



Cancer Therapy Evaluation Program Adverse Event Reporting System

Training Guide

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The Cancer Therapy Evaluation Program Adverse Event Reporting System (CTEP-AERS) Training Guide was prepared for:

Cancer Therapy Evaluation Program (CTEP)

Division of Cancer Treatment and Diagnosis (DCTD)

National Cancer Institute (NCI)

National Institutes of Health (NIH)

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Revision History

Date	Document Number	Revision Level	Reason for Revision
01/23/2014	001	.01	<p>Recipient page – use of comma only.</p> <p>Submission page – replaced screen graphic.</p> <p>Additional Information page – fax number displays at time of report submission.</p> <p>Prior Therapies – include therapies for current study disease and non-primary disease.</p>
08/13/2014	002	.01	<p>Adding Study Agents page – added the following information:</p> <ul style="list-style-type: none"> • Note regarding the use of the “Lot # (if known)” field. • Note regarding the use of the “Agent Start Date” and “Agent End Date” fields. • Note to clarify the use of the “Date last administered prior to the event that is being reported” field. <p>Minor adjustments to formatting.</p>
11/25/2014	003	.01	<p>The following information was revised due to the v3.0 release of CTEP-AERS which implemented a more streamlined manner of entering report data referred to as the “Simplified Pathway”:</p> <ul style="list-style-type: none"> • Adverse Event page: a) 'Verbatim' field label changed to 'Enter verbatim'; b) 'Start date' field is mandatory for the primary adverse event; b) 'Did AE Cause Hospitalization?' field is mandatory regardless of grade; c) '+Add Adverse Event' button label changed to 'Add/Edit Adverse Event'. • Review and Report page: a) 'Start Date' field is mandatory for the primary adverse event; b) 'Start Date' field is mandatory upon changing the primary adverse event; c) 'Recommended Actions' image updated; d) 'Available Actions' image updated. • Study Interventions/Agents page: a) 'Was an investigational agent administered to this subject on this protocol?' field is mandatory to enter an agent on the report and must be answered 'Yes' to enter investigational agents; note added to clarify when 'No' should be entered; Study Agent list of values includes either Investigational or Commercial after each agent name; b) 'Lot #, (if known)' field is optional regardless of agent type; c) 'Agent Start Date' and 'Agent End Date' fields are optional regardless of agent type; d) Date last administered prior to the event that is being reported' field is mandatory; e) The note "Certain study agent fields may not display if the study does not include an investigational agent as part of treatment." was deleted as all fields display on the Agents page. • Study Interventions/Device page: a) 'Was an investigational device administered to this subject on this protocol?' field is mandatory to enter a device on the report. • Subject's General Details page: a) Height and Weight fields are mandatory; b) image replaced to include the mandatory field symbol (i.e., asterisk) on Date of Birth field. • Subject's Disease Information page: a) Disease Information image updated; b) 'Other (disease)' field is mandatory if 'Hematopoietic malignancy, NOS' or 'Solid tumor, NOS' is selected in the 'Disease name' field; c) 'Primary site of disease'

			<p>field is mandatory; d) 'Other primary site of disease' field is mandatory if 'Other' is selected in the 'Primary site of disease' field.</p> <ul style="list-style-type: none"> • Subject's Prior Therapies page: Note modified to indicate that the No prior therapy value was moved to the top of the list of values; image of the value added. • Additional Information page: Removed the note regarding the display of fields dependent on commercial agents. • Manage Report page: a) removed references to AdEERS; b) addition of the 'Initiated, not submitted' Report Submission Status; c) Revised the Viewing Reports in AdEERS section to remove references to AdEERS and updated the process.
2/18/2015	004	.01	<ul style="list-style-type: none"> • Subject's Prior Therapies page: The Note was modified to indicate the requirements needed to create a unique prior therapy record when patients receive multiple therapies of the same type. • About Special Characters section created to describe the limitation of character entry and the conversion of special characters to inverted question marks based on the ISO-8859-1 character set used by CTEP-AERS. • Note added to the Step 3. Describe Event - Describing the Adverse Event section to highlight the character limitations of the Description & treatment of event(s) field based on the ISO-8859-1 character set used by CTEP-AERS.

If you have comments or questions regarding this Training Guide, please contact the NCI CTEP Help Desk at ncictephelp@ctep.nci.nih.gov.

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Welcome to CTEP-AERS

Welcome to the CTEP Adverse Event Reporting System (CTEP-AERS). CTEP-AERS replaces the Adverse Event Expedited Reporting System (AdEERS) and was built using the Cancer Adverse Event Reporting System (caAERS) developed by caBIG®.

Contacting the Help Desk Support

If you encounter problems working with CTEP-AERS that cannot be solved using the CTEP-AERS Online Help, please contact the following CTEP Help Desk resources for a quick resolution.

For technical questions, contact the NCI CTEP Help Desk at:

email: ncictephhelp@ctep.nci.nih.gov

phone: 1-888-283-7457

fax: (301) 948-2242

For medical questions, contact the AEMD Help Desk at:

email: aemd@tech-res.com

phone: (301) 897-7497

fax: (301) 230-0159

It is recommended to have the report's access key (i.e., ticket number, protocol number and subject ID) in the event it is needed.

CTEP-AERS Hardware and Software Requirements

The following hardware and software are required to use the CTEP-AERS application.

Hardware:

A PC with 2.4 GHz processing speed and 1GB or higher RAM. (Higher is recommended for better performance)

Broadband internet connection

JavaScript should be enabled on the Browser.

Pop-up blocker should be disabled on the browser.

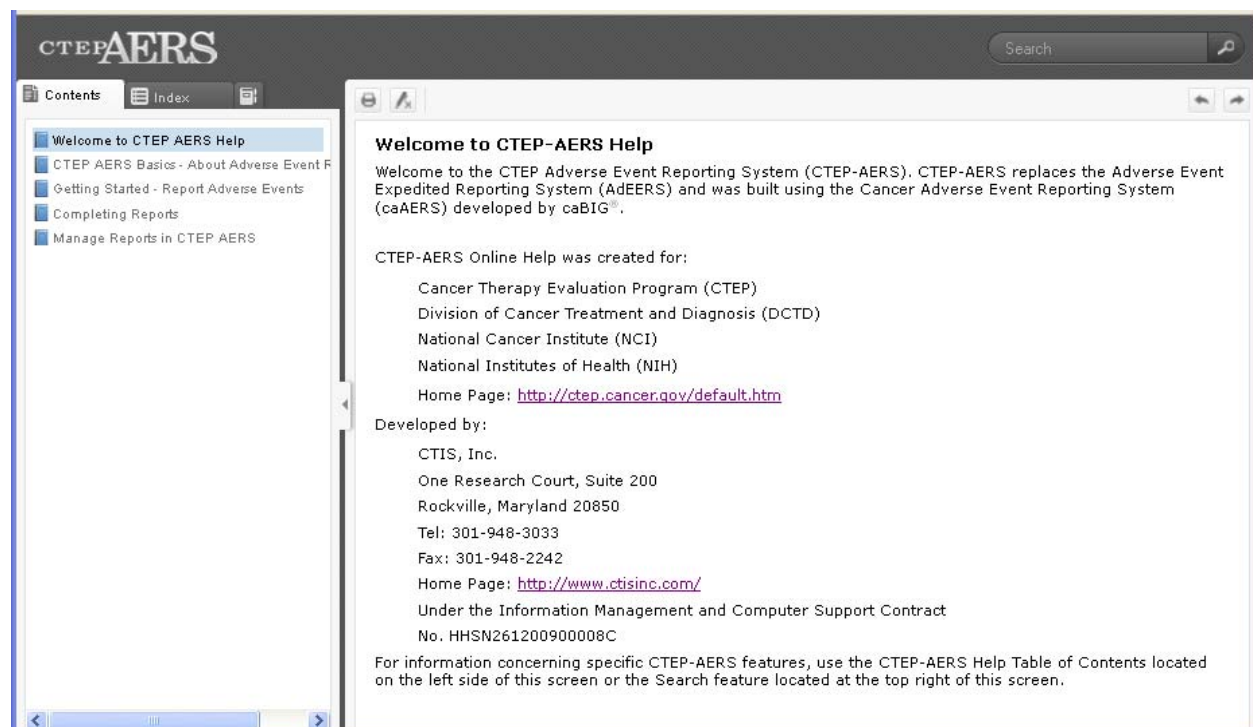
Software Requirements:

The web application is accessible using Internet Explorer 8.0 and Mozilla Firefox 3.6.







Using CTEP-AERS Online Help

CTEP-AERS Online Help Features

CTEP-AERS Help provides a variety of simple features to assist when navigating through the help topics or when searching for specific information.




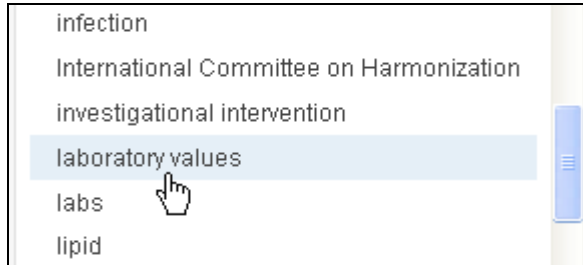
Using the Online Help Table of Contents

Convention	Description
 Contents	Click the Contents tab to open and view the help chapters.
 	Each help chapter is represented by a book icon. You may click the chapter heading to open and view the help topics within that chapter. Open chapters are represented by an opened book icon.
	Click the Hide/Show tab located between the Table of Contents and the help content to hide or show the Table of Contents panel.
 	Click the Previous or Next buttons to scroll through the help topic-by-topic.

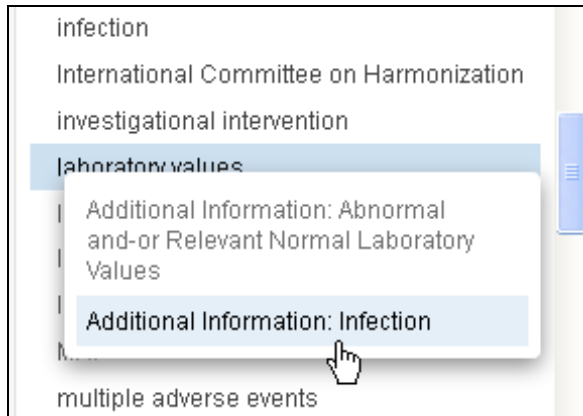
Using the Online Help Index

The CTEP-AERS Help includes an index where you can locate content related to terms that are used within the CTEP-AERS application and Help. To use this feature:

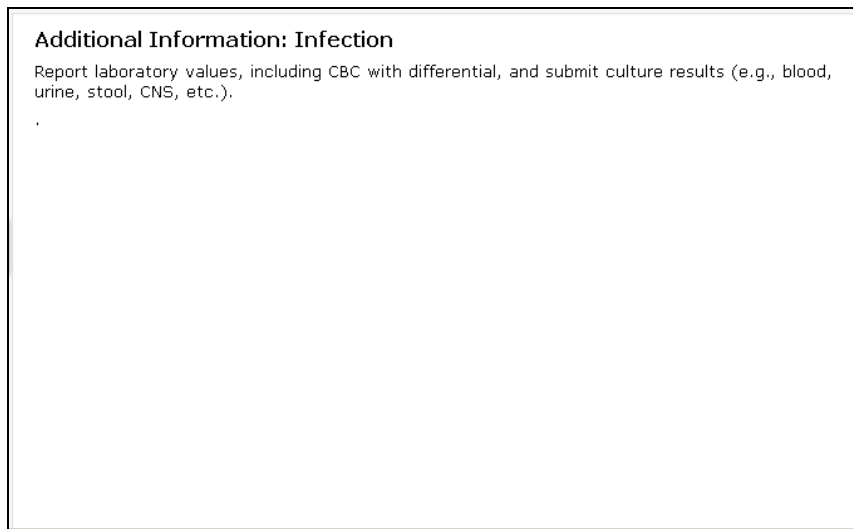
1. Click the Index tab  Index . The Index terms display in the left panel.
2. Use the scroll bar to locate the term for the content you wish to view.



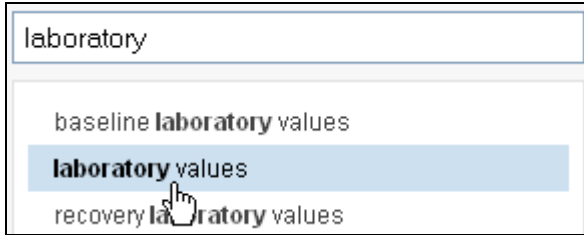
3. Click the term. The Index displays all Help topic titles associated with the term.



4. Click the topic you wish to view. The topic displays.




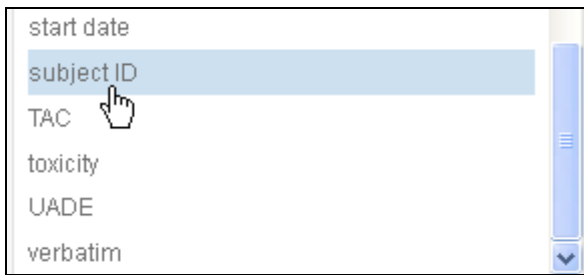
Alternatively, you can use the Index Search field to locate and view the topic content.



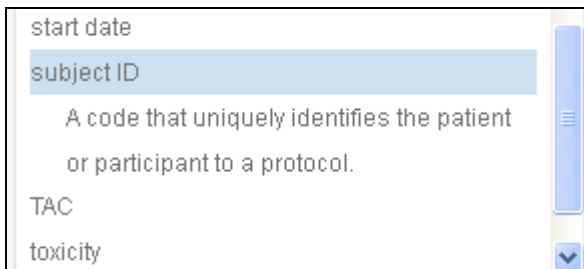
Using the Online Help Glossary

The CTEP-AERS Help includes a glossary to provide the definition of the terms used within the CTEP-AERS application. To use the glossary:

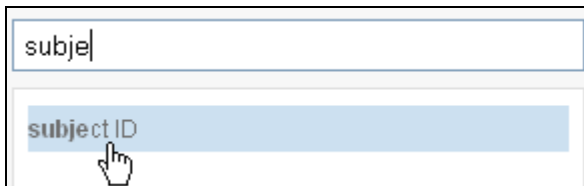
1. Click the Glossary tab . The Glossary terms display in the left panel.
2. Use the scroll bar to locate the term you wish to view.



3. Click on the term to display the definition.



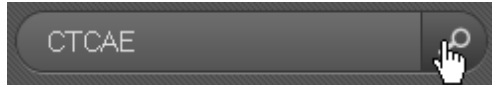
Alternatively, you can use the Glossary Search field to locate and view a term definition.



Online Help Search

The CTEP-AERS Help includes a search feature where you can locate content throughout the help topics. To use this feature:

1. Click within the Search field and type the term you wish to search, then click the Search button on the right.



2. The search results are displayed providing links to Help topics that include your search criteria.

Your search for "CTCAE" returned 3 result(s).

