caAERS V1.5 Admin Guide

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
V1.5	9/28/2008	Elizabeth Nobriga	Updates for V1.5

Copyright and License page

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[1]	Jennifer Reed[1]	Edmond Mulaire[1]
Joshua Philips[1]	Paul Galvin[3]	Ram Chilukuri[1]
Rhett Sutphin[2]	Elizabeth Nobriga[1]	
Krikor Krumlian[3]		
Srini Akkala[1]		
Biju Joseph[1]		
Karthik Iyer[1]		
Jared Flatow[2]		
Sean Whitaker[2]		
Key Contributors		
Sharon Elcombe, MA[4]	Ann Setser[7]	John Speakman[9]
Robert Morrell[5]	Anne Tompkins[8]	Christo Andonyadis[9]
Sonja Hamilton[4]		Warren Kibbe, Ph.D.[2]
Jennifer Frank[4]		Cal Collins[3]
Kim Livengood[5]		Lisamarie Schick[6]
Jean Hanson[4]		
Jennifer Sorbo[4]		
Steven Cheng[5]		
Larry Esser[4]		
Renee Webb, MA, CCRC[2]		
David Patton[2]		
[1]SemanticBits [2]Northwestern University [3]Akaza Research [4]Mayo Clinic [5]Wake Forest University [6]Booz Allen Hamilton [7]CTEP [8]DCP [9]NCI CBIIT		

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***
Caaers-News	Caaersappdev-news@gforge.nci.nih.gov	caAERS Public Listserv
Caaers-Technical	caaersappdev-technical@gforge.nci.nih.gov	caAERS Technical Listserv

Table of Contents

Overview

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 and is interoperable with other caBIG-compliant Clinical Trial Management System (CTMS) components.

Components of the Software

The caAERS application has six tabs:

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

Each of the tabs is used to collect or provide specific information. Used together, the tabs track, maintain, and report any adverse events that occur during a clinical study at any of the participating organizations. For information on the caAERS Administration and Rules tabs, see the caAERS Admin Guide.

System Requirements

caAERS is a web-based application. To access and use 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.

Resetting Your 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.

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 **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 **Username**.
5. Enter a new password.
6. Re-Enter the 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

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 (such as the Back or Forward buttons) should not be used. 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

To launch caAERS, open a web browser and enter the caAERS web address (provided by your system administrator). From here, you'll be asked for your username and password to log in. 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. The number of times and duration of lockout are features set up by your caAERS administrator during configuration. For assistance with your user name and password, contact your administrator.

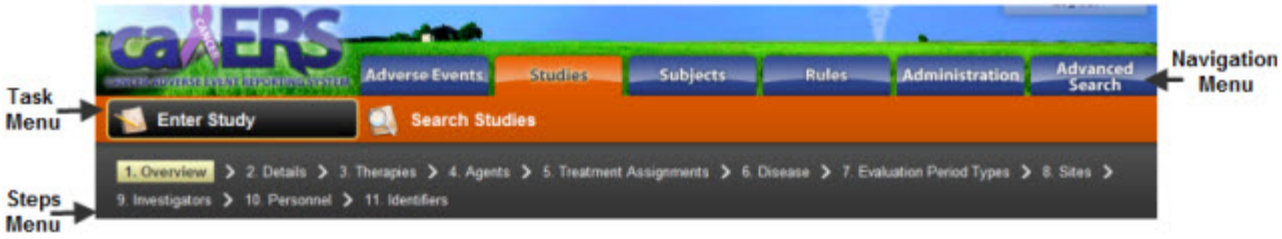
Exiting the application

To exit or logout of the caAERS application, click the Log out 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 tab 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), and the Steps menu (bottom row). Each page will also contain buttons to help navigate through the tasks.

