

Adverse Event Reporting




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SWOG Group Meeting
 Spring 2023









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Adverse Event (AE) Reporting: Outline







- Definitions and Background
- Relevant Information in SWOG Protocols
- Reporting Adverse Events
 - NCI Common Terminology Criteria for Adverse Events (CTCAE)
 - CTCAE grade (severity)
 - Attribution
 - Status code
- Online Data Submission: Adverse Events


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Definitions and Background

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Definition of Adverse Event



An **adverse event** is any unfavorable and unintended change in a patient's condition from the day protocol treatment began, regardless of cause.


An Adverse Event may be...

- A **new event** which was not pre-existing prior to initiation of study treatment
- A **pre-existing event which recurs** with increased severity (grade) or increased frequency following study drug administration
- An event present at the time of study drug administration which is **exacerbated** following initial study drug administration

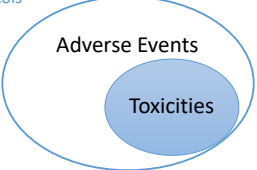



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Adverse Event versus Toxicity




A **toxicity** is an adverse event considered related or possibly related to the study drug or intervention.

Both terms may be used in SWOG protocols depending on the context; however, **patient assessments and reporting should encompass the broader category of adverse events.**

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Examples of Adverse Events



Which of the following should be reported as Adverse Events?


- Nausea or vomiting caused by study treatment
- Worsening of allergic rhinitis from seasonal allergies
- Wrist fracture due to fall
- Abnormal lab result that was not present at baseline
- Increasing tumor pain
- COVID-19 infection and related symptoms

Unless otherwise specified, **all grades of adverse events (1-5)**, including abnormal laboratory findings, **must be reported** on the study's Adverse Events Form (AE Form) regardless of clinical significance or attribution to protocol treatment.

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Serious Adverse Events (SAEs)



*A **Serious Adverse Event (SAE)** is an unexpected or severe reaction to protocol treatment.*


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Types of Adverse Event Reporting



Expedited reporting: reporting of adverse events meeting certain criteria (e.g. Serious Adverse Events and Adverse Events of Special Interest)

- Captured via Adverse Events eCRF and CTEP-AERS

Routine reporting: reporting of ALL adverse events, regardless of attribution or grade, unless otherwise specified

- Captured via Adverse Events eCRF at protocol-specified timepoints


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Importance of AE Reporting



Phase I trials

- Primary objective: accurately assess the safety of an experimental regimen and determine the maximum tolerated dose

Phase II single-arm trials

- Secondary objective: estimate the frequency and severity of toxicities in trial regimen

Phase II/III randomized trials


- Secondary objective: compare the frequency and severity of toxicities associated with each regimen

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AE Information in SWOG Protocols




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Relevant Protocol Sections

Section #	Section Name
3	Drug Information
8	Toxicities to be Monitored and Dosage Modifications
9	Study Calendar
14	Data Submission Schedule
16	Ethical and Regulatory Considerations

...and don't forget the Master Forms Set in CTSU!

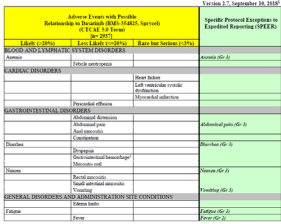







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Protocol Section 3.0 – Drug Information

- Includes information about study agents
- Lists known human toxicities for each study drug
 - Often presented in a *Comprehensive Adverse Events and Potential Risks (CAEPR) table*
 - Within the CAEPR are the Specific Protocol Exceptions to Expedited Reporting (SPEER)






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Protocol Section 8.0 – Toxicities to be Monitored and Dose Modifications

- Lists certain **toxicities** that may be seen on treatment and drugs to aid in **symptom management**
- Now includes **Adverse Event Reporting Requirements**
- Identifies version of Common Terminology Criteria for Adverse Events (**CTCAE**) used for study reporting
- Details **dosage changes** required during treatment in response to AEs
- Lists names and **contact information** of physicians to reach for assistance

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Example of Dose Modifications

Dose Modifications – Talazoparib (BMN 673)

Dose modifications should be made based on the observed toxicity, as summarized in the tables below.

