CTEP-AERS

Cancer Therapy Evaluation Program Adverse Event Reporting System

Training Presentation

CTEP-AERS Training Site:
https://betapps-ctep.nci.nih.gov/ctepaers/public/login

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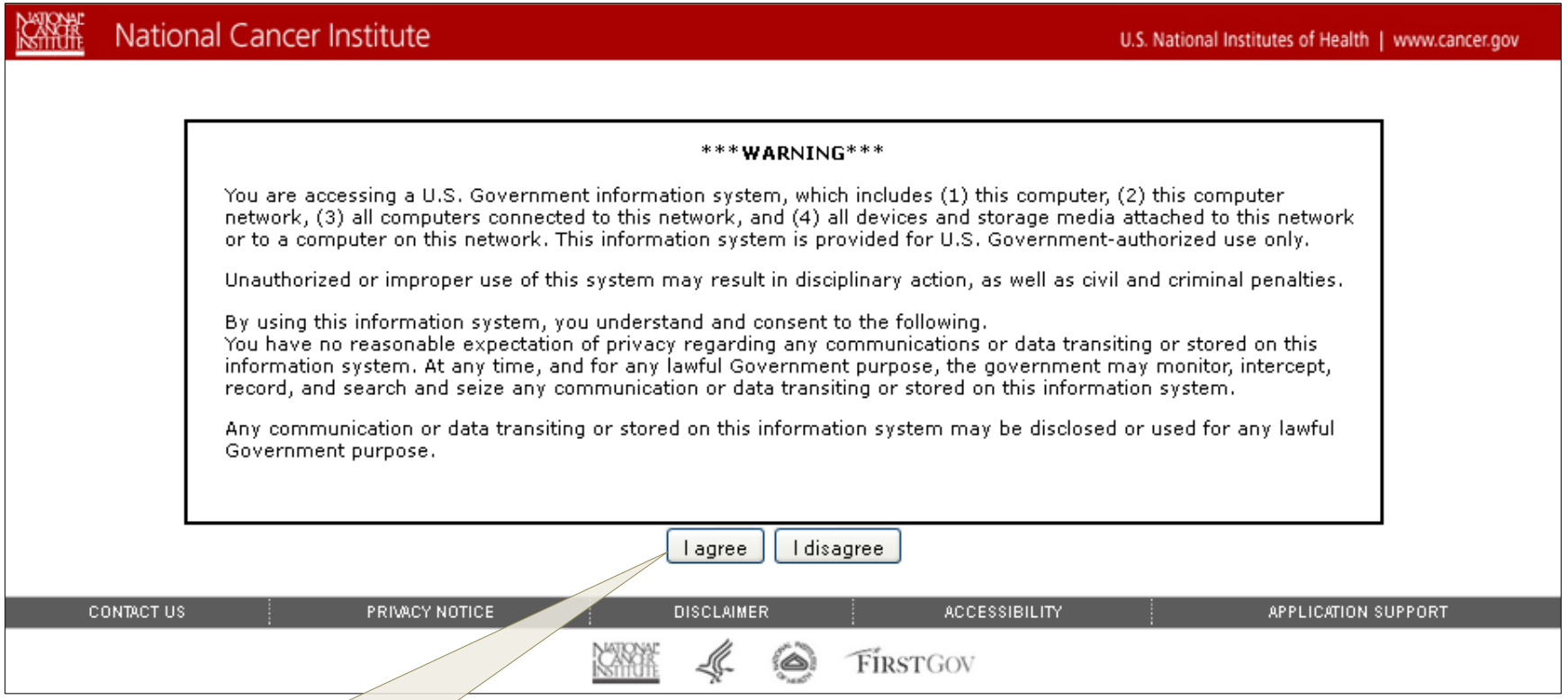
Welcome to CTEP-AERS

Two ways to access CTEP-AERS

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

NCI Warning Disclaimer



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 (CTEP, NCI staff only).

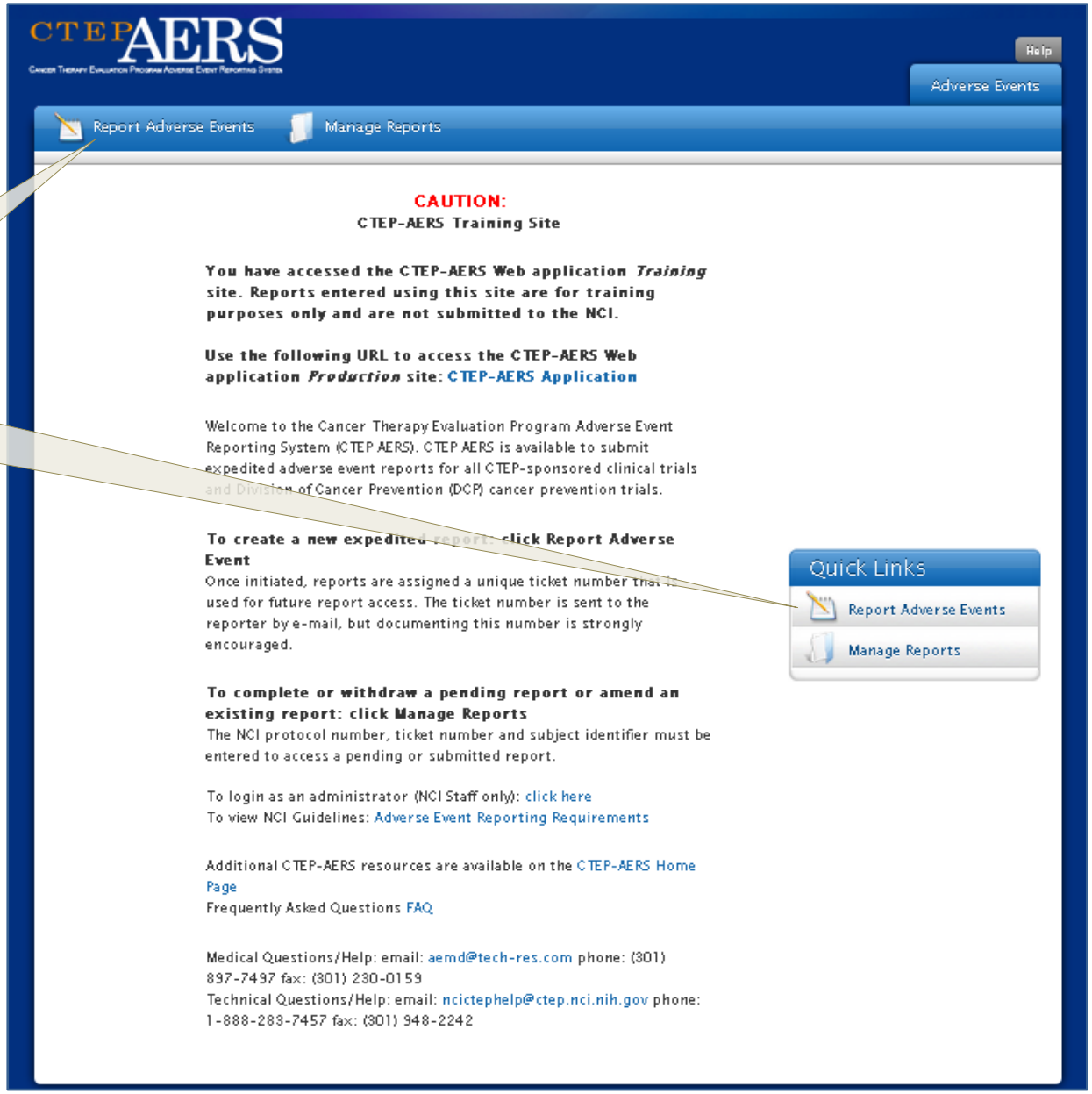
Link to the NCI Guidelines.

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

Contact information to the AEMD and NCICTEP Helpdesks.

Report Adverse Events

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

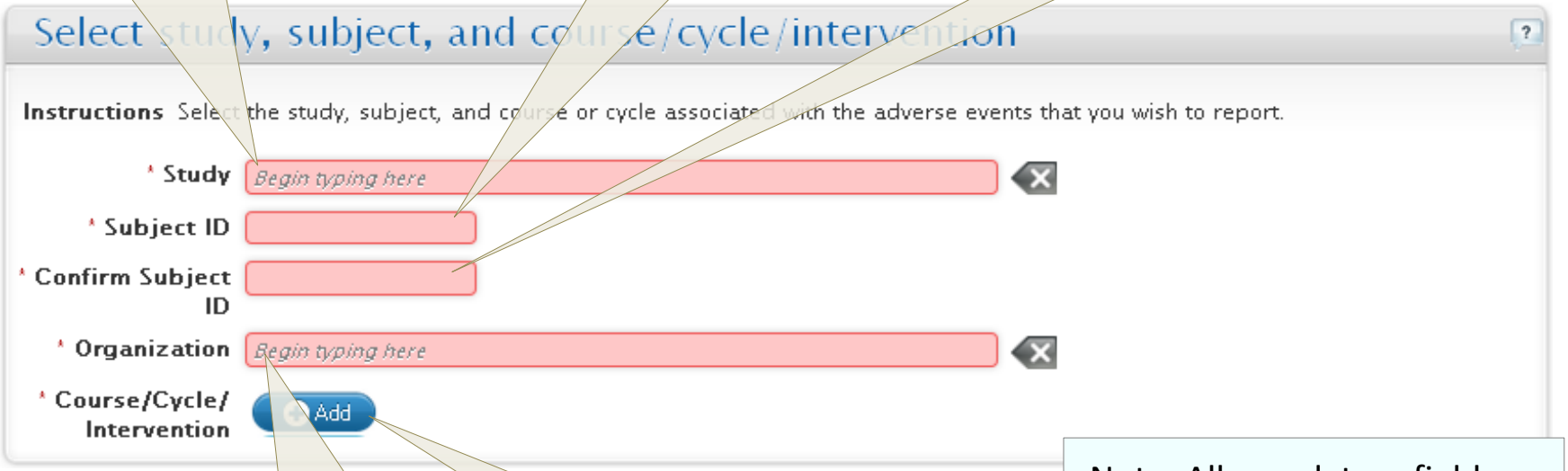


Select study, subject and course/cycle/intervention

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.



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

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

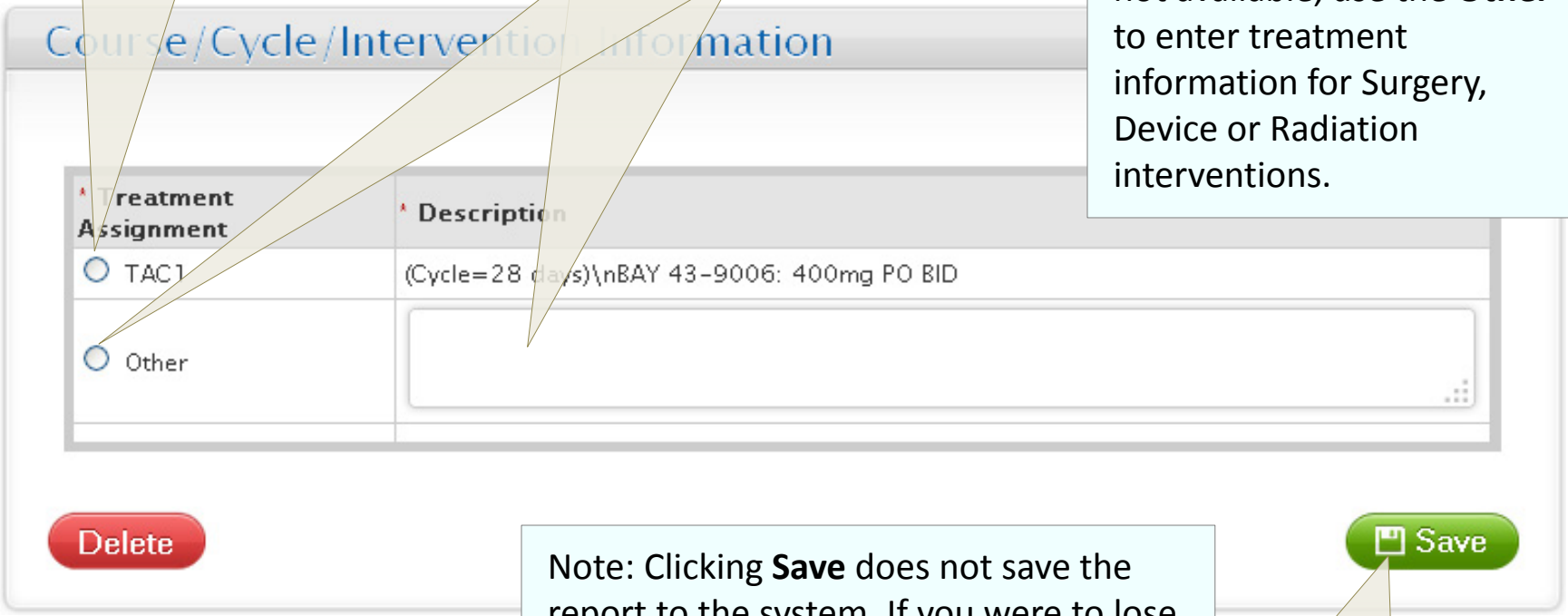
5. Click **+Add** to open the **Course/Cycle/Intervention** page.

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.

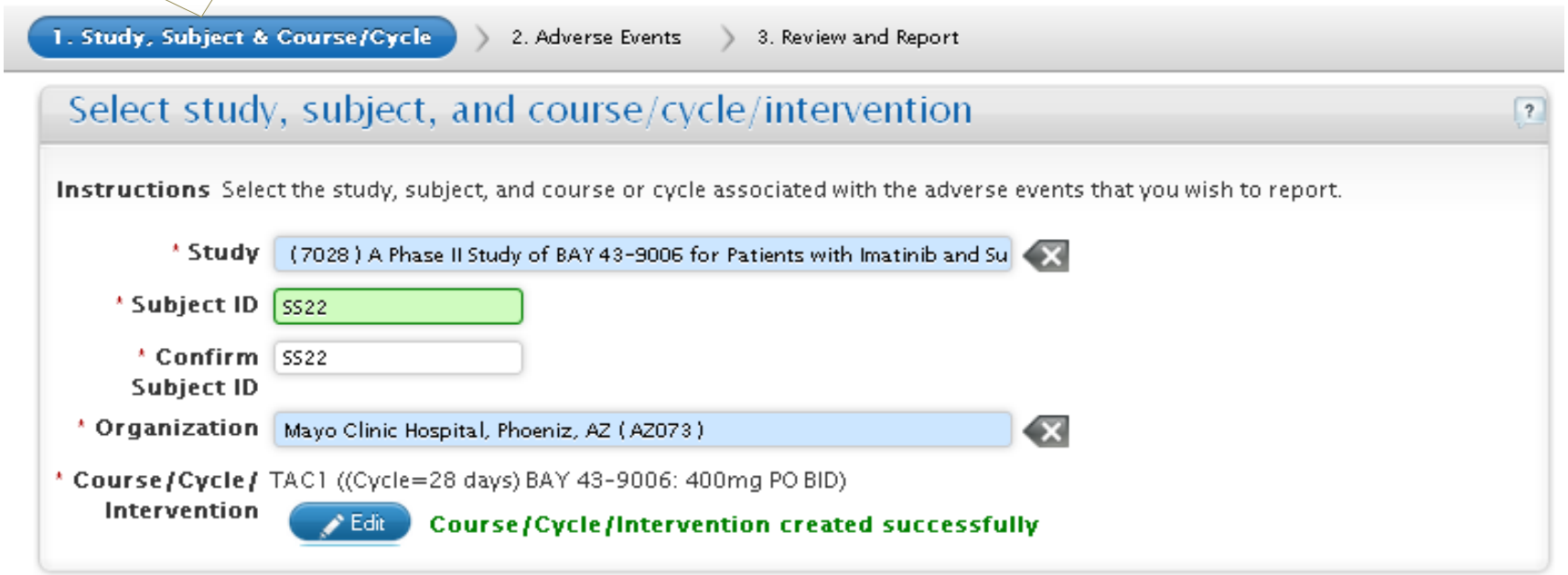


Note: Clicking **Save** does not save the report to the system. If you were to lose your browser connection at this time, you would need to reenter all information. More details will be provided on this later.

3. Click **Save**.

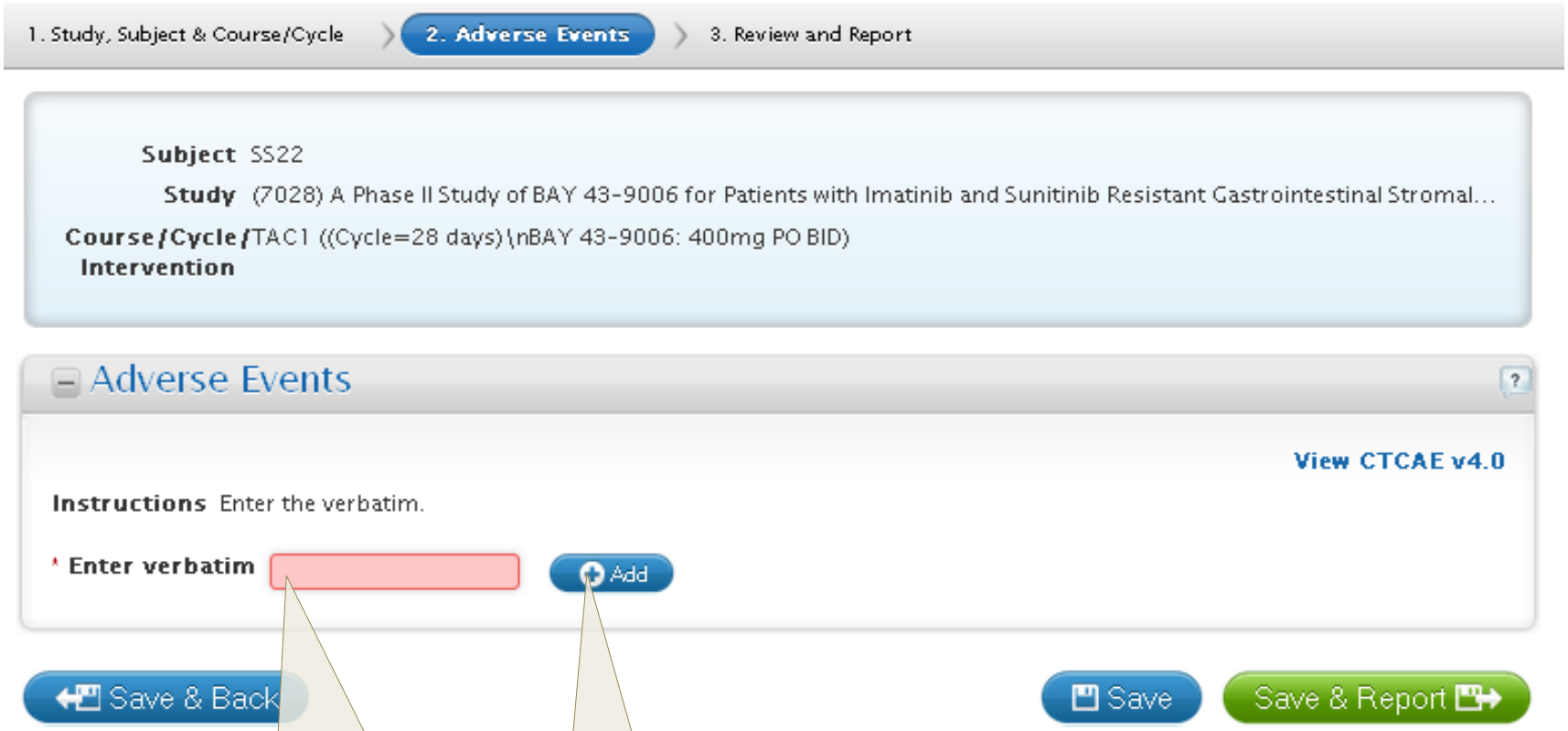
Select study, subject and course/cycle/intervention

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.