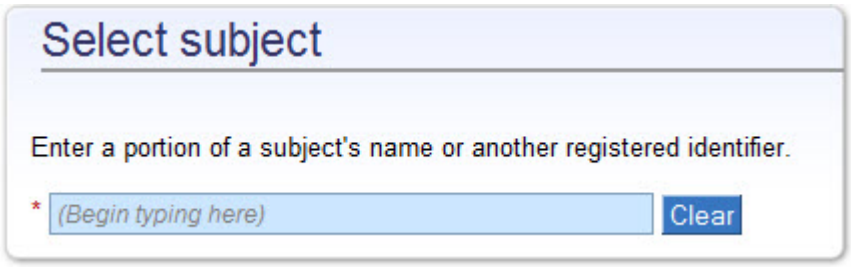


- **Navigation Menu:** The navigation menu allows access to the tabs. To access a tab, click on the tab, in the example above, the **Studies** tab is selected.
- **Task Menu:** Each tab may have multiple tasks associated to it, which are displayed in the Task menu. To access a task, click on it, for example, **Enter Study**.
- **Steps Menu:** Some tasks may have multiple steps, which are displayed in the steps menu. The step you are on is highlighted, for example **Overview**. In some tabs, if you are required to enter information for 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 pages for each step.
- **Buttons:** Many of the pages have task specific navigation buttons, which are described below.
    - **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.

Application Help

Instructions for the tab/task page If you select a tab or a task, you will often see instructions at the top of the page explaining the purpose of the tab and what information you need to supply.

Instructions for a field Similarly, some fields on a page for a tab or task will include instructions concerning the information you need to provide.
For Example:



In-line page help 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 tabs. 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.

