SWOG CANCER RESEARCH NETWORK

Expedited Reporting

A GUIDE TO SERIOUS ADVERSE EVENT REPORT SUBMISSION

NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

NCI National Clinical Trials Network

September 2024

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Tip: Use links to go to the different sections.

Definitions

Commonly Used Terms

CTCAE	The NCI **Common Terminology Criteria for Adverse Events (CTCAE)**. Provides a descriptive terminology that is to be utilized for AE reporting. A grading (severity) scale is provided for each AE term.
Date of Discovery	The date when you have the minimum information required to report an event (CTCAE term, grade, attribution to each protocol treatment, attribution to underlying cancer diagnosis).
Routine AE	**Routine Adverse Event.** An AE which does not meet the criteria for serious adverse event reporting.
Recommended Reporting Actions (**RAVE**)	The recommendation to report an SAE is based on basic reporting rules. *Note the recommendation is not always correct. SAE reporting should always be done in accordance with the criteria outlined in the protocol (or the 8/22/2024 CTEP Memo).
Recommended Actions (**CTEP-AERS)**	**Edit -** The report has been started but not submitted. **Create -** The report has yet to be started. **Amend -** The report has already been submitted but needs to be updated.
SAE	**Serious Adverse Event.** An AE that results in any of the following outcomes: Death, Life-threatening, Hospitalization/prolongation of hospitalization, Disability, Birth defect, Important medical event. Consult with protocol specific requirements to determine reportability.
Verbatim Term	The original wording provided by the patient or clinician to describe an event.

Types of Reports

24-Hour Notification

The 24-hour notification is required as an early detection system for potential safety problems. Its submission is due to the NCI within 24 hours of learning of an event.

5 Day Follow Up

Submit the complete CTEP-AERS Expedited Report within 5 calendar days after the 24-hour notification.

10 Day Follow Up

Submit the complete CTEP-AERS Expedited Report within 10 calendar days after the 24-hour notification.

10 Day Expedited Report

For Commercial Agent(s) Only: Due within 10 calendar days after notification of an event.

HOW LONG WILL A PENDING REPORT REMAIN IN THE SYSTEM?

5 Day Report

The unsubmitted report is automatically removed 8 days after the submission of the 24-Hour Notification.

10 Day Report

The unsubmitted report is automatically removed 11 days after the submission of the 24-hour Notification of the 10 Day Expedited report.

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Getting Started

Identify an Event

Confirm the following with the protocol:

- **Does the event meet the seriousness criteria and grade for the appropriate treatment arm assigned.**
- **Does the event require expedited reporting as an AESI?**
- **Is the event and grade listed on the SPEER exclusion list?**

Collect, at minimum, the required information to report the serious adverse event. (CTCAE term, grade, attribution to each protocol treatment, attribution to underlying cancer).

Enter the event(s) on the AE Report form in RAVE.

Complete the CTEP-AERS SAE report.

RAVE Entry

RAVE REPORTING PRECONDITIONS

THE FOLLOWING ITEMS ARE MANDATORY BEFORE ENTERING ADVERSE EVENTS INTO RAVE:

- Onstudy: Patient and Disease Description - Baseline and On Treatment Vital Status forms.
- The appropriate patient status form in order to roll out the course/cycle folder for the period for which the AE has occurred.
- Data entry on the previous cycle/course AE form, if applicable.

RAVE Entry

Entering the Adverse Event

Adverse Events: Assessment data

Enter course information data in the cycle in which the event occurred.

