

## Adverse Event Reporting

SWOG Clinical Trials

Louise Highleyman  
Clinical Research Data Coordinator  
SWOG Statistics and Data  
Management Center (SDMC)

---

---

---

---

---

---

---

## Adverse Event Reporting

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

---

---

---

---

---

---

---

## Definitions and Background

---

---

---

---

---

---

---

### Adverse Event (AE):

Any change in the patient's condition from the day protocol treatment began, regardless of cause.

Examples:

- Nausea and/or vomiting caused by treatment
- Sinusitis from seasonal allergies
- Breaking a leg
- Increasing cancer symptoms

---

---

---

---

---

---

---

### Toxicity:

Adverse symptom(s) caused or possibly caused by the drugs or treatment used in the study.

<u>Tissue</u>	<u>Toxicity</u>
Bone marrow	Myelosuppression
Mucous membranes	Nausea/Vomiting
Hair follicles	Alopecia

---

---

---

---

---

---

---

### Serious Adverse Event (SAE):

An unexpected or severe reaction to protocol treatment.

---

---

---

---

---

---

---

## Adverse Event Reporting

**Expedited reporting:** Serious Adverse Events (SAEs) and Adverse Events of Special Interest (AESIs)

**Routine reporting:** All adverse events, regardless of attribution or grade (unless otherwise specified in forms or protocol)

---

---

---

---

---

---

---

## Why do we collect routine AEs?

- **Phase I trials:**
  - Primary objective: to assess the safety of an experimental regimen and determine the maximum tolerated dose
- **Phase II single-arm trials:**
  - Secondary objective: to estimate the frequency and severity of toxicities in trial regimen
- **Phase II/III randomized trials:**
  - Secondary objective: to compare the frequency and severity of toxicities associated with each regimen

---

---

---

---

---

---

---

## Information in SWOG Protocols

---

---

---

---

---

---

---

### Protocol Table of Contents

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

...and the Master Forms Set!

---

---

---

---

---

---

---

---

### Protocol Section 3: Drug Information

- Lists known human toxicities for each study drug

---

---

---

---

---

---

---

---

### Protocol Section 8:

#### Toxicities to be Monitored and Dose Modifications

- Lists certain toxicities that may be seen on treatment
- Details dosage changes required during treatment in response to AEs

---

---

---

---

---

---

---

---

## Protocol Section 8:

### Toxicities to be Monitored and 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 BMN 673	Full	1000 mcg/day
	-1 Level	750 mcg/day
	-2 Level	500 mcg/day
	-3 Level	250 mcg/day
	-4 Level	Discontinue

Table 1: Renal Impairment Dose Modifications

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

## Protocol Section 8:

### Toxicities to be Monitored and Dose Modifications

- Lists drugs to aid in symptom management
- Lists names and contact information of physicians to reach for assistance
- Identifies version of Common Terminology Criteria for Adverse Events (CTCAE) used for study reporting

## Protocol Section 9: Study Calendar

- Indicates how often to assess adverse events while receiving protocol treatment

### Protocol Section 16: Ethical and Regulatory Considerations

- Includes instructions for reporting SAEs and AESIs (if applicable)

---

---

---

---

---

---

---

### Master Forms Sets/All Forms Packet

- Contains all study forms, including those used to document adverse events

---

---

---

---

---

---

---

### Reporting Adverse Events

Common Terminology Criteria for  
Adverse Events (CTCAE)

---

---

---

---

---

---

---

## Common Terminology Criteria for Adverse Events (CTCAE)

- Provides a list of specific adverse events (“CTCAE terms”), a description of each adverse event term, and guidelines on how to grade each event.
- Can find a copy of the CTCAE at [ctep.cancer.gov](http://ctep.cancer.gov)
  - Version 4.0: In use since October 2009
  - Version 5.0: Published in November 2017
    - All SAE reporting starting April 1, 2018
    - Routine AE reporting on all new studies
- Some studies may use a different CTCAE version for routine AE reporting vs. SAE reporting