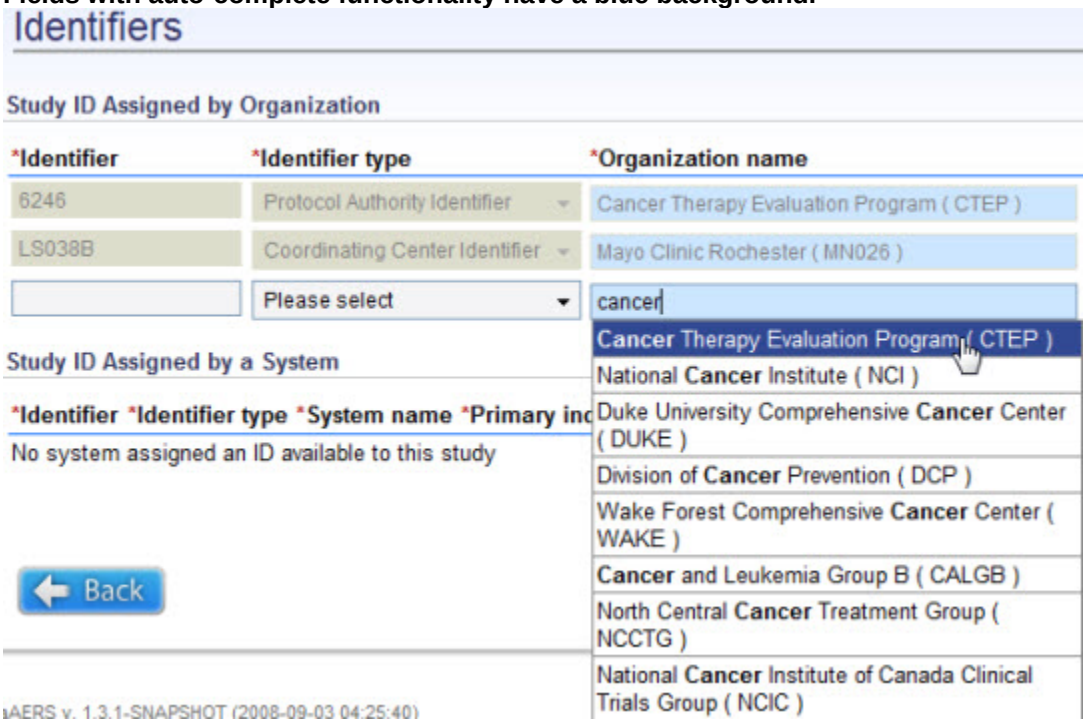
Important Interface features

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

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

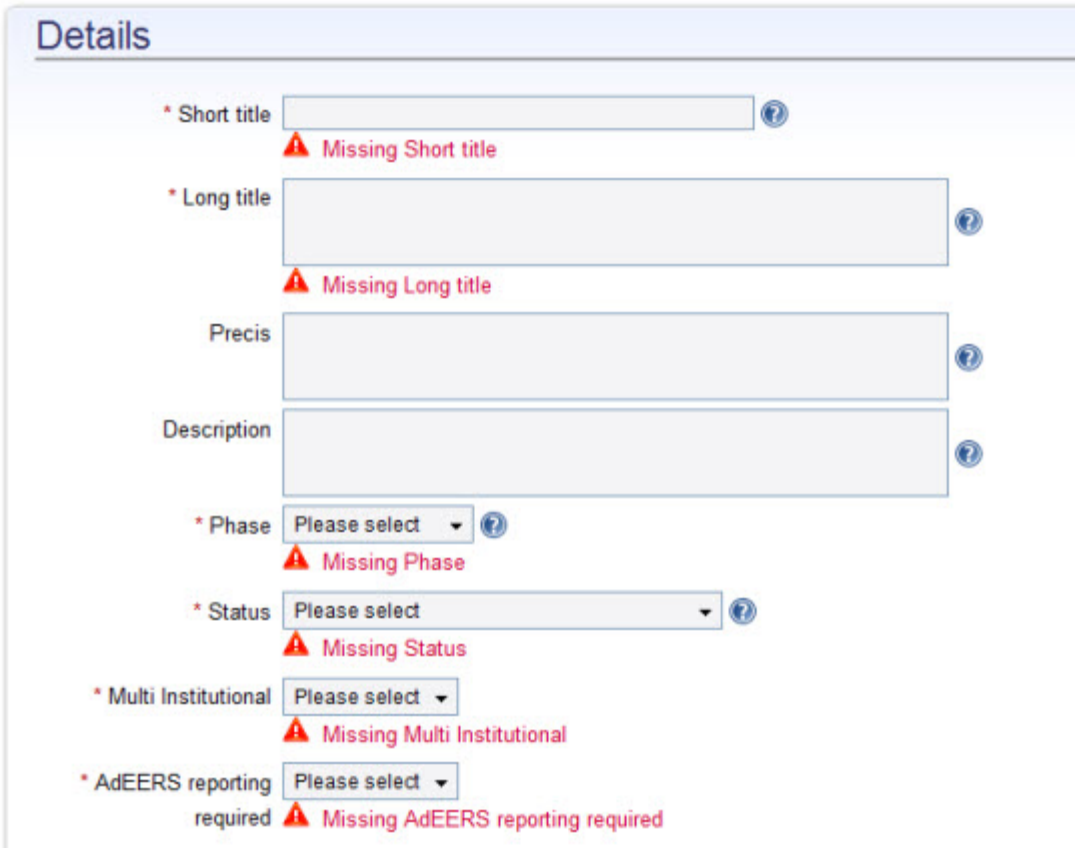
Auto-complete functionality
Several caAERS fields are built with an auto-complete function, similar to what you find when using Google search. If a field has auto-complete enabled, it will bring up a list of possible matches when you start to type. For example, if you type **cancer** in a field with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

Fields with auto-complete functionality have a blue background.



Search functionality There are two main search areas in caAERS: the Advanced Search Tab, which has tasks associated to many of the tabs, and search functionality directly associated to tabs and 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 fields/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. Required Information is identified by a red asterisk (*) to the left of the title (both field and section). 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.



Administration Tab

Configure caAERS

Click the **Administration** tab in the navigation bar. caAERS is installed with empty configuration information. You will need to enter information in the **Configure caAERS** task page 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.

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

Field Name	Description/Notes	Mail Server config	CCTS 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 sending e-mails – for alerts, reminders, and submission of some reports. In order to successfully send e-mails, caAERS must be set up to use a working Mail Server.

