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

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CTEP, NCI
October 2013

Welcome to CTEP-AERS

CTEP-AERS:

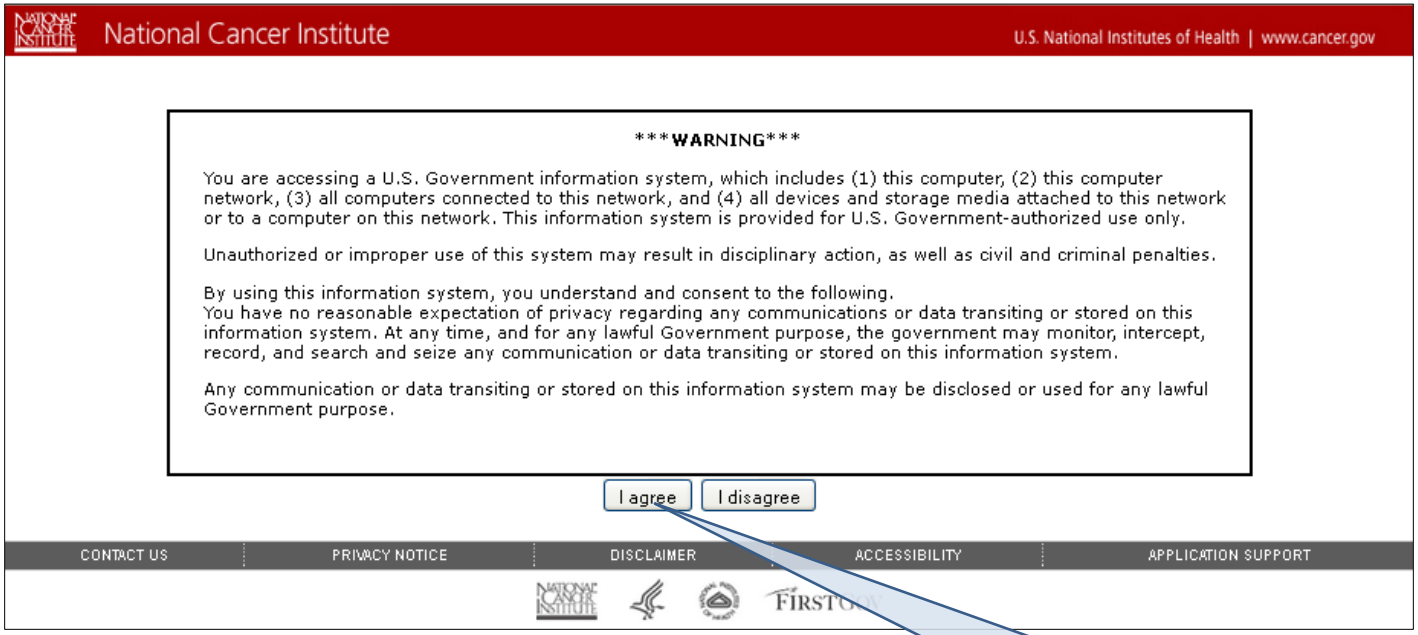
- Compliant with the new FDA Final Rule.
- Open public system – no login credentials needed.
- Supported with **Internet Explorer** and **Mozilla Firefox** , Google Chrome is not supported.
- Uses Protocol Specific Exceptions (PSEs) to provide immediate reporting recommendations to help reduce the number 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



This text says you agree to use the system responsibly.
Click **I agree**.

CTEP-AERS Home Page

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.

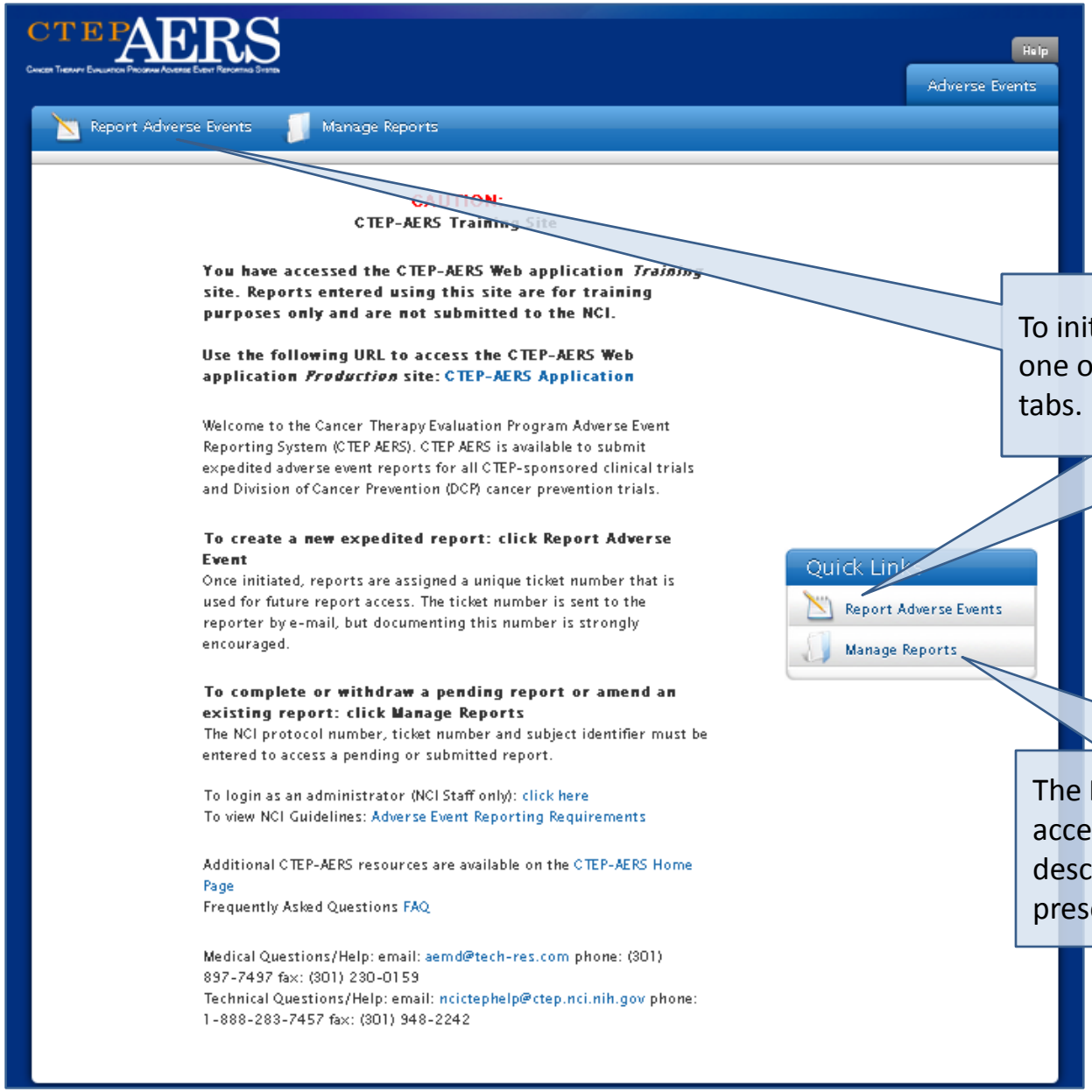
The link to Administrator login (for use by CTEP, NCI staff).

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.

CTEP-AERS Home Page

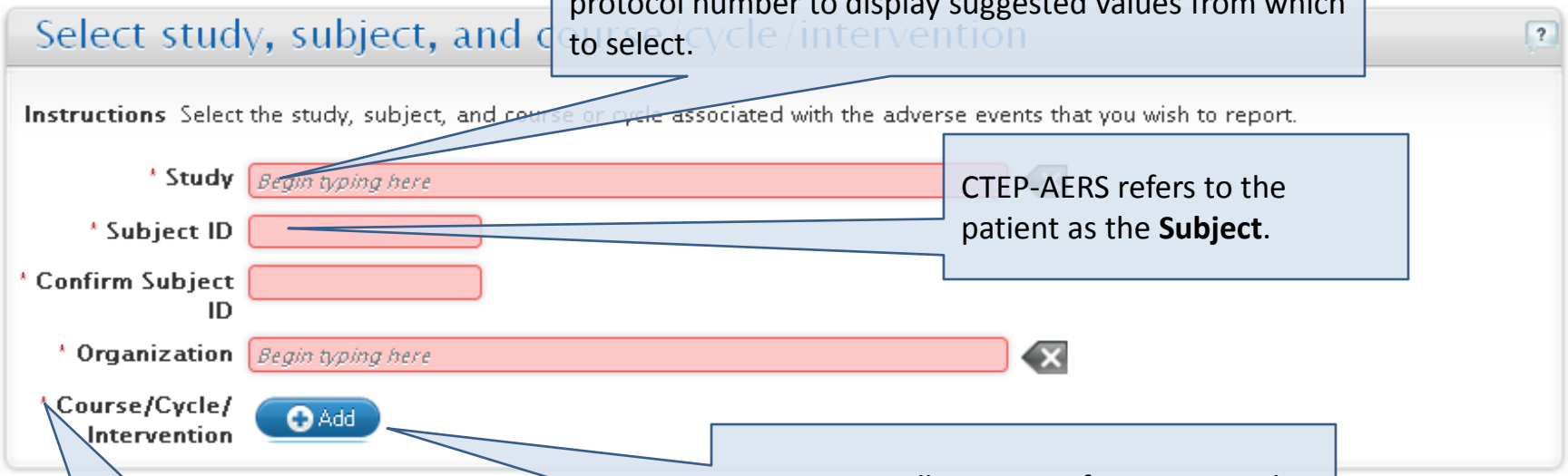


To initiate a new report, click either one of the **Report Adverse Events** tabs.

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.

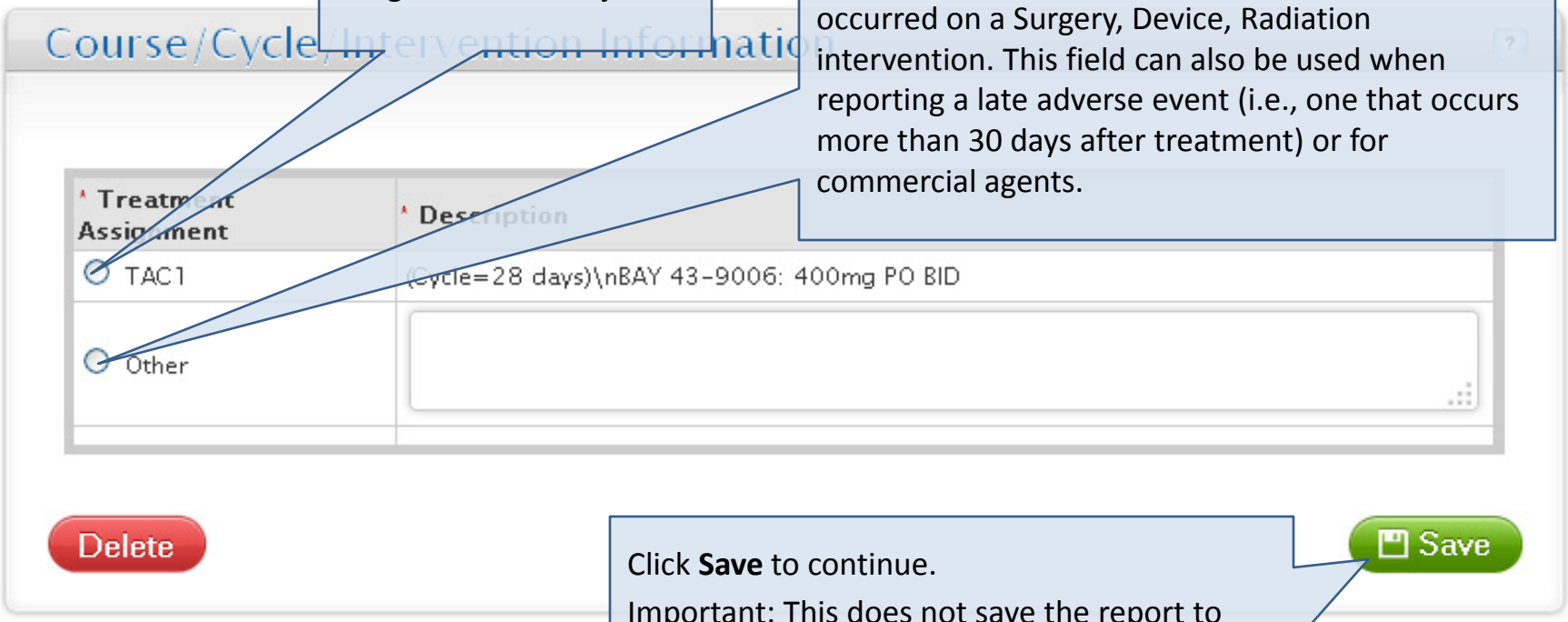
CTEP-AERS refers to the patient as the **Subject**.

Red asterisks (*) indicate a mandatory field.

CTEP-AERS collects TAC information at the initiation of a report. Click **+Add**. The **Course/Cycle/Intervention** page displays (see next slide).

Course/Cycle/Intervention Information

This page lists the treatment assignments associated with the study.



Select the TAC that was assigned to the subject.

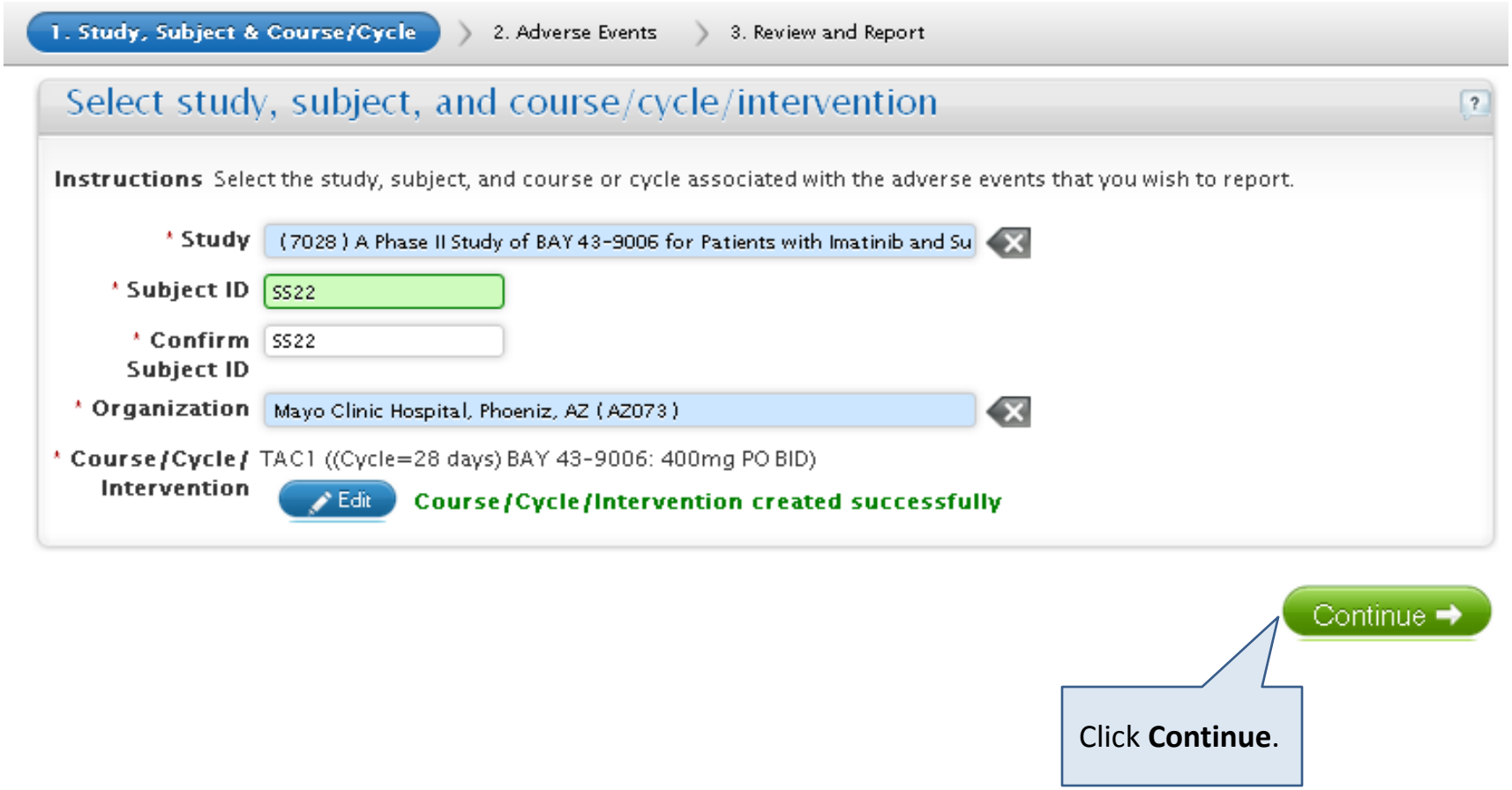
Select **Other** and provide a treatment description if the TAC is unavailable or when the adverse event occurred on a Surgery, Device, Radiation intervention. This field can also be used when reporting a late adverse event (i.e., one that occurs more than 30 days after treatment) or for commercial agents.

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).

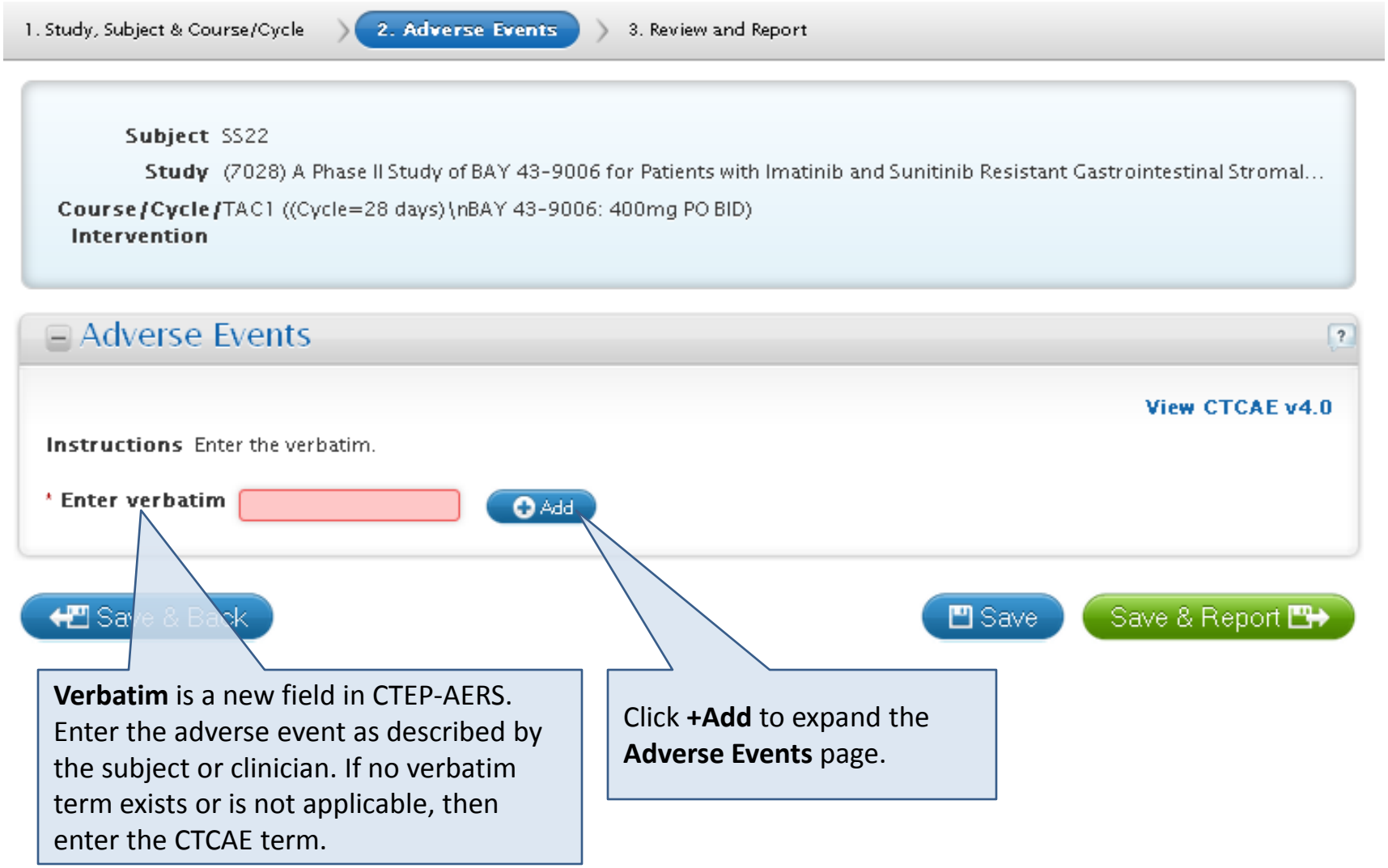
Select study, subject and course/cycle/intervention

The completed page displays.



