

CTEP-AERS

Cancer Therapy Evaluation Program Adverse Event Reporting System

Training Presentation

CTEP-AERS Training Site:

<https://betapps-ctep.nci.nih.gov/ctepaers/public/login>

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Welcome to CTEP-AERS

Two ways to access CTEP-AERS

- 1) Directly by URL: <https://eapps-ctep.nci.nih.gov/ctepaers>
- 2) The CTEP-AERS page via the CTEP Website: <http://ctep.cancer.gov/>

NCI Warning Disclaimer



*****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.

I agree

I disagree

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[ACCESSIBILITY](#)

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FIRSTGOV

This text says you agree to use the system responsibly.

Click **I agree**.

CTEP-AERS Home Page

The screenshot shows the CTEPAERS Home Page. At the top left is the logo for CTEPAERS (Cancer Therapy Evaluation Program Adverse Event Reporting System). To the right of the logo is a 'Help' button. Below the logo is a navigation bar with 'Report Adverse Events' and 'Manage Reports' buttons. The main content area features a 'CAUTION' section indicating it is a training site. Below this, there is a 'Quick Links' box with 'Report Adverse Events' and 'Manage Reports' buttons. The page also contains several paragraphs of text providing instructions on how to use the system, including links to the production site, administrator login, and NCI Guidelines. At the bottom, there is contact information for the AEMD and NCICTEP Helpdesks.

CTEP-AERS
Cancer Therapy Evaluation Program Adverse Event Reporting System

Help

Adverse Events

Report Adverse Events Manage Reports

CAUTION:
CTEP-AERS Training Site

You have accessed the CTEP-AERS Web application *Training site*. Reports entered using this site are for training purposes only and are not submitted to the NCI.

Use the following URL to access the CTEP-AERS Web application *Production site*: [CTEP-AERS Application](#)

Welcome to the Cancer Therapy Evaluation Program Adverse Event Reporting System (CTEP AERS). CTEP AERS is available to submit expedited adverse event reports for all CTEP-sponsored clinical trials and Division of Cancer Prevention (DCP) cancer prevention trials.

To create a new expedited report: click Report Adverse Event
Once initiated, reports are assigned a unique ticket number that is used for future report access. The ticket number is sent to the reporter by e-mail, but documenting this number is strongly encouraged.

To complete or withdraw a pending report or amend an existing report: click Manage Reports
The NCI protocol number, ticket number and subject identifier must be entered to access a pending or submitted report.

To login as an administrator (NCI Staff only): [click here](#)
To view NCI Guidelines: [Adverse Event Reporting Requirements](#)

Additional CTEP-AERS resources are available on the [CTEP-AERS Home Page](#)
Frequently Asked Questions [FAQ](#)

Medical Questions/Help: email: aemd@tech-res.com phone: (301) 897-7497 fax: (301) 230-0159
Technical Questions/Help: email: ncictephelp@ctep.nci.nih.gov phone: 1-888-283-7457 fax: (301) 948-2242

Quick Links

Report Adverse Events

Manage Reports

Click to access the CTEP-AERS online help.

Training site only, (use the production site to submit reports, the link is below).

The link to the production site, use to submit reports.

The link to Administrator login (CTEP, NCI staff only).

Link to the NCI Guidelines.

Link to resources on the CTEP-AERS page from the CTEP website.

Contact information to the AEMD and NCICTEP Helpdesks.

Report Adverse Events

CTEP-AERS
Cancer Therapy Evaluation Program Adverse Event Reporting System

Help
Adverse Events

Report Adverse Events Manage Reports

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Quick Links
Report Adverse Events
Manage Reports

To initiate a report, click **Report Adverse Events**.

Select study, subject and course/cycle/intervention

1. Enter at least three digits of the protocol number, then select from the list.

2. Enter the **Subject ID**.

3. Re-enter the **Subject ID** to confirm.

The screenshot shows a web form with the following fields and elements:

- Study**: A text input field with a red asterisk and placeholder text "Begin typing here".
- Subject ID**: A text input field with a red asterisk.
- Confirm Subject ID**: A text input field with a red asterisk.
- Organization**: A text input field with a red asterisk and placeholder text "Begin typing here".
- Course/Cycle/Intervention**: A dropdown menu with a red asterisk and a blue "+Add" button.

Instructions: Select the study, subject, and course or cycle associated with the adverse events that you wish to report.

4. Type at least three characters of the **Organization** name, then select from the list.

5. Click **+Add** to open the **Course/Cycle/Intervention** page.

Note: All mandatory fields are marked with a red asterisk (*).

Course/Cycle/Intervention Information

1. Click the **TAC** of which the adverse event occurred.

2. If the correct TAC is not available, click **Other**, then enter treatment information in the **Description** field.

Note: If the correct TAC is not available, use the **Other** to enter treatment information for Surgery, Device or Radiation interventions.

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

Delete Save

Note: Clicking **Save** does not save the report to the system. If you were to lose your browser connection at this time, you would need to reenter all information. More details will be provided on this later.

3. Click **Save**.

Select study, subject and course/cycle/intervention

The completed page displays.

1. Study, Subject & Course/Cycle > 2. Adverse Events > 3. Review and Report

Select study, subject, and course/cycle/intervention

Instructions Select the study, subject, and course or cycle associated with the adverse events that you wish to report.

* **Study** (7028) A Phase II Study of BAY 43-9006 for Patients with Imatinib and Su

* **Subject ID**

* **Confirm Subject ID**

* **Organization** Mayo Clinic Hospital, Phoenix, AZ (AZ073)

* **Course/Cycle/Intervention** TAC1 ((Cycle=28 days) BAY 43-9006: 400mg PO BID) **Course/Cycle/Intervention created successfully**

Continue →

Click **Continue**.

Adverse Events - Verbatim

1. Study, Subject & Course/Cycle > **2. Adverse Events** > 3. Review and Report

Subject SS22
Study (7028) A Phase II Study of BAY 43-9006 for Patients with Imatinib and Sunitinib Resistant Gastrointestinal Stromal...
Course/Cycle/Intervention TAC1 ((Cycle=28 days)\nBAY 43-9006: 400mg PO BID)

Adverse Events ?