To configure caAERS to work with your mail server:

1. Click the **Administration** tab to go to the **Configure caAERS** task page
2. Enter the **SMTP server**. This is The address of the outgoing mail server (e.g.: smtp.gmail.com).
3. Enter the **SMTP password**. This is only necessary if the mail server requires authentication.
4. Enter the **SMTP port**, if different than 25.
5. Select **Yes** or **No** for **Secure SMTP?**.
6. Enter the **SMTP user name**. This is only necessary if the mail server requires authentication.
7. Enter the **From address**. The "from" address for all mail sent by caAERS. This address does not have to be a real e-mail address.
8. 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

If you plan to use caAERS as a tab 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 the **Administration tab**.
2. Enter **ESB queue URL**. This is the URL for the enterprise service bus -- the value may not be applied until the application is restarted.
3. Enter the **LabViewer base URL**. This is the base URL for the LabViewer deployment to which this caAERS instance can link.
4. Enter the **Study Calendar base URL**. This is the base URL for the Study Calendar deployment to which this caAERS instance can link.
5. Click **Save** .

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

Investigator

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.

To Create/Edit an Investigator:

1. Click the **Administration** tab and click **Investigator** in the task menu.
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**. This is a pre-populated field. Enter the first few letters of the name of the Organization the Investigator is associated with and select it from the drop down menu that appears.
10. Select **Inactive** or **Active** from the **Status** drop down box.
11. If the Investigator works with another Organization, click **Add Organization** and repeat the steps above.
12. Click **Save**. If you entered information correctly into all the required fields you will see a confirmation message stating that the system has **Successfully saved the investigator**.

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

Searching for an Investigator

1. Click the **Administration** tab and click **Investigator** in the task menu and then click **Search Investigator** in the steps menu.
2. In the **Investigator Criteria** box enter in the First Name, Last Name, and/or the Investigator number field and then click **Search**.
   Note: You can also leave the fields blank and click **Search** to list all Investigators.

3. The Investigators available will be listed in the bottom of the page. You can sort the search results by entering the appropriate information in the **First Name**, **Last Name**, **Middle Name** or **NCI Institute Code** text fields top of each column and then clicking the **Filter** button in the top right hand of the **Search Results** box.
4. Click on the **First Name** of an investigator in the search results to view and/or edit the investigator profile.

Research Staff

Click the **Administration** tab and click **Research Staff** in the task menu. All users of the caAERS system have accounts, although their access rights vary. The Research Staff Page allows you to create the user accounts and assign their roles. 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 tabs; the user can document AEs and create reports, studies, and subjects
- **Study Coordinator** – Provides access to the Studies tab; the user can review studies, AEs, and expedited reports
- **Adverse Event (AE) Coordinator** – Provides access to the Adverse Events tab; the user can view and report AEs for studies they are assigned to
- **Site Coordinator** – Provides access to the Adverse Events, Studies, Rules, and Administration tabs; the user can report AEs, create studies, set up rules, and have access to administrative features of the application.
  Note: The only tasks the site coordinator doesn't have access to is documenting AEs.

If there is an **X** in the box, it means that role has access to that feature.

	System Admin	Site Coordinator	Study Coordinator	AE Coordinator	Subject Coordinator
AE Tab					
Manage Reports (View AEs)	**X**	**X** (for assigned studies)	**X** (for assigned studies)	**X** (for assigned studies)	**X** (for assigned studies)
Create/Edit AEs	**X**			**X** (for assigned studies)	**X** (for assigned studies)
Studies Tab					
Create/Edit AEs	**X**	**X**	**X**		**X** (for assigned studies)
View	**X**	**X**	**X**		**X** (for assigned studies)