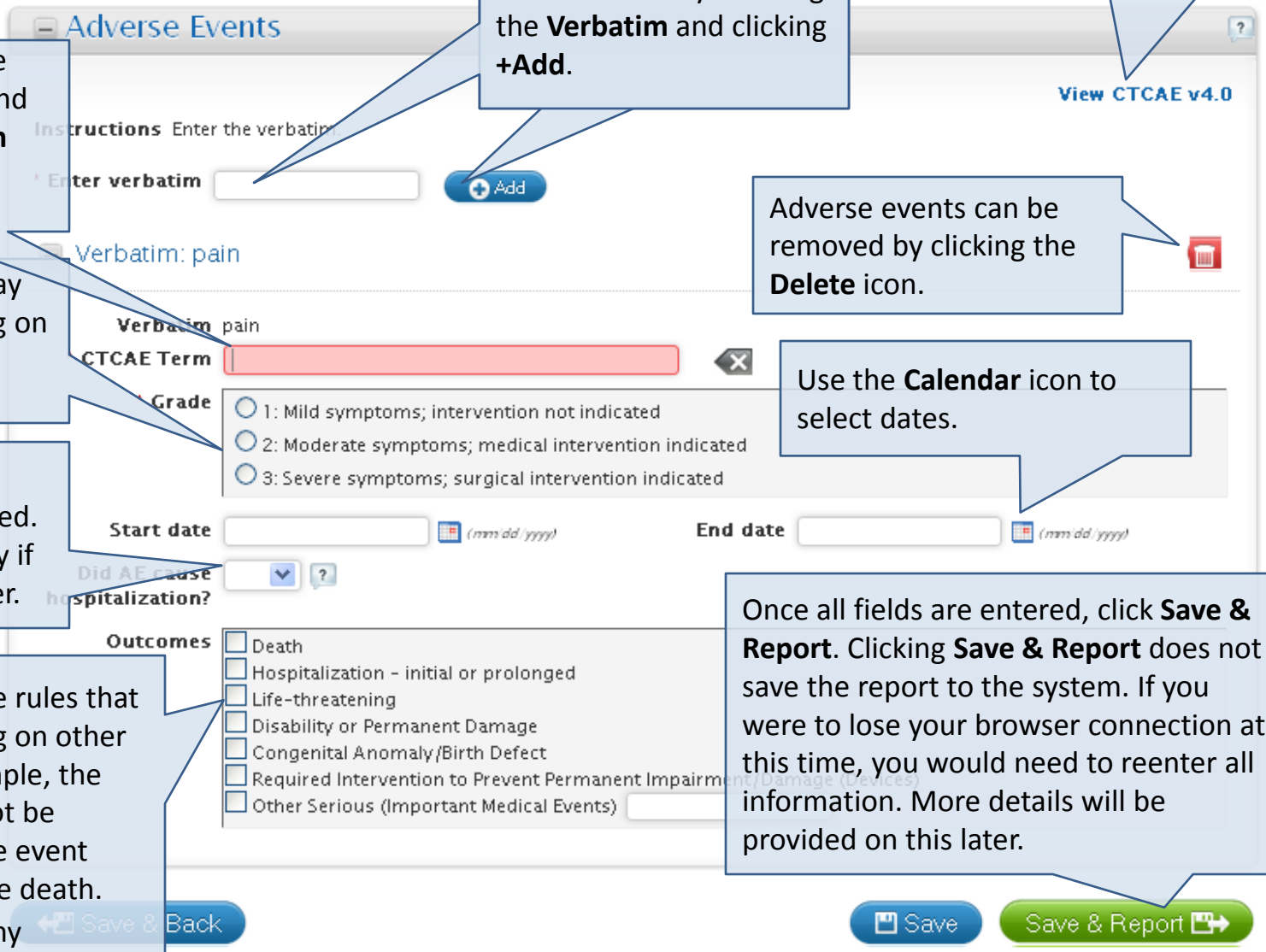
Adverse Events

The **Adverse Events** page displays.



Adverse Events

The expanded **Adverse Events** page displays.



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

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

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

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

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

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

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

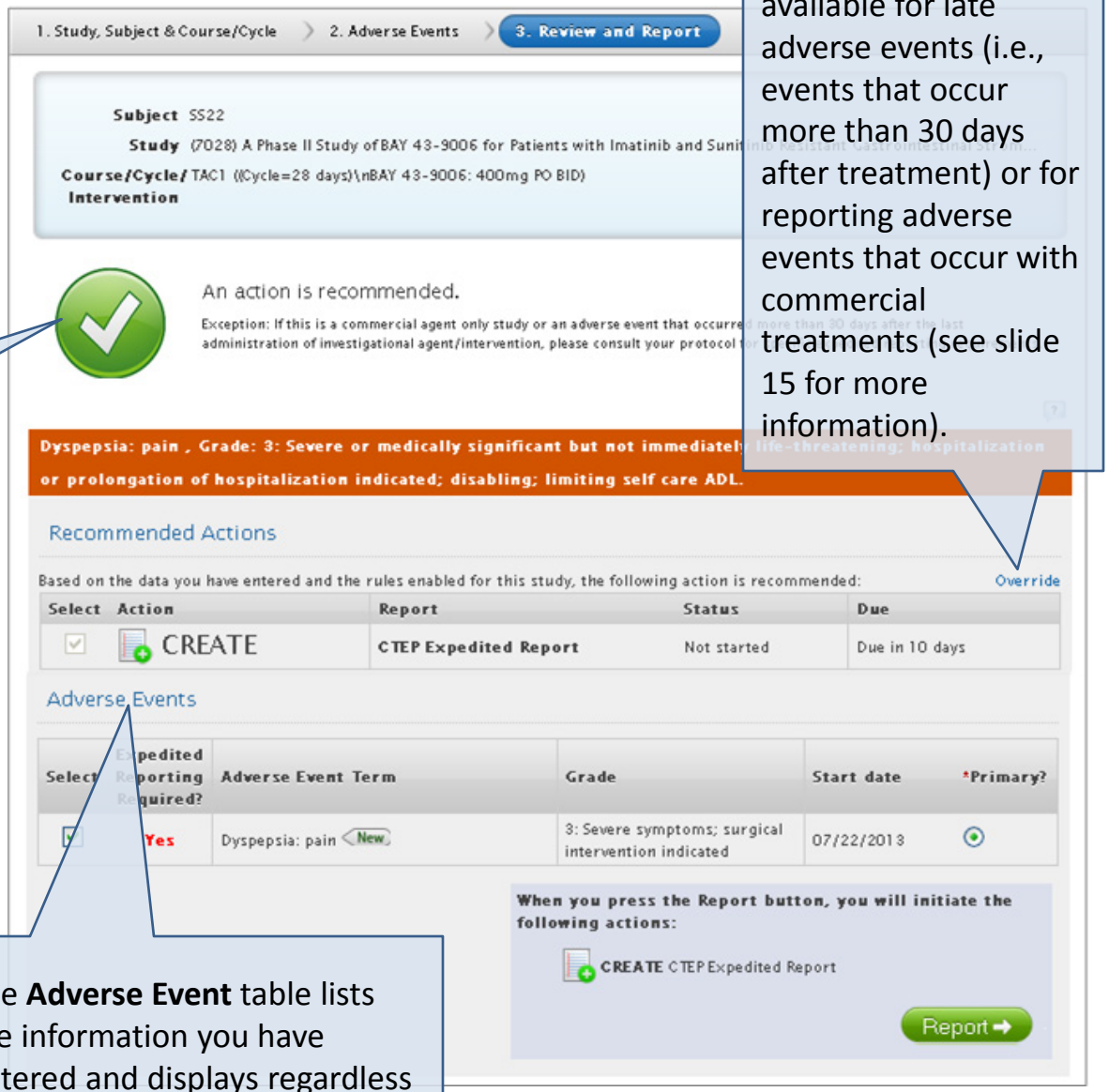
Once all fields are entered, click **Save & Report**. Clicking **Save & Report** does not save the report to the system. If you were to lose your browser connection at this time, you would need to reenter all information. More details will be provided on this later.

The **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.

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).

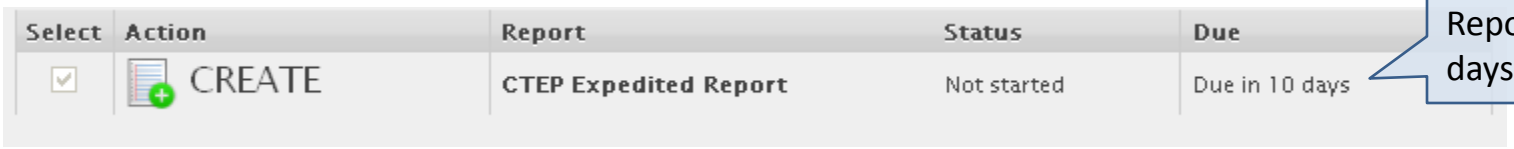


The **Override** option is available for late adverse events (i.e., events that occur more than 30 days after treatment) or for reporting adverse events that occur with commercial treatments (see slide 15 for more information).

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

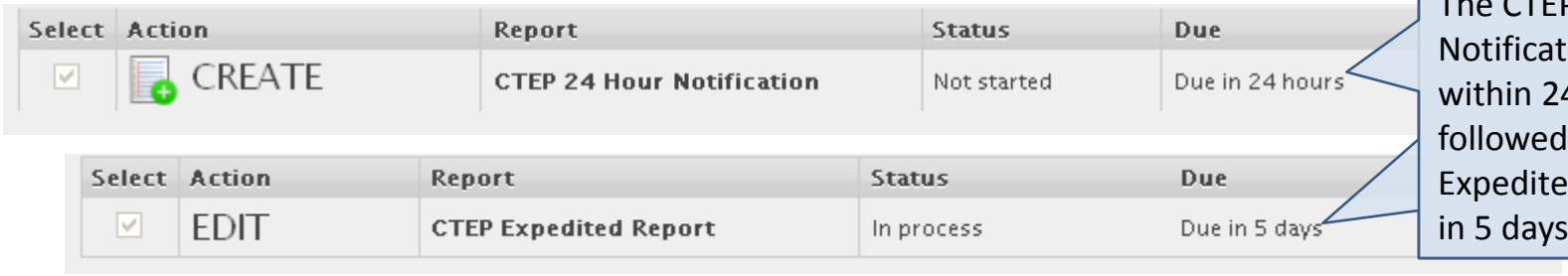
Review and Report – Recommended Actions

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



Select	Action	Report	Status	Due
☑	CREATE	CTEP Expedited Report	Not started	Due in 10 days

The CTEP Expedited Report is due in 10 days.



Select	Action	Report	Status	Due
☑	CREATE	CTEP 24 Hour Notification	Not started	Due in 24 hours
☑	EDIT	CTEP Expedited Report	In process	Due in 5 days

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
☑	CREATE	CTEP Expedited Report (15 Days)	Not started	Due in 15 days

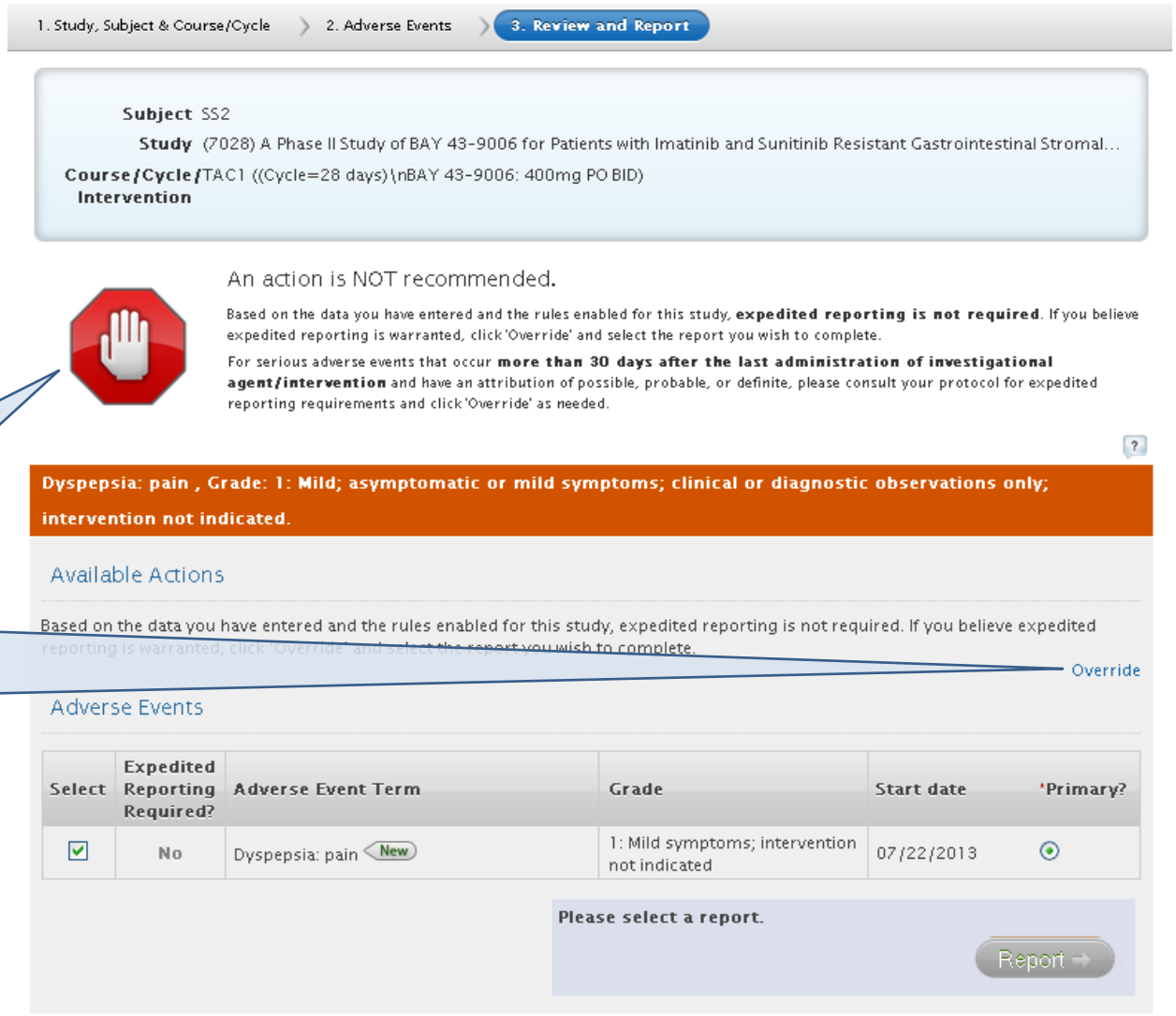
The CTEP Expedited Report for commercial agents is due in 15 days.

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.

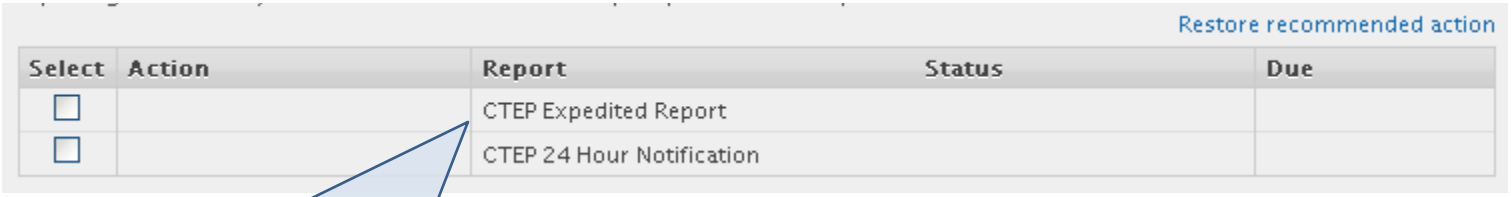
The **Review and Report** page displays a stop icon when a report is not required.

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.

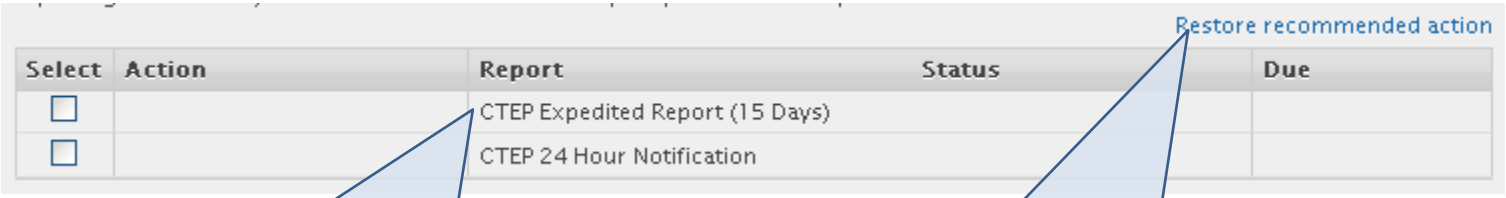


Review and Report – Override Option

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.



