

Contents

- 1 Document History
- 2 Introduction to the Guide
 - ◆ 2.1 Overview of the Guide
 - ◆ 2.2 Audience
 - ◆ 2.3 Organization of this Guide
 - ◆ 2.4 Relevant Documents
 - ◆ 2.5 Document Text Conventions
- 3 Overview of the Software
 - ◆ 3.1 Software Overview
 - ◆ 3.2 Components of the Software
 - ◆ 3.3 System Requirements
 - ◆ 3.4 User Name
 - ◆ 3.5 Password
- 4 User Interface
 - ◆ 4.1 Technical Overview
 - ◆ 4.2 User Interface
 - ◆ 4.3 Launching the application
 - ◆ 4.4 Exiting the application
 - ◆ 4.5 Application Workspace
 - ◆ 4.6 Help
 - ◆ 4.7 Miscellaneous Interface features
- 5 Administration module
 - ◆ 5.1 Chapter Organization and Content
 - ◆ 5.2 Configuring the Application
 - ◆ 5.3 Organization
 - ◆ 5.4 Investigators
 - ◆ 5.5 Research Staff
 - ◆ 5.6 Import
 - ◆ 5.7 Import MedDRA
 - ◆ 5.8 IND #
 - ◆ 5.9 Configure Password Policy
- 6 Rules Module
 - ◆ 6.1 Introduction
 - ◆ 6.2 Manage Rules
 - ◆ 6.3 List Rules
 - ◆ 6.4 Import Rulesets
 - ◆ 6.5 Create Report Definition
 - ◆ 6.6 List Report Definitions
- 7 Advanced Search
 - ◆ 7.1 Overview
 - ◆ 7.2 Study Search
 - ◆ 7.3 Subject Search

- ◆ [7.4 AE Search](#)
- ◆ [7.5 Expedited Report Search](#)
- ◆ [7.6 Routine AE Search](#)
- [8 Working with AdEERS](#)
 - ◆ [8.1 AdEERS Integration](#)
 - ◆ [8.2 Setting up AdEERS communication](#)
- [9 Error Messages/Indicators and Problem Resolutions](#)
 - ◆ [9.1 Error Messages](#)
 - ◆ [9.2 Support](#)
- [10 Technical Interface](#)
 - ◆ [10.1 Adverse Event Query API](#)
 - ◇ [10.1.1 Purpose](#)
 - ◇ [10.1.2 Interface](#)
 - ◇ [10.1.3 Implementation](#)
 - ◇ [10.1.4 Example Scenarios](#)
 - [10.1.4.1 Query by Study Filters](#)
 - [10.1.4.2 Query by Study and AdverseEvent Filters](#)
 - [10.1.4.3 Generate XML Results](#)
 - ◆ [10.2 caAERS Messaging and Services](#)
 - ◇ [10.2.1 Asynchronous mode of importing data into caAERS using JMS](#)
 - [10.2.1.1 Technical Overview](#)
 - [10.2.1.2 Message Exchange Flow](#)
 - [10.2.1.3 Message Identification](#)
 - [10.2.1.4 Message Types](#)
 - [10.2.1.5 References](#)
 - ◇ [10.2.2 Synchronous mode of importing data into caAERS using Webservices](#)
 - [10.2.2.1 Overview](#)
 - [10.2.2.2 Note](#)
 - [10.2.2.3 Call Flow](#)
 - ◆ [10.3 caAERS Excel Import Utility](#)
 - ◇ [10.3.1 Importing Data via Excel Import](#)
- [11 Appendix A. References](#)
 - ◆ [11.1 Technical Articles](#)
 - ◆ [11.2 Scientific Publications](#)
 - ◆ [11.3 caBIG Material](#)
 - ◆ [11.4 caGrid Material](#)
 - ◆ [11.5 caCORE Material](#)
- [12 Appendix B. Glossary](#)

Document History

Document Change History

Version Number	Date	Contributor	Description
V0.7	10/16/07	Paul Galvin	Up to date with Iteration 7 changes to the Administration module.
V0.8.1	10/29/07	Paul Galvin	Added rules module and made the manual more consistent with the end user manual.
V08.2	11/13/07	Paul Galvin	Provided reference and location of the QuickStart Guide.
V08.3	12/26/07	Jennifer Reed	Updated sections (mainly Rules and Admin), added front material, moved Quick Ref to sep doc
V0.9	01/08/08	Jennifer Reed	Added Index, updated to include updates from Iteration 9
V1.0	02/09/08	Jennifer Reed	Updates based on feedback and changes for new release

Copyright and License page

Copyright 2007 SemanticBits, LLC. This software was developed in conjunction with the National Cancer Institute, and the authors are co-authors, any rights in such works shall be subject to Title 17 of the United States Code, section 105.

Redistribution and use in source and binary forms, with or without modification, are permitted provided that the following conditions are met:

1. Redistributions of source code must retain the above copyright notice, this list of conditions and the disclaimer of A form must reproduce the above copyright notice, this list of conditions and the following disclaimer in the documentation and in any software distribution that accompanies the distribution.

2. The MedDRA terminology was developed by the International Conference on Harmonisation (ICH) and is owned by the International Pharmaceutical Manufacturers and Associations (IFPMA) acting as trustee for the ICH steering committee. The MedDRA source code is available at <http://www.meddraso.com>. For information about obtaining and using MedDRA, go to <http://www.meddraso.com>.

3. The end-user documentation included with the redistribution, if any, must include the following acknowledgment:

"This product includes software developed by SemanticBits, LLC and the National Cancer Institute (NCI).? If no such acknowledgment shall appear in the software itself, wherever such third-party acknowledgments normally appear.

4. The names "The National Cancer Institute", "NCI" and "SemanticBits, LLC" must not be used to endorse or promote products derived from this software without the prior written permission of SemanticBits, LLC.

5. This license does not authorize the incorporation of this software into any proprietary programs. This license does not authorize the use of any trademarks owned by either NCI or SemanticBits, LLC.

6. THIS SOFTWARE IS PROVIDED "AS IS," AND ANY EXPRESSED OR IMPLIED WARRANTIES, (INCLUDING BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE) ARE DISCLAIMED. THE NATIONAL CANCER INSTITUTE, SAIC, OR THEIR AFFILIATES BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO, PROCUREMENT OF GOODS AND SERVICES; LOSS OF USE, DATA, OR PROFITS; OR BUSINESS INTERRUPTION) HOWEVER CAUSED AND WHETHER IN CONTRACT, STRICT LIABILITY, OR TORT (INCLUDING NEGLIGENCE OR OTHERWISE) ARISING OUT OF OR IN CONNECTION WITH THE USE OF THIS SOFTWARE, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

Project Team

A number of people have made contributions to the development of caAERS. The table below lists the primary developers, subject matter experts, testers, technical writers, and key contributors.

Development Team

Development	Admin Guide	Program Management
Vinay Kumar	Jennifer Reed	Edmond Mulaire
Joshua Philips	Paul Galvin	Ram Chilukuri I
Rhett Sutphin		
Krikor Krumlian		
Srini Akkala		
Biju Joseph		
Karthik Iyer		
Jared Flatow		
Sean Whitaker		

Key Contributors

Sharon Elcombe, MA	Ann Setser	John Speakman
Robert Morrell	Anne Tompkins	Christo Andonyadis
Sonja Hamilton		Warren Kibbe, Ph.D.
Jennifer Frank		Cal Collins
Kim Livengood		Lisamarie Schick
Jean Hanson		
Jennifer Sorbo		
Steven Cheng		
Larry Esser		
Renee Webb, MA, CCRC		
David Patton		

Contacts and Support

Edmond Mulaire	edmond.mulaire@semanticbits.com
caAERS Project Site	http://gforge.nci.nih.gov/projects/caaersappdev/

LISTSERV Facilities Pertinent to software teams

LISTSERV	URL	Name
Caers-News	Caaersappdev-news@gforge.nci.nih.gov	caAERS Public Listserv
Caers-Technical	caaersappdev-technical@gforge.nci.nih.gov	caAERS Technical Listserv

Introduction to the Guide

Topics in this chapter include:

- Overview of the Guide
- Audience
- Organization of this Guide
- Relevant Documents
- Document Text Conventions

Overview of the Guide

The caAERS Admin Guide covers general administration tasks for caAERS. These tasks can only be performed by system administrators and site coordinators, so are separated from the general User's Guide. For information about installation and implementation of caAERS, see the [caAERS Installation Guide](#).

Sections 1-4 of this guide include general information on caAERS and an overview of the user interface. Sections 5-6 cover admin-specific areas of caAERS and include detailed instructions on performing specific tasks. Section 7 provides troubleshooting tips and information.

Audience

This guide is intended for caAERS administrators, both the system administrator and the site administrator (site coordinator). The administrators are responsible for setting up the caAERS system, including adding caAERS users and investigators, importing information from other systems, and creating and maintaining rules. Administrators are expected to have basic familiarity with caBIG systems and XML files. In addition, if you'll be doing any work on the server itself, you should be comfortable working with TomCat and Databases.

Organization of this Guide

This guide includes general caAERS information, task-specific steps, and troubleshooting information. Information is broken down by section, described through the section titles referenced and linked to the [contents guide](#) above.

Relevant Documents

This Guide addresses Admin tasks for caAERS. Additional information about caAERS can be found in the following documents:

Document	Location
caAERS_QuickStart_Guide	http://gforge.nci.nih.gov/frs/?group_id=249
caAERS_End_User_Guide	http://gforge.nci.nih.gov/frs/?group_id=249
caAERS_Installation Guide	http://gforge.nci.nih.gov/frs/?group_id=249
Online help	Accessed by clicking  , found in the upper-right hand corner of most windows
CTEP List of Organizations and Identifiers	http://ctep.cancer.gov/forms/Organization_Codes.txt
CTEP Therapy Classification	http://ctep.cancer.gov/guidelines/values.html

Document Text Conventions

The following table shows various typefaces to differentiate between regular text and menu commands, keyboard keys, and text that you type. This illustrates how conventions are represented in this guide.

Convention	Description	Example
Bold & Capitalized Command	Indicates a Menu command	Admin > Refresh
Capitalized command > Capitalized command	Indicates Sequential Menu commands	
TEXT IN SMALL CAPS + TEXT IN SMALL CAPS	Keyboard keys that you press simultaneously	Press SHIFT + CTRL and then release both.
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 type</i>	Text that you type	In the New Subset text box, enter <i>Proprietary Proteins</i> .
Note:	Highlights a concept of particular interest	Note: This concept is used throughout the installation manual.
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

Overview of the Software

This section provides an overview of the software. Topics include:

- Software Overview
- Component of software
- System Requirements
- User Names
- Passwords

Software Overview

The caAERS (Cancer Adverse Event Reporting System) application is an open source, standards-compliant application designed to collect, assess, and manage adverse events in cancer clinical trials. It is web-based, uses a controlled vocabulary, and enables multiple users to access, search for, and report on Adverse Events (AE), both in-house and to external agencies.

caAERS was developed to integrate with other caBIG-compliant CTMS components. This allows sharing of information across application. In addition, caAERS also has the ability to accept information from other systems by importing XML files containing the information.

caAERS is a caBIG silver-level compliant module (caBIG Compatibility Guidelines, Appendix A) and is interoperable with other caBIG-compliant Clinical Trial Management System (CTMS) components.

