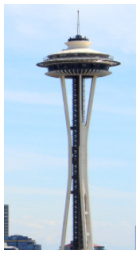
Adverse Event Reporting



Gabi Herbert
Clinical Research Data Coordinator III
Cancer Research And Biostatistics (CRAB)
SWOG Statistics and Data Management Center

SWOG Group Meeting
Spring 2026

1

Adverse Event (AE) Reporting: Outline

- Key Terms
- AE Information in SWOG Protocols
- Components of Reporting Adverse Events
  - CTCAE Terms and Grades
  - Attribution
  - Status code
- Online Data Submission: Adverse Events

2

Key Terms

3

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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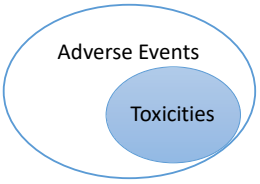
Adverse Event versus Toxicity

*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

- 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.

6

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

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

- Captured via Adverse Events eCRF at protocol-specified timepoints

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

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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 Dose Modifications
9	Study Calendar
14	Data Submission Schedule

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

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Protocol Section 8.0 – Toxicities to be Monitored and Dose Modifications

- Lists **Toxicities** that may be seen on treatment and drugs to aid in **symptom management**
- Provides **Adverse Event Reporting Requirements**
- Indicates the Common Terminology Criteria for Adverse Events (**CTCAE**) version used for study reporting
- Lists **Dosage changes** required during treatment in response to AEs
- Provides names and **contact information** of physicians to reach for assistance

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Protocol Section 8.0 – 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

- Questions about dose mods should always be directed to the **Study Chairs**

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Protocol Section 9.0 – Study Calendar

9.0 STUDY CALENDAR

	Refer to Table (Table Section 10.2)	Before Randomization Step 2	Treatment [A] Cycle 1	Cycle 2	Cycle 3	Cycle 4	Subsequent Cycles	Off Tx Pre-progression follow-up	Off Tx Post-progression follow-up
PHYSICAL									
History & Physical Exam		X	X	X	X	X	X	X [C]	X [C]
Weight & Zubrod Performance Status		X	X	X	X	X	X		
Disease Assessment		X			X		X [B]	X [B]	
Baseline Abnormality Assessment		X							
Toxicity Assessment			X	X	X	X	X	X [C]	X [C]

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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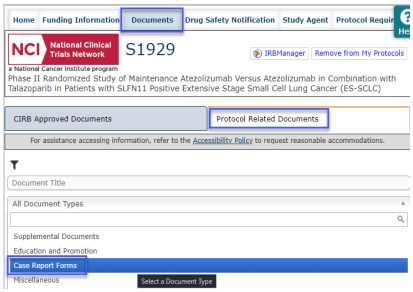
Master Forms Set (All CRFs)



- Available via CTSU (Document Type = Case Report Forms)
- Contains **all** case report forms (CRFs) for a particular protocol, including those used to report adverse events

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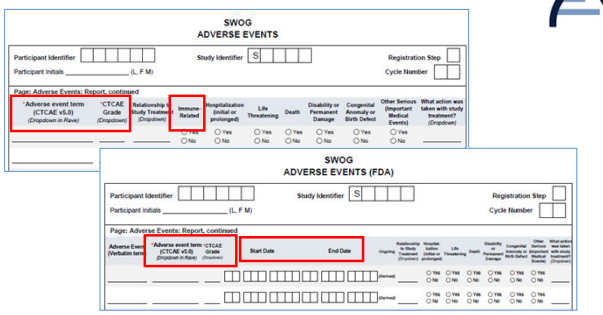
Master Forms Set (All CRFs)



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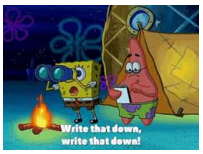
Reporting Adverse Events

CTCAE Terms and Grades
Attribution
Status Codes



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NCI Common Terminology Criteria for Adverse Events (CTCAE)

- CTCAE versions and other AE reporting resources are found at ctep.cancer.gov
  - Current SWOG trials use Version 5.0, which was published in NOV 2017
  - *Coming soon!* Version 6.0 was published in JUL 2025
    - Expected to be implemented in new SWOG trials starting later this year
- Some studies may use a different CTCAE version for routine AE reporting vs. SAE reporting.

