caAERS v 1.5
End User Guide

Document Change History

Version Number	*Date*	*Contributor*	*Description*
V0.05	June 12, 2007	Jason Carmichael	Initial Template
V0.1	July 29, 2007	Jason Carmichael	Initial Draft based on Iteration v. 4
V0.2	August 10, 2007	Paul Galvin	Completed draft of Chapter 2 halfway through expedited report.
V0.3	August 16	Paul Galvin	New format of the user guide based on tasks rather than modules.
V0.4	August 24	Paul Galvin	Redone with grammar and wording corrections.
V0.5	September 19	Paul Galvin	Incorporated feedback from BAH and WFU. Need to continue updating because of new flows
V0.6	11/13/2007	Paul Galvin	New format: added quick reference points for each section of the application.
V0.7	01/03/08	Jennifer Reed	Removed quick reference, added step-by-step instructions.
V0.8	01/07/08	Jennifer Reed	Added coverage of new functionality and fixes from Iteration 7, 8, and 9.
V0.9	02/09/08	Jennifer Reed	Updated to represented changes from last release
V1.0	02/12/08	Jennifer Reed	Minor updates
V1.1	02/27/08	Jennifer Reed	Updates to AE section
V1.5	9/26/2008	Elizabeth Nobriga	Updates for v1.5 Release

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Copyright and License page

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

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Table of Contents

Overview

Software Overview

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

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

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

Components of the Software

The caAERS application has six tabs:

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

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

System Requirements

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

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

User Name

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

email address. This field is case sensitive.

Resetting Your Password

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

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

1. Click **Forgot Password?** on the login screen.
2. Enter **Username** (email address) and click Reset Password.
3. caAERS will send you an email. Open the email and click on the link. **Note:** Your browser must be set up to allow new windows to open.
4. Enter your **Username**.
5. Enter a new password.
6. Re-Enter the password.
7. Click **Change Password**.

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

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.

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.

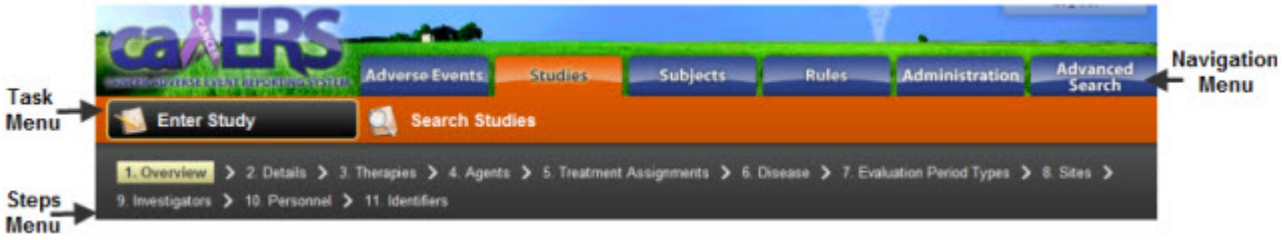
Exiting the application

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.



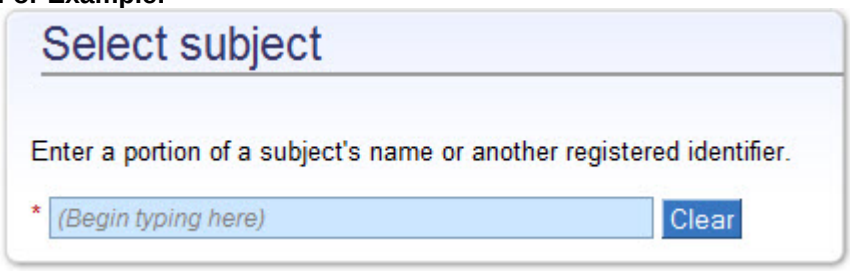
- **Navigation Menu:** The navigation menu allows access to the tabs. To access a tab, click on the tab, in the example above, the **Studies** tab is selected.
- **Task Menu:** Each tab may have multiple tasks associated to it, which are displayed in the Task menu. To access a task, click on it, for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

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.