Components of the Software

The caAERS application has six modules:

- Adverse Events
- Studies
- Subjects
- Rules
- Administration
- Advanced Search

Each of the modules is used to collect or provide specific information. Used together, the modules track, maintain, and report any adverse events that occur during a clinical study at any of the participating organizations.

caAERS was developed to integrate with other caBIG-compliant CTMS components. This allows sharing of information across application. In addition, caAERS also has the ability to accept information from other systems by importing XML files containing the information.

System Requirements

caAERS is a web-based application. To access caAERS, your computer must meet the following requirements:

- Internet connection: speed of 56K or faster (broadband) recommended
- Browser: Firefox 1.5 or 2.0, Internet Explorer 7.0 or higher supported
- Display: resolution of 1024 x 768 or better is recommended, 800 x 600 is supported

User Name

The system administrator will create your account and assign you the user roles. Once the account is created in the system, you will have a user name and password.

Your user name will always be your email address. This field is case sensitive.

Password

When your account is created, you will be sent an email with a link to create your password. Click on the link to create a password. There is a password policy created during caAERS setup, so you may be limited on what you can use for a new password. If the password you enter doesn't work, you will receive a message stating the password requirements that aren't met.

Resetting your password

If at any time you need to reset your password, you are able to do so from the login screen. To reset your password:

1. Click **Forgot Password?** on the login screen
2. Enter {**your Username (email address)**} and click **Reset Password**
3. caAERS will send you an email. Open the email and click on *the link*'

Note: Your browser must be set up to allow new windows to open

4. Enter {**your user name**}
5. Enter {**your password**}
6. Re-Enter {**your password**}
7. Click **Change Password**

If your password doesn't meet the security requirements for passwords, you will be given an error message stating the problem. If the password does match, you'll receive a message with a link to the login page.

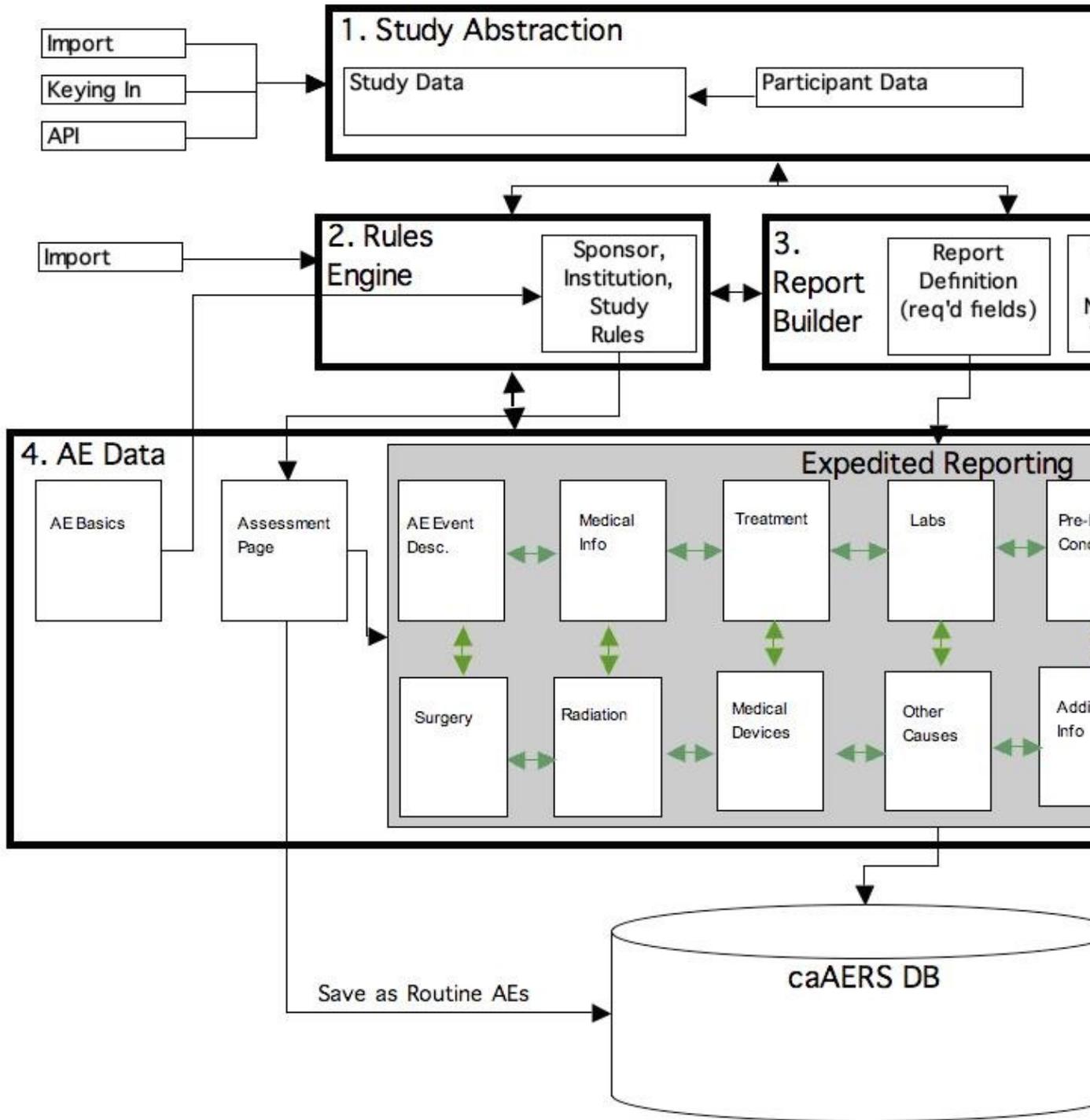
User Interface

This section provides an overview of the software. Topics include:

- Technical Overview
- User Interface
- Launching the application
- Exiting the application
- Application Workspace
- Help
- Miscellaneous Interface features

Technical Overview

The caAERS User Interface is built on Java-based software and supported by an Oracle or Postgres database. This application allows a user to enter clinical study information and report adverse events. The following diagram illustrates the caAERS system workflow and relationships to external systems. All bolded boxes are workflows associated with the caAERS system.



User Interface

caAERS is a web-based application, connected to a database. It was developed to work on all standard operating systems. Security measures include required user accounts and passwords, all controlled within the system.

To access caAERS, it must be installed on a local network. An end user connected to the network can launch their browser to access it.

Warning! The browser navigation elements should not be. Using them may cause problems with the system and could cause you to lose information if you are in the middle of entering a study or AE. The application contains all necessary navigation elements.

Launching the application

caAERS is a web-based application, so to launch it, just access the web address. From here, you'll be asked for your username and password to log in. Your user name is your email address and your default password is your last name. To change your password, use the **Forgot Password** link on the sign on page.

If you sign in with the wrong username or password, you will receive the message, "Incorrect username and/or password. Please try again." After entering invalid information a certain number of times, you will be locked out of the system for a certain period of time. How many times you can attempt to enter your username and password and how long you are locked out are configured by your caAERS administrator.

Exiting the application

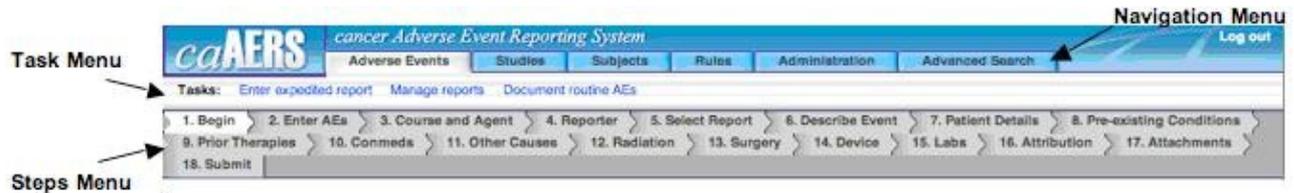
To exit or logout of the caAERS application, click the logout link located in the top right-hand corner of the window. You can also just close the browser by clicking on the x in the top right-hand corner of the window.

Warning: If you are in the middle of a module when you exit, your changes will not be saved. Be sure to complete your work before exiting.

Application Workspace

Navigation Elements

Navigation elements of caAERS are found at the top of the page. These include the Navigation Menu (tabs at the top), the Task menu (middle row of links), and the steps menu (bottom arrows). Each page will also contain buttons to help navigate through the tasks.



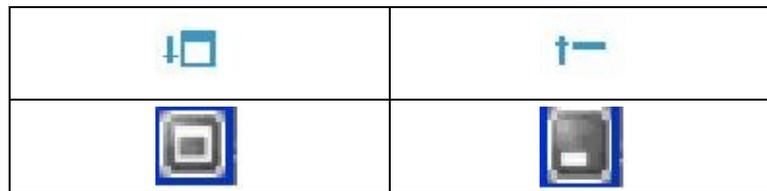
- **Navigation Menu:** The navigation menu allows access to the modules. To access a module, click on the tab, for example, Adverse Events.
- **Task Menu:** Each module may have multiple tasks associated to it, which are displayed in the Task menu. To access a task, click on it, for example, Enter expedited report.
- **Steps Menu:** Some tasks may have multiple steps, which are displayed in the steps menu. The step you are on is highlighted in white, for example Begin. In some modules, if you are required to enter information during that step, a green symbol, \$, or a * will appear to the left of the step number. You can access a step by clicking on it. However, as you use the buttons on the page, it will automatically navigate you through the steps.
- **Buttons:** Many of the pages have navigation buttons, such as Continue, Update, and Reset.
 - ◆ **Back ?** When selected, the user will be brought to the previous page. All unsaved data will be lost.
 - ◆ **Save and Back ?** When selected, caAERS will save the data and then take the user to the previous page.
 - ◆ **Continue ?** When selected, the user will move to the next page of the application. If any information was added to the page, it will be saved.
 - ◆ **Save ?** When selected, the information on the current page will be saved to the database and the user will stay on the same page.
 - ◆ **Save & Continue ?** When selected, the information on the current page will be saved to the database and the user will move on to the next page of the application.

Expanding and Collapsing Windows

Some of the modules and tasks have areas where you can add multiple items. For example, a report can have multiple notifications, and a ruleset can have multiple rules. These areas allow you to collapse the information to provide easier navigation and viewing.

These areas are identifiable by the expanding/collapsing icon in the upper right-hand corner of the area that can expand or collapse. Currently, there are two sets of icons. See Table 3 1 for examples of the icons.

Click to Expand	Click to Collapse
---------------------------------	-----------------------------------



Additional Icons

On different pages where you have the ability to add multiple sections, for example, rules to a ruleset, you may see a + and/or x next to a field or window. The + allows you to add another item. The x allows you to delete the item.

Some windows might also have a X in the upper right-hand corner. This allows you to completely remove the item, for example, removing a rule from a ruleset, or a notification from a report definition.

Help

caAERS has three types of help:

- Instructions for the module/task
- Instructions for a field
- In-line
- Online help

Instructions for the module/task

When you select a module or a task, you will often see instructions at the top of the screen explaining the purpose of the module and what information you need to supply.

Document routine AEs: Select participant and study

Instructions: Enter the patient and study for which you want to create an expedited report. You can begin the selection process by entering a patient or study first.

Select participant

Enter a portion of a subject's name or another registered identifier.