Adverse Events – AE Term and Related Information

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

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

3. Enter the **Start Date**.

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

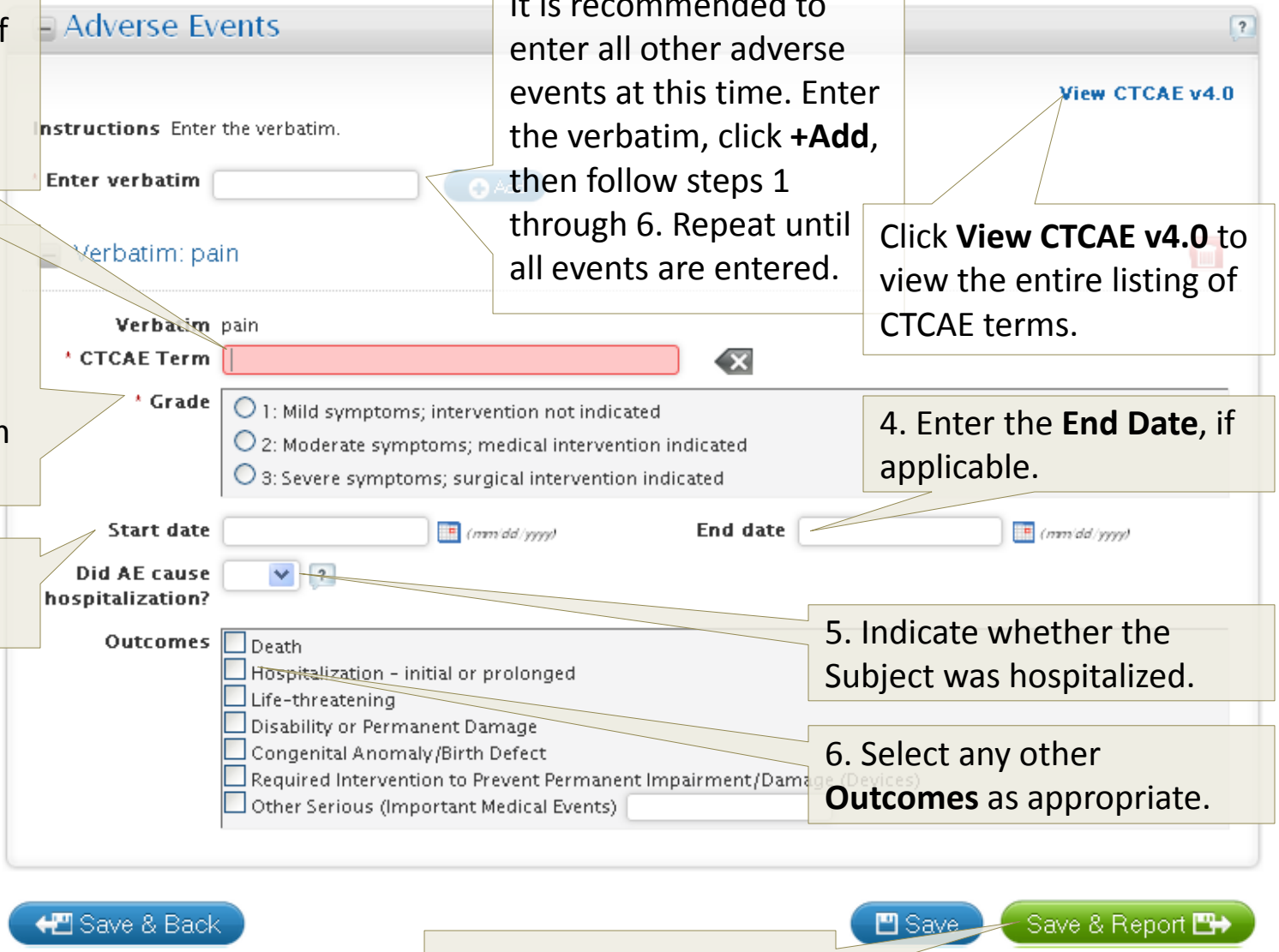
Click **View CTCAE v4.0** to view the entire listing of CTCAE terms.

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

5. Indicate whether the Subject was hospitalized.

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

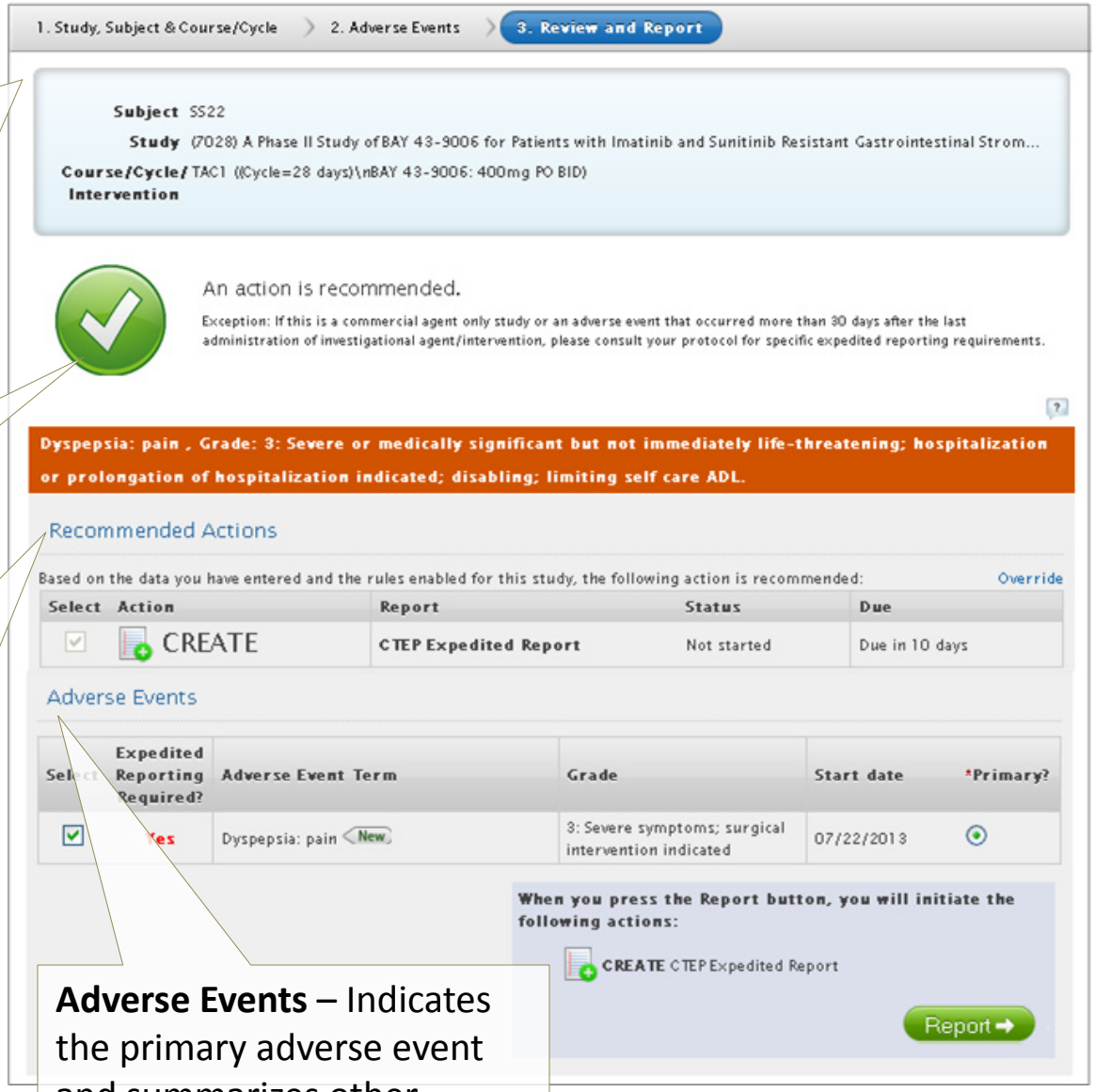
7. Click **Save & Report**.



Review and Report – Action Recommended

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

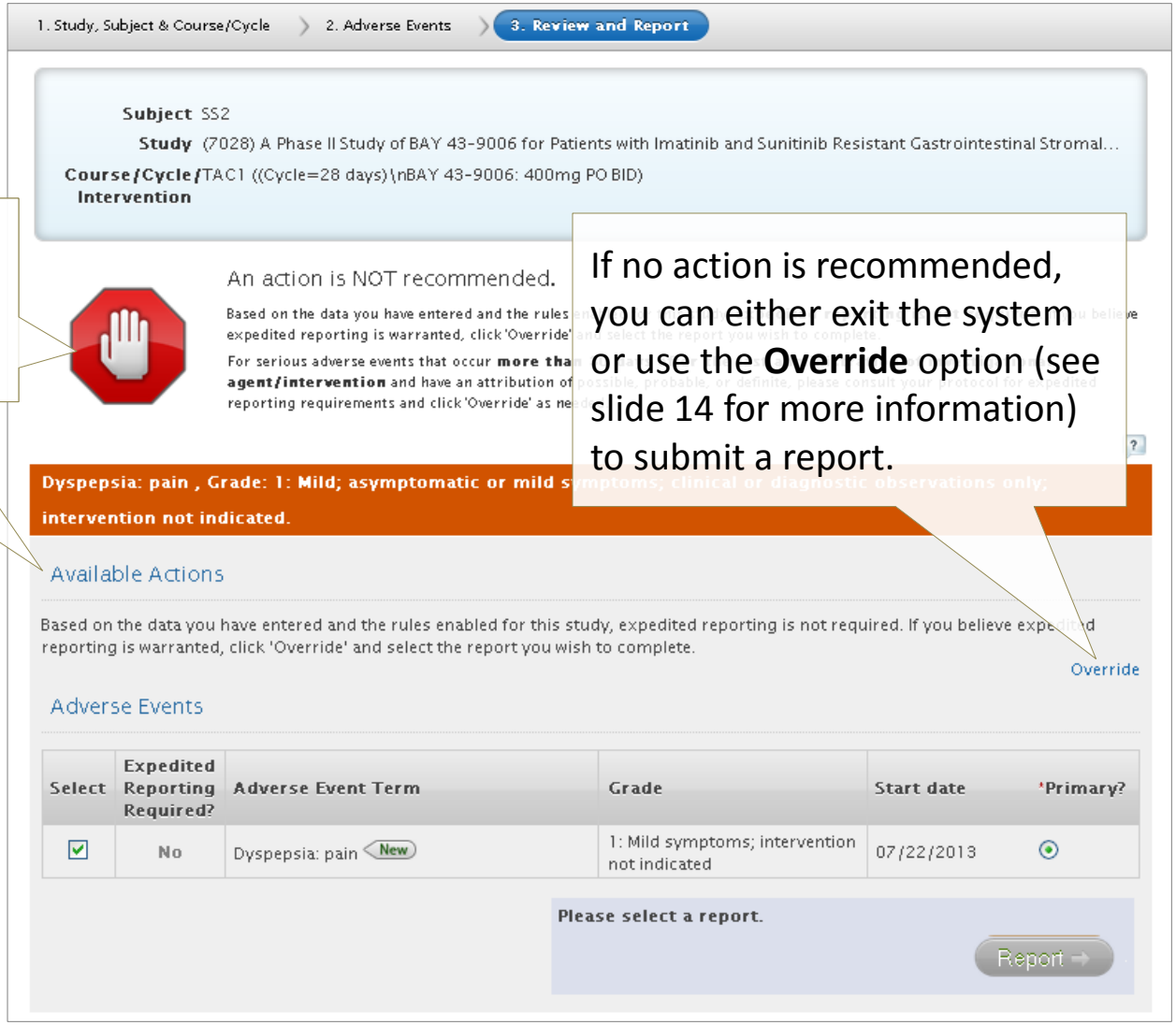
Recommended Actions – Indicates that a report is required and is displays the checkmark icon.
Available Actions displays when a report is not required (see next slide).
The **Override** option is available in both instances.



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

Review and Report – Action Not Recommended

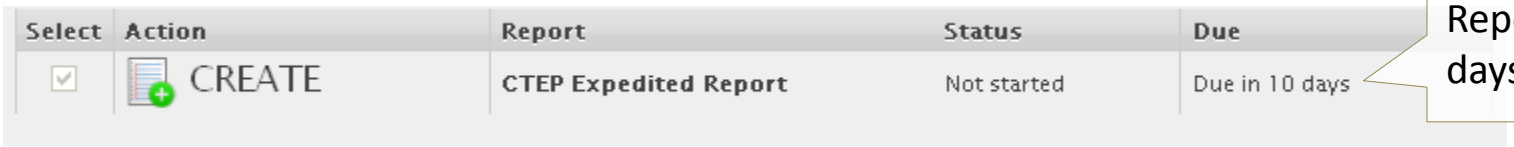
Available Actions – Indicates that a report is not required and displays the stop icon.



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

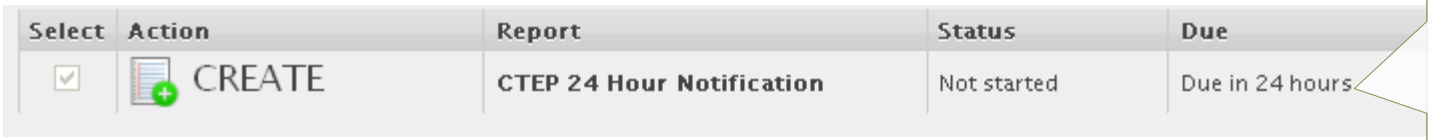
Review and Report – Recommended Actions

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

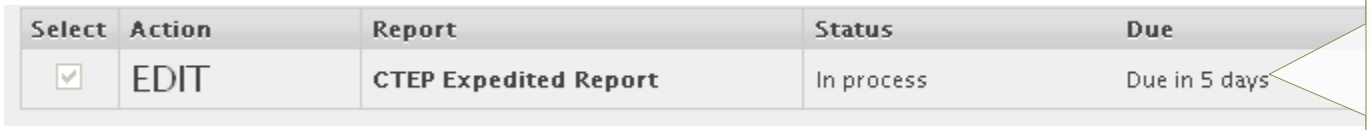


Select	Action	Report	Status	Due
☑	CREATE	CTEP Expedited Report	Not started	Due in 10 days

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



Select	Action	Report	Status	Due
☑	EDIT	CTEP Expedited Report	In process	Due in 5 days

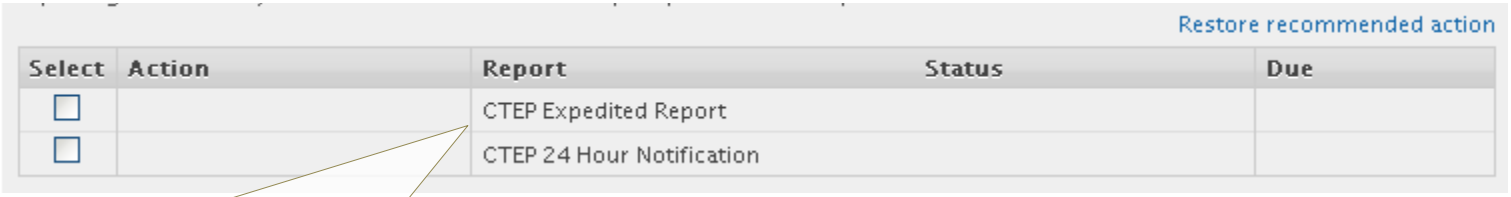
The CTEP 24-Hour Notification is due within 24-hours, followed by the CTEP Expedited Report, which is due in 5 days.

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

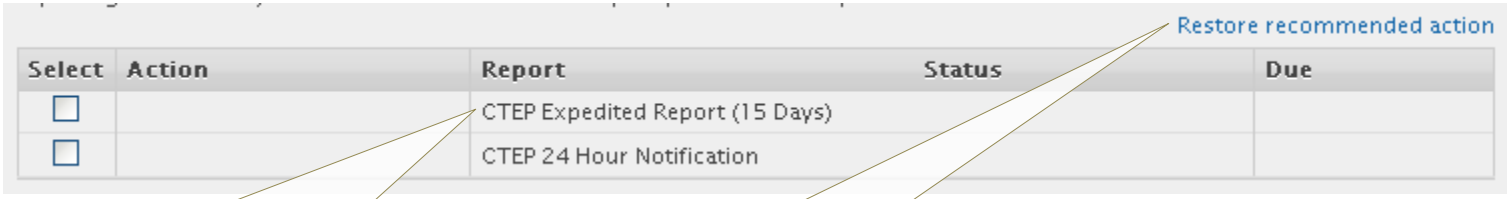
The CTEP Expedited Report for commercial agents is due in 15 days.

Review and Report – 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.



