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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.

Before You Begin

caAERS Administrators must enter pre-populated data for Investigators, Research Staff, Organizations, Studies and Registrations before end users can enter and save information into the caAERS application. If you are an Administrator and this is your first time using the caAERS application after it has been installed and configured, please go to the caAERSV1.5 Administration Guide.

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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

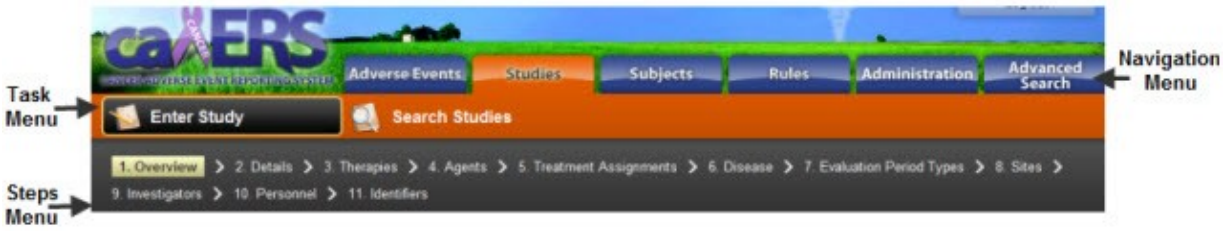
To launch caAERS, open a web browser and enter the caAERS web address (provided by your system administrator). From here, you?ll be asked for your username and password to log in. If you sign in with the wrong username or password, you will receive the message, ?Incorrect username and/or password. Please 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.



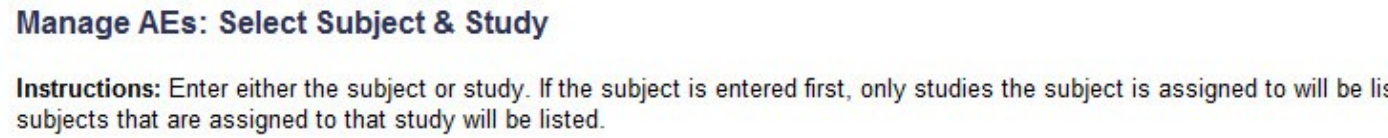
- **Navigation Menu:** The navigation menu allows access to the tabs. To access a tab, click on the tab, in the example above, the **Studies** tab is selected.
- **Task Menu:** Each tab may have multiple tasks associated to it, which are displayed in the Task menu. To access a task, click on it, for 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.

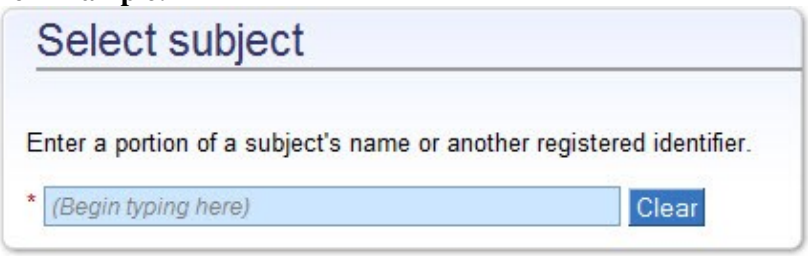
- **Save and Back** ? When selected, caAERS will save the data and then take the user to the previous page.
- **Continue** ? When selected, the user will move to the next page of the application. If any information was added to the page, it will be saved.
- **Save** ? When selected, the information on 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 When 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.
For Example:



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.

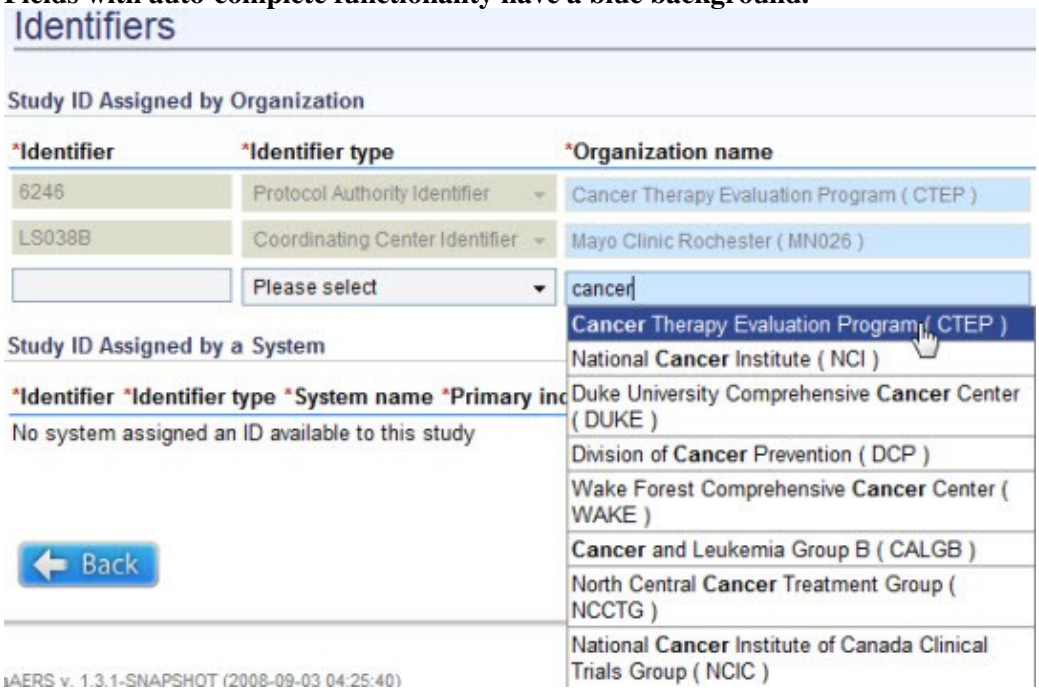
Online Help There is online help available for most tabs. To access the help, click on the icon, , located in the top right-hand corner. The help for the page you?re on will appear in another browser or on a separate tab. An index of the help content will also appear on the left-hand side of the window.

Important Interface features

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

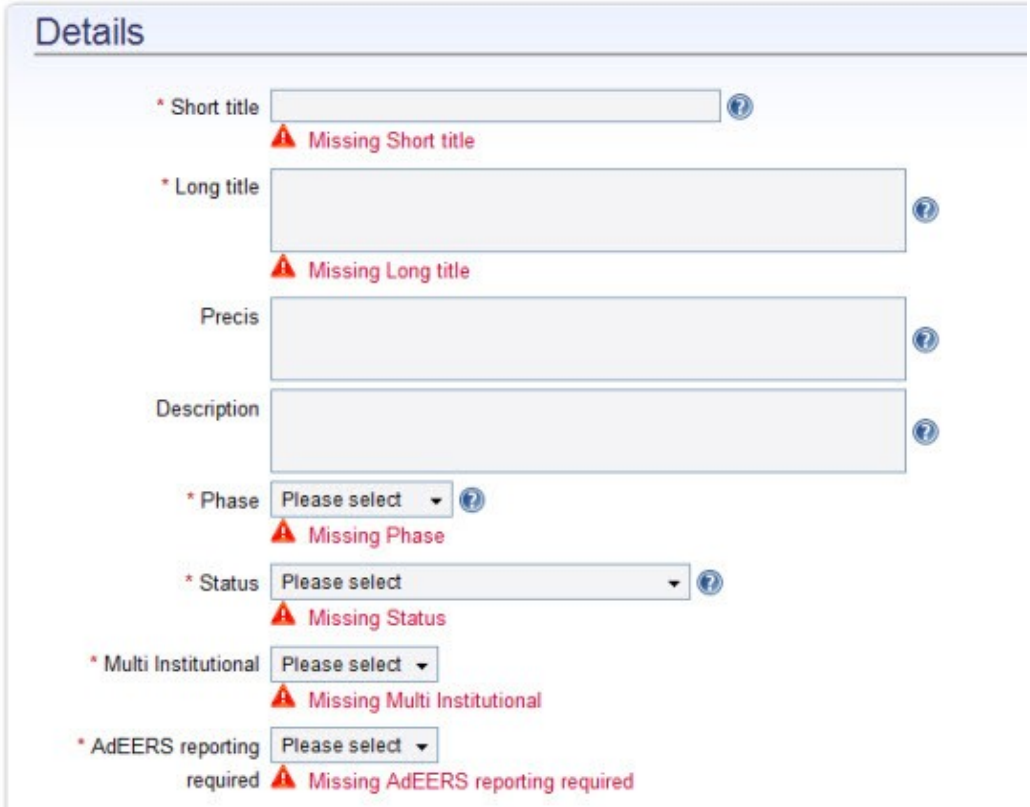
- Auto-complete functionality
- Search function
- Required fields/missing information

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.



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User Roles

Role Definitions

- **System Administrator (super user)** - Responsible for maintaining the caAERS hardware and software; has access to all modules in caAERS; resolves user issues
- **Site Coordinator** - Responsible for maintaining information about the site
- **Subject Coordinator** - Responsible for adding subjects and reporting adverse events
- **Study Coordinator** - Responsible for setting up the study in the system, creating the protocols, defining adverse events, and setting the general parameters of a study
- **Adverse Event (AE) Coordinator** - Responsible for reviewing adverse events as they are defined by the study or sponsor

The following section explains the different user's roles and lists the modules (tabs in caAERS application) with the details of operation that user having the selected role can perform.