*

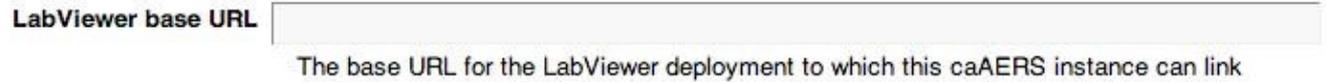
Select study

Enter a portion of a study's name or another registered identifier.

*

Instructions for a field

Similarly, some fields on a page for a module or task will include instructions concerning the information you need to provide.



In-line

Some fields will not have visible instructions. However, they may have the help icon  , next to the field. If you mouse over this icon, additional information will be provided.

Online Help

There is online help available for most modules. To access the help, click on the icon  , located in the top right-hand corner. The help for the page you're on will appear in another browser or on a separate tab. An index of the help content will also appear on the left-hand side of the window.

Miscellaneous Interface features

There are a few other interface features worth noting. These features are:

- Auto-complete functionality
- Search function
- Required fields/missing information

Auto-complete functionality

caAERS was built with an auto-complete function, similar to what you find when using Google search. If a field has auto-complete enabled, it will bring up a list of possible matches when you start to type. For example, if you type can in a field with auto-complete enabled, you will get a list of possibilities such as what's shown in the picture below.

Study ID Assigned by Organization			
*Identifier	*Identifier type	*Organization	*Primary indicator
<input type="text"/>	Medical Record Number	can Cancer Therapy Evaluation Program (CTEP)	<input checked="" type="checkbox"/>
Study ID Assigned by a System			
*Identifier	*Identifier type	*System name	*Primary Indicator
		Duke University Comprehensive Cancer Center (DUKE)	
		Division of Cancer Prevention (DCP)	
		American College of Surgeons Oncology Trials Group (ACOSOG)	
		Cancer and Leukemia Group B (CALGB)	
		North Central Cancer Treatment Group (NCCTG)	
		National Cancer Institute of Canada Clinical Trials Group (NCIC)	Identifier
		National Cancer Institute (NCI)	
		Wake Forest Comprehensive Cancer Center (WAKE)	Continue >

Fields with auto-complete enabled have a blue background while the other fields are grey, making these fields easy to recognize.

Search functionality

There are two main search areas in caAERS, the Advanced Search, which has tasks associated to many of the modules and searches associated to tasks. To search for information, choose the appropriate search and then click Search. Most fields you can leave blank before searching to see all results. If the field requires an entry, you can search for % (the percent sign) to have it display all results. You can also enter information into the search field to narrow down the search. Once a search is completed, the results are displayed and you can choose the item you want. If there are too many results, there are filter fields for each field displayed, allowing you to further narrow down the results until you find the item you are looking for.

Required Information/Missing information

As you use caAERS, you will find many of the tasks require you to add information before you can save or make changes. Information that is required is identified by a red asterisk (*) to the left of the title (both field and step titles). If you try to continue without including all required information, you will receive error messages indicating what information is missing. These error messages will appear in two locations, listed together at the top of the page and listed individually under the appropriate field.

Details

There are problems with your submission. Please correct them before proceeding.

- Please Specify the Ethnicity
- Please specify the Race
- Organization is required..!
- Identifier is required..!

Site

* Site

Participant Details

<p>* First Name <input type="text" value="j"/></p> <p>* Last Name <input type="text" value="r"/></p> <p>Maiden Name <input type="text"/></p> <p>Middle Name <input type="text"/></p>	<p>* Date of Birth <input type="text" value="12/19/2007"/></p> <p>* Gender <input type="text" value="Female"/></p> <p>* Ethnicity <input type="text" value="---"/></p> <p style="font-size: small; color: #A52A2A;">• Please Specify the Ethnicity</p> <p>* Race <input type="text" value="---"/></p> <p style="font-size: small; color: #A52A2A;">• Please specify the Race</p>
--	--

Study ID Assigned by Organization

* Identifier	* Identifier type	* Organization
<p style="font-size: small; color: #A52A2A;">• Identifier is required..!</p>	<p>Medical Record Number</p>	<p style="font-size: small; color: #A52A2A;">• Organization is required..!</p>

Administration module

Topics in this section include:

- Chapter Organization and Content
- Configuring caAERS
- Investigators
- Research Staff
- Import
- Import MedDRA
- IND#
- Organization
- Configure Password Policy

Chapter Organization and Content

After caAERS is installed, you need to complete a series of initial setup tasks before the users can fully use caAERSs. These tasks include:

- Configure the Application
 - ◆ To work with a mail server
 - ◆ To work as part of the CCTS Suite (optional)

- Add Organizations\sites

- Add Personnel
 - ◆ Investigators
 - ◆ Research Personnel\users

- Import information (optional)
 - ◆ Studies
 - ◆ Subjects
 - ◆ Legacy AE data
 - ◆ MedDRA vocabulary codeset

- Add INDs

- Configure the Password Policy

Unless otherwise noted, all these tasks are part of the **Administration Module**. To access the module, click on the **Administration** tab in the navigation menu.

Note: For security purposes, the Administration module is only accessible by Administrators and Site Coordinators.

For a quick lesson on configuring and setting up caAERS, you can also refer to the caAERS_QuickStart_Guide.

Configuring the Application

caAERS is installed with empty configuration information. You will need to use the **Configure caAERS** task to configure caAERS to work with a mail server and with caBIG Clinical Trials Suite (CCTS), if desired. All configuration is done on a single page, as shown below.

ESB queue URL	<input type="text"/>	URL for the enterprise service bus -- the value may not be applied until the application is restarted
LabViewer base URL	<input type="text"/>	The base URL for the LabViewer deployment to which this caAERS instance can link
Study Calendar base URL	<input type="text"/>	The base URL for the Study Calendar deployment to which this caAERS instance can link
Show debugging information	<input type="radio"/> Yes <input checked="" type="radio"/> No	Should there be extra context information at the bottom of each page? This information will make debugging easier. (Default: false)
SMTP server	<input type="text"/>	The address of the outgoing mail server (e.g.: smtp.gmail.com)
SMTP password	<input type="password"/>	Mail server password (only necessary if the mail server requires authentication)
SMTP port	<input type="text" value="25"/>	The port number of the outgoing mail server (Default: 25)
SMTP user name	<input type="text" value="caaers@semanticbits.com"/>	Mail server username (only necessary if the mail server requires authentication)
From address	<input type="text" value="caaers-admin@semanticbits.com"/>	The "from" address for all mail sent by caAERS. This address need not be a real e-mail address

The following table describes each field and notes whether it's for mail server configuration or CCTS 1.0 configuration.

Field Name	Description/Notes	Mail Server config	CCTS 1.0 config
ESB queue URL	End point URL for accessing the CCTS ESB component		Required for ESB
LabViewer base URL	URL for accessing the CCTS LabViewer component		Required for Labviewer
Study Calendar base URL	URL for accessing the Patient Study Calendar (PSC) application (allowing you to place AEs on the calendar)		Required for PSC
Show debugging information	Only necessary if you're interested in development		
SMTP server	Address of your outgoing mail server, for example, smtp.gmail.com	Required	
SMTP password	Server password used to send mail; it is only necessary if the mail server requires authentication	Sometimes required	
SMTP port	Port used to send mail; this defaults to 25, but can be changed if you use a different port to send outgoing mail	Required	
SMTP user name	Server user name; it is only necessary if the mail server requires authentication	Sometimes required	
From address	Email address to be displayed in the 'from' field of all mail sent from caAERS; this does not have to be a valid email address	Not required, but useful	

Note: The Show debugging information is not related to either mail server or CCTS configuration. This field is for developers only.

Configuring caAERS to work with a Mail Server

The caAERS application relies on being able to send emails for alerts, reminders, and submission of some reports. In order to successfully send emails, caAERS must be set up to use a working Mail Server. To configure caAERS to work with your mail server: 1. Click **Configure caAERS**

2. Enter {**SMTP server**}
3. Enter {**SMTP password**}, if required
4. Enter {**SMTP port**}, if different than 25
5. Enter {**SMTP user name**}, if required
6. Enter {**from address**}, if desired
7. Click **Save**

Note: If you do not provide information for your SMTP mail server, you will not be using caAERS full

capabilities.

Note: You may need to restart the caAERS server before all the changes are recognized.

Configuring caAERS to work with CCTS 1.0

If you plan to use caAERS as a module in the caBIG Clinical Trials Suite, you will need to complete the steps outlined in this section. If you will be using caAERS as a standalone application, you can leave these fields blank. To configure caAERS to work with CCTS:

1. Click **Configure caAERS**
2. Enter {**ESB queue URL**}, if desired
3. Enter {**LabViewer base URL**}, if desired
4. Enter {**Study Calendar base URL**}, if desired
5. Click **Save**

Note: You may need to restart the caAERS server before all the changes are recognized.

Organization

An Organization can be a site, a sponsor, or any institution associated with clinical trials and is a required field to add investigators and research staff. caAERS includes a large list of organizations as part of the basic install. If needed, additional organizations can be added to the list.

Searching for an Organization

Since Organizations are included in the installation, you should first search caAERS for the organization before you add it. To search for an organization:

1. Click **Organization > Search Organization** to bring up the Search Organization page
2. Enter {**search criteria**} in the **Name** and/or the **NCI Identifier** field and then click **Search**

Note: You can also just click Search to list all Organizations

3. The Organization available will be listed. You can further refine the search by typing something in the **Name** and/or the **NCI Identifier** filter area and then click **Filter**
4. To view the description and/or make changes to the organization, click on {**the organization**}

Organization Criteria

Name :

NCI Identifier :

Search Results

6 results found, displaying 1 to 6

Name
National Cancer Institute
Karthik Test Organization 1
↓
!@#\$\$%^&*()~./[]{}'":;
karthik test organization 4
National Cancer Institute of Canada Clinical Trials Group

Creating an Organization

1. Click **Organization** to open the **Create Organization** page
2. Enter the { **name** }
3. If you want to provide additional details, enter the { **description** }
4. Enter the { **NCI Identifier** }. The NCI Identifier is the primary id used by NCI and can be found at http://ctep.cancer.gov/forms/Organization_Codes.txt
5. Click **Save** to create the organization

Organization Details	
* Name	<input type="text"/>
Description	<input type="text"/> 
* NCI Identifier	<input type="text"/> 

Investigators

The **Investigators** tasks allow you to create Investigators and associate them to studies. It also allows you to search the system for Investigators to see if they are already in the system and/or associated to their studies. Investigators who are added to caAERS can receive email alerts and report submissions.

Create/Edit Investigator

1. Click **Investigator** to bring up the create/edit investigator page
2. Enter the {**First name**}
3. Enter the {**Middle name**} if desired
4. Enter the {**Last name**}
5. Enter the {**Investigator number**} if desired
6. Enter the {**Email address**}
7. Enter the {**Phone number**}
8. Enter the {**Fax number**} if desired
9. Enter the {**Organization**} and select {**Organization**}
10. Select **Inactive** or **Active**
11. If the Investigator works with another Organization, click **Add Organization** and repeat steps 9 and 10
12. Click **Save**

Note: If you want an Investigator to be able to log into caAERS, you will also need to add the Investigator to caAERS as a Research Staff/User. To do this, please see Research Staff.