Instructions Enter the verbatim. [View CTCAE v4.0](#)

Enter verbatim **+Add**

Save & Back **Save** **Save & Report**

1. Enter the **Verbatim**. If no verbatim term exists or is not applicable, then enter the CTCAE term.

2. Click **+Add** to expand the **Adverse Events** page.

Adverse Events – AE Term and Related Information

1. Type at least three characters of the **CTCAE Term**, then select from the list.

2. Click to select the **Grade**. The grades listed will change depending on the CTCAE Term selected.

3. Enter the **Start Date**.

It is recommended to enter all other adverse events at this time. Enter the verbatim, click **+Add**, then follow steps 1 through 6. Repeat until all events are entered.

Click **View CTCAE v4.0** to view the entire listing of CTCAE terms.

4. Enter the **End Date**, if applicable.

5. Indicate whether the Subject was hospitalized.

6. Select any other **Outcomes** as appropriate.

7. Click **Save & Report**.

The screenshot shows a web form titled "Adverse Events". At the top, there is a "Verbatim" field containing the text "pain". Below this is a "CTCAE Term" dropdown menu, which is currently empty. Underneath the dropdown is a "Grade" section with three radio button options: "1: Mild symptoms; intervention not indicated", "2: Moderate symptoms; medical intervention indicated", and "3: Severe symptoms; surgical intervention indicated". To the right of the grade options is a "View CTCAE v4.0" link. Below the grade options are two date fields: "Start date" and "End date", both with calendar icons and the format "(mm/dd/yyyy)". Below the date fields is a "Did AE cause hospitalization?" dropdown menu. At the bottom of the form is an "Outcomes" section with several checkboxes: "Death", "Hospitalization - initial or prolonged", "Life-threatening", "Disability or Permanent Damage", "Congenital Anomaly/Birth Defect", "Required Intervention to Prevent Permanent Impairment/Damage (Devices)", and "Other Serious (Important Medical Events)". At the very bottom of the page are three buttons: "Save & Back" (blue), "Save" (blue), and "Save & Report" (green).

Review and Report – Action Recommended

The **Review and Report** page displays either Recommended or Available Actions based on the adverse event information entered and the business rules created for this protocol, which include any applicable protocol specific exceptions to expedited adverse event reporting.

Recommended Actions –


Indicates that a report is required and is displays the checkmark icon.

Available Actions displays when a report is not required (see next slide).

The **Override** option is available in both instances.

1. Study, Subject & Course/Cycle > 2. Adverse Events > 3. Review and Report


Subject 5522
Study (7028) A Phase II Study of BAY 43-9006 for Patients with Imatinib and Sunitinib Resistant Gastrointestinal Strom...
Course/Cycle/ Intervention TAC1 ((Cycle=28 days)\nBAY 43-9006: 400mg PO BID)

 An action is recommended.
Exception: If this is a commercial agent only study or an adverse event that occurred more than 30 days after the last administration of investigational agent/intervention, please consult your protocol for specific expedited reporting requirements.



Dyspepsia: pain , Grade: 3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care ADL.

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

Adverse Events

Select	Expedited Reporting Required?	Adverse Event Term	Grade	Start date	*Primary?
<input checked="" type="checkbox"/>	Yes	Dyspepsia: pain 	3: Severe symptoms; surgical intervention indicated	07/22/2013	

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

 CREATE CTEP Expedited Report

[Report](#) 


Adverse Events – Indicates the primary adverse event and summarizes other information.

Review and Report – Action Not Recommended

Available Actions – Indicates that a report is not required and displays the stop icon.

1. Study, Subject & Course/Cycle > 2. Adverse Events > **3. Review and Report**

Subject SS2
Study (7028) A Phase II Study of BAY 43-9006 for Patients with Imatinib and Sunitinib Resistant Gastrointestinal Stromal...
Course/Cycle/Intervention TAC1 ((Cycle=28 days)\nBAY 43-9006: 400mg PO BID)

 An action is NOT recommended.
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.
For serious adverse events that occur **more than 7 days** after the start of the **agent/intervention** and have an attribution of **possible, probable, or definite**, please consult your protocol for expedited reporting requirements and click 'Override' as needed.

Dyspepsia: pain , Grade: 1: Mild; asymptomatic or mild symptoms, clinical or diagnostic observations only; 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](#)

Adverse Events


Select	Expedited Reporting Required?	Adverse Event Term	Grade	Start date	*Primary?
<input checked="" type="checkbox"/>	No	Dyspepsia: pain New	1: Mild symptoms; intervention not indicated	07/22/2013	<input checked="" type="radio"/>

Please select a report. [Report →](#)


If no action is recommended, you can either exit the system or use the **Override** option (see slide 14 for more information) to submit a report.

Review and Report – Recommended Actions

The **Review and Report** page displays the report due date depending on the results of the rules engine.

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

The CTEP Expedited Report is due in 10 days.

Select	Action	Report	Status	Due
<input checked="" type="checkbox"/>	 CREATE	CTEP 24 Hour Notification	Not started	Due in 24 hours

The CTEP 24-Hour Notification is due within 24-hours, followed by the CTEP Expedited Report, which is due in 5 days.

Select	Action	Report	Status	Due
<input checked="" type="checkbox"/>	EDIT	CTEP Expedited Report	In process	Due in 5 days

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

The CTEP Expedited Report for commercial agents is due in 15 days.

Review and Report – Override Option

For rare cases when the system does not recommend an action, but the treating physician feels the event should be reported expeditiously, you may use the **Override** option to submit a report regardless of the action provided on the **Review and Report** page. Make note that you can change the 10-day report to a 24-hour notification, but you cannot override a recommended 24-hour notification to that of a 10-day.

Select	Action	Report	Status	Due
<input type="checkbox"/>		CTEP Expedited Report		
<input type="checkbox"/>		CTEP 24 Hour Notification		

[Restore recommended action](#)

Depending on the outcome of the rules engine, the CTEP Expedited Report and 24-Hour Notification are options when **Override** is selected.

Select	Action	Report	Status	Due
<input type="checkbox"/>		CTEP Expedited Report (15 Days)		
<input type="checkbox"/>		CTEP 24 Hour Notification		

[Restore recommended action](#)

CTEP Expedited Report (15-day) for commercial agents is an option that displays for commercial agent studies.

Click **Restore recommended action** to cancel the override.

