

# CTEP-AERS

Cancer Therapy Evaluation Program Adverse Event Reporting System

## CTEP-AERS vs. AdEERS Training Supplement

CTEP-AERS Training Site:

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

CTEP-AERS Production Site:

<https://eapps-ctep.nci.nih.gov/ctepaers>

CTEP Website - CTEP-AERS Page:

[http://ctep.cancer.gov/protocolDevelopment/electronic\\_applications/adverse\\_events.htm](http://ctep.cancer.gov/protocolDevelopment/electronic_applications/adverse_events.htm)

Shanda Finnigan  
CTEP, NCI  
October 2013

# Welcome to CTEP-AERS

## CTEP-AERS:

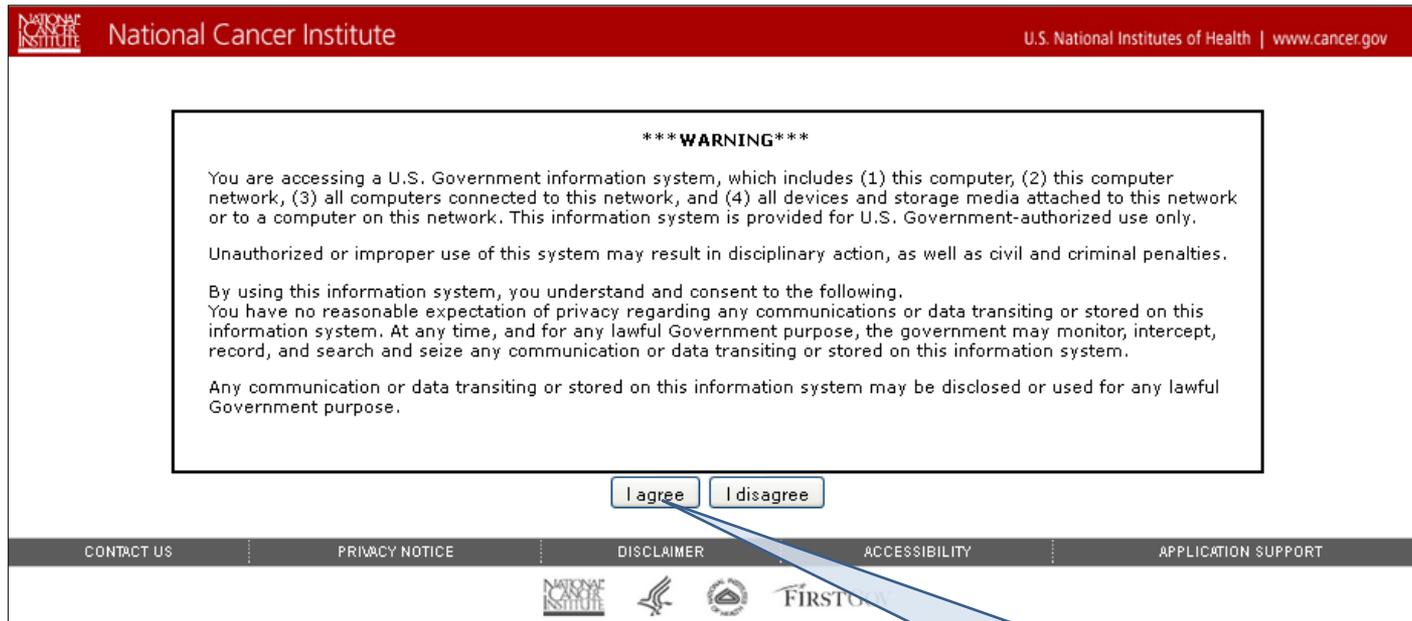
- Compliant with the new FDA Final Rule.
- Open public system – no login credentials needed.
- Supported with **Internet Explorer** and **Mozilla Firefox** , Google Chrome is not supported.
- Uses Protocol Specific Exceptions (PSEs) to provide immediate reporting recommendations to help reduce the number of unnecessary reports submitted to lower the burden on participating sites and CTEP.
- Updated user interface including autocomplete features.

# Welcome to CTEP-AERS

***This training presentation is specifically designed for users who have a familiarity with AdEERS and highlights the differences of CTEP-AERS.***

# Access CTEP-AERS Training Site

## NCI Warning Disclaimer



The screenshot shows the National Cancer Institute (NCI) website header with the NCI logo and the text "National Cancer Institute" on the left, and "U.S. National Institutes of Health | www.cancer.gov" on the right. The main content area is a white box with a black border containing the following text:

**\*\*\*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.

Below the text are two buttons: "I agree" and "I disagree".

The footer of the page is a dark grey bar with the following links: CONTACT US, PRIVACY NOTICE, DISCLAIMER, ACCESSIBILITY, and APPLICATION SUPPORT. Below the footer are several logos, including the NCI logo, the U.S. Department of Health and Human Services logo, and the "FIRST" logo.

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 CTEPAERS logo with the tagline '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. A 'CAUTION: CTEPAERS Training Site' message is prominently displayed in the center. Below this, there is a paragraph explaining that reports entered here are for training only and not submitted to the NCI. A 'Quick Links' box contains buttons for 'Report Adverse Events' and 'Manage Reports'. Further down, there are instructions on how to create a new report, complete or withdraw a pending report, and how to login as an administrator. At the bottom, there are links to NCI Guidelines, CTEPAERS Home Page, and Frequently Asked Questions. Contact information for AEMD and NCICTEP Helpdesks is provided at the very bottom.