Reminder: Protocol section 8 lists the CTCAE version used in the trial

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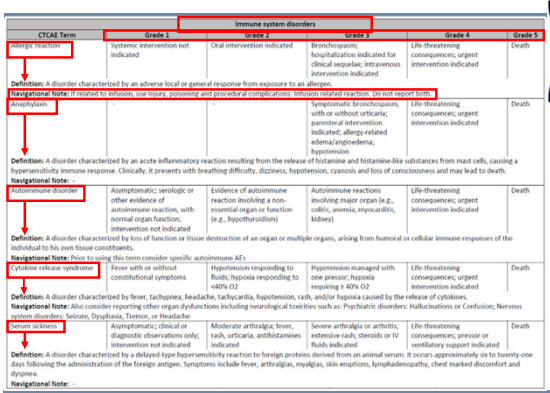

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Selecting CTCAE Terms

- 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!

CTRL+F is your BFF!

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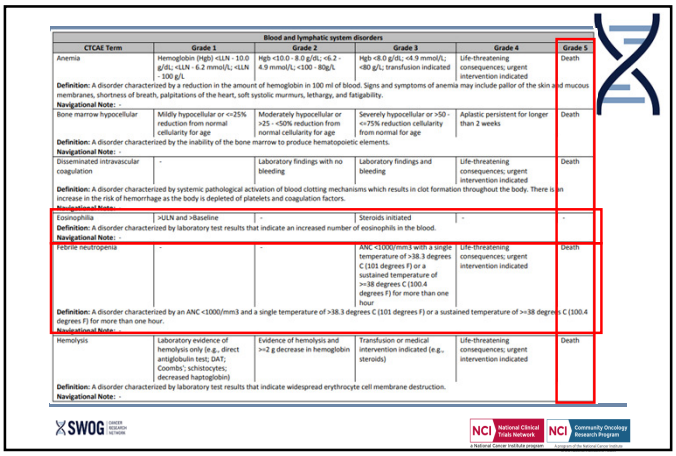

Blood and lymphatic system disorders					
CTCAE Term	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Anemia	Hemoglobin (Hgb) <LLN - 10.0 g/dL; <LLN - 6.2 mmol/L; <LLN - 100 g/L	Hgb <10.0 - 8.0 g/dL; <6.2 - 4.9 mmol/L; <100 - 80g/L	Hgb <8.0 g/dL; <4.9 mmol/L; <80 g/L; transfusion indicated	Life-threatening consequences; 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	>ULN 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/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. **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 *clearly not* related to the intervention
	2- Unlikely	The AE is *doubtfully* related to the intervention
Related to Investigational Agent/Intervention	**3-** Possible	The AE *may be* related to the intervention
	4- Probable	The AE is *likely* to be related to the intervention
	5- Definite	The AE is *clearly* 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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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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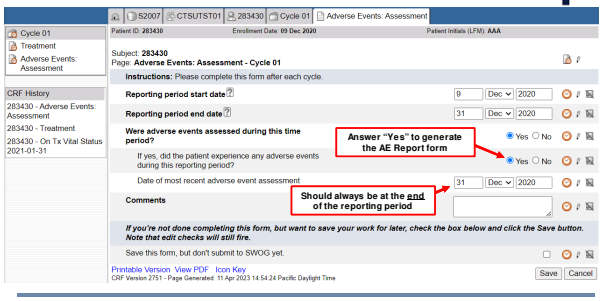
Online Data Submission: Adverse Events



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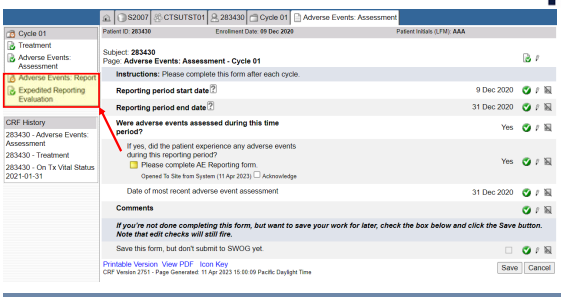

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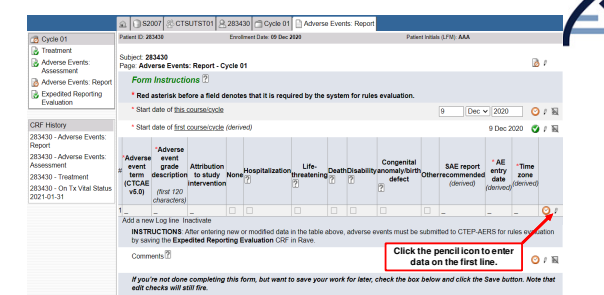

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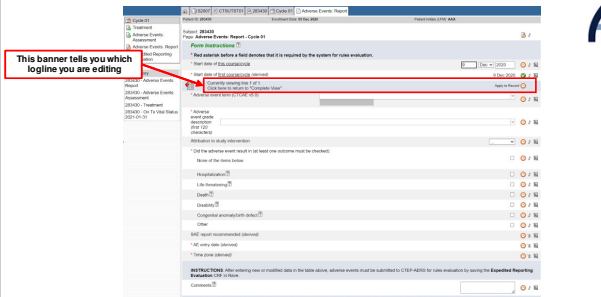

