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# Adverse Event Assessment & Reporting

Rose Ermete, RN, BSN, OCN<sup>®</sup>, CRN-BC<sup>™</sup>, CCRP  
Senior Quality Assurance Nurse Auditor  
Network Operations Center



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What is your current role?

- A. Data Management
- B. Clinical Research Nurse
- C. Regulatory Affairs
- D. Quality Assurance
- E. Administration
- F. Other



## What is the definition of an Adverse Event?

- A. A known toxicity of the study agent.
- B. Any untoward sign or symptom that occurs during the course of a clinical trial.
- C. Any event which the PI decides to report during the course of a clinical trial.
- D. A side effect caused by the study agent.

# ADVERSE EVENT (AE)



U.S. Office for Human Research Protections (OHRP)	U.S. Food and Drug Administration (FDA)	International Council on Harmonization (ICH)
<p>Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.</p>	<p>Any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related.</p>	<p>Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.</p>

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# SWOG Definition



Any unfavorable and unintended change in a patient's condition from the day protocol treatment began, REGARDLESS OF EXPECTEDNESS OR RELATIONSHIP TO RESEARCH.

[https://txwb.crab.org/TXWB/CRA\\_MANUAL/Vol1/chapter%2015\\_Adverse%20Event%20Assessments.pdf](https://txwb.crab.org/TXWB/CRA_MANUAL/Vol1/chapter%2015_Adverse%20Event%20Assessments.pdf)



# Unexpected Event

U.S. OHRP	U.S. FDA	ICH
<p>Any adverse event occurring in one or more subjects participating in a research protocol, the nature, severity, or frequency of which is <b>not</b> consistent with either:</p> <ul style="list-style-type: none"><li>• the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol-related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; <b>OR</b></li><li>• the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.</li></ul>	<p>An adverse event or suspected adverse reaction is considered "unexpected" if it is not listed in the investigator brochure or is not listed at the specificity or severity that has been observed; or, if an investigator brochure is not required or available, is not consistent with the risk information described in the general investigational plan or elsewhere in the current application, as amended.<sup>2</sup></p>	<p>An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product)</p>

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# Data Standards for AE Terms



Medical Dictionary for Regulatory Activities (MedDRA)



Common Terminology Criteria for Adverse Events (CTCAE)

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# Medical Dictionary for Regulatory Activities (MedDRA)



- Dictionary of clinically validated international medical terminology
- Developed by the International Council on Harmonisation (ICH)
- Used to facilitate sharing of regulatory information internationally for human medical products
- Available in 19 languages
- <http://www.meddramsso.com/>







# MedDRA v. 25.0 'Fatigue' hierarchy displayed (MedDRA ID 10016256)

- [-] [General disorders and administration site conditions](#)
  - o [Administration site reactions](#)
  - o [Body temperature conditions](#)
  - o [Complications associated with device](#)
  - o [Fatal outcomes](#)
  - o [-] [General system disorders NEC](#)
    - [Adverse effect absent](#)
    - [-] [Asthenic conditions](#)
      - [Adult failure to thrive](#)
      - [Asthenia](#)
      - [Autonomic nervous system imbalance](#)
      - [Cachexia](#)
      - [Cancer fatigue](#)
      - [Chronic fatigue syndrome](#)
      - [Decreased activity](#)
      - [Dysania](#)
      - [-] [Fatigue](#)
        - [Chronic fatigue](#)
        - [Depressive weariness](#)
        - [Energvation](#)
        - [Exhaustion](#)
        - [Exhaustion due to excessive exertion](#)
        - [Exhaustion due to exposure](#)
        - [Fatigability](#)
        - [Fatigability generalized](#)
        - [Fatigability lumbar](#)
        - [Fatigability of knees](#)
        - [Fatiguability](#)
        - [Fatiguability generalised](#)
        - [Fatigue aggravated](#)
        - [Fatigue extreme](#)
        - [Fatigueability generalized](#)
        - [Lassitude](#)
        - [Loss physical strength](#)
        - [Prostration](#)
        - [TATT](#)
        - [Tired all the time](#)
        - [Tired and heavy](#)
        - [Tired out](#)
        - [Tiredness](#)
        - [Washed-out](#)
        - [Weariness](#)
        - [Worn out](#)