Content Filtering

Organization based filtering:

- **Coordinating Center** - Typically a Co-op group or a Lead organization. The Coordinating Center for a study can see all of the data for all of the Study Sites on that study.
- **Study Site** - A study site user can only see data for the site to which they belong. They cannot see any data for any other sites on the study.

Study assignment filtering:

- **System Administrator (super user)** - No content filtering is applied based on Site or Study assignment.
- **Site Coordinator** - No Study assignment filtering applies, however, the Organization based filtering does apply (e.g. A Site Coordinator at a Study Site can only see data for the study site, where as a Site Coordinator at a Coordinating Center can see data for all study sites on the given study).
- **Study Coordinator** - No Study assignment filter applies for Study queries and on the Study module. Site filtering only should apply on these components. The reason for this is that a Study Coordinator will be creating studies and assigning personnel to studies and thus need access to Study information at an organization level. Study assignment filtering should apply to this role for all other application privileges.
- **AE Coordinator** - Study level filter applies to all application privileges.
- **Subject Coordinator** - Study level filter applies to all application privileges.

User Roles and Rights in caAERS

Each role provides access to different functions in caAERS. When you log in to

caAERS, you will only see the tabs and tasks that you have role authority for. The following table shows what functionality each role has access to.

✅ = rights/access
❌ or blank

= no rights or access If you feel you have not been assigned to the proper user role(s), contact your

caAERS Site Coordinator or System Administrator.

AE Module	AE Coordinator	Study Coordinator	Subject Coordinator	Site Coordinator	System Admin
AE Module tab	✅	✅	✅	✅	✅
document AEs • **evaluation periods** • **expedited reports** • **link from Manage report (when now AEs have**	✅ (for assigned studies)	❌	✅ (for assigned studies)	❌	✅

been documented yet)					
edit AEs • **evaluation periods** • **expedited report** • **Links from Manage reports (Submit, Amend, Withdraw, and report to PSC; hyperlink of expedited report and evaluation period)**	✔ (for assigned studies)	✖	✔ (for assigned studies)	✖	✔
View manage reports • **view details of evaluation periods, expedited reports, and routine AEs** • **Print PDFs of expedited reports** • **View expedited report in AdEERS**	✔ (for assigned studies)	✔ (for assigned studies)	✔ (for assigned studies)	✔	✔
Studies Module	**AE Coordinator**	**Study Coordinator**	**Subject Coordinator**	**Site Coordinator**	**System Admin**
Studies Module tab	✖	✔	✔	✔	✔
Create Study	✖	✔	✖	✔	✔
Edit Study	✖	✔	✖	✔	✔
View Study	✖	✔	✔ (for assigned studies)	✔	✔
Search Studies	✖	✔	✔ (for assigned studies)	✔	✔
Subjects Module	**AE Coordinator**	**Study Coordinator**	**Subject Coordinator**	**Site Coordinator**	**System Admin**
Subjects Module tab	✖	✔	✔	✔	✔
Create and Assign Subject	✖	✖	✔ (for assigned studies)	✔	✔
Assign a Subject to a Study (Subject already created)	✖	✔ (for assigned studies)	✔ (for assigned studies)	✔	✔
View Subject	✖	✔ (for assigned studies)	✔ (for assigned studies)	✔	✔
Search Subject	✖	✔ (for assigned studies)	✔ (for assigned studies)	✔	✔
Advanced Search Module					

	AE Coordinator	Study Coordinator	Subject Coordinator	Site Coordinator	System Admin
Advanced Search module tab	✔	✔	✔	✔	✔
Study Search	✖	✔	✔ (for assigned studies)	✔	✔
Subject Search	✖	✔ (for assigned studies)	✔ (for assigned studies)	✔	✔
Expedited Report Search	✔ (for assigned studies)	✔ (for assigned studies)	✔ (for assigned studies)	✔	✔
Rules module	**AE Coordinator**	**Study Coordinator**	**Subject Coordinator**	**Site Coordinator**	**System Admin**
Rules Module tab	✖	✖	✖	✔	✔
Create Rule	✖	✖	✖	✔	✔
Edit Rule	✖	✖	✖	✔	✔
Create Report Definition	✖	✖	✖	✔	✔
Edit Report Definition	✖	✖	✖	✔	✔
View Report Definition	✖	✖	✖	✔	✔
Admin module	**AE Coordinator**	**Study Coordinator**	**Subject Coordinator**	**Site Coordinator**	**System Admin**
Admin Module tab	✖	✖	✖	✔	✔
create/edit/search Organization	✖	✖	✖	✔	✔
create/edit/search Research Staff	✖	✖	✖	✔	✔
configure caAERS	✖	✖	✖	✔	✔
create/edit/search Investigator	✖	✖	✖	✔	✔
Import MedDRA	✖	✖	✖	✔	✔
IND	✖	✖	✖	✔	✔
Password Policy	✖	✖	✖	✔	✔
Import Study, Subject, Research Staff, Investigator	✖	✖	✖	✔	✔

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Studies tab

caAERS is used to track adverse events that occur in studies, so the studies must be added. All users can do this manually through the studies tab (except the Adverse Event Coordinator). Studies can also be imported from the local clinical trials management system. For information on importing studies, see the caAERS Administration Guide.

Enter Study

Click the **Studies** tab in the Navigation bar and click **Enter Study**. This will take you to the **Basic Details** task page. Creating a study is separated into 11 task pages:

1. Details
2. Therapies
3. Agents
4. Treatment Assignments
5. Disease
6. Evaluation Period Types
7. Expected AEs
8. Sites
9. Investigators
10. Personnel
11. Identifiers
12. Overview

Note: If you can?t enter all the information for the study in one sitting, complete the section you are on and then click the **Overview** section tab. This will allow you to save the study. To finish entering the information into the study at a later time, search for your saved study using the **Search Study** feature and click on it in the search results to open it and then click the **Edit** button.

To Create A Study:
Click the **Studies** tab in the Navigation bar and click **Enter Study** in the task menu. This will take you to the **Basic Details** task page.

1. **Details**
   The details section is where you enter the general information about the study.

   1. Enter a **Short title** (the title that the public will know the study by).
   2. Enter a **Long title** (the official title as provided by the investigator or sponsor).
   3. Enter a **Precis**, if desired (this is a short description of the primary purpose of the study, intended for the general public).
   4. Enter a **Description**, if desired (this is a detailed description of the study, including information not covered by other fields, such as comparison studies).
   5. Click the drop down list to select a **Phase**.
   6. Click the drop down list to select the **Status**.
   7. Click the drop down list to select Yes or No for **Multi Institutional**.
   8. Click the drop down list to select Yes or No for **AdEERS reporting required**.
   9. Click the drop down list to select the **Terminology**.
   10. Click the drop down list to select **CTC version**, if CTC was selected in step 9.
       OR
       Click the drop down list to select **MedDRA version** and go to step 12.
   11. Click the drop down list to select **Other MedDRA Version**.

12. Click the drop down list to select the **Disease coding Terminology**. You can select **CTEP**, **MedDRA**, or **Other-Specify**.
    Note: If you select **Other-Specify**, you will be asked to enter the terminology in the **Disease** task page of this form. If this study requires AdEERS reporting **do not** select the **Other-Specify** option.
13. Click the drop down list to select the **Study design**.
14. Select the appropriate checkboxes for **Expedited report formats**.
15. **Coordinating center:** Enter the first few letters of the name of the Coordinating center and select it from the drop down list that appears. **Note:** This is an auto-populated field. If the name you are looking for is not in the drop down list that appears, contact your caAERS system administrator.
16. Enter the **Coordinating center identifier**. This is the identifier that is found in the protocol.
17. **Funding Sponsor:** Enter the first few letters of the name of the Funding sponsor and select it from the drop down list that appears. **Note:** This is an auto-populated field. If the name you are looking for is not in the drop down list that appears, contact your caAERS system administrator.
18. Enter the **Funding sponsor identifier**. This is the identifier that is found in the protocol.
19. Click **Continue**.

2. **Therapies**
   There are five therapies that can be associated with the study:
   Agent
   Device
   Radiation
   Surgery
   Behavioral
   Select the checkbox next to any Therapy(s), if any, that will be used in the study and click **Continue**.
3. **Agents**
   If you selected **Agent** as a therapy on the previous task page, this is the page where you will add the specific agents. If you did not choose agent you can skip this step and click **Continue** to move to the next task page.
   To add an agent:

   1. Click the **Add Study Agent** button.
   2. **Agent:** Enter the first few letters of the name of the Agent and select it from the drop down list that appears.OR Select **Other** and enter the agent if the agent does not appear in the drop down list.
   3. Select the appropriate choice for **Enter IND Information** from the drop down list, if desired.
   4. **To add additional agents:** click the **Add Study Agent** button to add another agent; to delete an agent, click the **x** in the upper right-hand corner of the Study agent area
   5. Click **Continue** when you?ve added all agents and are ready to go to the next task page.
4. **Treatment Assignments**
   Your study may have treatment assignments (arm/cohorts) associated with it. If this is the case, you?ll want to add those on this page. If you don?t have treatment assignments associated to this study you can skip this section and click **Continue** to go to the next task page.
   To add a treatment:

   1. Click the **Add Treatment Assignment** button.
   2. Enter the **Code**. This is the code for the treatment that is found in the protocol.
   3. Enter the **Dose level order**, if desired.
   4. Enter a **Description**.
   5. Enter **Comments**, if desired.