DRUG	DOSE LEVEL	DOSE
Talazoparib	Full	1000 mcg/day
BMN 673	-1 Level	750 mcg/day
	-2 Level	500 mcg/day
	-3 Level	250 mcg/day
	-4 Level	Discontinue

Toxicity	Dose Modification
Grade 3	No hold on treatment required; treatment may continue at next lower dose
Grade 4	Hold protocol treatment until resolution to ≤ Grade 2; treatment may then resume at the next lower dose

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Protocol Section 9.0 – Study Calendar

9.0 STUDY CALENDAR

	Before Randomization Step 2	Treatment*				Interim Cycle	CR T1: Pre-progression follow-up	CR T1: Post-progression follow-up
		Cycle 1	Cycle 2	Cycle 3	Cycle 4			
PHYSICAL								
History & Physical Exam	X	X	X	X	X	X	X [†]	X [†]
Weight & Subject Performance	X	X	X	X	X	X		
ECOG	X	X	X	X	X	X [†]	X [†]	
Chemical Assessment	X							
Baseline Laboratory Assessment	X							
Toxicity Assessment	X	X	X	X	X	X	X [†]	X [†]

C: Toxicity assessment must continue until 30 days after the last dose of protocol treatment or until resolution of all acute adverse events, whichever is later.





- Assessments required where X is present
- Refer to study calendar footnotes for additional details
- Report all AEs through the *end-of-cycle* assessment
- “Late Adverse Events” may be captured during follow-up

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Protocol Section 16.0 – Ethical and Regulatory Considerations

- Includes information regarding informed consent, IRB, drug accountability, and monitoring
- Adverse Event Reporting Requirements (older SWOG protocols)

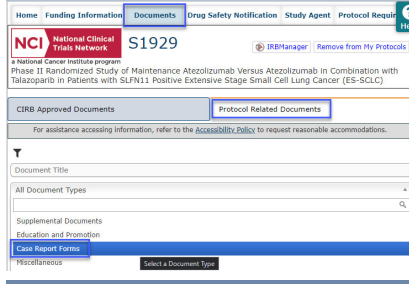









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Master Forms Set (All CRFs)

Available via CTSU (Document Type = Case Report Forms)

Contains all case report forms for a particular protocol, including those used to report adverse events

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Master Forms Set (All CRFs)

SWOG S2007 ADVERSE EVENTS

Instructions: Please complete this form after each cycle (post cycle > 21 days). Report adverse events occurring up until the next cycle of treatment begins. Document the worst Grade seen during the reporting period. Do not code a condition existing prior to registration as an adverse event unless it worsens, or improves and then recurs during a different cycle. An adverse event which improves and then recurs during a different cycle should be reported each cycle it recurs. Indicate if the adverse event results in hospitalization or discontinuation of therapy. Report duration for all events. Please refer to section 16.0 of the protocol for reporting requirements on this form. Categories listed may not include all adverse events from that category. Record any observed adverse events not listed on the status form of the event. Code in the SWOG XXXX format. Explain any blank dates or fields in the Comments section.

Reporting period start date (Day - of month - year)





Reporting period end date (Day - of month - year)

Was adverse event assessed during this time period? Yes No


If yes, did the patient experience any adverse events during this reporting period? (If yes, please complete AE Reporting form) Yes No

Date of most recent adverse event assessment

Adverse event grade (CTCAE v4.0)	Adverse event	Adverse event onset date (MM/DD/YYYY)	Adverse event end date (MM/DD/YYYY)	Adverse event severity (Grade)	Adverse event duration (Days)	Adverse event site	Adverse event description	Adverse event outcome	Adverse event action	Adverse event comment
	Neutropenia									
	Platelet thrombocytopenia									
	Adverse event									
	Constipation									
	Diarrhea									
	Nausea									
	Vomiting									
	Fatigue									
	Postoperative pain									
	Death postdate									
	Upper respiratory infection									