Click to access the CTEPAERS 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 (for use by CTEP, NCI staff).

Link to the NCI Guidelines.

Link to resources on the CTEPAERS page from the CTEP website.

Contact information to the AEMD and NCICTEP Helpdesks.

# CTEP-AERS Home Page

The screenshot shows the CTEPAERS Home Page. At the top left is the CTEPAERS logo with the tagline 'Cancer Therapy Evaluation Program Adverse Event Reporting System'. To the right are 'Help' and 'Adverse Events' buttons. Below the logo is a navigation bar with 'Report Adverse Events' and 'Manage Reports' tabs. A 'CAUTION!' banner reads 'CTEP-AERS Training Site'. The main content area contains instructions for reporting and managing reports. A 'Quick Link' box on the right contains 'Report Adverse Events' and 'Manage Reports' buttons. Two callout boxes provide additional context: one points to the 'Report Adverse Events' tab and the other points to the 'Manage Reports' button in the Quick Link box.

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

Quick Link  
Report Adverse Events  
Manage Reports

To initiate a new report, click either one of the **Report Adverse Events** tabs.

The **Manage Reports** option provides access to existing reports and is described on slide 46 of this presentation.

# Select study, subject and course/cycle/intervention

This page, similar to AdEERS, collects the highest level data to initiate the report.

The screenshot shows a web form titled "Select study, subject, and course/cycle/intervention". The form includes the following fields and a button:

- \* Study**: A text input field with the placeholder text "Begin typing here". A callout box explains: "The Autocomplete feature is available from many fields within CTEP-AERS. Type at least three digits of the protocol number to display suggested values from which to select."
- \* Subject ID**: A text input field. A callout box explains: "CTEP-AERS refers to the patient as the **Subject**."
- \* Confirm Subject ID**: A text input field.
- \* Organization**: A text input field with the placeholder text "Begin typing here" and a clear button (X).
- \* Course/Cycle/Intervention**: A section with a blue button labeled "+ Add". A callout box explains: "CTEP-AERS collects TAC information at the initiation of a report. Click **+Add**. The **Course/Cycle/Intervention** page displays (see next slide)."

Red asterisks (\*) indicate a mandatory field.

# Course/Cycle/Intervention Information

This page lists the treatment assignments associated with the study.

Select the TAC that was assigned to the subject.

Select **Other** and provide a treatment description if the TAC is unavailable or when the adverse event occurred on a Surgery, Device, Radiation intervention. This field can also be used when reporting a late adverse event (i.e., one that occurs more than 30 days after treatment) or for commercial agents.

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

Delete Save

Click **Save** to continue.

Important: This 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 (see slide 18).

# 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

The **Adverse Events** page displays.

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** /TAC1 ((Cycle=28 days)\nBAY 43-9006: 400mg PO BID)  
**Intervention**

**Adverse Events** ?

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

**Enter verbatim**  **+ Add**

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

**Verbatim** is a new field in CTEP-AERS. Enter the adverse event as described by the subject or clinician. If no verbatim term exists or is not applicable, then enter the CTCAE term.

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

# Adverse Events

The expanded **Adverse Events** page displays.

Use the Autocomplete feature (see slide 7) and select the **CTCAE Term** from the suggested values.

The **Grades** that display will change depending on the **CTCAE Term** you select.

Indicate whether the subject was hospitalized. This field is mandatory if the grade is 2 or higher.

The **Outcomes** include rules that are applied depending on other information. For example, the **Death** outcome cannot be selected if the adverse event grade does not include death. You may select as many **Outcomes** as applicable.

Additional adverse events can be added by entering the **Verbatim** and clicking **+Add**.

Click on the **View CTCAE v4.0** to view the entire list of adverse event terms.

Adverse events can be removed by clicking the **Delete** icon.

Use the **Calendar** icon to select dates.

Once all fields are entered, click **Save & Report**. Clicking **Save & Report** 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.

The screenshot shows the 'Adverse Events' form with the following fields and callouts:

- Instructions:** Enter the verbatim.
- Enter verbatim:** Text input field with an **+Add** button. Callout: 'Additional adverse events can be added by entering the **Verbatim** and clicking **+Add**.'
- Verbatim:** 'pain'. Callout: 'Use the Autocomplete feature (see slide 7) and select the **CTCAE Term** from the suggested values.'
- CTCAE Term:** Red highlighted dropdown menu. Callout: 'Click on the **View CTCAE v4.0** to view the entire list of adverse event terms.'
- Grade:** Radio buttons for 1, 2, and 3. Callout: 'The **Grades** that display will change depending on the **CTCAE Term** you select.'
- Start date:** Calendar icon and input field. Callout: 'Use the **Calendar** icon to select dates.'
- End date:** Calendar icon and input field.
- Did AE cause hospitalization?:** Dropdown menu. Callout: 'Indicate whether the subject was hospitalized. This field is mandatory if the grade is 2 or higher.'
- Outcomes:** List of checkboxes including Death, Hospitalization, Life-threatening, etc. Callout: 'The **Outcomes** include rules that are applied depending on other information. For example, the **Death** outcome cannot be selected if the adverse event grade does not include death. You may select as many **Outcomes** as applicable.'
- Buttons:** **Save & Back**, **Save**, and **Save & Report**. Callout: 'Once all fields are entered, click **Save & Report**. Clicking **Save & Report** 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.'
- Delete icon:** A red trash can icon. Callout: 'Adverse events can be removed by clicking the **Delete** icon.'