SOC

HLGT

HLT

PT

LLT

### KEY

- SOC: System Organ Class
- HLGT: High Level Group Term
- HLT: High Level Term
- PT: Preferred Term
- LLT: Lowest Level Term

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# Common Terminology Criteria for Adverse Events (CTCAE)



- Developed by NCI Cancer Therapy Evaluation Program (CTEP) as the Common Toxicity Criteria (CTC) in 1983
- Fundamentally agreed upon terminology for AEs that occur in oncology research
- Current version: 5
- Early 2024: version 6
- Organized by MedDRA
  - SOC (minus Product Issue SOC)
  - LLT

# CTCAE v 5



## Immune system disorders

CTCAE Term	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Allergic reaction	Systemic intervention not indicated	Oral intervention indicated	Bronchospasm; hospitalization indicated for clinical sequelae; intravenous intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
<p><b>Definition:</b> A disorder characterized by an adverse local or general response from exposure to an allergen.</p> <p><b>Navigational Note:</b> If related to infusion, use Injury, poisoning and procedural complications: Infusion related reaction. Do not report both.</p>					
Anaphylaxis	-	-	Symptomatic bronchospasm, with or without urticaria; parenteral intervention indicated; allergy-related edema/angioedema; hypotension	Life-threatening consequences; urgent intervention indicated	Death
<p><b>Definition:</b> 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.</p> <p><b>Navigational Note:</b> -</p>					
Autoimmune disorder	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
<p><b>Definition:</b> 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.</p> <p><b>Navigational Note:</b> Prior to using this term consider specific autoimmune AEs</p>					

[https://ctep.cancer.gov/protocolDevelopment/electronic\\_applications/docs/CTCAE\\_v5\\_Quick\\_Reference\\_8.5x11.pdf](https://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_8.5x11.pdf)

# 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!





# Severity Rating or Grading



Measures the severity of clinical findings and impact on the participant.



Promotes consistency for severity assessment.



Facilitates common understanding of shared AE data sets.

Provides framework to compare AEs across different studies.

# Reporting Adverse Events: CTCAE Grade



Adverse Event	Grade				
	1	2	3	4	5
Anemia	Hemoglobin (Hgb) <LLN - 10.0 g/dL; <LLN - 6.2 mmol/L; < LLN - 100 g/L	Hgb <10.0 - 8.0 g/dL; <6.2 - 4.9 mmol/L; <100 - 80g/L	Hgb <8.0 - 6.5 g/dL; <4.9 - 4.0 mmol/L; <80 - 65 g/L; transfusion indicated	Life-threatening consequences; urgent intervention indicated	Death