6. **To add additional treatments:** click the **Add Treatment Assignment** button to add another treatment; to delete a treatment, click the **x** in the upper right-hand corner of the Treatment Assignment area.
7. Click **Continue** when you?ve added all treatments and are ready to continue to the next task page.

5. **Disease**
   The Diseases section is where you add diseases that you want associated to your Study. Something must be selected here before you click **Save** or **Save & Continue**.
   Note: This page will be slightly different based on the terminology you selected for disease (CTEP, MedDRA, or Other-Specify) on the **Details** page.

   1. **For CTEP only:**

      1. Search for a Disease Category: **Enter the first few letters of the name of the Disease and select it from the drop down list that appears.**
      2. The **Sub Category** and **Diseases** fields will be populated with information that matches the category you selected. Select the appropriate Sub Category and Disease and click **Add disease**.
         Note: If you select All and then click **Add disease**, it will add all the diseases in the list.
      3. To select another disease from the provided list, select the Disease and click **Add disease**. OR To select another disease from a different category, click **Clear** and repeat steps 1-3.
   2. **For MedDRA:**

      1. Enter the name of the disease in the text box. This field is an auto-completer, so select the disease when it appears and click **Add disease**.
   3. **For Other-Specify:**

      1. Enter the name of the other disease or condition in the Disease text box. This is a modified auto-completer, so if the condition appears select it and click **Add condition**. If it does not appear, finish typing it in and click **Add condition** and click **OK** on the pop-up. The name of the disease or condition will appear in the **Selected Diseases** section in the right hand side of the page.
         Note: When you add a disease or condition that was not already in the list, it will be added to both the study and to list for future use.
   4. To remove a disease from the Selected Diseases list, click the red x next to it.
   5. To make a disease a primary disease, select the checkbox next to that disease in the Selected Diseases list.
   6. Once you added all the diseases or conditions, click **Save** or **Save & Continue**.

6. **Evaluation Period Types**
   Evaluation period types and solicited AEs are added in this section. An Evaluation Period Type is a portion of the study containing one or more study segments with a consistent objective such as screening subjects or treating disease. No subject can take part in more than one Evaluation Period Type at any point in time. Solicited AEs are adverse event terms for which a clinical evaluation is being requested during a specific evaluation period type. For example, it may be requested that "Nausea" be evaluated during a "Treatment" reporting period type.

   1. **Find & Add AEs:** Enter the first few letters of the name of the AE and select it from the drop down list that appears
      OR

Click the **Add Multiple** button, select the appropriate **CTC category(s)** and **CTC terms(s)** and click the **Add Terms** button (CTC v2.0 and CTCAE v3.0 only).
Note: If the Adverse event coding terminology you selected on the Details task page is CTC v2.0 or CTCAE v3.0, and you would like to enter MedDRA terminology, enter **Other** into the text box. Select the AE term you want from the drop down list and click **Add**. The term will appear in the Adverse Event Term column with a autocompleter box where you can enter the first few characters of the MedDRA term or code and select it from the drop down list that appears.

2. **Evaluation Period Types & Solicited Adverse Events:** To add an evaluation period type, click **Add**, type in a name for the evaluation period type (i.e. treatment, screening or follow up) and click **ok**.
   OR
   Click on the name of an evaluation period to change the name and click **ok** to save the new name.
   OR
   To delete an evaluation period type, click on the red x above the type.
   OR
   To add instructions to display when a user selects an evaluation period when documenting AEs, click **Edit Instructions**, type in the instructions, and click **Save**.
   OR
   Select the appropriate checkboxes in this section to associate a solicited AE to an evaluation period type and click **Continue**.

7. **Expected AEs**

   1. Based on the study protocol, determine any Adverse Events (AEs) defined as expected for AE reporting purposes and enter them on this page. This will help determine the appropriate expedited reports required for AEs observed during the study.
      Note: Make sure to only enter the expected Adverse Event terms that are listed in the study protocol. The study protocol may define expected adverse events for reporting purposes differently than other documentation or clinical knowledge related to the agent or intervention.
   2. Each expected AE term you enter for the study on this page will be saved in the system. If the expected AEs are observed during the study and entered into caAERS, they will automatically be flagged as expected. This information will then be used by the caAERS rules to help determine the reports required for the AE.

8. **Sites**
   Sites are added to the study on the Sites page. All studies require at least one site, but can have more than one site assigned to it.
   To assign a site:

   1. Click the **Add Study Site** button.
   2. Enter the first few letters of the name of the Site and select it from the drop down list that appears.
      Note: This is a pre-populated field. If the site you are looking for is not in the drop down list that appears, contact your caAERS system administrator.
   3. To select another site, click the **Add Study Site** button. .
   4. To remove a site, click **Delete** or to clear the site information and add a different site, click **Clear**.
   5. Once you have added all the sites, click **Continue**.

9. **Investigators**
   All studies require an investigator to be associated with it. This can be a principal investigator, a site

principal investigator, or a site investigator. The investigator can come from a site, the coordinating center, or the sponsor.

To add an investigator:

1. Select a site from the drop down list.
2. The investigator associated with that site may automatically appear if it is already associated with that site in the system. If not, click the **Add Investigator** button.
3. Enter the first few letters of the investigator name and select it from the drop down list that appears. **Note:** This is a pre-populated field. If the name you are looking for is not in the drop down list that appears, contact your caAERS system administrator.
4. Click the drop down list to select a **Role**.
5. Click the drop down list to select the **Status**.
6. To add another investigator from the same site, repeat steps 2-5. OR To add another investigator from a different site, repeat steps 1-5.
7. A summary of investigators to site appears to the right of the page. To review, click on the name of a site; to delete an investigator, click Delete next to the investigator?s name.
8. Once you have added the investigators, click **Continue**.

10. **Personnel**

Research staff can be associated to a study. The roles associated are Subject Coordinator, Study Coordinator, and Adverse Event Coordinator. The research staff can come from a site, the coordinating center, or the sponsor.

To add staff to a study:

1. Select a Site from the drop down list.
2. The staff associated with that site may come up. If not, click the **Add Research Staff** button.
3. Enter the name of the Research Staff you are looking for and select it from the drop down list. **Note:** This is a pre-populated field. If the name you are looking for is not in the drop down list that appears, contact your caAERS system administrator.
4. Select a **Role**.
5. Select the **Status**.
6. To add additional research staff from the same site, repeat steps 2-5 OR To add another research staff from a different site, repeat steps 1-5.
7. A summary of the research staff to the sites appears to the right of the page. To review, select a site; to delete a research staff, click **Delete** next to the staff?s name; once you have added all research staff, click **Continue**.

11. **Identifiers**

There are two types of study identifiers used in caAERS, Organization Identifier and System Identifier. Organization Identifiers are a number or code assigned by an Organization (such as Mayo Clinic, Wake Forest or Duke University). System Identifiers are a number or code assigned by a System (such as caAERS, C3PR or PSC). caAERS will have automatically add two Identifiers for Organization, based on what was entered for the Coordinating Center and the Funding Sponsor on the initial Details page. The Coordinating Center will be listed as the primary indicator. You can add as many Organization and System Identifiers as you would like.

To add an Identifier by Organization

1. Select **Add Organization Identifier**
2.Enter the first few letters of the Organization name and select the organization from the list
3.Select Identifier type
4.Enter the **Identifier Note:** The first part of the identifier an be found either in parentheses after the organization name or at http://ctep.cancer.gov/forms/Organization_Codes.txt

5.To mark it as the Primary Indicator, add a checkmark in the Primary Indicator column. **Note:** There must be a primary indicator, and there can only be one primary indicator.
6.To delete an identifier, click Delete next to the identifier; to add another Organization Identifier, repeat steps 1-5; to add a system identifier, see By System for instruction.
7.Click **Continue**

To add an Identifier by System

1.Select **Add System Identifier**
2.Enter the System name
3.Select Identifier type
4.Enter the Identifier
5.Select it as the Primary Indicator, if appropriate. **Note:** There can only be one primary indicator.
6. To delete an identifier, click **Delete** next to the identifier; to add another System Identifier, repeat steps 1-5; to add an Organization identifier, see By Organization for instruction
7.Click Continue

12. **Overview**
The Overview page summarizes all the information entered about the study. Review the information provided. If there are changes that you need to make, click Back or click the section that contains the information that needs to be changed. If the study is complete, click **Save**.
A confirmation page will be displayed showing the short title, primary identifier, coordinating center, funding sponsor, and phase.

Searching for a Study

The studies tab also has a search features that allows you to search for studies. You can search for a study based on the study?s Short Title, Primary Identifier, or Status.
To search for a study:

1. Click **Studies** in the navigation bar and click **Search Studies**.
2. Click the **Search By:** drop down list and select **Short Title** or **Identifier**.
3. Type your search criteria in the **Search By:** field and then click **Search**. **Note:** You can also type % to list all Studies.
4. The Studies available will be listed. You can sort search results by entering information in the **Primary ID**, **Short Title**, **Funding Sponsor**, **Phase**, and/or **Status** text boxes at the top of each column and clicking the **Filter** button.
5. To view the study and/or make changes to it, click on the **Primary ID** or **Short Title** of the study in the search results.