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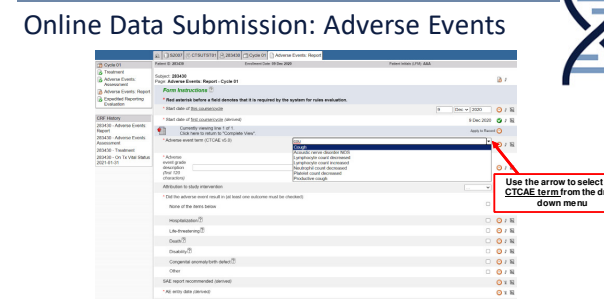

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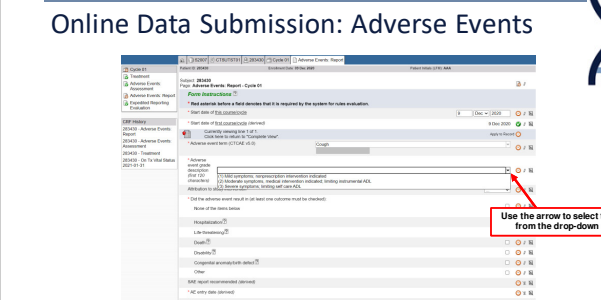

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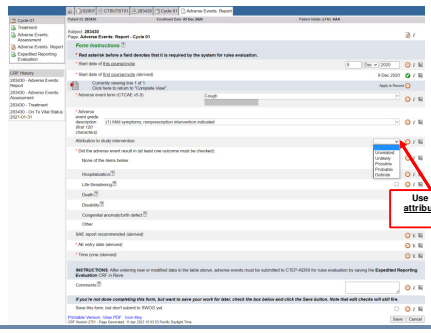

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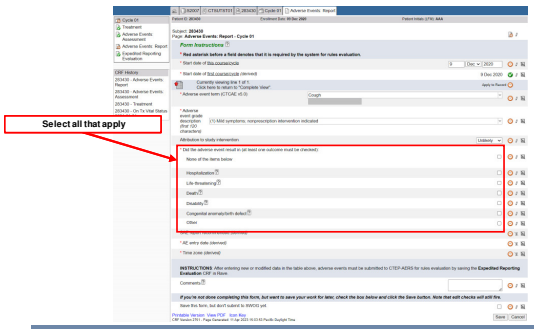

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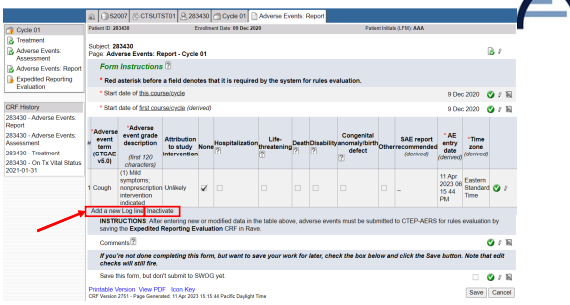

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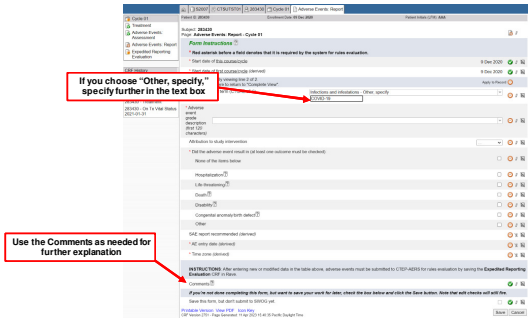

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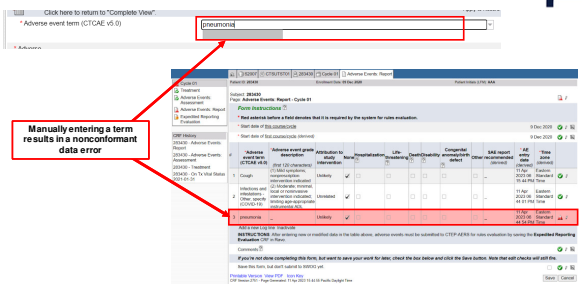

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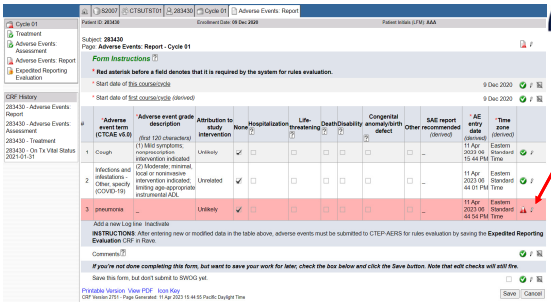