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Reporting Adverse Events

Common Terminology Criteria for Adverse Events (CTCAE)






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Reporting Adverse Events: NCI Common Terminology Criteria for Adverse Events (CTCAE)

- CTCAE versions and other AE reporting resources are found at ctep.cancer.gov
 - Version 5.0 published in November 2017
 - Used for all SAE reporting (April 2018 to present)
 - Used for routine AE reporting for newer SWOG protocols
- Some studies may use a different CTCAE version for routine AE reporting vs. SAE reporting




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CTCAE Term	Immune system disorders				
	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Allergic reaction Definition: A disorder characterized by an adverse local or general response from exposure to an allergen. Navigation Note: If related to infusion, use Injury, poisoning and procedural complications; Infusion related reaction. Do not report both.	Systemic intervention not indicated	Oral intervention indicated	Bronchospasm; hospitalization indicated for clinical sequelae; intravenous intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Anaphylaxis Definition: A disorder characterized by an acute inflammatory reaction resulting from the release of histamine and histamine-like substances from mast cells, causing a hypersensitivity immune response. Clinically, it presents with breathing difficulty, dizziness, hypotension, cyanosis and loss of consciousness and may lead to death. Navigation Note: -	-	-	Symptomatic bronchospasm, with or without urticaria; parenteral intervention indicated; allergy-related edema/angioedema; hypotension	Life-threatening consequences; urgent intervention indicated	Death
Autoimmune disorder Definition: A disorder characterized by loss of function or tissue destruction of an organ or multiple organs, arising from humoral or cellular immune responses of the individual to his own tissue constituents. Navigation Note: Prior to using this term consider specific autoimmune AEs	Asymptomatic; serologic or other evidence of autoimmune reaction, with normal organ function; intervention not indicated	Evidence of autoimmune reaction involving a non-essential organ or function (e.g., hypothyroidism)	Autoimmune reactions involving major organ (e.g., colitis, anemia, myocarditis, kidney)	Life-threatening consequences; urgent intervention indicated	Death
Cytokine release syndrome Definition: A disorder characterized by fever, tachypnea, headache, tachycardia, hypotension, rash, and/or hypoxia caused by the release of cytokines. Navigation Note: Also consider reporting other organ dysfunctions including neurological toxicities such as: Psychiatric disorders; Hallucinations or Confusion; Nervous system disorders; Seizure, Dysphasia, Tremor, or Headache	Fever with or without constitutional symptoms	Hypotension responding to fluids; hypoxia responding to <40% O2	Hypotension managed with one pressor; hypoxia requiring ≥ 40% O2	Life-threatening consequences; urgent intervention indicated	Death
Serum sickness Definition: A disorder characterized by a delayed-type hypersensitivity reaction to foreign proteins derived from an animal serum. It occurs approximately six to twenty-one days following the administration of the foreign antigen. Symptoms include fever, arthralgia, myalgia, skin eruptions, lymphadenopathy, chest marked discomfort and dyspnea. Navigation Note: -	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate arthralgia; fever, rash, urticaria, antihistamines indicated	Severe arthralgia or arthritis; extensive rash; steroids or IV fluids indicated	Life-threatening consequences; pressor or ventilatory support indicated	Death

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Reporting Adverse Events: CTCAE Terms

- CTCAE terms might not always be listed the way that you expect. Below are some examples of common AEs and their appropriate CTCAE v5.0 term:
 - Pneumonia → Lung infection
 - Thrombocytopenia → Platelet count decreased
 - Shortness of breath → Dyspnea
- Each system category includes an “Other, specify” option in the rare case there is no term is available for an adverse event. Please use “other” sparingly!