Subjects Tab					
Create and Assign/Edit	**X**				**X** (for assigned studies)
View	**X**				**X** (for assigned studies)
Rules Tab					
Create/Edit Rules	**X**	**X**			
View Rules	**X**	**X**			
Create/Edit Report Definitions	**X**	**X**			
View Report Definitions	**X**	**X**			
Administration Tab					
Create/Edit Users	**X**	**X**			
Create/Edit Investigators	**X**	**X**			
Import Studies/Subjects	**X**	**X**			
Import AEs	**X**	**X**			
Import Subjects	**X**	**X**			
Import MedDRA	**X**	**X**			
IND #	**X**	**X**			
Create/Edit Organizations	**X**	**X**			
Configure Password Policy	**X**	**X**			

Creating an account

1. Click the **Administration** tab and click **Research Staff** in the task menu.

2. Enter the **Organization**. This is a pre-populated field. Enter the first few letters of the name of the organization you are looking for and select it from the drop down menu that appears.
   Note: If you do not see the name of the organization in the drop down list you will need to add it. To do so, go to the **Creating an Organization** section of this guide for instructions.
3. Enter the user Details. The e-mail address is also the user name.
4. Select the appropriate checkboxes the **User Role**.
5. Click **Save & Continue**.

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

Searching for an account

1. Click the **Administration** tab, click **Research Staff** in the task menu and then click **Search Research Staff** in the steps menu.
2. Enter **Research Staff Criteria** in the First Name, Last Name, and/or the Organization fields and click **Search**.
   Note: You can also leave the fields blank and click **Search** to list all Research Staff.
3. Search results will be listed in the bottom of the page. You can sort search results by entering the appropriate text in the **First Name**, **Middle Name**, **Last Name** and **Organization** text fields at the top of each column and clicking the **Filter** button in the top right corner of the **Search Results** section.
4. Click the **First Name** of an individual to view and/or edit their profile.

Import

Studies, subjects, routine AEs, Investigators and Research staff can be imported into caAERS. If you have previously used other applications and databases to maintain this information you can import it instead of manually entering it. To import studies, subjects, Routine AEs, Investigators or Research staff 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 XLM 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:

1. Create an XML file containing the information you want to import.
2. Click the **Administration** tab and click **Import** in the task menu.
3. Click on **Import Study/Protocol**, **Import Subject**, **Import Routine AEs**, **Import Investigator** or **Import Research Staff**.
4. Click **Browse** to locate and select the XML file that contains the information.
5. Click **Save** or **Save & Continue**.
6. 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
7. To verify the information imported correctly, use the search task in the **Adverse Events**, **Studies**, or **Subjects Tab**.

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 mach the allowed format, the import will fail.

To import MedDRA files:

1. Locate the folder where MedDRA is stored.
2. Click the **Administration** tab and click **Import MedDRA** in the task menu.
3. Enter the full path to the file into the field and click **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. Click the **Administration** tab and click **IND#** in the task menu
2. Enter the **IND #**
3. Click the **IND held by?** drop down box to select **Organization** or **Investigator**.
4. Enter the **IND Holder**. This is a pre-populated field. Enter the first few letters of the name of the IND Holder and select it from the drop down menu that appears.
5. Click **Save**.

Searching for an IND

1. Click the **Administration** tab, click IND# in the task menu and click **Search IND#** in the steps menu.
2. Enter search criteria in the **IND #** and/or the **IND holder** field and then click **Search**.
   Note: You can leave the fields blank and click **Search** to list all INDs.
3. The INDs will be listed in the bottom of the page. You can sort search results by entering appropriate information for **IND #** and/or **Sponsor Name** in the text fields at the top of each column and clicking the **Filter** button the the top right corner of the **Search Results** section.

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 the **Administration** tab, click **Organization** in the task menu, click **Search Organization** in the steps menu 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 leave the fields blank and click **Search** to list all Organizations.
3. The Organizations available will be listed in the bottom of the page. You can sort the search results by entering the appropriate information in the **Name** and/or the **NCI Identifier** text fields at the top of each column and then clicking the **Filter** button in the top right corner of the **Search Results** section.