***If the event occurs mid-cycle, enter the current date as the cycle end date.**

RAVE Entry

Entering the Adverse Event, Continued

Enter Adverse Event data

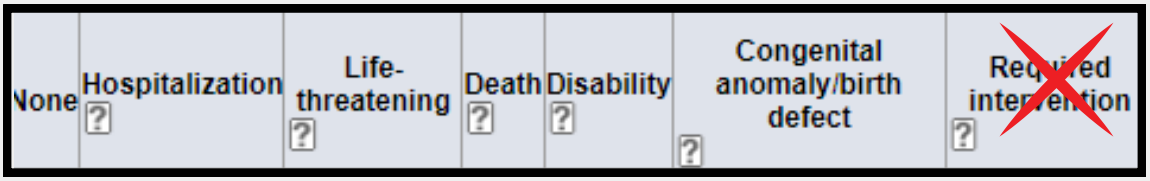
Page: **Adverse Events: Report - Cycle 01**

Form Instructions

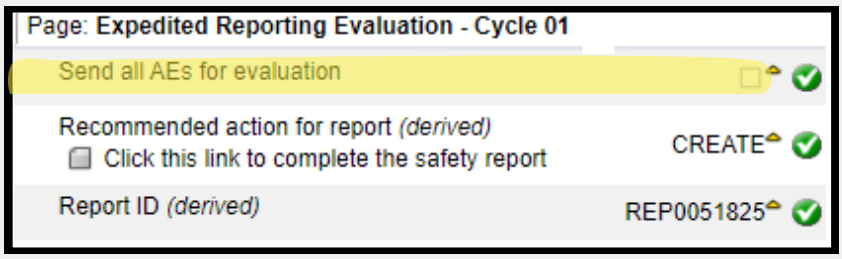
* Red asterisk before a field denotes that it is required by the system for rules evaluation.
* Start date of this course/cycle
* Start date of first course/cycle *(derived)*

#	*Adverse event term (CTCAE v5.0)	*Adverse event grade description *(first 120 characters)*	Attribution to study intervention	Treatment received for this AE	If yes, concomitant agent name	None	Hospitalization	Life-threatening	Death	Disability	Congenital anomaly/birth defect	Required intervention	Other	SAE report recommended *(derived)*
1	Lung infection	(3) IV antibiotic, antifungal, or antiviral intervention indicated; invasive intervention indicated	_	Yes	Oxygen, DuoNebs, Rocephin, Zosyn, azithromycin, morphine	☐	✓	☐	☐	☐	☐	☐	☐	No
2	Urinary tract infection	(3) IV antibiotic, antifungal, or antiviral intervention indicated; invasive intervention indicated	_	Yes	IV Rocephin, Zosyn, azithromycin	☐	✓	☐	☐	☐	☐	☐	☐	No
3	Hypoalbuminemia	(1) <LLN - 3 g/dL; <LLN - 30 g/L	_	No	_	✓	☐	☐	☐	☐	☐	☐	☐	No
4	White blood cell decreased	(2) <3000 - 2000/mm3; <3.0 - 2.0 x 10e9 /L	_	No	_	✓	☐	☐	☐	☐	☐	☐	☐	No
5	Neutrophil count decreased	(1) <LLN - 1500/mm3; <LLN - 1.5 x 10e9 /L	_	No	_	✓	☐	☐	☐	☐	☐	☐	☐	No
6	Pericardial effusion	(2) Asymptomatic effusion size small to moderate	_	No	_	✓	☐	☐	☐	☐	☐	☐	☐	No
7	Cardiac disorders - Other, specify (coronary artery disease)	(1) Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	_	No	_	✓	☐	☐	☐	☐	☐	☐	☐	No
8	Weight loss	(1) 5 to <10% from baseline; intervention not indicated	_	No	_	✓	☐	☐	☐	☐	☐	☐	☐	No

The seriousness criterion "Required Intervention" should only be used in DEVICE studies.