Editing a Study

Studies can be edited after they are created.

1. Search for the study following the step by step instructions in the **Searching for a Study** section above and select it by clicking on the **Primary ID** or **Short Title** of the study in the search results. This will open the Overivew task page of the study with the information filled in. Select the section

that contains the information you need to edit from the task menu at the top of the page, make edits, and click **Save** or **Save & Continue**.

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Subjects tab

Subjects are people enrolled in a clinical study. They must be added to caAERS before a routine or serious adverse event can be recorded. This can be done through the subject tab by the Subject Coordinator. Subjects can also be imported into caAERS, as described in the caAERS Administration Guide.

Enter Subject

Click the **Subjects** tab in the Navigation bar and click **Enter Subject**. This will take you to the **Basic Details** task page. There are four steps to complete to add a Subject:
1.Details
2.Choose a Study
3.Subject Medical History
4.Review

1. **Details**
   The details section is where you add general information on the subject and add an identifier.

   1. Select the **Site** from the drop down list.
   2. Enter **First Name**.
   3. Enter **Last Name**.
   4. Enter **Maiden Name** if desired.
   5. Enter **Middle Name** if desired.
   6. Enter **Date of Birth** (mm/dd/yyyy) Optionally, you can enter just the year of birth and not the full birth date
   7. Select **Gender**.
   8. Select **Ethnicity**.
   9. Select **Race**.
   10. Determine if you are entering a **System Identifier** or **Organization Identifier** (caAERS automatically displays the Organization Identified fields). If you are entering an Organization Identifier, enter the **Identifier**, select **Identifier Type**, and enter **Organization**. Select **Primary Indicator** if necessary. OR If you are entering a **System Identifier**, click the red X next to Organization Identifier and click **Add System Identifier**. From there, enter the **Identifier**, select **Identifier Type**, and enter **System name**. Select **Primary Indicator** if necessary.
   11. If there is more than one Identifier, click **Add System Identifier** or **Add Organization Identifier** and repeat step 10.
   12. Select **Primary Indicator** for only one Identifier, and then click Continue to select a study.

2. **Choose Study**
   You can select studies to search for by title or identifier. Once the studies are listed, you can select one or more before continuing.

   1. Select **Search Type**.
   2. Enter search criteria (at least one character or % to list all) and click Search.
   3. The studies that match your search will be listed under Choose Study. Select the study or studies the subject is associated to and then click **Continue**.
3. **Subject Medical History**

   1. **General**
      When a subject is added to caAERS, general information is provided for that subject. However, when an AE occurs, additional information is required.
      To enter subject details:

      1. Select the **Baseline performance**.
      2. Enter the **Height** and select units.
      3. Enter the **Weight** and select units.
         Note: Body surface area will automatically be calculated after enter height and weight; enter the information in either Inches and Pounds or Centimeters and Kilograms, do not mix the two units of measurement.
   2. **Disease Information**

      1. **Disease name:** Click the drop down menu to select the **Disease name**.
         Note: If disease coding terminology other than CTEP or MedDRA was entered for the study that was chosen for this subject, you can select it from this drop down menu.
      2. **Primary site of disease:** This is an auto-populated field; enter the first few letters of the name of the primary site of the disease and select the site from the list when it appears OR click **Show All** and select it from the list in the pop up window that appears.
      3. Enter the **Date of the initial diagnosis** (mm/dd/yyyy).
         Note: When you provide the date, the **DD** field is not required.
   3. **Metastatic Disease Site**

      1. This is an auto-populated field; enter the first few letters of the name of the metastatic site and select from the list that appears and click **Add** OR click **Show All** and select it from the list in the pop up window that appears.
      2. To add another metastatic site, repeat step 1.
   4. **Pre-existing Conditions**
      If the subject has any relevant medical history, add the information to the report.
      To add a relevant medical history:

      1. Select the condition from the **Pre-Existing condition** drop down list and click **Add**.
         Note: This list is based on MedDRA.
      2. To add additional medical history, repeat steps 1
         OR
         to delete a pre-existing condition, click the **X** in the right corner of the window.
   5. **Conmeds**
      Concomitant Medications (conmeds) may need to be provided in the report. Document any concomitant medications that might have contributed to an event.

To add a conmed:

1. Enter **Information about concomitant medication** and click **Add**.
2. Select the checkbox if the concomitant medication is still being taken.
3. Enter the date the subject starting taking the medication, if known.
4. Enter the date the subject stopped taking the medication, if it's been discontinued and is known.
5. To add another medication, repeat steps 1-4
   OR
   to delete a medication, click the **X** in the right corner of the window.

6. **Prior Therapies**
   Prior therapies for the primary disease need to be recorded. If the information is relevant, prior therapies for non-primary diseases should also be entered.
   To enter a prior therapy:

   1. Select **Prior therapy** and click **Add**.
      Note: **This list is based on the CTEP Therapy Classification.**
   2. Enter **Comments**, if applicable.
   3. Enter a **Therapy start date** (mm/dd/yyyy).
   4. Enter a **Therapy end date** (mm/dd/yyyy).
   5. For some prior therapies, an agent will be required. This is an auto-populated field; enter the first few letters of the name of the metastatic site and select from the list that appears and click **Add**.
   6. To add additional Therapy Types, repeat steps 1-5.
   7. To delete a therapy, click the **X** in the right corner of the window.
   8. Click **Save & Continue**.

4. **Review**

   1. Verify the information entered is complete and then click **Save** OR if you need to make changes, select **Back** to return to the previous sections.

Assign a Subject to a Study

You can add a subject to another study in caAERS at any time using the Assign Subjects to Studies task.
Note: You can only assign a subject to one study at a time, so if there are multiple studies the subject needs to be added to, you will need to repeat this task.

1. **Search for a Subject Subject**

   1. Select Subject criteria.
   2. Enter Search criteria and click Search.
   3. Select the subject from the results and click Continue.

2. **Choose Study**
   You can select studies to search for by title or identifier.

   1. Select Study criteria.
   2. Enter search criteria (at least one character or % to list all) and click Search.

3. The studies that match your search will be listed under Results. Select the study and site the subject is associated to.
4. Enter the study subject identifier (an id specific to the study-subject combination) and then click **Continue**.

3. **Subject Medical History**

    1. **General**
    When a subject is added to caAERS, general information is provided for that subject. However, when an AE occurs, additional information is required.
    To enter subject details:

        1. Select the **Baseline performance**.
        2. Enter the **Height** and select units.
        3. Enter the **Weight** and select units.
        Note: Body surface area will automatically be calculated after enter height and weight; enter the information in either Inches and Pounds or Centimeters and Kilograms, do not mix the two units of measurement.
    2. **Disease Information**

        1. Select **Disease name**.
        2. **Primary site of disease:** This is an auto-populated field; enter the first few letters of the name of the primary site of the disease and select the site from the list when it appears OR click **Show All** and select it from the list in the pop up window that appears.
        3. Enter the **Date of the initial diagnosis** (mm/dd/yyyy).
        Note: When you provide the date, the **DD** field is not required.
    3. **Metastatic Disease Site**

        1. This is an auto-populated field; enter the first few letters of the name of the metastatic site and select from the list that appears and click **Add** OR click **Show All** and select it from the list in the pop up window that appears.
        2. To add another metastatic site, repeat step 1.
    4. **Pre-existing Conditions**
    If the subject has any relevant medical history, add the information to the report.
    To add a relevant medical history:

        1. Select the condition from the **Pre-Existing condition** drop down list and click **Add**.
        Note: This list is based on MedDRA.
        2. To add additional medical history, repeat steps 1
        OR
        to delete a pre-existing condition, click the **X** in the right corner of the window.
    5. **Conmeds**
    Concomitant Medications (conmeds) may need to be provided in the report. Document any concomitant medications that might have contributed to an event.
    To add a conmed:

        1. Enter **Information about concomitant medication** and click **Add**.
        2. Select the checkbox if the concomitant medication is still being taken.
        3. Enter the date the subject starting taking the medication, if known.
        4. Enter the date the subject stopped taking the medication, if it's been discontinued and is known.

5. To add another medication, repeat steps 1-4
   OR
   to delete a medication, click the **X** in the right corner of the window.

6. **Prior Therapies**
   Prior therapies for the primary disease need to be recorded. If the information is relevant, prior therapies for non-primary diseases should also be entered.
   To enter a prior therapy:

   1. Select **Prior therapy** and click **Add**.
      Note: **This list is based on the CTEP Therapy Classification.**
   2. Enter **Comments**, if applicable.
   3. Enter a **Therapy start date** (mm/dd/yyyy).
   4. Enter a **Therapy end date** (mm/dd/yyyy).
   5. For some prior therapies, an agent will be required. This is an auto-populated field; enter the first few letters of the name of the metastatic site and select from the list that appears and click **Add**.
   6. To add additional Therapy Types, repeat steps 1-5.
   7. To delete a therapy, click the **X** in the right corner of the window.
   8. Click **Save & Continue**.

4. **Review**

   1. Verify the information entered is complete and then click **Save** OR if you need to make changes, select **Back** to return to the previous sections.