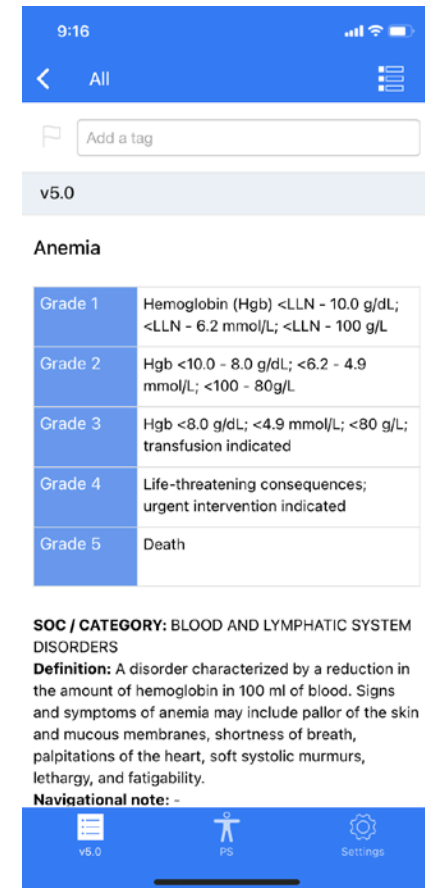
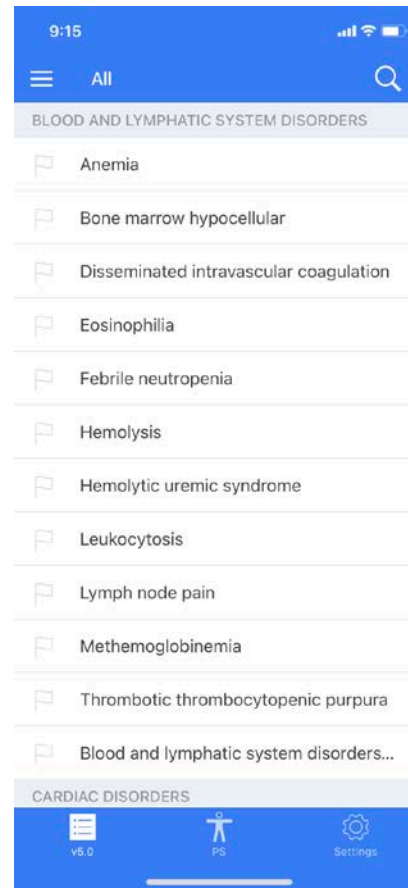
**Definition:** A disorder characterized by a reduction in the amount of hemoglobin in 100 ml of blood. Signs and symptoms of anemia may include pallor of the skin and mucous membranes, shortness of breath, palpitations of the heart, soft systolic murmurs, lethargy, and fatigability.

[https://ctep.cancer.gov/protocolDevelopment/electronic\\_applications/docs/CTCAE\\_v5\\_Quick\\_Reference\\_8.5x11.pdf](https://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_8.5x11.pdf)

# How to Access CTCAE



- Smartphone & tablet apps available
  - Use CTCAE+
  - Easy search feature
- NCI website
  - Search [pdf version](#)





# 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





# Determining Attribution...



What is already known about:

Drug or classification of the drug  
Therapy or intervention  
Expectedness



Is there a temporal relationship of the AE to the study intervention?



Does the AE improve or disappear when the intervention is discontinued?



If re-challenged with the intervention, does the AE reappear?

At the same severity?  
At the same time point?



## ... Determining Attribution



Is the AE a result of existing disease signs and symptoms?



Is the AE a result of existing baseline signs and symptoms?



Is the AE a result of an underlying concurrent medical condition(s)?



Is the AE a result of an underlying concurrent medication(s)?

# AE Assessment



- Obtained by nurse or investigator with input from the other members of the research team.
- Starts with a quality baseline assessment.
- Includes:
  - Physical exam
  - Review of medical record
  - Review of Laboratory Tests
  - Review of Radiology results
  - Review of Signs & Symptoms
- Solicited events vs spontaneously reported by a participant





# Documentation

- Medical Record documentation should include:
  - Date the event began; include time with infusion reaction.
  - Detailed description
  - Attribution
  - Immune relationship if applicable
  - Any treatment for the event
  - Impact on the clinical trial intervention
  - Date of resolution/improvement
  - Seriousness





# Example of documentation

Patient Name: \_\_\_\_\_ Study # \_\_\_\_\_ Cycle: \_\_\_\_\_

AE	Grade	Attribution	Start	Stop	Ongoing	Immune Related	Is this considered a serious AE needing expedited reporting	Action taken
					<input type="checkbox"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	

*Attribution: 1 definitely related; 2 unlikely related; 3 possibly related; 4 probably related; 5 unrelated*

Investigators Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Page: \_\_\_\_ of \_\_\_\_



Which statement represents the most complete description for adverse event reporting?