# Review and Report – Action Recommended

The **Review and Report** page uses Protocol Specific Exceptions (PSEs), NCI AE Reporting Guidelines and SPEER data to determine whether an expedited report is required.

The **Review and Report** page displays a checkmark icon when a report is required. Alternatively, it displays a stop icon when a report is not required (see slide 14 for more information).

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 Suni  
**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  
administration of investigational agent/intervention, please consult your protocol for

**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 →](#)

The **Override** option is available for late adverse events (i.e., events that occur more than 30 days after treatment) or for reporting adverse events that occur with commercial treatments (see slide 15 for more information).

The **Adverse Event** table lists the information you have entered and displays regardless of whether a report is required.

# 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, 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 – Action Not Recommended

The **Review and Report** page uses Protocol Specific Exceptions (PSEs), NCI AE reporting guidelines and SPEER data to determine whether an expedited report is required.

The **Review and Report** page displays a stop icon when a report is not required.

If no action is recommended, you can either exit the system or use the **Override** option (see slide 15 for more information) to submit a report.

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 30 days after the last administration of investigational 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 <span style="color: green;">New</span> | 1: Mild symptoms; intervention not indicated | 07/22/2013 | <input checked="" type="radio"/> |

Please select a report.

**Report** →

# 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](#)

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 for commercial studies only.

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 <span>New</span> | 3: Severe symptoms; surgical intervention indicated  | <input type="text"/><br>(mm/dd/YYYY) | <input checked="" type="radio"/> |
| <input checked="" type="checkbox"/> | Yes                           | Vomiting: throwing up <span>New</span>   | 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 <span>New</span>   | 3: Inadequate oral calories 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

Important: 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.

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** →

To continue with the report, click **Report**.

# Reporter

The information required on the **Reporter** page is the same as AdEERS.

## Reporter

**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.

### 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**

If the reporter and physician are the same person and after entering the **Reporter Details**, click this checkbox to copy the information to the **Treating Physician Details**.

Enter all mandatory fields then click **Save & Continue**.  
Note: The information on this page must be completed and saved in order for the report to be saved and the ticket number assigned (see next slide). At this time, CTEP-AERS begins the report due date countdown.

# Report Ticket Number

The report is saved to the system and the ticket number is assigned. The reporter is sent the access key through an e-mail that is generated immediately after completion of the Reporter page.

The report's **Ticket number** displays at the top of each page along with the **Subject ID** and **Protocol Number**. This information becomes the key for future access to the report.

**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)

You can now close your browser, if needed, and access the report through the **Manage Reports** module at a later time (see slide 46 for information on the **Manage Reports** module).

Please note that the information on the following slides highlight the differences in CTEP-AERS as compared to AdEERS. Please refer to the CTEP-AERS Training Guide or Training Presentation available from the CTEP website if more comprehensive information is needed. CTEP-AERS also includes an online help feature for access to quick instructive information.

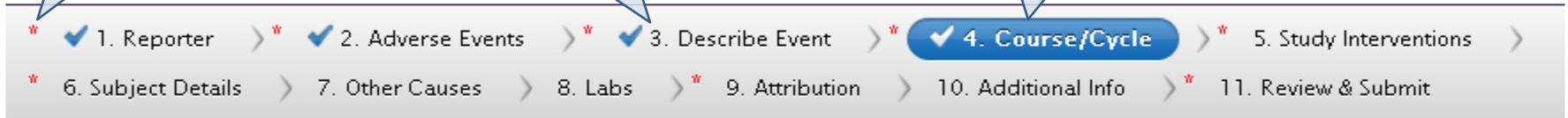
# Navigation Bar

CTEP-AERS displays the report section tabs at the top of each page.

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 again to review and revise entered information or to enter additional adverse events.

**Adverse Events** ?

**Instructions** Complete the required fields and add any additional information for each adverse event included in the report.

**+ Add Adverse Event**

**+ Dyspepsia pain , Grade: 3 [Primary]**

**← Save & Back**

**Save** **Save & Continue →**

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

The CTEP-AERS rules engine may re-evaluate the reporting requirements depending on added or revised adverse event information.

Click **+** to review the entered adverse event and revise, if necessary.

Click **Save & Continue**.

# Adverse Events – Reporting Death

Please refer to the [NCI Guidelines: Adverse Event Reporting Requirements](#) effective September, 2013.

The screenshot shows a form for reporting an adverse event. The title is "Death NOS Grade: 5 Verbatim: death". The form fields are as follows:

- Verbatim:** death
- AE term:** Death NOS (highlighted in red)
- Grade:** 5: Death
- Start date:** (empty field with a calendar icon and "(mm dd/yyyy)" format)
- End date:** (empty field with a calendar icon and "(mm dd/yyyy)" format)
- Did AE cause hospitalization?:** (dropdown menu with a question mark icon)
- Outcomes:**
  - Death
  - Hospitalization - initial or prolonged
  - Life-threatening
  - Disability or Permanent Damage
  - Congenital Anomaly/Birth Defect
  - Required Intervention to Prevent Permanent Impairment (Damage/Device)
  - Other Serious (Important Medical Events)

The CTCAE terms **Death Not Otherwise Specified (NOS)** and **Sudden Death NOS** do not require a positive attribution to submit a report.

