Training Presentation

CTEP-AERS Training Site:

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CTEP, NCI
November, 2013
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/
This text says you agree to use the system responsibly.

Click I agree.
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.
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.

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.

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.

Click Continue.
Adverse Events - Verbatim

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.
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.

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 **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 displays the checkmark icon. **Available Actions** displays when a report is not required (see next slide). The **Override** option is available in both instances.

**Adverse Events** – Indicates the primary adverse event and summarizes other information.
Available Actions – Indicates that a report is not required and displays the stop icon.

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.
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, which is 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>

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

Depending on the outcome of the rules engine, 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 that displays for commercial agent studies.

Click Restore recommended action to cancel the override.
### 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: &gt;= 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 caloric or fluid intake; tube feeding, TPN, or hospitalization indicated</td>
<td>07/22/2013</td>
<td></td>
</tr>
</tbody>
</table>

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

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

3. 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. At this time, CTEP-AERS begins the report due date countdown.
Report Ticket Number

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

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

If needed, click +Add Adverse Event 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.

1. Click ☰ to expand and review the entered adverse event.

2. Click Save & Continue.
3. 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.*

7. Click Save & Continue.

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

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

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

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

5. Click Save & Continue.
Study Interventions - Agents

1. Select Yes if the subject received an investigational agent.

2. Click +Add to expand the Agents page.

3. Select the agent from the list of values.

4. Enter the total dose amount given during the course and the unit of measure.

5. Enter the date the dose was last administered prior to the event.

6. Enter any delay in agent administration and indicate the time measure.

7. Enter any relevant or applicable comments.

8. Select any modification to the dose from the list of values, if applicable.

9. Click Save & Continue.
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.

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

8. Click Save & Continue.

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

4. Click **Save & Continue**.

Note: This page is applicable to only a small number of studies.
Subject Details - General

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

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.

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

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.

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).

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.*

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

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

7. Click Save & Continue.
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.
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.
1. For each possible cause, select an attribution from the list of values.

2. Click **Save & Continue**.

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

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

1. Click to expand the section.

- **Describe Event section**
- **Review & Submit section**
2. Click “Go back to this page”.
Review and Submit - Review and Physician Signoff

The page displays.

3. Add the required information.

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 message indicates that the physician signoff must be completed.

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.

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

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

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

12. Click **Submit**.
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.

14. Click **Save & Continue**.
11. Review & Submit

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).

15. 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).

16. Click **Submit**.
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.
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**.
4. Click **Continue**.
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*.

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*.
By selecting **Edit** from the options under the **Actions** 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 19 – 36 for instruction) then submit the report (see slides 37 – 46 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 slide 49 to modify and submit the report. The amendment number will display on the **Manage Reports** page.

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.

<table>
<thead>
<tr>
<th>Report Type</th>
<th>Amendment</th>
<th>Report Submission Status</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTEP Expedited Report</td>
<td>1</td>
<td>Due in 10 days</td>
<td>Options</td>
</tr>
<tr>
<td>CTEP Expedited Report</td>
<td>0</td>
<td>Amended on 12/12/2013</td>
<td>Options</td>
</tr>
<tr>
<td>CTEP 24 Hour Notification</td>
<td></td>
<td>Submitted successfully on 12/12/2013</td>
<td>Options</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.
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.

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.