4. To view and/or edit an organization listed in the search results, mouse over the Name and click on it.

Create an Organization

1. Click on the **Administration** tab and click **Organization** in the task menu 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.

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. Click the **Administration** tab and click **Configure Password Policy** in the task menu.
2. Enter **Maximum password age** – this determines how long a user can keep a password before having to reset it.
3. Enter **Number of allowed failed login attempts**.
4. Enter the **Lockout duration** – this determines how long a person is locked out of the system after entering the wrong password the number of allowed times.
5. Enter the **Minimum password age** – this prevents a user from recreating their password numerous times in a row to go back to the same password.
6. Enter the **Password history size** – this determines how many past passwords you keep in the system for a user.
7. Enter **Minimum password length**.
8. Select the appropriate checkboxes for the **Complexity Requirement**.
9. Enter largest substring of username allowed – this prevents users from having their password too similar to their user name.
10. Click **Save**.

Rules Tab

Manage & Create Rules

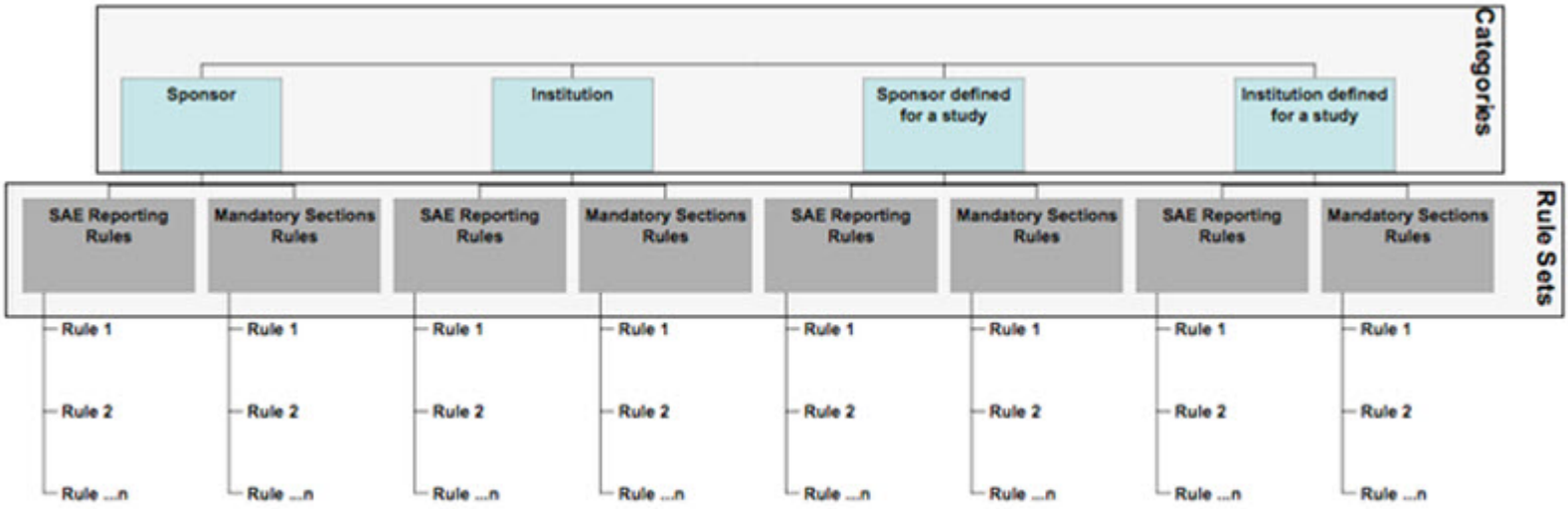
To create and manage rules click the **Rules** tab in the navigation bar.
There are four categories (or Rule Levels):

- 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.