Fetal death should be reported as grade 4 **Pregnancy, puerperium, and perinatal conditions – Other (pregnancy loss)**, under the Pregnancy, puerperium, and perinatal conditions SOC.

Death Neonatal should be reported as grade 4 **General disorders and administration – Other (neonatal loss)**, under the General disorders and administration SOC.

Neither event should be reported as a grade 5 event.

# Describe Event

The **Describe Event** page displays with variations to the field labels in AdEERS.

Enter all mandatory fields before continuing to the next page.

**Describe Event**

**Instructions** This is one of the most critical sections of the report. Provide detailed information about the presentation of the event, the treatment of the event, clinical findings, and the timing of 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?**

The **Description & treatment of event(s)** field is limited to 4,000 characters.

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.

Save & Back

Save

Save & Continue

Click **Save & Continue**.

This field has a limit of 4,000 characters.

# Course/Cycle

The **Course/Cycle** page displays with slight variations compared to AdEERS.

Enter all mandatory fields before continuing to the next page.

The screenshot shows a web form titled "Course/Cycle" with 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 red input field with a calendar icon and a help icon.
  - Start date of course associated with expedited report:** A red input field with a calendar icon and a help icon.
  - Course number on which event occurred:** A red input field.
  - Total number of courses to date:** A red input field.

The treatment information entered in the **Course/Cycle/Intervention Information** page (slide 7) displays. If needed, the TAC can be revised at this time.

These fields become mandatory for investigational agent studies.

Save & Back

Save

Save & Continue

Click **Save & Continue**.

# Study Interventions - Agents

The **Agents** intervention page displays with slight variations compared to AdEERS.

The screenshot shows the 'Agents' page with the following fields and callouts:

- Was an investigational agent administered to this subject on this protocol?** (Dropdown menu with a red highlight and a callout: "Select Yes to indicate that the subject received an investigational agent.")
- +Add** (Button with a callout: "Click +Add to expand the Agents page.")
- ()** (Button)
- Study agent** (Dropdown menu with a red highlight)
- Total dose administered this course** (Text input field with a red highlight)
- Unit of measure** (Dropdown menu with a red highlight)
- Date last administered prior to the event that is being reported** (Date input field with a calendar icon and format *(mm/dd/yyyy)*)
- Administration delay** (Text input field with a "Minutes" dropdown menu)
- Comments** (Text area)
- Dose modifications?** (Dropdown menu)

Enter all mandatory fields before continuing to the next page.

Save & Back

Save

Save & Continue

Click **Save & Continue**.

# Other Study Interventions

The **Devices**, **Surgery** and/or **Radiation** intervention page displays, if applicable to the protocol. Very few studies include these interventions at this time.

The screenshot shows a form with three sections: 'Devices', 'Surgery', and 'Radiation'. Each section has a '+ Add' button. The 'Devices' section contains a question: 'Was an investigational device administered to this subject on this protocol?' with a dropdown menu currently set to 'Yes'. A callout box points to the 'Yes' dropdown with the text: 'Select Yes to indicate that the subject received an investigational device.' Another callout box points to the '+ Add' buttons of all three sections with the text: 'Click +Add to expand the page. Enter all mandatory fields on the page before continuing to the next page.'

Save & Continue

Click **Save & Continue**.

# Subject Details – General

The **Subject Details** section includes several pages, starting with the **General** page.

The **Subject ID** may be revised, if needed. You must confirm the ID, if changed.

The **Organization** may be revised, if needed.

**General**

**Instructions** Enter general demographic information for the subject.

\* **Subject ID**

\* **Confirm Subject ID**

**Date of Birth**  /

\*MM \*YYYY

\* **Gender**

\* **Ethnicity**

\* **Race**

\* **Organization**

**Baseline performance**

\* **Height**

\* **Weight**

**Body surface area**

Enter all mandatory fields before continuing to the next page.

The subject's BSA will automatically display after **Height** and **Weight** entry.

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

# Subject Details – Disease Information

The **Subject Details, Disease Information** section is mandatory for all expedited reports.

The screenshot shows a web form titled "Disease Information". At the top, there is a tab with a minus sign and a question mark icon. Below the title, an "Instructions" section reads: "Enter the appropriate study disease/condition information for the subject." The form contains several fields: "Disease name" (a dropdown menu with a red border), "Other (disease)" (a text input field with a red border), "Primary site of disease" (a search bar with the placeholder "Begin typing here", a close button, and a "Show All" link), and "Date of initial diagnosis" (two input fields for month and year, with labels "MM" and "YYYY" below them). A callout box points to the "Disease name" field, and another callout box points to the "Other (disease)" field.