Blood and lymphatic system disorders					
CTCAE Term	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Anemia	Hemoglobin (Hgb) <10 g/dL in men, <11 g/dL in women, <6.2 mmol/L in men, <6.2 mmol/L in women	Hgb <10 g/dL in men, <11 g/dL in women, <6.2 mmol/L in men, <6.2 mmol/L in women	Hgb <8 g/dL in men, <9 g/dL in women, <5.1 mmol/L in men, <5.1 mmol/L in women; 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.					
Navigation Note: -					
Bone marrow hypocellular	Mildly hypocellular or <25% reduction from normalularity for age	Moderately hypocellular or >25 - <50% reduction from normalularity 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.					
Navigation Note: -					
Coagulopathy/abnormal coagulation		Laboratory findings with no bleeding	Laboratory findings with 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.					
Navigation Note: -					
Eosinophilia	>1.5x and >baseline	-	Steroids initiated	-	-
Definition: A disorder characterized by laboratory test results that indicate an increased number of eosinophils in the blood.					
Navigation Note: -					
Febriile neutropenia	-	-	ANC <1000/mm3 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/mm3 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.					
Navigation Note: -					
Hemolysis	Laboratory evidence of hemolysis only (e.g., direct antiglobulin test, DAT, "smear" schistocytes, increased 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.					
Navigation Note: -					

CTCAE v5.0 – November 27, 2017

[Back to TOC](#)

Page 4

## CTCAE Terms

- The terms might not always be listed the way you expect. Below are some examples of common AEs and the appropriate CTCAE v 5.0 term:

**Pneumonia**    **Lung infection**

**Thrombocytopenia**    **Platelet count decreased**

**Shortness of breath**    **Dyspnea**

- Each system category also includes an “Other” option (for example, “Investigations – Other”), but only use as a last resort.

### CTCAE Grades

**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

---

---

---

---

---

---

---

---

Blood and lymphatic system disorders					
CTCAE Term	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Anemia	Hemoglobin (mg/dL) <10.0 g/dL; <11.0 g/dL; <6.2 mmol/L; <11.0 mmol/L	Hgb <10.0; <5.5 g/dL; <5.2 - 4.5 mmol/L; <100 - 80g/L	Hgb <8.0 g/dL; <4.3 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: -					
Uncontrolled 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 deprived of platelets and coagulation factors.					
Navigational Note: -					
Eosinophilia	>4.5/L and >baseline	-	Steroids initiated	-	-
Definition: A disorder characterized by laboratory test results that indicate an increased number of eosinophils in the blood.					
Navigational Note: -					
Exfoliative dermatitis	-	-	ANC <1000/mm3 or a single temperature of >38.3 degrees C (101.3 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/mm3 and a single temperature of >38.3 degrees C (101.3 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: -					

---

---

---

---

---

---

---

---

### 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

---

---

---

---

---

---

---

---



## Status

The status code describes the state of the adverse event at various points throughout the study:

- New
- Continues at the same or lower grade
- Increased grade OR improved then worsened

---

---

---

---

---

---

---

## Additional AE Data Collection Items

Some additional data items that may be collected for each AE include:

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

---

---

---

---

---

---

---

## General Rules for AE Reporting

- Record and report adverse events as they occur
- List all adverse events, regardless of clinical significance
  - Exception: Only report AEs present at baseline if they worsen or reoccur after previously resolving
- On each cycle or reporting period: record the most severe grade experienced
- Avoid using "Other" CTCAE terms unless no specific CTCAE term applies
- When in doubt, document it!