[Death Unrelated to Adverse Event](#)
 Death Unrelated to Adverse Event To report a death unrelated to an adverse event:
[basics - death unrelated to adverse event.htm](#)

[Common CTEP AERS Screen Features](#)
 Common CTEP AERS Screen Features The CTEP AERS does not have a menu bar or a toolbar that contain commands and features. Instead, there are several tabs that provide access to the report sections you will want to complete. The following table provides more details about these features.
[basics - common_ctepaers_screen_features.htm](#)


[Frequently Asked Questions](#)
 Frequently Asked Questions Below are some of the commonly asked questions received through the CTEP AERS MD Help Desk and NCI CTEP Help Desk.
[help - frequently asked questions.htm](#)

3. Click on a link to display the topic content.

Common CTEP AERS Screen Features

The CTEP AERS does not have a menu bar or a toolbar that contain commands and features. Instead, there are several tabs that provide access to the report sections you will want to complete. The following table provides more details about these features.


Feature	Description
Blue Checkmark	✓ appears next to the step name and number at the top of the page and indicates that the step is complete.
Calendar icon	📅 is used to select a specific date.
View CTCAE v4.0	View CTCAE v4.0 link is available from the 2. Adverse Events tab from the Report Adverse Event workflow to search and view Adverse Event terms and grades.
Dialog box	A named box containing fields and options used to perform a particular task.

Notice that the search criteria are highlighted in yellow. To remove this highlight, click the Remove Highlights button .

NOTE: Partial words are included when using this feature. For example, the word "organ" will be captured when searching on the word "organization". If you do not see the word highlighted, as mentioned above, then an exact match was not made and you can ignore and close the topic.

Common CTEP-AERS Help Conventions

CTEP-AERS Help uses a number of text fonts, styles, and wording conventions to communicate specific information easily. The following table details these conventions.

Convention	Description
Bold	Indicates the name of a button, field, area, or screen.
ALL CAPITALS	Indicates key names and keyboard combinations. For example, TAB key and ALT+F.
<i>Italics</i>	Indicates a specific value you must type or select for a field. Italics are also used in references to book titles.
Green	Indicates an expanding glossary definition.
Blue	Indicates a link to an additional CTEP-AERS Help topic.
Click	Move the mouse pointer to a named item and press the left mouse button once.
Clear	Click in a check box to remove the check mark.
Double-click	Move the mouse pointer to a named item and press the left mouse button twice in quick succession.
Glossary Definition icon	 is used to display the definition of a glossary term.
Right-click	Move the mouse pointer to a named item and press the right mouse button once.
Type	Use the key board to type a value into a field.
Select	Mark text, cells, or items for action or click a check box to add the check mark.
Read-only; view-only	Refers to a screen feature, such as a field or dialog box, containing information that cannot be changed by the user.

CTEP-AERS Basics - About Adverse Event Reporting

According to the International Committee on Harmonization (ICH), an adverse event is any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered drug related. CTEP-AERS facilitates the efficient and accurate recording and reporting of adverse events that occur during clinical trials. The adverse event recording and reporting requirements for a clinical trial are specified in the protocol.

For specific information regarding the NCI's adverse events reporting requirements, refer to the NCI Guidelines for Investigators: Adverse Event Reporting Requirements for DCTD (CTEP and CIP) and DCP INDs and IDEs.

User Access to CTEP-AERS

CTEP-AERS is open for public use. User credentials (i.e., username, password) are not necessary to access the system.

If you have problems accessing CTEP-AERS, please contact the NCI CTEP Help Desk at:

email: ncictephelp@ctep.nci.nih.gov

phone: 1-888-283-7457

fax: (301) 948-2242

Logging into CTEP-AERS

User accounts and passwords are not necessary to access and submit expedited reports using CTEP-AERS.

To access the CTEP-AERS, perform the following:

1. Access the CTEP-AERS application via the CTEP web site.

The **Disclaimer** dialog box appears.

*****WARNING*****

You are accessing a U.S. Government information system, which includes (1) this computer, (2) this computer network, (3) all computers connected to this network, and (4) all devices and storage media attached to this network or to a computer on this network. This information system is provided for U.S. Government-authorized use only.

Unauthorized or improper use of this system may result in disciplinary action, as well as civil and criminal penalties.

By using this information system, you understand and consent to the following:
 You have no reasonable expectation of privacy regarding any communications or data transiting or stored on this information system. At any time, and for any lawful Government purpose, the government may monitor, intercept, record, and search and seize any communication or data transiting or stored on this information system.

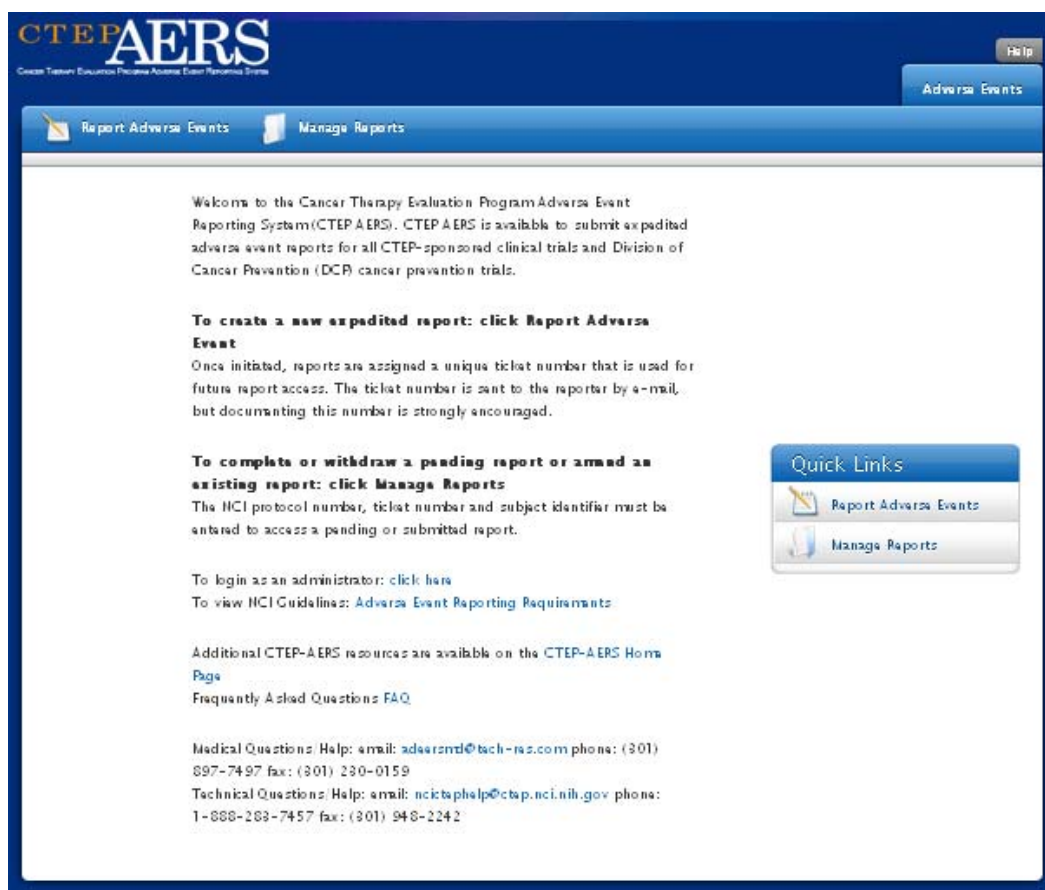
Any communication or data transiting or stored on this information system may be disclosed or used for any lawful Government purpose.

CONTACT US | PRIVACY NOTICE | **DISCLAIMER** | ACCESSIBILITY | APPLICATION SUPPORT

NCI | NIH | FIRSTGOV

2. Read the disclaimer and click **I agree**.

The **CTEP-AERS** home page displays.



3. Click one of the two tabs listed below:

Report Adverse Events to initiate an expedited report



or

Manage Reports to access an existing report.



Expedited Adverse Event Report Timelines

CTEP expedited reporting timelines are based on CTEP-funded and/or sponsored clinical studies including those sponsored by cooperative groups or networks, and studies sponsored by the Cancer Imaging Program (CIP) or the Division of Cancer Prevention (DCP).

Other factors are considered to determine the appropriate reporting timeline such as the seriousness (grade) of the event, the study phase, hospitalization, etc.

Refer to the NCI Guidelines for Investigators: Adverse Event Reporting Requirements for DCTD (CTEP and CIP) and DCP INDs and IDEs and the study protocol for more information.

NOTE: Refer to the study protocol for reporting adverse events that occur:

- greater than 30 days of the last agent administration; or
- on commercial agent-only trials. Reporting requirements for adverse events attributed to commercial agents experienced on CTEP-sponsored studies reflect current FDA guidelines and require report submission to the FDA within 15 calendar days. See the FDA [Enforcement of the Postmarketing Adverse Drug Reporting Regulation](#) for additional details.

CTEP 24-hour Notification

The 24-hour notification is required as an early detection system for potential safety problems. Its submission is due to the NCI within 24 hours of learning of the event. A subset of report data is required for successful submission.

After the initial 24-hour notification submission, the complete CTEP-AERS Expedited Report is due within five calendar days and must include all mandatory data required for the notification.

CTEP Expedited Report

The CTEP Expedited Report is due within 10 calendar days of the investigator learning of the event.

NOTE: Email notifications and reminders are sent by CTEP-AERS as a reminder of the report deadlines. If the report is not submitted by the due date, CTEP-AERS will send notification to the reporter that the report has been withdrawn from the system. System-withdrawn reports will list a **Report Submission Status** of *Initiated, not submitted* on the **Manage Reports** page.

Report Submission

CTEP Expedited Reports **MUST** be submitted through CTEP-AERS, even if internet connectivity or other issue forces the initial report submission to be made via fax.

Source documents (i.e., those selected on the **Additional Info** page) must be sent via fax.

The CTEP-AERS fax number is 301-230-0159.

To submit source documents:

- Write the **Subject ID** and the study's **Protocol Number** on each page submitted.
- Remove all personally identifiable information (i.e., subject's name, medical record number, financial account number, etc.).
- Include the **Report Ticket Number** on the fax cover sheet.

Notifications and Reminders

CTEP-AERS generates a variety of email notifications and reminders to ensure that your report is submitted in a timely manner. The following are notifications sent as part of the reporting process:

- The initial email is confirmation that a report was created and assigned a ticket number.
- Reminders are then emailed at certain intervals while the report is in progress. If the report is not submitted by the due date, CTEP-AERS will send notification to the reporter that the report has been withdrawn from the system. System-withdrawn reports will list a **Report Submission Status** of *Initiated, not submitted* on the **Manage Reports** page.
- Notification is emailed when the report is successfully submitted to the NCI or Central Processing.

NOTE: Email notifications associated with commercial agent adverse event reports are sent at the time the report is created and at the time the report is submitted only. No reminders are sent between report creation and report submission.

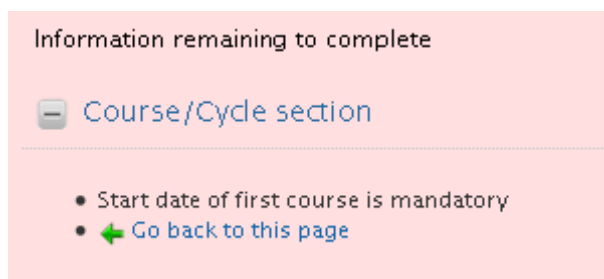
Required Fields in CTEP-AERS

All required fields in CTEP-AERS will appear in red and include a red asterisk (*) to the left of the field label, such as the illustration below.

* Start date of first course

Any mandatory field must be completed and saved prior to continuing to the next page.

CTEP-AERS will display an error message when a required field has not been completed and/or indicate that the field must be completed during the **Review & Submit** process, as shown below.



About Autocomplete

Many of the CTEP-AERS data entry fields utilize the autocomplete functionality which, after entering one or several characters, will provide a list of possible values to select from to populate the field.

Autocomplete fields are characterized by the instruction "Begin typing here" within the field and the remove icon located to the right of the field.

Begin typing here



The more characters that are entered into an autocomplete field, the faster the list of available values will be displayed. And although the wildcard (%) can be used within these fields, its use will not display the values any faster nor will the values be as exact as when characters are used.

NOTE: Due to the extensive list of studies and participating sites that CTEP supports, values display only when a minimum of three characters (letters or numbers) are entered within the Study and Organization fields located on the **Select study, subject, and course/cycle/intervention** page from **Report Adverse Events** workflow or the **Select study and subject** page from the **Manage Report** workflow. Only study numbers (i.e., NCI or local protocol numbers) can be used to query for the Study.

About Report Ticket Numbers

Once you have saved the reporter and treating physician information on the **Reporter** page, the ticket number will display within the blue overview box.

Ticket 2516758
Number

The ticket number is part of an access key that will allow you to retrieve pending or submitted reports in the future. The other two elements to the access key are the protocol number and subject ID. The reporter is sent the access key through an e-mail that is generated immediately after completion of the **Reporter** page. Regardless of this e-mail, it is recommended that you record the ticket number for future reference.

The ticket number is used throughout CTEP-AERS in the following manner:

- Once the ticket number is generated, the initiated report is considered pending and must be completed within time specified for the given report (i.e., 24-hour, 10-day, etc.).
- The ticket number is used to access the report either to complete or withdraw a pending report, or to review or amend a previously submitted report.
- When a report is amended, the ticket number continues to identify the report but with a corresponding amendment number.
- When contacting the NCI CTEP Help Desk, the ticket number provides reference for the Help Desk to access a specific report.

Blue Overview Box

Once the initial steps are completed and the report ticket number is assigned, a blue box displays at the top of each report page that lists the report's general information (i.e., subject, study and course/cycle).

Ticket Number	2600560
Subject ID	SS11
Study	(7028) A Phase II Study of BAY 43-9006 for Patients with Imatinib and Sunitinib Resistant Gastrointestinal Stromal Tumor
Course/Cycle	Cycle #: 2; Start Date: 02/18/2013

Once you have saved the reporter and treating physician information on the **Reporter** page, the ticket number will display. The ticket number is part of an access key that will allow you to retrieve pending or submitted reports in the future. The other two elements to the access key are the protocol number and subject ID. The reporter is sent the access key through an e-mail that is generated immediately after completion of the **Reporter** page. Regardless of this e-mail, it is recommended that you record the ticket number as a precaution and as future reference.

About Re-evaluation

If any of the adverse event information is modified and saved on the **Adverse Events** page, a message displays at the top of the page that warns you that re-evaluation of the data is needed to ensure that the proper report timeline is recommended.