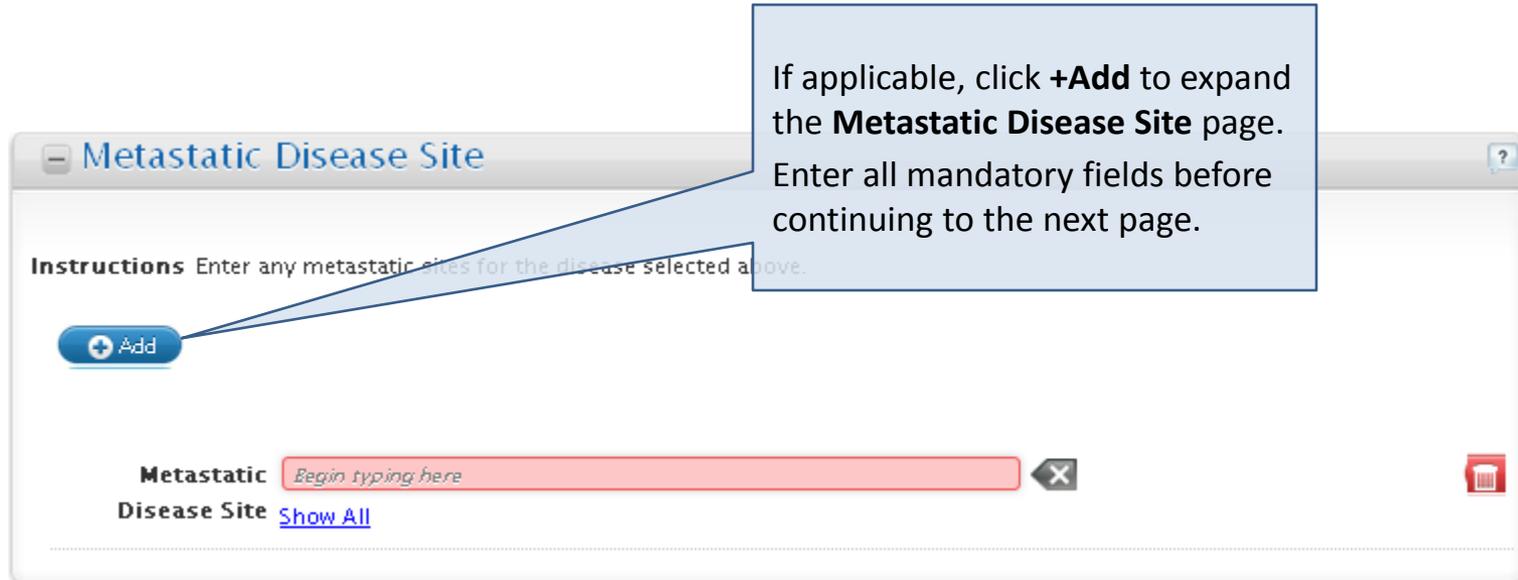
The **Other (disease)** field only displays when *Hematopoietic malignancy, NOS* or *Solid tumor, NOS* is selected from the **Disease name** field.

Enter all mandatory fields before continuing to the next page.

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

# Subject Details – Metastatic Disease Site

The **Subject Details, Metastatic Disease Site** section is optional for adverse event reporting.



The screenshot shows a web form titled "Metastatic Disease Site". At the top left, there is a minus sign icon and the title. Below the title, there is an "Instructions" section that reads: "Enter any metastatic sites for the disease selected above." To the left of the instructions is a blue button with a plus sign and the text "+ Add". Below the instructions is a text input field with the placeholder text "Begin typing here". To the right of the input field is a grey "X" icon. Below the input field, the text "Metastatic Disease Site" is followed by a blue link "Show All". To the right of the input field is a red trash can icon. A blue callout box points to the "+ Add" button.

If applicable, click **+Add** to expand the **Metastatic Disease Site** page. Enter all mandatory fields before continuing to the next page.

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

# Subject Details – Pre-Existing Conditions

The **Subject Details, Pre-Existing Conditions** section is optional for adverse event reporting.

**Pre-Existing Conditions**

**Instructions** If applicable, enter the relevant history, including pre-existing conditions, race, pregnancy, smoking and alcohol use, hepatic (renal dysfunction, etc.).

**+ Add**

**Pre-existing condition**

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

Enter all mandatory fields before continuing to the next page.

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

# Subject Details – Concomitant Medications

The **Subject Details, Concomitant Medications** section is optional for adverse event reporting.

The screenshot shows a web form titled "Concomitant Medications". At the top left, there is a minus sign icon and the title "Concomitant Medications". Below the title, there is an "Instructions" section with the text: "Document any non-protocol medications that might have contributed to the adverse event(s)". A blue button with a plus sign and the text "+ Add" is located below the instructions. Below the button is a minus sign icon. A red asterisk is positioned to the left of the label "Medication Name", which is followed by a red rectangular input field. Three callout boxes are present: one pointing to the "+ Add" button, one pointing to the "Medication Name" label, and one pointing to the input field.

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

Enter all mandatory fields before continuing to the next page.

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

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

# Subject Details – Prior Therapies

The **Subject Details, Prior Therapies** section is mandatory for all expedited reports.

**Prior Therapies**

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

**+ Add**

**\* Prior therapy**

**Comments**

**Start date**  /  /    
MM DD YYYY

**End date**  /  /    
MM DD YYYY

**Therapy agent(s)**  **+ Add**

**Agent name**

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

Click **+Add** to expand the **Prior Therapy** page.

Select "No prior therapy" from the Prior Therapy list of values if the subject received no prior therapy.

Enter all mandatory fields before continuing to the next page.

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

Click **Save & Continue**.

# Other Causes

The **Other Causes** page is optional for adverse event reporting.

**Other Causes**

**Instructions** Enter information regarding other circumstances that might have contributed to the event(s) being reported (e.g. the flu, Central Line Placement, IV hydration, etc.).

+ Add a cause

—

▲ Cause

Save & Back

Save

Save & Continue

If applicable, click **+Add** to expand the **Other Causes** page.  
Enter all mandatory fields before continuing to the next page.