Review and Report – Adverse Event Table

Adverse Events

Select	Expedited Reporting Required?	Adverse Event Term	Grade	Start date	*Primary?
<input checked="" type="checkbox"/>	Yes	Dyspepsia: stomach pain New	3: Severe symptoms; surgical intervention indicated	<input type="text"/> <small>(mm/dd/YYYY)</small>	<input checked="" type="radio"/>
<input checked="" type="checkbox"/>	Yes	Vomiting: throwing up New	3: ≥6 episodes (separated by 5 minutes) in 24 hrs; tube feeding, TPN or hospitalization indicated	07/22/2013	<input type="radio"/>
<input checked="" type="checkbox"/>	Yes	Nausea: upset stomach New	3: Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization indicated	07/22/2013	<input type="radio"/>

Deselect the **Select** checkbox if an adverse event is to be excluded from the report.

The **Start Date** can be entered here if omitted on the **Adverse Event** page.

The **Primary** adverse event can be reselected when more than one event is being reported.


Review and Report

Note: The report is still not saved to the system. Again, if you were to lose your browser connection, you would need to reenter all information.

To continue with the report, click Report.

1. Study, Subject & Course/Cycle > 2. Adverse Events > 3. Review and Report


Subject SS22
Study (7028) A Phase II Study of BAY 43-9006 for Patients with Imatinib and Sunitinib Resistant Gastrointestinal Strom...
Course/Cycle/ Intervention TAC1 ((Cycle=28 days)\nBAY 43-9006: 400mg PO BID)

 An action is recommended.
Exception: If this is a commercial agent only study or an adverse event that occurred more than 30 days after the last administration of investigational agent/intervention, please consult your protocol for specific expedited reporting requirements.



Dyspepsia: pain . Grade: 3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care ADL.

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

Adverse Events

Select	Expedited Reporting Required?	Adverse Event Term	Grade	Start date	*Primary?
<input checked="" type="checkbox"/>	Yes	Dyspepsia: pain 	3: Severe symptoms; surgical intervention indicated	07/22/2013	

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

 CREATE CTEP Expedited Report

Report →

1. Reporter

Reporter

1. Enter all mandatory fields in the **Reporter Details** section.

2. Click this checkbox if the Physician is the same as the Reporter.

If the Physician and Reporter are two different people, then enter the mandatory fields in the Treating Physician Details section.

Reporter

Instructions Enter contact information for the person reporting the adverse event. Select the person from the drop down list or enter the details.

Reporter Details

* First name

Middle name

* Last name

* E-mail address

* Phone

* Fax

If the Physician is the same as the Reporter click here

Treating Physician Details

* First name

Middle name

* Last name

* Email address

* Phone

Note: The information on this page *must* be completed and saved in order for the report to be saved and the ticket number assigned. At this time, CTEP-AERS begins the report due date countdown.

3. Click **Save & Continue**.

Save

Save & Continue

Report Ticket Number

Once the Reporter page is completed and saved, the report's ticket number displays at the top of each page.

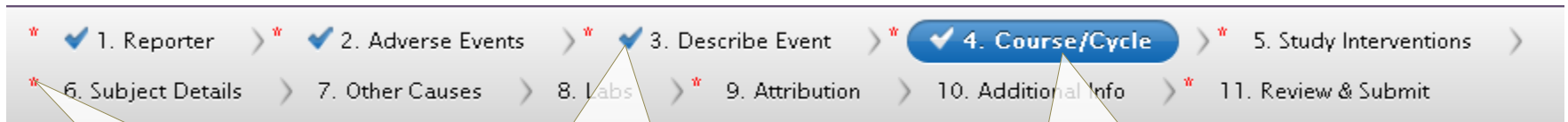
Ticket Number 2140590
Subject ID SS22
Study (7028) A Phase II Study of BAY 43-9006 for Patients with Imatinib and Sunitinib Resistant Gastrointestinal Stromal Tu...
Course/Cycle/Intervention TAC1 ((Cycle=28 days)\nBAY 43-9006, 400mg PO BID)

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.

It is recommended that you record the ticket number for future reference. This information will also be sent to you via email.

Navigation Bar

Use the Navigation Bar located at the top of each page to move from section to section.



Red asterisks (*) indicate a mandatory section.

Blue checkmarks (✓) indicate that the section has been completed and saved.

A highlighted tab indicates the section currently in use.

In most cases, the **Save & Continue** button is used to navigate from page to page.

Save & Continue 

Adverse Events

The **Adverse Events** page displays to review and revise entered information or to enter additional adverse events.

Note: Following any saved changes, additions or deletions to the **Adverse Events** page, CTEP-AERS will rerun the business rules to reassess the need for expedited reporting.

The screenshot shows the 'Adverse Events' page interface. At the top, there is a header 'Adverse Events'. Below it, an 'Instructions' section reads: 'Complete the required fields and add any additional information for each adverse event, including...'. A blue button with a plus icon and the text '+ Add Adverse Event' is visible. Below this, a list item is shown: '+ Dyspepsia pain , Grade: 3 [Primary]'. At the bottom of the page, there are three buttons: a blue 'Save & Back' button, a blue 'Save' button, and a green 'Save & Continue' button with a right-pointing arrow icon.

If needed, click **+Add Adverse Event** to enter additional adverse events.

+ Add Adverse Event

+ Dyspepsia pain , Grade: 3 [Primary]

← Save & Back

Save

Save & Continue →

1. Click **+** to expand and review the entered adverse event.

2. Click **Save & Continue**.

3. Describe Event

Describe Event

1. Enter all information related to the adverse event.

2. Select the subject's status from the list of values.

3. Enter the date the subject either recovered or died.*

4. Indicate whether the subject was re-treated after the event occurred.

5. Enter the date the subject was removed from the study, if applicable.

6. Click this checkbox to indicate that an autopsy was performed.*

*Note: The **Date of Recovery or death** and **Autopsy Performed?** fields display depending on the value entered in the **Subject's status at time of this report** field.

The screenshot shows a web form titled "Describe Event". At the top, there is a blue header with the text "Describe Event" and a question mark icon. Below the header, there is a section for "Instructions" which reads: "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." Below the instructions is a large red rectangular area labeled "Description & treatment of event(s)". Underneath this is a dropdown menu labeled "Subject's status at time of this report". Below the dropdown are two date input fields: "Date of recovery or death" and "Date removed from protocol", both with a calendar icon and a placeholder "(mm dd/yyyy)". Below the date fields is a dropdown menu labeled "Has the subject been re-treated?". Below that is a checkbox labeled "Autopsy performed?" with a question mark icon. At the bottom right of the form are two buttons: a blue "Save" button and a green "Save & Continue" button with a right-pointing arrow. Callout boxes with numbered instructions (1-7) point to various parts of the form: 1 points to the red description area; 2 points to the status dropdown; 3 points to the "Date of recovery or death" field; 4 points to the "Has the subject been re-treated?" dropdown; 5 points to the "Date removed from protocol" field; 6 points to the "Autopsy performed?" checkbox; and 7 points to the "Save & Continue" button.