Some of the key attributes of an adverse event have been modified. In order to be accurate, we recommend getting them re-evaluated by rules engine. Click [here](#) to evaluate them.

Click the [here](#) link to proceed.

The system returns to the **Recommended Actions** section of the **Review and Report** page.

NOTE: Depending on the added or modified data, the recommendation may be that a different report timeline be completed (i.e., 24-hour notification vs. a 10-day). Follow the recommendation or click [Override](#) and select a report appropriate for the event.

Reporting a Death

Any death occurring within 30 days of the last dose, regardless of attribution to the investigational agent/intervention, requires expedited reporting within 24 hours.

Any death occurring greater than 30 days after the last dose of the investigational agent/intervention requires expedited reporting within 24 hours only if it is *possibly*, *probably*, or *definitely* related to the investigational agent/intervention. Refer to the [NCI Guidelines for Investigators: Adverse Event Reporting Requirements for DCTD \(CTEP and CIP\) and DCP INDs and IDEs](#) for specific reporting requirements.

Death Unrelated to Adverse Event

To report a death unrelated to an adverse event:

1. Follow the Report Adverse Event workflow and enter the required information on the **Select Study, Subject and Course/Cycle/Intervention** page. Click **Continue**.
2. The **Adverse Events** page displays.
3. Enter the **Verbatim** and click **+Add**.
4. The **Adverse Events** page expands.
5. Enter the word *Death* and select one of the **CTCAE Terms** from the list of values.
6. Enter the fields remaining on the **Adverse Events** page and click **Save & Report**.
7. The **Recommended Actions** section of the **Review and Report** page will list the CTEP 24-Hour Notification as a required submission.
8. Click **Report** and enter the information required on the **Reporter** page, then click **Save & Continue**. The blue overview box displays with the newly assigned report ticket number while the **Adverse Events** page is displayed in the lower area of the page. Follow the workflow to complete the report.

NOTES: The following are CTCAE terms available for reporting a death. These terms do not require a positive attribution to submit the report.

Death Not Otherwise Specified (NOS):

Sudden death NOS: A sudden (defined as instant or within one hour of the onset of symptoms) or an unobserved cessation of life that cannot be attributed to a CTCAE term associated with grade 5.

Death due to progressive disease should be reported as Grade 5 "*Neoplasms benign, malignant and unspecified (incl cysts and polyps) - Other (progressive disease)*" under the category or system organ class (SOC) of the same name. Evidence that the death was a manifestation of underlying disease (e.g., radiological changes suggesting tumor growth or progression; clinical deterioration associated with a disease process) should be submitted.

Relevant additional information must be submitted to accompany the report when a death is reported for any reason.

Central Processing

For those studies where central processing is required, CTEP-AERS will forward the completed report (5- or 10-day) to the study's lead group or network for review prior to submission to CTEP.

NOTE: 24-hour notifications are only submitted to CTEP for adverse events that warrant notification. (i.e., central processing is not an option).

Upon submission of the report, a message will display on the **Submission Status** page indicating that the report was submitted to the group.



Submitted successfully to group on 07/18/2013

Email notification is sent to the reporter and Group Coordinator once the report is submitted to central processing.

Reports submitted to central processing are then indicated as **Reports Submitted to Group** within the Manage Reports module. During the review period, the report is available as view-only; modifications or amendments to the report cannot be made. Remember that the central processing review must be completed and the report submitted within the reporting timeline.

Manage Reports			
Course	# of Reports	# of AEs	Report Submission Status
	2	1	Reports Submitted to Group







Any changes by the group or network will be available through CTEP-AERS once the review is complete.

NOTE: It is recommended to print or save a PDF copy of the original report to compare to the reviewed report.

Common CTEP-AERS Screen Features

The CTEP-AERS does not have a menu bar or a toolbar that contain commands and features. Instead, the features are displayed throughout the report sections that you will complete. The following table provides more details about these features.

Feature	Description
Blue Checkmark	appears next to the step name and number at the top of the page and indicates that the step is complete.
Calendar icon	is used to select a specific date.
View CTCAE v4.0	View CTCAE v4.0 link is available from the 2. Adverse Events tab from the Report Adverse Event workflow to search and view Adverse Event terms and grades.
Dialog box	A named box containing fields and options used to perform a particular task.
Field-level help icon	displays next to a field and provides specific instruction about that field.
Fields	A named text box in which information can be entered, selected,

Feature	Description
	and/or displayed.
Information Saved Successfully	 <i>Information saved successfully</i> displays when the values entered are saved to the application.
List of Values	 The square command button is used to display a static list of optional values from which one specific value can be selected for a field.
Minus Sign	 is used to minimize a section of information on a page.
Page areas	Refers to a specifically named area that is usually contained within a border. Many of the pages may contain more than one area.
Plus Sign	 is used to expand a section of information on a page.
Red Asterisk	* indicates that entry of the field is mandatory and must be completed prior to continuing to the next page.
Delete icon	 is used to delete a record from a page. Please note that this delete is effective immediately and cannot be undone.
Remove icon	 is used to remove a value from a field so that a new value can be selected using autocomplete.
Show all link	Show All displays a list of values available for entry when the number of values warrants a navigation aid.

About Special Characters

The CTEP-AERS supports the ISO-8859-1 character set which limits the characters allowed for entry within the system. When special characters (i.e., characters other than those included in the ISO-8859-1 character set) are entered into CTEP-AERS, they are automatically converted to an inverted question mark (¿). This is done to prevent potential submission failures and to provide the user an easy way to identify and revise the inverted question mark.

The **Description of Event** field is generally the most common field for entry of special characters due to the use of the copy/paste option to enter data from an outside source. For example, the user copies and pastes "Lab tests revealed total leukocyte count = 16,800cells/μL with neutrophilia" into the field.

* Description & treatment of event(s)

Lab tests revealed total leukocyte count=16,800cells/μL with neutrophilia.

The prefix "micro" (i.e., "μ" symbol), is not included within the ISO-8859-1 character set. To alert the user that a special character was converted within the data field, CTEP-AERS displays the following message:

A character(s) was converted to an inverted question mark (¿) because it is not part of the CTEP-AERS character set (ISO-8859-1). The inverted question mark(s) is acceptable for report submission, but, to ensure report accuracy, should be replaced with characters using the keyboard for entry. Please see the online help for more information.

OK

To provide accurate report data, review the content and replace the inverted question mark with a character(s) using the computer keyboard for entry.

Unfortunately, finding and replacing inverted question marks may become a burden if most of the 4,000 allowable characters were copied to the **Description of Event** field. To simplify this task, you may copy the converted text from the field and use a *Search and Replace* feature within Microsoft Word or other wordprocessing application. The following instructions describe how to insert the inverted question mark into the Search field:

1. Click the **Search** field to place the cursor within the field.
2. Hold down the **Alt** key and type **0919** or **168** from the numeric keypad.
3. Release the **Alt** key.

The inverted question mark will display within the field.

Conduct the search as normal and replace the inverted symbol with appropriate characters using the keyboard for entry.

Getting Started - Report Adverse Events in CTEP-AERS

The Report Adverse Events option provides a workflow that is used to initiate the CTEP 24-hour Notification or Expedited Report. Mandatory data entry fields are marked with a red asterisk (*) and may vary depending on the protocol.

NOTE: See **Manage Reports** to access and submit a pending report, to amend a previously submitted report or to withdraw a pending report.

To initiate the report:

Click the **Report Adverse Event** tab.



Three smaller tabs are displayed to indicate the initial steps you will perform during the process. The steps include:

Step 1. Study, Subject and Course/Cycle/Intervention

1. Study, Subject & Course/Cycle

This page is used to enter report information that will display within the blue overview box throughout the life of the report.

Step 2. Adverse Events

2. Adverse Events

This page is used to enter a minimum set of adverse event information that is used by CTEP-AERS to determine whether a report is warranted.

Step 3. Review and Report

3. Review and Report

This page indicates the type of report that should be submitted based on the adverse event, grade and other criteria. It also provides you an **override** option for those events that CTEP-AERS deems unnecessary to report.

NOTE: If the Recommended Action given is to submit a report, a fourth step is necessary to complete the **Reporter** page at which time the report ticket number is assigned.

Step 1 – Select Study, Subject and Course/Cycle/Intervention

To identify the adverse event study, subject, site and course:

Click the **Report Adverse Events** tab.



The **Select study, subject, and course/cycle/intervention** page opens allowing you to find a study, subject, and course/cycle/intervention combination to which you will add an adverse event.

To specify the study, subject, and course/cycle/intervention:

1. Use the autocomplete feature to enter the **Study** (i.e., NCI or local protocol number) and select a study from the list. Only study numbers can be used to query the study.
2. Enter the **Subject ID** using the patient's ID as assigned on the study. The maximum number of characters allowed in this field is twenty (20). The following special characters can be used within the **Subject ID** field: !@#\$%^&*()_+ -=|\":;.
3. Enter the **Confirm Subject ID** to confirm correct ID entry.
4. Use the autocomplete feature to enter the **Organization** name and select the organization from the list.
5. Click **+ Add** at the **Course/Cycle/Intervention** field.

The **Course/Cycle/Intervention Information** pop-up page displays.

Treatment Assignment	Description
<input type="radio"/> TAC1	(Cycle=28 days)\nBAY 43-9006: 400mg PO BID
<input type="radio"/> Other	

6. Select the Treatment Assignment code (TAC) from those listed in the table or, if the correct TAC is not available and/or the adverse event occurred during a surgery or radiation intervention, click **Other** and enter the treatment assignment (i.e., agent name, doses defined in the protocol, route, schedule, etc.) in the **Description** field. See **Using 'Other' to Assign a Treatment Regimen**, below, for additional information.
7. To save your changes, click **Save**.

The pop-up page closes and the system returns to the **Select Study, Subject, Course/Cycle/Intervention** page with the message *Course/Cycle/Intervention created successfully* displayed.

Click **Continue** to advance to the **Adverse Events** page, where the adverse event information is entered.

Using 'Other' to Assign a Treatment Regimen

If the correct TAC is not available and/or the adverse event occurred during a surgery or radiation intervention, information describing the treatment must be provided in the **Other** field.



NOTE: When reporting adverse events for surgery or radiation interventions, enter intervention details only within the **Other** field, no other information is necessary

Use the following format and extent when entering treatment assignments in the **Other** field:

Agent names(s), dose as defined in the protocol (i.e., amount per kg, m2, etc.) route, and schedule.

Other Treatment Regimen: Example of mandatory data

Agent Name	Dose as Defined in Protocol	Route	Schedule and Treatment Arm or Dose Level
Pathostatin	25 mcg/m2	IV	Over 24 hrs continuous IV over 24 hrs Day 1 and Day 8 Every 28 day cycle
Biologic A	1.5 Million IU/m2	SQ	Daily Days 1 to 5 Every 28 day cycle

Step 2 – Add the Adverse Event



To add the adverse event:

1. **Enter Verbatim** using the original wording provided by the subject or clinician to describe the adverse event.
2. Click **+Add** to display the adverse event details. You cannot edit the **Enter verbatim** field after clicking the **+Add** button.

The screenshot shows a web form titled "Verbatim: pain". It contains several sections for data entry:

- CTCAE Term:** A text input field with a red border and a clear button (X).
- Grade:** A radio button selection menu with five options:
 - 1: Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.
 - 2: Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL.
 - 3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care ADL.
 - 4: Life-threatening consequences; urgent intervention indicated.
 - 5: Death related to AE.
- Start date:** A text input field with a calendar icon and the format "(mm dd yyyy)".
- End date:** A text input field with a calendar icon and the format "(mm dd yyyy)".
- Did AE cause hospitalization?:** A dropdown menu with a question mark icon.
- Outcomes:** A list of checkboxes:
 - Death
 - Hospitalization - initial or prolonged
 - Life-threatening
 - Disability or Permanent Damage
 - Congenital Anomaly/Birth Defect
 - Required Intervention to Prevent Permanent Impairment/Damage (Devices)
 - Other Serious (Important Medical Events) [text input field]

3. Use the autocomplete feature to enter the **CTCAE Term** then select a term from the list of values.

NOTE: To report a Death unrelated to Adverse Event, select one of the two Death adverse event terms available from the list of values. These terms allow a negative (i.e., unrelated, unlikely) attribution when submitting the report.

4. Specify the **Grade** or severity of the adverse event. The grades that display will vary based on the selected adverse event term.
5. Enter the **Start date** and **End date** of the adverse event in the format MM/DD/YYYY. You can also click the calendar icon to select the date. The **Start date** is a mandatory field for the primary adverse event. Because the **End date** is not always known, it is not a mandatory field.
6. Answer the question, **Did AE Cause Hospitalization?** to specify whether the adverse event caused a hospital stay or the extension of a hospital stay. This is a mandatory field.
7. Select the checkbox for all **Outcomes** that apply to the adverse event. Additional details are entered in the **Other Serious** field to describe important medical events that are not associated with the listed outcomes.

NOTE: The outcome **Death** is automatically selected when *Grade 5* is chosen for the **CTCAE term**. Additionally, the outcome **Hospitalization - initial or prolonged** is automatically selected when *Yes* is chosen for **Did AE cause hospitalization?**

Repeat the above steps as many times as necessary to add all adverse events for the subject and course/cycle.

8. Click **Save & Report** to save your changes and continue to the **Review and Report** page, or
 - Click **Save** to save the information you entered.


- Click **Save & Back** to save your changes and return to the previous page.

Step 3 - Review and Report

After adding an adverse event(s) and clicking **Save & Report**, CTEP-AERS runs the rules defined for the selected study to determine whether any safety reporting actions are recommended. The results of the rules are displayed on the **Review and Report** page. Please note that although CTEP-AERS provides safety reporting recommendations, the user still must review these recommendations (or lack thereof) and act upon them in order to ensure accurate and timely safety reporting which complies with the trial protocol, institutional, regulatory, and other applicable reporting requirements or guidelines.

The **Review and Report** page organizes the results in the following manner:

Recommended Actions



An action is recommended.


Possible exceptions (please consult your protocol for specific expedited reporting requirements):

- Commercial agent only studies
- Studies utilizing one of the legacy AE Reporting tables (those that incorporate expectedness and attribution into the table)
- Adverse events that occurred more than 30 days after the last administration of investigational agent/intervention or >10 radioactive half-lives for PET or SPECT agents

Dyspepsia: stomach pain , 3: Severe symptoms; surgical intervention indicated

Recommended Actions

Based on the data you have entered and the rules enabled for this study, the following action is recommended: [Override](#)

Select	Action	Report	Status	Due
<input checked="" type="checkbox"/>	 CREATE	CTEP Expedited Report	Not started	Due in 10 days

The **Recommended Actions** table displays when the rules defined in CTEP-AERS result in a required report. If the adverse event is associated with a commercial agent or if the event occurred more than 30 days after the last administration of the investigational agent or intervention there may be an exception; refer to the study protocol for reporting requirement information.