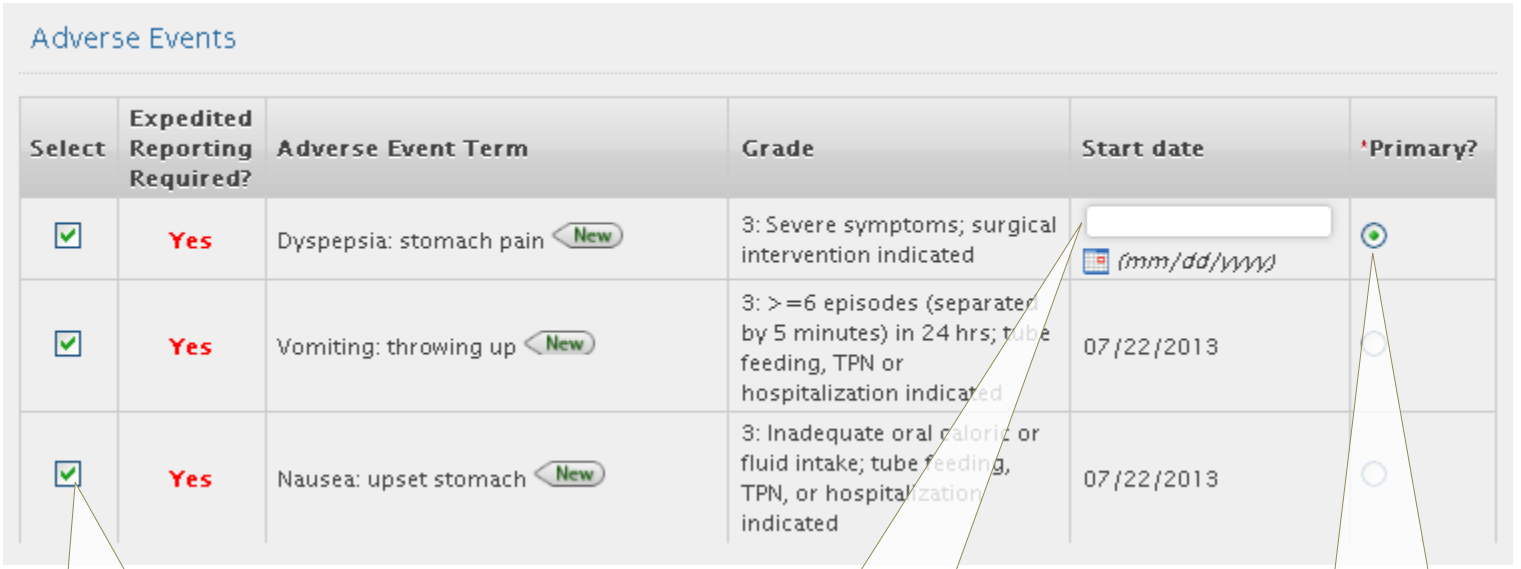
Depending on the outcome of the rules engine, the CTEP Expedited Report and 24-Hour Notification are options when **Override** is selected.



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.

Review and Report – Adverse Event Table



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

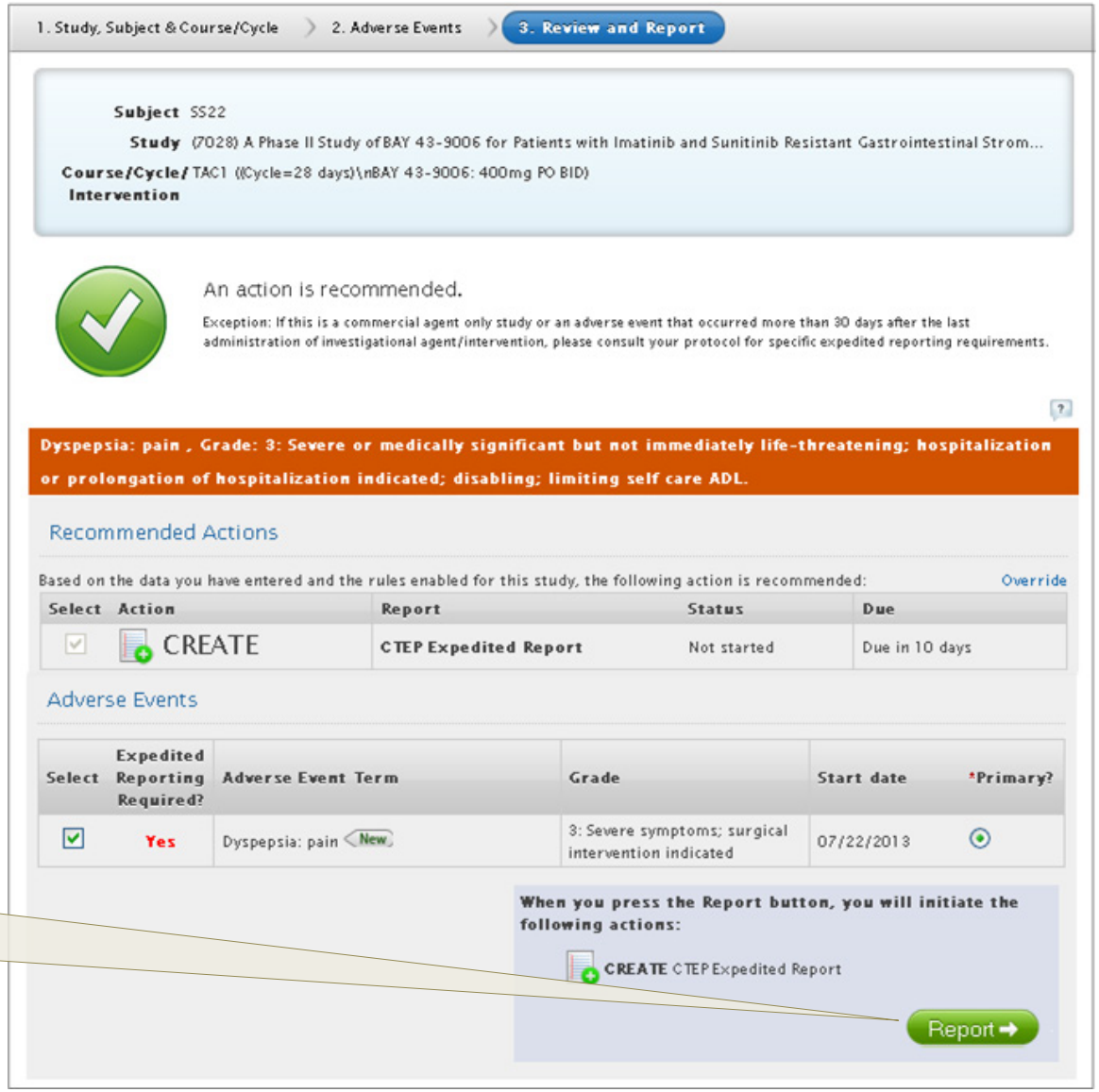
The **Start Date** can be entered here if omitted on the **Adverse Event** page.

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

Review and Report

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.

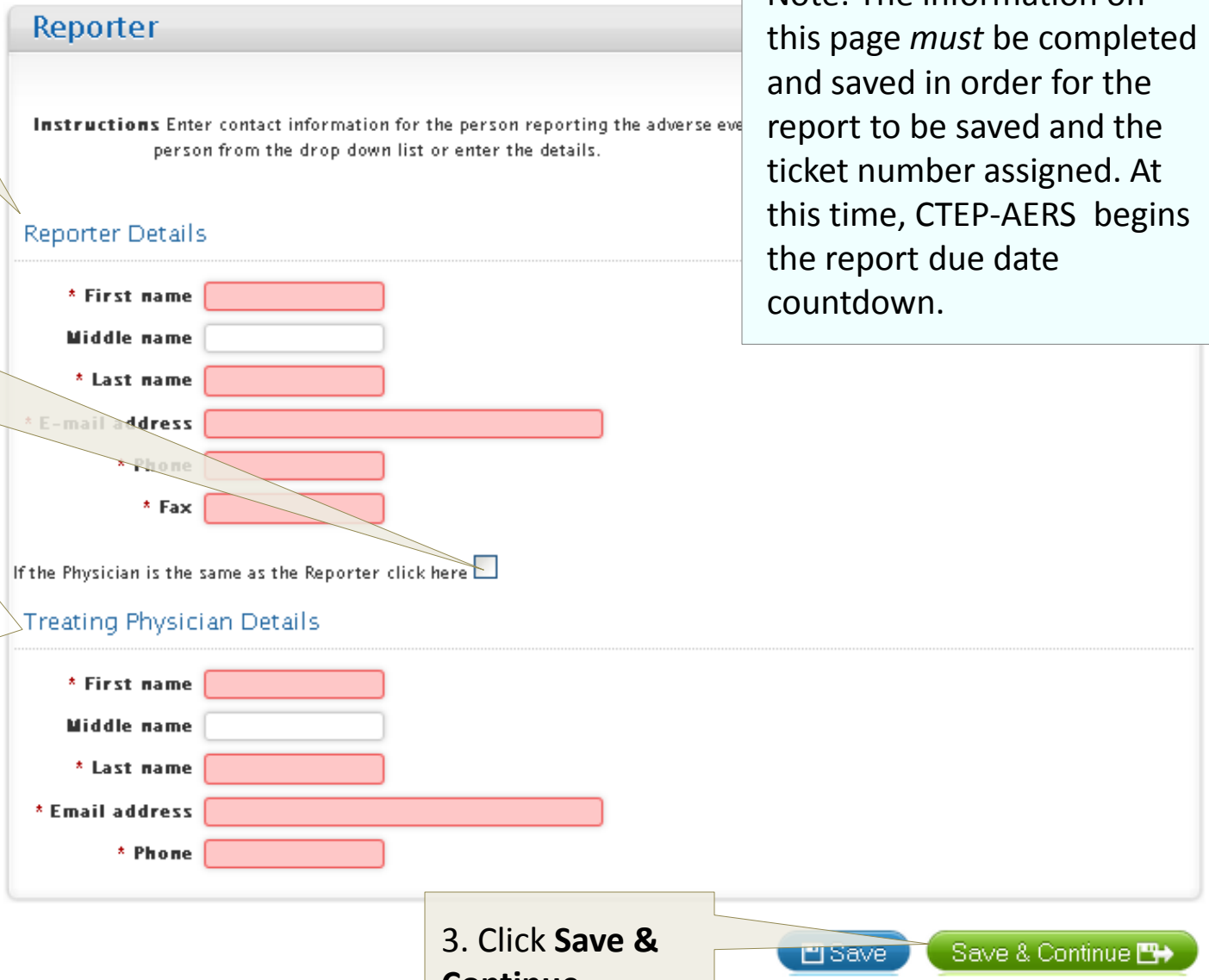


1. Reporter

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

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

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

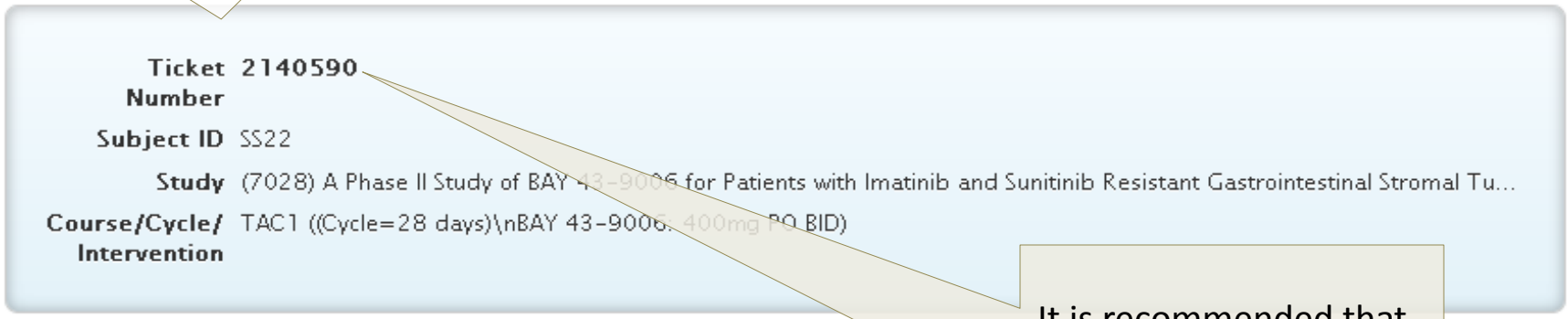


Note: The information on this page *must* be completed and saved in order for the report to be saved and the ticket number assigned. At this time, CTEP-AERS begins the report due date countdown.

3. Click **Save & Continue**.

Report Ticket Number

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

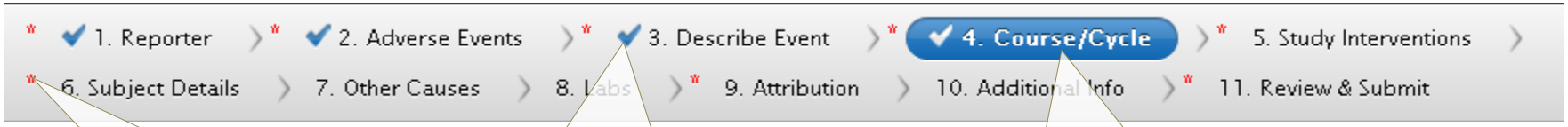


It is recommended that you record the ticket number for future reference. This information will also be sent to you via email.

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.

Navigation Bar

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



Red asterisks (*) indicate a mandatory section.

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

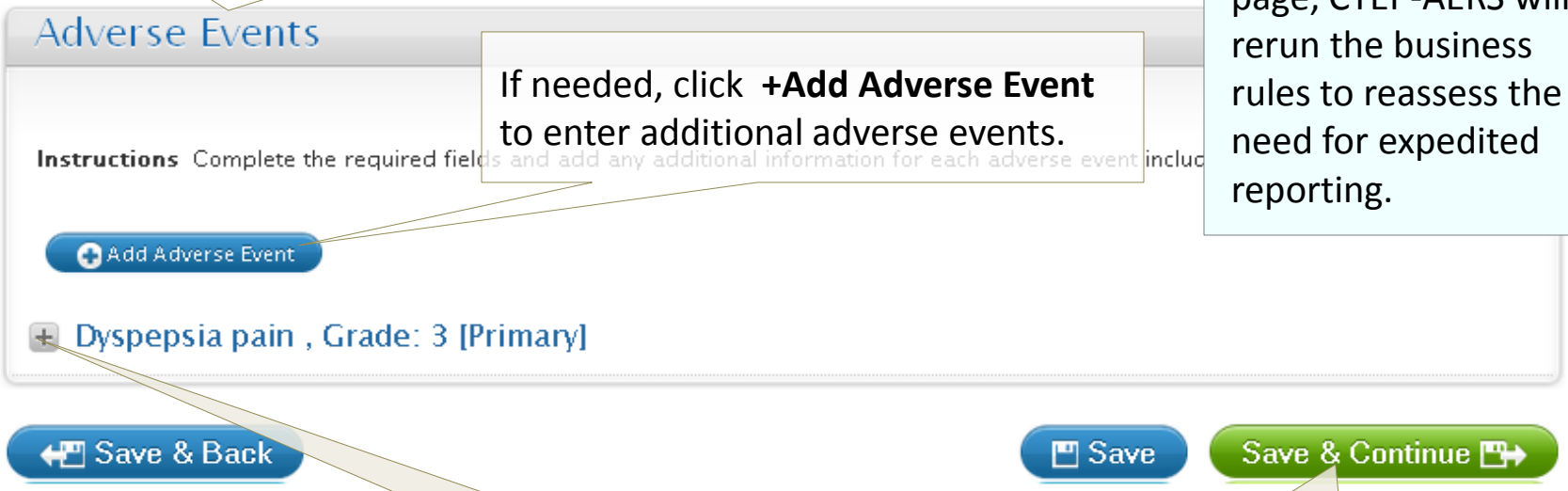
A highlighted tab indicates the section currently in use.

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

2. Adverse Events

Adverse Events

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

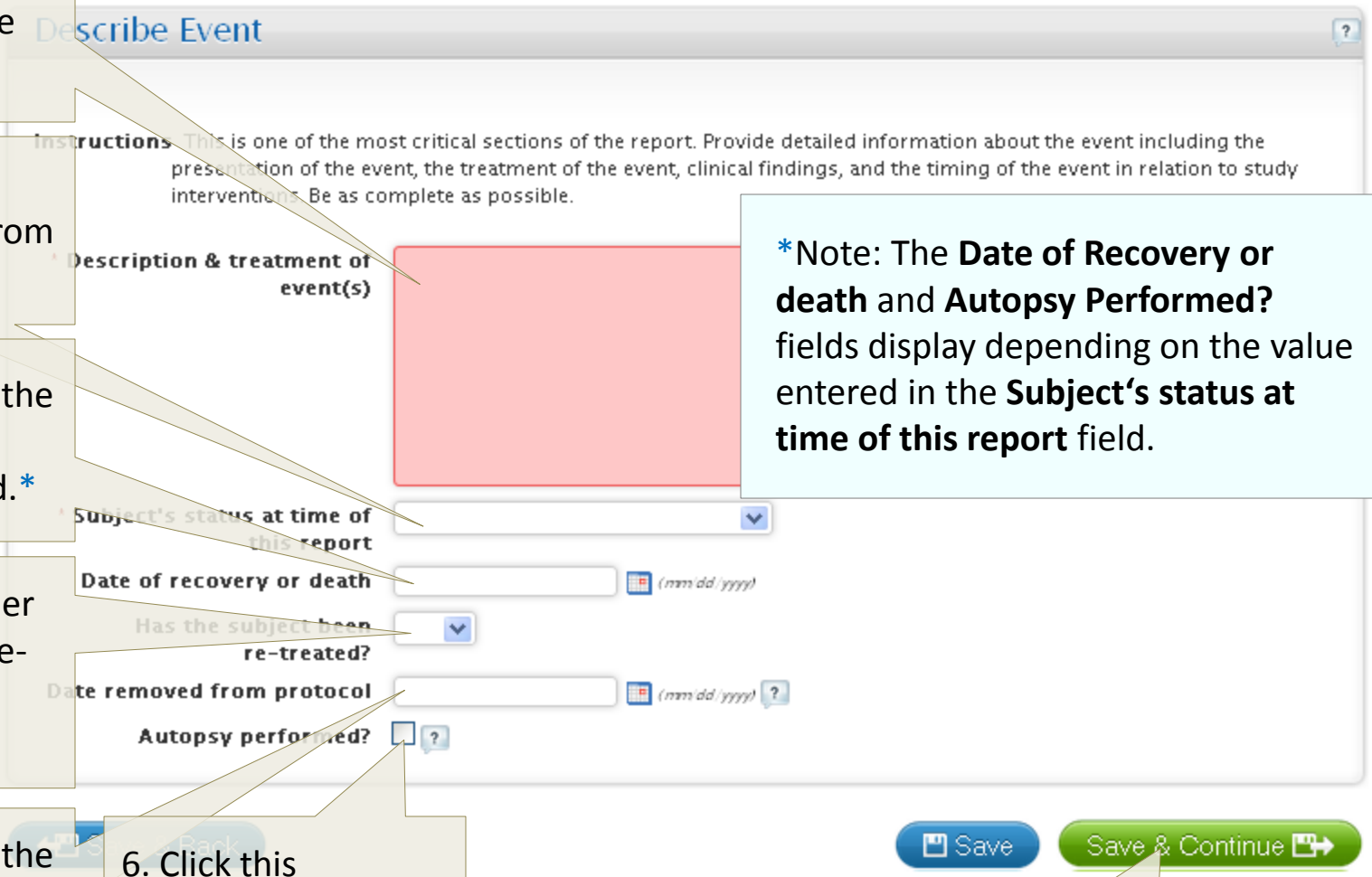
1. Enter all information related to the adverse event.

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.



*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.