Searching for a Subject

You can search for subjects to see if they have already been added to caAERS and then make changes to their general information. To change the studies the subject is assigned to, see the Assign Subjects to Studies section of this chapter.
To search for a subject:

1. Click the **Subjects** tab in the navigation bar and click **Search Subjects**.
2. Enter search criteria in the **Identifier**, **First Name**, and/or **Last Name** fields and click **Search**. **Note:** You can also leave the search fields blank click **Search** to list all subjects.
3. The subjects available will be listed in the bottom of the page. You can sort the search results by entering appropriate information in the **First Name**, **Last Name**, and/or **Primary ID** text fields at the top of each column and then clicking the **Filter** button in the top right corner of the **Subject Search Results** section.
4. Click on the **First Name** or the **Primary ID** of a subject in the search results to view and/or edit the subject profile.

Editing a Subject

Subjects can be edited after they are created.

1. Search for the subject and select him/her. This will open Review section of the create subject task, with the information filled in.
2. To modify the subject's demographic information and to add, modify, or delete the subject's Organization and System Identifiers, click **Details**, make the changes, and click **Save**.
3. To modify the subject's Medical History associated with a study, click **Details**, select the study primary id from Study Subject Assignments, and click **Save & Continue**. On the Subject Medical History page, add, modify, or delete information from the various sections and then click **Save**.
   Note: The information on this page will appear in any expedited reports for the subject-study combination. If someone has created an expedited report for the subject-study combination and added medical history, that information will also be included here.

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Rules Tab

Manage & Create Rules

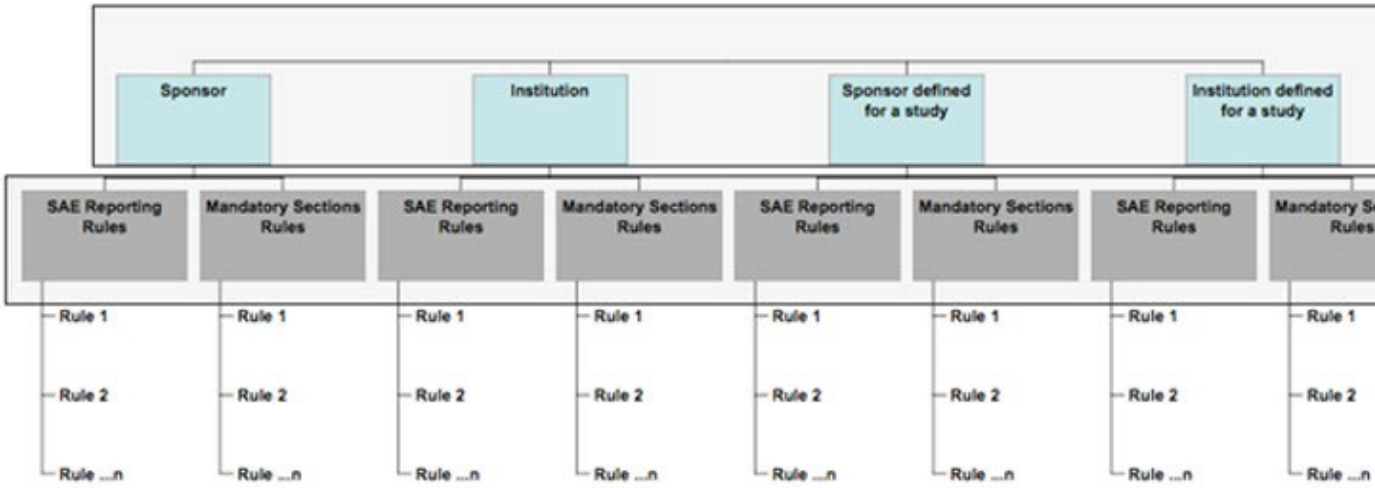
To create and manage rules click the **Rules** tab in the navigation bar.
There are four categories (or Rule Levels):

- 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.

To manually enter rules:

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,
https://gforge.nci.nih.gov/plugins/scmsvn/viewcvs.php/docs/rules/1.5/?root=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.

Configure Reporting Definitions

When you first install caAERS and import the XML Rules files we provide, caAERS will create skeleton Reporting Definitions for CTEP reports. If the rules state that a report is required, a skeleton Report Definition will be created. These skeleton reporting definitions do not include all the necessary information.
For example, it won't have the following:

- Information to electronically submit reports to AdEERS
- Notifications that are sent o interested parties
- Defined mandatory fields to assist the users with creating expedited reports.

Note: caAERS will not create skeleton Report Definitions for DCP reports. If you import the DCP rules before you create the Report Definitions, you will want to delete and re-import the rules to guarantee they function correctly.

This spreadsheet provides a matrix on how to configure the Reporting Definitions. Some note about the spreadsheet:

- The first tab of the spreadsheet includes information for the first two tabs of the setup process, including details and delivery details.
- The second tab provides information for the third step of the process, the mandatory fields.
- The third tab provides the notifications we've set up for the reports.
- The file displays the information for the AdEERS staging system. To submit an expedited report to this site, the study must already be entered in the staging system.
- Some of the information listed in the spreadsheet is suggested data while other sections are 100% define. View the page/section column to determine what can be modified (Delivery Details for example) and what must be entered as displayed (Mandatory Fields for example).

In addition, if your organization has other reporting requirements, you can use the spreadsheet as a reference sheet to help configure the report definitions.

To configure reporting definitions:

1. Log in to caAERS using an account with access to the Administration area
2. Go to Rules
3. Select List Reporting Definitions
4. Select a Report and modify the information

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.

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.

Each role provides access to different functions in caAERS. When you log in to

caAERS, you will only see the tabs and tasks that you have role authority for. The following table shows what functionality each role has access to.

✓ = rights/access
✗ or blank

= no rights or access If you feel you have not been assigned to the proper user role(s), contact your

caAERS Site Coordinator or System Administrator.

AE Module	AE Coordinator	Study Coordinator	Subject Coordinator	Site Coordinator	System Admin
AE Module tab	✓	✓	✓	✓	✓
document AEs • **evaluation periods** • **expedited reports** • **link from Manage report**	✓ (for assigned studies)	✗	✓ (for assigned studies)	✗	✓

(when now AEs have been documented yet)					
edit AEs • **evaluation periods** • **expedited report** • **Links from Manage reports (Submit, Amend, Withdraw, and report to PSC; hyperlink of expedited report and evaluation period)**	✔ (for assigned studies)	✖	✔ (for assigned studies)	✖	✔
View manage reports • **view details of evaluation periods, expedited reports, and routine AEs** • **Print PDFs of expedited reports** • **View expedited report in AdEERS**	✔ (for assigned studies)	✔ (for assigned studies)	✔ (for assigned studies)	✔	✔
Studies Module	**AE Coordinator**	**Study Coordinator**	**Subject Coordinator**	**Site Coordinator**	**System Admin**
Studies Module tab	✖	✔	✔	✔	✔
Create Study	✖	✔	✖	✔	✔
Edit Study	✖	✔	✖	✔	✔
View Study	✖	✔	✔ (for assigned studies)	✔	✔
Search Studies	✖	✔	✔ (for assigned studies)	✔	✔
Subjects Module	**AE Coordinator**	**Study Coordinator**	**Subject Coordinator**	**Site Coordinator**	**System Admin**
Subjects Module tab	✖	✔	✔	✔	✔
Create and Assign Subject	✖	✖	✔ (for assigned studies)	✔	✔
Assign a Subject to a Study (Subject already created)	✖	✔ (for assigned studies)	✔ (for assigned studies)	✔	✔
View Subject	✖	✔ (for assigned studies)	✔ (for assigned studies)	✔	✔
Search Subject	✖	✔ (for assigned studies)	✔ (for assigned studies)	✔	✔

Advanced Search Module	AE Coordinator	Study Coordinator	Subject Coordinator	Site Coordinator	System Admin
Advanced Search module tab	✔	✔	✔	✔	✔
Study Search	✘	✔	✔ (for assigned studies)	✔	✔
Subject Search	✘	✔ (for assigned studies)	✔ (for assigned studies)	✔	✔
Expedited Report Search	✔ (for assigned studies)	✔ (for assigned studies)	✔ (for assigned studies)	✔	✔
Rules module	**AE Coordinator**	**Study Coordinator**	**Subject Coordinator**	**Site Coordinator**	**System Admin**
Rules Module tab	✘	✘	✘	✔	✔
Create Rule	✘	✘	✘	✔	✔
Edit Rule	✘	✘	✘	✔	✔
Create Report Definition	✘	✘	✘	✔	✔
Edit Report Definition	✘	✘	✘	✔	✔
View Report Definition	✘	✘	✘	✔	✔
Admin module	**AE Coordinator**	**Study Coordinator**	**Subject Coordinator**	**Site Coordinator**	**System Admin**
Admin Module tab	✘	✘	✘	✔	✔
create/edit/search Organization	✘	✘	✘	✔	✔
create/edit/search Research Staff	✘	✘	✘	✔	✔
configure caAERS	✘	✘	✘	✔	✔
create/edit/search Investigator	✘	✘	✘	✔	✔
Import MedDRA	✘	✘	✘	✔	✔
IND	✘	✘	✘	✔	✔
Password Policy	✘	✘	✘	✔	✔
Import Study, Subject, Research Staff, Investigator	✘	✘	✘	✔	✔

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/1.5 .
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 folder that is located on the server which contains the files to be imported click **Import MedDRA**. **Note:** The MedDRA files and folder must be **located on the server** that caAERS is installed on. You cannot import files from a folder that is located on the "client side" or desktop computer.