The following information is listed for the recommended action:

A checked **Select** box indicates a recommendation of completing a new or in-progress report. A cleared **Select** box indicates a recommendation to withdraw a report.

The **Action** column has several possible entries:

Edit - The report has been started but has not been submitted.

Withdraw - The report is being canceled.

Create - The report has yet to be started.

Amend - The report has already been submitted, but it needs to be updated.

The **Report** column indicates the report required, based on the reporting timelines. The following reports will display based on the rules defined for the study:

24-Hour Notification - Due within 24 hours of report creation.

CTEP Expedited Report -

Due in 5 days: Submit the report within 5 days of the 24-Hour Notification submission. CTEP-AERS automatically removes the unsubmitted report 8 days after submission of the 24-Hour Notification.

Due in 10 days: Submit the report within 10 days of report creation. CTEP-AERS automatically removes the unsubmitted report 11 days after its creation.

Due in 15-days: Submit the report within 15 days of report creation when reporting adverse events associated with commercial agent clinical trials. CTEP-AERS automatically removes the unsubmitted report 20 days after its creation.

The **Status** column references the report status and has several possible entries:


In Progress - More information needs to be completed to submit the report.

Withdrawn - The report was selected, but now it will not be submitted.

Not Started - The report is selected but has not been created.

The **Due** column lists the due date for submission of the expedited report.

Available Actions



An action is NOT recommended.

Based on the data you have entered and the rules enabled for this study, **expedited reporting is not required.**

Possible exceptions (please consult your protocol for specific expedited reporting requirements):

- Commercial agent only studies
- Studies utilizing one of the legacy AE Reporting tables (those that incorporate expectedness and attribution into the table)
- Adverse events that occurred more than 30 days after the last administration of investigational agent/intervention or >10 radioactive half-lives for PET or SPECT agents

[?](#)

Dyspepsia: stomach pain , 1: Mild symptoms; intervention not indicated

Available Actions

Based on the data you have entered and the rules enabled for this study, expedited reporting is not required. If you believe expedited reporting is warranted, click 'Override' and select the report you wish to complete.

[Override](#)

The **Available Actions** table displays when the CTEP-AERS rules determine that an expedited report is not required.

To determine whether an override is warranted, consult the study protocol in cases where:

- The study utilizes only commercial agents.
- The protocol's adverse event reporting requirements are based on a legacy AE Reporting Table that includes expectedness and attribution.
- The adverse event occurred more than 30 days of the last administration of investigational agent or intervention and includes a positive attribution (i.e., *Possible, Probable, Definite*).
- The event is associated with PET or SPECT agents with an administration greater than 10 radioactive half-lives.

NOTE: See ***Overriding an Action*** for more information about overrides.

Adverse Events

The **Adverse Events** table is listed regardless of the Recommended or Available Action and displays the adverse events which are available for reporting.

The following information is listed for each adverse event in the **Adverse Events** table:

Under the Select column, a checked **Select** box indicates that the adverse event will be included in the report. You can click to clear the **Select** box to exclude an adverse event from expedited reporting for reports with multiple events.

Adverse Events					
Select	Expedited Reporting Required?	Adverse Event Term	Grade	Start date	*Primary?
<input checked="" type="checkbox"/>	Yes	Dyspepsia: stomach pain 	3: Severe symptoms; surgical intervention indicated	10/01/2013	


Expedited Reporting Required? indicates whether CTEP-AERS recommends including the corresponding adverse event in the selected expedited report.

Yes indicates that an expedited report is required to be submitted for the adverse event.

No indicates that the adverse event does not require an expedited report.

Adverse Event Term is the CTCAE term and verbatim that describes the adverse event.

After the display of the adverse event term is an indication of the **Adverse Event Status** which is the status of the adverse event on a report:

Reported  indicates that the adverse event is already included in a submitted report.

New  indicates that the adverse event is new to the report.

Deleted  indicates that the adverse event was deleted from the report.

NOTE: See *Deleting an Adverse Event from a Pending Report* to permanently remove an adverse event from a pending report. You may also exclude the event from the report by deselecting the **Select** box.

Grade is the severity selected for the adverse event.

The **Start Date** is the date when the adverse event began. If the date does not display, you may enter the date in the format mm/dd/yyyy or click the calendar icon and select a date.

The **Start Date** is mandatory for the primary adverse event included in the report and CTEP-AERS will prevent the report from being submitted until this information is entered.



Under the **Primary?** column, a checked **Primary?** radio button indicates that the adverse event is the primary event included on the report. You can click to reselect the primary adverse event when the report includes more than one event. If changing the primary adverse event, make sure to enter the event's **Start Date** as it is mandatory for report submission.



Depending on the recommended action, you may:

- Click **Report** to continue to the **Reporter** page, to obtain the report ticket number and submit the report.
- End the session based on the available action of *no report required*.
- Override the action and continue to the **Reporter** page, to obtain the ticket number and submit the report.

Overriding an Action

From the **Review and Report** page, you may override CTEP-AERS in instances where the action indicates that no report is necessary or to change from a 10-day report to a 24-hour notification. You cannot however, override a recommended 24-hour notification to that of a 10-day.

To override the CTEP-AERS-based recommended reporting action:

1. Click the blue Override link.

The following message displays:

Are you sure you want to bypass the CTEP AERS-based report selection above and instead manually select from the list of all reports defined for this study?

2. Click **Ok** to continue.

The override options will display as shown below. The options available will depend on the type of study (i.e., investigational agent) you are reporting.

Select	Action	Report	Status	Due
<input type="checkbox"/>		CTEP Expedited Report (15 Days)		
<input checked="" type="checkbox"/>	 CREATE	CTEP Expedited Report	Not started	Due in 10 days

3. Select the report you wish to submit and click **Report** to continue to the **Reporter** page, obtain the report ticket number and submit the report.

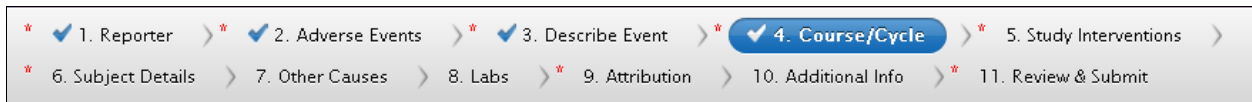
If you wish to restore the CTEP-AERS recommended report selection, click the **Restore Recommended Action** link.

Completing Reports - Adding Information to the Expedited Reports

To summarize the steps completed so far, you have:

- Initiated the report through the Report Adverse Events workflow,
- Entered mandatory information on the **Select study, subject, and course/cycle/intervention** page,
- Entered mandatory information on the **Adverse Events** page,
- Received a **Recommended Action** on the **Review & Report** page indicating the appropriate expedited report to submit,
- Entered mandatory information on the **Reporter** page, and
- Received the report ticket number.

If you choose to continue the report process, the steps to complete the process are numbered and displayed as a banner at the top of the CTEP-AERS application. The same steps that display from within the Manage Reports workflow.

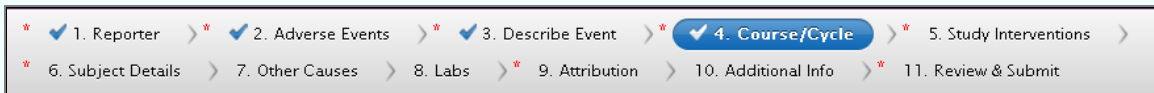


Mandatory steps will display a red asterisk (*) next to them. When you complete a step, a blue check mark ✓ will appear next to the step title. If you do not fill in all the mandatory fields on a page, you cannot continue to the next page. In some cases, fields in one step may become mandatory depending on information entered in another step. In this situation, CTEP-AERS will display a message to guide you to the area requiring additional information.

The following is an example of this situation.

Example

The check marks in the illustration below indicate that the information you have entered in steps 1 through 4 have satisfied the mandatory reporting requirements.



Report Section Banner – 4. Course/Cycle complete

You proceed to the **Study Interventions** page (step 5), and enter the mandatory agent information.


Continued

Information entered on the Agents page

After clicking **Save**, the following message displays:

- There are problems with your submission. Please correct them before proceeding.
- Course Information must be provided in the Course/Cycle page (tab 4).

Message displayed after saving the information on the Agents page.

Although the **Course/Cycle** page (step 4) displayed a blue check mark  prior to the entry of the agent information, the message implies that additional information is required and the blue check mark no longer displays at the **Course/Cycle** page.

Report Section Banner – 4. Course/Cycle incomplete

Upon opening the **Course/Cycle** page, four additional mandatory fields display. These fields must be entered and saved to continue the reporting process.

Continued

Course/Cycle

Treatment Information

* Treatment assignment code: TAC1

Description of treatment assignment or dose level: (Cycle=28 days) BAY 43-9006: 400mg PO BID

Course Information

* Start date of first course

* Start date of course associated with expedited report

* Course number on which event occurred

* Total number of courses to date

Mandatory entry fields on the Course/Cycle page

Complete the entries, click **Save & Continue** and go to the next step.

The tabs that display in CTEP-AERS identify the steps to complete the report, they include:

1. Reporter
2. Adverse Events
3. Describe Event
4. Course/Cycle
5. Study Interventions
6. Subject Details
7. Other Causes
8. Labs
9. Attribution
10. Additional Information
11. Review & Submit

NOTE: The information that you are prompted for in this workflow is dependent on the report timeline, so you may not see all the fields presented. Also, if you enter information that is relevant to more than one report type, you will not have to fill in the information more than once.

Step 1. Reporter - Adding Reporter and Treating Physician Details

The **Reporter** page enables you to enter contact information about the treating physician and the person reporting the adverse event. Once the page is completed and saved, the report ticket number is generated and displayed within the blue overview box located at the top of each report section.

The screenshot shows a web form titled "Reporter" with a help icon in the top right corner. Below the title is an "Instructions" box stating: "Enter contact information for the person reporting the adverse event and the treating physician. You can select the person from the drop down list or enter the details." The form is divided into two main sections: "Reporter Details" and "Treating Physician Details".

Reporter Details section includes the following fields:

- * First name (text input)
- Middle name (text input)
- * Last name (text input)
- * E-mail address (text input)
- * Phone (text input)
- * Fax (text input)

Below these fields is a checkbox with the text: "If the Physician is the same as the Reporter click here".

Treating Physician Details section includes the following fields:

- * First name (text input)
- Middle name (text input)
- * Last name (text input)
- * Email address (text input)
- * Phone (text input)

Adding Reporter Details

To add the contact information of the person reporting the adverse event, enter the reporter's:

- First name**
- Middle name** (optional)
- Last name**
- E-mail address**
- Phone** number
- Fax** number

If the reporter details represent the physician (the physician responsible for addressing questions about this report) click in the box ☐ next to **If the Physician is the same as the Reporter** and the reporter information will populate the physician fields. If the physician is a different person than the person reporting the adverse event, enter the fields in the **Treating Physician Details** section as described below.

Adding Treating Physician Details

To add the physician who was treating the participant at the time of the adverse event, enter the physician's:

First name

Middle name (optional)

Last name

E-mail address

Phone number

Fax number

Click **Save & Continue** to save and continue to the **Adverse Events** page, or

- Click **Save** to save the information you entered.
- Click **Save & Back** to save your changes and return to the previous page.


NOTE: At this time the report's due date is generated and an email notification is sent to the reporter to confirm the report's creation.

Step 2. Adverse Events - Reviewing the Adverse Events

The **Adverse Events** page enables you to review and, if needed, edit the adverse event information or add additional adverse events.

The selected report timeline determines the mandatory fields that appear on each report page. These instructions describe all possible fields for the section of the expedited report.

To review the adverse event:

1. Click the plus sign  icon to the left of the adverse event, to expand the page and display the adverse event details. You can modify the information or maintain the original information.
2. Click **Save & Continue** to save and continue to the **Describe Event** page or
 - Click **Save** to save your changes.
 - Click **Save & Back** to save and return to the previous page.

To add a new adverse event:

1. Click **+Add/Edit Adverse Event** to display the **Enter verbatim** field.

2. **Enter verbatim** using the original wording provided by the subject or clinician to describe the adverse event.
3. Click **+Add** to display the adverse event details. You cannot edit the **Enter verbatim** field after clicking the **+Add** button.
4. Enter the **CTCAE Term** by typing the term or a portion of the adverse event term in the field, then select a term from the list.
5. Specify the **Grade** or severity of the adverse event. The grades that display will vary based on the selected adverse event term.
6. Enter the **Start date** and **End date** of the adverse event in the format MM/DD/YYYY. You can also click the calendar icon to select that date. The **Start date** is a mandatory field for the primary adverse event. Because the **End date** is not always known, it is not a mandatory field.
7. Answer the question, **Did AE Cause Hospitalization?** to specify whether the adverse event caused a hospital stay or the extension of a hospital stay. This is a mandatory field.
8. Enter any additional **Outcomes** by clicking the corresponding checkbox.

NOTE: The outcome **Death** is automatically selected when *Grade 5* is chosen for the **CTCAE Term**. Additionally, the outcome **Hospitalization - initial or prolonged** is automatically selected when *Yes* is chosen for **Did AE cause hospitalization?**

Repeat the above steps as many times as necessary to add all adverse events for the subject and course/cycle.

9. Click **Save & Continue** to save and continue to the Describe Event page, or
 - Click **Save** to save the information you entered.
 - Click **Save & Back** to save your changes and return to the previous page.

NOTE: Depending on the new or modified adverse event information, CTEP-AERS may require you to re-evaluate the report submission.

Step 3. Describe Event - Describing the Adverse Event

The **Describe Event** page is one of the most critical sections of the report. Detailed information must be provided to evaluate the event(s) and/or death reported. Do not just describe the primary adverse event, but include all of the adverse events that the subject experienced. Include a presentation of each event, the treatment of the event, clinical findings, and the timing of the event in relation to study interventions.

Provide information regarding physical assessment findings, results of diagnostic tests, and other pertinent information. Document procedures performed (e.g., surgery, thoracentesis, colonoscopy, autopsy). Be as complete as possible.

Additional information, including supporting documentation for the adverse event must be faxed with the report.

Describe Event

Instructions This is one of the most critical sections of the report. Provide detailed information about the event including the presentation of the event, the treatment of the event, clinical findings, and the timing of the event in relation to study interventions. Be as complete as possible.

*** Description & treatment of event(s)**

*** Subject's status at time of this report**

Date of recovery or death

Has the subject been re-treated?

Date removed from protocol

Autopsy performed?

NOTE: If you modified the adverse events on the previous page, a message displays at the top of the Describe Event page: *Some of the key attributes of an adverse event were modified.* In order to be accurate, it is recommended to re-evaluate the report attributes before continuing report entry.

To describe the adverse event:

1. In **Description & treatment of event(s)**, specify information about the event including information on the presentation of the event, clinical findings, treatment of the event, and timing of the event related to agent administration. This field has a limit of 4,000 characters.

