CTEP-AERS vs. AdEERS
Training Supplement

CTEP-AERS Training Site:

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

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CTEP, NCI
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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

***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.

Click I agree.
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 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.

CTEP-AERS refers to the patient as the Subject.

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.

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.
The Adverse Events page displays.

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 **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).

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

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).
Review and Report – Recommended Actions

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

<table>
<thead>
<tr>
<th>Select</th>
<th>Action</th>
<th>Report</th>
<th>Status</th>
<th>Due</th>
</tr>
</thead>
<tbody>
<tr>
<td>✅</td>
<td>CREATE</td>
<td>CTEP Expedited Report</td>
<td>Not started</td>
<td>Due in 10 days</td>
</tr>
</tbody>
</table>

- The CTEP Expedited Report is due in 10 days.

<table>
<thead>
<tr>
<th>Select</th>
<th>Action</th>
<th>Report</th>
<th>Status</th>
<th>Due</th>
</tr>
</thead>
<tbody>
<tr>
<td>✅</td>
<td>CREATE</td>
<td>CTEP 24 Hour Notification</td>
<td>Not started</td>
<td>Due in 24 hours</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Select</th>
<th>Action</th>
<th>Report</th>
<th>Status</th>
<th>Due</th>
</tr>
</thead>
<tbody>
<tr>
<td>✅</td>
<td>EDIT</td>
<td>CTEP Expedited Report</td>
<td>In process</td>
<td>Due in 5 days</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Select</th>
<th>Action</th>
<th>Report</th>
<th>Status</th>
<th>Due</th>
</tr>
</thead>
<tbody>
<tr>
<td>✅</td>
<td>CREATE</td>
<td>CTEP Expedited Report (15 Days)</td>
<td>Not started</td>
<td>Due in 15 days</td>
</tr>
</tbody>
</table>

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

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.

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.
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.

The CTEP Expedited Report and 24-Hour Notification are options when **Override** is selected.

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

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

### Adverse Events

<table>
<thead>
<tr>
<th>Select</th>
<th>Expedited Reporting Required?</th>
<th>Adverse Event Term</th>
<th>Grade</th>
<th>Start date</th>
<th>‘Primary’</th>
</tr>
</thead>
<tbody>
<tr>
<td>✔</td>
<td>Yes</td>
<td>Dyspepsia: stomach pain</td>
<td>3: Severe symptoms; surgical intervention indicated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>✔</td>
<td>Yes</td>
<td>Vomiting: throwing up</td>
<td>3: ≥6 episodes (separated by 5 minutes) in 24 hrs; tube feeding, TPN or hospitalization indicated</td>
<td>07/22/2013</td>
<td></td>
</tr>
<tr>
<td>✔</td>
<td>Yes</td>
<td>Nausea: upset stomach</td>
<td>3: Inadequate oral intake; fluid intake; tube feeding, TPN, or hospitalization indicated</td>
<td>07/22/2013</td>
<td></td>
</tr>
</tbody>
</table>
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.

To continue with the report, click **Report**.
The information required on the **Reporter** page is the same as AdEERS.

**Reporter Details**

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

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**.

**Treating Physician Details**

- **First name**
- **Middle name**
- **Last name**
- **Email address**
- **Phone**

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.

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.
Adverse Events

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

- If needed, click +Add Adverse Event to enter additional adverse events.
- Click to review the entered adverse event and revise, if necessary.
- The CTEP-AERS rules engine may re-evaluate the reporting requirements depending on added or revised adverse event information.
- Click Save & Continue.
Adverse Events – Reporting Death

Please refer to the NCI Guidelines: Adverse Event Reporting Requirements effective September, 2013.

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.

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

This field has a limit of 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.

Enter all mandatory fields before continuing to the next page.

Click **Save & Continue**.

The **Description & treatment of event(s)** field is limited to 4,000 characters.
The **Course/Cycle** page displays with slight variations compared to AdEERS.

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

Enter all mandatory fields before continuing to the next page.

These fields become mandatory for investigational agent studies.

Click **Save & Continue**.
Study Interventions - Agents

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

Select Yes to indicate that the subject received an investigational agent.

Click **+Add** to expand the **Agents** page.

Enter all mandatory fields before continuing to the next page.

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.

- **Devices**: Select Yes to indicate that the subject received an investigational device.
- **Surgery**: Click **+Add** to expand the page. Enter all mandatory fields on the page before continuing to the next page.
- **Radiation**

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.

- 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 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.

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.

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.

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.

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.

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.

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

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

Click Save & Continue.
The Attribution page is mandatory for all expedited reports.

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.

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.

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.

- **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**
    - **Review & Submit section**

Click to expand the section.
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.

The information required is described.

Click Go back to this page.
The page requiring additional information displays.

Add the required information.

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 **Review & Submit** section will be the last section to address.

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.

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

Click **Actions** and select **Export AERS PDF** to generate a pre-submission report for the physician’s review.
Review and Submit - Review and Physician Signoff

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

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

The Review & Submit section displays Ready to submit!

Click Submit.
Review and Submit - Submitter

The Submitter page displays.

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.

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.

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

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.

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.

Click **Manage Reports**.
Manage Reports – Select study and subject

The Select study and subject page displays.

Enter the access key (ticket number, protocol number and subject ID).

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**.

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.

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

<table>
<thead>
<tr>
<th>Report Type</th>
<th>Amendment #</th>
<th>Report Submission Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTEP Expedited Report</td>
<td>1</td>
<td><strong>Due in 10 days</strong></td>
</tr>
<tr>
<td>CTEP Expedited Report</td>
<td>0</td>
<td><strong>Amended on 12/12/2013</strong></td>
</tr>
<tr>
<td>CTEP 24 Hour Notification</td>
<td></td>
<td><strong>Submitted successfully on 12/12/2013</strong></td>
</tr>
</tbody>
</table>
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 – 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.
Thank you for participating in the CTEP-AERS training course!
Additional Resources


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

CTEP-AERS Online Help
Click any help link within the CTEP-AERS application.