---

---

---

---

---

---

---

### Online Data Submission: Adverse Events

- CRA Workbench (legacy trials only)
- **Medidata Rave**
  - AE data submission
  - New NCI-mandated AE form with CTEP-AERS integration

---

---

---

---

---

---

---

### Online AE Submission Medidata Rave

---

---

---

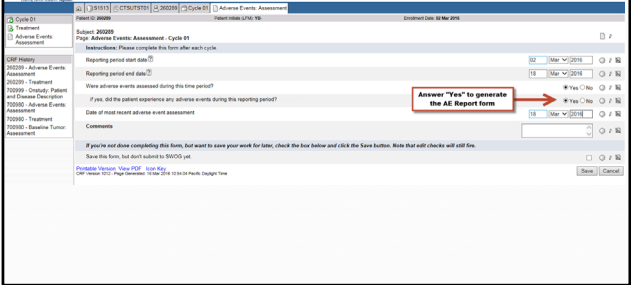
---

---

---

---

### Online AE Submission: Medidata Rave



---

---

---

---

---

---

---

## Online AE Submission: Medidata Rave

# Online AE Submission: Medidata Rave

## Online AE Submission: Medidata Rave

Online AE Submission: Medidata Rave

Patient ID: 00000 End Date: 02 May 2018

Subject: 00000 Page: Adverse Events Report - Cycle 01

Instructions: 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. Indicate the adverse event results in hospitalization or prolongation of existing hospitalization for 24 hours. Follow instructions in Section 5.2 of the protocol for expected reporting requirements on this study.

CTC adverse event term	CTC adverse event grade	CTC adverse event status code	CTC adverse event status code	Rehospitalization (at least 24 hours)
1. Lung infection	1	Unk	New	Y

CTC adverse event term: Data entered is non-compliant (invalid format). Please correct.

Comments: Add a new Log line here.

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

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

Printable Version View PDF View Help

CRF Version: 1002 Page: Adverse Events Report - Cycle 01

Save Cancel

## Online AE Submission: Medidata Rave

Online AE Submission: Medidata Rave

Patient ID: 00000 End Date: 02 May 2018

Subject: 00000 Page: Adverse Events Report - Cycle 01

Instructions: 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. Indicate the adverse event results in hospitalization or prolongation of existing hospitalization for 24 hours. Follow instructions in Section 5.2 of the protocol for expected reporting requirements on this study.

CTC adverse event term	CTC adverse event grade	CTC adverse event status code	CTC adverse event status code	Rehospitalization (at least 24 hours)
1. Lung infection	1	Unk	New	Y

CTC adverse event term: Data entered is non-compliant (invalid format). Please correct.

Comments: Add a new Log line here.

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

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

Printable Version View PDF View Help

CRF Version: 1002 Page: Adverse Events Report - Cycle 01

Save Cancel

## Online AE Submission: Medidata Rave

Online AE Submission: Medidata Rave

Patient ID: 00000 End Date: 02 May 2018

Subject: 00000 Page: Adverse Events Report - Cycle 01

Instructions: 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. Indicate the adverse event results in hospitalization or prolongation of existing hospitalization for 24 hours. Follow instructions in Section 5.2 of the protocol for expected reporting requirements on this study.

CTC adverse event term	CTC adverse event grade	CTC adverse event status code	CTC adverse event status code	Rehospitalization (at least 24 hours)
1. Lung infection	1	Unk	New	Y

CTC adverse event term: Data entered is non-compliant (invalid format). Please correct.

Comments: Add a new Log line here.

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

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

Printable Version View PDF View Help

CRF Version: 1002 Page: Adverse Events Report - Cycle 01

Save Cancel

Online AE Submission: Medidata Rave

Cycle 01

202009

Page: Adverse Events Report - Cycle 01

Subject: 202009

Page: Adverse Events Report - Cycle 01

Instructions: 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. Indicate if the adverse event results in inpatient hospitalization or prolongation of existing hospitalization for > 24 hours. Follow instructions in Section 10.0 of the protocol for expected reporting requirements on this study.