7. Click **Save & Continue**.

Course/Cycle

Treatment Information section displays to review and/or revise entered Information.

To revise the TAC, select from the list of values and enter the required information.

1. Enter the start date the subject received his or her first course of treatment.

The fields in the **Course Information** section become mandatory for investigational agent studies.

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

3. Enter the course number of which the adverse event occurred.

4. Enter the total number of courses the subject has received to date.

2. Enter the start date of the course associated with the adverse event.

5. Click **Save & Continue**.

Save & Back

Save

Save & Continue

Study Interventions - Agents

The screenshot shows a web form titled "Agents" with the following fields and callouts:

- 1.** Callout: "1. Select Yes if the subject received an investigational agent." points to the "Yes" dropdown menu.
- 2.** Callout: "2. Click **+Add** to expand the **Agents** page." points to the "+ Add" button.
- 3.** Callout: "3. Select the agent from the list of values." points to the "Study agent" dropdown menu.
- 4.** Callout: "4. Enter the total dose amount given during the course and the unit of measure." points to the "Total dose administered this course" and "Unit of measure" fields.
- 5.** Callout: "5. Enter the date the dose was last administered prior to the event." points to the "Date last administered prior to the event that is being reported" field.
- 6.** Callout: "6. Enter any delay in agent administration and indicate the time measure." points to the "Administration delay" field and the "Minutes" dropdown.
- 7.** Callout: "7. Enter any relevant or applicable comments." points to the "Comments" text area.
- 8.** Callout: "8. Select any modification to the dose from the list of values, if applicable." points to the "Dose modifications?" dropdown.
- 9.** Callout: "9. Click **Save & Continue**." points to the "Save & Continue" button.

Study Interventions - Devices

Note: This page is applicable to only a small number of studies.

Devices

Was an investigational device administered to this subject on this protocol?

1. Select **Yes** to indicate that the subject received an investigational device.

2. Click **+Add** to expand the **Devices** page.

3. Select the device from the list of values. The **Brand name**, **Common name** and **Device type** displays after the selection is made.

4. Enter all other information related to the device.

5. Click **Save & Continue**.

*** Study device**

Brand name

*** Common name**

Device type

Manufacturer name

Manufacturer city

Manufacturer state

Model number

Lot number

Catalog number

Expiration date (mm dd/yyyy)

Serial number

Other number

Device operator

If implanted, enter a date (mm dd/yyyy)

If explanted, enter a date (mm dd/yyyy)

Is this a single use device that was reprocessed and reused?

Evaluation availability

Study Interventions - Radiation

Note: This page only displays for studies with a radiation component.

Radiation

+ Add

1. Click **+Add** to expand the **Radiation** page.

2. Select the radiation type from the list of values.

3. Enter the total dose and the unit of measure.

4. Enter the date of the last treatment the subject received.

5. Enter the number of radiation sessions planned for the subject.

6. Enter the number of days the therapy was not performed due to the adverse event.

7. Select the adjustment from the list of values.

The screenshot shows a form with the following fields:

- Type of radiation administration (dropdown menu)
- Total dose (to date) (text input)
- Unit of measure (dropdown menu)
- Date of last treatment (calendar icon, text input)
- Schedule number of fractions (text input)
- Number of elapsed days (text input)
- Adjustment (dropdown menu)

Save & Continue

8. Click **Save & Continue**.

Study Interventions - Surgery

Note: This page is applicable to only a small number of studies.

Surgery

+ Add

1. Click **+Add** to expand the **Surgery** page.

2. Type at least three characters of the **Intervention site**, then select from the list.

3. Enter the surgery date.

* Intervention site

Begin typing here

* Date of intervention

(mm dd / yyyy)

Save & Continue

4. Click **Save & Continue**.

Subject Details - General

General

Instructions Enter general demographic information for the subject

Subject ID SS22

* Confirm Subject ID SS22

Date of Birth /

*MM *YYYY

* Gender

* Ethnicity

* Race

* Organization Mayo Clinic Hospital, Phoenix, AZ (AZ073)

Baseline performance Please select

* Height Centimeter

* Weight Kilogram

Body surface area

1. The Subject ID displays. You may revise the Subject ID at this time, if needed. You must confirm the ID, if changed.

2. Enter the subject's birth date.

3. Select the subject's gender from the list of values.

4. Select the subject's ethnicity from the list of values.

5. Select the subject's race from the list of values.

6. The Organization displays. You may revise the Organization at this time, if needed.

7. Select the subject's baseline performance from the list of values.

8. Enter the subject's height, including the unit of measure.

9. Enter the subject's weight, including the unit of measure.

The subject's BSA will automatically display.

10. Scroll down to the **Disease Information** page.

Subject Details – Disease Information

1. Select the name of the subject's disease from the list of values.

*Note: The **Other (disease)** field only displays when *Hematopoietic malignancy, NOS* or *Solid tumor, NOS* is selected in the **Disease name** field.

2. Enter the other disease name, if applicable.*

3. Type at least three characters and select the primary disease site from the list.

4. Enter the date the subject was initially diagnosed with the disease, if known.

5. Scroll down to the **Metastatic Disease Site** page.

The screenshot shows a web form titled "Disease Information" with a help icon in the top right. Below the title is an "Instructions" section: "Enter the appropriate study disease /condition information for the subject." The form contains several fields:

- Disease name**: A dropdown menu with a red border and a downward arrow.
- Other (disease)**: A text input field with a red border.
- Primary site of disease**: A text input field with a blue border and the placeholder text "Begin typing here". To its right is a search icon (magnifying glass) and a "Show All" link.
- Date of initial diagnosis**: A date input field with a calendar icon, split into "MM" and "YYYY" sections.

Callout boxes from the surrounding text point to these fields: box 1 points to the "Disease name" dropdown; box 2 points to the "Other (disease)" text field; box 3 points to the "Primary site of disease" text field; box 4 points to the "Date of initial diagnosis" date field.