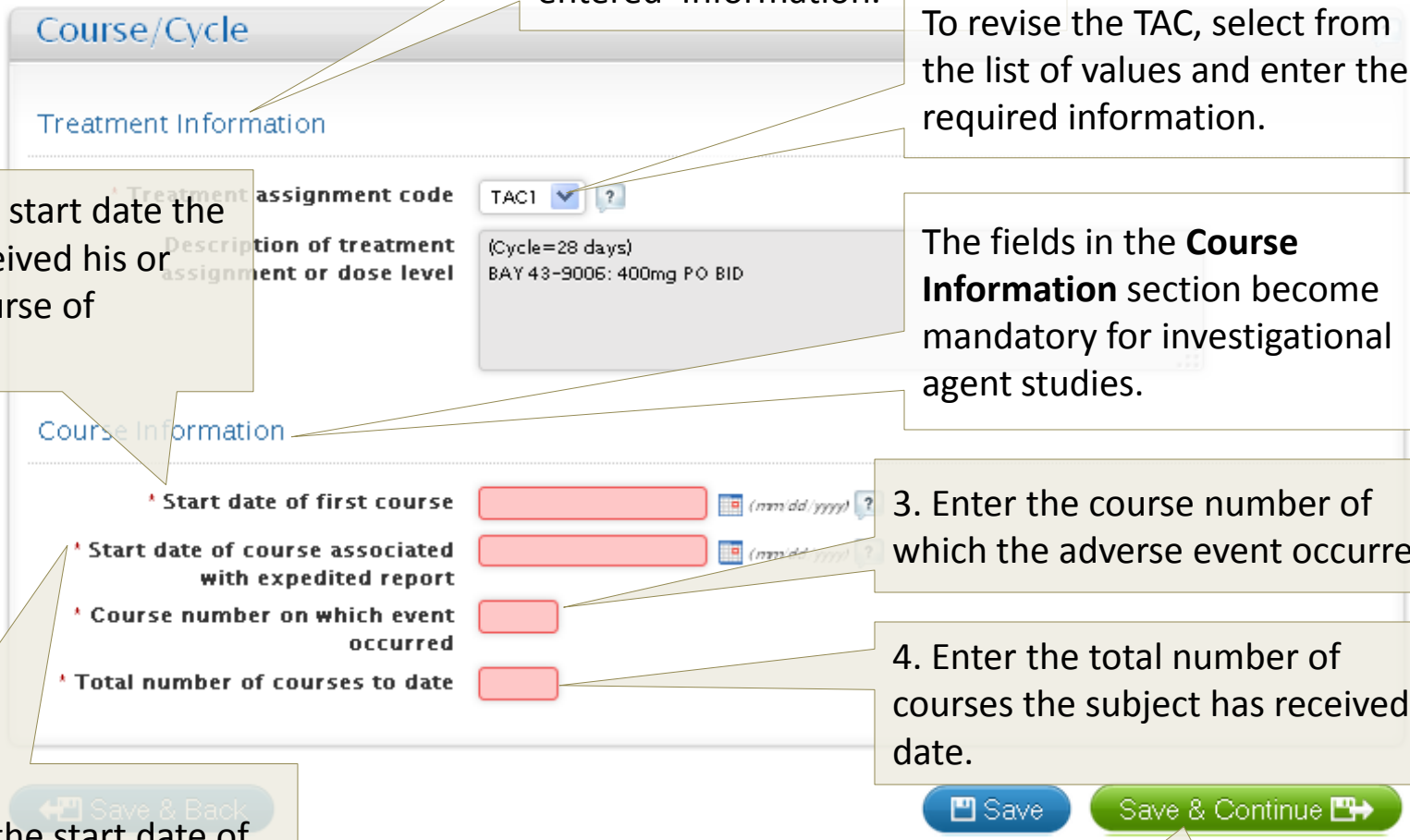
6. Click this checkbox to indicate that an autopsy was performed.*

7. Click **Save & Continue**.

Course/Cycle

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

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



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

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

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

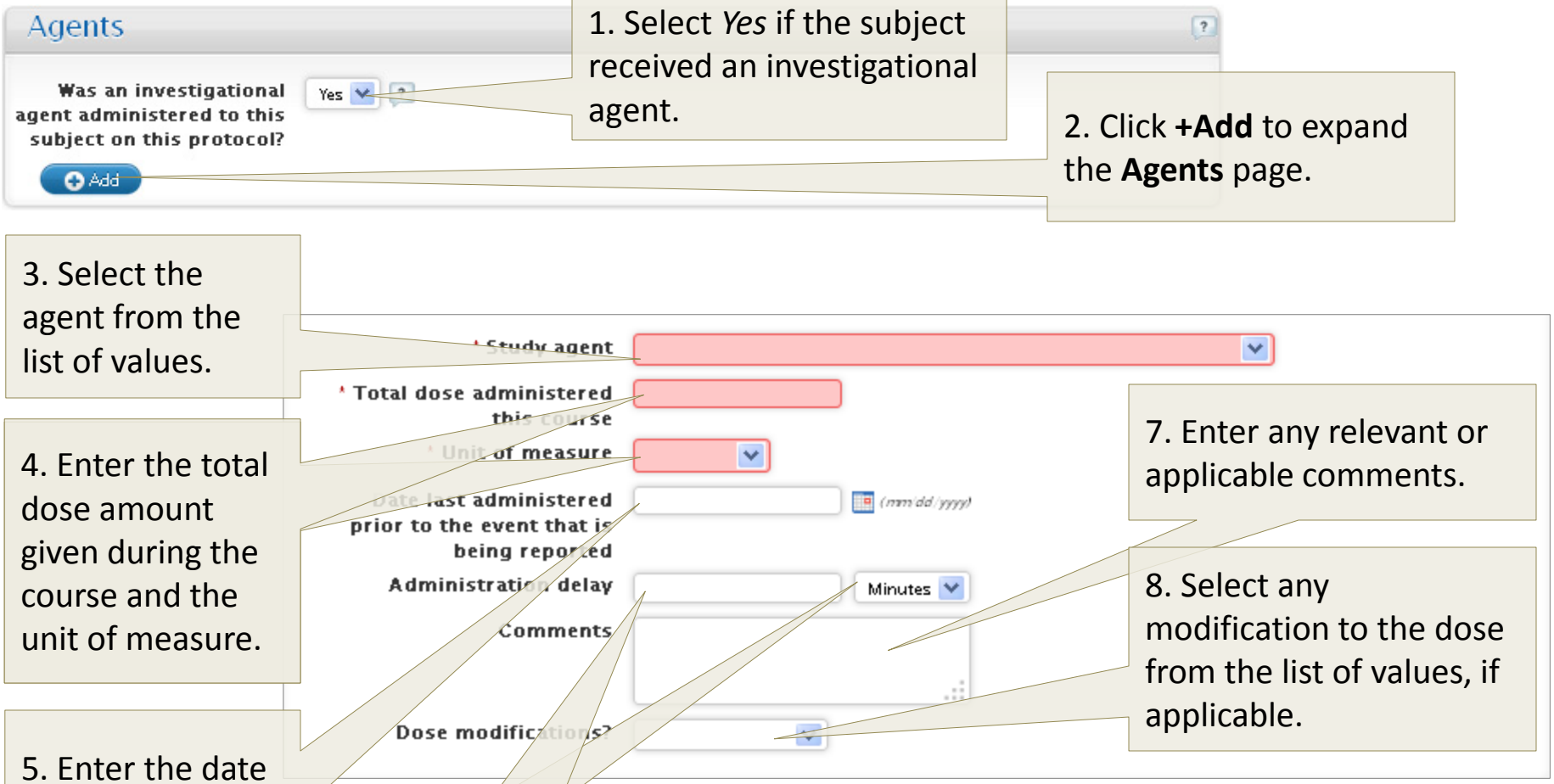
4. Enter the total number of courses the subject has received to date.

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

5. Click **Save & Continue**.

5. Study Interventions

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.

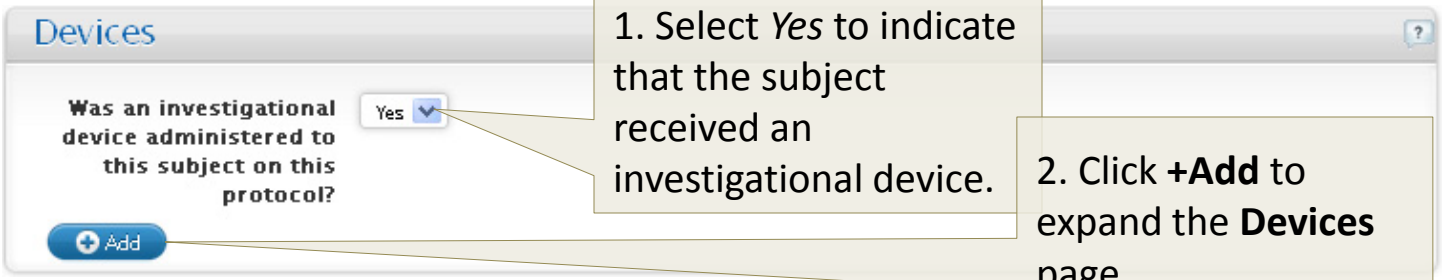
8. Select any modification to the dose from the list of values, if applicable.

9. Click **Save & Continue**.

5. Study Interventions

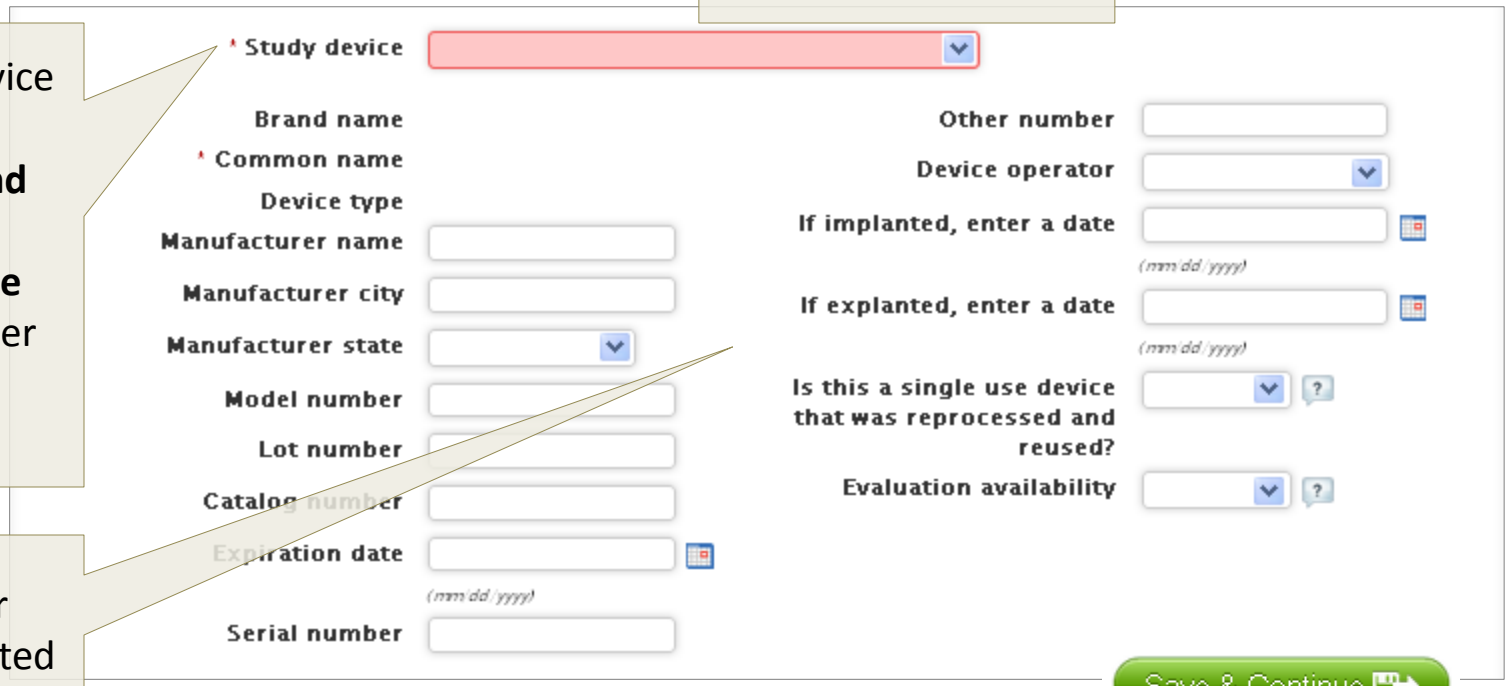
Study Interventions - Devices

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



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.

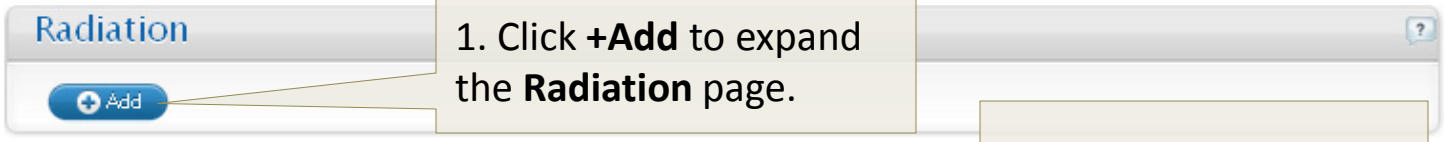
4. Enter all other information related to the device.

5. Click **Save & Continue**.

5. Study Interventions

Study Interventions - Radiation

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



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

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

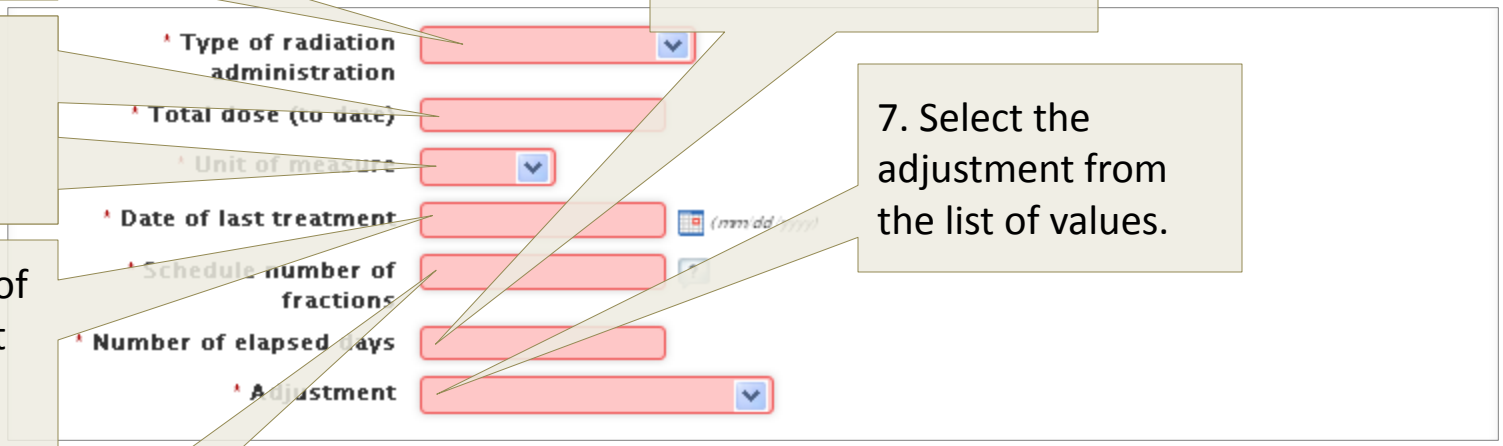
3. Enter the total dose and the unit of measure.

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.

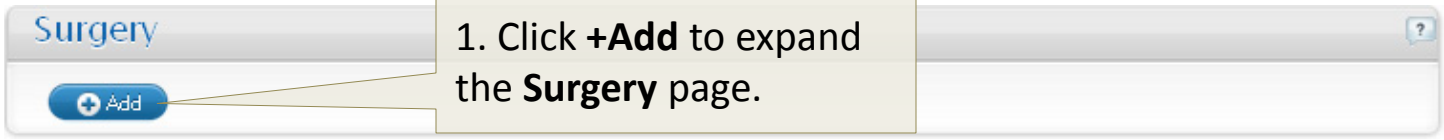
7. Select the adjustment from the list of values.



8. Click **Save & Continue**.

5. Study Interventions

Study Interventions - Surgery



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.

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

4. Click **Save & Continue**.

6. Subject Details

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 sex 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.

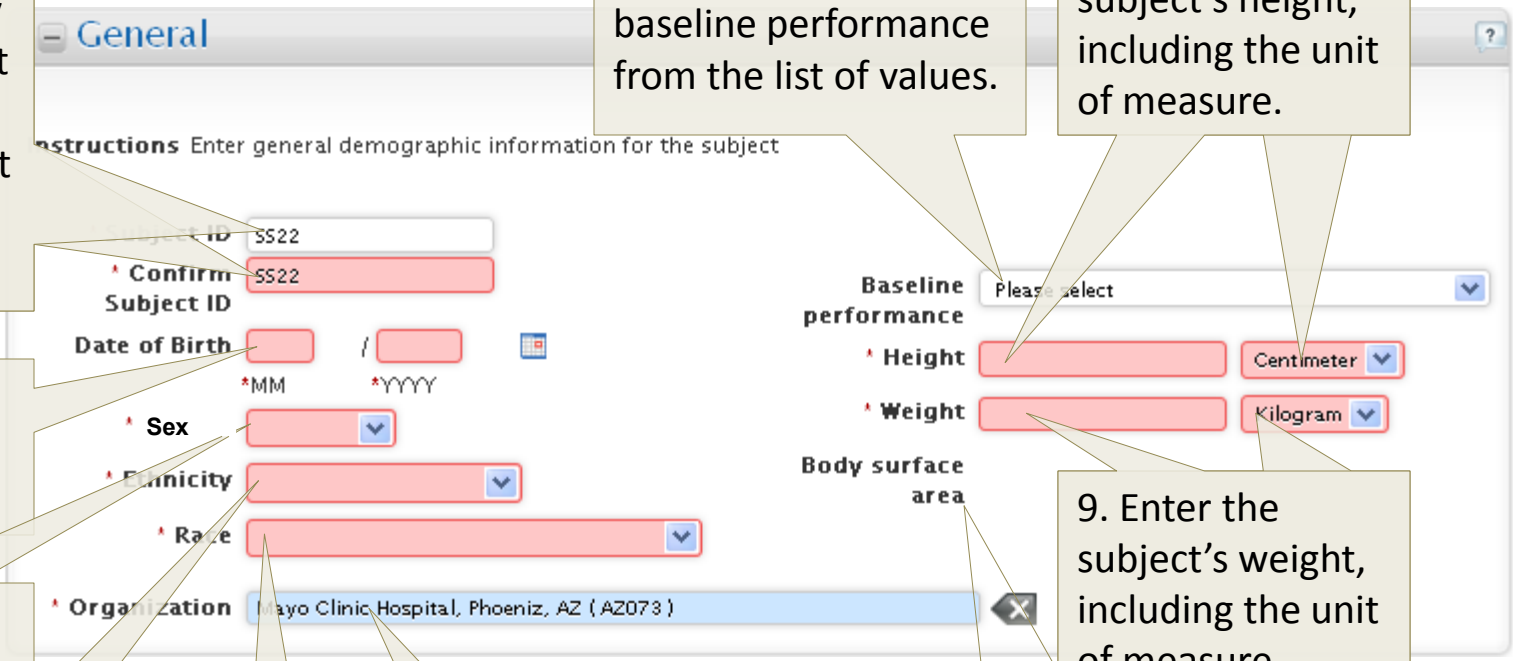
7. Select the subject's baseline performance from the list of values.