CTC adverse event term

CTCAE (AE) grade

CTC adverse event attribution code

CTC adverse event status code

Regeneration

1

Lung infection

2

Unknown

Continued at same or lower grade

at least 24 hours

Comments

Add a new Log Line Inactive

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 SMOG yet.

Save

Cancel

Printable Version View PDF Icon Key

Get version 10.1 Page Generated: 10 May 2016 11:10:30 Pacific Daylight Time

Non-conformant data error

---

---

---

---

---

---

---

---

Online AE Submission: Medidata Rave

Cycle 01

202009

Page: Adverse Events Report - Cycle 01

Subject: 202009

Page: Adverse Events Report - Cycle 01

Instructions: 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. Indicate if the adverse event results in inpatient hospitalization or prolongation of existing hospitalization for > 24 hours. Follow instructions in Section 10.0 of the protocol for expected reporting requirements on this study.

CTC adverse event term

CTCAE (AE) grade

CTC adverse event attribution code

CTC adverse event status code

Regeneration

1

Lung infection

2

Unknown

Continued at same or lower grade

at least 24 hours

Comments

Add a new Log Line Inactive

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 SMOG yet.

Save

Cancel

Printable Version View PDF Icon Key

Get version 10.1 Page Generated: 10 May 2016 11:10:30 Pacific Daylight Time

Non-conformant data error

---

---

---

---

---

---

---

---

Online AE Submission: Medidata Rave

Cycle 01

202009

Page: Adverse Events Report - Cycle 01

Subject: 202009

Page: Adverse Events Report - Cycle 01

Instructions: 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. Indicate if the adverse event results in inpatient hospitalization or prolongation of existing hospitalization for > 24 hours. Follow instructions in Section 10.0 of the protocol for expected reporting requirements on this study.

CTC adverse event term

CTCAE (AE) grade

CTC adverse event attribution code

CTC adverse event status code

Regeneration

1

Lung infection

2

Unknown

Continued at same or lower grade

at least 24 hours

Comments

Add a new Log Line Inactive

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 SMOG yet.

Save

Cancel

Printable Version View PDF Icon Key

Get version 10.1 Page Generated: 10 May 2016 11:10:30 Pacific Daylight Time

Non-conformant data error

---

---

---

---

---

---

---

---

Adverse Event Reporting

13



## Online AE Submission: Medidata Rave

Online AE Submission: Medidata Rave

Adverse Events Report

Report ID: 200000 Patient ID: 123456 Cycle: 01 Enrollment Date: 01 Mar 2015

Subject: 200000 Page: Adverse Events Report - Cycle 01

Instructions: 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. Indicate if the adverse event results in inpatient hospitalization or prolongation of existing hospitalization for a 24-hour period. Follow instructions in Section 16.2 of the protocol for expected reporting requirements on this study.

CTC adverse event term	CTCAE (4.0) grade	CTC adverse event attribution code	CTC adverse event status code	Hospitalization (at least 24 hours)
1 Lung Infection	2*	Unlikely	Continues at same or lower grade	
2 Entry Error		Unlikely	Continues at same or lower grade	
3 Entry Error		Unlikely	Continues at same or lower grade	
4 Entry Error		Unlikely	Continues at same or lower grade	
5 Entry Error		Unlikely	Continues at same or lower grade	
6 Entry Error		Unlikely	Continues at same or lower grade	
7 Entry Error		Unlikely	Continues at same or lower grade	
8 Entry Error		Unlikely	Continues at same or lower grade	
9 Entry Error		Unlikely	Continues at same or lower grade	
10 Entry Error		Unlikely	Continues at same or lower grade	
11 Entry Error		Unlikely	Continues at same or lower grade	
12 Entry Error		Unlikely	Continues at same or lower grade	
13 Entry Error		Unlikely	Continues at same or lower grade	
14 Entry Error		Unlikely	Continues at same or lower grade	
15 Entry Error		Unlikely	Continues at same or lower grade	
16 Entry Error		Unlikely	Continues at same or lower grade	
17 Entry Error		Unlikely	Continues at same or lower grade	
18 Entry Error		Unlikely	Continues at same or lower grade	
19 Entry Error		Unlikely	Continues at same or lower grade	
20 Entry Error		Unlikely	Continues at same or lower grade	

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 all checks will still fire.

