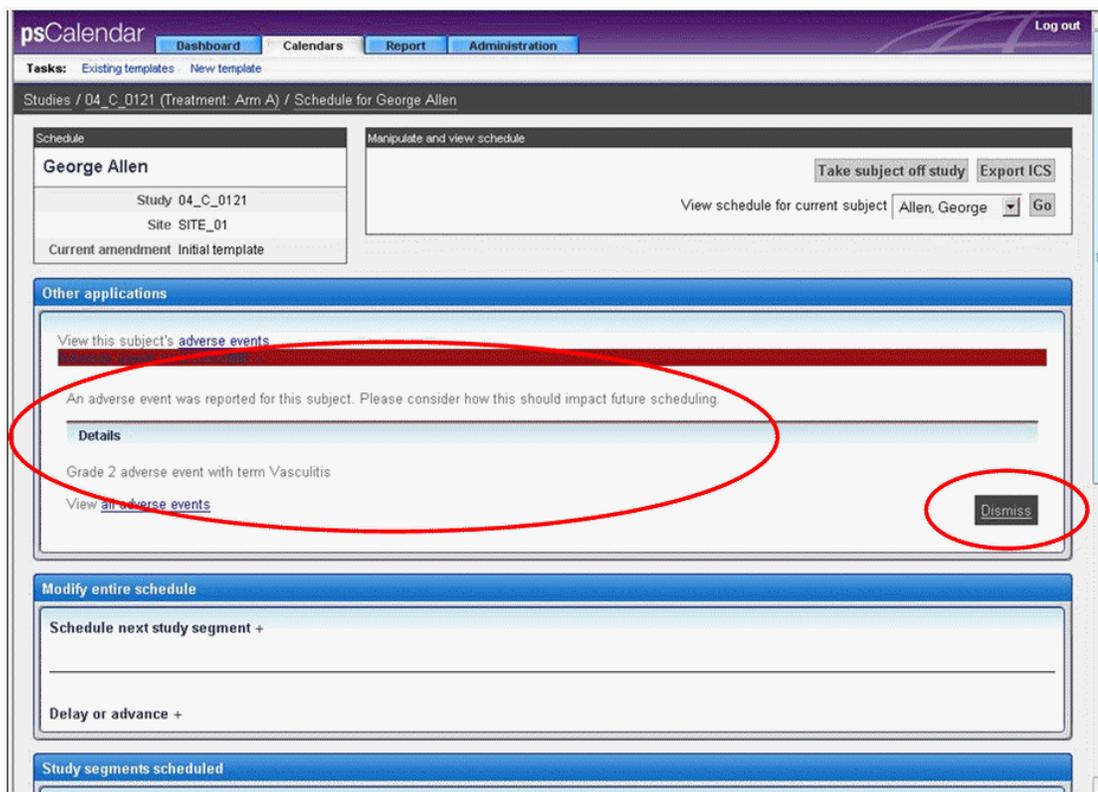


Figure 3.14 Notification and Dismiss button in the Study Calendar

Once the AE has been investigate or addressed, the CRA dismisses the AE notification by clicking the **Dismiss** button on the right of the alert as seen above and then no longer sees it in the user interface (*Figure 3.15*).