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.

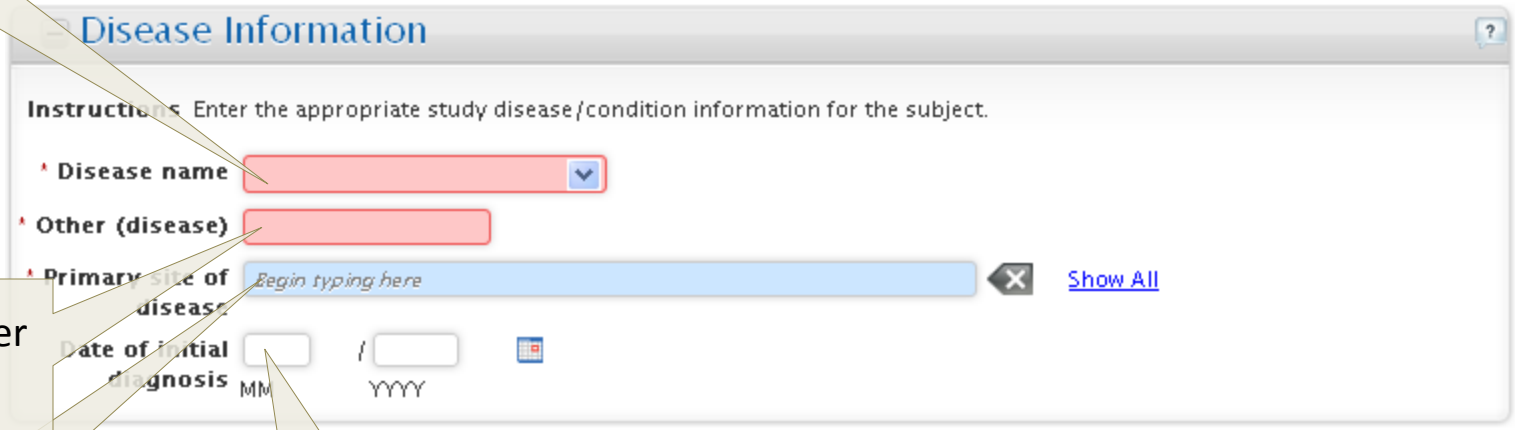


6. Subject Details

Subject Details – Disease Information

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

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



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

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

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

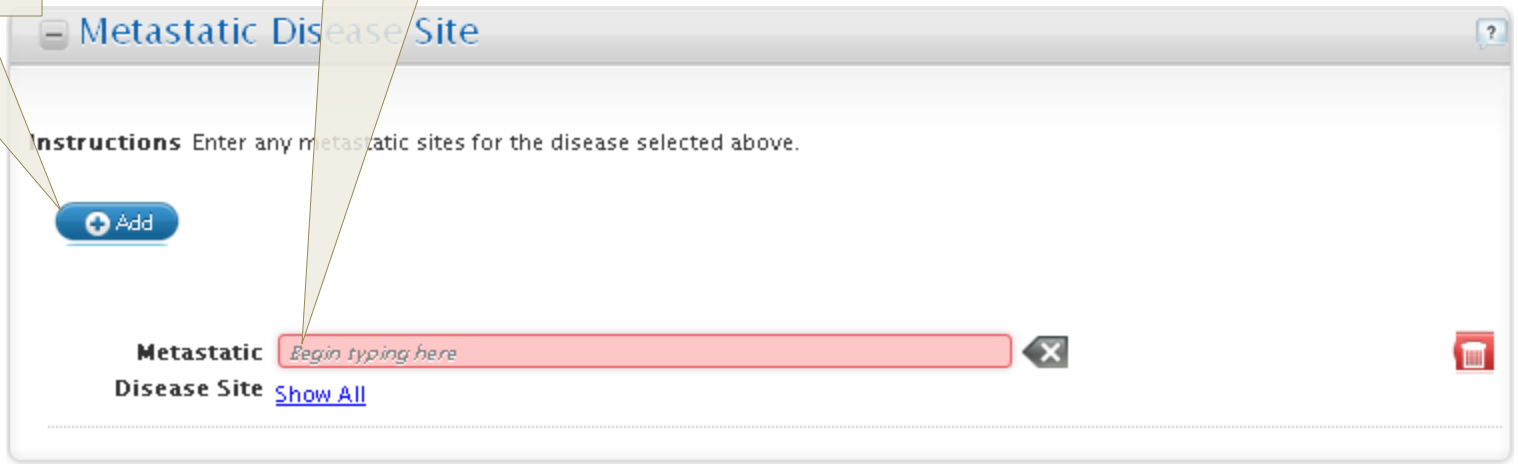
5. Scroll down to the **Metastatic Disease Site** page.

6. Subject Details

Subject Details – Metastatic Disease Site

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

2. Type at least three characters or click Show All and select the disease from the list.



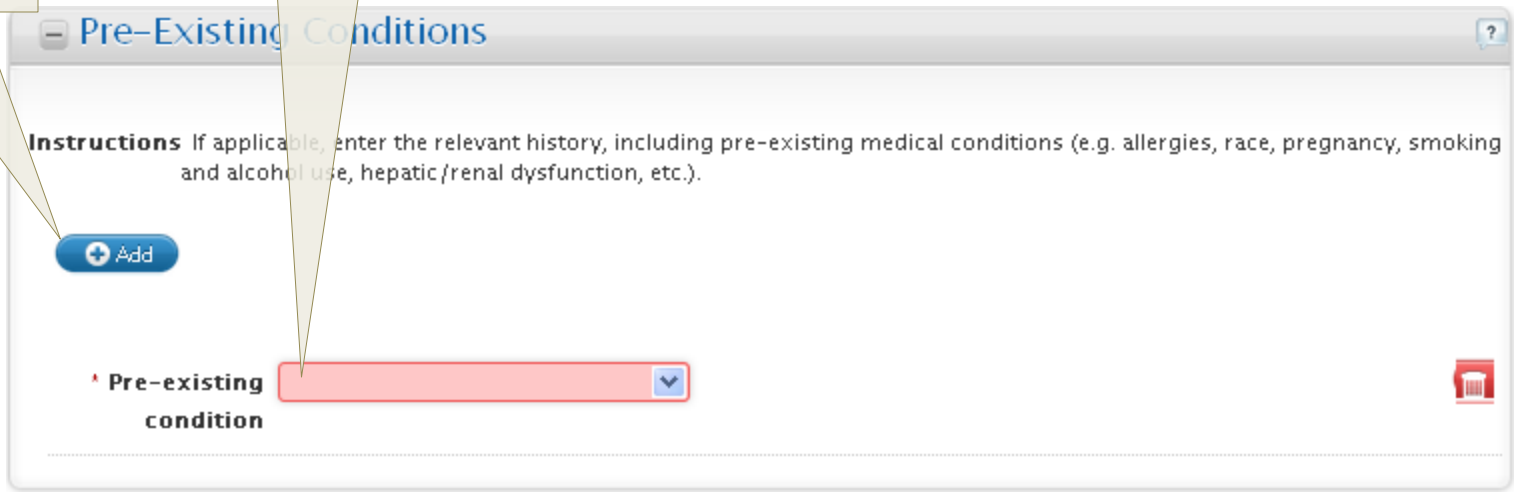
3. Scroll down to the **Pre-Existing Conditions** page.

6. Subject Details

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.

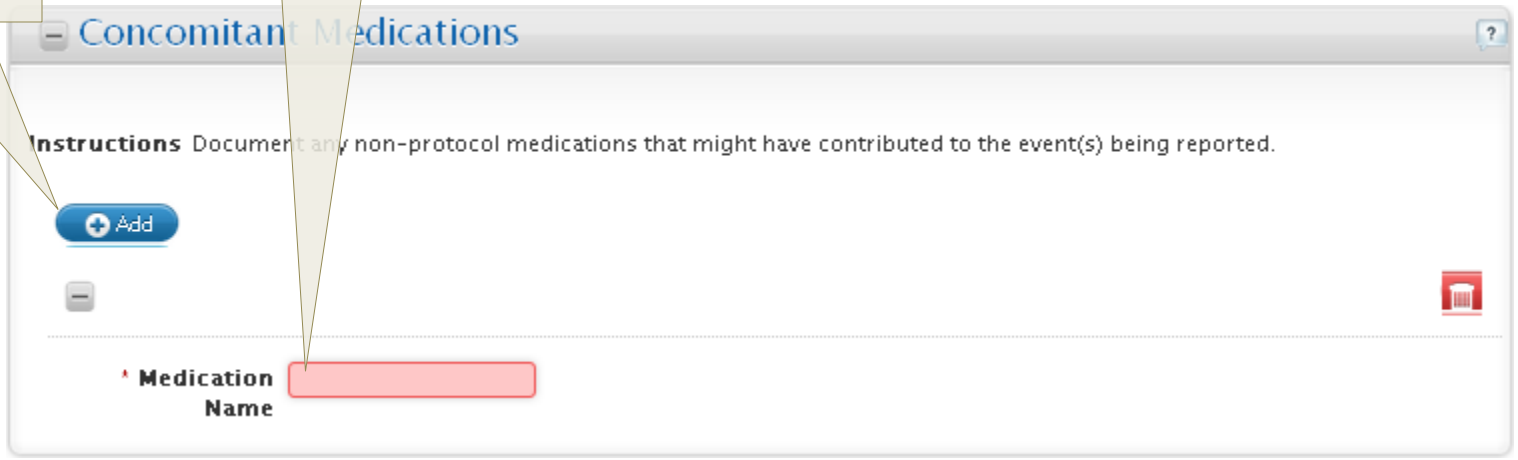
6. Subject Details

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.

6. Subject Details

Subject Details – Prior Therapies

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

2. Select the therapy from the list of values.

3. Enter additional information regarding the therapy.

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

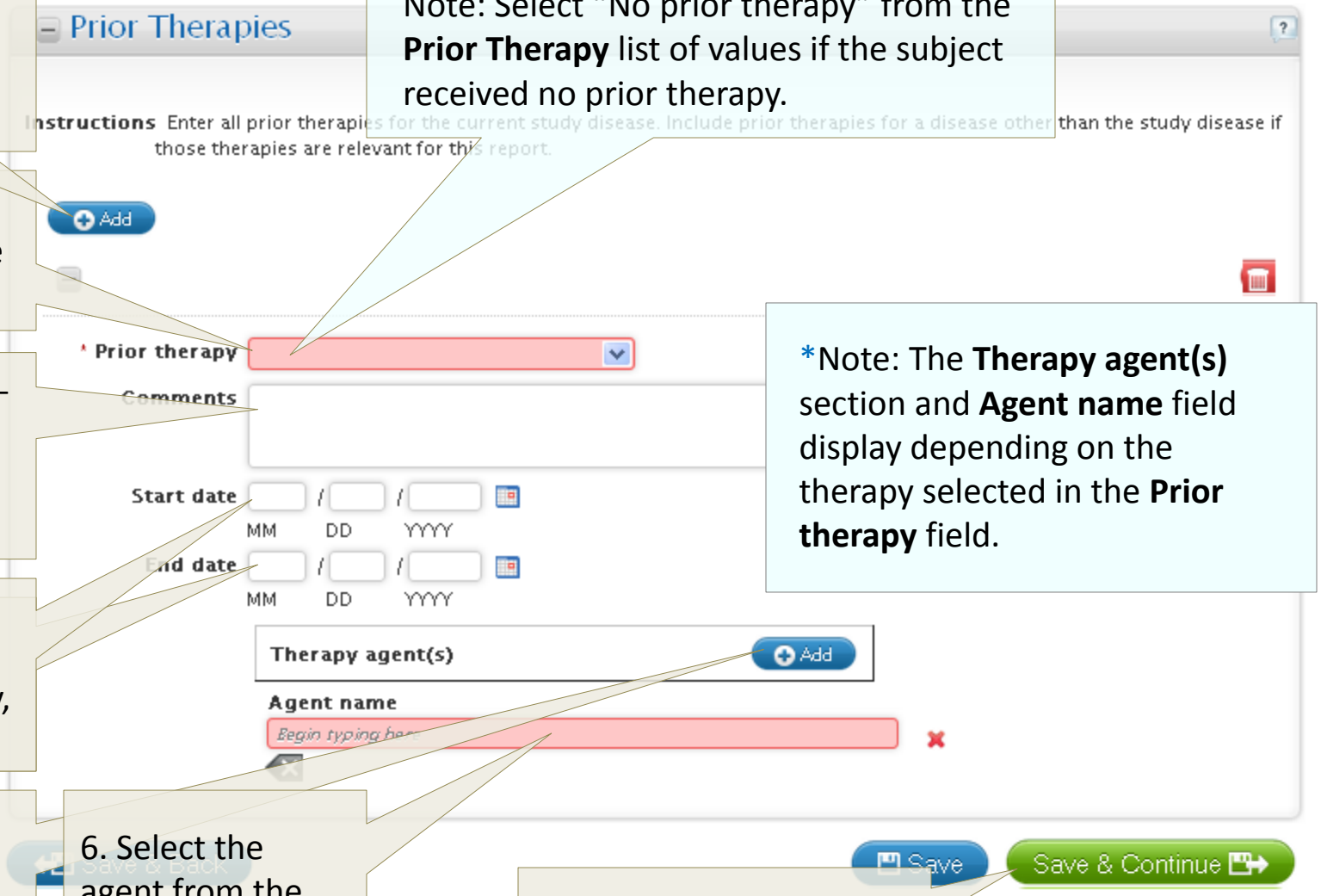
5. Click **+Add** to expand the **Therapy agents** section.*

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

7. Click **Save & Continue**.

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

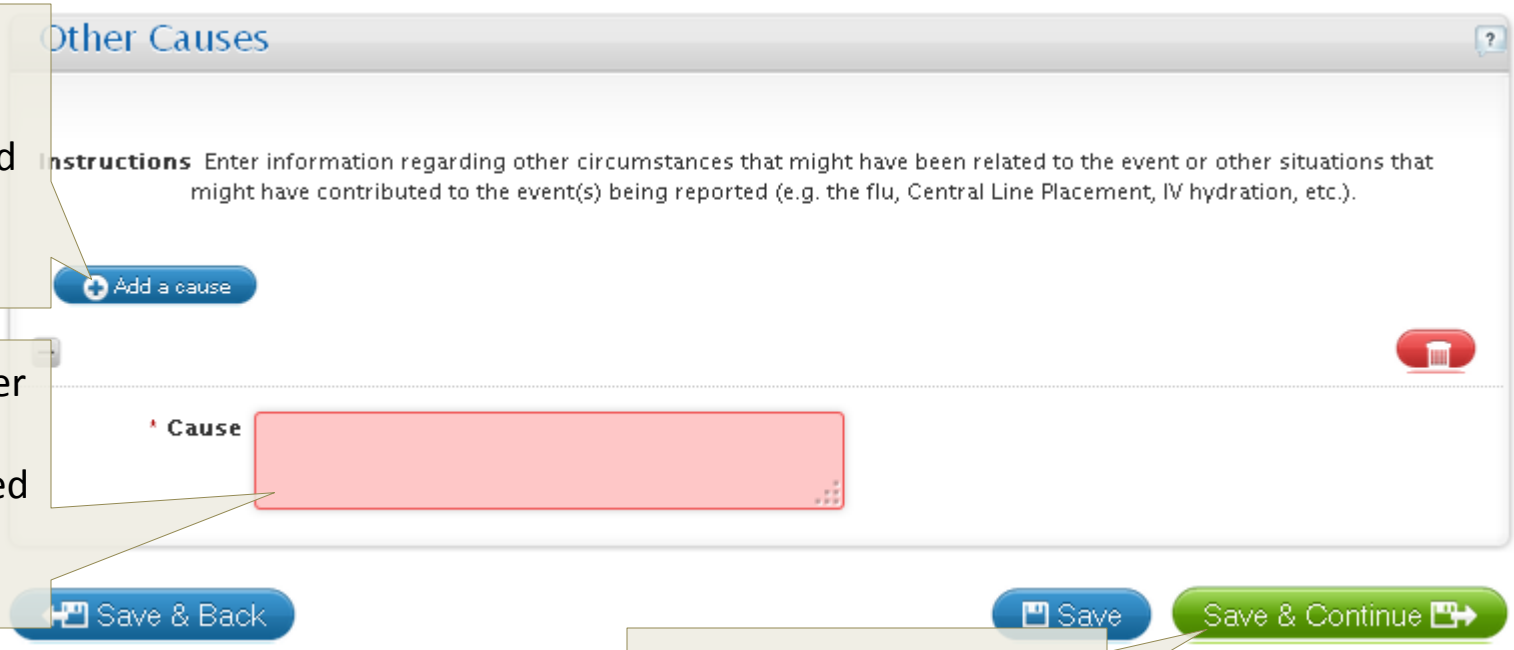
*Note: The **Therapy agent(s)** section and **Agent name** field display depending on the therapy selected in the **Prior therapy** field.