Subject Details – Metastatic Disease Site

1. If applicable, click **+Add** to expand the **Metastatic Disease Site** page.

2. Type at least three characters or click [Show All](#) and select the disease from the list.

The screenshot shows a web form titled "Metastatic Disease Site". At the top, there is a blue button with a plus sign and the text "+Add". Below this is a section labeled "Instructions" with the text "Enter any metastatic sites for the disease selected above." The main form area contains a label "Metastatic Disease Site" followed by a text input field with the placeholder text "Begin typing here". To the right of the input field is a clear button (an 'X' in a square). Below the input field is a blue link labeled "Show All". A red trash can icon is visible in the bottom right corner of the form area. Two callout boxes are present: one pointing to the "+Add" button and another pointing to the "Show All" link.

3. Scroll down to the **Pre-Existing Conditions** page.

Subject Details – Pre-Existing Conditions

1. If applicable, click **+Add** to expand the **Pre-Existing Conditions** page.

2. Select the condition from the list of values.

The screenshot shows a web form titled "Pre-Existing Conditions". At the top left, there is a minus sign icon and the title. At the top right, there is a question mark icon. Below the title, there is an "Instructions" section with the text: "If applicable, enter the relevant history, including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.).". Below the instructions is a blue button with a plus sign and the text "+ Add". Below the button is a red-bordered input field with the label "Pre-existing condition" and a dropdown arrow on the right. A red trash can icon is located in the bottom right corner of the form area. Two callout boxes are present: one pointing to the "+ Add" button and another pointing to the dropdown menu of the "Pre-existing condition" field.

3. Scroll down to the **Concomitant Medications** page.

Subject Details – Concomitant Medications

1. If applicable, click **+Add** to expand the **Concomitant Medications** page.

2. Enter the name of the medication the subject received.*

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

The screenshot shows a web application window titled "Concomitant Medications". Below the title bar, there is a section with the heading "Instructions" and the text "Document any non-protocol medications that might have contributed to the event(s) being reported." Below the instructions, there is a blue button with a plus sign and the text "+ Add". Below the button, there is a red input field with the label "Medication Name" and a red asterisk. A red icon is visible in the bottom right corner of the form area.

3. Scroll down to the **Prior Therapies** page.

Subject Details – Prior Therapies

1. Click **+Add** to expand the **Prior Therapies** page.

2. Select the therapy from the list of values.

3. Enter additional information regarding the therapy.

4. Enter the start and end date of the prior therapy, if known.

5. Click **+Add** to expand the **Therapy agents** section.*

6. Select the agent from the list of values.*

7. Click **Save & Continue**.

Note: Select “No prior therapy” from the **Prior Therapy** list of values if the subject received no prior therapy.

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.

* **Prior therapy**

Comments

Start date

MM / DD / YYYY

MM DD YYYY

End date

MM / DD / YYYY

MM DD YYYY

Therapy agent(s)

Agent name

Begin typing here

*Note: The **Therapy agent(s)** section and **Agent name** field display depending on the therapy selected in the **Prior therapy** field.

Other Causes

1. If applicable, click **+Add a cause** to expand the **Other Causes** page.

2. Enter an other cause that may have contributed to the adverse event.

3. Click **Save & Continue**.

The screenshot shows a web form titled "Other Causes" with a help icon in the top right. Below the title is an "Instructions" section: "Enter information regarding other circumstances that might have been related to the event or other situations that might have contributed to the event(s) being reported (e.g. the flu, Central Line Placement, IV hydration, etc.)." Below the instructions is a blue button with a plus icon and the text "Add a cause". To the right of this button is a red trash can icon. Below these is a text input field with a red border and a red asterisk, labeled "Cause". At the bottom of the form are three buttons: "Save & Back" (blue), "Save" (blue), and "Save & Continue" (green with a right arrow icon). Three callout boxes provide instructions: the first points to the "Add a cause" button, the second points to the "Cause" text field, and the third points to the "Save & Continue" button.

Labs

1. If applicable, click **+Add a lab** to expand the **Labs** page.

2. Select the lab category from the list of values.*

3. Select the name of the lab from the list of values.

4. Enter the lab values and the associated dates.

5. Click **Save & Continue**.

*Note: When the **Microbiology** category is selected, enter the **Site**, **Date**, and **Infectious Agent** fields that display.

Labs

Instructions Enter any labs that are relevant for describing the event.

+ Add a lab

- Hematologic :

Lab Category

^ Lab name

Units

Baseline value date (mm dd/yyyy)

Nadir/Worst value date (mm dd/yyyy)

Recovery/Latest value date (mm dd/yyyy)

Save & Back **Save** **Save & Continue**

Site

Date (mm dd/yyyy)

Infectious Agent

Attribution

Note: The adverse event must have at least one cause with a positive attribution (i.e., Possible, Probable, or Definite) to submit the report.

1. For each possible cause, select an attribution from the list of values.

Attribution

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

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	AE 2 SEVERE Nausea: queasiness
Disease		
Gastrointestinal stromal tumor	<input type="text" value=""/>	<input type="text" value=""/>
Study Agent		
724772::Sorafenib (BAY 43-9006; Nexavar) (125mg)	<input type="text" value=""/>	<input type="text" value=""/>

 Save & Back

 Save

 Save & Continue 

2. Click **Save & Continue**.

Additional Info

1. If applicable, click each checkbox to identify the information to be submitted with the report.

Additional Info ?

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

<p>Autopsy report <input type="checkbox"/></p> <p>Consults <input type="checkbox"/></p> <p>Discharge summary <input type="checkbox"/></p> <p>Flow sheets /case report forms <input type="checkbox"/></p> <p>Laboratory reports <input type="checkbox"/></p> <p>OBA form <input type="checkbox"/></p> <p>Pathology report <input type="checkbox"/></p> <p>Other information <input style="width: 100%; height: 100%;" type="text"/></p>	<p>Progress notes <input type="checkbox"/></p> <p>Radiology report <input type="checkbox"/></p> <p>Referral letters <input type="checkbox"/></p> <p>Summary report sent to IRB <input type="checkbox"/></p> <p>Operative Report <input type="checkbox"/></p> <p>Admission H&P <input type="checkbox"/></p> <p>Other <input type="checkbox"/></p>
--	---

If information provided is not listed above, type the information being provided. Separate each item with a comma ",".

Notes: Supporting documentation must be faxed to 301-230-0159 and must include the **Report Ticket Number** on the fax cover sheet and the **Subject ID** and the study's **Protocol Number** on each page submitted.