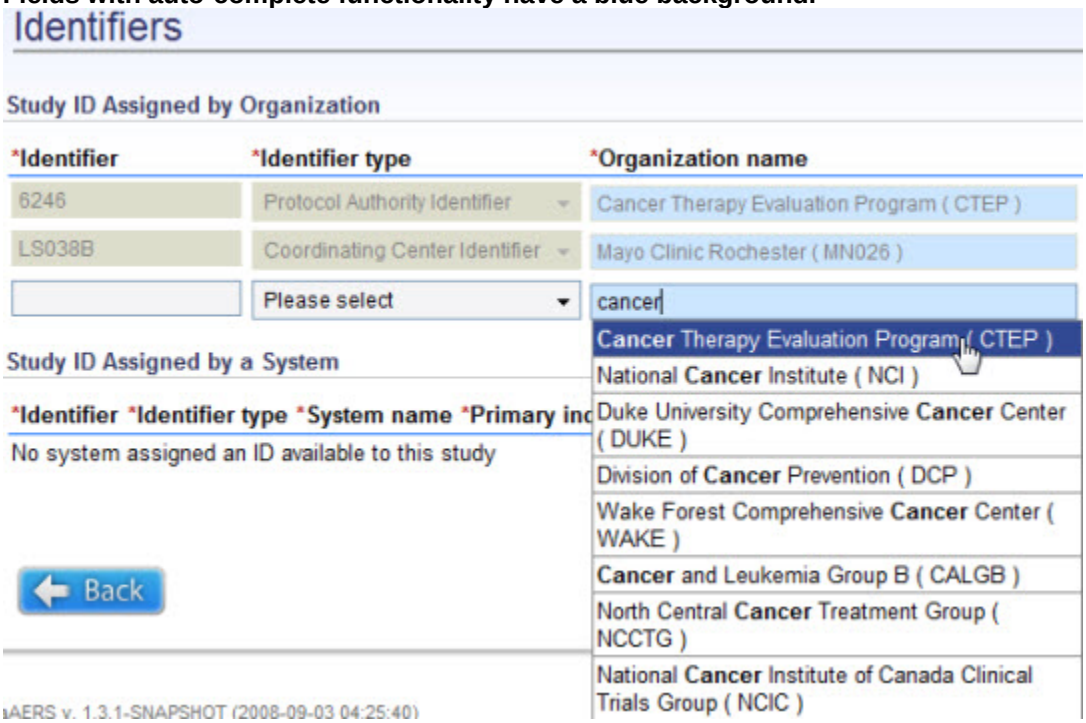
Important Interface features

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

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

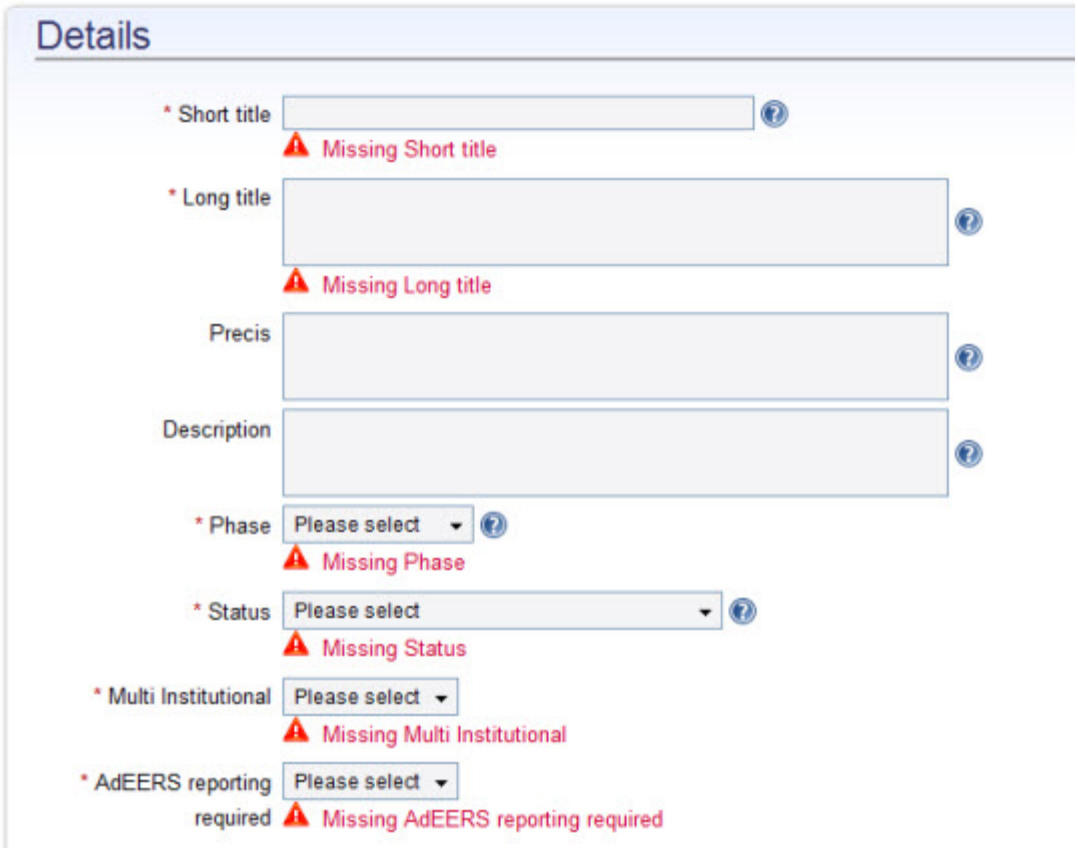
Auto-complete functionality
Several caAERS fields are built with an auto-complete function, similar to what you find when using Google search. If a field has auto-complete enabled, it will bring up a list of possible matches when you start to type. For example, if you type **cancer** in a field with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