For example: If you are 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 five sections:

1. Select Category (Rule Level)
2. Select Ruleset
3. Create Rules
4. Review
5. Enable Rule Set

1. Select Category

The first step for creating rules is to determine what category the rule falls in. Click the Rules tab in the navigation bar. 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. Make a selection in the **Rule Level** section and the associated text field will appear on the page.
2. Enter information into the fields that appear. This may mean you're entering a Sponsor or an Institution, with the possibility of entering a study.
   Note: These are pre-populated fields. Enter the first few letters of the name of the **Sponsor** or **Institution** you are looking for and select it from the drop down menu.

3. Click **Continue**.

2. Select Ruleset

The next page allows you to select the rulesets. 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 the Ruleset that already exists. Making changes to an existing Ruleset will not create a separate Ruleset.

1. Select the radio button next to an existing Ruleset in the **Rule Set** section.
2. Click **Continue**.

If no rulesets exist you will need to create a Rule Set.

3. Create Rules

1. Click the **Create Rule Set** button.
2. Select one of the options from the **Rule Set Name** field.
3. Click the **Continue** button.

On the **Rules** page you can add rules to the Ruleset by clicking the **Add Rule** button in the right hand side of the page.
Note: If you chose an exiting Ruleset for the Sponsor or Institution category, there may be rules 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 do not have to enter the information again. You can then add or delete rules.
Important: Changes you make by following these instructions only apply to the ruleset associated with the Sponsor defined for a study or Institution defined for a study category. Changes do not apply for the original Sponsor or Institution category.

1. Click **Add Rule** in the right hand side of the page and a form will appear that will allow you to define the rules that go with the Ruleset. There are four drop down boxes.
2. **Select Domain Object:** Select Adverse Event, Study, or Report Definition from the Domain Object drop down menu.
3. **Select Field:** Select an option from the Field drop-down menu. The options available are dependent on what was selected as the Domain Type.
4. **Select operator:** 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 Value:** Select a value from the Value drop-down menu. The options will vary based on the Domain Object and Field selected.

6. If there are additional conditions you want to assign to this Rule, click on the Plus () icon and repeat the steps above.
   Note: All of the conditions listed must be met for the Rule to be completed and saved in the system. If you do not require all the conditions to be met, create a separate Ruleset.
   Note: You can remove conditions by clicking on the Red x icon.
   Continue to step 7 if there are no additional conditions to assign to this Rule.
7. Select an option from the **Action** box.
8. To continue, click the **Continue** button. To add another rule, click **Add Rule** and repeat the steps above. To delete a rule, click the icon,  , in the right-hand corner of the rule.

4. 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 **Back** to go back and make changes.

5. Enable Rule Set

All new rules sets are given the status of Not Enabled. Go to the **Action** column and click **Enable**. Or you can leave the status as Not Enabled and return to the **List Rules** task page at a later time to enable it.

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. In addition, you can Export/Download the Ruleset to an XML file.

- **Enabling Rulesets**

Rulesets may have a Status of Not Enabled. 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 Rules

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 Gforger project site, http://gforge.nci.nih.gov/projects/caaersappdev/.

To import rulesets:

1. Click the **Rules** tab and click **Import Rules** in the task menu.
2. Click **Browse** to locate and select the XML file that contains the ruleset.
3. Click **Import**.
4. 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 it. Rulesets imported into caAERS should be obtained from the caAERS ruleset library or else they should be created in caAERS using the Ruleset XML export feature.

Create Report Definition

Click the **Rules** tab and click **Create Report Definition** in the task menu. 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 definition is done in five steps:

1. Basic Details – enter the general information for the report
2. Delivery Details – enter who receives the report
3. Mandatory Fields – enter what information is mandatory
4. Notifications – enter reminders for the report
5. Review – review the settings for the report

1. Basic Details

The Basic Details page defines the general information for the report. A red asterisk * next to a field means it is required information.