The **Additional Info** fields may not be available depending on the protocol and commercial agent reporting requirements.

3. Click **Save & Continue**.

Review and Submit - Review and Physician Signoff

The **Review and Submit** page automatically displays sections that require additional information.

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.

Review & Submit

1. Click **+** to expand the section.

CTEP Expedited Report

Status *Due on 12/21/2013*

Amendment # 0

Information remaining to complete

+ Describe Event section

+ Review & Submit section

Actions ▾

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.

Review & Submit

CTEP Expedited Report

Status *Due on 12/21/2013*

Amendment # 0

Information remaining to complete

- Describe Event section

- Has the subject been re-treated? is mandatory
-  Go back to this page

+ Review & Submit section

Actions ▾

2. Click "Go back to this page".

The page displays.

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**

* **Has the subject been re-treated?**

Date removed from protocol
(mm/dd/yyyy)

3. Add the required information.

Save & Back

Save

Save & Continue

4. Click **Save**.

5. Click the **Review & Submit** tab (tab 11).

The **Review and Submit** page displays with the corrected section removed.

6. Click **+** to expand the section.

The screenshot displays two stacked panels. The top panel, titled "Physician signoff", contains a checkbox and the text: "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." The bottom panel, titled "Review & Submit", shows a "CTEP Expedited Report" header. Below this, it displays "Status Due on 12/21/2013" and "Amendment # 0". A pink highlighted area contains the text "Information remaining to complete" and a button labeled "+ Review & Submit section". An "Actions" dropdown menu is visible in the bottom right corner of the panel.

Review and Submit - Review and Physician Signoff

The message indicates that the physician signoff must be completed.

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.

Review & Submit

CTEP Expedited Report

Status *Due on 12/21/2013* Amendment # 0

Information remaining to complete

Review & Submit section

- Physician sign-off is mandatory for this report.
- Scroll up 

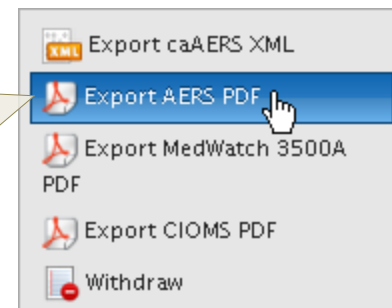
Actions ▾

7. Click **Actions** to generate the pre-submission report for the physician's review.

Notes: CTEP recommends that the report be reviewed by the physician prior to entering the signoff checkbox.

The physician signoff is not required when submitting a 24-hour notification.

8. Select **Export AERS PDF** then follow instructions to either open or save the file.



The pre-submission report displays or is saved, depending on the previous selection.

Follow your site's processes to gain physician approval.

Department of Health and Human Services		Public Health Service	
(Site Reported)		National Institutes of Health	
National Cancer Institute		Bethesda, Maryland 20892	
Run Date : 12/11/2013 3:24:32 PM	Pre-Submission Adverse Event Expedited Report		
<hr/>			
Protocol Number: 7028	CTC Version: 4.0	Principal Investigator: Hedy Kindler	
Title: A Phase II Study of BAY 43-9006 for Patients with Imatinib and Sunitinib Resistant Gastrointestinal Stromal Tumor			
Institution: Mayo Clinic Hospital	Report Type: Original	Ticket #: 2922013	Amendment #: 0
Created Date: 12/11/2013			
<hr/>			
<u>Reporter Information</u>			
Reporter Name : jack jason	Phone : 301-589-9981	Fax : 301-589-8891	Email : jmcmlty@ctisinc.com
Submitter Name : jack jason	Phone : 301-589-9981	Fax : 301-589-8891	Email : jmcmlty@ctisinc.com
Physician Name : jack jason	Phone : 301-589-9981	Fax :	Email : jmcmlty@ctisinc.com
<hr/>			
<u>Patient Information</u>			
Patient ID :	SS4	Birth Date :	11/ 1949
Race :	White	Ethnicity :	Not Reported
Height(Centimeter) :	33.0	Weight(Kilogram) :	333.0
Baseline performance status at initiation of protocol - ECOG/Zubrod scale :			3
Disease Name :	Hematopoietic malignancy, NOS		

11. Once approved, click the **Physician signoff** 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.

The **Review & Submit** section displays **Ready to submit!**

Review & Submit

CTEP Expedited Report

Status *Due on 12/21/2013* Amendment # 0

 **Ready to submit!**

Submit **Actions** ▾

12. Click **Submit**.

Review and Submit - Submitter

The **Submitter** page displays.

13. Click one checkbox to indicate whether the submitter is the same person as the reporter or physician. The submitter details will automatically display.

If the submitter is different than the reporter or physician, then enter all mandatory submitter detail fields.

Submitter

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**

Physician

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

14. Click **Save & Continue**.

Review and Submit - Recipients

The **Recipients** page displays the email addresses of the reporter, physician and submitter. Additional recipients, such as PI, Adverse Event Coordinators, etc. can be viewed from the **View Recipients** option under the **Actions** button from the **Manage Reports** page (see slide 53).

Recipients

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

- NCI CTEP
- rasontl@ame.edu (SUB)
- rasontl@ame.edu (REP)
- rasontl@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

[Back](#) [Submit](#)

15. To specify additional recipients, enter the email addresses in the **Cc** field. Only use comas to separate the addresses (do not use hard returns or semicolons).

16. Click **Submit**.

Review and Submit - Submission Status

The **Submission Status** page displays the successful submission message.

After a 24-hour notification submission, CTEP-AERS displays a link which will return you directly to the 5-day report.

Submission Status

Instructions 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.

Alternatively, you may access and submit the report at a later time using the 'Manage Reports' workflow.

Additional Info: 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.

Submitted successfully on 01/22/2014

Actions ▾

The fax number is provided if additional information is to be faxed (see slide 36). The FAQ link is also provided to reference details on submitting additional information.

You can click **Export** to generate a report file.

Manage Reports

The screenshot shows the CTEP AERS website. At the top left is the logo 'CTEP AERS' with the tagline 'Cancer Therapy Evaluation Program Adverse Event Reporting System'. On the top right, there are 'Help' and 'Adverse Events' buttons. Below the header is a navigation bar with 'Report Adverse Events' and 'Manage Reports' tabs. The main content area contains a welcome message and instructions. A callout box on the left points to the 'Manage Reports' tab and the 'Manage Reports' link in the 'Quick Links' section. The 'Quick Links' section also has a callout box pointing to the 'Manage Reports' link.