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

Printable Version View PDF View Key Log Version 1.0.1 Page 1 of 10 11/20/2015 11:20:20 Pacific Daylight Time

## Online AE Submission New NCI-Mandated Rave Form with CTEP-AERS Integration

Online AE Submission  
New NCI-Mandated Rave Form  
with CTEP-AERS Integration

## Online AE Submission: New NCI-Mandated Rave Form with CTEP-AERS Integration

- CTSU has created Rave Adverse Events forms that integrate directly with the CTEP-AERS expedited reporting system
  - Reduces double data entry
- All new SWOG studies are required to use this form to collect adverse events
  - S1505 was the pilot SWOG study to use this form
  - Currently, ten active trials across most disease sites
  - Five studies currently in development
- For studies using this form, SAEs must be entered in Rave first

### Online AE Submission: New NCI-Mandated Rave Form with CTEP-AERS Integration

**Form Instructions**

**\* red asterisk before a field denotes a required response**

**For all Steps:** 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. Indicate if the adverse event results in inpatient hospitalization or prolongation of existing hospitalization for 24 hours. Follow instructions in Section 16.0 of the protocol for expedited reporting requirements on this study. Category links may not include all adverse events from that category.

**\* Start date of this course/cycle**

**Start date of first course/cycle (derived)**

Is the AE related?	Adverse event term (CTCAE v5.0)	MedDRA adverse event term (CTCAE v5.0)	Adverse event grade description (first 120 characters)	Attribution to study intervention	Adverse event term (CTCAE v5.0)	None	Hospitalization	Life-threatening	Death	Congestive heart failure	Required intervention	SAE report recommended	AE entry date (derived)	Time zone (derived)	Adverse event term (CTCAE v5.0)
1	No	Dyspnea	100 (386) Respiratory distress and dyspnea	4 - Probable		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2 Mar 2019 07:24	Eastern Standard Time	

**Add a new Log line**

**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, but don't submit to SIVOD yet.**

Printable Version | View PDF | Log Key | CTR Version 2019 | Page Generated: 22 Mar 2019 10:03:05 Pacific Daylight Time

---

---

---

---

---

---

---

---

---

---

### Online AE Submission: New NCI-Mandated Rave Form with CTEP-AERS Integration

**\* Start date of this course/cycle**

**Start date of first course/cycle (derived)**

**\* Adverse event term (CTCAE v5.0)**

**\* MedDRA adverse event code (CTCAE v5.0) (derived)**

**\* Adverse event grade description (first 120 characters)**

**\* Attribution to study intervention**

**Did the adverse event result in:**

None	<input type="checkbox"/>
Hospitalization	<input type="checkbox"/>
Life-threatening	<input type="checkbox"/>
Death	<input type="checkbox"/>
Congestive heart failure	<input type="checkbox"/>
Required intervention	<input type="checkbox"/>
Other	<input type="checkbox"/>

**SAE report recommended (derived)** ☐

**AE entry date (derived)**

**Time zone (derived)**

---

---

---

---

---

---

---

---

---

---

### Online AE Submission: New NCI-Mandated Rave Form with CTEP-AERS Integration

**Form Instructions**

**\* red asterisk before a field denotes a required response**

**For all Steps:** 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. Indicate if the adverse event results in inpatient hospitalization or prolongation of existing hospitalization for 24 hours. Follow instructions in Section 16.0 of the protocol for expedited reporting requirements on this study. Category links may not include all adverse events from that category.