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Reporting Adverse Events: COVID-19

- Document COVID-19 infection as an adverse event as follows:
 - CTCAE Term = Infections and infestations - Other, specify
 - Specify = COVID-19
- Report any other AEs that the patient experiences
- If applicable, report via CTEP-AERS

Additionally, the following trials also require the first positive COVID-19 test to be reported on the COVID-19 Diagnosis form in RAVE:

S1418, S1501, S1826, S1918, and S1925




  

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Reporting Adverse Events: CTCAE Grade

The CTCAE displays Grades 1 through 5 with unique clinical descriptions of severity for each AE based on this general guideline:

- Grade 1** Mild
- Grade 2** Moderate
- Grade 3** Severe or medically significant but not immediately life threatening
- Grade 4** Life-threatening consequences
- Grade 5** Death related to AE

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CTCAE Term	Blood and lymphatic system disorders				
	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Anemia	Hemoglobin (mg) <11N - 10.0 g/dL; <11N - 6.2 mmol/L <11N - 100 g/L	Hgb <10.0 - 9.0 g/dL; <6.2 - 4.9 mmol/L; <100 - 80g/L	Hgb <8.0 g/dL; <4.9 mmol/L; <80 g/L; transfusion indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a reduction in the amount of hemoglobin in 100 ml of blood. Signs and symptoms of anemia may include pallor of the skin and mucous membranes, shortness of breath, palpitations of the heart, soft systolic murmurs, lethargy, and fatigability.					
Navigational Note: -					
Bone marrow hypocellular	Mildly hypocellular or <=25% reduction from normal cellularity for age	Moderately hypocellular or >25 - <50% reduction from normal cellularity for age	Severely hypocellular or >50 - <=75% reduction cellularity from normal for age	Aplastic persistent for longer than 2 weeks	Death
Definition: A disorder characterized by the inability of the bone marrow to produce hematopoietic elements.					
Navigational Note: -					
Disseminated intravascular coagulation	-	Laboratory findings with no bleeding	Laboratory findings and bleeding	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by systemic pathological activation of blood clotting mechanisms which results in clot formation throughout the body. There is an increase in the risk of hemorrhage as the body is depleted of platelets and coagulation factors.					
Navigational Note: -					
Eosinophilia	>10N and >baseline	-	Steroids initiated	-	-
Definition: A disorder characterized by laboratory test results that indicate an increased number of eosinophils in the blood.					
Navigational Note: -					
Febrile neutropenia	-	-	ANC <1000/mm ³ with a single temperature of >=38.3 degrees C (101 degrees F) or a sustained temperature of >=38 degrees C (100.4 degrees F) for more than one hour	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an ANC <1000/mm ³ and a single temperature of >=38.3 degrees C (101 degrees F) or a sustained temperature of >=38 degrees C (100.4 degrees F) for more than one hour.					
Navigational Note: -					
Hemolysis	Laboratory evidence of hemolysis only (e.g., direct antiglobulin test; DAT; Coombs'; schistocytes; decreased haptoglobin)	Evidence of hemolysis and >=2 g decrease in hemoglobin	Transfusion or medical intervention indicated (e.g., steroids)	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by laboratory test results that indicate widespread erythrocyte cell membrane destruction.					
Navigational Note: -					

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Reporting Adverse Events: Attribution

The attribution code describes, **in the opinion of the investigator**, how likely it is that the adverse event is due to protocol treatment:

Relationship	Attribution	Description
Unrelated to Investigational Agent/Intervention	1- Unrelated	The AE is <i>clearly not</i> related to the intervention
	2- Unlikely	The AE is <i>doubtfully</i> related to the intervention
Related to Investigational Agent/Intervention	3- Possible	The AE <i>may be</i> related to the intervention
	4- Probable	The AE is <i>likely</i> to be related to the intervention
	5- Definite	The AE is <i>clearly</i> related to the intervention




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Reporting Adverse Events: Status Code

Some SWOG studies will collect **status** in addition to grade and attribution. The status code describes the state of the adverse event at various points throughout the study.


Status Codes range from 1 to 3:

- 1 = New
- 2 = Continues at same or lower grade
- 3 = Increased grade OR improved then worsened

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Additional AE Data Collection Items




Some additional data items may be collected for AE reporting purposes:

- Serious?
- Hospitalization?
- Is the AE immune-related?
- Onset date
- Resolution date
- Ongoing?
- Action taken with study drug
- Outcome of AE
- Treatment received for AE?