User Roles

The five user roles of caAERS provide access to different tabs of the application. When your account is created, you can be assigned one or more user roles, depending on your responsibilities. The roles and their responsibilities are:

- **System Administrator** (super user) – Responsible for maintaining the caAERS hardware and software; has access to all tabs in caAERS; resolves user issues
- **Site Coordinator** – Responsible for maintaining information about the site
- **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 Coordinator** – Responsible for entering adverse events as they are defined by the study or sponsor
- **Subject Coordinator** – Responsible for adding subjects and may also report adverse events

In addition to the user roles that allow access to caAERS, there are two other roles that do not have access to caAERS but are necessary for the proper use of caAERS. These user roles are:

- **Study Subject** – a qualified patient enrolled in a study
- **Investigator** – person or organization who is leading a study

Note: If an investigator wants to/needs to access caAERS, an account can be created for him/her.

However, investigators are not required to have caAERS access.

Roles to Tasks

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. If there is an **X** in the box, it means that role has access to that feature. If you feel you have not been assigned to the proper user role(s), contact your caAERS Site Coordinator or System Administrator.

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

View Rules	**X**	**X**			
Create/Edit Report Definitions	**X**	**X**			
View Report Definitions	**X**	**X**			
Administration Tab					
Create/Edit Users	**X**	**X**			
Create/Edit Investigators	**X**	**X**			
Import Studies/Subjects	**X**	**X**			
Import AEs	**X**	**X**			
Import Subjects	**X**	**X**			
Import MedDRA	**X**	**X**			
IND #	**X**	**X**			
Create/Edit Organizations	**X**	**X**			
Configure Password Policy	**X**	**X**			

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.

Create A 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. Sites
8. Investigators
9. Personnel
10. Identifiers
11. 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 box to select a **Phase**.
   6. Click the drop down box to select the **Status**.
   7. Click the drop down box to select Yes or No for **Multi Institutional**.
   8. Click the drop down box to select Yes or No for **AdEERS reporting required**.
   9. Click the drop down box to select the **Terminology**.
   10. Click the drop down box to select **CTC version**, if CTC was selected in step 9.
   11. Click the drop down box to select **Other MedDra Version**.
   12. Click the drop down box to select the disease coding **Terminology**.
   13. Click the drop down box 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 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.
   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 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.
   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 menu, 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. If there are no diseases associated with your study you can skip this section and click **Continue**.
   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 sub category to narrow down the Diseases list.
   3. 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.
   4. 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 1-4.
   5. To remove a disease from the Selected Diseases list, click the red x next to it.
   6. To make a disease a primary disease, select the checkbox next to that disease in the Selected Diseases list.
   7. Once you added all the diseases, click **Continue**.
6. **Evaluation Period Types**
   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.

2. **Evaluation Period Types & Solicted Adverse Events:** Select the appropriate checkboxes in this section and click **Continue**.

7. **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: 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**.
8. **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 box.
   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 box to select a **Role**.
   5. Click the drop down box 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**.
9. **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 box.
   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**.
10. **Identifiers**
    There are two types of study identifiers used in caAERS, Organization and System. Organization Identifiers identify the study with the different Organizations involved and are generally the identifier used for most studies. System Identifiers identify the study with different systems, such

as caBIG. caAERS will have automatically add two Identifiers for Organization, based on what you entered for Coordinating Center and Funding Sponsor on the Details page, with the Coordinating Center being the primary indicator. If these identifiers aren't adequate to identify the study, you can add additional Organization and System Identifiers.