- A. Ms. Smith states she had some diarrhea after her last treatment, that stopped with Imodium.
- B. She stated she had 6 stools a day after her last treatment. The diarrhea stopped 4 days ago.
- C. Patient states she had 6 stools a day, which is 5 above baseline.
- D. She states she had 6 stools a day, which is 5 above baseline. This started 5 days after her treatment. She took Imodium, and it slowed to 2 stools a day yesterday.



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# Online Data Submission

Adverse Events

# Online Data Submission: Adverse Events



Home S2007 CTSUTST01 283430 Cycle 01 Adverse Events: Assessment

Patient ID: 283430 Enrollment Date: 09 Dec 2020 Patient Initials (LFM): AAA

Subject: 283430  
Page: Adverse Events: Assessment - Cycle 01

**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

**Answer "Yes" to generate the AE Report form** →

Date of most recent adverse event assessment 31 Dec 2020

**Comments**

**Should always be at the end of the reporting period** →

*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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Save Cancel



# Online Data Submission: Adverse Events



S2007 CTSUTST01 283430 Cycle 01 Adverse Events: Assessment

Patient ID: 283430 Enrollment Date: 09 Dec 2020 Patient Initials (LFM): AAA

Subject: 283430  
Page: Adverse Events: Assessment - Cycle 01

**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	✓	✎	✕
If yes, did the patient experience any adverse events during this reporting period?	Yes	✓	✎	✕
Date of most recent adverse event assessment	31 Dec 2020	✓	✎	✕

**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 SWOG yet.  ✓ ✎ ✕

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- Cycle 01
  - Treatment
  - Adverse Events: Assessment
  - Adverse Events: Report**
  - Expedited Reporting Evaluation
- CRF History
- 283430 - Adverse Events: Assessment
  - 283430 - Treatment
  - 283430 - On Tx Vital Status 2021-01-31



# Online Data Submission: Adverse Events



[Home](#) | [S2007](#) | [CTSUTST01](#) | [283430](#) | [Cycle 01](#) | [Adverse Events: Report](#)

Patient ID: 283430      Enrollment Date: 09 Dec 2020      Patient Initials (LFM): 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 first course/cycle (derived)      9 Dec 2020

#	*Adverse event term (CTCAE v5.0)	*Adverse event grade description (first 120 characters)	Attribution to study intervention	None	Hospitalization ?	Life-threatening ?	Death ?	Disability ?	Congenital anomaly/birth defect ?	SAE report (derived)	Other recommended (derived)	* AE entry date (derived)	* Time zone (derived)
1	-	-		<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 line    Inactivate

**INSTRUCTIONS:** After entering new or modified data in the table above, adverse events must be submitted to CTEP-AERS for rules evaluation by saving the **Expedited Reporting Evaluation** CRF in Rave.

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 SWOG yet.           

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CRF Version 2751 - Page Generated: 11 Apr 2023 15:01:40 Pacific Daylight Time

Save    Cancel

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



# Online Data Submission: Adverse Events



CRF History

- 283430 - Adverse Events: Report
- 283430 - Adverse Events: Assessment
- 283430 - Treatment
- 283430 - On Tx Vital Status 2021-01-31

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 first course/cycle (derived) [9 Dec 2020]

Currently viewing line 1 of 1.  
Click here to return to "Complete View".

\* Adverse event term (CTCAE v5.0)

	<input type="text" value="Cough"/>	<input type="text" value=""/>	<input type="text" value=""/>
--	------------------------------------	-------------------------------	-------------------------------

\* Adverse event grade description (first 120 characters)

Attribution to study intervention

\* Did the adverse event result in (at least one outcome must be checked):

- None of the items below
- Hospitalization
- Life-threatening
- Death
- Disability
- Congenital anomaly/birth defect
- Other

SAE report recommended (derived)

\* AE entry date (derived)

\* Time zone (derived)

**INSTRUCTIONS:** After entering new or modified data in the table above, adverse events must be submitted to CTEP-AERS for rules evaluation by saving the **Expedited Reporting Evaluation** CRF in Rave.