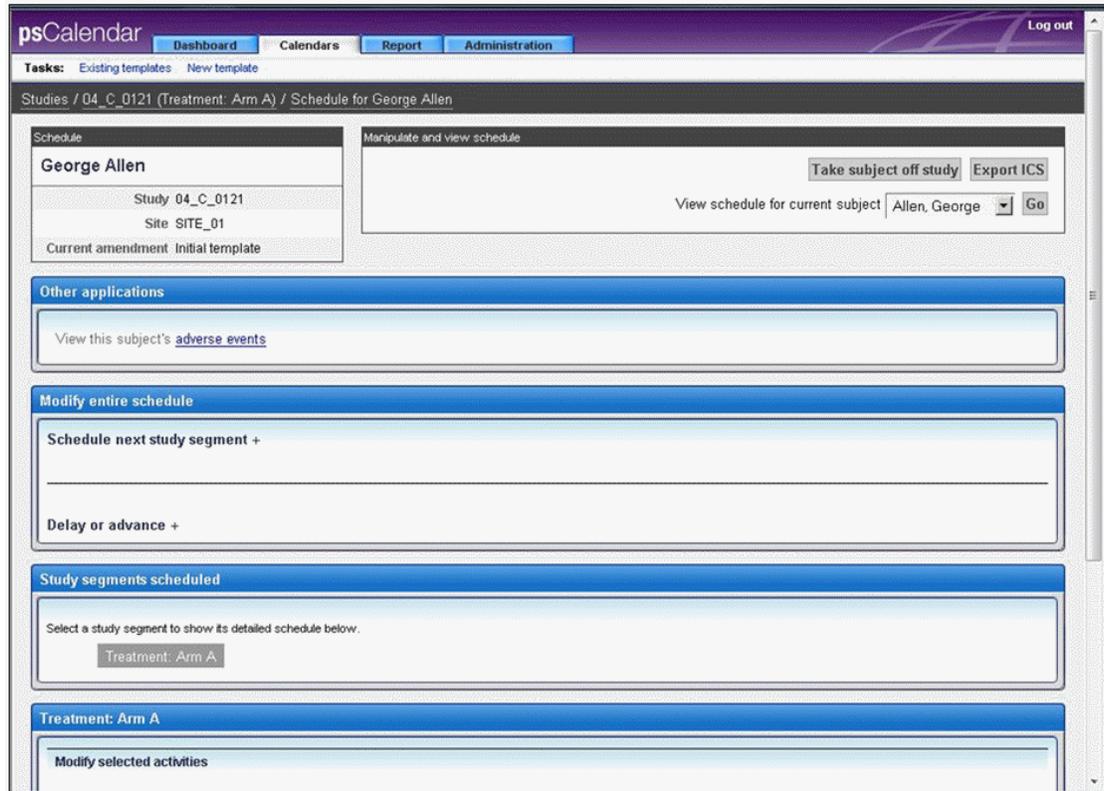


Figure 3.15 Dismissed AE Notification no longer visible in the Study Calendar

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

CHAPTER 4 TROUBLESHOOTING

This chapter briefly describes how you can address troubleshooting issues in the Suite.

Application specific errors are covered in the individual application installation and user guides of the component applications for version 1.0 of the Suite. System-level errors for the Suite are often of a technical nature and are logged by caXchange and the individual applications instead of being presented to the user (see [Figure 4.1](#) for an example). For errors of this nature, contact your system administrator to diagnose and resolve the problem.