7. Other Causes

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

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



3. Click **Save & Continue**.

8. Labs Labs

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

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

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

4. Enter the lab values and the associated dates.

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

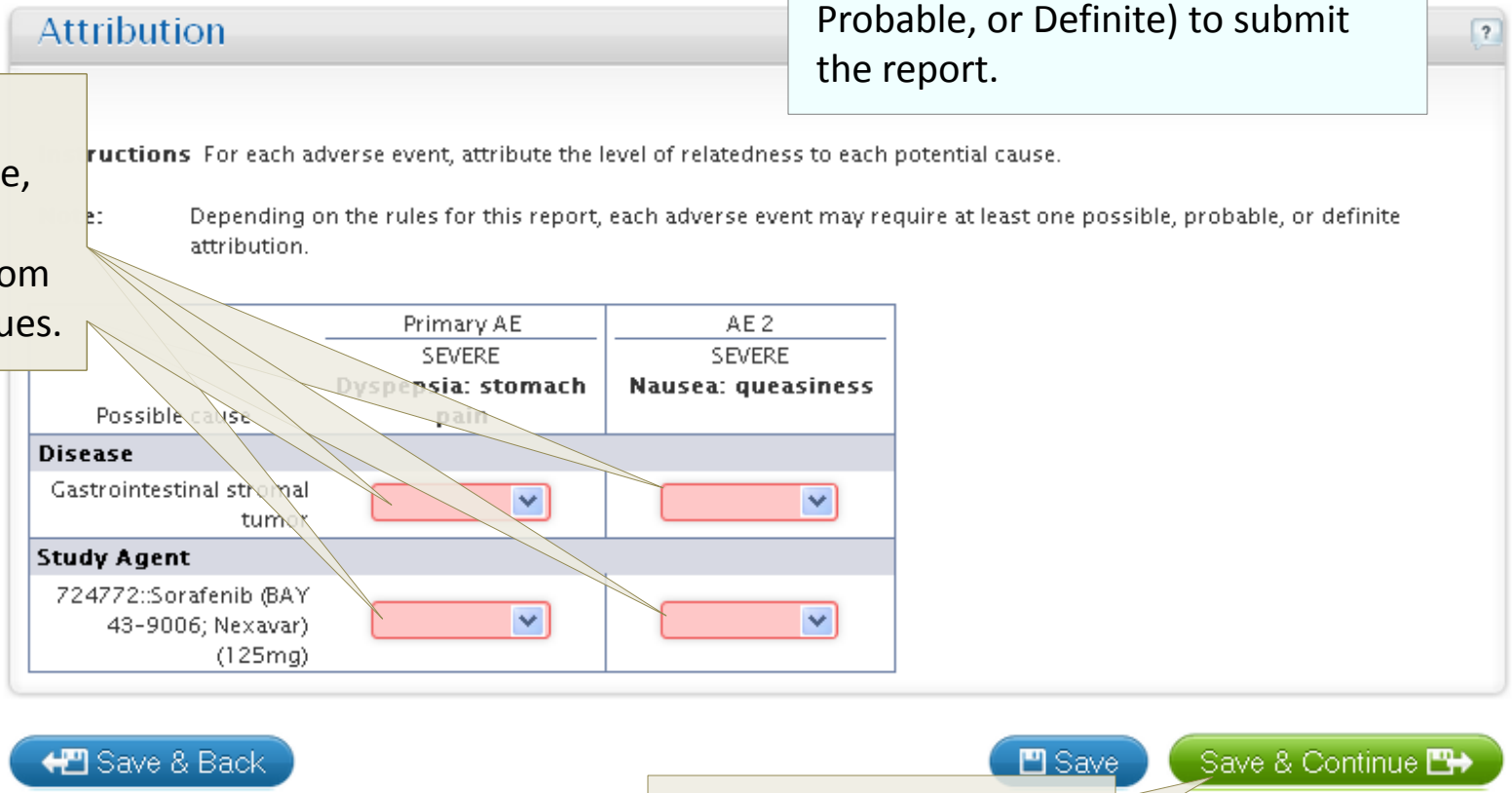
5. Click **Save & Continue**.

9. Attribution

Attribution

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

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

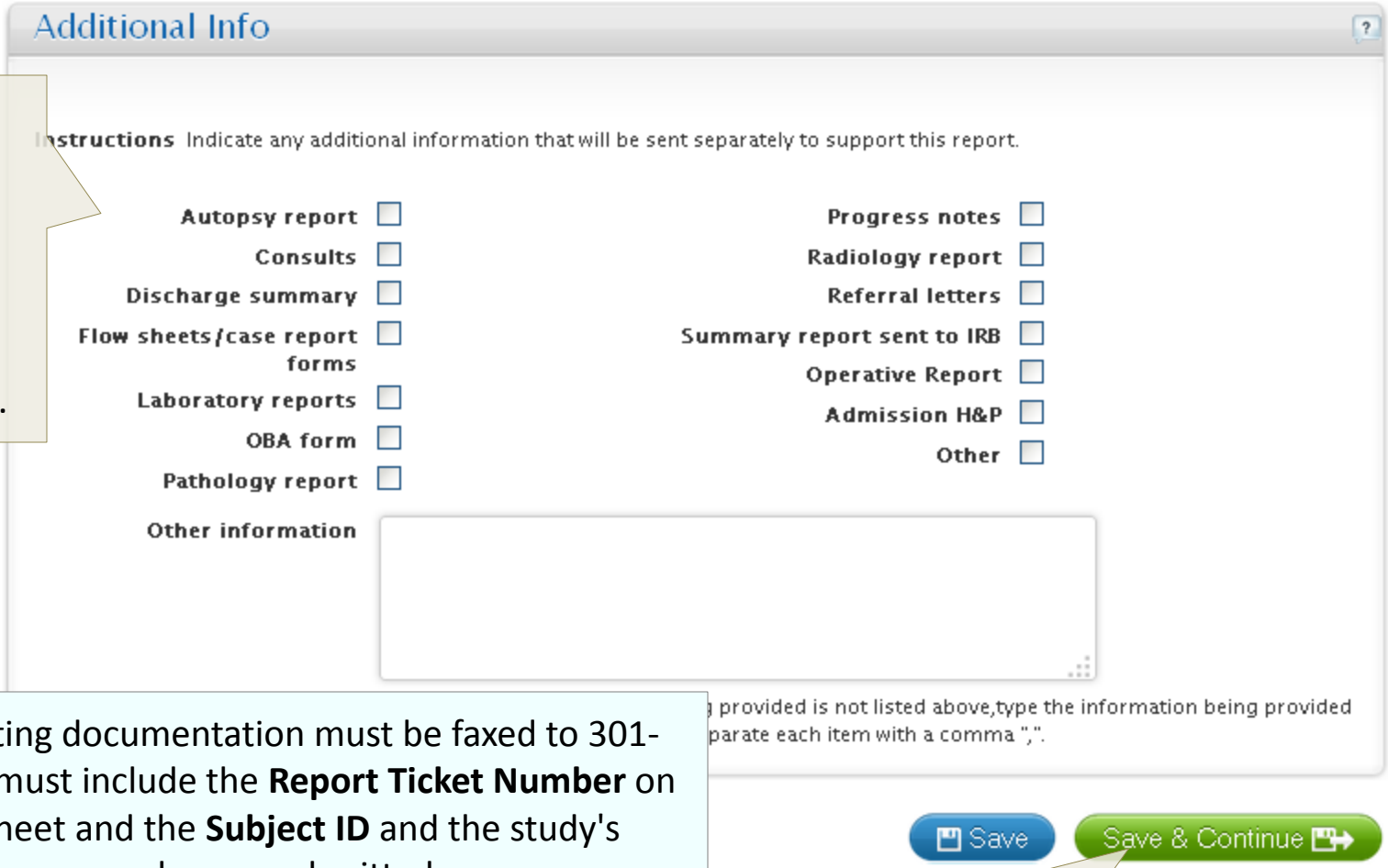


2. Click **Save & Continue**.

10. Additional Info

Additional Info

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.

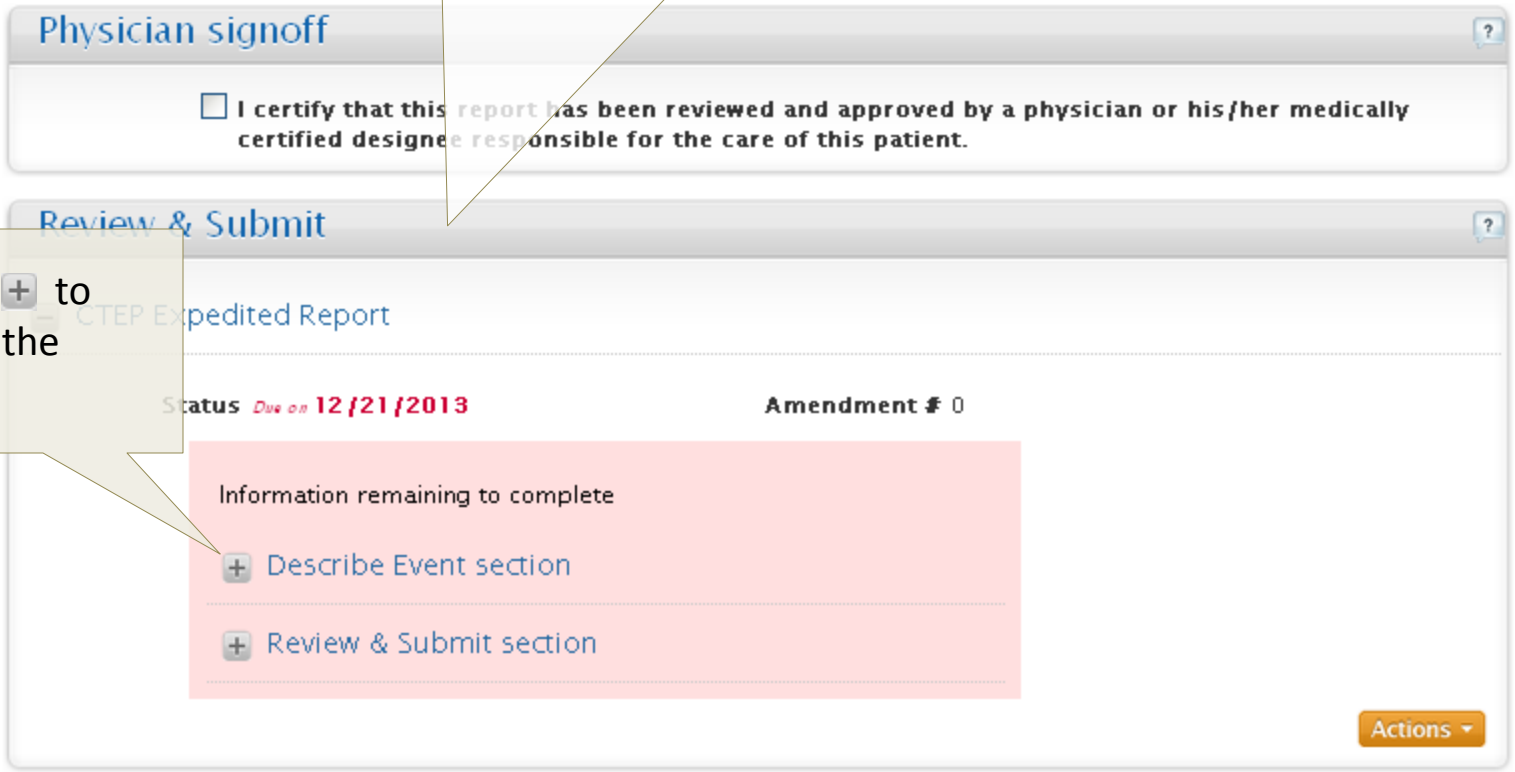
The **Additional Info** fields may not be available depending on the protocol and commercial agent reporting requirements.

3. Click **Save & Continue**.

11. Review & Submit

Review and Submit - Review and Physician Signoff

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



1. Click + to expand the section.

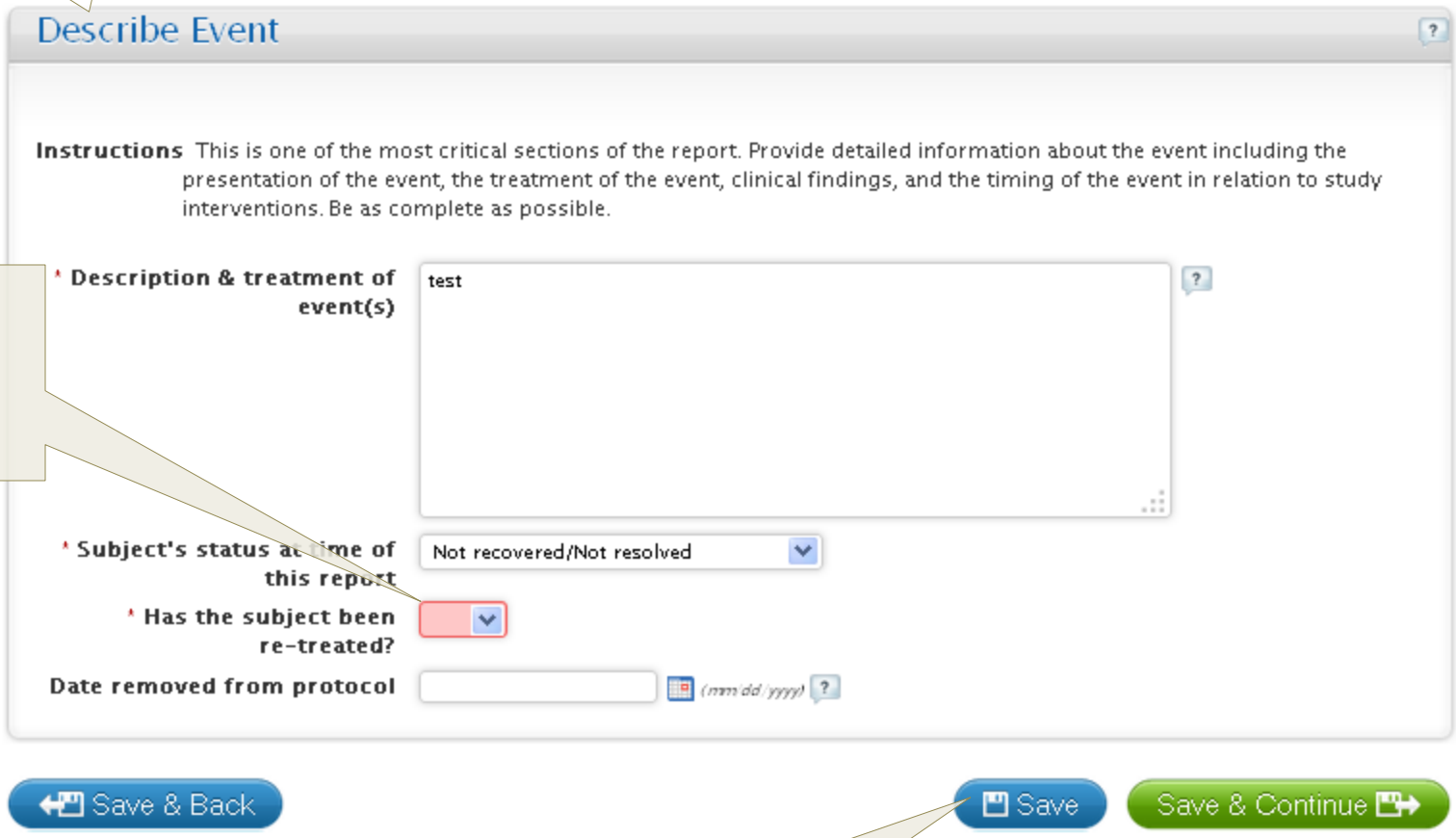
11. Review & Submit

Review and Submit - Review and Physician Signoff

2. Click “Go back to this page”.

11. Review & Submit — Review and Submit - Review and Physician Signoff

The page displays.



3. Add the required information.

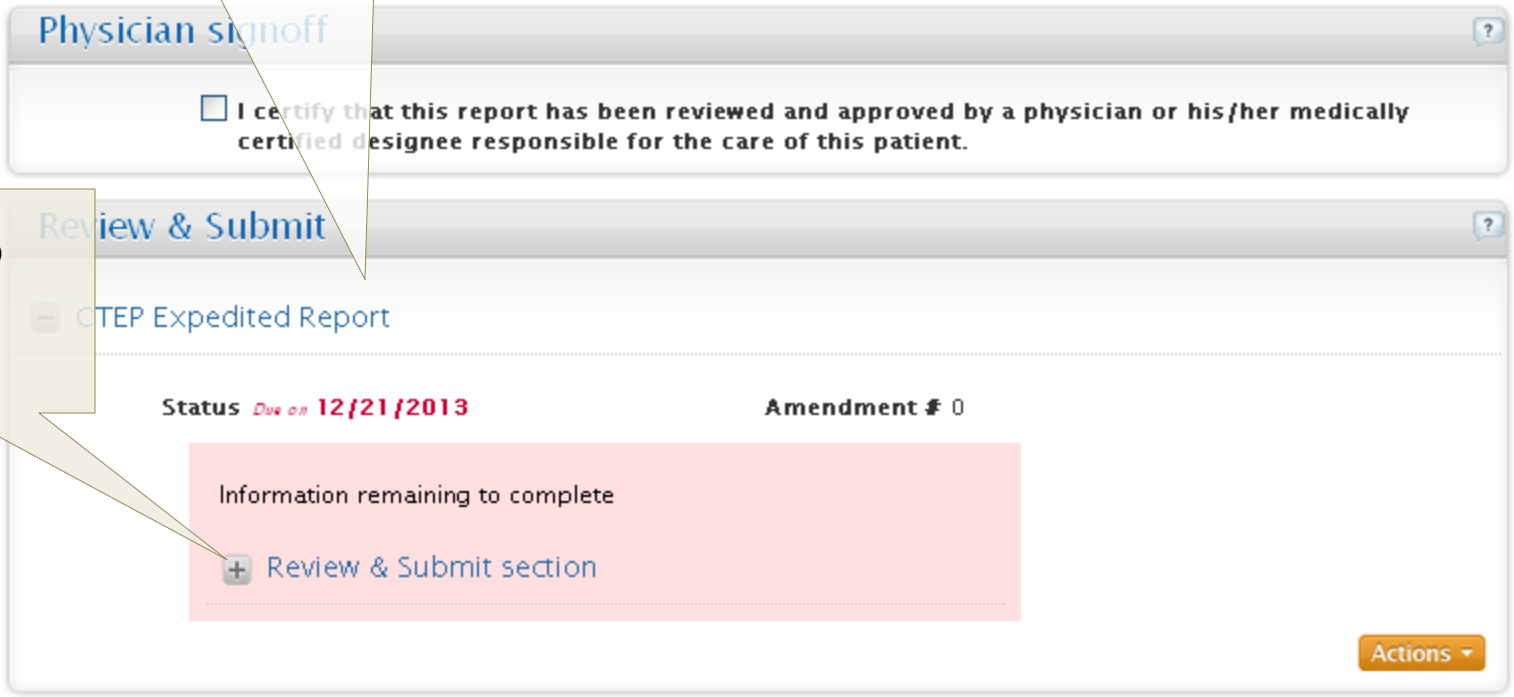
4. Click **Save**.