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 SWOG yet.

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Save Cancel

Use the arrow to select the CTCAE term from the drop-down menu

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

# Online Data Submission: Adverse Events



S2007 CTSUTST01 283430 Cycle 01 Adverse Events: Report

Patient ID: 283430 Enrollment Date: 09 Dec 2020 Patient Initials (LFM): 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 first course/cycle (derived) 9 Dec 2020

#	*Adverse event term (CTCAE v5.0)	*Adverse event grade description (first 120 characters)	Attribution to study intervention	None	Hospitalization	Life-threatening	Death	Disability	Congenital anomaly/birth defect	SAE report Other recommended (derived)	* AE entry date (derived)	*Time zone (derived)
1	Cough	(1) Mild symptoms; nonprescription intervention indicated	Unlikely	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	11 Apr 2023 06 15 44 PM	Eastern Standard Time

**Add a new Log line** **Inactivate**

**INSTRUCTIONS:** After entering new or modified data in the table above, adverse events must be submitted to CTEP-AERS for rules evaluation by saving the **Expedited Reporting Evaluation** CRF in Rave.

Comments ?

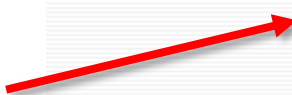
*If you're not done completing this form, but want to save your work for later, check the box below and click the Save button. Note that edit checks will still fire.*

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

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Save Cancel



(2018) CTEP Guidance for recording adverse event start & end dates

# Online Data Submission: COVID-19



S2007 CTSUTST01 283430 Cycle 01 Adverse Events: Report

Patient ID: 283430 Enrollment Date: 09 Dec 2020 Patient Initials (LFM): 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 first course/cycle (derived) 9 Dec 2020

by viewing line 2 of 2.  
to return to "Complete View".

Apply to Record

Infections and infestations - Other, specify  
COVID-19

\* Adverse event grade  
description (first 120 characters)

Attribution to study intervention

\* Did the adverse event result in (at least one outcome must be checked):

None of the items below

Hospitalization

Life-threatening

Death

Disability

Congenital anomaly/birth defect

Other

SAE report recommended (derived)

\* AE entry date (derived)

\* Time zone (derived)

**INSTRUCTIONS:** After entering new or modified data in the table above, adverse events must be submitted to CTEP-AERS for rules evaluation by saving the **Expedited Reporting Evaluation** CRF in Rave.

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 SWOG yet.

Printable Version View PDF Icon Key  
CRF Version 2751 - Page Generated: 11 Apr 2023 15:40:35 Pacific Daylight Time

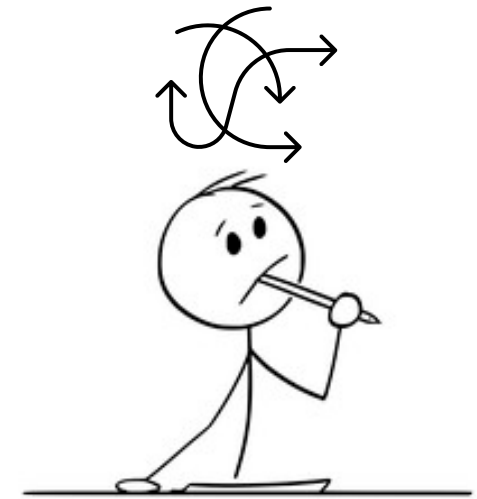
Save Cancel

If you choose "Other, specify," specify further in the text box

Use the Comments as needed for further explanation



# Nuances in AE Reporting





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# Common Reporting Errors

- Non-clinically significant lab abnormalities
- Symptoms vs Condition
- Procedure vs disease that resulted in the procedure
- Progression
- Not reporting baseline conditions that worsen or reoccur after previously resolving.