CTEP AERS
Cancer Therapy Evaluation Program Adverse Event Reporting System

Help
Adverse Events

Report Adverse Events Manage Reports

Welcome to the Cancer Therapy Evaluation Program Adverse Event Reporting System (CTEP AERS). CTEP AERS is available to submit expedited adverse event reports for all CTEP-sponsored clinical trials and Division of Cancer Prevention (DCP) cancer prevention trials.

To create a new expedited report: click Report Adverse Event
Once initiated, reports are assigned a unique ticket number that is used for future report access. The ticket number is sent to the reporter by e-mail, but documenting this number is strongly encouraged.

To complete or withdraw a pending report or amend an existing report: click Manage Reports
The NCI protocol number, ticket number and subject identifier must be entered to access a pending or submitted report.

To login as an administrator (NCI Staff only): [click here](#)
To view NCI Guidelines: [Adverse Event Reporting Requirements](#)

Additional CTEP-AERS resources are available on the [CTEP-AERS Home Page](#)
Frequently Asked Questions [FAQ](#)

Medical Questions/Help: email: aemd@tech-res.com phone: (301) 897-7497 fax: (301) 230-0159
Technical Questions/Help: email: ncictephelp@ctep.nci.nih.gov phone: 1-888-283-7457 fax: (301) 948-2242

Quick Links
Report Adverse Events
Manage Reports

CONTACT US PRIVACY NOTICE DISCLAIMER ACCESSIBILITY APPLICATION SUPPORT

To complete or withdraw an initiated report or to amend a report, click **Manage Reports**.

Manage Report - Select study and subject

1. Enter the report ticket number.

2. Type at least three digits of the protocol number, then select from the list.

3. Enter the **Subject ID**.

The screenshot shows a web form titled "Select study and subject" with a search icon in the top right corner. The form contains three input fields, each with a red border and a red asterisk indicating a required field:

- *Ticket Number**: A text input field.
- *Study**: A text input field containing the placeholder text "Begin typing here" and a clear button (X) on the right.
- *Subject ID**: A text input field.

Three callout boxes with arrows point to these fields: the first points to the Ticket Number field, the second points to the Study field, and the third points to the Subject ID field.

Continue →

4. Click **Continue**.

Manage Report - Overview

The **Manage Report** page displays the information associated with the report.

The **Amendment #** begins after the expedited report is submitted with the number '1'.

The Report Submission Status is listed here. Status values include: *Due in (number) Days*, the *Submission Response* or whether the report is *Withdrawn, Initiated, not submitted or Overdue*.

Manage Reports

Instructions The table below summarizes reports for the given Ticket Number. Click Actions and select the option you wish to perform.

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.

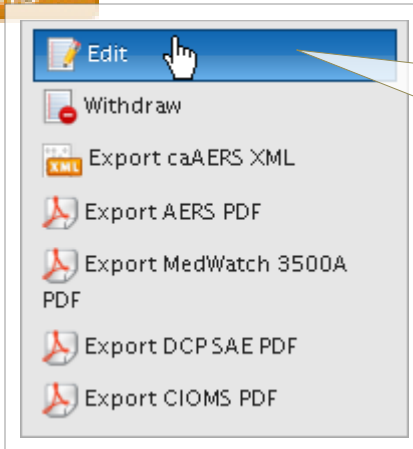
Report Type	Amendment #	Report Submission Status	Options
CTEP Expedited Report	1	<i>Due in 10 days</i>	Actions ▾
CTEP Expedited Report	0	<i>Amended on 12/12/2013</i>	Actions ▾
CTEP 24 Hour Notification		<i>Submitted successfully on 12/12/2013</i>	Actions ▾

The **Report Type** displays *CTEP Expedited Report*, *CTEP 24-Hour Report* or other types depending on the protocol and report selected.

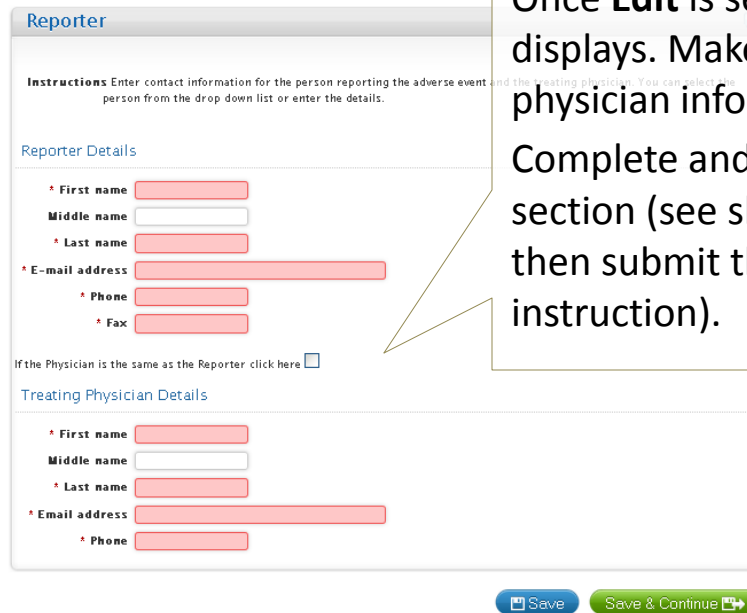
Click **Actions** to continue. Depending on the report status, the options available may include: *Edit, Withdraw, Export, Amend, View the Report or View Participants*.

Manage Reports – Edit Option

Actions ▾



By selecting **Edit** from the options under the **Actions** button, you can add or modify information, then submit report.

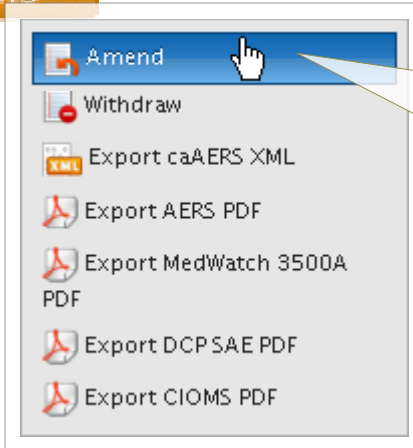
A screenshot of the 'Reporter' page in a web application. The page title is 'Reporter'. Below the title, there are instructions: 'Instructions Enter contact information for the person reporting the adverse event and the treating physician. You can select the person from the drop down list or enter the details.' The form is divided into two sections: 'Reporter Details' and 'Treating Physician Details'. Each section contains several text input fields with red borders, some marked with an asterisk to indicate they are mandatory. The fields include 'First name', 'Middle name', 'Last name', 'E-mail address', 'Phone', and 'Fax'. At the bottom of the page, there are two buttons: 'Save' and 'Save & Continue'.