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General Rules for AE Reporting




- Record and report adverse events as they occur
- Unless otherwise stated in the protocol...
 - Report all adverse events, regardless of attribution or clinical significance
 - After each treatment cycle or reporting period, report the most severe grade experienced during the cycle
- Avoid using "Other, specify" for reporting, unless no specific CTCAE term applies
- Know your protocol and ensure events are reported in the required timeframe, whether routine or expedited
- When in doubt, reach out!

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Online Data Submission

Adverse Events






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Online Data Submission: Adverse Events

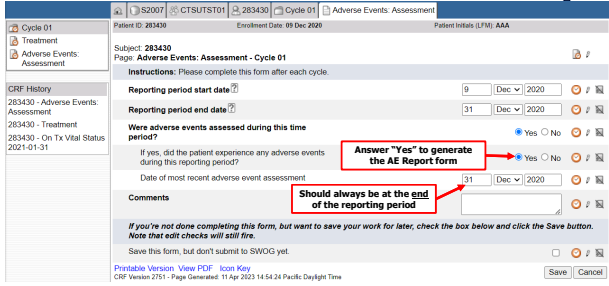
SWOG has two EDC systems in use:

- CRA Workbench (legacy trials only)
- Medidata RAVE

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Online Data Submission: Adverse Events



Instructions: Please complete this form after each cycle.

Reporting period start date: 9 Dec 2020

Reporting period end date: 31 Dec 2020

Were adverse events assessed during this time period? Yes No

If yes, did the patient experience any adverse events during this reporting period? Yes No

Date of most recent adverse event assessment: 31 Dec 2020

Comments:

Answers "Yes" to generate the AE Report form

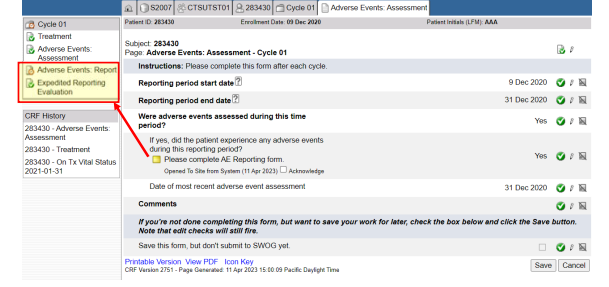
Should always be at the end of the reporting period

Printable Version View PDF Icon Key

SWOG logo, National Clinical Trial Network logo, Community Oncology Research Program logo

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Online Data Submission: Adverse Events



Instructions: Please complete this form after each cycle.

Reporting period start date: 9 Dec 2020

Reporting period end date: 31 Dec 2020

Were adverse events assessed during this time period? Yes No

If yes, did the patient experience any adverse events during this reporting period? Yes No

Date of most recent adverse event assessment: 31 Dec 2020

Comments:

Adverse Events Report

Expedited Reporting Evaluation

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Online Data Submission: Adverse Events

23 Cycle 01 | Patient ID: 283430 | Enrollment Date: 9 Dec 2020 | Patient Initials: (L)M:AAA

Subject: 283430
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: 9 Dec 2020
- Start date of SAE course/cycle (derived): 9 Dec 2020

Adverse event terms (CTCAE v5.0)	Adverse event grade	Attribution description (Intervention)	None	Hospitalization	Life-threatening	Death	Disability	anomaly/defect	Congenital defect	SAE report (derived)	Other recommended	AE entry date (derived)	Time zone (derived)
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Add a new Log link. Inactivate

INSTRUCTIONS: After entering new or modified data in the table above, adverse events must be submitted to CTSP-ADSR for rules evaluation by pressing the Expedited Reporting Evaluation CRF in Risk.

Click the pencil icon to enter data on the first line.

If you're not done completing this form, but want to save your work for later, check the box below and click the Save button. Note that edit checks will still fire.

Save this form, but don't submit to SWOG yet.