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

11. Review & Submit

Review and Submit - Review and Physician Signoff

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

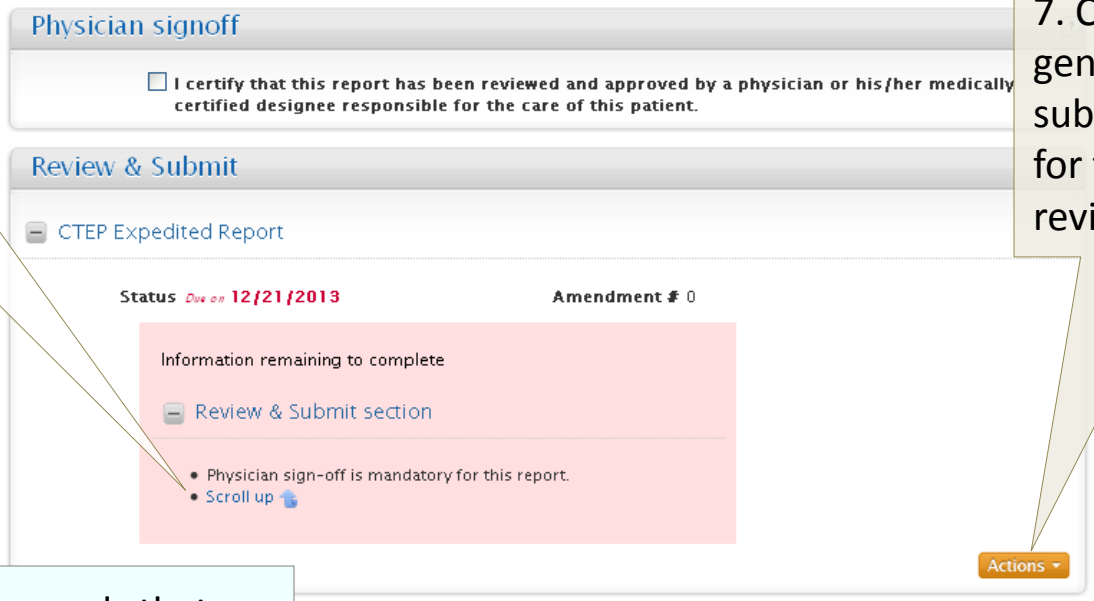


6. Click + to expand the section.

11. Review & Submit

Review and Submit - Review and Physician Signoff

The message indicates that the physician signoff must be completed.

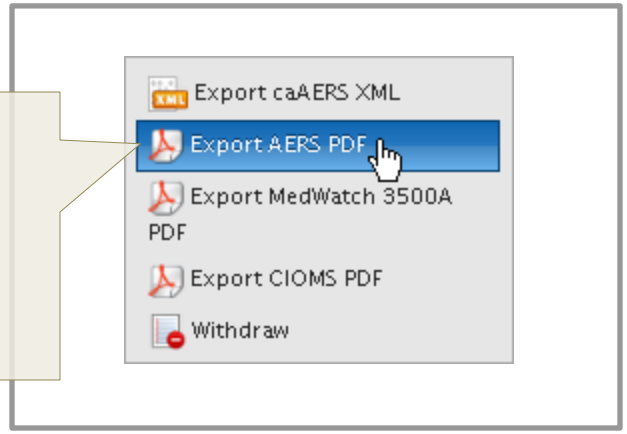


7. Click **Actions** to generate the pre-submission report for the physician's review.

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

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

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

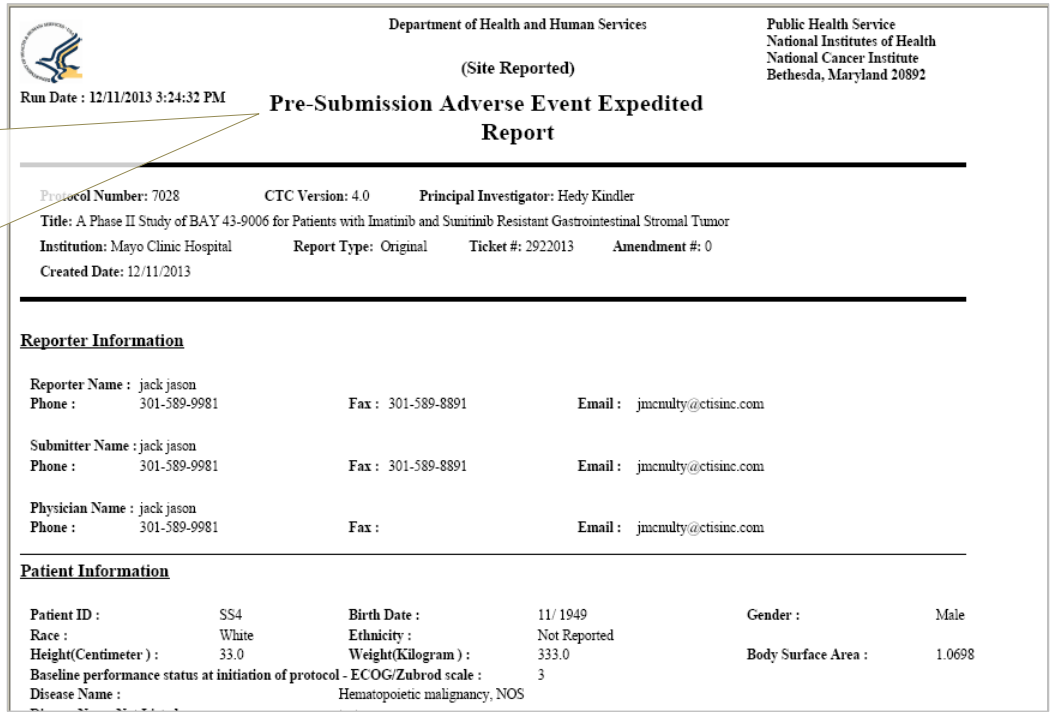


11. Review & Submit

Review and Submit - Review and Physician Signoff

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

Follow your site's processes to gain physician approval.



Department of Health and Human Services

Public Health Service
National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Run Date : 12/11/2013 3:24:32 PM

(Site Reported)

Pre-Submission Adverse Event Expedited Report

Protocol Number: 7028 **CTC Version:** 4.0 **Principal Investigator:** Hedy Kindler
Title: A Phase II Study of BAY 43-9006 for Patients with Imatinib and Sunitinib Resistant Gastrointestinal Stromal Tumor
Institution: Mayo Clinic Hospital **Report Type:** Original **Ticket #:** 2922013 **Amendment #:** 0
Created Date: 12/11/2013

Reporter Information

Reporter Name : jack jason
Phone : 301-589-9981 **Fax :** 301-589-8891 **Email :** jmcnulty@ctisinc.com

Submitter Name : jack jason
Phone : 301-589-9981 **Fax :** 301-589-8891 **Email :** jmcnulty@ctisinc.com

Physician Name : jack jason
Phone : 301-589-9981 **Fax :** **Email :** jmcnulty@ctisinc.com

Patient Information

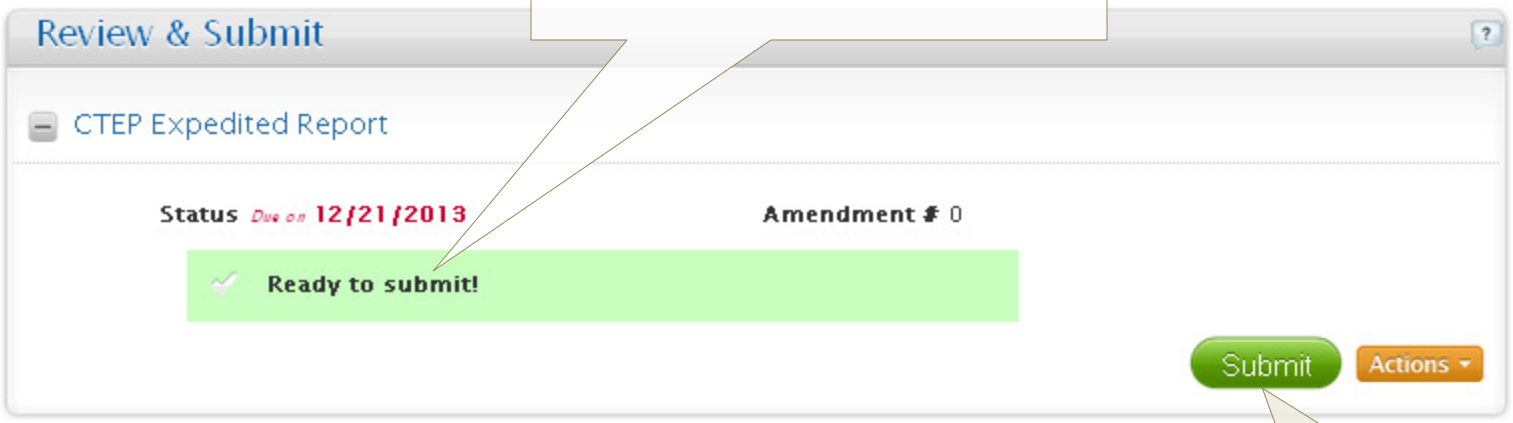
Patient ID :	SS4	**Birth Date :**	11/ 1949	**Gender :**	Male
Race :	White	**Ethnicity :**	Not Reported		
Height(Centimeter) :	33.0	**Weight(Kilogram) :**	333.0	**Body Surface Area :**	1.0698
Baseline performance status at initiation of protocol - ECOG/Zubrod scale :			3		
Disease Name :		Hematopoietic malignancy, NOS			

11. Review & Submit

Review and Submit - Review and Physician Signoff

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

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

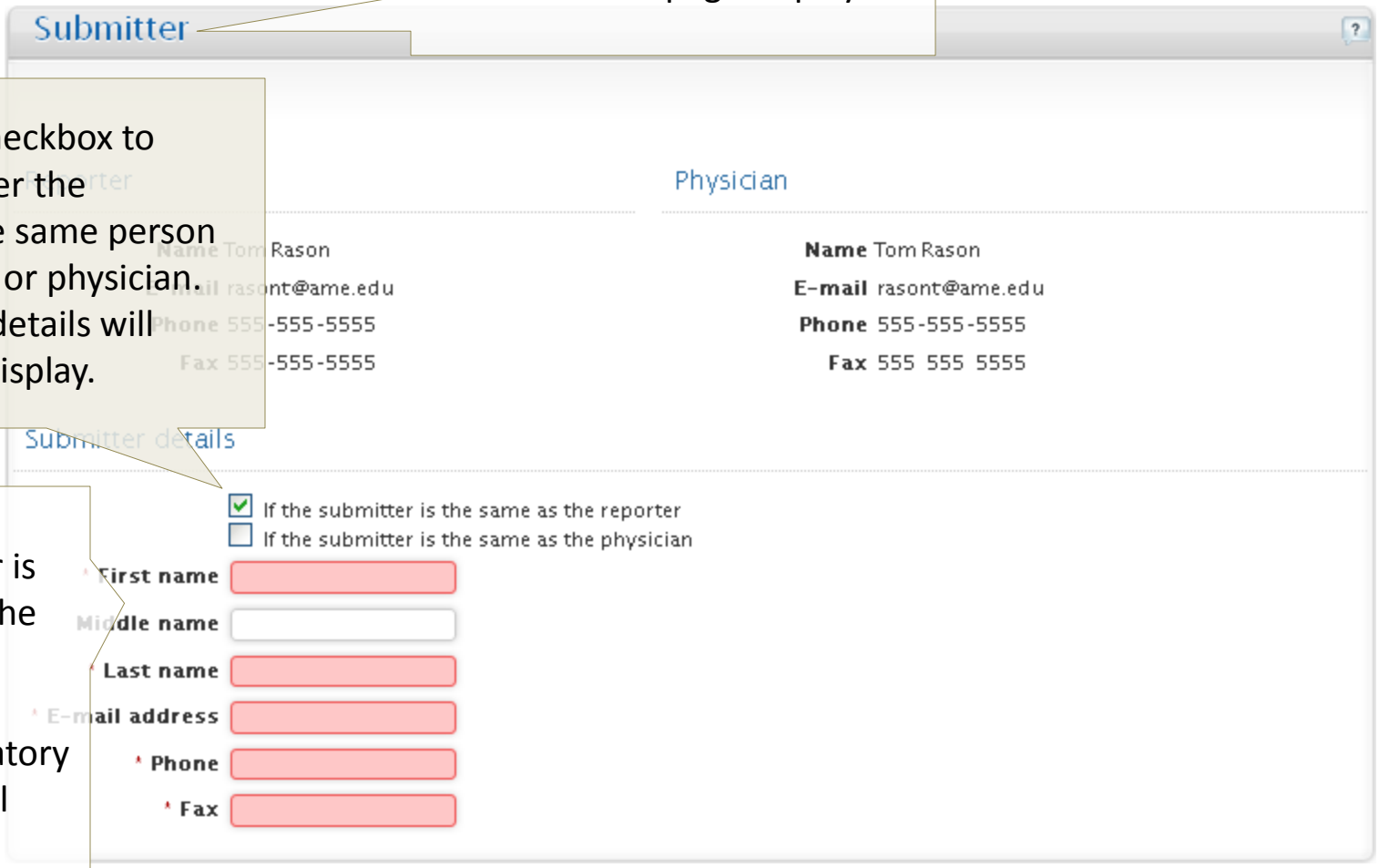


12. Click **Submit**.

11. Review & Submit

Review and Submit - Submitter

The **Submitter** page displays.



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

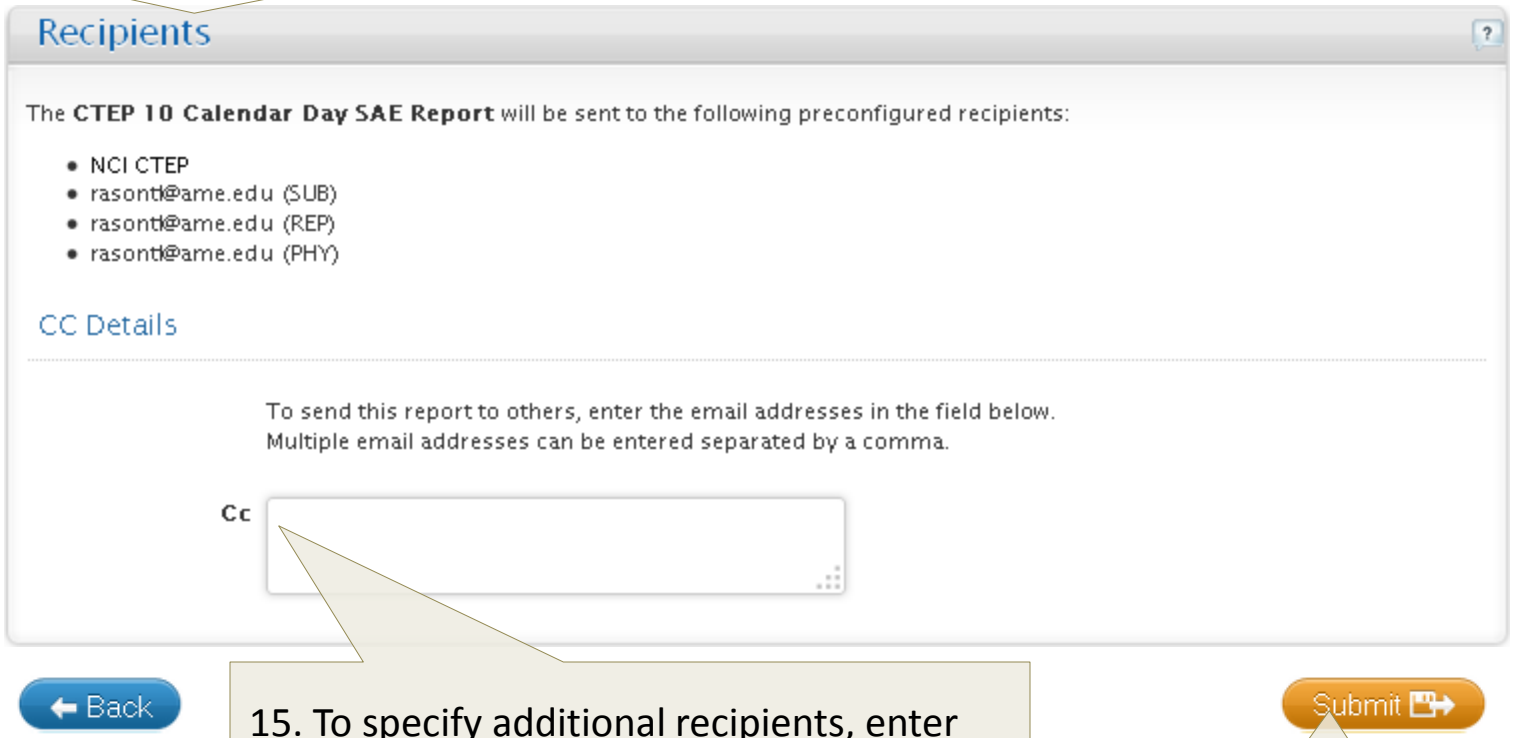
If the submitter is different than the reporter or physician, then enter all mandatory submitter detail fields.

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 comas to separate the addresses (do not use hard returns or semicolons).

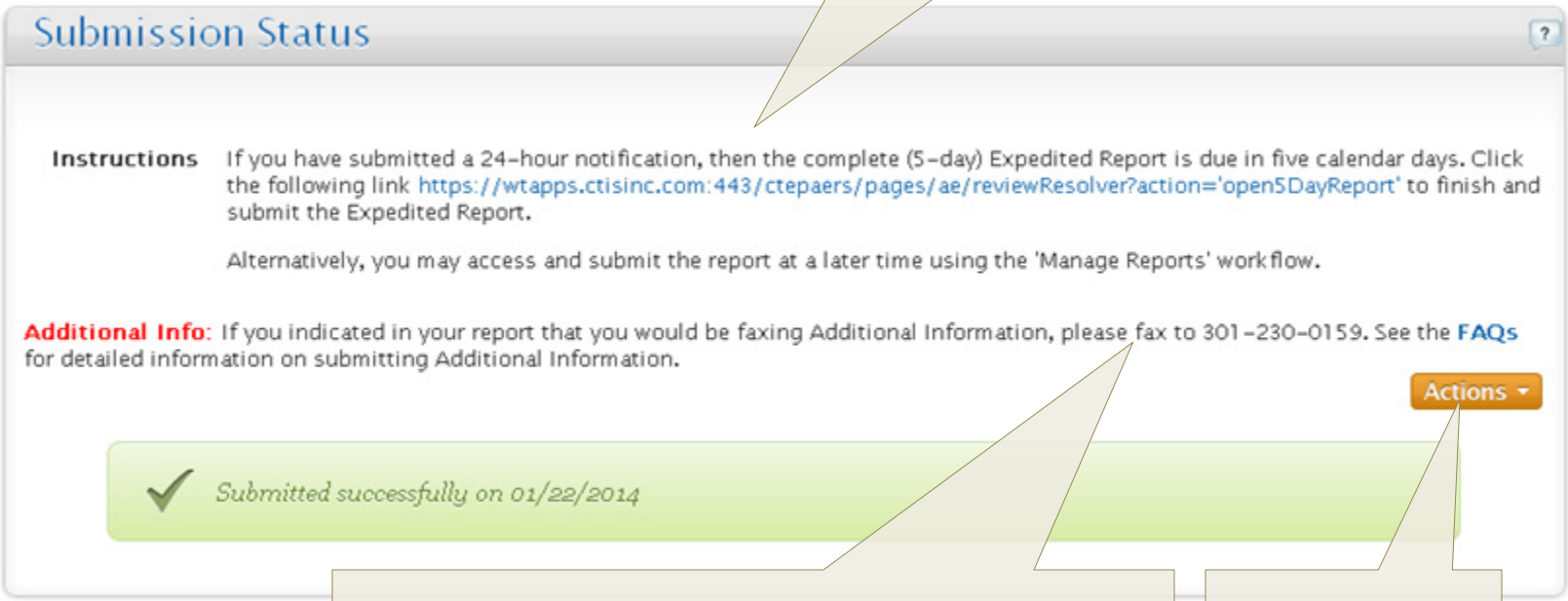
16. Click **Submit**.