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

11. **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 box 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 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**.

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.

Create A Subject

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 box.
   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** yyyy mm dd) 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 **Organzation 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 patient is added to caAERS, general information is provided for that patient. However, when an AE occurs, additional information is required.
      To enter patient 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 patient 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 box 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 patient starting taking the medication, if known.
      4. Enter the date the patient 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. You can make the assignment by either searching for a subject or searching for a study.
Note: This method allows assignment to one study at a time, so if there are multiple studies the subject needs to be added to, you will repeat this task.

Assignment by Selecting a Study

1. Search Study
   1. Select Study criteria.
   2. Enter Search criteria and click Search Studies.
   3. Select the study, select the corresponding site, and then click Save & Continue.
2. Search Subject
   1. Select Subject criteria.
   2. Enter Search criteria and click Go.
   3. Select the subject and click Save & Continue.
3. Review and Submit
   1. Review the information to verify the study selected. If it's correct, click **Save**; if not, click **Save & Back** to go back and make changes.
4. View Subject
   1. After you click Save, the View Subject page appears and shows all the studies the subject is assigned to as well as the subject's details. To assign to another study, click the **Assign Subjects to Studies** task under the **Subjects** tab.

Assignment by Selecting A Subject

1. Searching Subject
   1. Select Subject criteria.
   2. Enter Search criteria and click Search Subjects.
   3. Select the subject from the results and click Save & Continue.
2. Search Study
   1. Select Study criteria.
   2. Enter Search criteria and click Go.
   3. Select the study, select the corresponding site, and then click Save & Continue.
3. Review and Submit
   1. Review the information to verify the study selected and patient assignment. If it's correct, click Save; if not, click Save & Back to go back and make changes.
4. View Subject

1. After you click Save, the View Subject page appears and shows all the studies the subject is assigned to as well as the subject's details. To assign to another study, click the **Assign Subjects to Studies** task under the **Subjects** tab.

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. #Select Details to modify the information, and 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 menu 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

1. **Evaluation Period:** Click the drop down box to select an existing evaluation period. To create a new evaluation period, select **Create New** from the drop down box.
2. If you select **Create New** an **Evaluation Period Details** form will appear. Complete the fields with appropriate information.
   Note: All fields with a red asterisk (*) are required.
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**.

5. The full Adverse Event pages opens with sections for evaluation period details, observed adverse events, and solicited adverse events.
   Note: All fields with a red asterisk (*) are required.
   - To edit the evaluation period details, click **Edit**. The **Evaluation Period Details** form will appear. Complete the fields with appropriate information and click **Save**.
   - To add a single adverse event, type in the adverse event, select it from the drop down box and click **Add**.
   - 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**.
   - Enter details for each adverse event you've added, entering all required information and
   - Enter details for the solicited adverse events. Based on your response to **Grade**, other fields may be required
6. Click **Save** to Save the changes, or **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 menu.
   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 box 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 box.
    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 additional information about the adverse event term in the **Comments** field.
13. If you want to add another AE, click **Add another AE** and repeat steps 1-8; click **Save & Continue** when you have added all AEs.
    Note: Any AE you add in the expedited report flow will also be added to the evaluation period.

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 patient was receiving at the onset of the AE helps determine that relationship.

To enter treatment information:

1. Select the **Treatment assignment code** from the drop down box; 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 box.
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 box.
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 box.
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 box.
7. Select **Yes** or **No** for the **Was study agent stopped/interrupted/reduced in response to event** drop down box.
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 box.
14. Select **Yes** or **No** for the **Did event reappear...?** drop down box.
15. Click Save or **Save & Continue**.

Patient Details

The **Patient Details** task combines several sections of the expedited report. The individual sections may

already have Information in them, based on information provided during the patient-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 patient is added to caAERS, general information is provided for that patient. However, when an AE occurs, additional information is required.
   To enter patient 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 patient 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 box 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 patient starting taking the medication, if known.
   4. Enter the date the patient 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 box.
3. Enter the **Dosage** of radiation and select **Unit of measure** from the drop down box.
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 box.
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 menu 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 box.
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 box.
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 box.
3. Select the **Lab test name** from the drop down box. 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 box 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 box.
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 need 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**.**

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.