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 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**.

Adverse Events tab

caAERS is used to report and document any AEs that occur during clinical trials. There are two different types of AEs, Serious AEs and Routine AEs. All AEs are entered into caAERS through the Enter AEs task, to organize the AEs via Evaluation Periods. After you've documented the AEs, your entries will trigger rules behind the scene that will determine if an Expedited Report is required. You will have the option to create that Expedited Report, create another Expedited report, not create any reports, or create multiple reports. You also can select the AEs to include in the report.

Manage Reports

The Manage reports task of the Adverse Event tab is a centralized area where you can view the AEs and reports, organized by evaluation period, for a given user-study combination. From this page, you can open both evaluation periods and expedited reports, check the status of data entry for the evaluation period or expedited report, submit, amend, or withdraw a report, and print a report.
To manage a subject?s reports for a specific study:

1. Click the Adverse Events tab in the navigation bar and Enter the first few letters of the subject?s name in the **Select subject** field and select the subject?s name from the drop down list that appears.
2. Enter the first few letters of the name of the study in the **Select study** field and select it from the drop down list that appears.
3. Click **Continue**. **Note:** You can select the study first ? the order does not matter
4. On the next page you can view all the information. Click on the arrow next to ***Evaluation Period*** to view the reports and AEs associated to the evaluation period. Click on ***Evaluation Period*** to go to the evaluation period to view full details, edit the evaluation period details, and/or edit the AE information in the evaluation period. Click on ***Report*** to open the expedited report flow to view full details and/or edit the report.

Note: There may be additional actions based on the report selected.

Enter AEs

All AEs, both routine and serious, are captured in the **Enter AEs** task. The AEs are documented for an evaluation period, and caAERS runs rules to determine if any expedited reports are required. You also have the option to create an expedited report, even if caAERS does not recommend that a report be created.
To document AEs, or to find out if the AE you are entering requires reporting, select the **Adverse Events** tab and click Enter **Enter AEs**.
The sections for documenting the AEs and determining reporting requirements are:

- Begin
- Adverse Events
- Review & Report

Begin

1. Select the **Adverse Events** tab and click **Enter AEs**.
2. **Select Subject:** Enter the first few letters of the subject?s name in the **Select Subject box** and select the subject?s name from the list when it appears.
3. **Select Study:** Enter the first few letters of the name of the study in the Select study box and select the study from the list when it appears.
4. Click **Continue**.
   Note: You can select the study first ? the order does not matter.

Adverse Events

All fields with a red asterisk (*) are required.
Evaluation Period

1. **Evaluation Period:** Click the drop down list to select an existing evaluation period. To create a new evaluation period, select **Create New** from the drop down list.

   - To edit the evaluation period details, click **Edit**. The **Evaluation Period Details** form will appear. Complete the fields with appropriate information and click **Save**.
2. If you select **Create New** an **Evaluation Period Details** form will appear. Complete the fields with appropriate information.
3. Click **Save** when you are done.
4. If you have completed all of the required fields correctly you will see a **Confirmation** page. Click **OK**.

Evaluation Period Details
You can review the following details for an evaluation period:

- Start date
- End date
- Type
- Cycle number

- Description
- Treatment assignment
- Treatment description
- Start date of first course

Observed Adverse Events
Observed Adverse Events are events that occur during the study but that are not on the solicited AE list.
To Enter an Observed Adverse Event:

1. Enter the first few letters of the Adverse Event term, select it from the drop down list and click **Add**.
2. To add multiple adverse events, click **Add Multiple**.
   Note: This page will look different based on the vocabulary chosen for the study (CTC or MedDRA). Select the AEs to enter and click Add.
3. Enter details for each adverse event you've added:

   - Enter the AE term as written in the clinical chart in the **Verbatim** text box
   - Make a selection from the **Grade**, **Attribution**, **Hospitalization** and **Expected** drop down menus.
     Note: If the Adverse Event term you enter has been set as **Expected** for the study in the system, **Yes** will automatically be selected for the **Expected** drop down menu.

Solicited Adverse Events
Solicited Adverse Events are entered with the initial study information in the system. These are events that information should be captured for if they occur.

1. Enter details for each Solicited Adverse Event listed that has occurred.

   - Enter notes from the chart in the **Verbatim** text box.
   - Make a selection from the **Grade**, **Attribution**, **Hospitalization** and **Expected** drop down menus.
     Note: If the Adverse Event term you enter has been set as **Expected** for the study in the system, **Yes** will automatically be selected for the **Expected** drop down menu.

Complete all of the required information for this page and click **Save** to save the changes, or click **Save & Continue** to determine if reporting is required.

Review & Report

This page will let you know if any of the AEs you have entered require reporting. If no reports are required then you are done. **OR** You can choose to create a report even if it is not required.

1. **Required Report:** If any of the AEs you have entered require expedited reporting it will state Yes in the **Required** column. If the AEs do not require an expedited report but you would like to create one anyway, click **Manually Select Report(s)** and then select the appropriate checkboxes.
2. **Adverse Event(s) Requiring Reporting:**This section will list any Adverse Events that require reporting. You can click the ▶ icon to hide or show information.
3. **Observed Adverse Event(s):** This section will display all observed adverse events that didn't require reporting. If you want to include one of these AEs on the expedited report, select the appropriate

checkboxes. You can click the ▶ icon to hide or show information.

4. **Solicited Adverse Event(s):** This section will display all solicited adverse events. If you want to include one of these AEs on the expedited report, select the appropriate checkboxes. You can click the ▶ icon to hide or show information.
5. Click the **Report** button if you want to start the process of creating or editing a report.
6. The **Report Create New/ Edit'** ***screen will appear. To edit an existing report, click*** *Amend* next to the report from the **Edit In-progress Reports** heading. To create a new report click **Create New Report(s)**.

Expedited Report

After you have followed the step-by-step instructions in the **Enter AEs** section and clicked the **Create New Report(s)** button you will be at the first task page of creating an expedited report.

There are a possible 13 task pages for an expedited report. report. In general, 7 task pages are required, while the rest of the task pages may be optional, based on the study and AE. :

1. Reporter
2. Enter AEs
3. Course and Agent
4. Describe Event
5. Patient Details
6. Other Causes
7. Radiation
8. Surgery
9. Device
10. Labs
11. Attribution
12. Attachments
13. Submit

Reporter

You need to capture who reported the adverse event and who the attending physician was. This is the information captured on the Reporter page.

To enter reporter details:

1. If the person entering the information is associated to the study, select their name from the **Research Staff** drop down list.
   Note: if you select someone from this list, fields will automatically be populated by information in the system. All required fields may be populated, but you need to verify they are. If the person is not listed, continue to step 2.
2. Enter **Job Title**
3. Enter **First name**.
4. Enter **Middle name**, if desired.

5. Enter **Last name**.
6. Enter **E-mail address**.
7. Enter **phone number**, if desired.
8. Enter **fax number**, if desired.
9. Enter the **Street**, if desired.
10. Enter the **City**, if desired.
11. Enter the **State**, if desired.
12. Enter the **Zip**, if desired.

To enter physician details:

1. If the physician is the person entering the AE information, select **Physician is same as the Reporter** checkbox; If not, continue to step 9.
   Note: this will copy the information from the Reporter details section into the physician details section.
2. Select the **Title** and enter the **First name**.
3. Enter the **Middle name**, if desired.
4. Enter the **Last name**.
5. Enter the **E-mail address**.
6. Enter the **Phone** number, if desired.
7. Enter the **Fax** number, if desired.
8. Enter the **Street**, if desired.
9. Enter the **City**, if desired.
10. Enter the **State**, if desired.
11. Enter the **Zip**, if desired.
12. Click **Save & Continue**.

Enter AEs

The AEs that were documented in the **Enter AE** task will appear on this page with many of the fields pre-populated. Verify all required fields are populated and enter any additional information for the optional fields.
Note: This page will look different based on the vocabulary chosen for the study (CTC or MedDRA). All AEs can be added on this page (SAE and AE), you don?t need to create a separate report for each AE.

1. Use the drop down list to select the **CTC Category**.
2. If the **CTC term** field is not already pre-populated, enter the first few letters of the CTC term that you are looking for and select it from the drop down list that appears.
   Note: You can click **Show All** to see all CTC terms associated to the category you selected. OR Begin typing the adverse event and select the MeDRA term from the list of potential MeDRA terms.
3. Select the **Grade** of the Adverse Event.
4. Enter **Start date** (mm/dd/yyyy).
   Note: This is required for the primary AE.
5. Enter the **End date** (mm/dd/yyyy), if known.
   Note: This may not be known, so is not always required. If it?s required and you?ve left it blank, you will receive a message before you can proceed.
6. Select the **Attribution to study**. This field may already be selected based on information that has been previously entered.

7. Enter the **Event time**, if known.
8. Enter **Where was the patient when the event occurred?**, if known.
9. Select if **Hospitalization or prolongation of existing hospitalization** occurred.
10. Was this AE an expected result? Select Yes or No. from the **Expected** drop down list.
    Note: When the study is testing a single commercial agent, if it was expected it will be indicated in the package insert. If this is a single agent (Phase 1 trial), expected AEs will be defined in certain sections of the protocol and brochure. You may also find information on expected AEs in the AdEERS Agent Specific Adverse Event List (ASAEL) and in the informed consent documents.
11. Select any serious indicators from **Outcomes**.
    Note: This will only appear for DCP studies.
12. Provide any additional pertinent information about the adverse event in the **Comments** field and click **Save & Continue**.