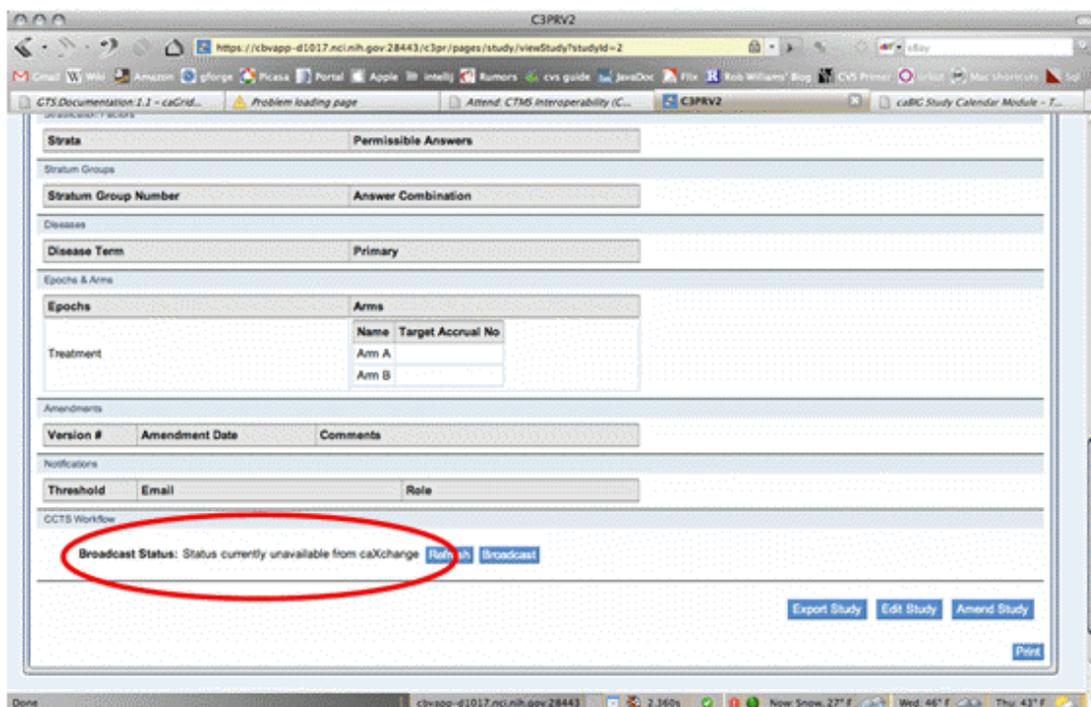


Figure 4.1 System-level error message example

APPENDIX
A
 GLOSSARY

Term	Definition
AJAX	Asynchronous JavaScript And XML
AdEERS	Adverse Event Expedited Report System
AE	Adverse Event
API	Application Programming Interface
BC	Binding Component
BRIDG	Biomedical Research Integrated Domain Group
C3D	Cancer Centralized Clinical Database
C3PR	Cancer Central Clinical Participant Registry
caAERS	Cancer Adverse Event Reporting System
caBIG	cancer Biomedical Informatics Grid
caCORE	Cancer Common Ontologic Reference Environment
caGrid	The underlying service oriented architecture for caBIG
caXchange	clinical trials data and message exchange system
CBIIT	Center for Biomedical Informatics and Information Technology
CCTS	caBIG Clinical Trials Suite
CDE	Common Data Element
CDMS	Clinical Data Management System
CRA	Clinical Research Associate
CRF	Case Report Form
CSM	Common Security Module

Table A.1 CCTS-related terms

Term	Definition
CTEP	Cancer Therapy Evaluation Program
CTMS	Clinical Trials Management Systems
CTODS	Clinical Trials Object Data System
DAO	Data Access Objects
DCP	Department of Cancer Prevention
DWR	Direct Web Remoting
ESB	Enterprise Service Bus (open source)
EVS	Enterprise Vocabulary Service
FDA	Food and Drug Administration
GAARDS	Grid Authentication and Authorization with Reliably Distributed Services
GUI	Graphical User Interface
HASTE	High-level Automated System Test Environment
HL7	Health Level Seven
HTTP	Hypertext Transfer Protocol
IdP	Identity Provider
IND	Investigational New Drug
JAAS	Java Authentication and Authorization Service
JDBC	Java Database Connectivity
JMS	Java Message Service
JSP	Java Server Pages
NCI	National Cancer Institute
NCICB	National Cancer Institute Center for Bioinformatics
NMR	Normalized Message Router
ORM	Object Relational Mapping
PDF	Portable Document Format (Adobe)
PSC	Patient Study Calendar
RDBMS	Relational Database Management System
SAE	Serious Adverse Event
SDK	Software Development Kit
SE	Service Engine
SVN	Subversion (a version control system)
UAT	User Acceptance Testing
UML	Unified Modeling Language
VCDE	Vocabularies & Common Data Elements

Table A.1 CCTS-related terms

Term	Definition
WAR	Web ARchive file
WSRF	Web Service Resource Framework
XML	eXtensible Markup Language
XSD	XML Schema Definition

Table A.1 CCTS-related terms

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