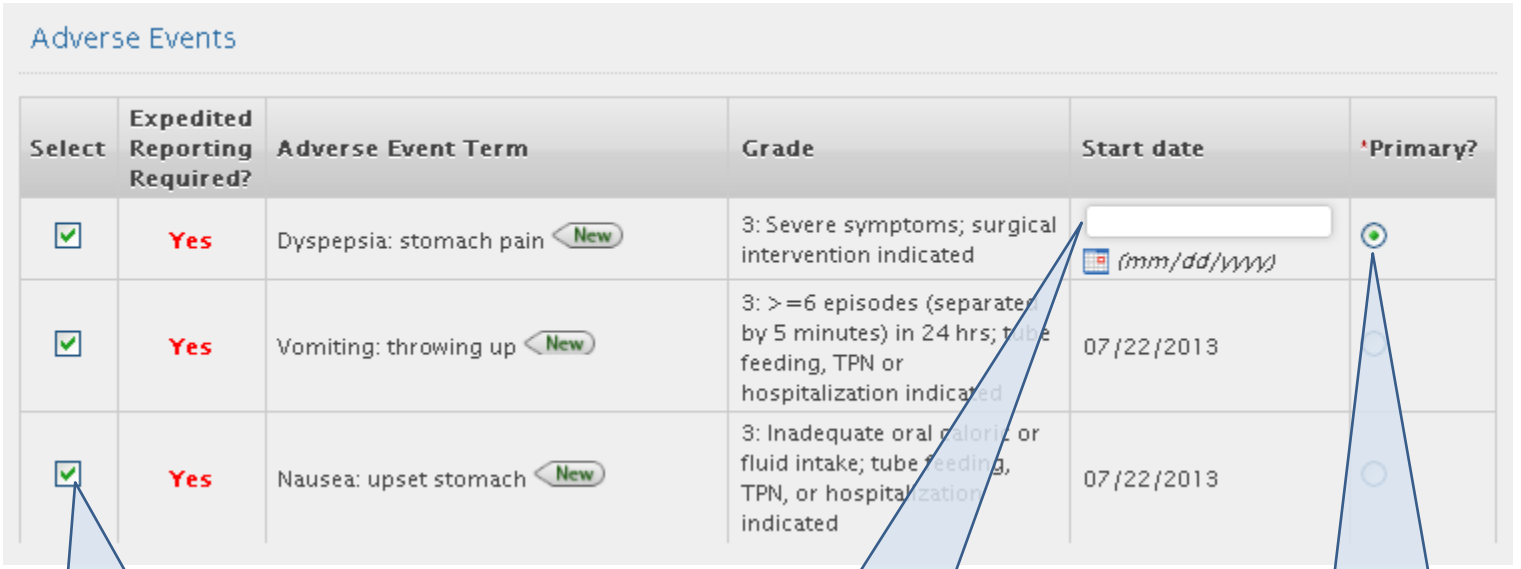
The CTEP Expedited Report and 24-Hour Notification are options when **Override** is selected.



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

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

Review and Report – Adverse Event Table



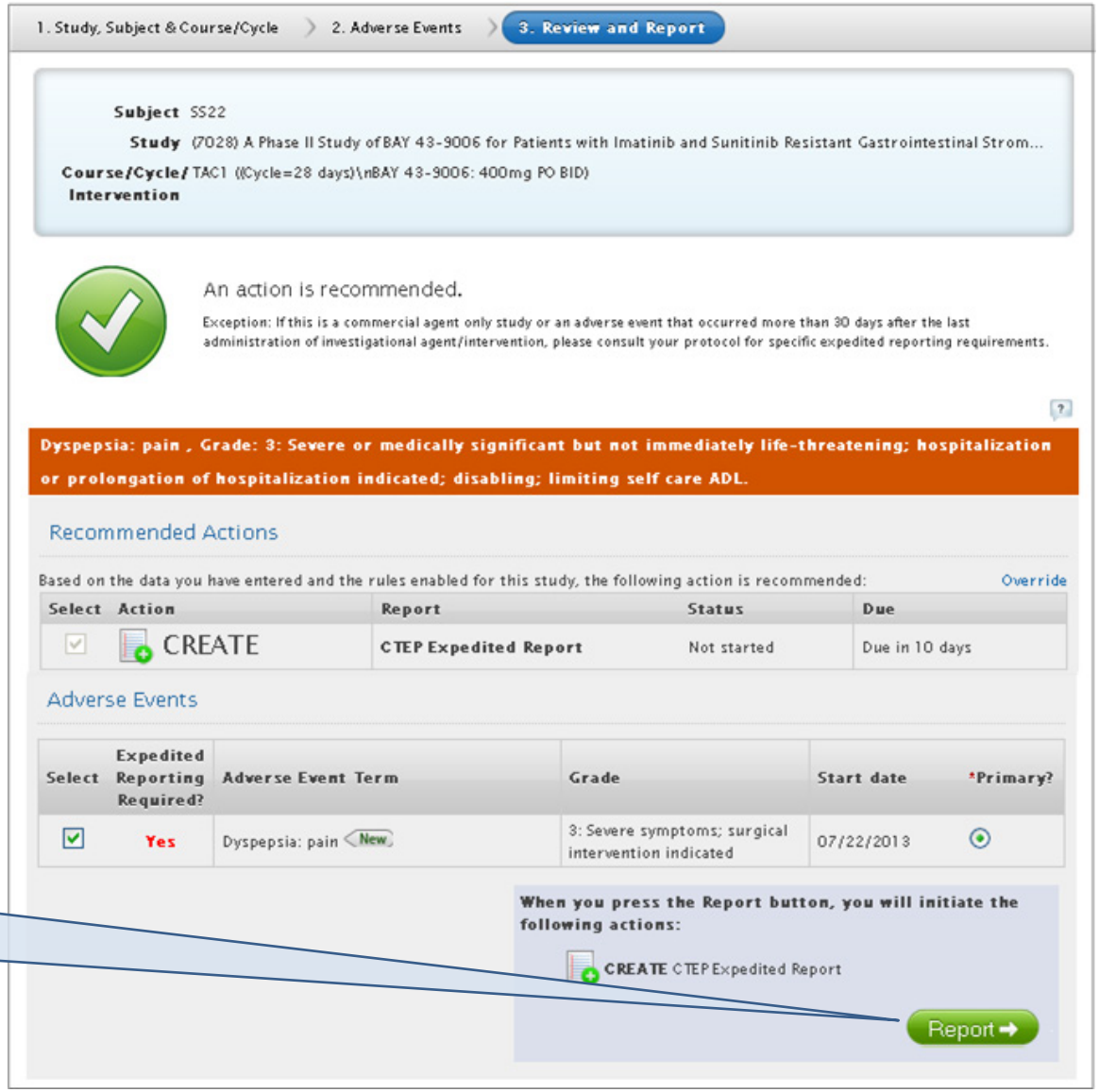
Deselect the **Select** checkbox if an adverse event is to be excluded from the report.

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.

Review and Report

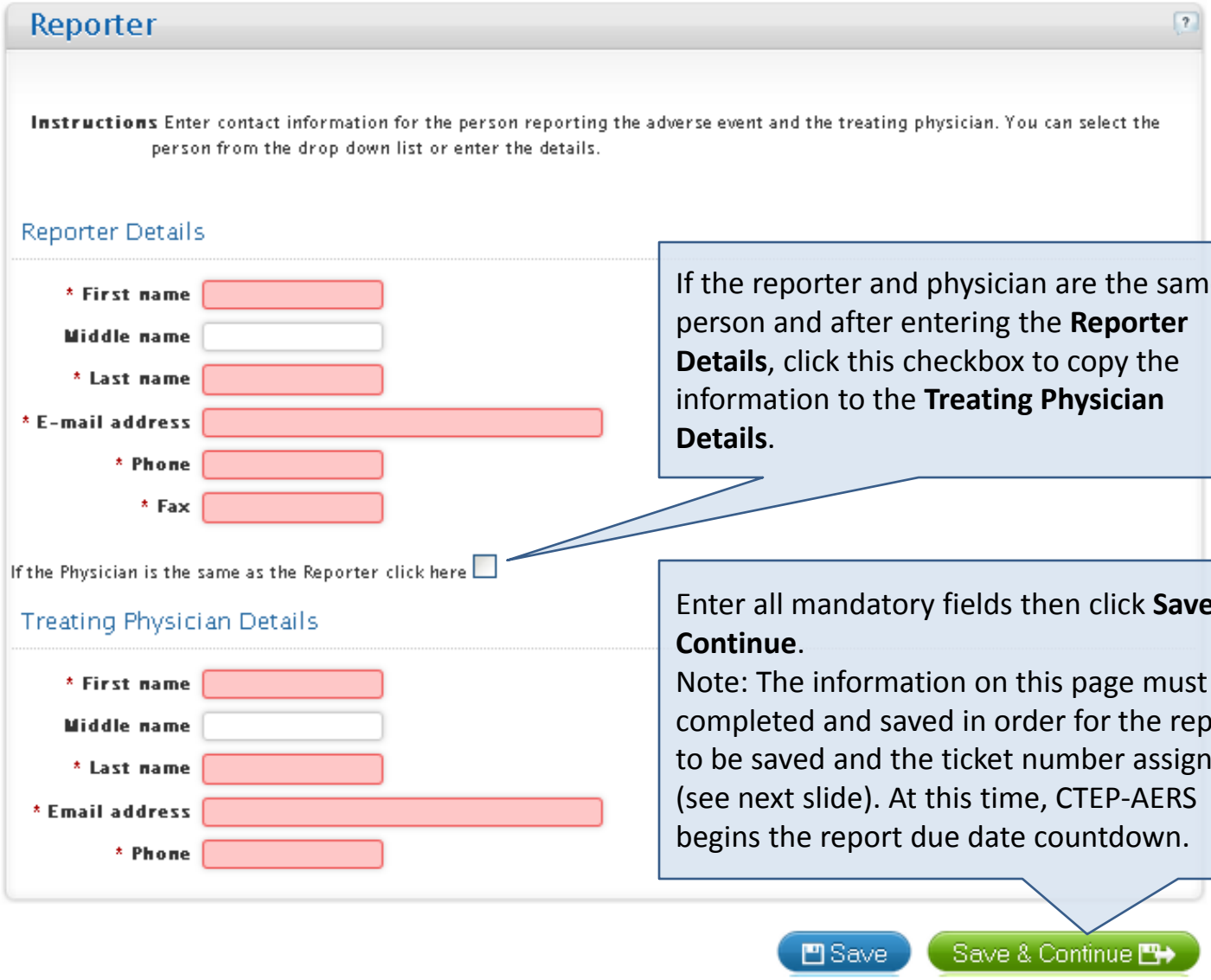
Important: The report is still not saved to the system. Again, if you were to lose your browser connection, you would need to reenter all information.



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

Reporter

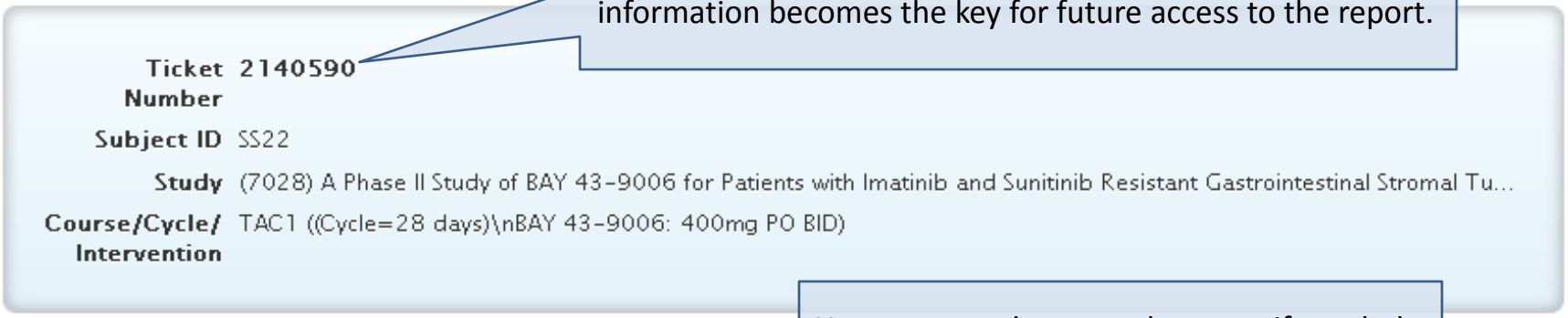
The information required on the **Reporter** page is the same as AdEERS.



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.

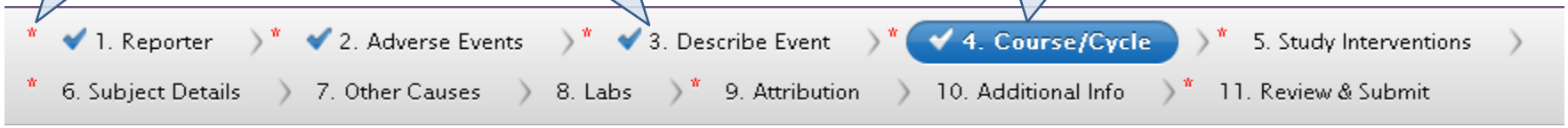
Navigation Bar

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.

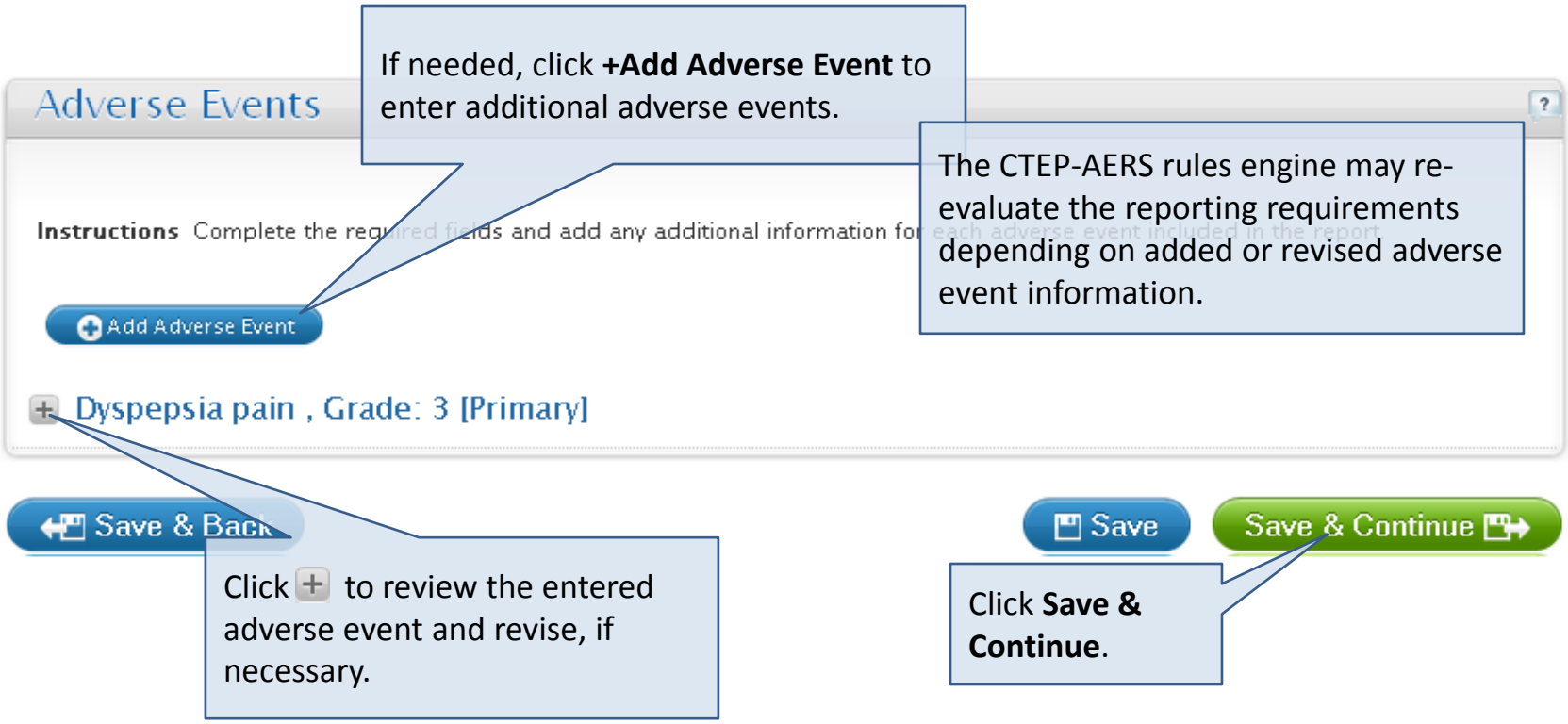
A highlighted tab indicates the section currently in use.



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

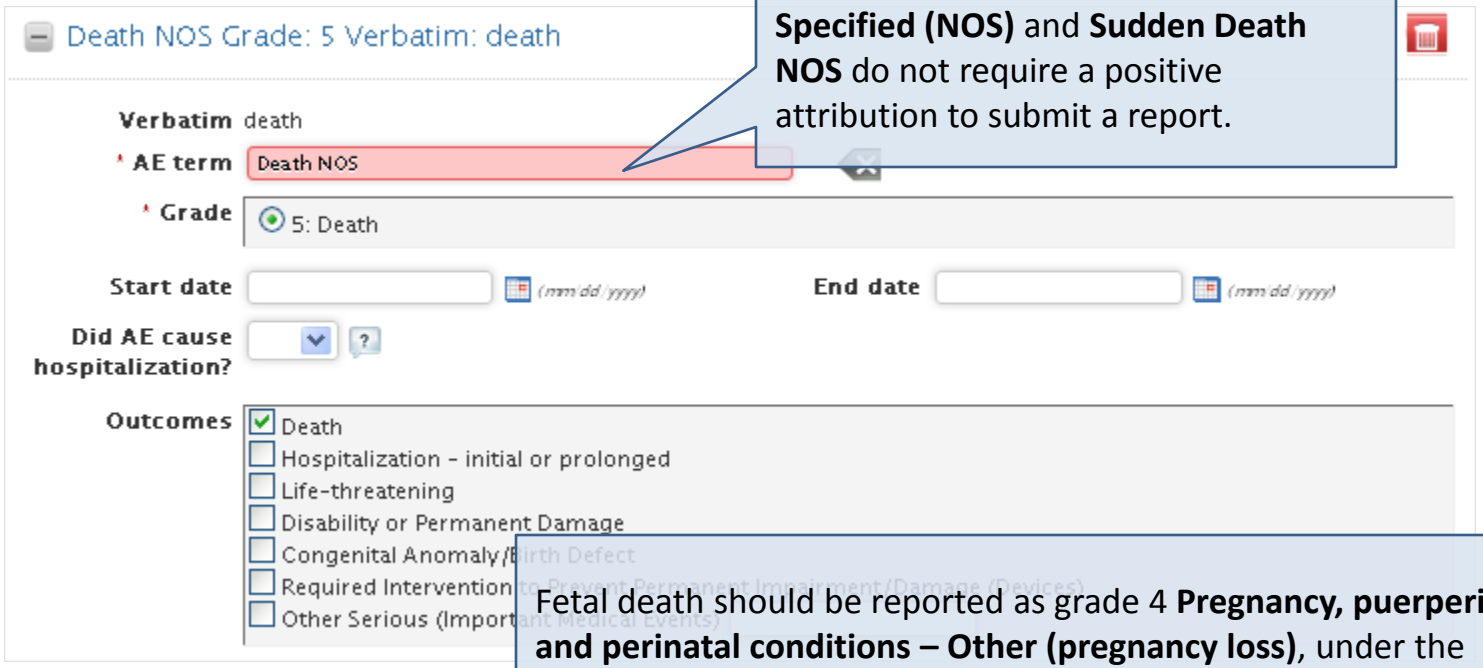
Adverse Events

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



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.