1. Enter the organization in the **Organization** field. This is a pre-populated field. Enter the first few letters of the name of the Organization you are looking for and select it from the drop-down menu that appears.
2. Enter a name in the **Name** field.
3. Enter a name in the **Display Name** field. Keep the name simple but descriptive.
4. Enter a **Description** if you want to add more information for the report.
5. Select **Yes** or **No** for **Amendable**. This field defaults to Yes, which means the report can be added.
6. Select **Yes** or **No** for **Report is expedited?**.
7. Make a selection from the **Report Format** drop down list. Format choices are: caAERS XML, AdEERS PDF, MedWatch 3500A PDF, DCP SAE PDF, CIOMS PDF and DCP Safety Report PDF.
   Note: The selection of Mandatory fields you can select from will vary in the following **Mandatory Fields** task page based on the Report Format you select.
8. Select **Yes** or **No** for **Attribution** required. This field defaults to No. If you change it to Yes, it means that any time an AE is reported on, it must be related to an attribute.
9. Select a value for **Time Scale UOM** (unit of measurement) from the drop down box. This value tells you the measurement of time before the report is due.

10. Enter a number for **Time until 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, you're setting the report to be due 5 days after you document the AE.
11. Click **Continue** to go to the next step.

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.

2. 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.

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 the **Add eMail** button.
2. Enter the Name. This can be the recipient's name or another way to identify the role.
3. Enter 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.

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. Fill in the **Name** field. This can be the recipient's name or another way to identify the email address.
3. Enter the appropriate information 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 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. Enter the **Name**. 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. Enter the **URL**.
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**.

3. Mandatory Fields

The mandatory fields page allows you to select the specific information to be included in the report. The selections are based on the sections of the report, where information is entered into the appropriate fields. The selections available on this page will depend on the Report Format you selected on the previous **Basic Details** page.

- Select **Optional**, **Mandatory** or **Not Applicable** from the drop down lists under each heading. Once you have completed your selections, click **Continue** to add notifications.

Note: This page is very long with multiple sections.

4. 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 the number from the **Time Scale** box. 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** and enter an email address or click **Add Role** to select a role from the list. You can add multiple recipients to the notification.
3. To add a variable, place your cursor where you want the variable to appear, then select the variable from the **Insert a substitution variable** drop down box.
4. Enter a **Subject Line**.
5. 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 a variable from the **Insert a substitution variable** drop down box.
6. Click **Reset** to clear the information, or **Delete** to completely remove the notification, or **Continue** to review the report.

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 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 box. 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.

5. Review

The Review page allows 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

Click the **Rules tab** and click **List Report Definitions** in the task menu. 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 **Name** of the report definition. This will open the definition in create/edit mode.

Working with AdEERS

caAERS is capable of sending AE reports to AdEERS. However, the systems are independent of each other so a platform independent and context-free communication approach was developed. 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 the following:

- Report Definitions
- Studies
- Expedited Reports

Report Definitions

AdEERS communication is set up through the report definition tab 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. In the **Report Delivery Details** step you need to add the URL of the web server for AdEERS.

- Go to the **Report Delivery Details** section of this guide for step-by-step instructions. If you do not have the URL for the AdEERS web server, contact AdEERS 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** task page of the **Create Study** process. See the caAERS End User Manual for step-by-step instructions on how to require AdEERS reporting in the Details task page.

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. Go to the **Find Out If AEs Require Reporting** section in the caAERS End User Guide for step-by-step instructions.

Support

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

References

Technical Articles

- Foundations of Object-Relational Mapping: http://www.chimu.com/publications/objectRelational/
- Object-Relational Mapping articles and products: http://www.service-architecture.com/object-relational-mapping/
- Hibernate Reference Documentation: http://www.hibernate.org/hib_docs/reference/en/html/
- Basic O/R Mapping: http://www.hibernate.org/hib_docs/reference/en/html/mapping.html
- Java Programming: http://java.sun.com/learning/new2java/index.html
- Javadoc tool: http://java.sun.com/j2se/javadoc/
- Extensible Markup Language: http://www.w3.org/TR/REC-xml/
- XML Metadata Interchange: http://www.omg.org/technology/documents/formal/xmi.htm

Scientific Publications

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

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/ccts/

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

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 Tab
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