NOTE: Characters entered in the **Description & treatment of event(s)** field may be converted to an inverted question mark (¿) if the character is outside the ISO-8859-1 character set. When this occurs, the following message displays to indicate that the user should replace the inverted symbol to ensure accurate report data.

A character(s) was converted to an inverted question mark (¿) because it is not part of the CTEP-AERS character set (ISO-8859-1). The inverted question mark(s) is acceptable for report submission, but, to ensure report accuracy, should be replaced with characters using the keyboard for entry. Please see the online help for more information.

OK

Please see the *Error! Reference source not found.* section for more information.

2. Select the **Subject's status at time of this report** to indicate the patient's current state. The value *Fatal/Died* can only be entered when a grade 5 adverse event was entered in the Adverse Event page.
3. Enter the subject's **Date of recovery or death** or leave this field blank if recovery or death did not occur. This field only displays and is mandatory when *Fatal/Died*, *Recovered/Resolved with Sequelae* or *Recovered/Resolved without Sequelae* is selected in the **Subject's status at time of this report** field.
4. Answer **Has the subject been re-treated?**
5. Enter **Date removed from protocol** to indicate the date that the patient was removed from the study, if necessary, in the format mm/dd/yyyy or click the calendar icon and select a date. This field becomes mandatory when *Fatal/Died* is selected in the **Subject's status at time of this report** field.
6. Click the checkbox to answer **Autopsy performed?** This field only displays and is mandatory when *Fatal/Died* is selected in the **Subject's status at time of this report** field.
7. Click the **Save & Continue** to save and continue to the **Course/Cycle** page, or:
 - Click **Save** to save your changes.
 - Click **Save & Back** to save and return to the previous page.

Step 4. Course/Cycle - Specifying the Course of Treatment

The **Course** page lists treatment information on the course that the patient received during the adverse event. This information is necessary to see how the treatment information is related to the adverse event. Knowing what dose the subject received at the onset of the adverse event helps determine that relationship.

The screenshot shows a web form titled "Course/Cycle" with a help icon. It is divided into two main sections: "Treatment Information" and "Course Information".

Treatment Information:

- Treatment assignment code:** A dropdown menu showing "TAC1" with a help icon.
- Description of treatment assignment or dose level:** A text area containing "(Cycle=28 days)" and "BAY 43-9006: 400mg PO BID".

Course Information:

- Start date of first course:** A date input field with a calendar icon and a help icon, with the format "(mm/dd/yyyy)".
- Start date of course associated with expedited report:** A date input field with a calendar icon and a help icon, with the format "(mm/dd/yyyy)".
- Course number on which event occurred:** A numeric input field.
- Total number of courses to date:** A numeric input field.

To enter treatment and course information:

1. Select the **Treatment assignment code (TAC)** from the list of values. The **Description of treatment assignment or dose level** automatically populates with TAC details.

NOTE: If the correct TAC is not available from the list of values or, if the correct TAC is not available and/or the adverse event occurred during a surgery or radiation intervention, select *Other* from the **Treatment assignment code** list of values and enter the TAC information (i.e., agent name, doses defined in the protocol, route, schedule, etc.) in the **Enter a description of treatment assignment or dose level** field.

2. Enter the **Start date of first course** of treatment in the format mm/dd/yyyy or click the calendar icon and select a date.
3. Enter the **Start date of course associated with expedited report** in the format mm/dd/yyyy or click the calendar icon and select a date.
4. Enter the **Course number on which event occurred**.

NOTE: Some protocols do not have defined courses or cycles, such as those with daily administration of an agent. For these protocols the field **Course number on which event occurred** is to be entered as 1 (one).

5. Enter the **Total number of courses to date** or the total number of courses of treatment the subject has taken up to this point.
6. Click **Save & Continue** to save and continue to the **Study Interventions** page, or
 - Click **Save** to save your changes.
 - Click **Save & Back** to save your changes and go to the previous page.

Step 5. Study Interventions - Adding Study Interventions

The **Study Interventions** page enables you to add any interventions during the study that may have caused an adverse event. At least one study intervention must be entered in order to continue the report. Study interventions fall into the following four categories:

- **Agents** - The medication, vitamin, mineral, or food supplement for the dose level/treatment arm indicated.
- **Radiation** - A local treatment that acts only on the part of the body that is exposed to the radiation.
- **Surgery** - The location of the surgery or the intervention site.
- **Device** - Any device (implant) involved in the study or in an intervention.

NOTE: Access to each intervention page is dependent on the study protocol (i.e., the **Device** page will only display for studies using a device).

Adding Study Agents

Agents

Was an investigational agent administered for this subject on this protocol? Yes

()

* Study agent

* Total dose administered this course

* Unit of measure

Date last administered prior to the event that is being reported (mm/dd/yyyy)

Administration delay Minutes

Comments

Dose modifications?

To specify study agents:

1. Answer the question, **Was an investigational agent administered to this subject on this protocol?** This field is mandatory when an agent is added and saved to the report.


Select *Yes* if the subject received an investigational agent at any time while enrolled on the study. Selecting *Yes* is mandatory if an investigational agent is to be added to the report.

Select *No* if the patient did not receive an investigational agent. Selecting *No* allows entry of commercial agents, if included on the study.

NOTE: Enter *No* in the **Was an investigational agent administered to this subject on this protocol?** field if there are no investigational agents available from the **Study Agent** list of values.

For increased accuracy, the **Study Agent** list of values includes either *Investigational* or *Commercial* after each agent name.

2. Click **+Add** to add an agent intervention.
3. Select the **Study agent** that may have caused the adverse event from the list of values.
4. Enter the agent **Lot #, (if known)**. Entry of this field is optional.
5. Enter the **Total dose administered this course** and select the **Unit of Measure** from the list of values.


6. Enter the **Agent Start Date** in the format mm/dd/yyyy or click the calendar icon and select a date. The **Agent Start Date** is the date the agent was first administered to the patient on the initial course of treatment.
7. Enter the **Agent End Date** in the format mm/dd/yyyy or click the calendar icon and select a date. The **Agent End Date** is the date the agent was last administered to the patient and can be the same date as that entered in the **Date last administered prior to the event that is being reported** field.
8. Enter the **Date last administered prior to the event that is being reported** to indicate the date that the study agent was last administered to the patient prior to experiencing the adverse event. Enter this date in the format mm/dd/yyyy or click the calendar icon and select a date. This is a mandatory field and may be the same date as that entered in the **Agent End Date** field.
9. Indicate whether there was an **Administration delay** that occurred prior to the adverse event by entering the quantity of time and selecting the measurement.
10. Enter **Comments** about the administration delay and the modified dose, if applicable.
11. Answer whether there were **Dose modifications?** prior to the adverse event by selecting from the list of values to indicate a dose alteration relative to the dose level/treatment ARM. For example, if the total dose was supposed to be 300mg (3 days in a row of 100mg a day), but the third day the subject was only given 50 mg, you would select *Dose reduced* then enter *Only gave 50 mg on 3rd day* in the **Comments** box.
12. Click **Save & Continue** to save and continue to the **Subject Details** page, or
 - Click **Save** to save your changes and continue to the **Radiation** intervention section, if applicable to the study.
 - Click **Save & Back** to save your changes and go to the previous page.
 - Click **+Add** to add another study agent.
 - Click the delete icon  to delete a study agent.

Repeat these steps multiple times to add all agents for the dose level/treatment arm indicated. You must include information on all of the agents that the subject received.

Adding Study Device

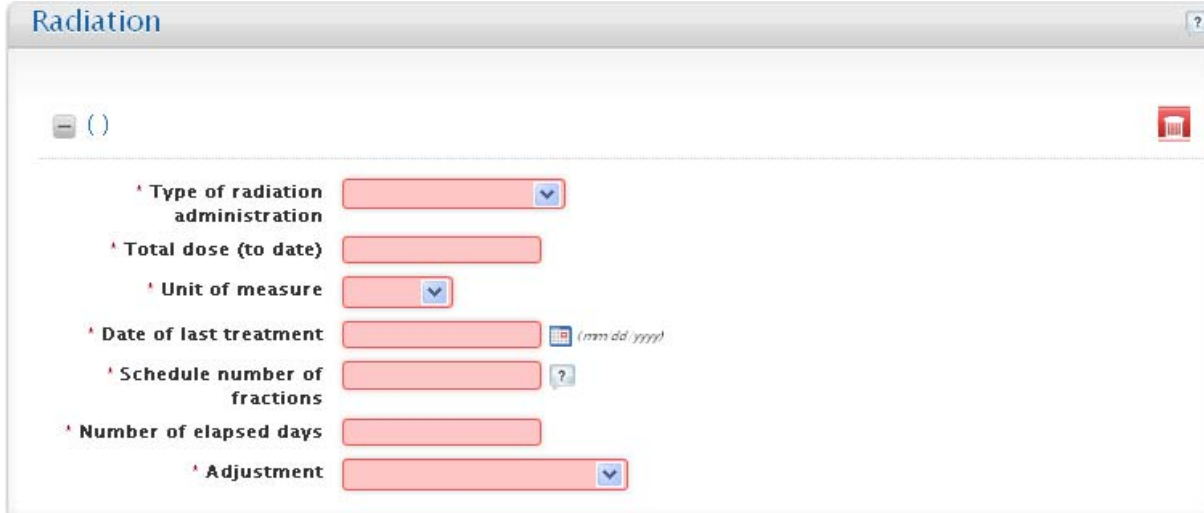
To specify the study device:

1. Answer the question, **Was an investigational device administered to this subject on this protocol?** This field is mandatory and must be entered when any type of device (i.e., investigational, commercial, etc.) is included on the protocol.
 Select *Yes* if the subject received an investigational device at any time while enrolled on the study.
 Select *No* if the subject did not receive an investigational device. Selecting *No* allows entry of commercial devices, if included on the study.
2. Click **+Add** to add the medical device and select from the list of values.
3. Select the **Study device** from the list of values.
 The **Brand name**, **Common name** and **Device type** are displayed.
4. Enter the **Manufacturer name** or company that manufactured the device.
5. Enter the **Manufacturer city** where the device was manufactured.
6. Select the **Manufacturer state** from the list of values.
7. Enter the **Model number** to identify the device.
8. Enter the **Lot number** assigned to the device.
9. Enter the **Catalog number** from the medical catalog to identify the medical device.
10. Enter the **Expiration date** of the device (when the device expires) in the format mm/dd/yyyy or click the calendar icon.

11. Enter the **Serial number** to identify the device.
12. Enter any **Other number**, if applicable, to identify the device.
13. Select a **Device operator** from the list of values to specify the person who used the device.
14. **If implanted, enter a date** in which the device was implanted in the participant.
Enter the date in the format mm/dd/yyyy or click the calendar icon and select a date.
15. **If explanted, enter a date** in which the device was removed from the participant.
Enter the date in the format mm/dd/yyyy or click the calendar icon and select a date.
16. Answer the question **Is this a single use device that was reprocessed and reused?** by selecting from the list of values.
17. Select the device's **Evaluation availability** from the list of values.
18. Click **Save & Continue** to save and continue to the **Subject Details** page, or
 - Click **Save** to save your changes.
 - Click **Save & Back** to save your changes and go to the previous page.
 - Click **+Add** to add another device.
 - Click the delete icon  to delete a study device.


NOTE: The **Device** page only displays if there is a device included as part of the study treatment.

Adding Study Radiation




To specify study radiation:


1. Click **+Add** to add a radiation intervention.
2. Select the **Type of radiation administration** from the list of values.
3. Enter the **Total dose (to date)** and select **Unit of measure** from the list of values.
4. Enter the **Date of last treatment** of radiation in the format mm/dd/yyyy or click the calendar icon and select a date.
5. Enter the **Schedule number of fractions**, which is the planned number of radiation sessions.

6. Enter the **Number of elapsed days**, which is the number of days that the therapy has not been performed due to the adverse event.
7. Select the **Adjustment** from the list of values.
8. Click **Save & Continue** to save and continue to the **Subject Details** page, or
 - Click **Save** to save your changes and continue to the **Surgery** intervention section, if applicable to the study.
 - Click **Save & Back** to save your changes and go to the previous page.
 - Click **+Add** to add another radiation.
 - Click the delete icon  to delete a study radiation.

Adding Study Surgeries



To specify the study surgery:



1. Click **+Add** to add a surgery intervention.
2. Use the autocomplete feature to enter the **Intervention site** and select it from the list.
3. Enter the **Date of intervention**, (i.e., the date of the surgery) in the format mm/dd/yyyy or click the calendar icon and select a date.
4. Click **Save & Continue** to save and continue to the **Subject Details** page, or
 - Click **Save** to save your changes and continue to the **Device** intervention section, if applicable to the study.
 - Click **Save & Back** to save your changes and go to the previous page.
 - Click **+Add** to add another surgery.
 - Click the delete icon  to delete a study surgery.

Step 6. Subject Details - Adding Subject Details

The **Subject Details** page combines several sections of the expedited report that should be complete and accurate. Since information may have already been entered based on the initial adverse event entries, you will need to verify and add or update those entries depending on their relevance to the adverse event. Make any necessary additions, changes, or deletions in the following sections:

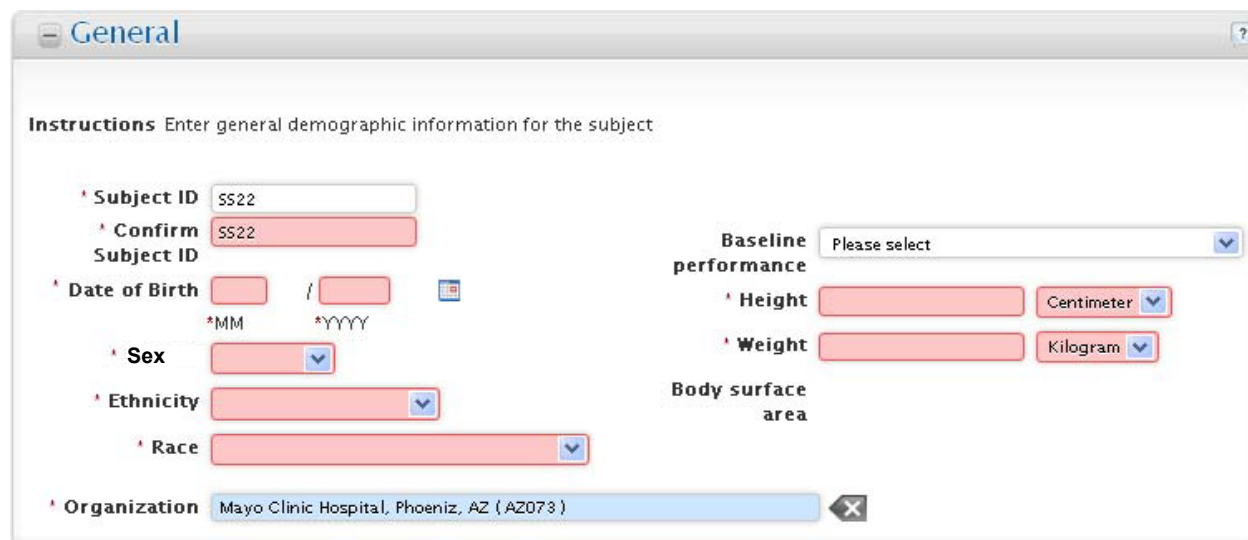
- **General** - General information about the subject needed for the report.
- **Disease Information** - Disease information about the subject's primary, initial disease site.
- **Metastatic Disease Site** - The location where the disease spread.