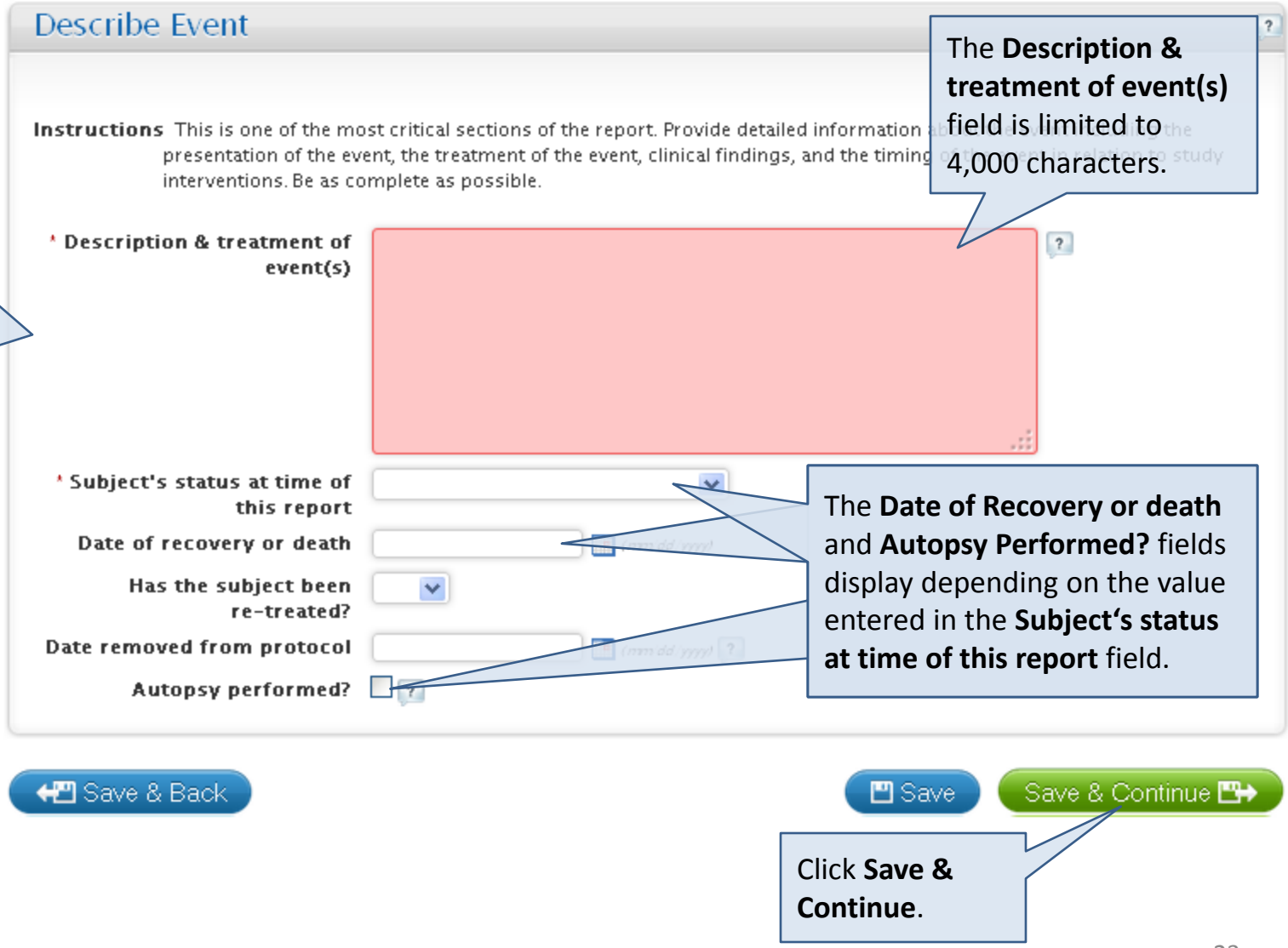
Fetal death should be reported as grade 4 **Pregnancy, puerperium, and perinatal conditions – Other (pregnancy loss)**, under the Pregnancy, puerperium, and perinatal conditions SOC.

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.



Enter all mandatory fields before continuing to the next page.

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

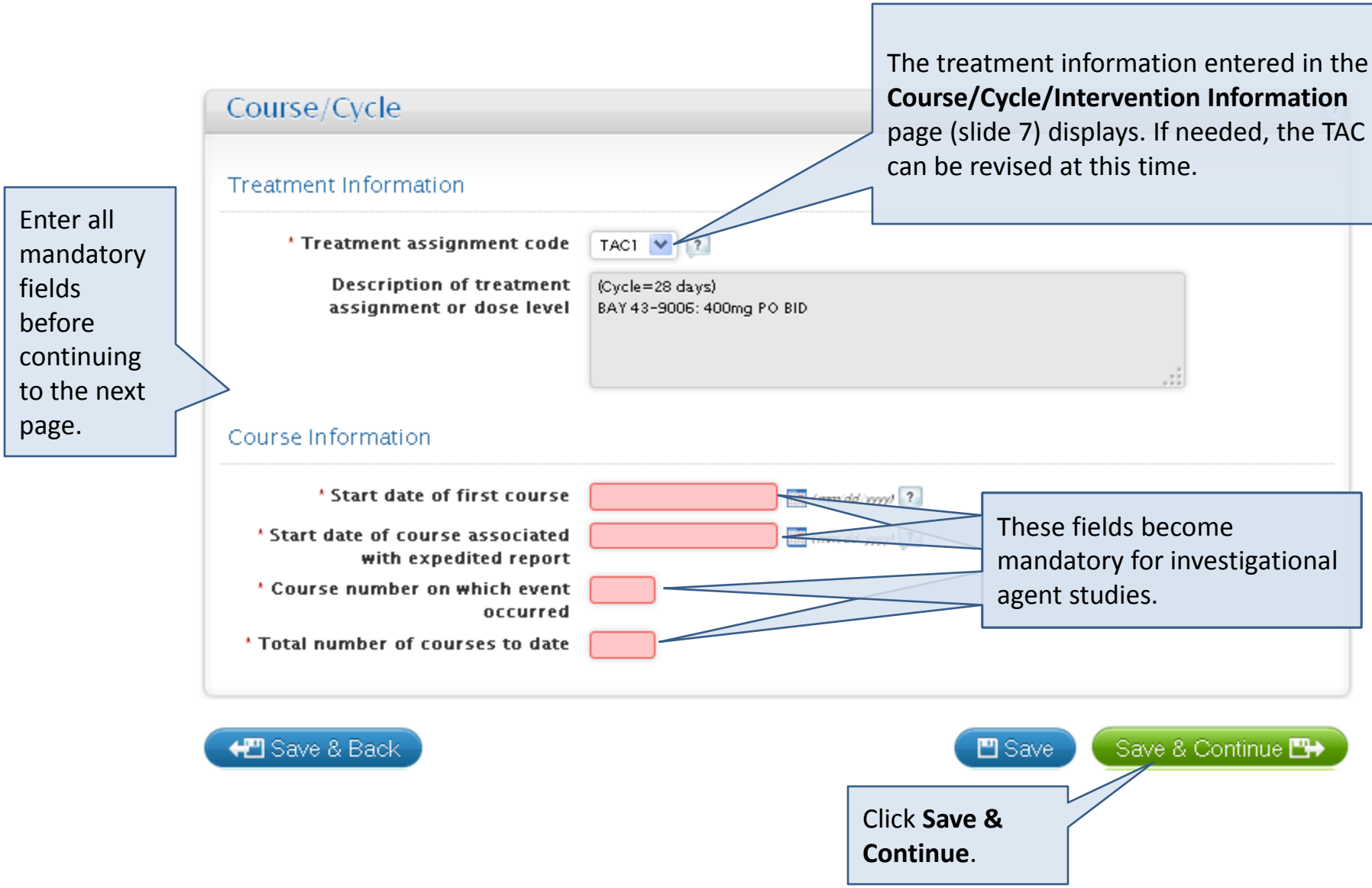
The **Date of Recovery or death** and **Autopsy Performed?** fields display depending on the value entered in the **Subject's status at time of this report** field.

Click **Save & Continue**.

This field has a limit of 4,000 characters.

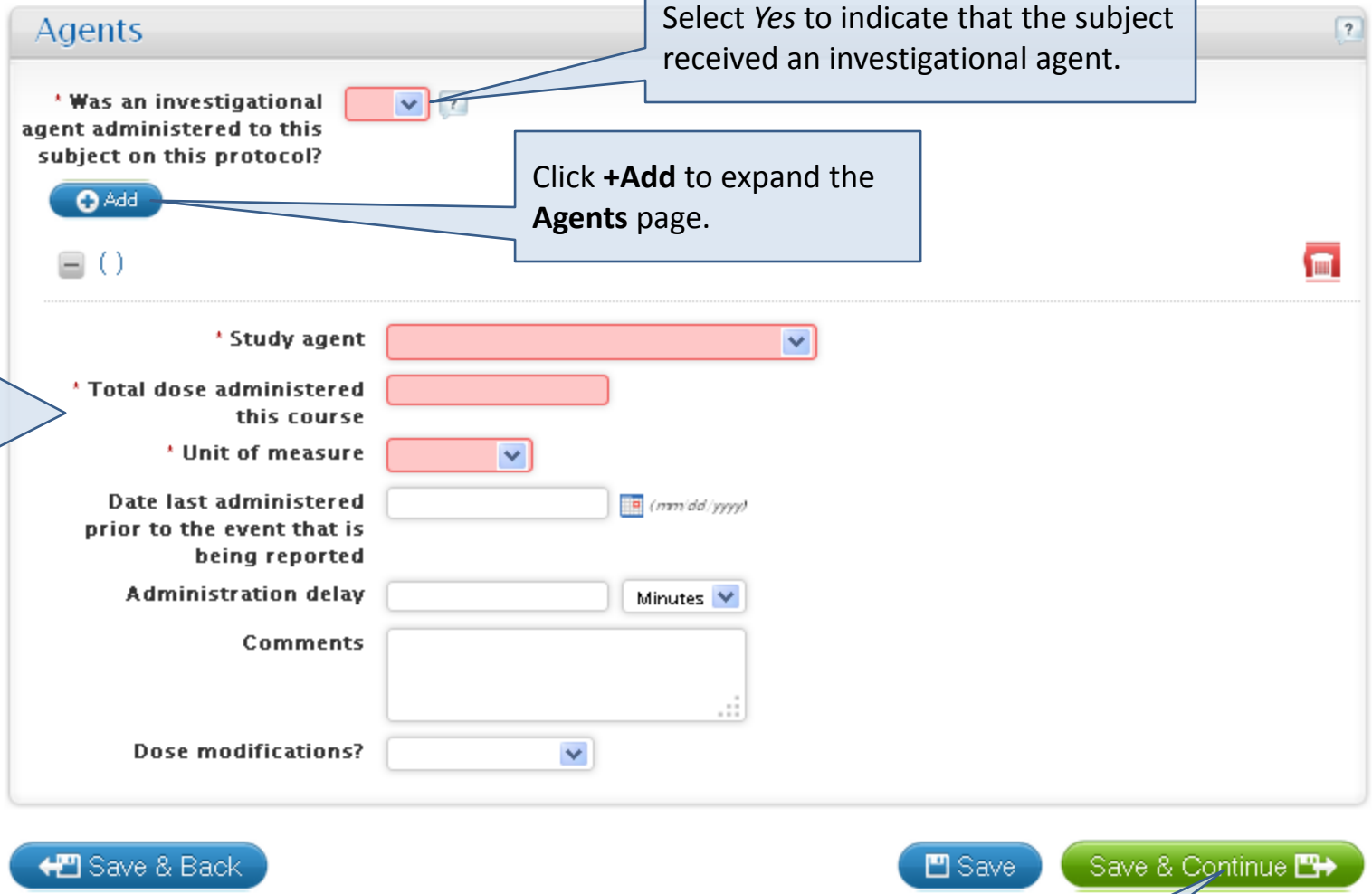
Course/Cycle

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



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.

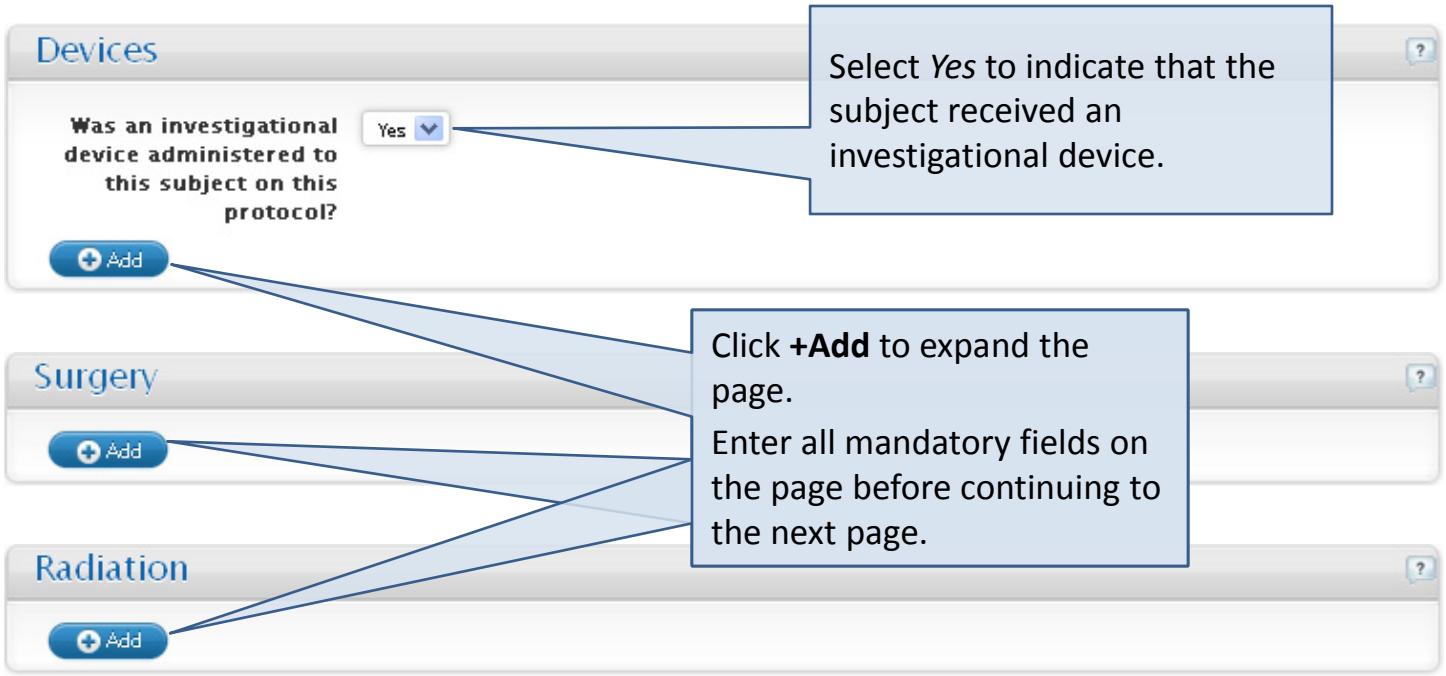
Click **+Add** to expand the **Agents** page.

Enter all mandatory fields before continuing to the next page.

Click **Save & Continue**.

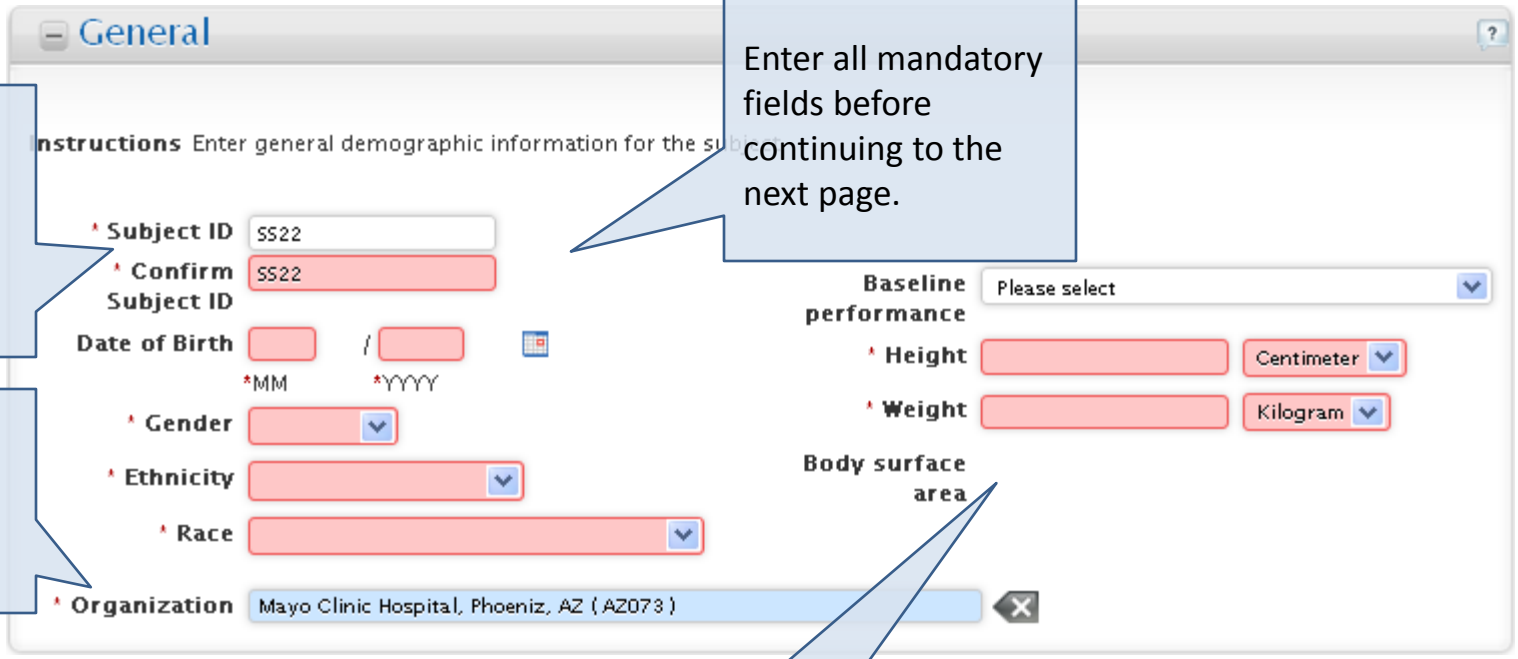
Other Study Interventions

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



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.

Enter all mandatory fields before continuing to the next page.

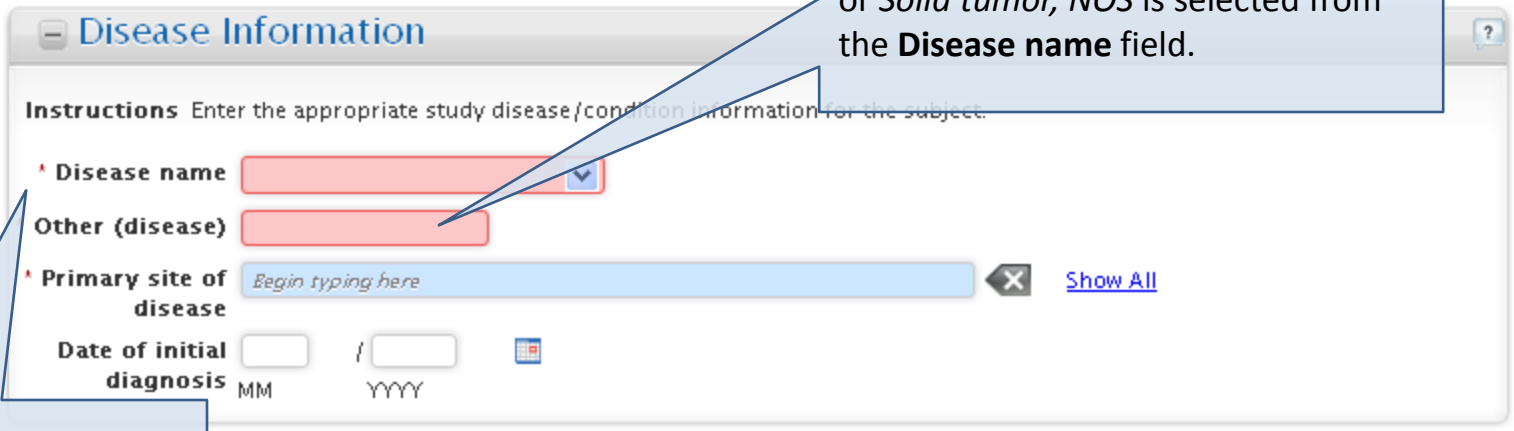
The **Organization** may be revised, if needed.