**\* Start date of this course/cycle**

**Start date of first course/cycle (derived)**

Is the AE related?	Adverse event term (CTCAE v5.0)	MedDRA adverse event term (CTCAE v5.0)	Adverse event grade description (first 120 characters)	Attribution to study intervention	Adverse event term (CTCAE v5.0)	None	Hospitalization	Life-threatening	Death	Congestive heart failure	Required intervention	SAE report recommended	AE entry date (derived)	Time zone (derived)	Adverse event term (CTCAE v5.0)
1	No	Dyspnea	100 (386) Respiratory distress and dyspnea	4 - Probable		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2 Mar 2019 07:24	Eastern Standard Time	

**Add a new Log line**

**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, but don't submit to SIVOD yet.**

Printable Version | View PDF | Log Key | CTR Version 2019 | Page Generated: 22 Mar 2019 10:03:05 Pacific Daylight Time

---

---

---

---

---

---

---

---

---

---



## Online AE Submission: New NCI-Mandated Rave Form with CTEP-AERS Integration

**Form Instructions**

**A delay is expected when the safety system is called for AE evaluation.**

Note: Do not open more than one ticket per course/cycle in CTEP-AERS. If more than one serious adverse event occurs this course/cycle, amend the report so both events are entered on the same ticket.

Send all AEs for evaluation

Whenever the AE form is updated, the adverse events have to be evaluated to determine if expedited reporting is recommended. Please check this checkbox and save the form to determine if expedited reporting is recommended.

☐ Check this box and save the form.

Report ID (derived)

Printable Version View PDF Icon Key

CRF Version 2000 - Page Generated: 23 Mar 2019 12:17:13 Pacific Daylight Time

## Online AE Submission: New NCI-Mandated Rave Form with CTEP-AERS Integration

**Form Instructions**

**A delay is expected when the safety system is called for AE evaluation.**

Note: Do not open more than one ticket per course/cycle in CTEP-AERS. If more than one serious adverse event occurs this course/cycle, amend the report so both events are entered on the same ticket.

Send all AEs for evaluation

Recommended action for report (derived)

☐ An expedited report is NOT recommended. If the investigator believes an expedited report is warranted, use the link below to move to CTEP-AERS to complete the expedited report.

☐ Click this link to complete the safety report

Report ID (derived)

REP0169555\*

Printable Version View PDF Icon Key

CRF Version 2103 - Page Generated: 25 Mar 2019 12:39:53 Pacific Daylight Time

## Online AE Submission: New NCI-Mandated Rave Form with CTEP-AERS Integration

**Form Instructions**

**A delay is expected when the safety system is called for AE evaluation.**

Note: Do not open more than one ticket per course/cycle in CTEP-AERS. If more than one serious adverse event occurs this course/cycle, amend the report so both events are entered on the same ticket.

Send all AEs for evaluation

Recommended action for report (derived)

☐ An expedited report is RECOMMENDED. If the investigator believes an expedited report is not warranted, (e.g. per protocol, commercial agreement, medical judgement, etc.), set the Recommended action for report field to indicate NONE.

☐ Click this link to complete the safety report

Report ID (derived)

REP0318107\*

Recommended report type (derived)

CTEP 24 Hour SAE Notification

Report due by (derived)

Friday, March 22, 2019\*

Printable Version View PDF Icon Key

CRF Version 2103 - Page Generated: 21 Mar 2019 12:50:18 Pacific Daylight Time

**Still Have Questions?  
Please Email Us:**

BreastQuestion@crab.org	LungQuestion@crab.org
CancerControlQuestion@crab.org	LungMAPQuestion@crab.org
GIQuestion@crab.org	LymphomaQuestion@crab.org
GUQuestion@crab.org	MelanomaQuestion@crab.org
GYNQuestion@crab.org	MyelomaQuestion@crab.org
LeukemiaQuestion@crab.org	

**And refer to the ORP Manual available at  
[www.SWOG.org](http://www.SWOG.org)**

---

---

---

---

---

---

---

---