Once **Edit** is selected, the **Reporter** page displays. Make revisions to the reporter or physician information, if necessary.

Complete and/or modify each mandatory section (see slides 19 – 36 for instruction) then submit the report (see slides 37 – 46 for instruction).

Manage Reports – Amend Option

Actions ▾



By selecting **Amend** from the options under the **Action** button, you can modify and submit a previously submitted report. Note that the 24-hour notification cannot be amended.

Follow the instruction on slide 49 to modify and submit the report.

The amendment number will display on the **Manage Reports** page.

Manage Reports

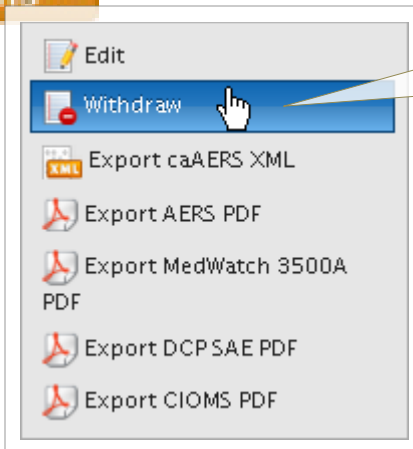
Instructions The table below summarizes reports for the given Ticket Number. Click Actions and select the option you wish to perform.

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.

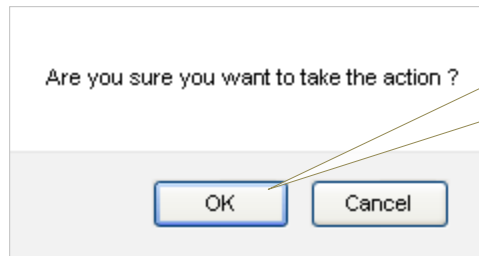
Report Type	Amendment	Report Submission Status	Options
CTEP Expedited Report	1	<i>Due in 10 days</i>	Actions ▾
CTEP Expedited Report	0	<i>Amended on 12/12/2013</i>	Actions ▾
CTEP 24 Hour Notification		<i>Submitted successfully on 12/12/2013</i>	Actions ▾

Manage Reports – Withdraw Option

Actions ▾



By selecting **Withdraw** from the options under the **Action** button, you can remove a pending report from the system.



Click **OK** to confirm the action you are taking.

Manage Reports

Instructions The table below summarizes reports for the given Ticket Number. Click Actions and select the option you wish to perform.

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.

Report Type	Amendment #	Report Submission Status	Options
CTEP Expedited Report	1	Withdrawn on 12/20/2013	<i>NO reporting action available for this report</i>
CTEP Expedited Report	0	Amended on 12/12/2013	Actions ▾
CTEP Expedited Report	0	Submitted successfully on 12/12/2013	Actions ▾

The withdrawn status displays on the **Manage Reports** page.

Manage Reports – View Recipients Option

Actions ▾

View in AdEERS
View Recipients
 Export caAERS XML
 Export MedWatch 3500A PDF
 Export CIOMS PDF

By selecting **View Recipients** from the options under the **Action** button, you can access the list of persons who have received the report.

Are you sure you want to take the action ?

OK Cancel

Click **OK** to confirm the action you are taking.

View Recipients (Group)

NCI Protocol No. : CALGB-105 (CTCAE v4.0) -- A Phase III Intergroup CLL Study of Asymptomatic Patients with Unreated Chronic Lymphocytic Leukemia Randomized to Early Intervention Versus Observation with Later Treatment in the High Risk Genetic Subset with IGVH Unmutated Disease

NCI Protocol Number:	CALGB-105
Expedited Report Ticket Number:	2332791
Patient ID :	SS2
Amendment Number :	0

This report was Successfully Submitted to the following:

Recipient Type	Recipients	Name	Email	Phone
Lead Group	Cancer and Leukemia Group B (Legacy)	Debbie S Pierce	debbie.sawyer@incl.org.x	Not Available
		Gabrielle Sawyer	centraloffice@incl.org.x	Not Available
		Ramanand Pierce	ram.schant@incl.org.x	Not Available
		Fat Namara	mcnamara.patricia@incl.org.x	Not Available
		Brad Anders	andersen.bradley@incl.org.x	Not Available
		Darin Brand	darin.brandon@incl.org.x	Not Available
		Joshua Yoder	josh.yoder@incl.org.x	Not Available
		Adil Khan	adil.a.khan@incl.org.x	Not Available
		Tony Haynes	tony.cervata@incl.org.x	Not Available
		Tonya Brown	thaynes2@incl.org.x	Not Available
Mary Claire	mpierce@incl.org.x	Not Available		
Participant Group	Cancer Trials Support Unit	Gladys Brosn	gbrown@nullinc.com	Not Available
Submitter	Mayo Clinic Health System Eau Claire Hospital-Luther Campus	jason.jackson	jmcnulty@nullinc.com	Not Available
Physician	Mayo Clinic Health System Eau Claire Hospital-Luther Campus	jason.jackson	jmcnulty@nullinc.com	Not Available
PI	Cancer and Leukemia Group B (Legacy)	John Byrns	john.b@nullinc.com	Not Available

Close Window

The recipients display.

You have completed the CTEP-AERS training course.
Thank you for participating!

Additional Resources

NCI Guidelines for Investigators: Adverse Event Reporting Requirements for DCTD (CTEP and CIP) and DCP INDs and IDEs.

http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/aeguidelines.pdf

NCI CTEP Help Desk (technical issues)

email: ncictephelp@ctep.nci.nih.gov

phone: 1-888-283-7457

fax: (301) 948-2242

AEMD Help Desk (medical questions)

email: aemd@tech-res.com

phone: (301) 897-7497

fax: (301) 230-0159

CTEP-AERS Training Guide

http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/CTEP-AERS_Training_Guide.pdf

CTEP-AERS Online Help

Click any help link within the CTEP-AERS application.