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.



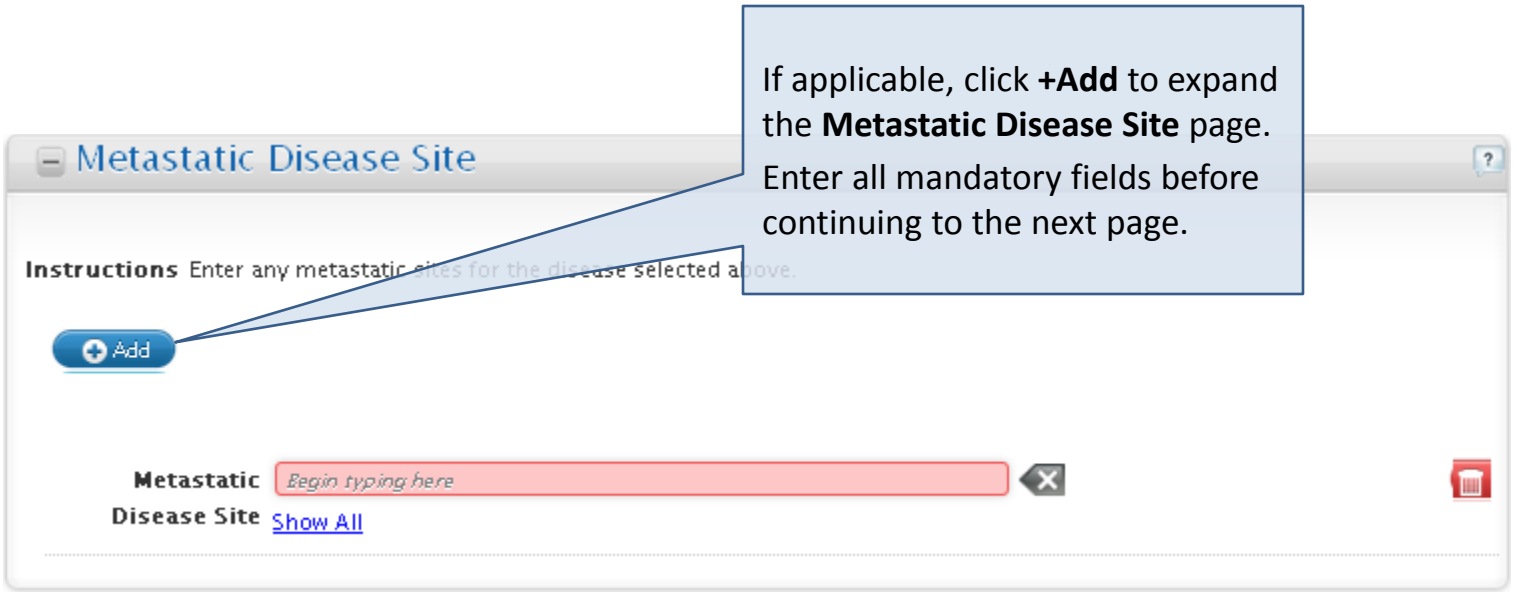
The **Other (disease)** field only displays when *Hematopoietic malignancy, NOS* or *Solid tumor, NOS* is selected from the **Disease name** field.

Enter all mandatory fields before continuing to the next page.

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

Subject Details – Metastatic Disease Site

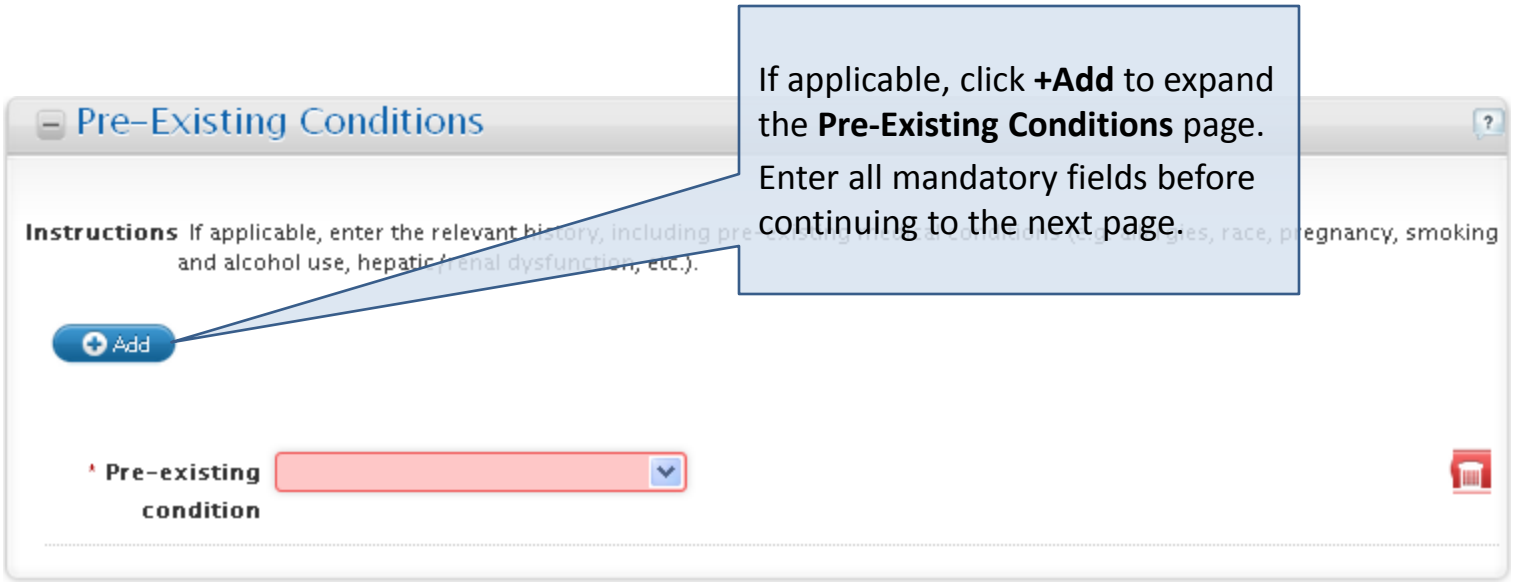
The **Subject Details, Metastatic Disease Site** section is optional for adverse event reporting.



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.



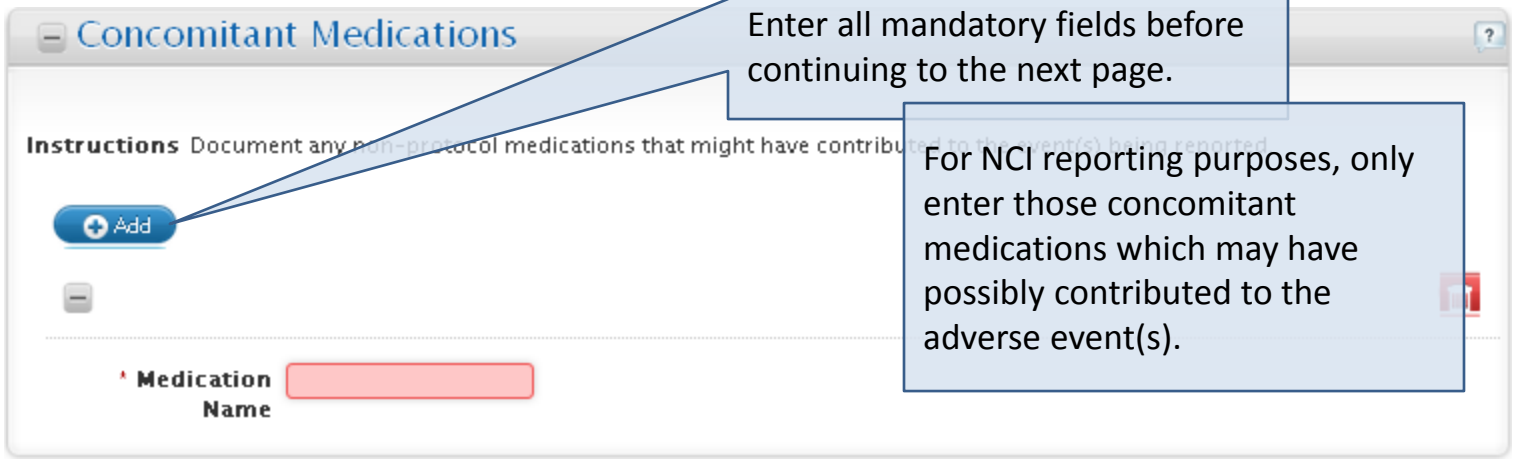
If applicable, click **+Add** to expand the **Pre-Existing Conditions** page.

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.

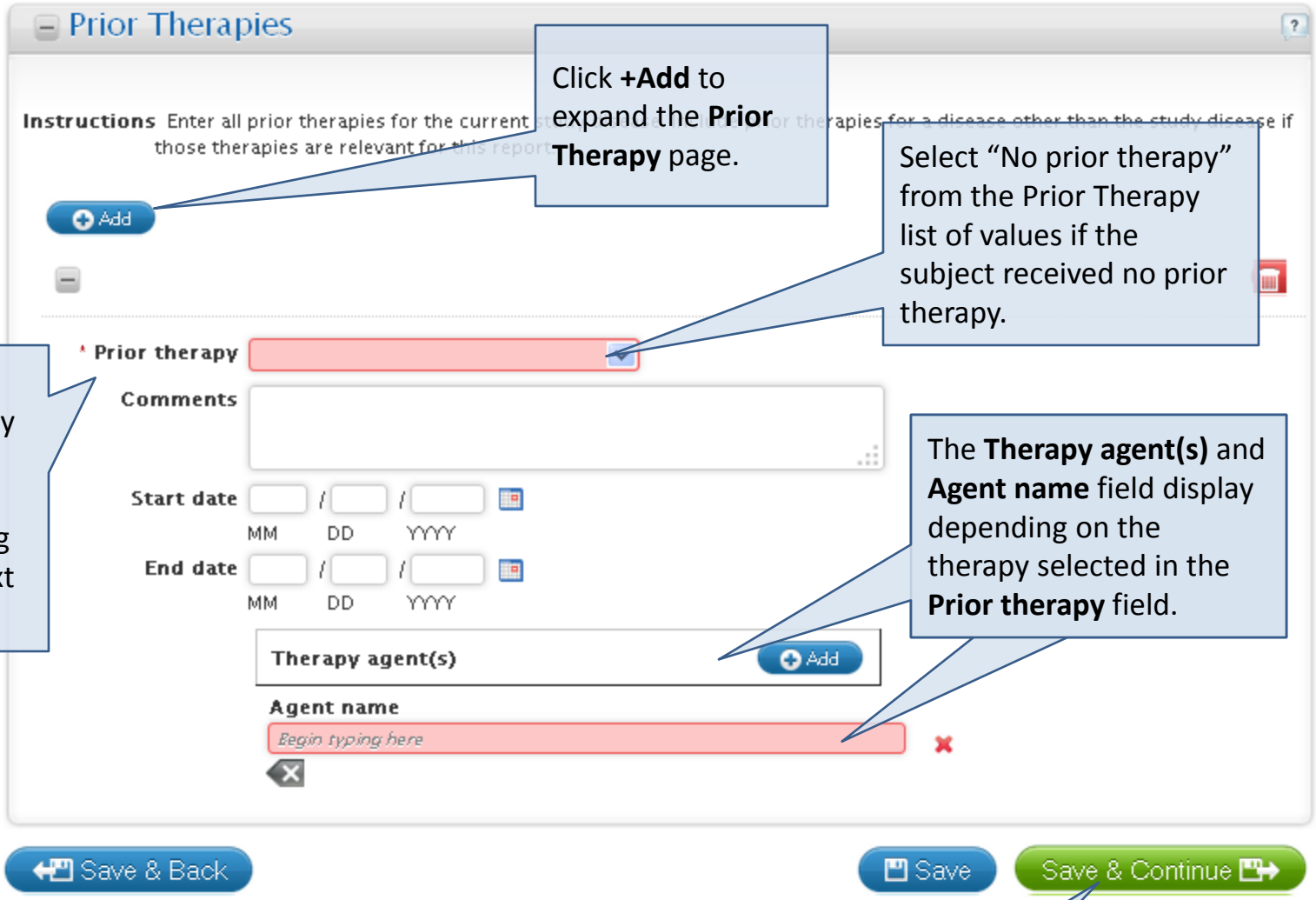
Enter all mandatory fields before continuing to the next page.

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.