Investigator Details

Investigator Details

<p>* First Name <input style="width: 90%;" type="text"/> </p> <p>Middle Name <input style="width: 90%;" type="text"/> </p> <p>* Last Name <input style="width: 90%;" type="text"/> </p> <p>Investigator number <input style="width: 90%;" type="text"/> </p>	<p>* Email address <input style="width: 90%;" type="text"/></p> <p>* Phone <input style="width: 90%;" type="text"/></p> <p>Fax <input style="width: 90%;" type="text"/></p>
--	--

Associate Organizations

* Organization	* Status
	Please select

Searching for an Investigator

1. Click **Search Investigator** from the **Investigator** task
2. Enter {search criteria} in the **First Name**, **Last Name**, and/or the **Investigator number** field and then click **Search**

Note: You can also just click Search to list all Investigators

3. The Investigators available will be listed. You can further refine the search by typing something in any of the **Name** filter fields and/or the **NCI Institute Code** filter field and then clicking **Filter**
4. To view the description and/or make changes to the investigator, click on {the investigator}

Research Staff

All users of the caAERS system have accounts, although their access rights vary. The Research Staff Page allows you to create the user accounts.

Access to the different areas of caAERS is controlled by the user roles and each user can be assigned to multiple roles. These roles are:

- **Subject Coordinator** ? Provides access to the Adverse Events, Studies, and Subjects modules; the user can document AEs and create reports, studies, and subjects
- **Study Coordinator** ? Provides access to the Studies module; the user can review studies, AEs, and expedited reports
- **Adverse Event Coordinator** ? Provides access to the Adverse Events module; the user can view and report AEs for studies they are assigned to
- **Site Coordinator** ? Provides access to the Adverse Events, Studies, Rules, and Administration modules; the user can report AEs, create studies, set up rules, and have access to administrative features of the application

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

The following matrix shows what modules and tasks a user role has access to. If there is a ? in the box, it means that role has access to that task

	System Admin	Site Coordinator	Study Coordinator	AE Coordinator	Subject Coordinator
AE Module					
Manage Reports (View AEs)	?	? (for assigned studies)			
Create/Edit AEs	?			? (for assigned studies)	? (for assigned studies)
Studies Module					
Create/Edit	?	?	?		?(for assigned studies)
View	?	?	?		? (for assigned studies)
Subjects Module					
Create and Assign/Edit	?	?			? (for assigned studies)
View	?	?			? (for assigned studies)
Rules Module					
Create/Edit Rules	?	?			

View Rules	?	?
Create/Edit Report Defs	?	?
View Report Defs	?	?
Administration Module		
Create/Edit Users	?	?
Create/Edit Investigators	?	?
Import Studies/Subjects	?	?
Import AEs	?	?
Import Subjects	?	?
Import MedDRA	?	?
IND #	?	?
Create/Edit Organizations	?	?
Configure Password Policy	?	?

Creating an account

1. Click **Research Staff** to access the **Create Research Staff** page
2. Enter the {**Organization**} and select {**Organization**}
3. Enter the user details
4. Select the **User Role(s)** and click **Save**

Details

Site

*** Organization**

Details

<p>* First name <input style="width: 150px;" type="text" value=""/></p>	<p>* Email address <input style="width: 150px;" type="text" value=""/></p>
<p>Middle name <input style="width: 150px;" type="text" value=""/></p>	<p>* Phone <input style="width: 150px;" type="text" value=""/></p>
<p>* Last name <input style="width: 150px;" type="text" value=""/></p>	<p>Fax <input style="width: 150px;" type="text" value=""/></p>
<p>Researcher ID <input style="width: 150px;" type="text" value=""/></p>	

User Role (Check all that apply)

Subject coordinator

Study coordinator

Adverse event coordinator

Site coordinator

Both the user name and password are case sensitive. The user name will be what was entered in the **Email Address** field.

Note: If the user forgets their password, he/she can reset it by clicking **Reset Password** on the login window.

Searching for an account

1. Click **Search Research Staff** from the Research Staff task
2. Enter {search criteria} in the **First Name**, **Last Name**, and/or the **Organization** field and then click **Search**

Note: You can also just click **Search** to list all Research Staff

3. The users will be listed. You can further refine the search by typing something in any of the **Name** filter fields and/or the **Organization** filter field and then click **Filter**

4. To view the description and/or make changes to the user, click on {the user}

Details	
Site	
* Organization	<input type="text"/>
Details	
* First name	<input type="text"/>
Middle name	<input type="text"/>
* Last name	<input type="text"/>
Researcher ID	<input type="text"/>
* Email address	<input type="text"/>
* Phone	<input type="text"/>
Fax	<input type="text"/>
User Role (Check all that apply)	
Subject coordinator	<input type="checkbox"/>
Study coordinator	<input type="checkbox"/>
Adverse event coordinator	<input type="checkbox"/>
Site coordinator	<input type="checkbox"/>

Import

Studies, subjects, and routine AEs can be imported into caAERS. This means if you've previously used other applications and databases to maintain this information, an import will alleviate the need to manually enter the individual pieces of information. To import studies, subjects, or AEs, create valid XML files from the information in your existing application/database. Create separate XML files for each type of data (studies, subjects, and AEs). Combining everything into a single XML file will cause the import to fail. To review copies of the XSD files and sample XML files, go to <https://gforge.nci.nih.gov/svnroot/caaersappdev/docs/import/>.

To import the studies, subjects, or routine AEs:

1. Create an XML file containing the information you want to import
2. Select the **Import** task from the **Administration** Module
3. Click on **Import {type}**
4. Click **Browse** to locate and select the XML file that contains the information, then select **Save & Continue**

5. The system will validate the XML file and show a synopsis of what will be imported on the **Review and Submit** page; if the information looks correct, click Save; depending on the size of the file, this could take minutes to hours to complete

Study Identifier	Study Short Title	Possible Problem
le049	Pancreatic Cancer Study ph 5	- The selected investigator Babik Roma is not Valid - The selected investigator Karl Pavano is not Valid - The selected personnel Baron Davis is not Valid

6. To verify the information imported correctly, use the search task in the **Adverse Events, Studies, or Subjects** Module.

Import MedDRA

The caAERS installation includes the CTC v2 and CTCAE v3 vocabulary. CTC is a free open-source medical vocabulary that can be used to code clinical studies. An alternative to CTC is MedDRA terminology. If your organization uses MedDRA, the vocabulary can be imported into the application. Currently, only MedDRA versions 9.0, 9.1, and 10.0 are supported.

MedDRA is stored in several ASCII (.asc) files. If the file format you try to import does not match the allowed format, the import will fail.

To import MedDRA files: 1. Locate the folder where MedDRA is stored

2. Click **Import MedDRA**
3. Enter {the full path} into the field provided and click **Import MedDRA**

Import MedDRA Dictionary

To import the **MedDRA** terminology you need to specify the full path of the folder that contains the ASCII files, and then hit the **Import Meddra** button. MedDRA delivers the terminology as a set of ASCII files, file extensions end with .asc. Currently we support MedDRA version 25.1.

Import Meddra

IND

Investigational new drugs (IND) can be added in caAERS for use in studies. By adding the IND information, adverse events related to a particular IND can be tracked more efficiently.

Creating an IND

1. Type the {IND #}
2. Select {who holds the IND}
3. Enter the {IND Holder} and click **Save**

Investigational New Drug Details

You can add the details of an Investigational New Drug(IND)here.

* IND #

* IND held by?

* IND Holder

Clear

Searching for an IND

1. Click **Search IND** from the IND# task
2. Enter {search criteria} in the **IND #** and/or the **IND holder** field and then click **Search**

Note: You can also just click Search to list all INDs

3. The INDs will be listed. You can further refine the search by typing something in the **IND #** and/or the **Sponsor holder** filter fields and then clicking **Filter**

Configure Password Policy

caAERS allows you to create specific rules regarding the creation of user passwords. This creates a more secure environment and allows you to control the level of security for user passwords. To configure the password policy:

1. Enter { **maximum password age** } ? this determines how long a user can keep a password before having to reset it
2. Enter { **number of allowed failed login attempts** }
3. Enter { **lockout duration** } ? this determines how long a person is locked out of the system after entering the wrong password the number of allowed times
4. Enter { **minimum password age** } ? this prevents a user from recreating their password numerous times in a row to go back to the same password
5. Enter { **password history size** } ? this determines how many past passwords you keep in the system for a user
6. Enter { **minimum password length** }
7. Select { **complexity requirements** }
8. Enter { **largest substring of username allowed** } ? this prevents users from having their password too similar to their user name
9. Click **Save**

Investigational New Drug Details

You can add the details of an Investigational New Drug(IND)here.

* IND #

* IND held by?

* IND Holder

Rules Module

This section describes the Rules module. Topics include:

- Introduction
- Manage Rules
- List Rules
- Import Rulesets
- Create Report Definitions
- List Report Definitions

Introduction

To help organizations stay in compliance with AE reporting regulations, the caAERS 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 caAERS 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, caAERS 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.

To use caAERS, you must first set up a set of rules and report definitions. The rules and report definitions used by caAERS can be authored within the application itself or imported from a library.

This section describes the Rules Module, which allows you to:

- Create new rules
- View and modify existing rules

- Import rules from other sources
- Create and modify reports

Manage Rules

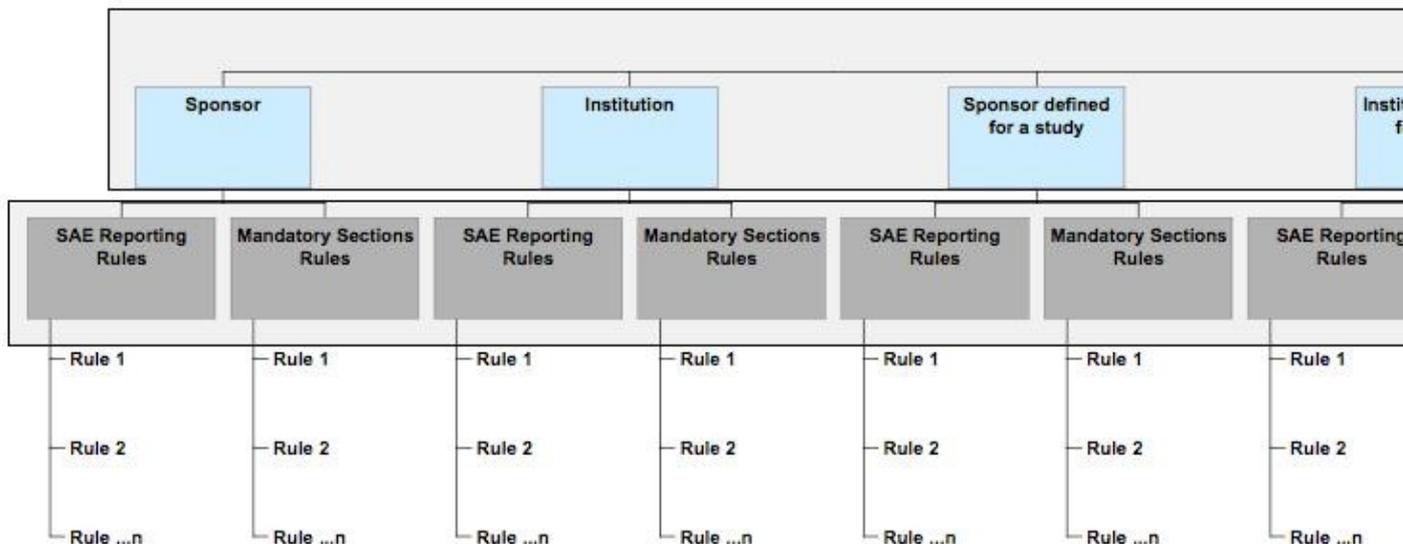
There are four categories (or Rule Levels) for rules:

- Sponsor
- Institution
- Sponsor defined for a study
- Institution defined for a study

Each category can have multiple rulesets associated to it. At this time, there are two rulesets:

- SAE Reporting Rules
- Mandatory Sections Rules

Each of these rulesets can then have one or more rules associated to it. The following diagram shows this visually.