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Online Data Submission: Adverse Events

23 Cycle 01 | Patient ID: 283430 | Enrollment Date: 9 Dec 2020 | Patient Initials: (L)M:AAA

Subject: 283430
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: 9 Dec 2020
- Start date of SAE course/cycle (derived): 9 Dec 2020

This banner tells you which logline you are editing

Adverse event terms (CTCAE v5.0)	Adverse event grade	Attribution description (Intervention)	None	Hospitalization	Life-threatening	Death	Disability	anomaly/defect	Congenital defect	SAE report (derived)	Other recommended	AE entry date (derived)	Time zone (derived)
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Add a new Log link. Inactivate

INSTRUCTIONS: After entering new or modified data in the table above, adverse events must be submitted to CTSP-ADSR for rules evaluation by pressing the Expedited Reporting Evaluation CRF in Risk.

If you're not done completing this form, but want to save your work for later, check the box below and click the Save button. Note that edit checks will still fire.

Save this form, but don't submit to SWOG yet.

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Online Data Submission: Adverse Events

23 Cycle 01 | Patient ID: 283430 | Enrollment Date: 9 Dec 2020 | Patient Initials: (L)M:AAA

Subject: 283430
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: 9 Dec 2020
- Start date of SAE course/cycle (derived): 9 Dec 2020

Use the arrow to select the CTCAE term from the dropdown menu

Adverse event terms (CTCAE v5.0)	Adverse event grade	Attribution description (Intervention)	None	Hospitalization	Life-threatening	Death	Disability	anomaly/defect	Congenital defect	SAE report (derived)	Other recommended	AE entry date (derived)	Time zone (derived)
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Add a new Log link. Inactivate

INSTRUCTIONS: After entering new or modified data in the table above, adverse events must be submitted to CTSP-ADSR for rules evaluation by pressing the Expedited Reporting Evaluation CRF in Risk.

If you're not done completing this form, but want to save your work for later, check the box below and click the Save button. Note that edit checks will still fire.

Save this form, but don't submit to SWOG yet.

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Online Data Submission: Adverse Events

Use the arrow to select the grade from the drop-down menu

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Online Data Submission: Adverse Events

Use the arrow to select the attribution from the drop-down menu

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Online Data Submission: Adverse Events

Select all that apply

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Online Data Submission: Adverse Events

Adverse event description

Adverse event description (CTCAE v5.0)	Attribution to study intervention?	Hospitalization?	Life-threatening?	Death/Disability/Permanent/Other?	Congenital defect?	SAE report (selected)	SAE entry date (selected)	Time zone (selected)
Cough nonprescription Unlikely respiratory infection	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11 Apr 2023 06:12:44 PM	Eastern Standard Time

INSTRUCTIONS: After entering new or modified data in the table above, adverse events must be submitted to CTEP/AERS for rates evaluation by hitting the Expedited Reporting Evaluation (ERE) in Row.

Comments:

If you're not done completing this form, but want to save your work for later, check the box below and click the Save button. Note that edit checks will still fire.

Save this form. Do not Submit to SWOG yet. Save Cancel

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Online Data Submission: Adverse Events

Attribution to study intervention? **Other**

Comments:

INSTRUCTIONS: After entering new or modified data in the table above, adverse events must be submitted to CTEP/AERS for rates evaluation by hitting the Expedited Reporting Evaluation (ERE) in Row.

Comments:

If you're not done completing this form, but want to save your work for later, check the box below and click the Save button. Note that edit checks will still fire.

Save this form. Do not Submit to SWOG yet. Save Cancel

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Online Data Submission: Adverse Events

Adverse event term (CTCAE v5.0) Empiricism

Adverse event description (CTCAE v5.0)	Attribution to study intervention?	Hospitalization?	Life-threatening?	Death/Disability/Permanent/Other?	Congenital defect?	SAE report (selected)	SAE entry date (selected)	Time zone (selected)
Cough nonprescription Unlikely respiratory infection	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11 Apr 2023 06:12:44 PM	Eastern Standard Time

INSTRUCTIONS: After entering new or modified data in the table above, adverse events must be submitted to CTEP/AERS for rates evaluation by hitting the Expedited Reporting Evaluation (ERE) in Row.