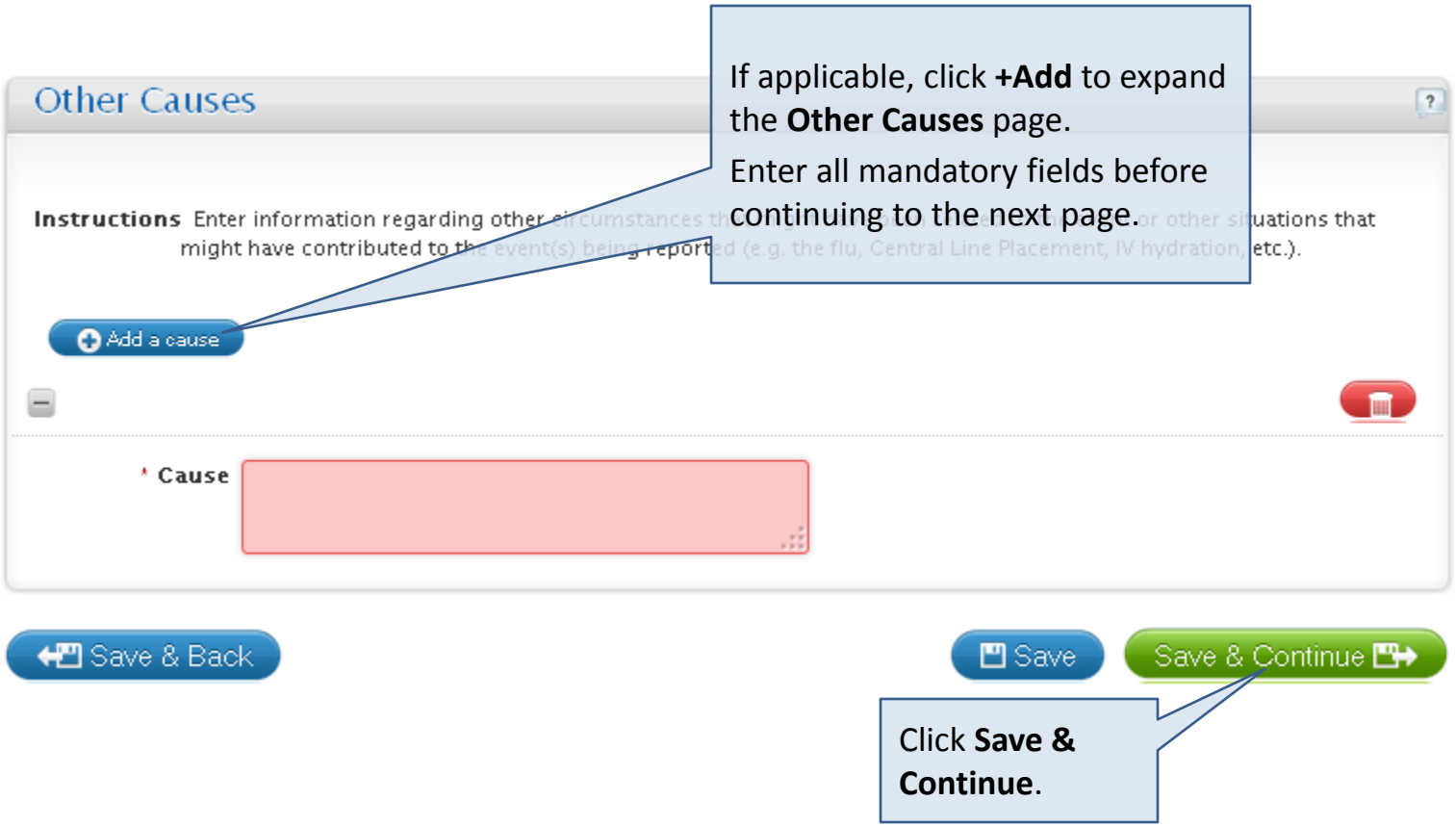
Subject Details – Prior Therapies

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



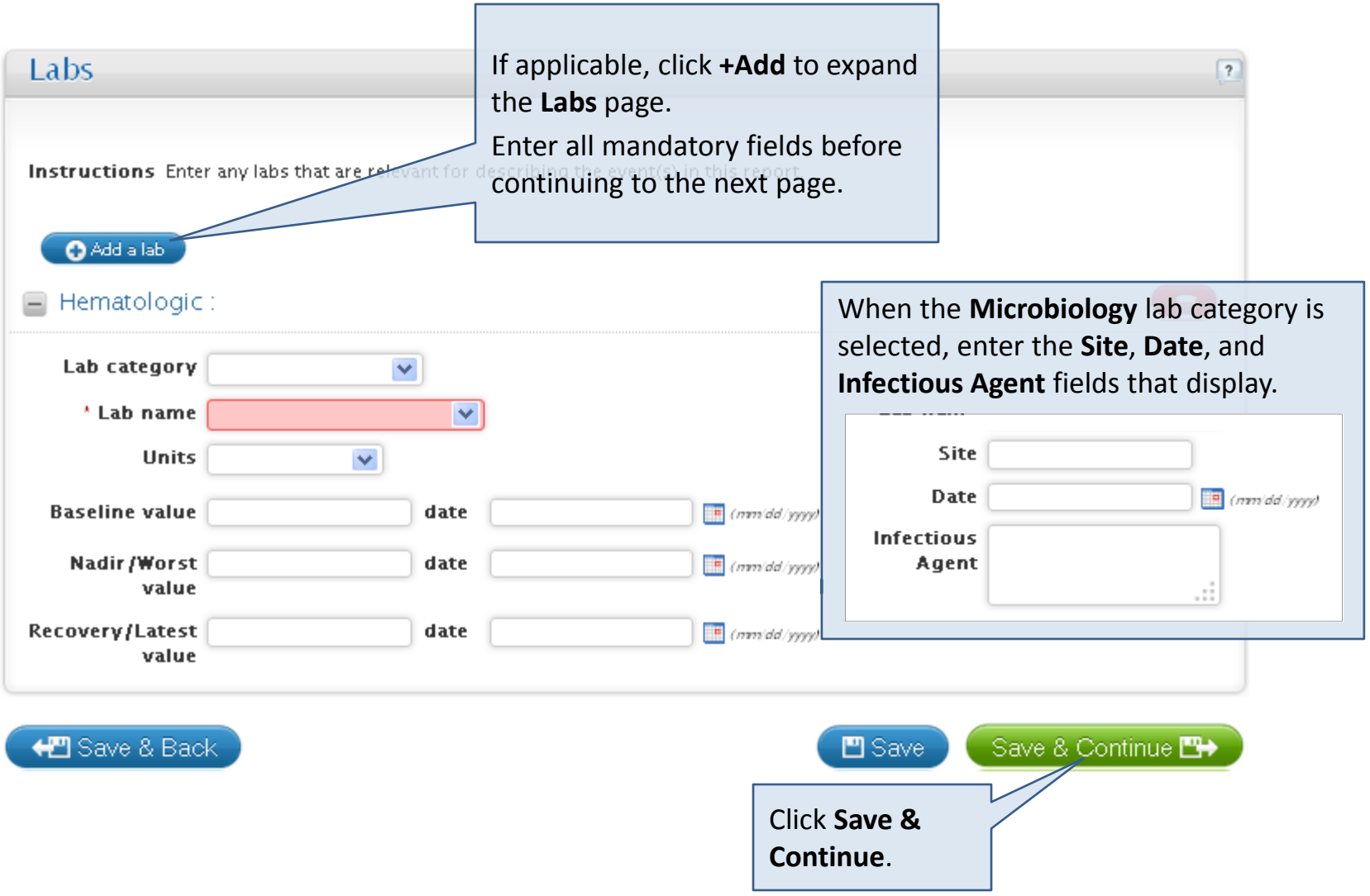
Other Causes

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



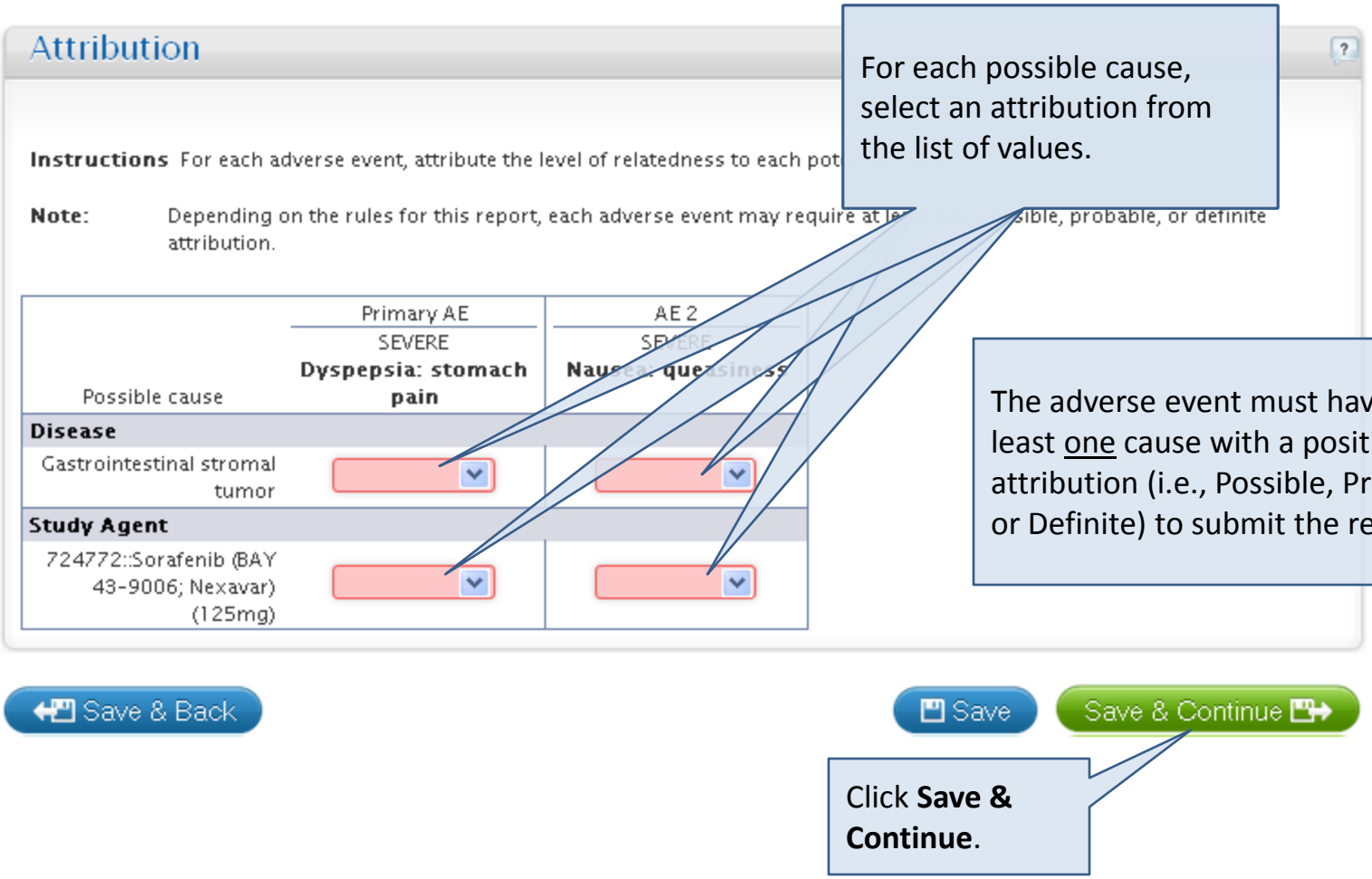
Labs

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



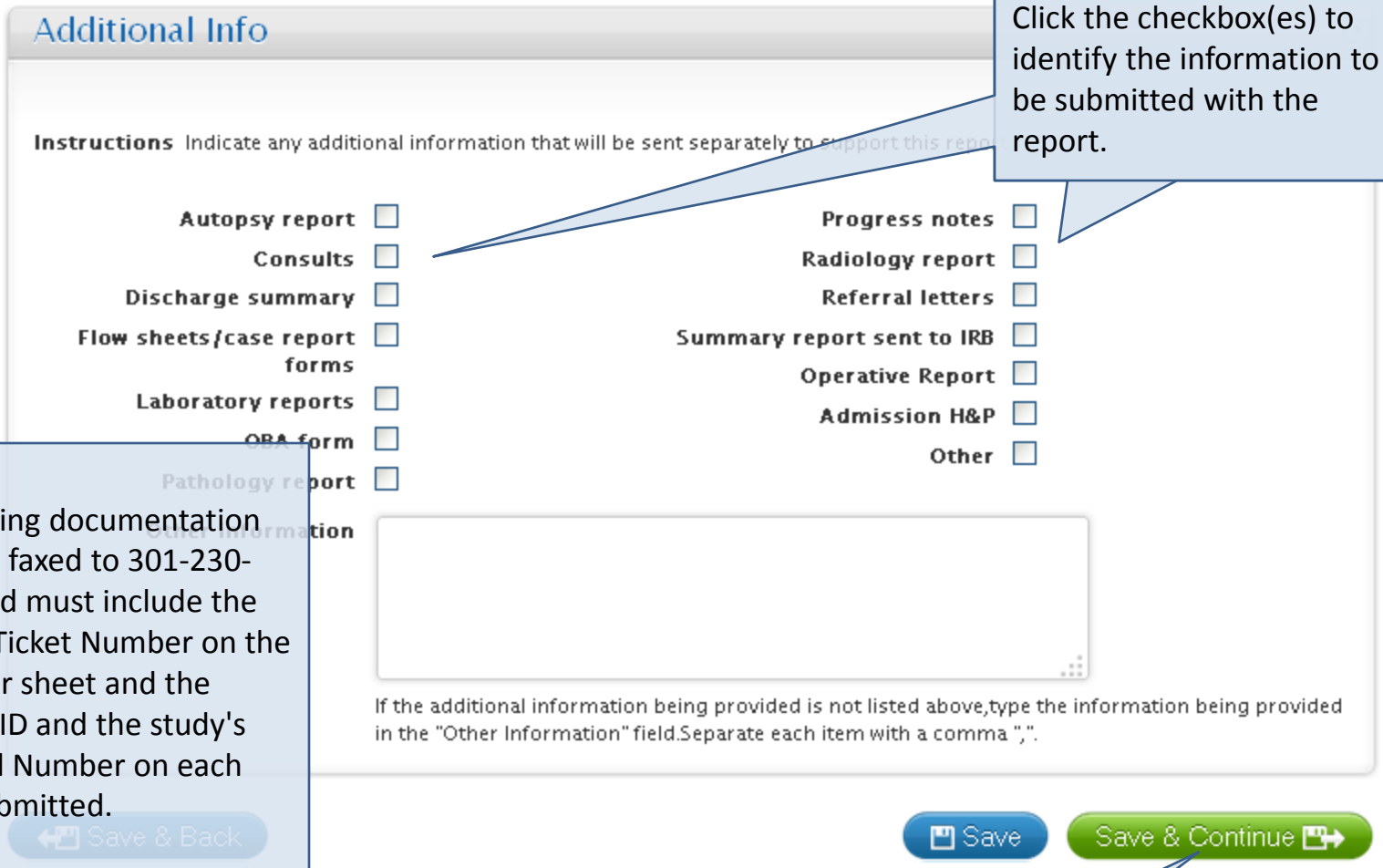
Attribution

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



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.



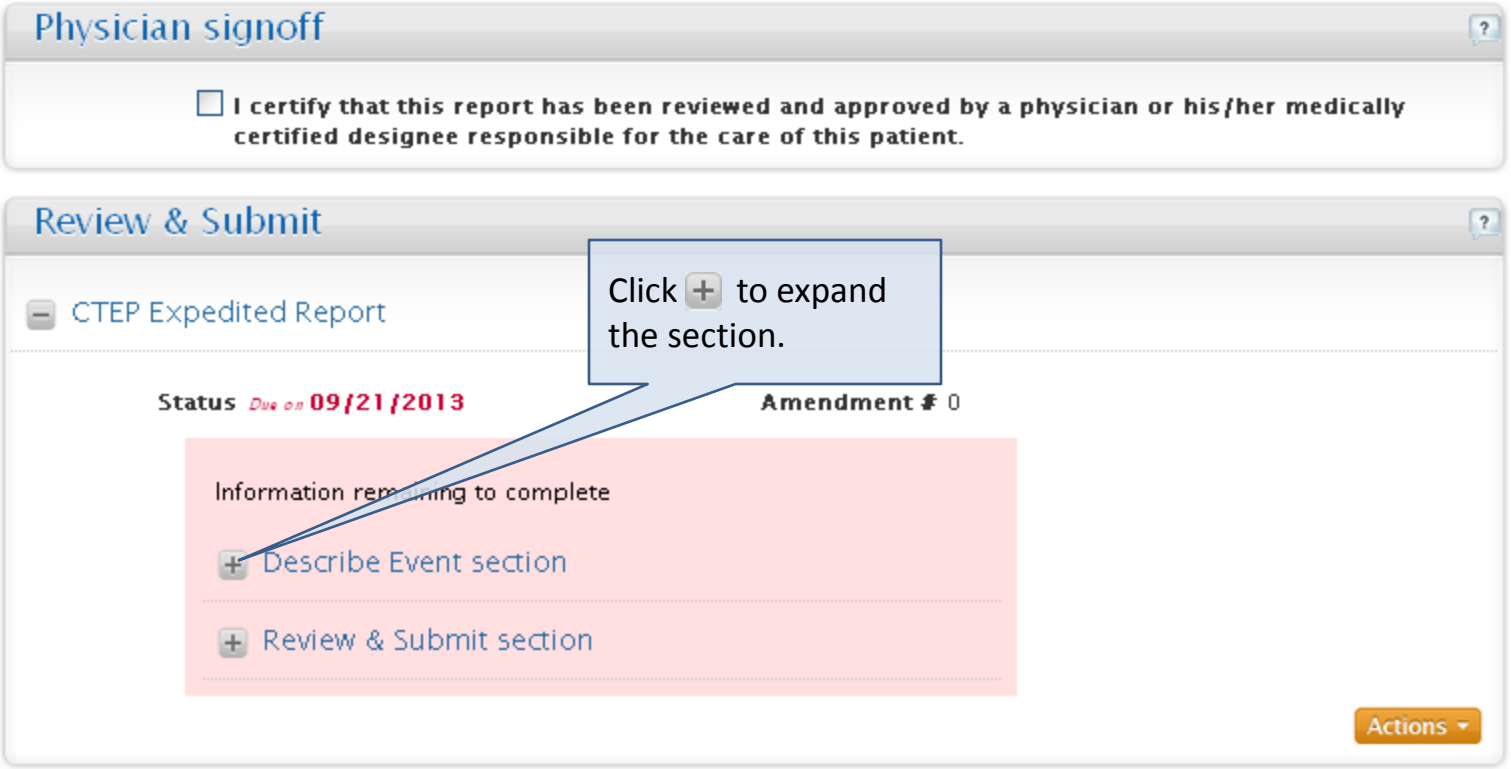
Click the checkbox(es) to identify the information to be submitted with the report.

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**.

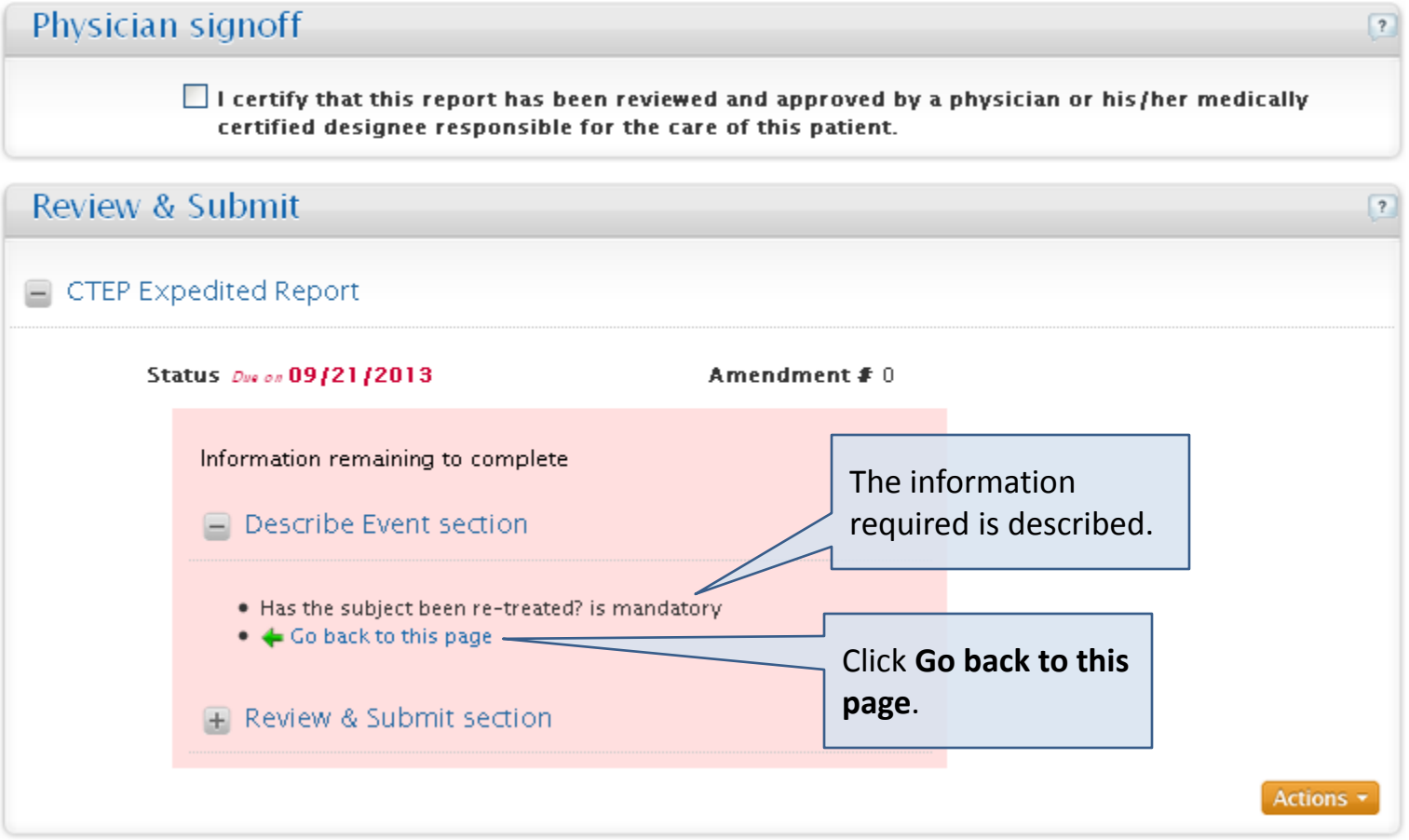
Review and Submit - Review and Physician Signoff

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



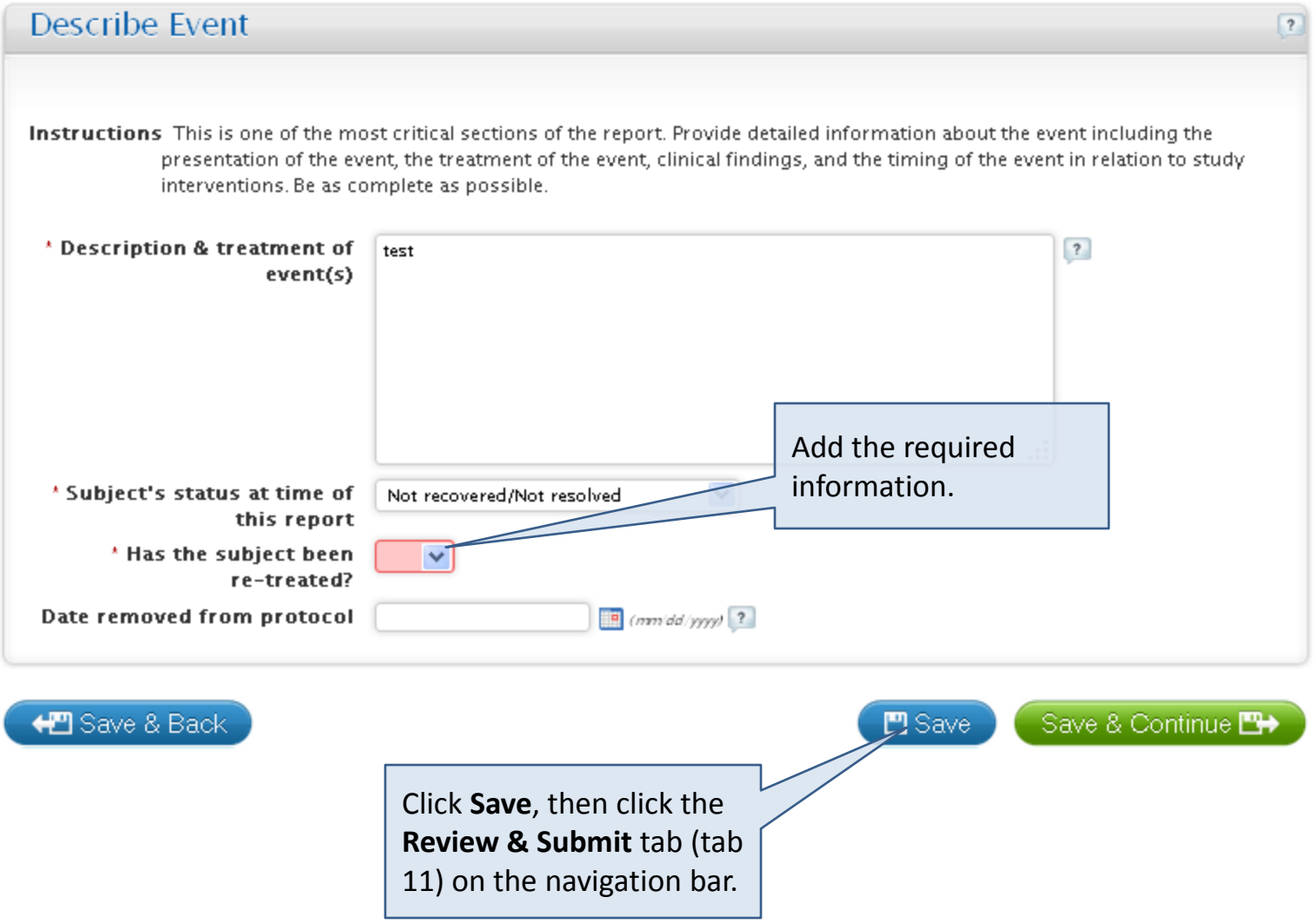
Review and Submit - Review and Physician Signoff