Click **Save & Continue**.

# Labs

The **Labs** page is optional for adverse event reporting.

**Labs**

**Instructions** Enter any labs that are relevant for describing the event(s) in this report.

[+ 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)

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

**Site**

**Date**  (mm dd / yyyy)

**Infectious Agent**

[Save & Back](#) [Save](#) [Save & Continue](#)

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

Enter all mandatory fields before continuing to the next page.

Click **Save & Continue**.

# Attribution

The **Attribution** page is mandatory for all expedited reports.

**Attribution**

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

**Note:** Depending on the rules for this report, each adverse event may require at least one attribution (i.e., Possible, Probable, or Definite).

| Possible cause   | Primary AE<br>SEVERE<br>Dyspepsia: stomach<br>pain | AE 2<br>SEVERE<br>Nausea, queasiness |
|--|--|--------------------------------------|
| <b>Disease</b><br>Gastrointestinal stromal<br>tumor                          | <input type="text"/>                               | <input type="text"/>                 |
| <b>Study Agent</b><br>724772::Sorafenib (BAY<br>43-9006; Nexavar)<br>(125mg) | <input type="text"/>                               | <input type="text"/>                 |

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

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

 Save & Back

 Save

 Save & Continue

Click **Save & Continue**.

# Additional Info

The **Additional Info** page is optional for adverse event reporting. Some fields may not be available depending on the protocol and commercial agent reporting requirements.

**Additional Info**

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

|                                       |                          |                                   |                          |
|---------------------------------------|--------------------------|-----------------------------------|--------------------------|
| <b>Autopsy report</b>                 | <input type="checkbox"/> | <b>Progress notes</b>             | <input type="checkbox"/> |
| <b>Consults</b>                       | <input type="checkbox"/> | <b>Radiology report</b>           | <input type="checkbox"/> |
| <b>Discharge summary</b>              | <input type="checkbox"/> | <b>Referral letters</b>           | <input type="checkbox"/> |
| <b>Flow sheets /case report forms</b> | <input type="checkbox"/> | <b>Summary report sent to IRB</b> | <input type="checkbox"/> |
| <b>Laboratory reports</b>             | <input type="checkbox"/> | <b>Operative Report</b>           | <input type="checkbox"/> |
| <b>OBA form</b>                       | <input type="checkbox"/> | <b>Admission H&amp;P</b>          | <input type="checkbox"/> |
| <b>Pathology report</b>               | <input type="checkbox"/> | <b>Other</b>                      | <input type="checkbox"/> |

**Other Information**

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 ",".

Click the checkbox(es) to identify the information to be submitted with the report.

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.

Click **Save & Continue**.

# Review and Submit - Review and Physician Signoff

The **Review and Submit** page automatically displays sections that require additional information. There are several steps to complete before you can submit the report.

The screenshot displays two main sections in a light gray header:

- 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."
- Review & Submit**: Contains a minus sign icon and the text "CTEP Expedited Report". Below this, it shows "Status Due on 09/21/2013" and "Amendment # 0". A pink shaded area contains the text "Information remaining to complete" followed by two expandable items: "+ Describe Event section" and "+ Review & Submit section". A blue callout box with a white background and a blue border points to the first "+" icon, containing the text "Click + to expand the section." In the bottom right corner of the "Review & Submit" section, there is an orange button labeled "Actions" with a downward arrow.

# Review and Submit - Review and Physician Signoff

Once expanded, a description of the needed information will be provided as well as a link to the section.

**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* **09/21/2013**      **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** ▾

The information required is described.

Click **Go back to this page**.

# Review and Submit - Review and Physician Signoff

The page requiring additional information 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)

Add the required information.

Save & Back

Save

Save & Continue

Click **Save**, then click the **Review & Submit** tab (tab 11) on the navigation bar.

# Review and Submit - Review and Physician Signoff

The **Review and Submit** page displays with the corrected section removed. Repeat this process until all sections are complete.

The screenshot displays two main sections: "Physician signoff" and "Review & Submit".

**Physician signoff** (top section):  
Contains a checkbox with 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."

**Review & Submit** (bottom section):  
Contains a minus sign icon and the text "CTEP Expedited Report".  
Below this, it shows "Status Due on 09/21/2013" and "Amendment # 0".  
A red shaded area contains the text "Information remaining to complete" and a plus sign icon next to "Review & Submit section".  
An "Actions" dropdown menu is visible in the bottom right corner.

Callout 1 (top): The **Review & Submit** section will be the last section to address.

Callout 2 (bottom): Click **+** to expand the section.

# Review and Submit - Review and Physician Signoff

The **Review and Submit** page 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 09/21/2013* Amendment #

Information remaining to complete

Review & Submit section

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

Actions ▾

- Export caAERS XML
- Export AERS PDF
- Export MedWatch 3500A PDF
- Export CIOMS PDF
- Withdraw

Click **Actions** and select **Export AERS PDF** to generate a pre-submission report for the physician's review.

Remember, the physician signoff is not required when submitting a 24-hour notification.

# Review and Submit - Review and Physician Signoff

Complete the **Review and Submit** page physician signoff and begin the submission process.

## 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.

Follow your site's processes to obtain physician approval. Once approved, click the **Physician signoff** checkbox.

## Review & Submit

CTEP Expedited Report

Status *Due on* **09/21/2013**

Amendment # 0

✓ Ready to submit!