- **Pre-Existing Conditions** - Medical conditions present in the subject prior to the participating on the study.
- **Concomitant Medications** - Prescription and over-the-counter drugs the subject had taken during the study.
- **Prior Therapies** - Therapies for non-primary diseases taken by the subject at any point.

NOTE: To collapse or minimize a section of information, click the minus sign  next to the section name. Click the plus sign  to expand and display the information.

Adding the Subject's General Details

Enter information regarding the subject's birth date, sex, etc.



The screenshot shows a web form titled "General" with a minus sign icon on the left and a help icon on the right. Below the title is an instruction: "Enter general demographic information for the subject". The form contains several fields:

- Subject ID**: Text input with value "SS22".
- Confirm Subject ID**: Text input with value "SS22".
- Date of Birth**: Two text inputs for MM and YYYY, with a calendar icon to the right.
- Sex**: Dropdown menu.
- Ethnicity**: Dropdown menu.
- Race**: Dropdown menu.
- Organization**: Text input with value "Mayo Clinic Hospital, Phoenix, AZ (AZ073)".
- Baseline performance**: Dropdown menu with value "Please select".
- Height**: Text input with a unit dropdown menu set to "Centimeter".
- Weight**: Text input with a unit dropdown menu set to "Kilogram".
- Body surface area**: Text input.

To specify general information about the subject:

1. Enter the subject's **Date of birth** using the MM/YYYY format or click the calendar icon and select a date.
2. Select the subject's **Sex** from the list of values.
3. Select the subject's **Ethnicity** from the list of values.
4. Select the subject's **Race** from the list of values.
5. Select the **Baseline performance**, which is the subject's performance status at the initial time point in a clinical trial just prior to the subject receiving the investigational treatment being studied. Refer to the ECOG/Zubrod scale and map to this scale when the protocol uses the Karnofsky or Lansky scale.

ECOG/Zubrod Scale

ECOG (Zubrod)		Karnofsky		Lansky (<i>for Pediatrics</i>)	
Score	Description	Score	Description	Score	Description
0	Fully active, able to carry on all pre-disease performance without restriction.	100	Normal, no complaints, no evidence of disease.	100	Fully active, normal.
		90	Able to carry on normal activity; minor signs or symptoms of disease.	90	Minor restrictions in physically strenuous activity.
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work.	80	Normal activity with effort; some signs or symptoms of disease.	80	Active, but tires more quickly
		70	Cares for self, unable to carry on normal activity or do active work.	70	Both greater restriction of and less time spent in play activity.
2	Ambulatory and capable of all self care but unable to carry out any work activities. Up and about more than 50% of waking hours.	60	Requires occasional assistance, but is able to care for most of his/her needs.	60	Up and around, but minimal active play; keeps busy with quieter activities.
		50	Requires considerable assistance and frequent medical care.	50	Gets dressed, but lies around much of the day; no active play; able to participate in all quiet play and activities.
3	Capable of only limited self care, confined to bed or chair more than 50% of waking hours.	40	Disabled, requires special care and assistance.	40	Mostly in bed; participates in quiet activities.
		30	Severely disabled, hospitalization indicated. Death not imminent.	30	In bed; needs assistance even for quiet play.
4	Completely disabled. Cannot carry on any self care. Totally confined to bed or chair.	20	Very sick, hospitalization indicated. Death not imminent.	20	Often sleeping; play entirely limited to very passive activities.
		10	Moribund, fatal processes progressing rapidly.	10	No play; does not get out of bed.

6. Enter the subject's **Height** and **Weight** after the adverse event. Only centimeters and kilograms are available for entry in the Units field. Both **Height** and **Weight** fields are mandatory for report submission. Once this information is entered, the subject's body surface area (BSA) is calculated and displayed.
7. Click **Save** to save your entries and continue to the **Disease Information** section, or
 - Click **Save & Continue** to save and continue to the **Other Causes** page.
 - Click **Save & Back** to save your changes and return to the previous page.

Adding the Subject's Disease Information

Enter the appropriate disease and primary site of disease for the subject.

To define primary disease information:

1. Select a **Disease name** from the list of values available for the study.

NOTE: If the disease name does not appear on the list of values, select either *Solid Tumor, NOS* or *Hematopoietic malignancy, NOS* from the list of values and enter the disease name in the **Other (disease)** field.

2. Enter the **Other (disease)** information. This field is mandatory only displays when *Hematopoietic malignancy, NOS* or *Solid tumor, NOS* is selected in the **Disease name** field.
3. Use the autocomplete feature to enter the **Primary site of disease** and select a site from the list. To see all of the sites, click the [Show All](#) link and select a site. This field is mandatory and must be entered prior to report submission.

NOTE: If the primary site of disease is not available from the list, select *Other* from the list of values, then enter the site in the **Other primary site of disease** field.


4. Enter the **Other primary site of disease**. This field is mandatory and only displays when *Other* is selected in the **Primary site of disease** field.
5. Enter the **Date of the initial diagnosis** of the disease in the format mm/dd/yyyy or click the calendar icon and select a date.
6. Click **Save** to save your entries and continue to the **Metastatic Disease Site** section, or

- Click **Save & Continue** to save and continue to the **Other Causes** page.
- Click **Save & Back** to save your changes and go to the previous page.

Adding the Subject's Metastatic Disease Site

If applicable, enter the subject's metastatic disease site.

To define the metastatic disease site information:


1. Click **+ Add**.
2. Use the autocomplete feature to enter the Metastatic disease **Site name** and select it from the list. To see all of the sites, click the blue *Show All* link.
3. Click **Save** to save your entries and continue to the **Pre-Existing Conditions** section, or
 - Click **Save & Continue** to save and continue to the **Other Causes** page.
 - Click **Save & Back** to save your changes and return to the previous page.
 - Click **+ Add** to add another disease site.
 - Click the delete icon  to delete a disease site.

Adding the Subject's Pre-existing Conditions

If applicable, enter any medical conditions that existed before the subject entered the study, such as allergies, race, pregnancy, smoking and alcohol use, and hepatic/renal dysfunction that may have affected the adverse event.

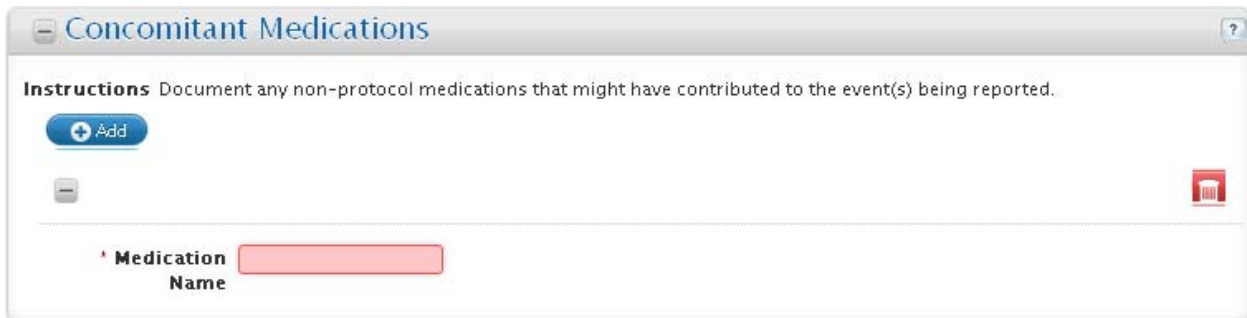
To specify pre-existing conditions:

1. Click **+ Add**.


2. Click the drop-down arrow and select a condition from the **Pre-existing condition** list of values. The pre-existing condition list is based on MedDRA.
3. Click **Save** to save your entries and continue to the **Concomitant Medications** section, or
 - Click **Save & Continue** to save and continue to the **Other Causes** page.
 - Click **Save & Back** to save your changes and return to the previous page.
 - Click **+Add** to add another pre-existing condition.
 - Click the delete icon  to delete a pre-existing condition.

Adding the Subject's Concomitant Medications

Document any concomitant medications that may have contributed to the adverse event(s) reported.



To specify concomitant medications:

1. Click **+Add**.
2. Enter the **Medication name**.
3. Click **Save** to save your entries and continue to the **Prior Therapies** section, or
 - Click **Save & Continue** to save and continue to the **Other Causes** page.
 - Click **Save & Back** to save your changes and return to the previous page.
 - Click **+Add** to add another concomitant medication.
 - Click the delete icon  to delete a concomitant medication.

NOTE: For NCI reporting purposes, only enter those concomitant medications which may have possibly contributed to the adverse event(s).

Adding the Subject's Prior Therapies

Prior Therapies

Instructions Enter all prior therapies for the current study disease. Include prior therapies for a disease other than the study disease if those therapies are relevant for this report.

+ Add

*** Prior therapy** [Dropdown]

Comments

Start date / / MM DD YYYY

End date / / MM DD YYYY

Therapy agent(s) **+ Add**

Agent name Begin typing here X

Document all therapies received before the study for the current study disease and any relevant therapies for non-primary diseases that the subject received during or before the study.

Completing and saving the **Subject's Prior Therapies** section is mandatory for report submission. If the subject received no prior therapies, then select *No prior therapy* from the top of the **Prior Therapy** list of values.

No prior therapy




To define prior therapies:

1. Click **+ Add**.
2. Click the drop-down arrow and select a prior therapy from the **Prior therapy** list of values. The Prior therapy list is based on the CTEP Therapy Classification. Select *No prior therapy* from the **Prior Therapy** list of values if the subject received no prior therapy.

NOTE: By selecting *No prior therapy*, the option to add prior therapies is removed from the screen. Alternately, if a prior therapy is selected, then the *No prior therapy* value is removed from the list of values. To correct an inadvertent entry (i.e., determining that the patient did receive prior therapy after *No prior therapy* was entered), you must first delete the incorrect entry then re-enter the correct information.

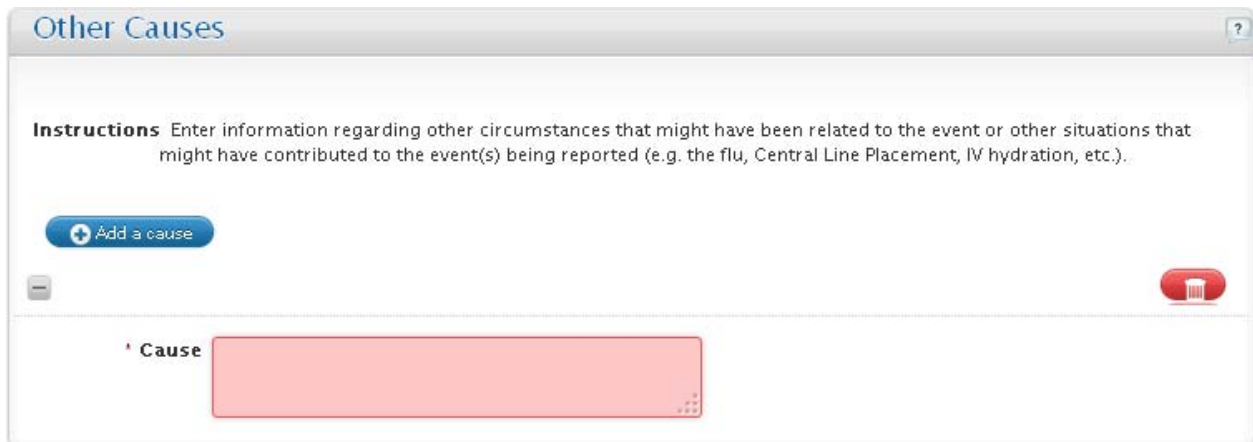
3. Enter any **Comments**, if applicable.

NOTE: If two of the same prior therapies are entered for the subject, for example the subject received two different Chemotherapy (NOS) treatments; make sure to enter different start dates to create two unique prior therapy entries for inclusion on the report.

4. Enter the **Start date** of the therapy in the format mm/dd/yyyy or click the calendar icon and select a date.
5. Enter the **End date** of the therapy in the format mm/dd/yyyy or click the calendar icon and select a date.
6. The **Therapy agent(s)** and **Agent name** fields display depending on the therapy selected in the **Prior therapy** field. To specify the agent:
 - a) Click **+Add**.
 - b) Use the autocomplete feature to enter the **Agent name** and select it from the list.
 If necessary you may click the remove icon  to clear the field and re-enter the agent or click  to delete the agent.
7. Click **Save & Continue** to save and continue to the **Other Causes** page, or
 - Click **Save & Back** to save your changes and return to the previous page.
 - Click **+Add** to add another prior therapy.
 - Click the delete icon  to delete a prior therapy.


Step 7. Other Causes - Entering Other Causes of the Adverse Event

The **Other Causes** page allows entry of information regarding other circumstances possibly related to the event or other situations that may have contributed to the event, such as the flu, central line placement, or IV hydration.



To include an other cause:

1. Click **+Add a cause**.
2. Enter the details describing the cause.
3. Click **Save & Continue** to save your entries and continue to the **Labs** page, or

- To add another cause, click **+Add a cause** and continue.
- Click **Save** to save your changes.
- Click **Save & Back** to save your changes and return to the previous page.
- To delete a cause, click the delete icon  to the right of the cause.

Step 8. Labs - Entering Adverse Event Lab Information

Certain lab results may suggest an adverse event, so on the **Labs** page enter the lab information for an expedited report. For example, if a lab result indicates that white blood cell count is low, that is an adverse event and should be included. The **Lab** page may vary based on the **Lab Category** that you select. This topic describes all possible options.



To enter lab information for the adverse event:

1. Click **+Add a lab**.
2. Select a **Lab category** from the list of values.
3. Select the **Lab name** from the list of values. The **Lab name** list of values will vary depending on the value selected for **Lab category**.


The **Labs** page displays additional fields depending on **Lab Category** selected:

- a) When the *Microbiology* lab category is selected, the **Site**, **Date** and **Infectious Agent** fields display.



- 1) Describe the **Site** of infection or the source of the culture specimen.
 - 2) Enter **Date** of infection in the format mm/dd/yyyy or click the calendar icon and select the date.
 - 3) Enter the **Infectious Agent** associated with the microbiology lab.
- b) When any other **Lab Category** is selected, the **Baseline**, **Nadir/Worst**, and **Recovery/Latest value** fields display.