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



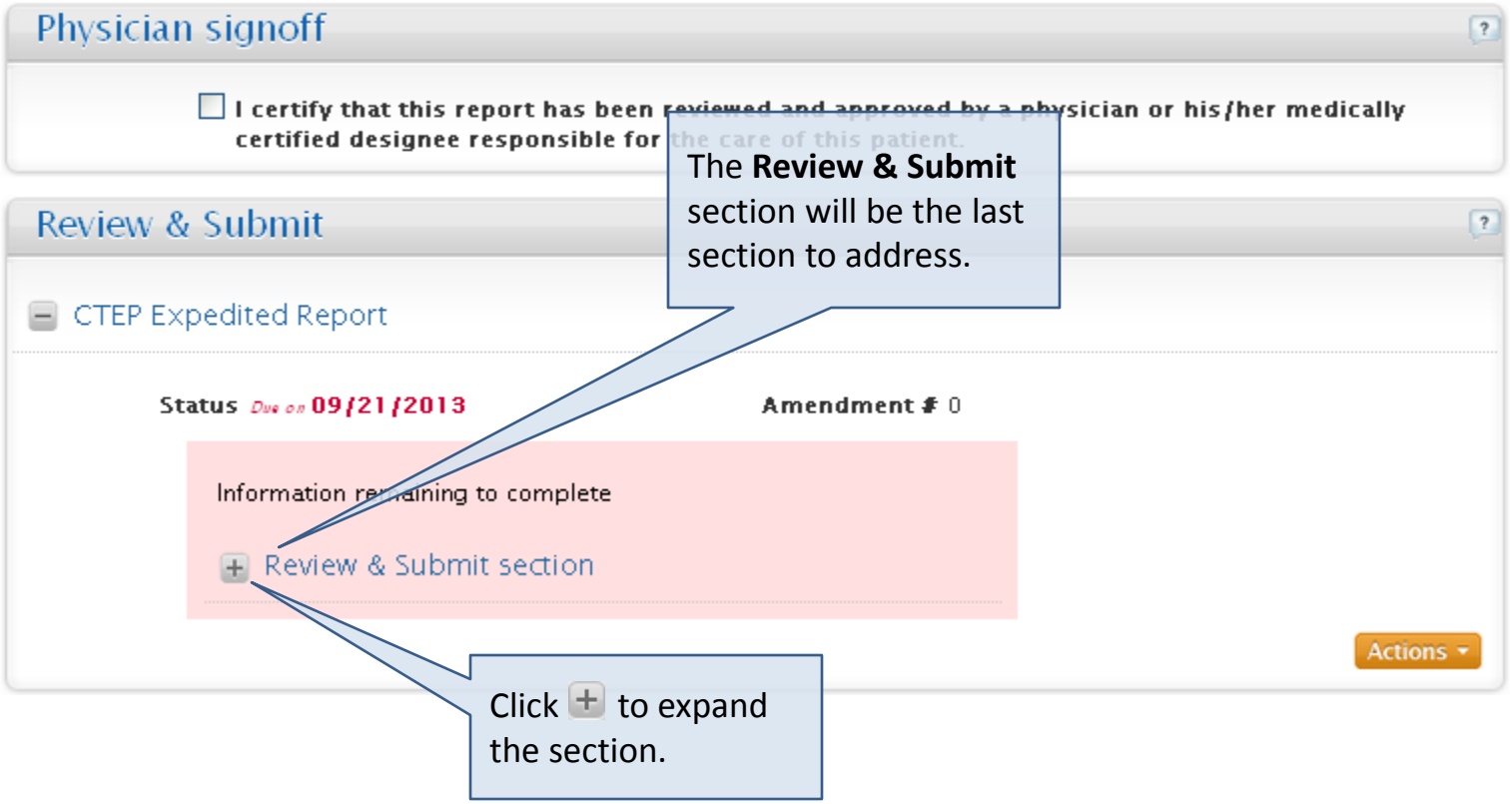
Review and Submit - Review and Physician Signoff

The page requiring additional information displays.



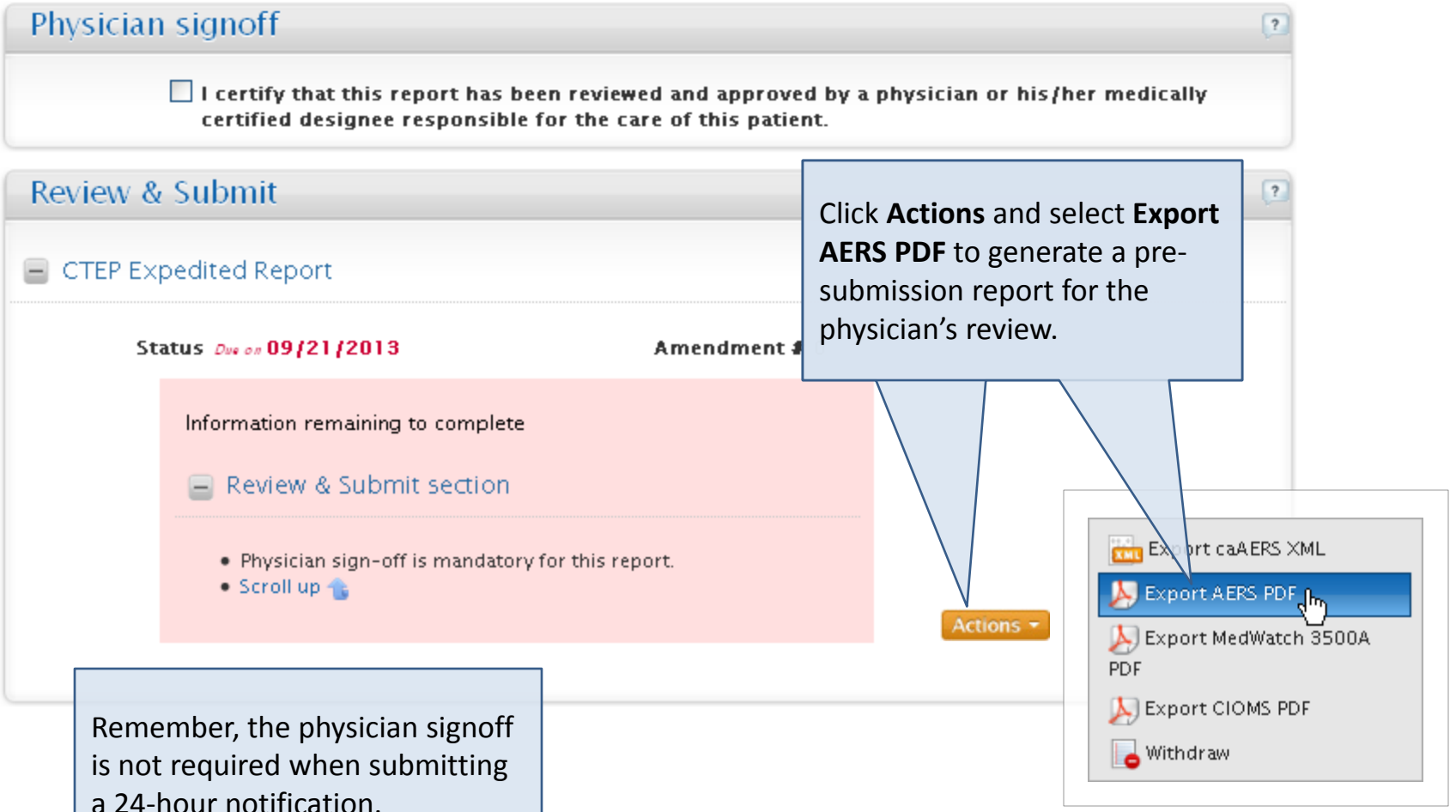
Review and Submit - Review and Physician Signoff

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



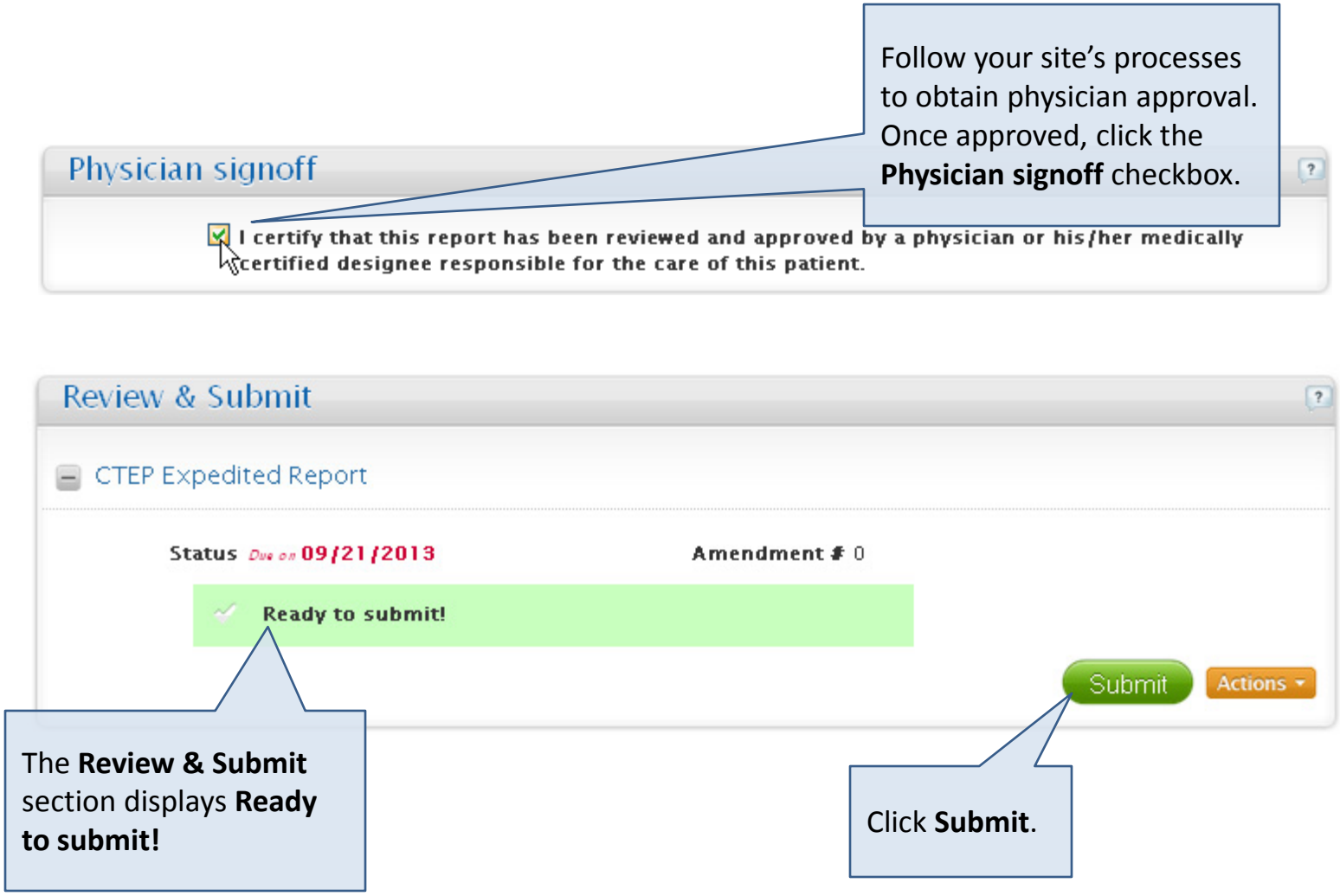
Review and Submit - Review and Physician Signoff

The **Review and Submit** page indicates that the physician signoff must be completed.



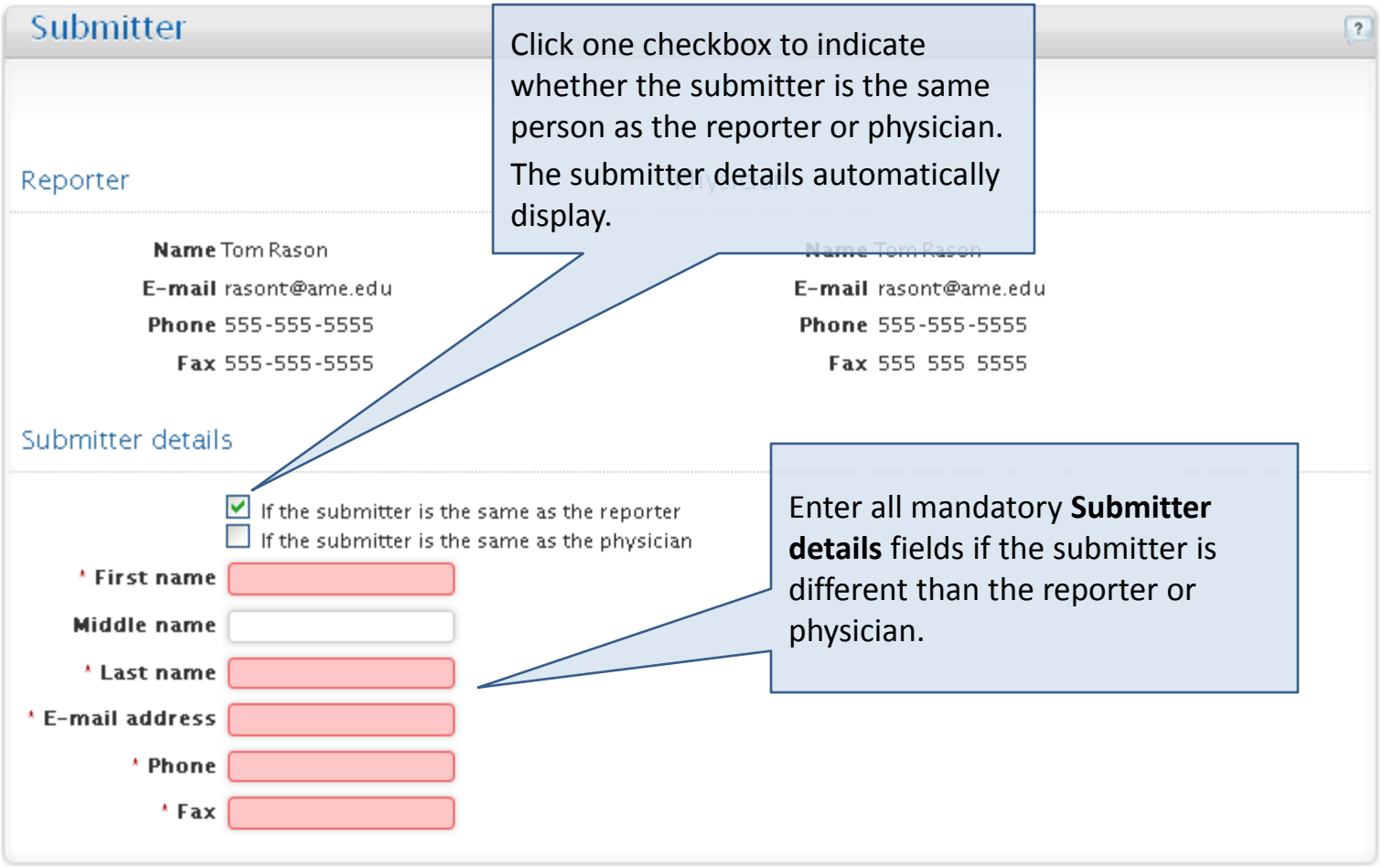
Review and Submit - Review and Physician Signoff

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



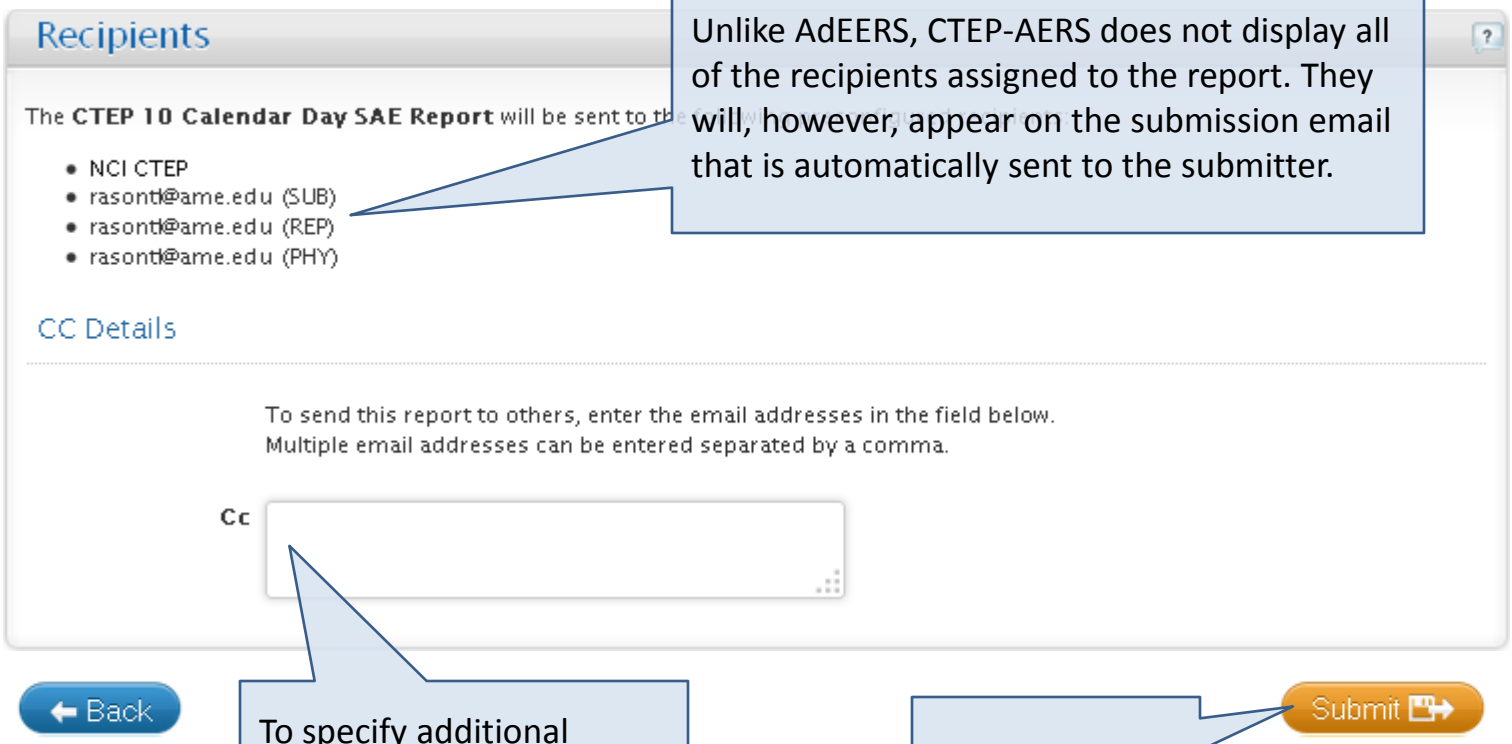
Review and Submit - Submitter

The **Submitter** page displays.