Comments:

If you're not done completing this form, but want to save your work for later, check the box below and click the Save button. Note that edit checks will still fire.

Save this form. Do not Submit to SWOG yet. Save Cancel

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Online Data Submission: Adverse Events

Form Instructions: * Red asterisk before a field denotes that it is required by the system for rules evaluation.

Adverse event grade	Adverse event description	Attribution to study intervention	Hospitalization	Life-threatening	Death/Disability	Congestive anomaly/other effect	SAE report recommended (Y/N)	AE entry date (YYYYMMDD)	Time zone (YYYYMMDD)
1	Cough (1) Mild symptoms, nonproductive (2) Moderate, minimal infections and interactions (3) Severe, minimal infections and interactions (4) Severe, minimal infections and interactions (5) Severe, minimal infections and interactions	Unlikely	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	11 Apr 2020 06:44:01	Eastern Standard Time
2	Infections and interactions (COVID-19)	Unrelated	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	11 Apr 2020 06:44:01	Eastern Standard Time
3	Long infection (1) Moderate, minimal infections and interactions (2) Severe, minimal infections and interactions (3) Severe, minimal infections and interactions (4) Severe, minimal infections and interactions (5) Severe, minimal infections and interactions	Unlikely	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	11 Apr 2020 06:44:01	Eastern Standard Time

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Online Data Submission: Adverse Events

Adverse event grade	Adverse event description	Attribution to study intervention	Hospitalization	Life-threatening	Death/Disability	Congestive anomaly/other effect	SAE report recommended (Y/N)	AE entry date (YYYYMMDD)	Time zone (YYYYMMDD)
1	Cough (1) Mild symptoms, nonproductive (2) Moderate, minimal infections and interactions (3) Severe, minimal infections and interactions (4) Severe, minimal infections and interactions (5) Severe, minimal infections and interactions	Unlikely	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	11 Apr 2020 06:44:01	Eastern Standard Time
2	Infections and interactions (COVID-19)	Unrelated	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	11 Apr 2020 06:44:01	Eastern Standard Time
3	Long infection (1) Moderate, minimal infections and interactions (2) Severe, minimal infections and interactions (3) Severe, minimal infections and interactions (4) Severe, minimal infections and interactions (5) Severe, minimal infections and interactions	Unlikely	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	11 Apr 2020 06:44:01	Eastern Standard Time

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Online Data Submission: Adverse Events

Form Instructions: * Red asterisk before a field denotes that it is required by the system for rules evaluation.


Run the Expedited Reporting Evaluation form to fill the SAE Report Recommended column

Adverse event grade	Adverse event description	Attribution to study intervention	Hospitalization	Life-threatening	Death/Disability	Congestive anomaly/other effect	SAE report recommended (Y/N)	AE entry date (YYYYMMDD)	Time zone (YYYYMMDD)
1	Cough (1) Mild symptoms, nonproductive (2) Moderate, minimal infections and interactions (3) Severe, minimal infections and interactions (4) Severe, minimal infections and interactions (5) Severe, minimal infections and interactions	Unlikely	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	11 Apr 2020 06:44:01	Eastern Standard Time
2	Infections and interactions (COVID-19)	Unrelated	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	11 Apr 2020 06:44:01	Eastern Standard Time
3	Long infection (1) Moderate, minimal infections and interactions (2) Severe, minimal infections and interactions (3) Severe, minimal infections and interactions (4) Severe, minimal infections and interactions (5) Severe, minimal infections and interactions	Unlikely	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	11 Apr 2020 06:44:01	Eastern Standard Time

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**Still have questions?
Please email us:**



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GIQuestion@crab.org	LymphomaQuestion@crab.org
GUQuestion@crab.org	MelanomaQuestion@crab.org
GYNQuestion@crab.org	MyelomaQuestion@crab.org
LeukemiaQuestion@crab.org	RareTumors@crab.org

➤ Also refer to the *CRA Manual (for Oncology Research Professionals)*, available on the CRA Workbench!