Course and Agent

Treatment information on the course and agent the subject received during the AE is necessary to see how the treatment information is related to the AE. Knowing what agents, dosage, etc the subject was receiving at the onset of the AE helps determine that relationship.
Note: The fields that appear on this page are determined by the report(s) you selected, so one or more of the fields listed in the instructions below may not be on the page. The instructions describe all possible fields for the Course and Agent section of the expedited report.

To enter treatment information:

1. Select the **Treatment assignment code** from the drop down list; if one is not available, select **Enter a description of treatment assignment or dose level** and enter the treatment assignment and dose level.
2. Enter the **Start date of first course** (mm/dd/yyyy).
3. Enter the **Start date of course associated with the report** (mm/dd/yyyy).
4. Enter the **Treatment time**, if known.
5. Enter the **Course number on which event occurred**.
6. Enter the **Total number of courses to date**.
7. Click **Add a study agent**.
   Note: You will repeat steps 8-16 multiple times, adding all agents for the dose level/treatment arm indicated. You must include information on all the agents the subject was supposed to get.
8. Select **Study Agent** from the drop down list.
9. Enter the **Formulation**, if known.
10. Enter the **Lot #**, if known.
11. Enter the **Total dose administered this course**.
12. Select the **Unit of measure** from the drop down list.
13. Enter the **Date last administered** (mm/dd/yyyy.)
14. **Administration delay:** Enter the quantity of time and select measurement, if there was an administration delay.
15. Enter **Comments** about Administration delay and modified dose, if applicable.
16. Select the **Dose Modified** checkbox if the dose was altered relative to the dose level/treatment arm and then enter the Modified Dose and select units; for example, if the total dose was supposed to be 300mg (3 days in a row of 100mg a day), but the 3rd day the subject was only given 50 mg, you?d select Dose Modified and enter 50 mg, and enter (Only gave 50 mg on 3rd day) in the comments

field.
17. If you want to add another study agent click **Add a study agent** and repeat steps 8-16.
18. Click **Save & Continue** when you are done and are ready to continue to the next task page.

Describe Event

A description of the event must be included with the report. You will describe the presentation of event, clinical findings, the treatment of events, and the timing of the events related to agent administration or investigation administration.
Note: The fields that appear on this page are determined by the the report(s) you selected, so one or more of the fields listed in the instructions below may not be on the page. The instructions describe all possible fields for the Describe Event section of the expedited report.

To describe the event:

1. Enter a **Description**; include information on the presentation of the event, clinical findings, treatment of the event, and timing of the event related to agent administration.
2. Select the **Present status**.
3. Enter the **Date of recovery or death** (mm/dd/yyyy), if applicable.
   Note: This field may be mandatory, depending on information provided in other fields. If it is required, you will see an error stating so when you try to move to the next section.
4. Select **Yes** or **No** for the **Has the participant been re-treated** drop down list.
5. Enter the **Date removed from protocol** (mm/dd/yyyy), if applicable.
6. Select **Yes** or **No** for the **Was blind broken due to event?** drop down list.
7. Select **Yes** or **No** for the **Was study agent stopped/interrupted/reduced in response to event** drop down list.
8. Enter **New Dose**, if the dose was reduced.
9. Enter **Date Reduced**, if the dose was reduced.
10. Enter **Number of days not given**, if the dose was interrupted.
11. Select the checkbox if an **Autopsy** was performed.
12. Enter the **Cause of death**.
13. Select **Yes** or **No** for the **Did event abate...?** drop down list.
14. Select **Yes** or **No** for the **Did event reappear...?** drop down list.
15. Click Save or **Save & Continue**.

Subject Details

The **Subject Details** task combines several sections of the expedited report. The individual sections may already have Information in them, based on information provided during the subject-study registration. If information already appears in any of the sections, verify that it is pertinent to the adverse event that occurred and make any necessary additions/deletions.

1. **General**
   When a sbuject is added to caAERS, general information is provided for that subject. However, when an AE occurs, additional information is required.
   To enter subject details:

    1. Select the **Baseline performance**.
    2. Enter the **Height** and select units.
    3. Enter the **Weight** and select units.
       Note: Body surface area will automatically be calculated after enter height and weight; enter the information in either Inches and Pounds or Centimeters and Kilograms, do not mix the two units of measurement.
2. **Disease Information**

    1. **Disease name**: Click the drop down menu to select the **Disease name**.
       Note: This list will populate based on the diseases entered for the study, regardless of the disease coding terminology (CTEP, MedDRA, or Other - Specify) used.
    2. **Primary site of disease:** This is an auto-populated field; enter the first few letters of the name of the primary site of the disease and select the site from the list when it appears OR click **Show All** and select it from the list in the pop up window that appears.
    3. Enter the **Date of the initial diagnosis** (mm/dd/yyyy).
       Note: When you provide the date, the **DD** field is not required.
3. **Metastatic Disease Site**

    1. This is an auto-populated field; enter the first few letters of the name of the metastatic site and select from the list that appears and click **Add** OR click **Show All** and select it from the list in the pop up window that appears.
    2. To add another metastatic site, repeat step 1.
4. **Pre-existing Conditions**
   If the subject has any relevant medical history, add the information to the report.
   To add a relevant medical history:

    1.
        1. Select the condition from the **Pre-Existing condition** drop down list and click **Add**.
           Note: This list is based on MedDRA.
    2. To add additional medical history, repeat steps 1
       OR
       to delete a pre-existing condition, click the **X** in the right corner of the window.
5. **Conmeds**
   Concomitant Medications (conmeds) may need to be provided in the report. Document any concomitant medications that might have contributed to an event.
   To add a conmed:

    1. Enter **Information about concomitant medication** and click **Add**.
    2. Select the checkbox if the concomitant medication is still being taken.
    3. Enter the date the subject starting taking the medication, if known.
    4. Enter the date the subject stopped taking the medication, if it's been discontinued and is known.
    5. To add another medication, repeat steps 1-4
       OR
       to delete a medication, click the **X** in the right corner of the window.
6. **Prior Therapies**
   Prior therapies for the primary disease need to be recorded. If the information is relevant, prior therapies for non-primary diseases should also be entered.
   To enter a prior therapy:

1. Select **Prior therapy** and click **Add**.
   Note: **This list is based on the CTEP Therapy Classification.**
2. Enter **Comments**, if applicable.
3. Enter a **Therapy start date** (mm/dd/yyyy).
4. Enter a **Therapy end date** (mm/dd/yyyy).
5. For some prior therapies, an agent will be required. This is an auto-populated field; enter the first few letters of the name of the metastatic site and select from the list that appears and click **Add**.
6. To add additional Therapy Types, repeat steps 1-5.
7. To delete a therapy, click the **X** in the right corner of the window.
8. Click **Save & Continue**.

Other Causes

If there are any other circumstances that may be related to the event, they need to be included in the report.
To include another cause:

1. Click **Add a cause**.
2. Enter **Cause** details.
3. To add another possible cause, repeat steps 1-2.
4. Click **Save** or **Save & Continue**.

Note: To delete Other Cause information, click the X in the right corner of the window.

Radiation

If the study involves Radiation intervention, information about the radiation needs to be included in the report.
To add radiation information:

1. Click **Add a radiation**.
2. Select the **Type of radiation administration** from the drop down list.
3. Enter the **Dosage** of radiation and select **Unit of measure** from the drop down list.
4. Enter the **Date of last treatment** (mm/dd/yyyy).
5. Enter the **Scheduled number of fractions**. This is the planned number of radiation sessions.
6. Enter the **Number of elapsed days**.
7. Select the **Adjustment** from the drop down list.
8. Click **Save** or **Save & Continue**.

Note: To delete Radiation information, click the X in the right corner of the window.

Surgery

In the course of some studies, surgery is required. The place where the surgery occurred (the intervention site) needs to be included with the report.
To add a surgery intervention to the report:

1. Click **Add a Surgery intervention**.
2. **Intervention site:** This is a pre-populated field. Enter the first few letters of the name of the intervention site and select it from the drop down list that appears.
3. Enter the **Date of intervention** (mm/dd/yyyy).
4. Click **Save** or **Save & Continue.**

Note: To delete Surgery information, click the X in the right corner of the window.

Device

If there are devices involved in the study or in an intervention, the information about the device needs to be included in the report.
To add a device:

1. Click **Add a Medical device**.
2. Enter the **Brand name**.
3. Enter the **Common name**.
4. Enter the **Device type**.
5. Enter the **Manufacturer name**.
6. Enter the **Manufacturer city**.
7. Select the **Manufacturer state** from the drop down list.
8. Enter **Model number**.
9. Enter **Lot number**, if desired.
10. Enter **Catalog number**, if desired.
11. Enter **Expiration date** (mm/dd/yyyy), if desired.
12. Enter **Serial number**.
13. Enter **Other number**, if desired.
14. Select a **Device operator** from the drop down list.
15. Enter **Other device operator**, if desired.
16. Enter the **Implanted** date (mm/dd/yyyy), if implanted.
17. Enter the **Explanted** date (mm/dd/yyyy), if explanted.
18. Enter **Reprocessor name**, if desired.
19. Enter **Reprocessor address**, if desired.
20. Select **Yes** or **No** for evaluation availability.
21. Enter **Returned date** (mm/dd/yyyy).
22. Click **Save** or **Save & Continue**.