To provide a specific example, If you're entering rules for the Sponsor Wake Forest, it could have an SAE Reporting Ruleset and a Mandatory Sections Ruleset, each with their own rules. Wake Forest may also have specialized rulesets for a specific study. Another Sponsor, DCP might only have the SAE Reporting Ruleset, and it'd be completely separate from Wake Forest.

The creation process is broken into four sections:

- Select Category (Rule Level)
- Select Ruleset
- Create Rules
- Review

Select Category

The first step for creating rules is to determine what category the rule falls in. You do this on the Select Rule Set page. As discussed in the introduction, there are four different categories to choose from:

- Sponsor
- Institution
- Sponsor defined for a study
- Institution defined for a study

1. Select the radio button associated with the rule level you want to use
2. Enter information into the fields that appear (the auto complete feature is available). This may mean you're entering {**a Sponsor**} or {**an Institution**}, with the possibility of entering {**a study**}
3. Click **Save & Continue**

The screenshot shows a web form titled "Rule Level". It contains four radio button options: "Sponsor rules", "Institution rules" (which is selected), "Sponsor defined rules for a study", and "Institution defined rules for a study". Below these options is a text input field labeled "Select Instiution" (note the typo) containing the text "Johns Hopkins University". A dropdown menu is open below the input field, showing "Johns Hopkins University" as the selected option. To the right of the input field is a "Clear" button. At the bottom right of the form is a "Continue >" button.

Select Ruleset

The next page allows you to select the rulesets to use. It will display any existing rulesets associated with the rule level you selected. You have the option to select an existing ruleset or create a new ruleset.

Existing Rulesets

If you chose **Sponsor defined for a study** or **Institution defined for a study**, and you've already went through the process for Sponsor or Institution rules, some of the information may already exist.

Note: Remember, there are only two Rulesets to choose from, and you can only have one of each type. So, if there's an existing Ruleset, any changes you make to the rules will override what currently exists, not create a separate Ruleset.

1. Select the radio button next to an existing Ruleset.
2. Click **Save & Continue**.

No existing Rulesets

1. Click **Create RuleSet**
2. Select one of the options from the **RuleSet Name** field
3. Click **Save & Continue**

Rules

On the Rules page you will add rules to the Ruleset.

Note: If you chose an exiting Ruleset for the **Sponsor** or **Institution** category, it's possible that rules are already associated with it. Any changes you make will override what currently exists, not create a separate Ruleset.

Note: If you chose an existing Ruleset for the **Sponsor defined for a study** or **Institution defined for a study** category, the Rulesets for the corresponding **Sponsor** or **Institution** category are automatically included so you don't have to reenter the information. You can then add or delete rules. These changes will

only affect the ruleset associated with the **Sponsor defined for a study** or **Institution defined for a study** category, not for the original **Sponsor** or **Institution** category.

1. Click **Add Rule** to bring up a form which will allow you to define the rules that go with the Ruleset.
2. Select **Adverse Event, Study, or Report Definition** from the **Domain Object** drop-down menu.
3. Select an option from the **Field** drop-down menu. The options available are dependent on what was selected as the Domain Type.
4. Select an option from the **Operator' drop-down menu** . *This menu will always list Equal to and Not Equal to, and depending on your previous selections, may also list Greater Than or Equal To and Less Than or Equal To.*
5. Select a value from the **Value** drop-down menu. The options will vary based on the Domain Object and Field selects.
6. If there are additional conditions you want to assign to this Rule, click on the **Plus** () icon and repeat steps 2-5.

Note: All of the conditions listed must be met for the Action to be completed. If you don't require all the conditions to be met, create a separate Ruleset.

Note: You can remove conditions by clicking on the Red x () icon.

Else Continue to step 7

7. Select an option from the **Action** box.
8. To continue, click **Save & Continue**. To add another rule, click **Add Rule** and then repeat steps 1-7. To delete a rule, click the icon  in the right-hand corner of the rule.

Rules

RuleSet Name Mandatory Sections Rules

Rule - (1)

Name Rule-1

Condition(s)

IF	Study	IND Holder
Equal To	Cancer Therapy Evaluation Program	
AND	Study	Therapy
Equal To	Agent Radiation Surgery	
AND	Study	Therapy
Not Equal To	Agent Radiation Surgery	
AND	Report Definition	Name
Equal To	CTEP 24 Hour SAE Notification CTEP 10 Calendar Day SAE Report CTEP 5 Calendar Day SAE Report	

Action(s)

Enter AEs Adverse events Reporter

[« Back](#)

Review

The Review page allows you to review and verify the information before saving the ruleset. Click the **Save** button to save the rule you've created, or click **Save & Back** to go back and make changes.

Review

Please review the details furnished below, then press save to persist the modifications.

Rule Set Details

Rule Set Level	Rules for Sponsor
Rule Set Name	Mandatory Sections Rules
Organization Name	Cancer Therapy Evaluation Program
Organization Role	Sponsor

Rule-1

IF
 Study Agent IND Holder is 'Cancer Therapy Evaluation Program'
 AND
 Study Therapy is 'Agent'
 AND
 Study Therapy is not 'Behavioral' or 'Device' or 'Surgery' or 'Radiation'
 AND
 Report Definition is 'CTEP 5 Calendar Day SAE Report' or 'CTEP 10 Calendar Day SAE Report'

ACTION(S) :
 Enter AEs
 Adverse events
 Reporter
 Select Report
 Describe Event
 Patient Details
 Course and Agent
 Prior Therapies
 Attribution

[← Back](#)

All new rules sets are given the status of **Disabled**. To modify the ruleset, including its status, go to the List Rulesets Module.

List Rules

The **List Rules** page displays all Rules that exist in the system. For each Ruleset, you can view the Level, the Organization, the Study, and the Status. You can also choose to Enable, Disable, or Delete the Ruleset, or Export/Download the Ruleset to an XML file.

6 results found, displaying 1 to 6  [Filter](#) [Clear](#)

Rule Level	Rule Set	Organization	Study	Status	Action
Sponsor rules	Mandatory Sections Rules	Cancer Therapy Evaluation Program	N/A	Not Enabled	Enable Disable Export/Download Delete
Sponsor rules	SAE Reporting Rules	Cancer Therapy Evaluation Program	N/A	Enabled	Enable Disable Export/Download Delete
Sponsor rules	Mandatory Sections Rules	Division of Cancer Prevention	N/A	Enabled	Enable Disable Export/Download Delete
Sponsor rules	SAE Reporting Rules	Division of Cancer Prevention	N/A	Enabled	Enable Disable Export/Download Delete
Sponsor rules	Mandatory Sections Rules	Karthik Test Organization 1	N/A	Enabled	Enable Disable Export/Download Delete
Sponsor defined rules for a study	SAE Reporting Rules	Cancer Therapy Evaluation Program	Test study jan 5th	Enabled	Enable Disable Export/Download Delete

Enabling Rulesets

Rulesets may have a Status of **Not Enabled**, such as newly created Rulesets. To enable a ruleset, click **Enable** from the Action column.

Disabling Rulesets

If you don't want a ruleset to be active anymore, you can disable it by clicking **Disable** from the Action column.

Export/Download Rulesets

You have the ability to export the ruleset to XML files. To export a ruleset, click **Export/Download** from the Action column.

Deleting Rulesets

If the ruleset is no longer valid, you can delete it by clicking **Delete** from the Action Column.

Import Rulesets

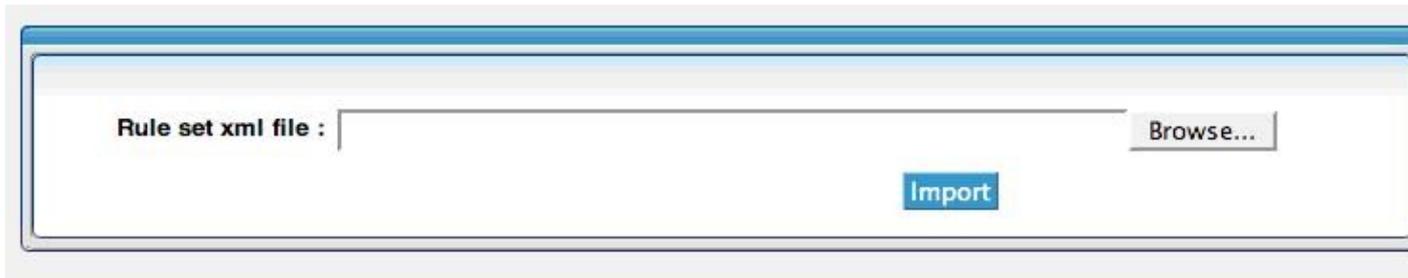
You can import existing rulesets into caAERS. This is an easier and faster way to set up rules in caAERS.

At present, there is a small set of existing rules covering the baseline reporting rules for most CTEP sponsored trials. New rulesets are being developed and added to this library. Copies of these existing rulesets can be obtained from the caAERS Gforge project site, <http://gforge.nci.nih.gov/projects/caaersappdev/>.

To import rulesets:

Import Rulesets

1. Click **Browse** to locate and select the XML file that contains the ruleset
2. Click **Import**
3. If the import was successful, you will receive the message "Rules imported successfully". If it was not successful, you will receive a message telling you to contact the system administrator.



Note: Although it is possible to create rulesets for importing using an XML authoring tool, we recommend against presently. Rulesets that are to be imported into caAERS should be obtained from the caAERS ruleset library or else should be created in caAERS using the Ruleset XML export feature.

Create Report Definition

Report definitions are the backbone of caAERS, identifying what information is required in a report and who receives the report. The report definitions you create will be used when defining rules for your rulesets. Creating a report definitions is done in five steps:

- Basic Details ? enter the general information for the report
- Report Delivery Details ? enter who receives the report
- Mandatory Fields ? enter what information is mandatory
- Notifications ? enter reminders for the report
- Review ? review the settings for the report

Basic Details

The Basic Details page has you setup the general information for the report. A "?" next to a field means it is required information.

1. Enter the organization in the **Organization** field.
2. Type a name in the **Name** field. Keep the name simple but descriptive.
3. Add a description if you want to add more information for the report.
4. Select **Yes** or **No** for **Amendable**. This field defaults to **Yes**, which means the report can be added to.

5. Select **Yes** or **No** for **Attribution required**. This field defaults to **No**. If you change it to **Yes**, it means any time an AE is reported on, it must be related to an attribute.
6. Select a value for **Time Scale UOM** (unit of measurement). This value tells you the measurement of time before the report is due.
7. Enter a number for **Time Till Report Due**. This number is associated with what you selected for Time Scale UOM, and determines the specific measurement for when the report is due. For example, if you chose **Days** for Time Scale UOM, and then entered 5 here, you're saying the report will be due 5 days after you document the AE ad click **Save and Continue**.
8. To add delivery information, click **Continue**

Warning! If you navigate from this page to a different area of caAERS without completing the entire report definition process, all information will be lost, even if you have clicked **Continue**.