Send all AEs for evaluation on the *Expedited Reporting Evaluation Form*

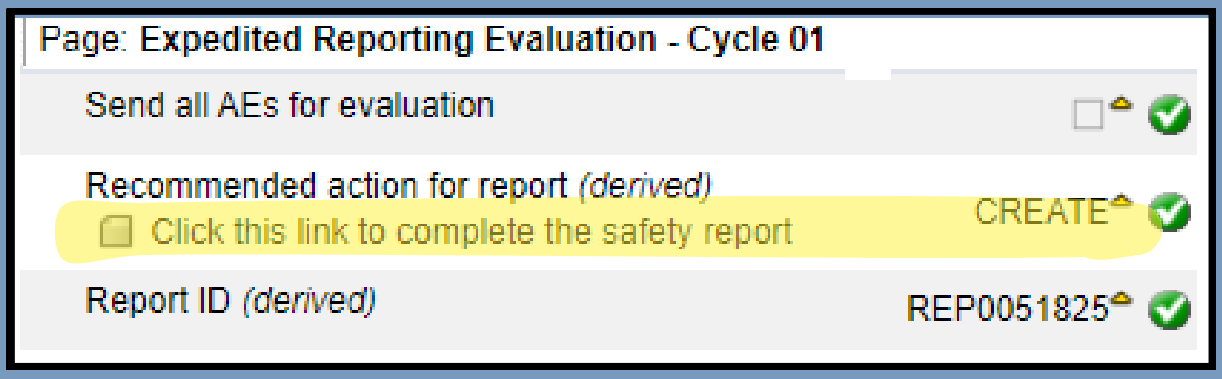


Navigating to CTEP-AERS

In the event an expedited report is recommended by CTEP-AERS or required per protocol requirements, the user will proceed to the CTEP-AERS system to complete the expedited reporting process.

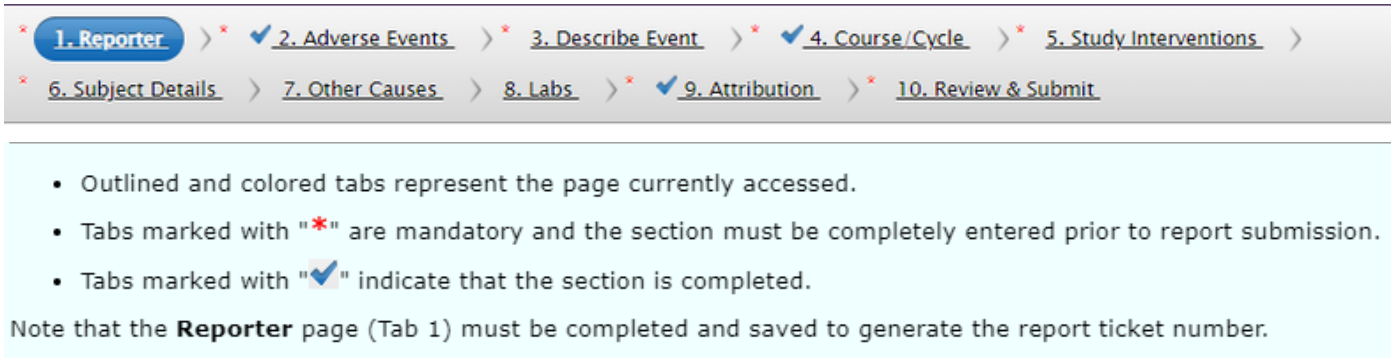
Users must access the CTEP-AERS application from RAVE when initializing a report, or when editing/amending* an already existing report by clicking on the link provided on the *Expedited Reporting Evaluation* form.

**When editing/amending a report with information not included in RAVE (CTCAE term, grade, attribution, or seriousness criteria), changes will be made directly within CTEP-AERS.*



CTEP-AERS

Completing the Report



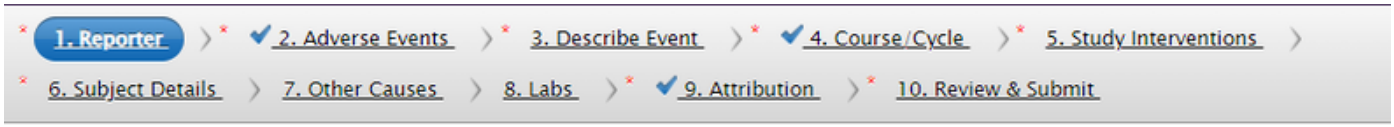
- Outlined and colored tabs represent the page currently accessed.
- Tabs marked with "*" are mandatory and the section must be completely entered prior to report submission.
- Tabs marked with "✔" indicate that the section is completed.