Submit

Actions ▾

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

Click **Submit**.

# Review and Submit - Submitter

The **Submitter** page displays.

**Submitter**

**Reporter**

**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**

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

Enter all mandatory **Submitter details** fields if the submitter is different than the reporter or physician.

Click **Save & Continue**.

# Review and Submit - Recipients

The **Recipients** page displays the email addresses of the reporter, physician and submitter.

**Recipients**

The **CTEP 10 Calendar Day SAE Report** will be sent to the

- 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

Unlike AdEERS, CTEP-AERS does not display all of the recipients assigned to the report. They will, however, appear on the submission email that is automatically sent to the submitter.

← Back

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).

Click **Submit**.

Submit →

# Review and Submit - Submission Status

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

The screenshot shows a web interface titled "Submission Status". It contains the following text:

**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.

At the bottom right, there is an orange button labeled "Actions" with a dropdown arrow. Below the text is a green banner with a checkmark icon and the text "Submitted successfully on 01/22/2014".

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

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 **Manage Reports** module provides access to initiated or previously submitted reports and provides options to amend submitted reports or withdraw pending reports.

The screenshot shows the CTEP AERS website interface. At the top left is the logo for CTEP AERS (Cancer Therapy Evaluation Program Adverse Event Reporting System). In the top right corner, there is a 'Help' button and a 'Adverse Events' tab. Below the header, there are two main navigation buttons: 'Report Adverse Events' and 'Manage Reports'. A callout box on the left points to the 'Manage Reports' button with the text 'Click Manage Reports.' Another callout box on the right points to the 'Manage Reports' button in the 'Quick Links' section. The main content area contains the following text:

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: [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: [adeersmtd@tecl-ns.com](mailto:adeersmtd@tecl-ns.com) phone: (301) 897-7497 fax: (301) 230-0159

Technical Questions/Help: email: [ncictphelp@ctep.nci.nih.gov](mailto:ncictphelp@ctep.nci.nih.gov) phone: 1-888-288-7457 fax: (301) 948-2242

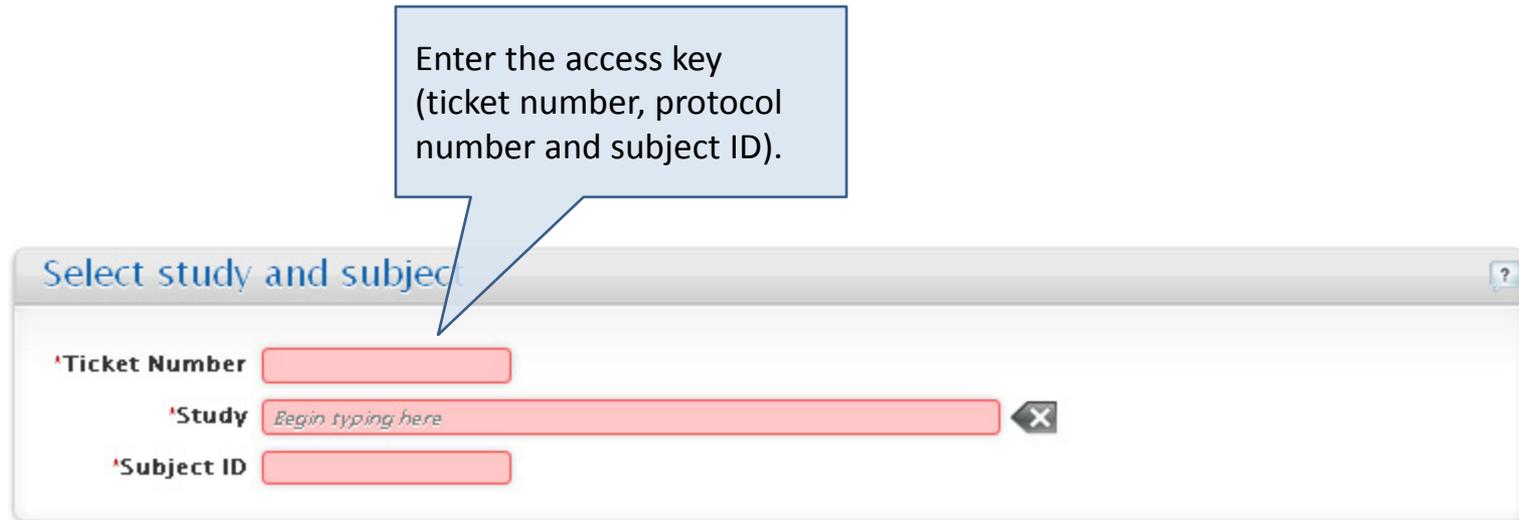
Click Manage Reports.

## Quick Links

- [Report Adverse Events](#)
- [Manage Reports](#)

# Manage Reports – Select study and subject

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



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

- \*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.

A blue callout box with a pointer to the top of the form contains the text: "Enter the access key (ticket number, protocol number and subject ID)."