The screenshot shows a web form titled "Basic Details" with the following fields and controls:

- * Organization**: A text input field with a light blue background. Below it is the instruction: "Enter a portion of the organization name that you are looking".
- * Name**: A text input field.
- Description**: A larger text input field.
- * Amendable?**: A dropdown menu with "Yes" selected.
- * Attribution required?**: A dropdown menu with "No" selected.
- * Time Scale UOM**: A dropdown menu with "Select a Value" selected.
- * Time Till Report Due**: A text input field.

A blue button labeled "Continue »" is positioned at the bottom right of the form.

Report Delivery Details

The delivery details allow you to setup recipients of this report. The report can be sent to a specific email address, a role, or a URL. Reports sent to email addresses and roles are sent as PDF files while reports sent to URLs go through as XML files.

Delivery Details

You are entering final report delivery information for **test**.

Email Recipients

Click on Add eMail or Add Role button to add an email address or role respectively. A PDF version of the final report will be delivered to the email address entered.

Name	* Role/EmailAddress
No eMail delivery definitions configured	

System Recipients

Click on Add URL button to add a system URL. An XML version of the final report will be posted to the system URL.

* Name	Username	Password	* URL
No system delivery definitions configured			

Send to email

Use this option if you want the report to always go to a specific e-mail address.

Note: This is less flexible than using **Send to Role**, since all studies using this report definitions will go to the e-mail address listed

1. Click **Add Email**
2. Type {**name**} in the **Name** field. This can be the recipient's name or another way to identify the role.
3. Type {**the email address**} in the **Role/Email Address** field.
4. If at any time you want to remove information you've added, click the **Delete** button that corresponds to the information you want to remove. To add mandatory information, click **Continue**.

Send to role

Use this option to always send the report to a role. This offers flexibility, since it will send it to the e-mail address listed for the role for the study using the report definition. This way, if the person(s) listed for the role changes, the report will automatically be sent to the new person in the role.

1. Click **Add Role**

2. Type {**name**} in the **Name** field. This can be the recipient's name or another way to identify the email address

3. Select {**the role**} from the **Role/Email Address** field

4. If at any time you want to remove information you've added, click the **Delete** button that corresponds to the information you want to remove. To add mandatory information, click **Continue**.

Send to URL

Use this role for electronic submission of a report. The URL is typically a web service that can consume the report, such as AdEERS.

1. Click **Add URL**

2. Type {**name**} in the **Name** field. This can be the recipient's name or another way to identify the URL

3. If the site requires a username and password to access it, enter the information in the **Username** and **Password** fields

4. Type {**the URL**} in the **URL** field

5. If at any time you want to remove information you've added, click the Delete button that corresponds to the information you want to remove. To add mandatory information, click **Continue**.

Mandatory Fields

The mandatory fields page allows you to select the specific information that must be included in the report. The sections are based on the sections of the expedited report, where you will enter the information into the appropriate fields

To make a field a required field when creating an expedited report, select the checkbox associated with it on this page. Once you have completed your selections, click **Continue** to add notifications.

Note: This page is very long with multiple sections.

Mandatory Fields	
<p>Select the fields of adverse event entry screen which are to be made mandatory, when test report definition is associated to a adverse event report. TODO: need a better instruction...</p>	
Reporter information	
Reporter details	Physician details
<p>First name <input type="checkbox"/></p> <p>Middle name <input type="checkbox"/></p> <p>Last name <input type="checkbox"/></p> <p>E-mail address <input type="checkbox"/></p> <p>Phone <input type="checkbox"/></p> <p>Fax <input type="checkbox"/></p>	<p>First name <input type="checkbox"/></p> <p>Middle name <input type="checkbox"/></p> <p>Last name <input type="checkbox"/></p> <p>E-mail address <input type="checkbox"/></p> <p>Phone <input type="checkbox"/></p> <p>Fax <input type="checkbox"/></p>
Medical information	
<p>Baseline performance <input type="checkbox"/></p> <p>Disease name <input type="checkbox"/></p> <p>Primary site of disease <input type="checkbox"/></p> <p>Date of initial diagnosis <input type="checkbox"/></p>	<p>Weight Quantity <input type="checkbox"/> Units <input type="checkbox"/></p> <p>Height Quantity <input type="checkbox"/> Units <input type="checkbox"/></p> <hr/> <p>Metastatic disease information</p> <p>Site name <input type="checkbox"/></p>
Intervention information	
Radiation intervention	Surgery intervention
<p>Type of radiation administration <input type="checkbox"/></p> <p>Dosage <input type="checkbox"/></p> <p>Dosage unit <input type="checkbox"/></p> <p>Last treatment date <input type="checkbox"/></p> <p>Schedule number of fractions <input type="checkbox"/></p>	<p>Intervention site <input type="checkbox"/></p> <p>Intervention date <input type="checkbox"/></p>

Notifications

Notifications can be set up to send reminders to people about the report. Multiple reminders can be created for the same report, reminding people that the report is almost due or informing them the report is past due.

Adding a notification

1. Select **{number}** from the Time Scale. For example, if your report is due on Day 5 (as selected on the Basic Details page), you could select **2** to send a reminder three days before the report is due.
2. Add a recipient. Click **Add Email** to enter **{email address}** or click **Add Role** to select **{a role}** from the list. You can add multiple recipients to the notification.
3. Type **{a subject line}**. To add a variable, place your cursor where you want the variable to appear, then select **{the variable}** from the variable list.
4. Type the body of the message in the **Message** field. To add a variable, place your cursor where you want the variable to appear, then select **{the variable}** from the variable list.
5. Click **Reset** to clear the information, **Delete** to completely remove the notification, or **Continue** to review the report.

Time Scale

You are configuring reminder notifications for **test**. Choose the DAY, and configure the notification(s)

DAY | 0 | 1 | **2** | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27

Configure Notification for DAY : 2

Email Notification 1

Recipients

Insert a substitution variable

Subject Line

Message

[Add eMail](#)
[Add Role](#)

[◀ Back](#)
[Delete](#)

[Add Notific](#)
[Conti](#)

Adding additional notifications for the same time period

You can have multiple notifications sent out for the same Time Period. For example, you could have two different notifications being sent three days before the report is due. To do this, click **Add Notification** and a

Create Report Definition

45

second Email notification will appear in the same area.

Note: The notifications can be minimized by clicking on the minimize icon.

Adding notifications for a different time period

If you want to add a notification for a different time period, for example, the day after the report was due, select a new {**number**} from Time Scale. The notifications you've previously created will be saved and the page will only show notifications setup for the new time select. From here, follow the steps described previously for *Adding a notification*.

Review

The Review pages allow you to review the Report Definition you've created. If the information is correct, click **Save**. If you want to make changes, click **Back** to return to previous sections and made your changes.

List Report Definitions

The list report definition page displays all the report definitions that have been created in caAERS. This page shows some general information about the definition, including the name, description, organization it is for, and when the final report is due.

To see more information about the report definition, click on the {**report definition name**}. This will open the definition in create/edit mode.

8 results found, displaying 1 to 8			
Name	Description	Organization	Final Report Due
CTEP 5 Calendar Day SAE Report		Cancer Therapy Evaluation Program (CTEP)	5 Day(s)
CTEP 24 Hour SAE Notification		Cancer Therapy Evaluation Program (CTEP)	2 Day(s)
CTEP 10 Calendar Day SAE Report		Cancer Therapy Evaluation Program (CTEP)	10 Day(s)
test RD		Duke University Comprehensive Cancer Center (DUKE)	2 Hour(s)
48-Hour SAE Report to NCI Medical Monitor and CCSA	48 Hour SAE Report to CCSA and NCI Medical Monitor	Division of Cancer Prevention (DCP)	2 Day(s)
Mayo IRB 24 Hour Notification		Mayo Clinic Rochester (MN026)	24 Hour(s)
10-Day Report Submission to AdEERS	10-Day Report Submission to AdEERS (DCP Trial)	Division of Cancer Prevention (DCP)	10 Day(s)
KARTHIK TEST REPORT	SOME TEST REPORT. Random report	Karthik Test Organization 1 (nci-kto1)	2 Week(s)

Advanced Search

Topics in this section include:

- Overview
- Study Search
- Subject Search
- AE search
- Expedited Report search
- Routine AE search

Overview

The Advanced Search module enables a user to quickly search and locate different information in caAERS. Different users will have access to different search tasks, based on the roles they were assigned. Each of the search tasks work the same way as the searches in the other modules. The following sections provide step-by-step instructions on using these search options.

Study Search

The study search allows the user to locate a particular study, searching by study or subject information. To search for a study: 1. Click **Study search** from the Advanced Search module

2. Enter {**search criteria**} in any of the fields of the **Study Criteria** box, the **Subject Criteria** box, or both and then click **Search**

Note: You can also just click **Search** to list all Studies

3. The Studies available will be listed. You can further refine the search by typing something in the **Primary ID, Short Title, Sponsor, Phase,** and **Status** filter fields and then clicking **Filter**

4. To view the study and/or make changes to it, click on {**the study?s Primary ID**}

Subject Search

The subject search allows the user to locate a particular subject, searching by study or subject information. To search for a subject:

1. Click **Subject search** from the Advanced Search module
2. Enter {**search criteria**} in any of the fields of the **Study Criteria** box, the **Subject Criteria** box, or both and then click **Search**

Note: You can also just click **Search** to list all Subjects

3. The Subjects available will be listed. You can further refine the search by typing something in the **Primary ID, First Name, Last Name, Gender, Race, Ethnicity,** and **Associated Study ID(s)** filter fields and then clicking **Filter**

4. From here, you can view the subject by clicking on {**the subject?s Primary ID**} or view the associated study and/or make changes to it by clicking on {**the associated study?s ID**}

AE Search

The AE search allows the user to locate an AE, searching by AE, study, or subject information. To search for an AE:

1. Click **AE search** from the **Advanced Search** module
2. Enter {**search criteria**} in any of the fields of the **AE Criteria** box, **Study Criteria** box, the **Subject Criteria** box, or all three and then click **Search**

Note: You can also just click **Search** to list all Subjects

3. The AEs available will be listed. You can further refine the search by typing something in the **Study ID, Sponsor, AE Type, CTC Category, CTC Term, Grade, MedDRA Code,** and **Start Date** filter fields and then clicking **Filter**

Expedited Report Search

The Expedited Report search allows the user to locate a report searching by expedited report, study, or subject information. To search for an expedited report:

1. Click **Expedited Report** search from the **Advanced Search** module

2. Enter {search criteria} in any of the fields of the **Expedited Report Criteria** box, **Study Criteria** box, the **Subject Criteria** box, or all three and then click **Search**

Note: You can also just click **Search** to list all Subjects

3. The expedited reports available will be listed. You can further refine the search by typing something in the **Primary CTC term, Grade, Attribution, Start Date, Study ID, and Subject ID** filter fields and then clicking **Filter**

4. From here, you can view the associated study or subject and/or make changes to it by clicking on {**the study?s ID**} or the {**the subject ID**}

Routine AE Search

The Routine AE search allows the user to locate a Routine AE report, searching by Routine report, study, or subject information. To search for a routine AE report:

1. Click **Routine AE** search from the **Advanced Search** module

2. Enter {search criteria} in any of the fields of the **Routine Report Criteria** box, **Study Criteria** box, the **Subject Criteria** box, or all three and then click **Search**

Note: You can also just click Search to list all Subjects

3. The Routine AE reports available will be listed. You can further refine the search by typing something in the **Primary CTC term, Grade, Attribution, Observation Dates, Study ID, and Subject ID** filter fields and then clicking **Filter**

4. From here, you can view the associated study or subject and/or make changes to it by clicking on {**the study?s ID**} or the {**the subject ID**}

Working with AdEERS

Topics in this section include:

- AdEERS Integration
- Setting up AdEERS Communication

AdEERS Integration

caAERS is capable of sending AE reports to AdEERS. However, the systems are independent of each other so a platform agnostic and context-free communication approach was developed. Messages are also required to be transmitted reliably and securely.