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# Grading based on the use of Medication



Just because someone is taking a medication, does not mean that they have the condition.

- Prophylactic use
- Medications have multiple uses







# Grading conditions present at Baseline

Not all events can be assigned a grade at baseline.

CTCAE Term	Grade 1	Grade 2	Grade 3	Grade 4
Hyperglycemia	Abnormal glucose above baseline with no medical intervention	Change in daily management from baseline for a diabetic; oral antiglycemic agent initiated; workup for diabetes	Insulin therapy initiated; hospitalization indicated	Life-threatening consequences; urgent intervention indicated
Hypertension	<p><b>Adult:</b> Systolic BP 120 - 139 mm Hg or diastolic BP 80 - 89 mm Hg;</p> <p><b>Pediatric:</b> Systolic/diastolic BP &gt;90th percentile but &lt; 95th percentile;</p> <p><b>Adolescent:</b> BP <math>\geq</math>120/80 even if &lt; 95th percentile</p>	<p><b>Adult:</b> Systolic BP 140 - 159 mm Hg or diastolic BP 90 - 99 mm Hg if previously WNL; change in baseline medical intervention indicated; recurrent or persistent (<math>\geq</math>24 hrs); symptomatic increase by &gt;20 mm Hg (diastolic) or to &gt;140/90 mm Hg; monotherapy indicated initiated;</p>	<p><b>Adult:</b> Systolic BP <math>\geq</math>160 mm Hg or diastolic BP <math>\geq</math>100 mm Hg; medical intervention indicated; more than one drug or more intensive therapy than previously used indicated;</p> <p><b>Pediatric and adolescent:</b> Systolic and/or diastolic &gt; 5 mmHg above the 99th</p>	<p><b>Adult and Pediatric:</b> Life-threatening consequences (e.g., malignant hypertension, transient or permanent neurologic deficit, hypertensive crisis); urgent intervention indicated</p>
Diarrhea	Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline	Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline; limiting instrumental ADL	Increase of $\geq$ 7 stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self care ADL	Life-threatening consequences; urgent intervention indicated



# Which Cycle does an AE get reported in?

## Screening

4/8/22

- Dyspnea grade 2
- Anemia grade 2

## Registration

4/24/22 / NOON

- Labs at 9:00 am
- Physical at 9:30 am

## Cycle 1

4/27/22 / NOON Tx

- Labs drawn at 9:00 am
- Physical at 9:30 am

## Cycle 2

5/25/22 / Noon Tx

- Labs drawn at 9:00 am
- Physical at 9:30 am

### Adverse events

Anemia gr 1

Dyspnea gr 3

Albumin gr 1

### Adverse events

Anemia gr 0

Dyspnea gr 2

Albumin gr 1

Fatigue gr 1

### Adverse Events

Anemia gr 1

Dyspnea gr 1

Albumin gr 1

Fatigue gr 2



Below are some events that occurred during Cycle 1. Which one(s) should be reported, based on general SWOG guidance on AE reporting:

1. Fatigue, gr 1, attributed to working long hours, was 0 at baseline.
  2. Increased non-fasting glucose, previously WNL. Not clinically significant.
  3. Shortness of breath gr 2, same as baseline.
  4. 5% weight loss, found on Day 1 of Cycle 2, prior to treatment.
- A. All listed events
  - B. Fatigue & Shortness of Breath
  - C. Fatigue, increased glucose & weight loss.
  - D. Fatigue, increased glucose & shortness of breath.

# Adverse Event Escape Room

[https://docs.google.com/presentation/d/1cm\\_dIq8VsnkjJd5R4vPUCXZ4s3UfYzMO002IWxD17RE/preview?slide=id.p](https://docs.google.com/presentation/d/1cm_dIq8VsnkjJd5R4vPUCXZ4s3UfYzMO002IWxD17RE/preview?slide=id.p)



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# Questions