Review and Submit - Recipients

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



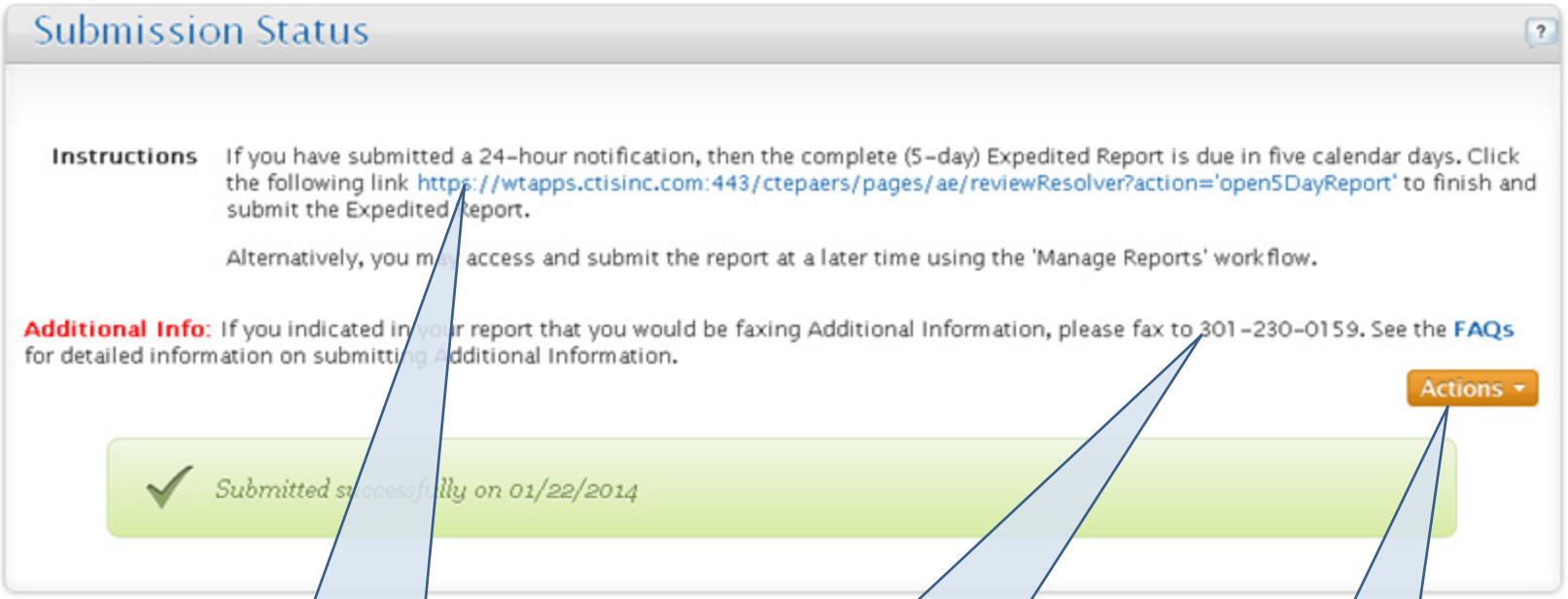
Unlike AdEERS, CTEP-AERS does not display all of the recipients assigned to the report. They will, however, appear on the submission email that is automatically sent to the submitter.

To specify additional recipients, enter the email addresses in the **Cc** field. Only use comas 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.

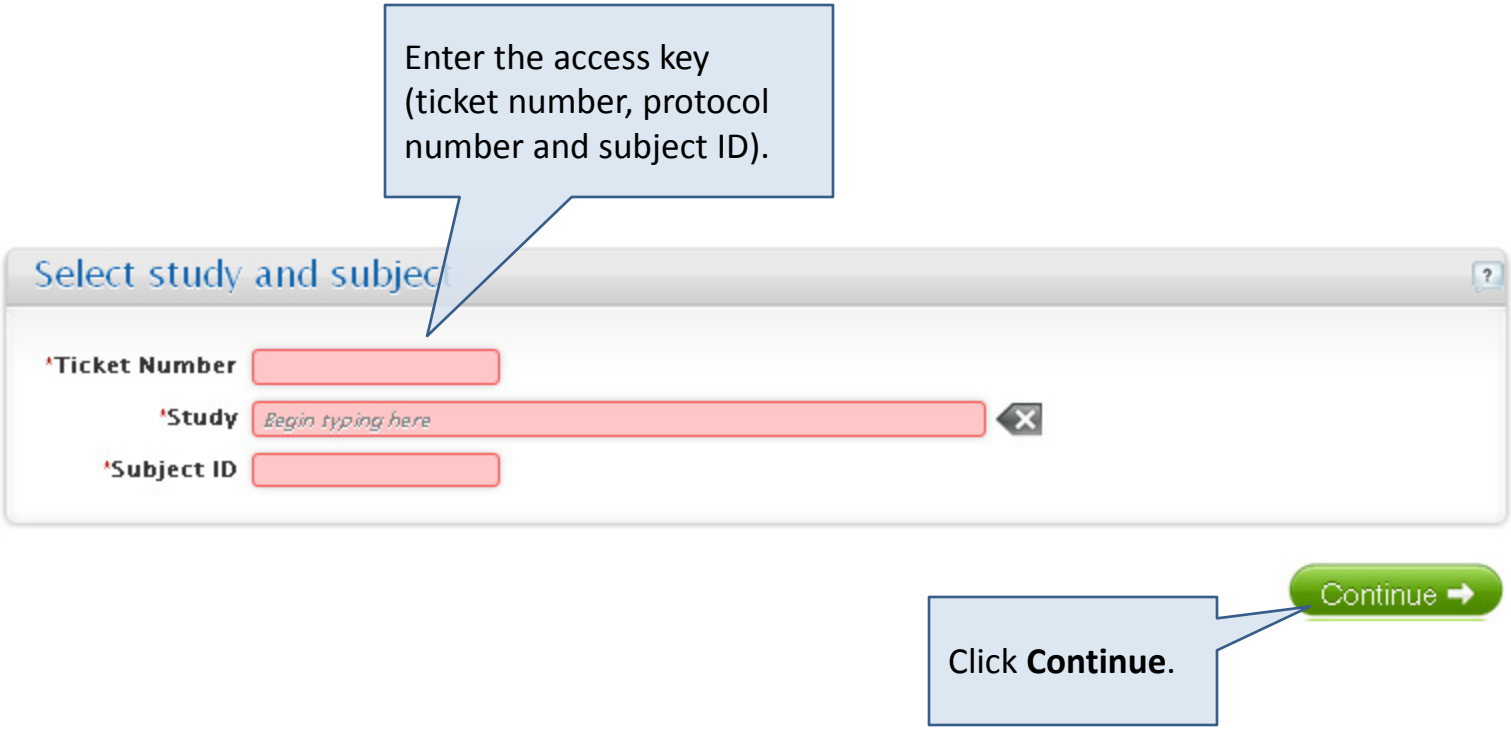
Manage Reports

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

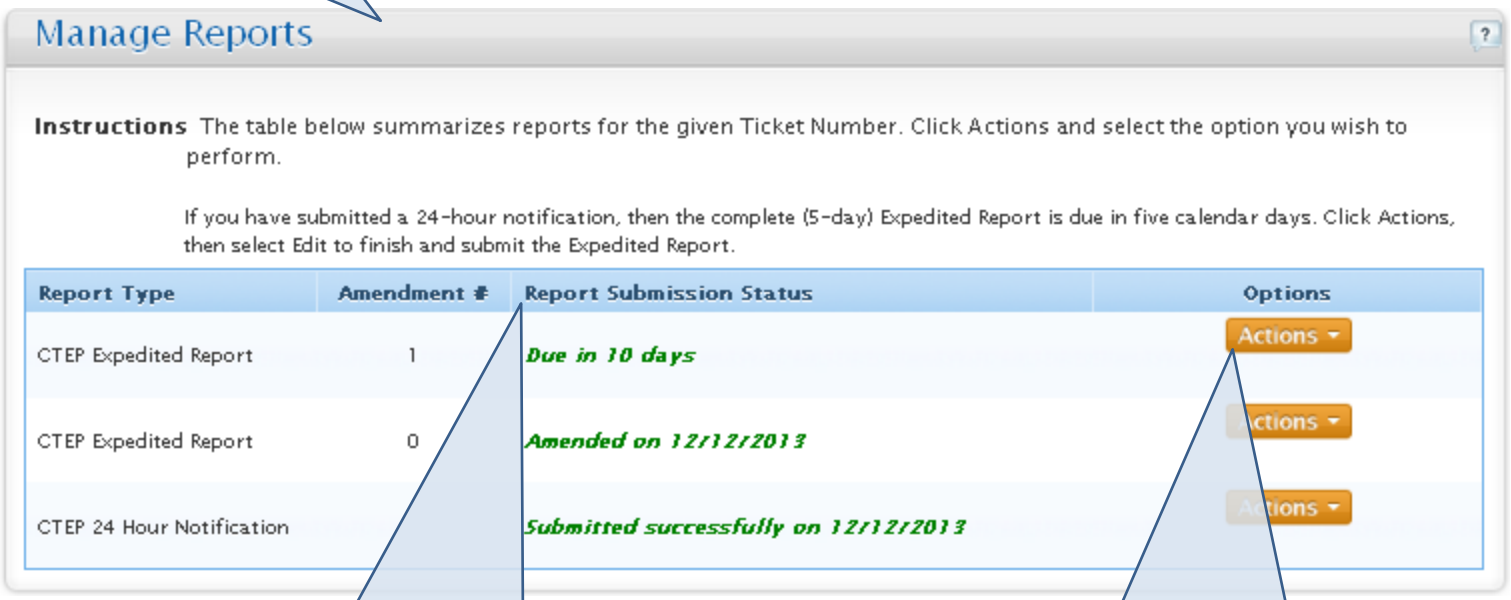
The **Select study and subject** page displays.



Manage Reports – Overview

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

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



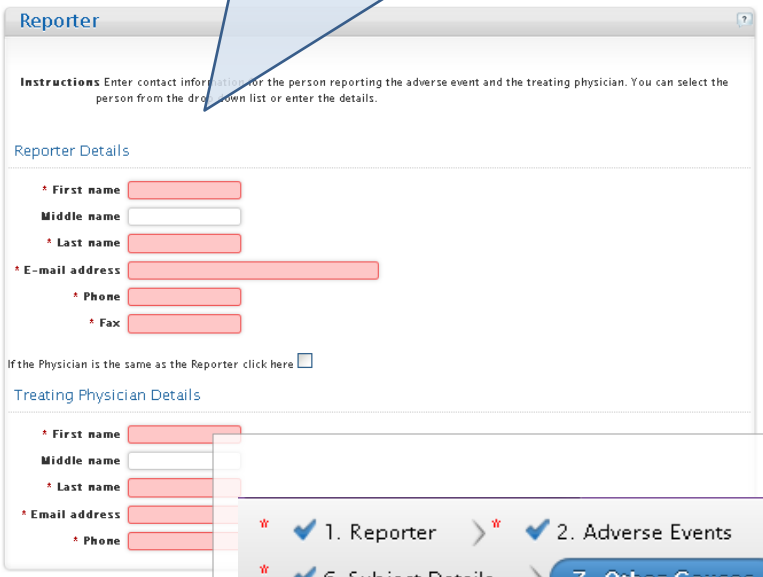
The Report Submission Status displays values including: *Due in (number) Days*, the *Submission Response* or whether the report is *Withdrawn*, *Initiated, not submitted* or *Overdue*.

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

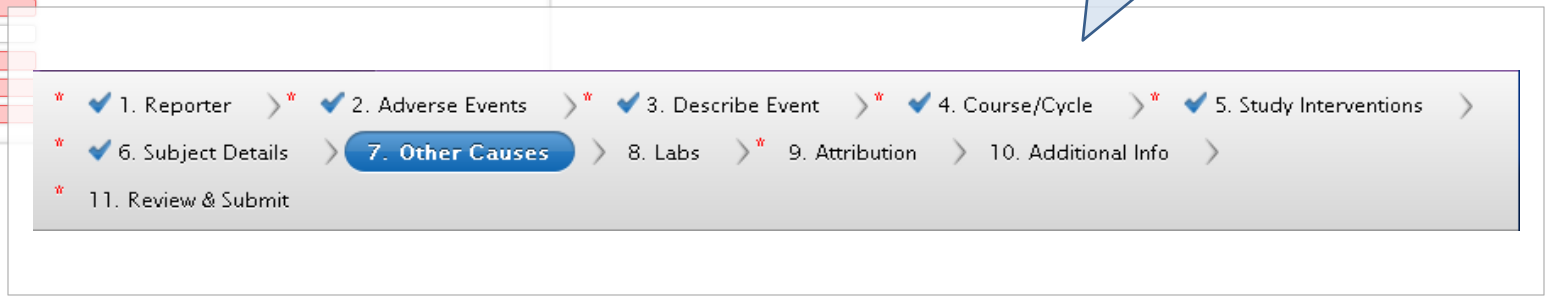
Manage Reports – Edit Option

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).

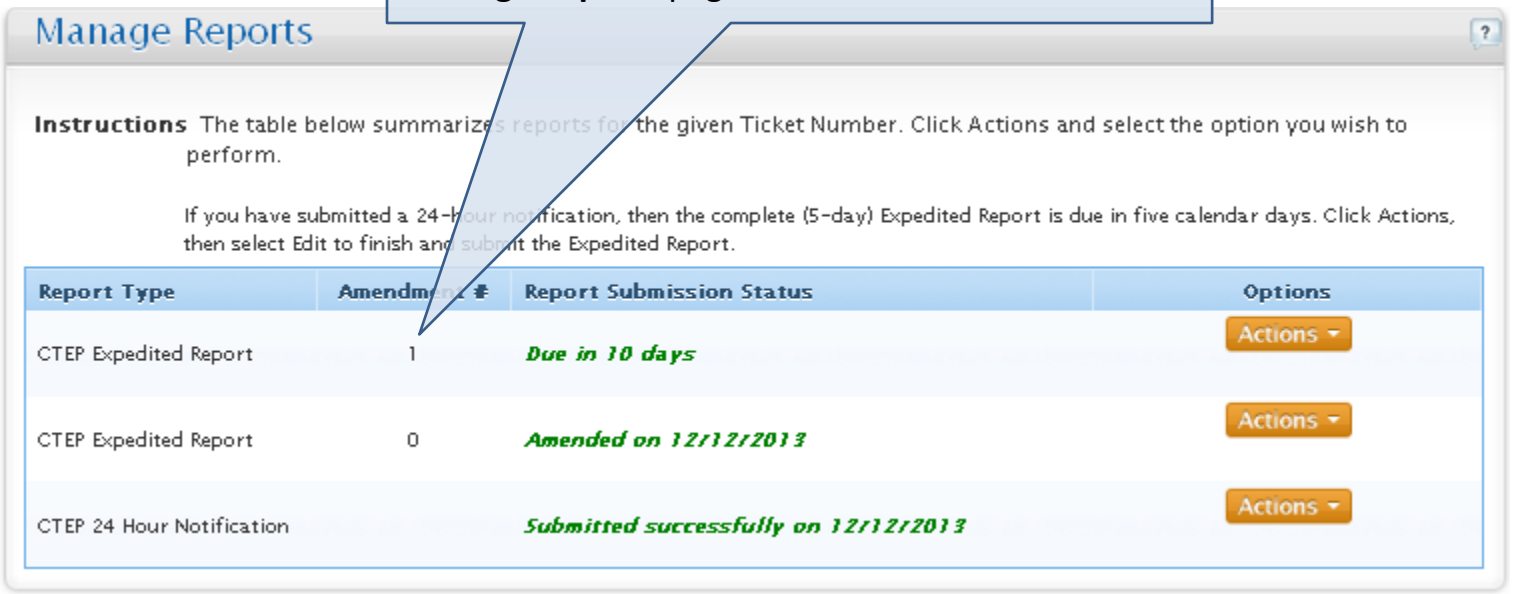


Manage Reports – Amend Option

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.

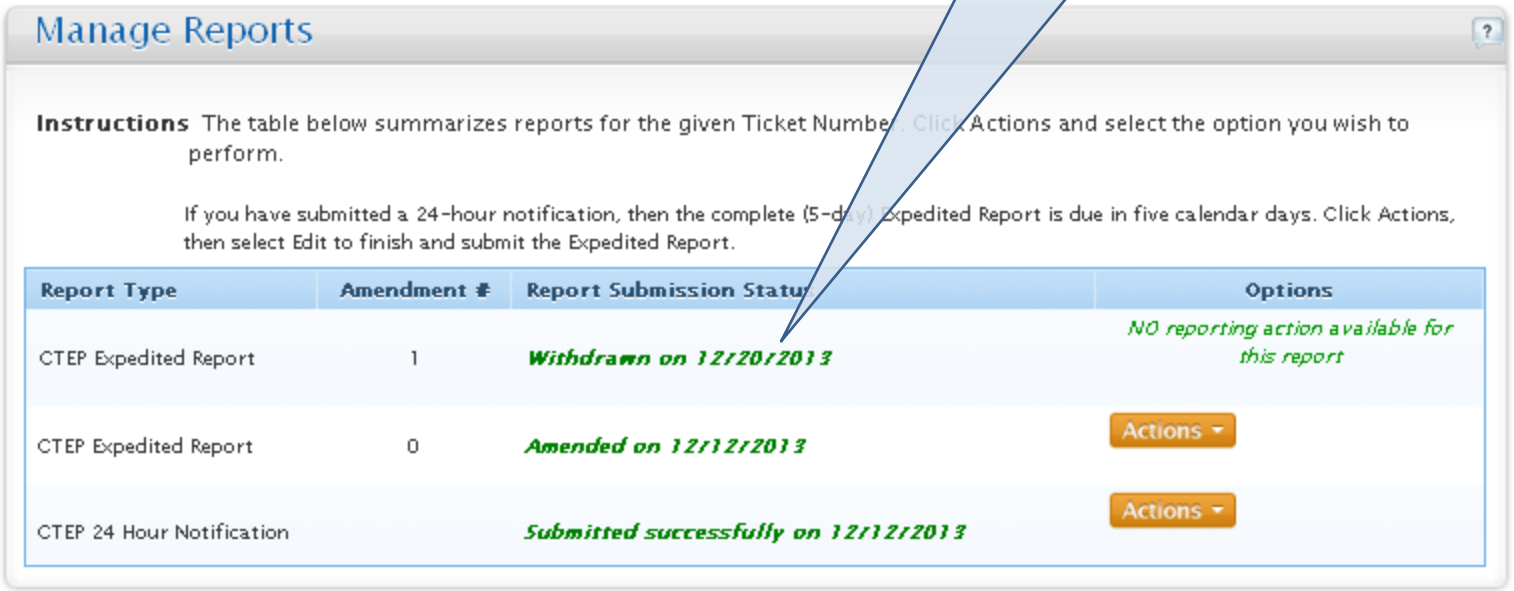


Manage Reports – Withdraw Option

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.

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 Sucessfully Submitted to the following:

Recipient Type	Recipients	Name	Email	Phone
Lead Group	Cancer and Leukemia Group B (Legacy)	Debbie S Pierce	debbie.sawyer@incl.org.x	Not Available
		Gabrielle Sawyer	centraloffice@incl.org.x	Not Available
		Ramanand Pierce	ram.achanta@incl.org.x	Not Available
		Pat Namara	mcnamara.patricia@incl.org.x	Not Available
		Brad Anders	andersen.bradley@incl.org.x	Not Available
		Darrin Brand	darrin.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	Not Available
		Mary Claire	mpierce@incl.org.x	Not Available
Participant Group	Cancer Trials Support Unit	Gladys Broson	gbrown@nullinc.com	Not Available
Submitter	Mayo Clinic Health System Eau Claire Hospital-Luther Campus	jason jackson	jmcnulty@nullinc.com	Not Available
Physician	Mayo Clinic Health System Eau Claire Hospital-Luther Campus	jason jackson	jmcnulty@nullinc.com	Not Available
PI	Cancer and Leukemia Group B (Legacy)	John Byrns	john.b@nullinc.com	Not Available

Close Window

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

NCI CTEP Help Desk (technical issues)
email: ncictephelp@ctep.nci.nih.gov
phone: 1-888-283-7457
fax: (301) 948-2242

AEMD Help Desk (medical questions)
email: aemd@tech-res.com
phone: (301) 897-7497
fax: (301) 230-0159

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

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