Since AdEERS has already published the necessary WSDLs, the caAERS AdEERS communication infrastructure implements SOAP messaging. In addition, caAERS has infrastructure in place that can handle exceptions returned by AdEERS. These exceptions may be generated due to various reasons, such as:

- The caAERS message being malformed
- A particular job ID not being found

Setting up AdEERS communication

When caAERS is installed, it has all the components necessary to communicate with AdEERS. It simply requires specific information be added during the creation of

- Report Definitions
- Studies
- Expedited Reports

Report Definitions

AdEERS communication is set up through the report definition module in caAERS. Existing or new report definitions can be set up for caAERS-AdEERS integration. This is done during the **Report Delivery Details** step of the Create Report Definition task. Here you will add the URL of the web server for AdEERS. See Report Delivery Details for step-by-step instructions. If you do not have the URL for the web server, contact Support.

Note: You should not have any problems if you have a firewall set up.

Studies

A study can also be defined to require AdEERS reporting. This is setup in the **Details** step of the **Create Study** task, part of the **Studies** module. See the *caAERS End User Manual* for step-by-step instructions.

Expedited Reports

Based on the rules set up for the studies, an Expedited Report may prompt you to submit an AdEERS report. If an AdEERS report is not required, you can still manually select to send one. See **Creating an Expedited Report** in the *caAERS End User Guide* for step-by-step instructions.

Error Messages/Indicators and Problem Resolutions

Topics in this section include:

- Error messages/Issues
- Support

Error Messages

caAERS has been setup to provide descriptive messages whenever it encounters a problem.

- submission errors
- import issues
- activity issues
- system errors

Submission Errors

I get an error when I try to save or continue

As you go through the modules and try to save changes, you may forget to add information and receive an error. The error will state what information is missing.

Details

There are problems with your submission. Please correct them before proceeding.

- Please Specify the Ethnicity
- Please specify the Race
- Organization is required..!
- Identifier is required..!

Site

* Site

Participant Details

<p>* First Name <input type="text" value="j"/></p> <p>* Last Name <input type="text" value="r"/></p> <p>Maiden Name <input type="text"/></p> <p>Middle Name <input type="text"/></p>	<p>* Date of Birth <input type="text" value="12/19/2007"/></p> <p>* Gender <input type="text" value="Female"/></p> <p>* Ethnicity <input type="text" value="---"/></p> <p style="font-size: small; color: #A52A2A;">• Please Specify the Ethnicity</p> <p>* Race <input type="text" value="---"/></p> <p style="font-size: small; color: #A52A2A;">• Please specify the Race</p>
--	--

Study ID Assigned by Organization

* Identifier	* Identifier type	* Organization
<input type="text"/> <p style="font-size: small; color: #A52A2A;">• Identifier is required..!</p>	<input type="text" value="Medical Record Number"/>	<input type="text"/> <p style="font-size: small; color: #A52A2A;">• Organization is required..!</p>

I get an error when I try to go back to a previous step

caAERS is setup to check a page for all required information before moving to the next step. If you want to go to a previous step, you may receive an error on the previous page about missing information. This is just the information it expected to be entered before you went back. At other times, it may not allow you to go back until you fill out the required fields (the information will be saved when you come back to the page).

Import Errors

When importing XML files, you may receive error messages. The message could mean some of the information won't be imported if you continue, or it could prevent the import completely. If you receive an error during an import, verify the file is the correct format and doesn't contain the wrong information. If it is and you still have issues, contact the support team.

Activity Issues

I was taken back to the log on page

caAERS automatically logs out inactive accounts. If you've been inactive and then you try to access a module or click on a button, it'll have you log back in before accessing the module. You will lose any unsaved information. caAERS will automatically log you out after approximately 30 minutes of idle time.

I had to start over while entering information

If you went idle while entering information across multiple pages, such as an adverse event, you may lose your information because the system automatically logged you out. To verify the information is lost, you can use the advanced search feature to search for the partially created report, study, etc.

Memory Issues

During installation, the memory should have been set up in Tomcat. If it was not, you will need to increase the memory setting to 512.

Tomcat is a standalone application

Open **catalina.bat** and add the following line:

- set CATALINA_OPTS=-XX:MaxPermSize=128m -Xmx512

Tomcat is running as a service

Open the Tomcat service console and enter **512** for **Maximum memory pool**, then click **Apply**

System Errors

You may run into a system error. If this happens, contact the support team. They may request the detailed error information, so take screen shot and/or write down the exact error and what you were doing when you received it.

Support

To get support when you have issues, please check the caAERS Project site, <http://gforge.nci.nih.gov/projects/caersappdev/> or contact support at edmond.mulaire@semanticbits.com.

Technical Interface

Adverse Event Query API

Purpose

Designed to query Adverse Events based on different criterion. You can search caAERS database by any filters on Study, Participant and Adverse Event. Implementation is based on hibernate Query By Example . Basically, you instantiate one of your objects with the corresponding values. Hibernate then builds the corresponding query using the non-null field values.

Interface

`gov.nih.nci.cabig.caaers.api.AdverseEventQueryService`

Implementation

`gov.nih.nci.cabig.caaers.api.AdverseEventQueryServiceImpl`

Example Scenarios

```
AdverseEventQueryService adverseEventQueryService = (AdverseEventQueryService)
getDeployedApplicationContext().getBean("adverseEventQueryService");
```

Query by Study Filters

Search for Adverse Events where Study phase is phase 2 and short title is like RTOG.

Method : `getByStudy(Study study);`

Example :

```
Study study = new Study();
```

```
study.setPhaseCode("Phase II Trial");
```

```
study.setShortTitle("RTOG");
```

```
List<AdverseEvent>
```

```
adverseEvents = adverseEventQueryService.getByStudy(study);
```

In this example study object is populated with phase and shortTitle . Service performs search only based on phase and shortTitle.

Query by Study and AdverseEvent Filters

Search for Adverse Events where Study phase is phase 2 and AdverseEvent grade is 3.

Method : `getByStudy(Study study);`

Example :

```
Study study = new Study();
```

```
study.setPhaseCode("Phase II Trial");
```

```
AdverseEvent ae = new AdverseEvent();
```

```
ae.setGrade(Grade.SEVERE);
```

```
List<AdverseEvent>
```

```
adverseEvents = adverseEventQueryService.getByStudy(study , ae);
```

In this example study object is populated with phase and AdverseEvent Object is populated with Grade. Service performs search only based on phase and Grade.

Generate XML Results

Pass the result list of AdverseEvents to the following method to get results in XML format. String xml = adverseEventQueryService.getXML(List<AdverseEvent adverseEvents>

? Please refer to the API for all available methods.

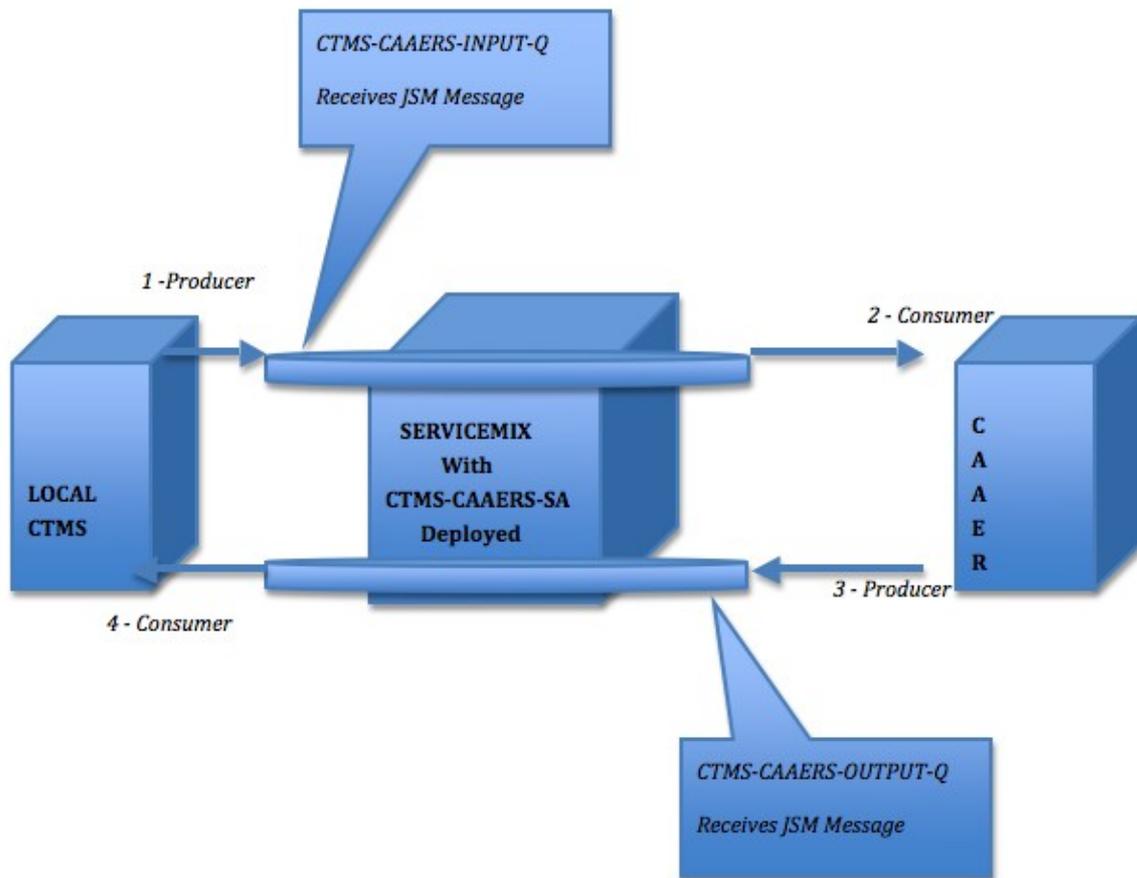
<https://gforge.nci.nih.gov/plugins/scmsvn/viewcvs.php/trunk/projects/core/src/main/java/gov/nih/nci/cabig/caaers/api/>

caAERS Messaging and Services

Asynchronous mode of importing data into caAERS using JMS

Technical Overview

caAERS supports asynchronous mode of message exchange. The different types of message's supported by caAERS are Study, Participant, Investigator and Research Staff. Apache ServiceMix is the ESB (Enterprise Service Bus) used to accomplish the message exchange. Apache ServiceMix has JMS support using ActiveMQ. The figure below is a high level overview of the message exchange process.