Baseline value	<input type="text"/>	date	<input type="text"/>	 (mm/dd/yyyy)
Nadir /Worst value	<input type="text"/>	date	<input type="text"/>	 (mm/dd/yyyy)
Recovery/Latest value	<input type="text"/>	date	<input type="text"/>	 (mm/dd/yyyy)

- 1) Select the **Units** to be associated with the Baseline, Worst, and Recovery values.
 - 2) Enter the **Baseline** value of the event and the **Date** on which the baseline occurred in the format mm/dd/yyyy or click the calendar icon and select the date.
 - 3) Enter the **Worst** value of the event and the **Date** on which the worst value occurred in the format mm/dd/yyyy or click the calendar icon and select the date.
 - 4) Enter the value considered the **Recovery** value and the **Date** on which recovery occurred in the format mm/dd/yyyy or click the calendar icon and select a date.
4. Click **Save & Continue** to save your entries and continue to the **Attribution** page, or
- Click **Save** to save your changes.
 - Click **Save & Back** to save your changes and return to the previous page.
 - To delete a lab, click the delete icon  to the right of the lab.

Step 9. Attribution - Assigning an Attribution to Each Possible Cause

An attribution indicates how likely the cause created the adverse event. On the **Attributions** page, each adverse event is shown as a column. The causes of the adverse event are listed along the left side. The reporter/physician must assign an attribution to each cause listed.

Adverse event reporting requirements may vary depending on the protocol, grade, hospitalization, etc. In most cases, however, an adverse event must have at least one cause assigned with a positive attribution (i.e., Possible, Probable, Definite) to warrant expedited reporting. Refer to the NCI Guidelines for Investigators: Adverse Event Reporting Requirements for DCTD (CTEP and CIP) and DCP INDs and IDEs for more information.

Attribution

Instructions For each adverse event, attribute the level of relatedness to each potential cause.

Note: Depending on the rules for this report, each adverse event may require at least one possible, probable, or definite attribution.

Possible cause	Primary AE SEVERE Dyspepsia: stomach pain
Disease	
Gastrointestinal stromal tumor	<input type="text" value=""/>
Study Agent	
724772::NEW - BAY 43-9006 tosylate (BAY 54-9085; sorafenib tosylate)	<input type="text" value=""/>

To assign an attribution to the causes:

Causes of the adverse event are listed in rows along the left side. The possible causes include the following:

Disease - A disease that may have caused the adverse event.

Course (agent) - Medicine, vitamin, mineral, or food supplements.

Surgery - Where a device may be implanted in the participant.

Radiation - Local treatment that acts only on the part of the body that is exposed to the radiation.

Concomitant Medications - Medications a person is taking that are not being studied and may have contributed to an adverse event.

Other causes - Additional possible causes of the adverse event not listed.

The adverse events are displayed at the top of each column.

- Specify the attribution for the cause from the list of values; at least one cause assigned to an adverse event must have the attribution of **Possible**, **Probably**, or **Definite**. The available attributions include the following:
 - Unrelated* - The cause is **not related** to the adverse event.
 - Unlikely* - The cause is **not likely** what the cause created the adverse event.
 - Possible* - The cause could **have possibly created** the adverse event.
 - Probable* - The cause **probably created** the adverse event.
 - Definite* - The cause **definitely** created the adverse event.
- Click **Save & Continue** to save your entries and continue to the **Additional Info** page, or
 - Click **Save** to save your changes.
 - Click **Save & Back** to save your changes and return to the previous page.

Step 10. Additional Info - Including Additional Documents with the Expedited Report

On the **Additional Info** page, you can submit additional documents to help clarify the items in the expedited report and facilitate independent assessment of the event by CTEP physicians.

Additional Info ?

Instructions Indicate any additional information that will be sent separately to support this report.

Autopsy report <input type="checkbox"/>	Pathology report <input type="checkbox"/>
Consults <input type="checkbox"/>	Progress notes <input type="checkbox"/>
Discharge summary <input type="checkbox"/>	Radiology report <input type="checkbox"/>
Flow sheets/case report forms <input type="checkbox"/>	Referral letters <input type="checkbox"/>
Laboratory reports <input type="checkbox"/>	Summary report sent to IRB <input type="checkbox"/>
OBA form <input type="checkbox"/>	Other <input type="checkbox"/>
Other information <input type="text"/>	

If the additional information being provided is not listed above, type the information being provided in the "Other Information" field. Separate each item with a comma ",".

The following are examples of information to submit for the representative events:

Death

Relevant additional information must be submitted when reporting a death, regardless of the reason for death.

Death due to Progressive Disease:

Submit objective confirmation of disease progression (e.g., CT, MRI, x-ray, autopsy report).

In the unusual event where objective confirmation cannot be obtained, provide a copy of the attending physician's note and/or copy of the death certificate.

The death certificate provides documentation of the most immediate cause of death. When Death due to Progressive Disease is reported, the organ system involved in the immediate cause of death must be reported. Often, the death certificate is the most reliable source for this information. If progressive disease is not objectively confirmed by CT, MRI, etc., a copy of the death certificate is to be submitted with the report.

Progressive Disease

Progressive disease reports must include documentation of progression: CT scans, tumor markers, radiographs, etc.

Abnormal Liver Function

Submit copies of concomitant medications and the dates of their administration temporally related to the investigational intervention and the event(s). Concomitant medications, dosages, and dates of administration can also be entered in the text field on the **Describe Event** page. It is important to indicate whether a concomitant

medication was taken chronically prior to or during participation on the trial or if a concomitant medication was recently prescribed and/or administered.

Provide information regarding blood transfusions and dates of administration on the **Describe Event** page.

Provide information regarding prior history of hepatic problems such as hepatitis. Indicate whether or not hepatitis screening was done and provide the results on the **Describe Event** page.

If there is suspicion of increased liver metastases or dilated hepatic ducts, submit copies of CT scan/ultrasound reports.

Abnormal and/or Relevant Normal Laboratory Values

Include baseline and recovery laboratory values on the **Labs** page. Note that baseline refers to pre-study, prior to receiving protocol therapy. If these labs were not drawn pre-study, indicate initial dates and values the labs were obtained while on-study.

Cardiac Event

Provide the history of the subject's cardiac problems and describe the history of a prior similar event. Also record risk factors such as family history, smoking, hypertension, cholesterol/lipid abnormalities, obesity, etc.

Thrombotic Event

Provide the subject's history of prior thrombotic event(s) and describe known risk factors. Also include the history of decreased activity due to adverse events related to treatment or due to disease.

Infection

Report laboratory values, including CBC with differential, and submit culture results (e.g., blood, urine, stool, CNS, etc.).

To add information to the expedited report:

1. Check any items that should be submitted with the expedited report.
2. Enter additional items that need to be submitted in the **Other information** field. Items listed in this field must be separated using a comma (,). Examples of other information include death certificate and concomitant medications.
3. Click **Save & Continue** to save your entries and continue to the **Review and Submit** page, or
 - Click **Save** to save your changes.
 - Click **Save & Back** to save your changes and return to the previous page.

Fax additional information documentation for CTEP sponsored INDs to 301-230-0159. For easy reference, this fax number is displayed on the **Submission Status** page at the time the report is submitted

NOTE: The **Report Ticket Number** must be included on the cover sheet that is faxed with the source documents. The **Subject ID** and the study's **Protocol Number** must be written on each page of all documents submitted. Any personally identifiable information (i.e., the subject's name, medical record number, financial account number, etc.) included on the documentation must be removed.

Also check the reporting requirements section of the protocol to determine if documentation is to be sent to any other additional recipients (i.e., Cooperative Group, IND Sponsor, device supplier, etc.).

Step 11. Review and Submit - Completing Required Tasks

The **Review & Submit** page initiates the report submission process and includes the following steps:

1. An automated review of all entries including the validation and correction of all mandatory fields required for the report. This includes the treating physician's review and signoff of the Expedited Report (24-hour notification does not require physician signoff).
2. Entry of Submitter information.
3. Entry of Recipient information.
4. Submission and Submission Status.

Review and Submit - Review and Physician Signoff

The **Review & Submit** page automatically identifies the report sections where information needs to be completed or corrected. The information required is dependent on the report timeline you are following.

The screenshot shows a web interface titled "Review & Submit". Below the title is a tab labeled "CTEP Expedited Report". The main content area displays "Status Due on 08/26/2013" and "Amendment # 0". A red rectangular box contains the text "Information remaining to complete" and a plus sign icon next to the text "Review & Submit section". In the bottom right corner, there is an orange button labeled "Actions".

To complete required and incomplete tasks:

1. Click the Plus Sign to expand the report section and read the description of incomplete or incorrect items.
2. Click the Go back to this page [Go back to this page](#) link.
3. Make the necessary changes and click **Save**.
4. Click the **Review & Submit** tab to return to the review process and repeat the process until all listed report sections are complete.
5. The **Review & Submit** page will display the **Physician Signoff** checkbox when an Expedited Report (5- or 10-day) is being submitted. This checkbox must be checked before you can continue the complete Expedited Report submission process. Once the report information is approved by the physician you can enter the checkbox.



Physician signoff

☐ I certify that this report has been reviewed and approved by a physician or his/her medically certified designee responsible for the care of this patient.

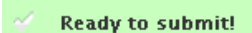
NOTE: Because the physician's signoff is only required for Expedited Reports (5- or 10-day), the signoff checkbox does not display when submitting a 24-hour notification.

CTEP recommends that the report be reviewed by the physician prior to entering the checkbox. Follow the instruction below to provide a pre-submission report for the physician's review:

- a. Click **Actions** and select the report that you wish to export.

The pre-submission report is available for physician sign-off under the *Export AERS PDF* option prior to report submission.

- b. Select *Open with* or *Save File* and click **OK**.
- c. Forward the file to the physician in print form (hard copy) or send via email.
- d. Check the checkbox only after the physician has reviewed and approved the report.

When all required information is entered and/or the physician signoff is complete, the  displays.

6. Click **Submit** to continue to the **Submitter** screen.

Review and Submit - Submitter

The top of the **Submitter** page lists contact information for the Reporter and Physician associated with the report.

Use the **Submitter details** section to determine whether the submitter is the same person as the reporter or treating physician or to enter the contact information of the person submitting the report.

Submitter

Reporter

Name Tom Rason
E-mail rasont@ame.edu
Phone 555-555-5555
Fax 555-555-5555

Physician

Name Tom Rason
E-mail rasont@ame.edu
Phone 555-555-5555
Fax 555 555 5555

Submitter details

☒ If the submitter is the same as the reporter
☐ If the submitter is the same as the physician

* **First name**
Middle name
 * **Last name**
 * **E-mail address**
 * **Phone**
 * **Fax**

To specify submitter information:

1. If the report submitter is the same as the reporter, check the first box. If the report submitter is the same as the treating physician, check the second box. You can check both.
2. Enter the submitter's **First**, **Middle**, and **Last name**, **E-mail address**, **Phone** and **Fax** numbers.
3. Click **Save & Continue** to continue to the **Recipients** page, or click **Save** to save your changes.

Review and Submit - Recipients

The **Recipients** page will display the email addresses of those persons who will receive the report and append the addresses with the following:

(SUB) for Submitter

(REP) for Reporter

(PHY) for Physician

You can specify the email addresses of any additional people to be copied when the report is submitted.

Recipients

The **CTEP 10 Calendar Day SAE Report** will be sent to the following preconfigured recipients:

- NCI CTEP
- rasont@ame.edu (SUB)
- rasont@ame.edu (REP)
- rasont@ame.edu (PHY)

CC Details

To send this report to others, enter the email addresses in the field below.
Multiple email addresses can be entered separated by a comma.

Cc

To specify additional recipients:

1. Enter the email addresses of the recipients in **Cc** field. Separate each address with a comma if multiple email addresses are entered. Do not use semicolons or hard returns within this field.
2. Click **Submit** to save and submit the report.

The **Submission Status** displays.

NOTE: When sending reports through central processing, the full list of recipients will not display. You may view the list of recipients from the **Manage Reports** page, under the **View Recipients** option from the **Actions** button. The recipients will also be listed as part of the submission notification email.

Review and Submit - Submission Status

The **Submission Status** page indicates whether the submission was successfully completed.

To review the status:

If the submission is successful, the message *Submitted successfully on <date>* is displayed and a report submission status notification is sent by email to all of the recipients set up on the **Recipients** page.



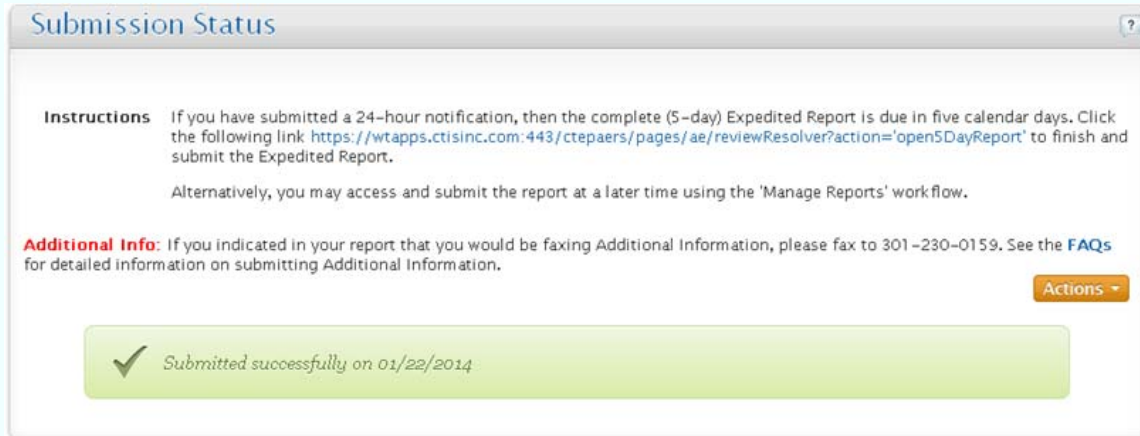
A PDF copy of the final report can also be exported by clicking **Export**.

In the rare instance of a submission failure, you may contact the NCI CTEP Help Desk for assistance:

email: ncictephhelp@ctep.nci.nih.gov

phone: 1-888-283-7457

NOTE: After submission of a 24-hour notification, the **Submission Status** page will display a reminder that the complete expedited report is due in five calendar days.