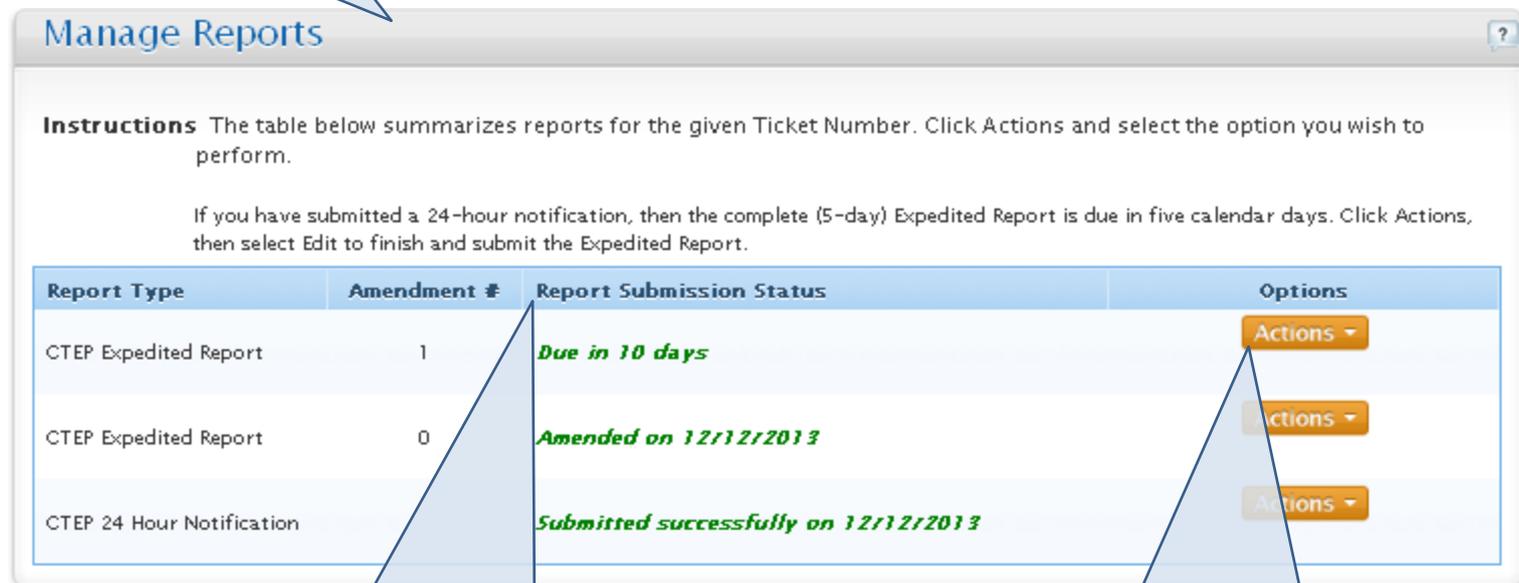


A green button with the text "Continue" and a right-pointing arrow is shown. A blue callout box with a pointer to the button contains the text: "Click **Continue**."

# Manage Reports – Overview

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

CTEP-AERS does not include an option for **Copy Report**.



**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 Submission Status displays values including: *Due in (number) Days*, the *Submission Response* or whether the report is *Withdrawn*, *Initiated*, *not submitted* or *Overdue*.

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

# Manage Reports – Edit Option



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

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

**Reporter**

**Instructions** Enter contact information for the person reporting the adverse event and the treating physician. You can select the person from the dropdown 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

Complete and/or modify each mandatory section (see slides 20 – 36 for instruction) then submit the report (see slides 37 – 45 for instruction).

- \*  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 Info >
- \* 11. Review & Submit

# Manage Reports – Amend Option



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 slides 48 and 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



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.

The withdrawn status displays 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           | <b>Withdrawn on 12/20/2013</b>              | <i>NO reporting action available for this report</i> |
| CTEP Expedited Report     | 0           | <b>Amended on 12/12/2013</b>                | Actions ▾  |
| CTEP 24 Hour Notification |             | <b>Submitted successfully on 12/12/2013</b> | Actions ▾  |

# Manage Reports – View Recipients Option



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



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

The recipients display.

### View Recipients (Group)

NCI Protocol No. : CALGB-105 (CTCAE v4.0) -- A Phase III Intergroup CLL Study of Asymptomatic Patients with Untreated 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         |
|--------------------------|---|------------------|------------------------------|---------------|
| <b>Lead Group</b>        | 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.achanta@incl.org.x       | Not Available |
|                          |   | Pat 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.cervati@incl.org.x      | Not Available |
|                          |   | Tonya Brown      | thaynes2@incl.org.x          | x             |
|                          |   | Mary Claire      | mpierce@incl.org.x           | Not Available |
| <b>Participant Group</b> | Cancer Trials Support Unit                                  | Gladys Brosn     | gbrown@nullinc.com           | Not Available |
| <b>Submitter</b>         | Mayo Clinic Health System Eau Claire Hospital-Luther Campus | jason jackson    | jmcnulty@nullinc.com         | Not Available |
| <b>Physician</b>         | Mayo Clinic Health System Eau Claire Hospital-Luther Campus | jason jackson    | jmcnulty@nullinc.com         | Not Available |
| <b>PI</b>                | Cancer and Leukemia Group B (Legacy)                        | John Byrns       | john.b@nullinc.com           | Not Available |

Close Window

Thank you for participating in the  
CTEP-AERS training course!

# 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](http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/aeguidelines.pdf)

## **NCI CTEP Help Desk (technical issues)**

email: [ncictephelp@ctep.nci.nih.gov](mailto:ncictephelp@ctep.nci.nih.gov)

phone: 1-888-283-7457

fax: (301) 948-2242

## **AEMD Help Desk (medical questions)**

email: [aemd@tech-res.com](mailto: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](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.