Note that the **Reporter** page (Tab 1) must be completed and saved to generate the report ticket number.

01	Reporter	Enter the contact information for both the Reporter and the Physician. If the treating physician is reporting the event, click in the box next to *If the Physician is the same as the Reporter.*
02	Adverse Events	Enter the verbatim term for those events to be included on the report. Deselect any events that should not be included in the report by clicking *Edit Adverse Events*.
03	Describe Event	Enter detailed information to evaluate the event(s). Include information for all of the events included on the report. Detailed information can include presentation of the event, treatment of the event, clinical findings, and timing of the event in relation to study interventions. Be as complete as possible.
04	Course/Cycle	This section describes the Course/Cycle the patient was on at the time of the serious adverse event(s).
05	Study Interventions	Add all protocol treatment the patient was randomized to here. *In the event the patient does not receive the intended treatment, “0” can be entered for the *Total Dose Administered.*

CTEP-AERS

Completing the Report, Cont.



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06	Subject Details	Enter the following information: General - demographic information about the patient Disease Information - information about the patient's primary, initial disease site Metastatic Disease Site - the location(s) of disease spread Pre-Existing Conditions - contributing medical conditions present in the patient prior to participating in the study Concomitant Medications - prescription and over-the-counter drugs that are relevant to the SAE Prior Therapies - relevant prior therapies for the underlying cancer
07	Other Causes	Enter information regarding any other circumstances possibly related to the event or other situations that may have contributed to the event.
08	Labs	Enter any labs pertinent to the adverse event(s).
09	Attribution	Enter the relationships (attributions) to the adverse event(s). ***There must be a minimum of one attribution of at least possibly related***
10	Review & Submit	Review the report for accuracy. If the SAE has been assessed by the Investigator, you may check the *Physician Signoff* box and submit the report.

CTEP-AERS

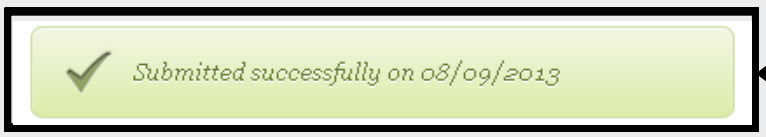
Submitting the Report

Any incomplete tasks will be shown in **RED** in Section 10 of the report. Click the + sign to expand the report section and read the description of any incomplete or incorrect items.

When all required information has been entered, and the Physician signoff box has been checked, you will be able to submit the report.

Ready to submit!

When the report has been submitted successfully, you will see the green checkmark.



Helpful Hints

There must be an attribution of at least possibly related EXCEPT when the event is *Death NOS* or *Sudden Death NOS*. Add an 'other cause' if the event is unrelated to protocol treatment and cancer.

There are two steps for reports that require 24-hour notification: the initial 24-hour notification and a second report due within 5 or 10 calendar days.

Death NOS should only be used when the death cannot be attributed to a Grade 5 CTCAE term.

All protocol treatments assigned to the patient should be included in the report, even if they do not receive their dose as intended. If they did not receive their dose, enter Total Dose Administered as "0."

If updating information that is not required in RAVE, amend the report directly in CTEP-AERS.

Additional Resources

SWOG.org SAE Page

CTEP-AERS Online Help

SWOG SAE Reporting Flowchart

RAVE - Expedited Safety Reporting Rules Evaluation

CTEP-AERS Start/End Date Guidance

CTCAE Version 5.0

CTEP-AERS Training Guide, Feb 2015

SAE Escape Room

NCI Guidelines: Adverse Event Reporting Requirements

Global Safety Update to Expedited Reporting

CTEP-AERS Help Desk Support

For technical questions, contact NCI Help Desk at:

- Email: ctephelpdesk@nih.gov
- Phone: 1.888.283.7457

For medical questions, contact the AEMD Help Desk at:

- Email: aemd@tech-res.com
- Phone: 301.897.7497

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Contact us for further inquiries

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