The screenshot shows a web browser window titled "Submission Status". Inside the window, there is a section titled "Instructions" which states: "If you have submitted a 24-hour notification, then the complete (5-day) Expedited Report is due in five calendar days. Click the following link <https://wtapps.ctisinc.com:443/ctepaers/pages/ae/reviewResolver?action='open5DayReport'> to finish and submit the Expedited Report." Below this, it says: "Alternatively, you may access and submit the report at a later time using the 'Manage Reports' workflow." There is also a section titled "Additional Info" which says: "If you indicated in your report that you would be faxing Additional Information, please fax to 301-230-0159. See the [FAQs](#) for detailed information on submitting Additional Information." To the right of this section is an orange button labeled "Actions". At the bottom of the window, there is a green bar with a checkmark icon and the text "Submitted successfully on 01/22/2014".

A link is also provided that will return you to the **Reporter** page thereby eliminating the use of the **Select study and subject** page to access the report. If you do not wish to complete the report at this time, you can access, complete and submit the report at a later time.

Manage Reports in CTEP-AERS

The **Manage Reports** option enables you to select a ticket, study and subject and edit the pending or view a previously submitted report. You can also perform the following tasks with the report:

- **Export** to an adverse event report to a file.
- **Withdraw** a pending report from submission.
- **Amend** a submitted adverse event report.
- **View** a submitted adverse event report.
- **Change the Subject ID** on a pending report.
- **Change the Organization** on a pending report or amendment.
- **Delete an Adverse Event** from a pending report.
- **View Recipients** of a submitted report.

To access the adverse event report(s) for a ticket, study and subject:

1. Click the **Manage Reports** tab.



The **Select study and subject** page displays.

2. Specify the **Ticket Number**, **Study and Subject ID** of the report:
 - a. Enter the **Ticket Number** or a portion of the ticket number that was originally assigned to the report. Select the ticket number from the list.
 - b. Use the autocomplete feature to enter the Study (i.e., NCI or local protocol number) and select a study from the list. Only study numbers can be used to query the study.
 - c. Enter the **Subject ID** or a portion of the identifier. Select one of the identifiers from the list.
3. Once the three fields are entered, click **Continue** to open the **Manage Reports** page.

The report(s) available for the ticket number is displayed in a table format providing the following information.

Manage Reports			
<p>Instructions The table below summarizes reports for the given Ticket Number. Click Actions and select the option you wish to perform.</p> <p>If you have submitted a 24-hour notification, then the complete (5-day) Expedited Report is due in five calendar days. Click Actions, then select Edit to finish and submit the Expedited Report.</p>			
Report Type	Amendment #	Report Submission Status	Options
CTEP Expedited Report	1	<i>Due in 10 days</i>	Actions ▾
CTEP Expedited Report	0	<i>Amended on 12/12/2013</i>	Actions ▾
CTEP 24 Hour Notification		<i>Submitted successfully on 12/12/2013</i>	Actions ▾

Report Type is the name of the report based on the report timeline.

Amendment # indicates how many times the report was revised and submitted. The most recent amended report will appear at the top of the table.

Report Submission Status indicates whether there is a report that is:

Due – A pending report; displays the number of days remaining until the report is due.

Overdue – The 24-hour notification was not submitted within 24 hours of the CTEP-AERS ticket's creation; displays only for the 24-hour notification.

Withdrawn – The report was manually withdrawn by the reporter.

Submitted Successfully – The report was successfully submitted.

Initiated, not submitted – The report was not submitted by the due date and was automatically withdrawn by the system.

Amended – The original report was revised and re-submitted; displays an amendment number.

The **Options** column displays the **Actions ▾** button to provide the ability to *edit, withdraw, export, amend, view report* or *view recipients*.

NOTE: If the report is already submitted, you cannot edit the adverse event, subject or site information. If the report has not been submitted, you can edit, add or delete adverse event information. You can also edit the **Subject ID** and/or **Organization**. To edit a previously submitted report, see **Amending an Adverse Event Report**

4. Select an option from the **Actions ▾** button to continue the process. The options provided include:
 - a. **Edit** the information to complete a pending report.
 - b. **Export** to an adverse event report to a file.
 - c. **Withdraw** a pending report from submission.
 - d. **Amend** a submitted adverse event report.
 - e. **View** a submitted adverse event report.
 - f. **View Recipients** of the submitted report.

Editing a Pending Adverse Event Report

With the Manage Reports option you can edit a pending report to complete and submit the report within the required timeframe.

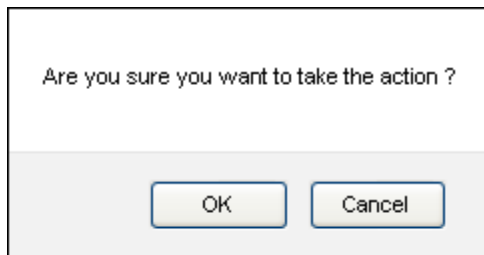
To edit a pending expedited report:

1. Click the **Manage Reports** option to access the pending adverse event report for a ticket, study and subject.

The **Manage Report** page opens.

2. Locate the row of the report you wish to complete.
3. Click **Actions** under the **Options** column and select **Edit**.

The following message displays:



4. To continue, click **OK**.

The expedited report opens at the **Reporter** page.

5. Make the changes as needed using the section tabs or the **Save & Continue** button to navigate. Complete and submit the report.

Exporting an Adverse Event Report

With the Manage Reports option you can export an adverse event report to XML or PDF format.

To export an adverse event report to an output file:

1. Click the **Manage Reports** tab.

The **Select study and subject** page displays.

2. Specify the **Ticket Number, Study and Subject ID** of the report.

The **Manage Report** page opens.

3. In the row of the report to be exported, click **Actions** under the **Options** column and select any one of the available formats.

The pre-submission report is available for physician signoff under the *Export AERS PDF* option prior to report submission.

4. Follow the prompts to save the file.


Withdrawing an Adverse Event Report

With the Manage Reports option, you can withdraw an unsubmitted report to prevent its submission.

To withdraw an adverse event report from submission:

1. Follow the **Manage Reports in CTEP-AERS** procedure to access the adverse event report(s) for a ticket, study and subject.

The **Manage Report** page opens.

2. In the row of the report to be withdrawn, click **Actions** under the **Options** column and select  **Withdraw**.

The **Report Submission Status** changes to *Withdrawn*.

NOTE: The *Withdraw* option only displays for reports that have not been previously submitted.

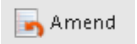
Amending an Adverse Event Report

With the Manage Reports option you can amend and resubmit an adverse event report if, for example, the original adverse event reappears during the same course/cycle/intervention but is more severe (i.e., higher grade).

To amend a submitted expedited report:

1. Follow the **Manage Reports in CTEP-AERS** procedure to access the adverse event report(s) for a ticket, study and subject.

The **Manage Report** page opens.

2. In the row of the report to be amended, click **Actions** under the **Options** column and select  **Amend**.

NOTES: The Amend option only displays under the most recently submitted report. If the same adverse event reappears later in the course but is *not* as severe and the subject is recovering, then you do not need to amend the expedited report.

The following message displays:

Are you sure you want to take the action ?

3. To continue, click **OK**.

The expedited report opens at the **Reporter** page.

4. Make the changes as needed to amend and submit the report.

NOTE: If the amendment includes modification to the adverse event information, for example, to a higher grade, CTEP-AERS may require a re-evaluation of the data to the NCI reporting requirements. Follow the instructions to determine the recommended action.

Viewing an Adverse Event Report

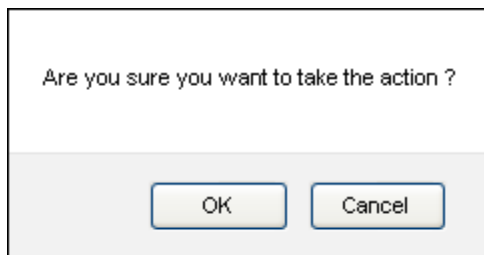
To view an adverse event report:

1. Follow the **Manage Reports in CTEP-AERS** procedure to access the adverse event report(s) for a ticket, study and subject.

The **Manage Report** page opens.

2. In the row of the report you wish to view, click **Actions** under the **Options** column option and select **View Adverse Event Report**.

The following message displays:



3. To continue, click **OK**.
The report displays in PDF format. You may view, print or save the report as needed.
4. Close the PDF viewer to return to **Manage Reports**.

Viewing the Report's Recipients

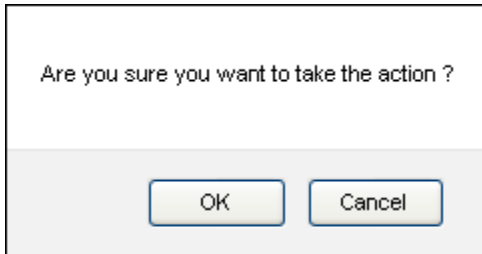
To view the list of recipients who have received the report:

1. Follow the **Manage Reports in CTEP-AERS** procedure to access the adverse event report(s) for a ticket, study and subject.

The **Manage Report** page opens.

2. In the row of the report you wish to view recipients, click **Actions** under the **Options** column option and select **View Recipients**.

The following message displays:



3. To continue, click **OK**.
4. The **View Recipients** screen opens and displays the *Recipients Type* and *Recipients*, as well as the recipient name and contact information, if available.
5. Click **Close Window** to return to **Manage Reports**.

Changing the Subject ID

A **Subject ID** can be changed in CTEP-AERS prior to the submission of the 24-hour notification or 10-day report. The pending report is accessed and the Subject ID is changed using the **General** section of the **Subject Details** page. Subject IDs cannot be changed on a submitted report, nor can they be changed by creating a report amendment.

NOTE: Contact the NCI CTEP Help Desk if the **Subject ID** must be changed on a previously submitted report.

To change the ID of a subject:

1. Access the pending adverse event report for a ticket using the **Select study and subject** page from the Manage Reports workflow.
2. Click on tab **6. Subject Details** and scroll down to the **General** section.
3. Enter the new **Subject ID**. The maximum number of characters allowed in this field is twenty (20). The following special characters can be used within the **Subject ID** field: !@#\$%^&*()_+ -= | \ ' " ; ;
4. Enter the **Confirm Subject ID** to confirm correct ID entry.


5. Click **Save & Continue** to save and continue to the **Other Causes** page, or
 - Click **Save** to save your changes and continue to other sections of the **Subject Details** page or other sections of the report.
 - Click **Save & Back** to save your changes and return to the previous page.

Changing the Organization

An organization can be changed at any time in CTEP-AERS by accessing the pending report or amendment and selecting a new organization in the General section of the **Subject Details** page. Organizations cannot be changed on a previously submitted report.

To change the organization:

1. Access the pending report or amendment using the **Select study and subject** page from the Manage Reports workflow.
2. Click on tab **6. Subject Details** and scroll down to the **General** section.
3. Enter the new **Organization** using the autocomplete feature and select the organization from the list.

Organization Mayo Clinic Hospital, Phoenix, AZ (AZ073) 

4. Click **Save & Continue** to save and continue to the **Other Causes** page, or
 - Click **Save** to save your changes and continue to other sections of the **Subject Details** page or other sections of the report.
 - Click **Save & Back** to save your changes and return to the previous page.

Deleting an Adverse Event from a Pending Report

CTEP-AERS provides the ability to remove an adverse event from a pending report with multiple adverse events. An amendment may be sent to remove an adverse event after report submission.

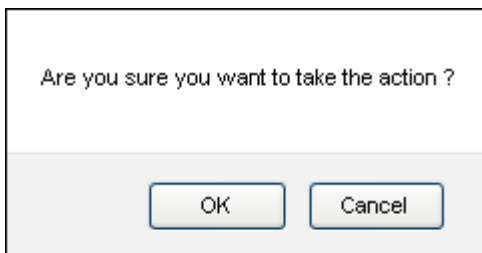
NOTES: At least one adverse event is required to submit a report.

Depending on the amount of information entered for the report, you may choose instead to withdraw a pending report. CTEP-AERS will automatically withdraw a pending report if the report is not submitted prior to the due date.

To delete an adverse event:

1. Click the Manage Reports tab and enter criteria in the **Select study and subject** page. Click **Continue**.
2. Click **Actions** under the **Options** column and select **Edit**.

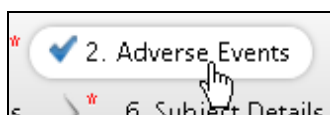
The following message displays:



Are you sure you want to take the action ?


OK Cancel

3. To continue, click **OK**.
The **Reporter** page displays.
4. Click the **2. Adverse Events** tab.



- Click **+Add/Edit Adverse Event**.

The existing adverse events are listed with the delete icon  displayed.

- Click the delete icon  for the adverse event you wish to delete.

The following message displays:

- To continue, click **OK**.
- Click **Save & Report**.


The **Review & Report** page displays. The Adverse Event table lists the adverse event with the deleted icon.

Adverse Events					
Select	Expedited Reporting Required?	Adverse Event Term	Grade	Start date	'Primary?
	Yes	Dyspepsia: stomach pain Deleted	3: Severe symptoms; surgical intervention indicated	08/05/2013	
<input checked="" type="checkbox"/>	No	Vomiting: vomiting	1: 1 - 2 episodes (separated by 5 minutes) in 24 hrs	08/05/2013	<input type="radio"/>
<input checked="" type="checkbox"/>	No	Nausea: upset stomach	1: Loss of appetite without alteration in eating habits	08/05/2013	<input type="radio"/>

9. Reassign the **Primary?** adverse event, if necessary.
 10. Click **Report**.
- Continue entry of report information and submit the report.

NOTE: Depending on the added or modified adverse event, CTEP-AERS may alter the reporting requirements and recommend a different report timeline to be completed (i.e., a 24-hour notification vs. a 10-day).


In the example below, with the grade 4 Dyspepsia deleted, the 24-hour notification is no longer required and the action to withdraw the report is recommended.

Available Actions				
Based on the data you have entered and the rules enabled for this study, there are no CTEP AERS recommended actions. You may continue working on the reports below or click 'Override' to manually select optional actions.				
Override				
Select	Action	Report	Status	Due
<input checked="" type="checkbox"/>	 WITHDRAW	CTEP 24 Hour Notification	Being withdrawn	

Adverse Events					
Select	Expedited Reporting Required?	Adverse Event Term	Grade	Start date	'Primary?
	Yes	Dyspepsia: stomach pain Deleted	3: Severe symptoms; surgical intervention indicated	08/05/2013	
<input checked="" type="checkbox"/>	No	Vomiting: vomiting	1: 1 - 2 episodes (separated by 5 minutes) in 24 hrs	08/05/2013	<input type="radio"/>
<input checked="" type="checkbox"/>	No	Nausea: upset stomach	1: Loss of appetite without alteration in eating habits	08/05/2013	<input type="radio"/>

In this instance, the only option is to click override or withdraw the report.

When you press the Report button, you will initiate the following actions:

 WITHDRAW CTEP 24 Hour Notification

Report ➔

Once **Report** is clicked, CTEP-AERS removes the ticket number and returns to the **2. Adverse Event** tab to allow the addition or modification of adverse events.