Note: To delete Medical Device information, click the X in the right corner of the window.

Labs

If tests were sent to a lab and are possibly related to the AE, include them in the report.
To add a lab:

1. Click A**dd a lab**.
2. Select the **Lab category** from the drop down list.
3. Select the **Lab test name** from the drop down list. If the lab test is not listed, select **Other, specify** and enter the lab test name in the **Other** field.
   Note: If you selected Microbiology for the Lab category, go to step 8.
4. Select the **Units** from the drop down list that will be associated with the Baseline, Worst, and Recovery values.
5. Enter **Baseline value** and **date** (mm/dd/yyyy).
6. Enter **Worst value** and **date** (mm/dd/yyyy).
7. Enter **Recovery value** and **date** (mm/dd/yyyy), if applicable and go to step 11.
8. Enter the **Site** associated with the lab test.
9. Enter the **Date** of the test.
10. Enter details for the **Infectious Agent**.
11. To add another lab, repeat steps 1-10.
12. Click **Save & Continue**.

Note: To delete lab information, click the X in the right corner of the window.

Attribution

For each AE, the reporter/physician must assign an attribution to each possible cause. For each AE, at least one cause has to be assigned an attribution of possible, probable, or definite for.
The possible attributions are:

- Unrelated
- Unlikely
- Possible
- Probable
- Definite

The possible causes are:

- Disease
- Course (agent)
- Surgery
- Radiation
- Medical device
- Concomitant Medications
- Other causes

Note: If a section on this attribution list is not appropriate/has not been entered, you will not have an option to select an attribution. Instead you will see a message. For example, if there was no medical device associated to this report, it would say ?No medical devices for this report?.

To enter the relationship between a possible cause and an AE:

1. Select attribution for the associated cause from the drop down list.
2. Click **Save** or **Save and Continue**.

Attachment

For some expedited reports, it may be beneficial to submit additional information to help clarify the information provided in the report.
In this section, identify which types of information you will be submitting:

1. Select the appropriate checkbox for any additional information that will be submitted.
2. Enter **Other Information** if anything needs to be attached that is not included in the list or if there?s additional information that may be helpful.
3. Click **Save** or **Save & Continue**.

Submit

The submit page shows all reports that are being worked for the adverse events selected. If the report has all the necessary information, it will have submit/withdraw options. If it is missing information, it will show what information is missing in the **Ready to submit?** field. **Important:** Until all the issues are resolved, you will not be able to submit the report. The § icon on the Section tabs will help you locate what sections are missing information.

1. If a report is missing information, review the **Ready to submit?** field for information about what is missing and return to the section(s) that are missing information (look for the § icon on the Section tabs).
2. If you are not ready to submit the report, click **Save & Back** or **Save**
   OR
   If all information is provided and you are ready to submit the report, click **Submit**.

Submitter
The submitter page verifies you have physician sign-off and collects the submitter?s information.
To complete the page:

1. Select **Yes** or **No** for physician sign-off.
2. If the submitter is either the reporter or the physician, select Submitter same as reporter or Submitter same as physician; if not, continue to step 3.
   Note: this will copy the information from the Reporter details section into the physician details section.
3. Enter the submitter?s First Name.
4. Enter the submitter?s Middle Name, if desired.
5. Enter the submitter?s Last Name.
6. Enter the submitter?s E-mail address.
7. Enter the submitter?s Phone number, if desired.
8. Enter the submitter?s Fax number, if desired.

9. Click Save or Save & Continue.

Submit Report

1. Verify where the report is being sent. If the report needs to go to more locations than appear under Email/URL, enter the email addresses in the CC field.
2. Click **Save** to submit the report.

Amend an Expedited Report

To Amend a Submitted Expedited Report through the Enter AE flow:

1. Click the **Adverse Events** tab and select **Enter AEs**.
2. Enter the **Subject** and **Study** combination that has the expedited report you want to edit associated with it, and click **Continue**.
3. At the next page, select the appropriate **Evaluation Period**. A green R icon will appear next to AEs that are included in expedited reports that have a Submitted status in the system.
4. Edit AEs as you would like and click **Save & Continue**.
   Note: If you delete an AE that has the green R icon associated to it, you will receive a pop-up message. Read the **Instructions** in the window that appears and click Amend. The green icons will disappear from all AEs that were included on the report that you have just selected to Amend.
5. If you have made changes to an AE that had the green R icon associated to it, you will receive a pop-up message. Read the **Instructions** in the window that appears and click Amend.
   Note: If you click **Don't Amend**, you will need to go back to the **Adverse Events** page and manually set the information you edited back to the previous settings.
6. On the **Review and Report** page, click **Continue**. In the window that appears, the status of any report that had a **Data Entry Status** of Submitted/Data Complete will now be listed as Pending, and the **Revision Number** will have changed.
7. Click **Edit** next to the report that you've just amended to go to the expedited report and complete the amendment process.
   Note: If you deleted any AEs, be sure to go to **2. Enter AEs** to verify the primary AE has a start date associated to it. If you don't visit this page, and there's no start date for the primary AE, when you try to resubmit your expedited report, it will fail.

To Amend a Submitted Expedited Report through Manage Reports:
You can also amend a submitted expedited report through Manage Reports. Changes made to the AEs in the expedited report when you choose to amend the report from Manage Reports will also appear in the Enter AE flow.
Note: A specific reason to amend from Manage Reports instead of through the Enter AE flow is if you want to remove an observed or solicited AE from the expedited report but not from the evaluation period.

1. Click the **Adverse Events** tab and select **Manage AEs**.
2. **Search for AE Report:** Enter the **Subject** and **Study** combination that has the expedited report you want to edit associated with it, and click **Continue**.
3. Expand the **Evaluation Period** that has the expedited report you want to amend.
4. From the **Options** column, click **Amend**. This will open the expedited report so you can make changes, and change the **Data Entry Status** to Pending, and update the **Revision Number** to reflect a new version has been created.

Advanced Search

The Advanced Search tab allows you 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. 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 the **Advanced Search** tab in the navigation bar.
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 leave the Search criteria fields blank and click **Search** to list all Studies.
3. The Studies available will be listed in the bottom of the page. You can further sort search results by entering the appropriate information in the **Primary ID**, **Short Title**, **Sponsor**, **Phase**, and **Status** text fields at the top of each column and clicking the **Filter** button in the top right corner of the **Study search results** section.
4. Click on the **Primary ID** of a study in the search results to view and/or edit it.

Subject 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 the **Advanced Search** tab in the navigation bar and click the **Subject search** button.
2. Enter search criteria in any of the fields of the **Subject Search Criteria** or **Study Search Criteria** boxes and click **Search**. **Note:** You can also leave the Search Subject criteria fields blank and click **Search** to list all Subjects.
3. The Subjects available will be listed in the bottom of the page. You can further sort search results by entering the appropriate information in the **Primary ID**, **First Name**, **Last Name**, **Gender**, **Race**, **Ethnicity** and **Associated Study ID(s)** text fields at the top of each column and clicking the **Filter** button in the top right corner of the **Study search results** section.
4. Click on the **Primary ID** of a subject in the search results to view and/or edit the subject profile.

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 the Advanced Search tab in the navigation bar and click **Expedited Report search**.
2. Enter search criteria in any of the fields of the **Expedited AE report criteria** box, **Study criteria** box, the **Subject criteria** box, or all three and then click **Search**. **Note:** You can also leave the search criteria fields blank click **Search** to list all reports.
3. The expedited reports available will be listed in the bottom of the page. You can further sort the search results by entering the appropriate information in the **Primary CTC term**, **Grade**, **Attribution**, **Start Date**, **Study ID**, and **Subject ID** filter fields and clicking the **Filter** button in the top right hand corner of the **Expedited AE report search results** section.
4. Click on the **Study ID** or **Participant ID** to view and/or edit it.

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 the **Advanced Search** tab in the navigation bar and click **Routine AE search**.
2. Enter search criteria in any of the fields of the **Routine AE criteria** box, **Study criteria** box, the **Subject criteria** box, or all three and click **Search**.
   Note: You can also leave all of the search fields blank and click **Search** to list all Routine AEs.
3. The Routine AE reports available will be listed in the bottom of the page. You can sort the search results by entering the appropriate information in the **Primary CTC term**, **Grade, Attribution**, **Observation Dates**, **Study ID**, and **Subject ID** text fields at the top of each column and clicking the **Filter** button in the top right hand corner of the **Routine AE search results** section.
4. Click on the **Study ID** or the the **Participant ID** to view and/or edit the associated study or subject.

Error Messages/Indicators and Problem Resolutions

caAERS has been setup to provide descriptive messages whenever it encounters a problem for the following:

- 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 tabs and try to save changes, you may forget to add information and receive an error. The error will state what information is missing.

I get an error when I try to go back to a previous section
caAERS is setup to check a page for all required information before moving to the next section. If you want to go to a previous section, 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).

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 tab or click on a button, it?ll have you log back in before accessing the tab. 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.

System Errors

You may run into a system error. If this happens, you should contact the support team. They may request the detailed error information, so either save the website or copy the information.

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.