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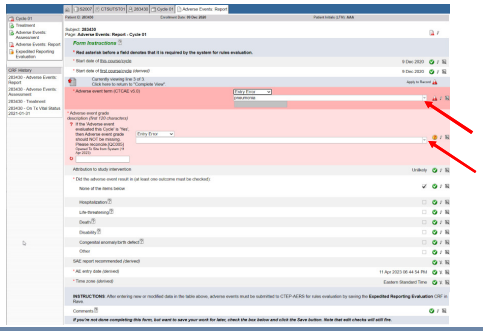

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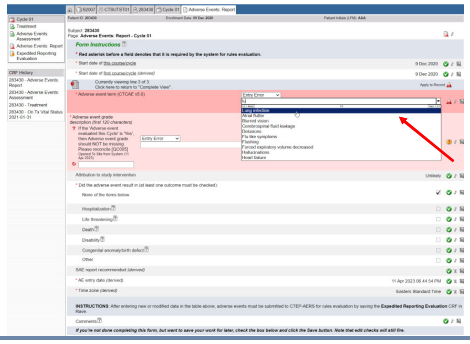

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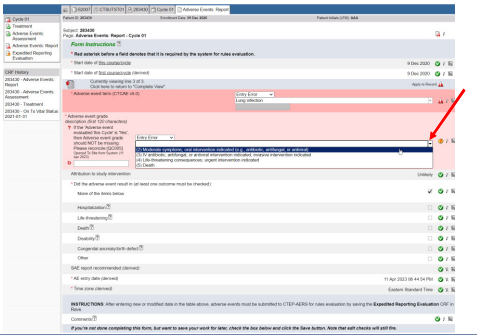

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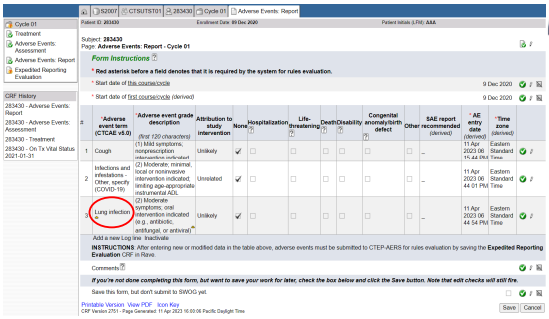

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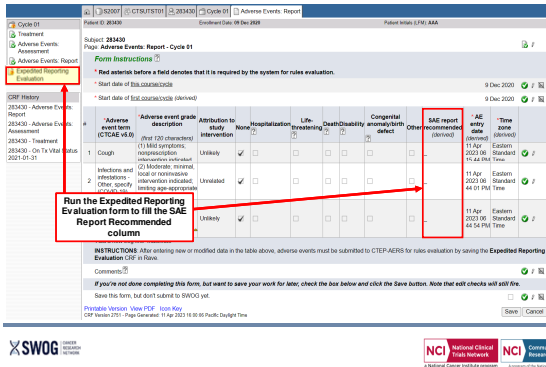

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Adverse Event Escape Room Assessment

Designed to cover the various aspects of adverse event in a fun, interactive learning environment.

- You are locked in a room and need to solve various clues related to adverse events.
- Each clue leads to a number in the code to escape the room.
- Resources are available on the bookshelf in the room.
- Use the QR code to access
- Click on the question mark to start.

Please send feedback to remete@swog.org

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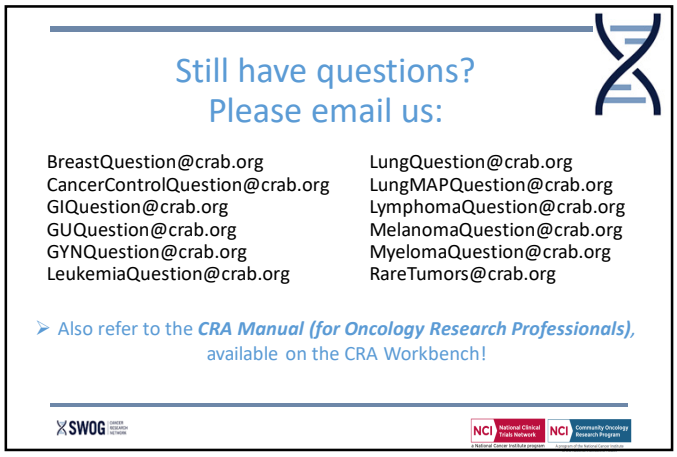
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GIQuestion@crab.org
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RareTumors@crab.org
Also refer to the CRA Manual (for Oncology Research Professionals), available on the CRA Workbench!
SWOG
NCI National Clinical Trials Network
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