Message Exchange Flow

1. Local Ctms system produces / generates a JMS Message, the payload of the JMS Message will be the actual message to be exchanged. The JMS Message is then delivered to the CTMS-CAAERS-INPUT-Q. The payload of the JMS Message is an XML document, which can be Study, Participant, Investigator or ResearchStaff messages, the xml document should conform to their respective schema. For e.g. Study Xml Document should conform to StudySchema.xsd. Participant Xml document should conform to ParticipantSchema.xsd, so on and so forth.
2. caAERS has a consumer configured to receive JMS Messages from CTMS-CAAERS-INPUT-Q. Once the message is received, caAERS validates the message and process the message.
3. Once the Processing is complete caAERS produces / generates appropriate response message and delivers the message to CTMS_CAAERS-OUTPUT-Q. The response message is also a JMS Message and the payload of the JMS Message will contain an XML document with the actual details.
4. Local Ctms system configures a consumer to receive response messages on CTMS-OUTPUT-Q. Upon receipt of the response ctms system process's the response as desired.

Message Identification

Every JMS message produced / generated by the local ctms system, should contain a Unique ID. This Unique ID is set in the JMS header field. The JMS header field, which holds this unique ID, is referred to as JMSCorelationID. caAERS sends the same JMSCorelationID with the response it generates for every request message. This way the Response received can be matched to the request sent.

Message Types

There are 8 message types which caAERS supports. Listed below are the message types:

- CREATE_STUDY
- UPDATE_STUDY
- CREATE_PARTICIPANT
- UPDATE_PARTICIPANT
- CREATE_INVESTIGATOR
- UPDATE_INVESTIGATOR
- CREATE_RESEARCHSTAFF
- UPDATE_RESEARCHSTAFF

When the local ctms system produces / generates a JMS Message, a JMS header key "MESSAGE_KEY" needs to be set with the value being one of the message types mentioned above. Caers consumer requires this MESSAGE_TYPE value, to decipher the appropriate course of action.

References

SampleMessageConsumer	
SampleMessageProducer	
SampleMessages	Study / Participant Sample Data
Caers Schema Files	

Synchronous mode of importing data into caAERS using Webservices

Overview

The different types of message's supported by caAERS are Study, Participant, Investigator and Research Staff. caAERS exposes 4 different Webservice's. The webservices are named as StudyService, ParticipantService, InvestgatorService and ResearchStaffService. Once caAERS is up and running, the url provided can be used to get to the page where all the caaers web services are listed. <http://<host>:<port>/caaers/services>

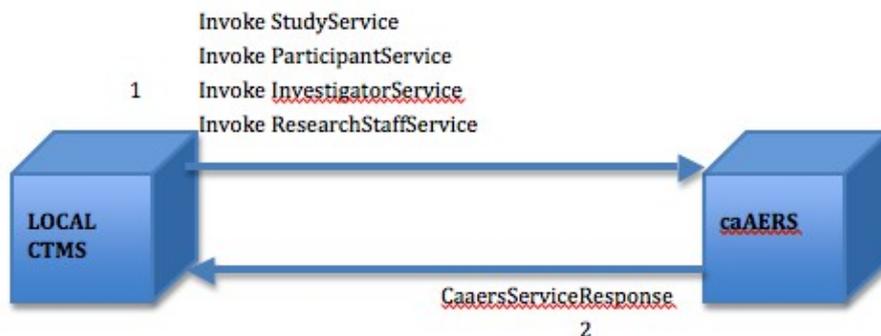
The URL's provided below can be used to access the WSDL of each of the service mentioned above (<host> & <port> to be replaced accordingly):

- <http://<host>:<port>/caaers/services/StudyService?wsdl>
- <http://<host>:<port>/caaers/services/ParticipantService?wsdl>
- <http://<host>:<port>/caaers/services/InvestgatorService?wsdl>
- <http://<host>:<port>/caaers/services/ResearchStaffService?wsdl>

Note

caAERS demo site has the webservices hosted. If need be the wsdl's can be looked up here. To test the actual imports install caAERS locally and use the webservices hosted on the local instance of caAERS. <http://sbdev1000.semanticbits.com:18030/caaers/services> (Please do not use this for testing purposes)

The Figure below is a high level overview of the Webservice Call to caaers.



Call Flow

1. Local Ctms system produces / generates an XML document, which can be Study, Participant, Investigator or ResearchStaff, the xml document should conform to their respective schema. For e.g.

Study Xml Document should conform to StudySchema.xsd. Participant Xml document should conform to ParticipantSchema.xsd, so on and so forth. The xml document should then be wrapped in SOAP Message. The Soap Header of the Soap Message is not required. This Soap Message is then used to invoke the relevant webservice in caAERS.

2. caAERS processes the request and sends back a Soap Message. This response will contain the outcome of caAERS processing.

caAERS Excel Import Utility

Importing Data via Excel Import

Prerequisites

1. JDK1.5 or Later.
2. Ant 1.6 or Later. Please refer to Ant Installation.
3. caAERS source. Please checkout caAERS source from Gforge.

Procedure to use the importexcel target

1. Open a command prompt or a Terminal Window.
2. Change to the directory where caAERS source is checked out/downloaded.
3. Execute the below given command
4. **ant importexcel -Dfilelocation=<<excel file>> examples**

1. *ant importexcel -Dfilelocation=C:\temp\validstudy.xls*

2. *ant importexcel -Dfilelocation=/Users/Moni/temp/Mayo-22-protocols-v1.xls*

5. Excel Import Summary is displayed in the Command Prompt or Terminal Window.

Excel Formatting Information

1. No cell can be blank or have unprintable characters ['\n,\t'] etc.
2. No sheet should have rows with duplicate information.
3. The database must have associated information available [for example: LOVs for organizations, agents etc]
4. The number '0' is not a valid value
5. In case some information is not available [like investigator phone number], the word 'null' should be mentioned as a placeholder.

6. There should be exactly one sheet with each of the following sheetnames:

- admin info
- agent info
- disease info
- TAC info
- organizations
- investigators
- therapies

7. The information will be mapped to the study object as follows:

- Primary Funding Sponsor: CTEP
- Short Title: Local Document Number
- AE Terminology = CTC
- Disease Terminology = CTEP
- MultiInstitutionIndicator: Yes

Please refer to the [Excel Samples](#) further understanding.

Note

The above command, can be executed from the machine where caAERS is installed or from any other machine.

If executed from a machine where caAERS is NOT installed, the user should have to provide the database information to the importexcel utility. To do this, user will have to create a .cafers folder under USER_HOME directory. This directory should contain a file referred to as datasource.properties. The content of this file depends on which database is being used by caAERS, Oracle or Postgres ? accordingly copy content from the [templates](#) provided and paste them in the datasource.properties file, replace correct datasource.url , datasource.username and datasource.password and save the datasource.properties file. After the datasource information is provided follow the procedure outlined above.

Appendix A. References

Technical Articles

1. Foundations of Object-Relational Mapping: <http://www.chimu.com/publications/objectRelational/>

2. Object-Relational Mapping articles and products:
<http://www.service-architecture.com/object-relational-mapping/>

3. Hibernate Reference Documentation: http://www.hibernate.org/hib_docs/reference/en/html/
4. Basic O/R Mapping: http://www.hibernate.org/hib_docs/reference/en/html/mapping.html
5. Java Programming: <http://java.sun.com/learning/new2java/index.html>
6. Javadoc tool: <http://java.sun.com/j2se/javadoc/>
7. Extensible Markup Language: <http://www.w3.org/TR/REC-xml/>
8. XML Metadata Interchange: <http://www.omg.org/technology/documents/formal/xmi.htm>

Scientific Publications

1. Cancer Therapy Evaluation Program, "Common Terminology Criteria for Adverse Events, Version 3.0", ctep.cancer.gov/forms/CTCAEv3.pdf
2. Cancer Therapy Evaluation Program, "Adverse Event Expedited Reporting System (AdEERS)", ctep.cancer.gov/forms/CTCAEv3.pdf
3. Cancer Therapy Evaluation Program, "CTEP, NCI Guidelines: Adverse Event Reporting Requirements", http://ctep.cancer.gov/reporting/newadverse_2006.pdf
4. Division of Cancer Prevention, "DCP Serious Adverse Event Reporting Procedures and Guidelines", <http://dcp.cancer.gov/clinicaltrials/management/consortia/step-3/adverse>
5. Division of Cancer Prevention, "DCP Serious Adverse Event Reporting Form", http://dcp.cancer.gov/Files/clinical-trials/sae_guidelines.doc
6. FDA, "The FDA Safety Information and Adverse Event Program?", <http://gforge.nci.nih.gov/projects/cts/>

caBIG Material

- caBIG: <http://cabig.nci.nih.gov/>
- caBIG Compatibility Guidelines: http://cabig.nci.nih.gov/guidelines_documentation
- caBIG Clinical Trial Suite Project Site: <http://gforge.nci.nih.gov/projects/cts/>

caGrid Material

- caGrid: <http://www.cagrid.org/mwiki/index.php?title=CaGrid>

caCORE Material

- caCORE: <http://ncicb.nci.nih.gov/core>
- caBIO: <http://ncicb.nci.nih.gov/core/caBIO>
- caDSR: <http://ncicb.nci.nih.gov/core/caDSR>
- EVS: <http://ncicb.nci.nih.gov/core/EVS>
- CSM: <http://ncicb.nci.nih.gov/core/CSM>

Appendix B. Glossary

The following is a list of terms and their definitions that you may find useful as you work with caAERS.

Term	Definition
AdEERS	Adverse Event Expedited Reporting System
API	Application Programming Interface
caArray	cancer Array Informatics
caBIG	cancer Biomedical Informatics Grid
caBIO	Cancer Bioinformatics Infrastructure Objects
caCORE	cancer Common Ontologic Representation Environment
caDSR	Cancer Data Standards Repository
caMOD	Cancer Models Database
cardinality	Cardinality describes the minimum and maximum number of associated objects within a set
CSM	Common Security Module
CTEP	Cancer Therapy Evaluation Program
CUI	Concept Unique Identifier
CVS	Concurrent Versions System
EVS	Enterprise Vocabulary Services
GAI	CGAP Genetic Annotation Initiative
HTTP	Hypertext Transfer Protocol
JDBC	Java Database Connectivity

JET	Java Emitter Templates
JMI	Java Metadata Interface
JSP	JavaServer Pages
LLT	Lowest Level Term
MedDRA	Medical Dictionary for Regulatory Activities
metadata	Definitional data that provides information about or documentation of other data.
multiplicity	Multiplicity of an association end indicates the number of objects of the class on that end may be associated with a single object of the class on the other end
NCI	National Cancer Institute
NCICB	National Cancer Institute Center for Bioinformatics
OIL	Ontology Inference Layer
OilEd	Ontology editor allowing you to build ontologies using DAML+OIL
PT	Preferred Term
SQL	Structured Query Language
SSC	Special Search Categories
SOAP	Simple Object Access Protocol
UML	Unified Modeling Language
UMLS	Unified Medical Language System
UPT	User Provisioning Tool
URL	Uniform Resource Locators
WSDL	Web Service Descriptive Language
XML	Extensible Markup Language