11. Review & 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

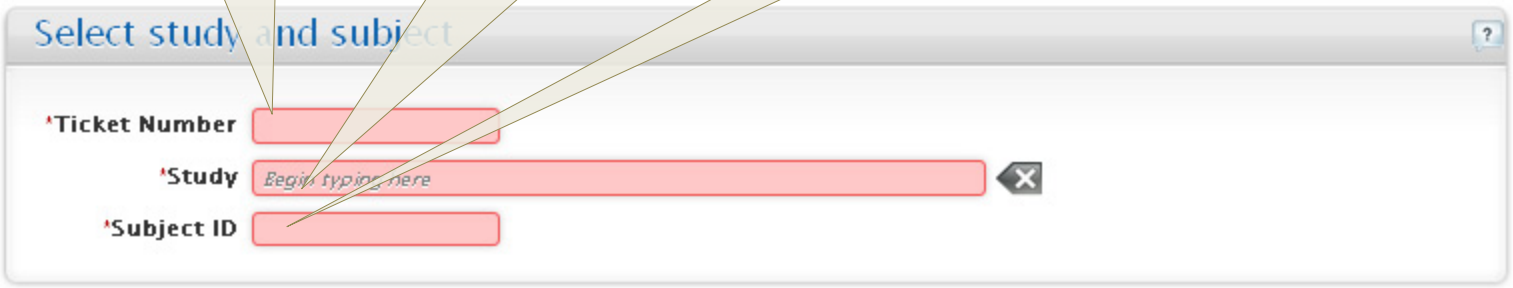
To complete or withdraw an initiated report or to amend a report, click **Manage Reports**.

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**.



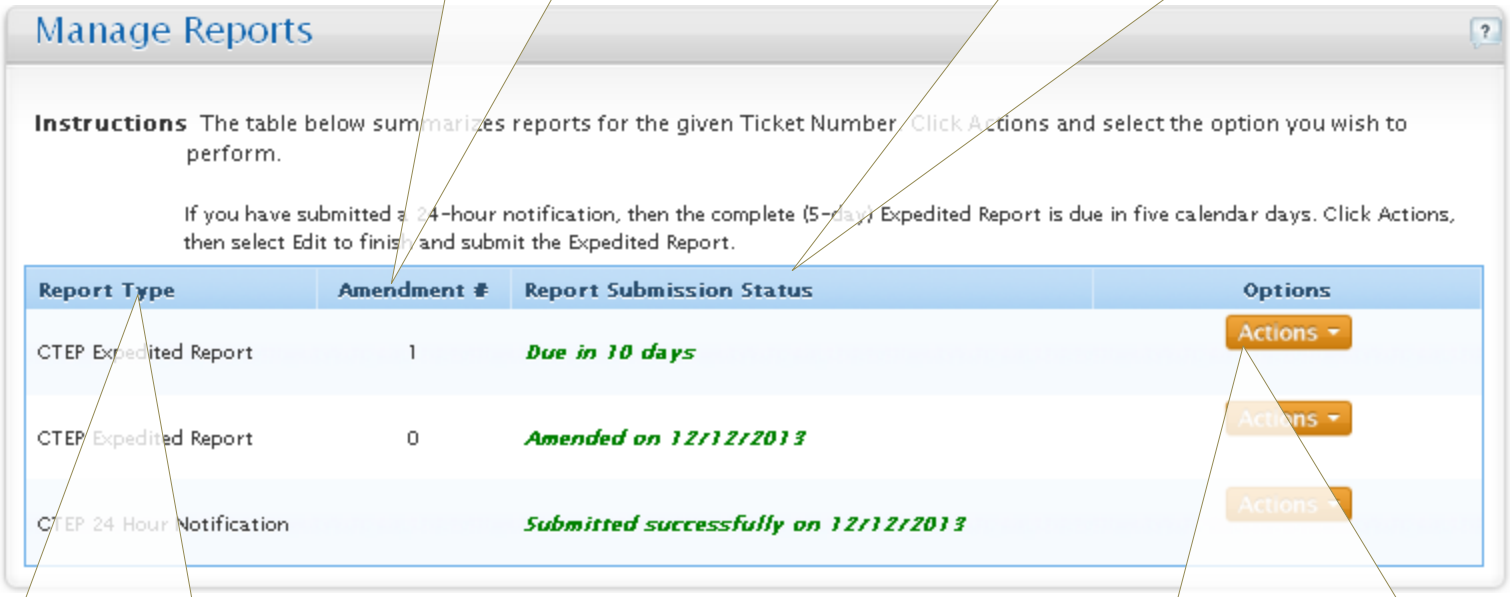
4. Click **Continue**.

Manage Report - Overview

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

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

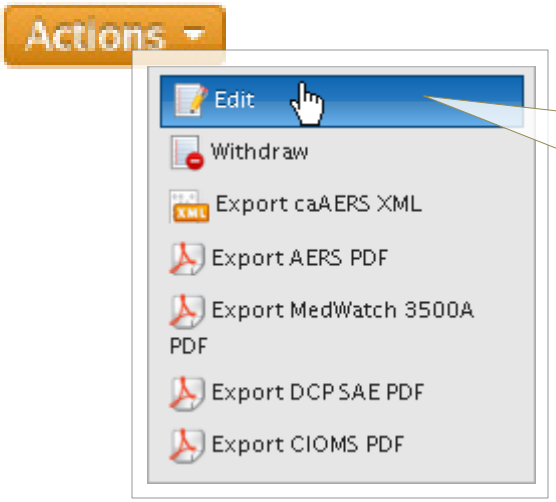
The Report Submission Status is listed here. Status values include: *Due in (number) Days*, the *Submission Response* or whether the report is *Withdrawn*, *Initiated*, *not submitted* or *Overdue*.



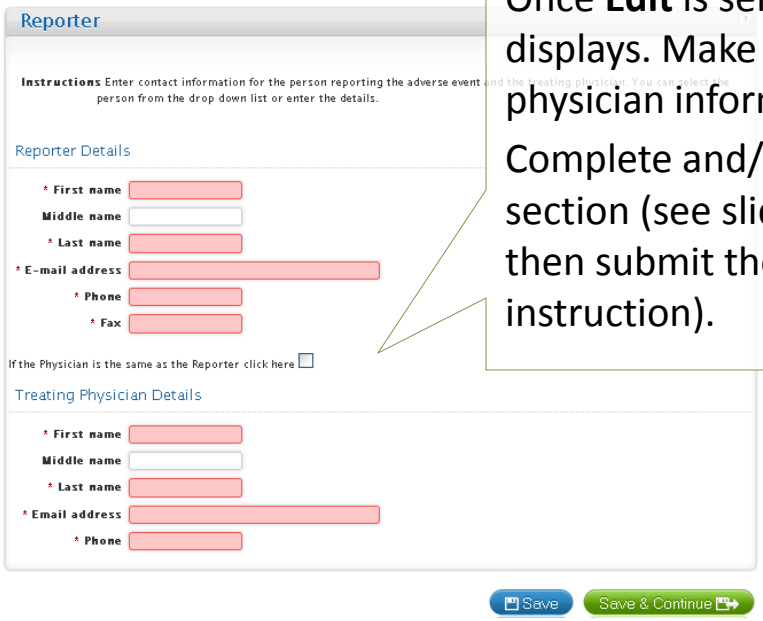
The **Report Type** displays *CTEP Expedited Report*, *CTEP 24-Hour Report* or other types depending on the protocol and report selected.

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

Manage Reports – Edit Option



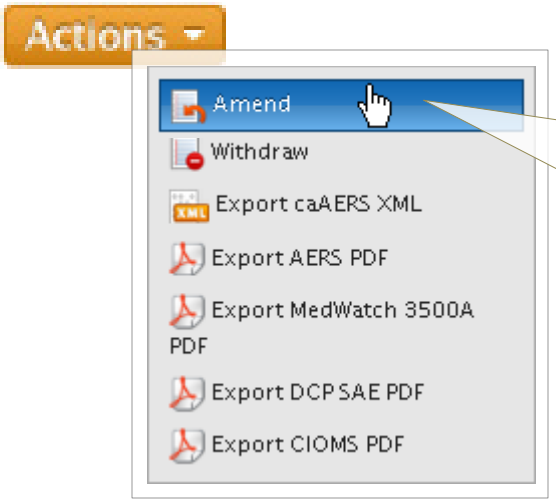
By selecting **Edit** from the options under the **Actions** button, you can add or modify information, then submit report.



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).

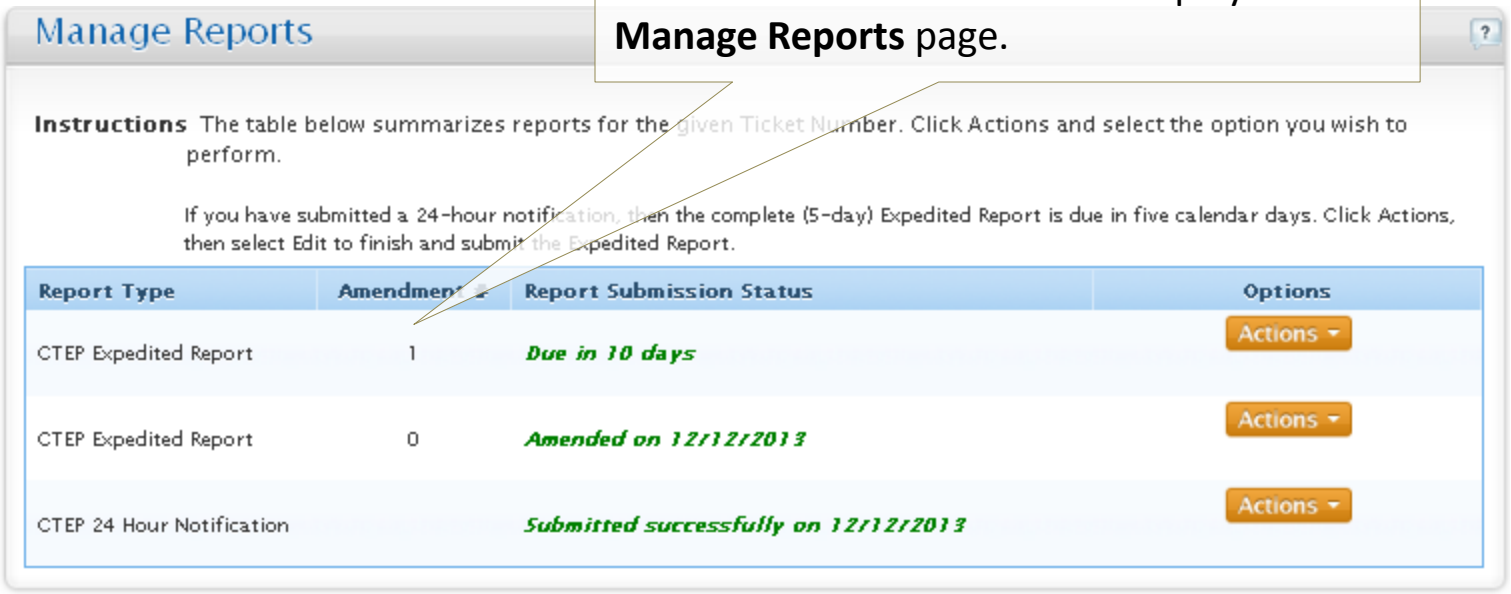
Manage Reports – Amend Option



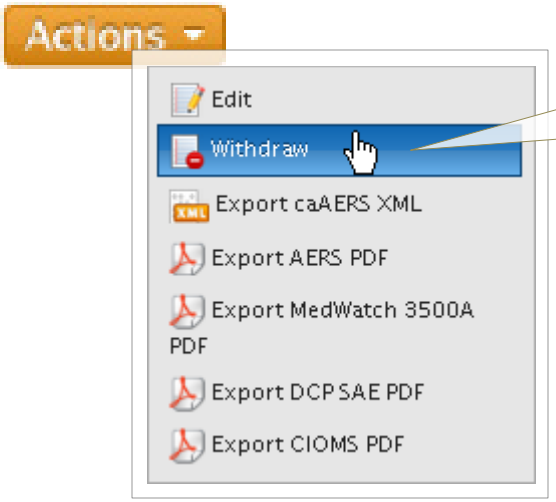
By selecting **Amend** from the options under the **Action** button, you can modify and submit a previously submitted report. Note that the 24-hour notification cannot be amended.

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

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

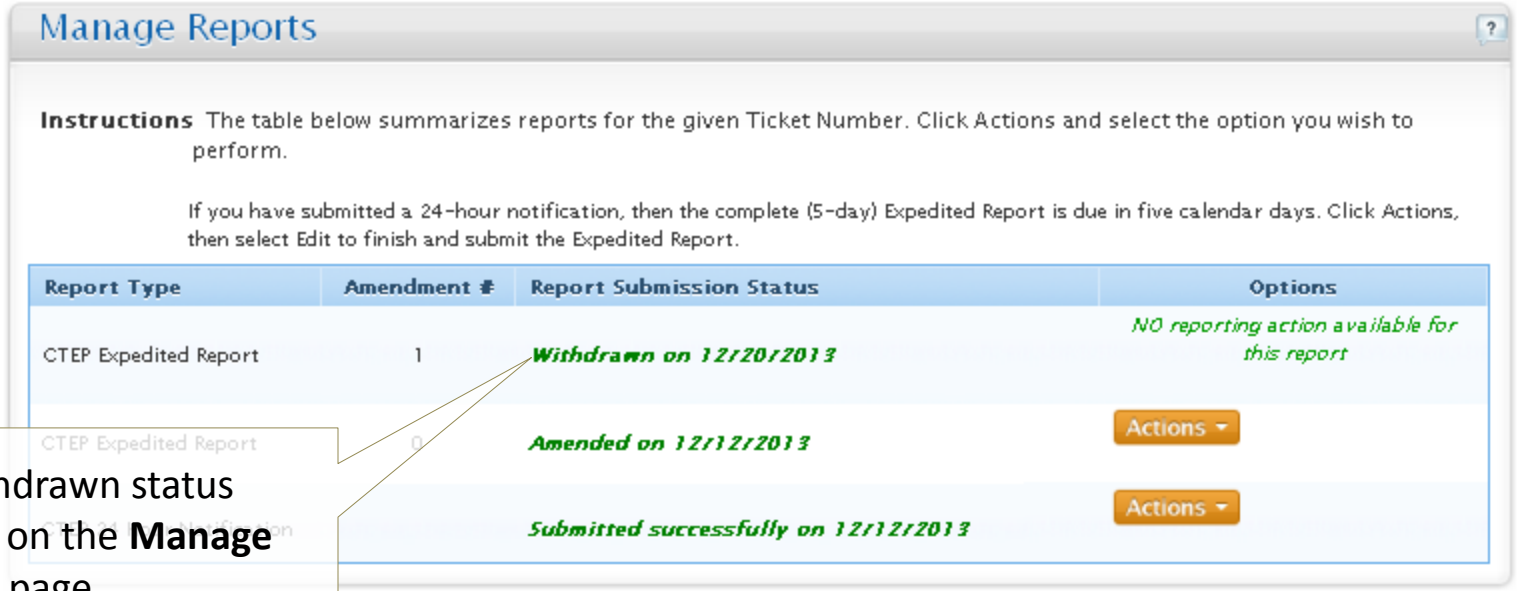


Manage Reports – Withdraw Option



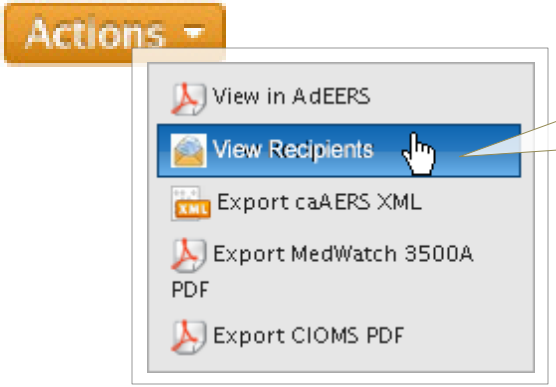
By selecting **Withdraw** from the options under the **Action** button, you can remove a pending report from the system.

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



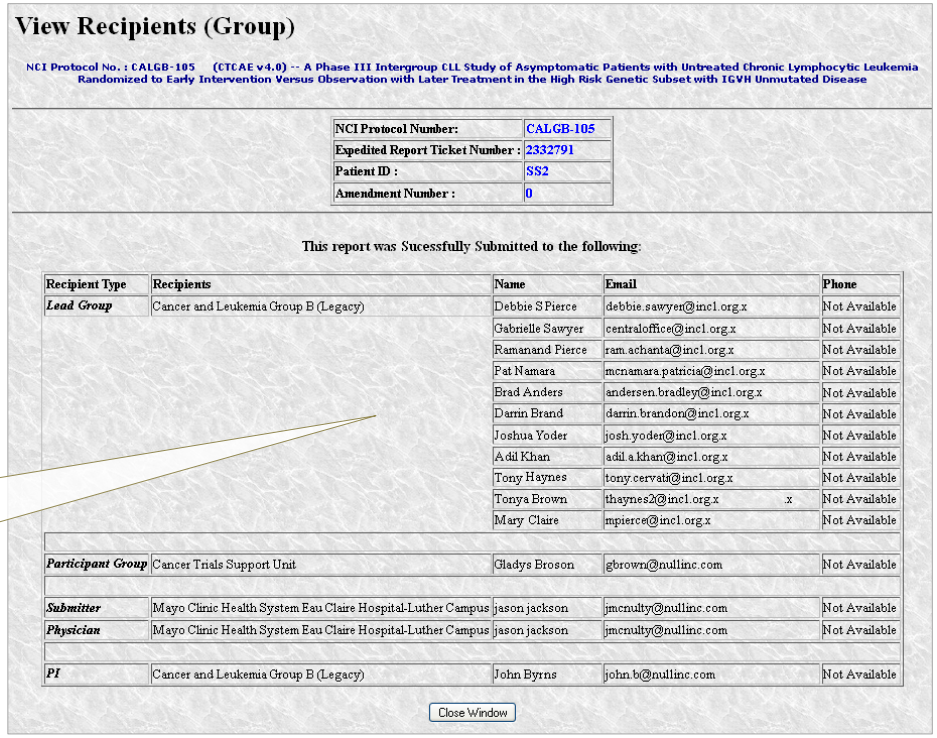
The withdrawn status displays on the **Manage Reports** page.

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.



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

The recipients display.

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

Additional Resources

NCI Guidelines for Investigators: Adverse Event Reporting Requirements for DCTD (CTEP and CIP) and DCP INDs and IDEs.
http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/aeguidelines.pdf

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

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

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

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