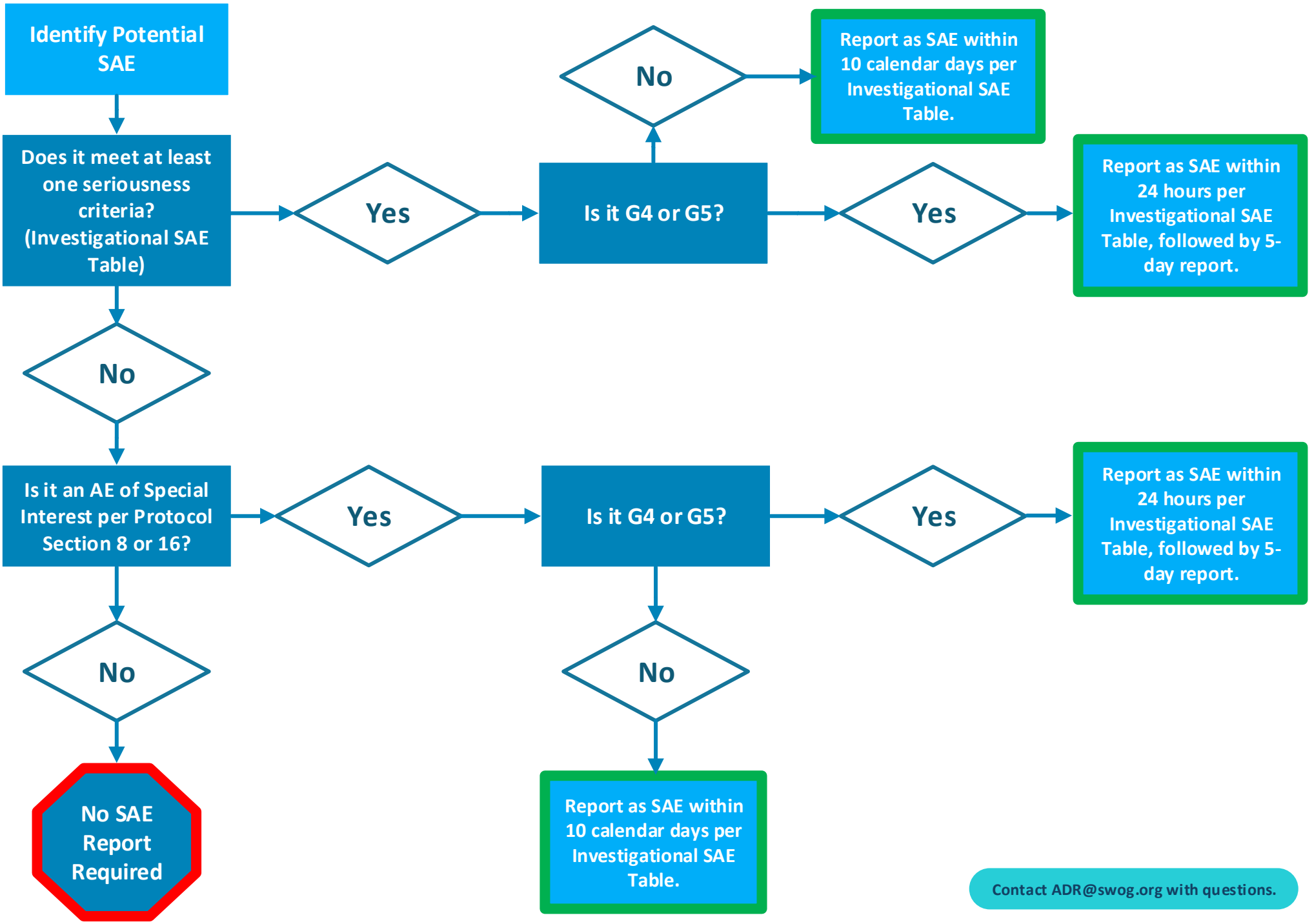
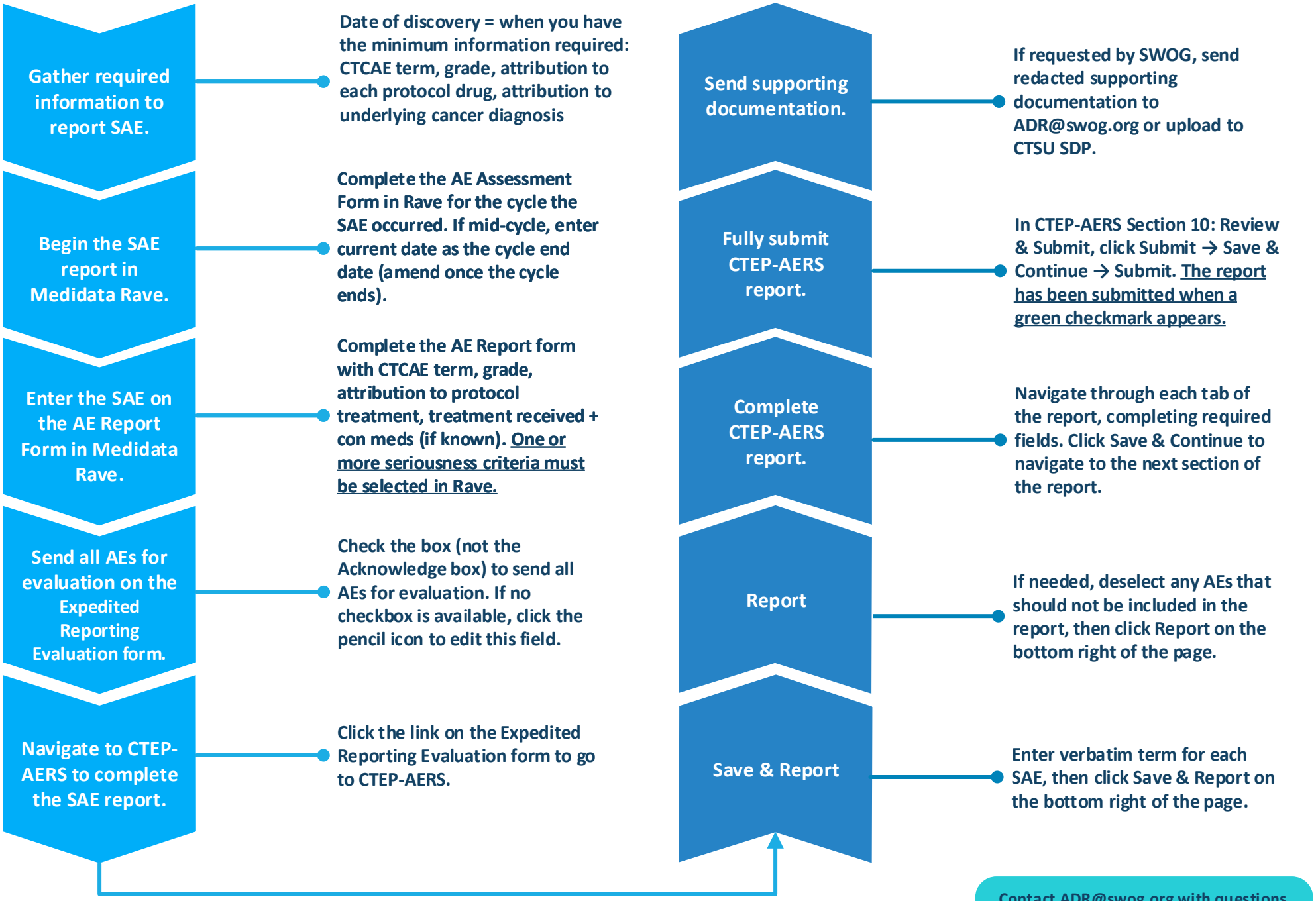
SAE Reporting - Investigational Treatment Arms

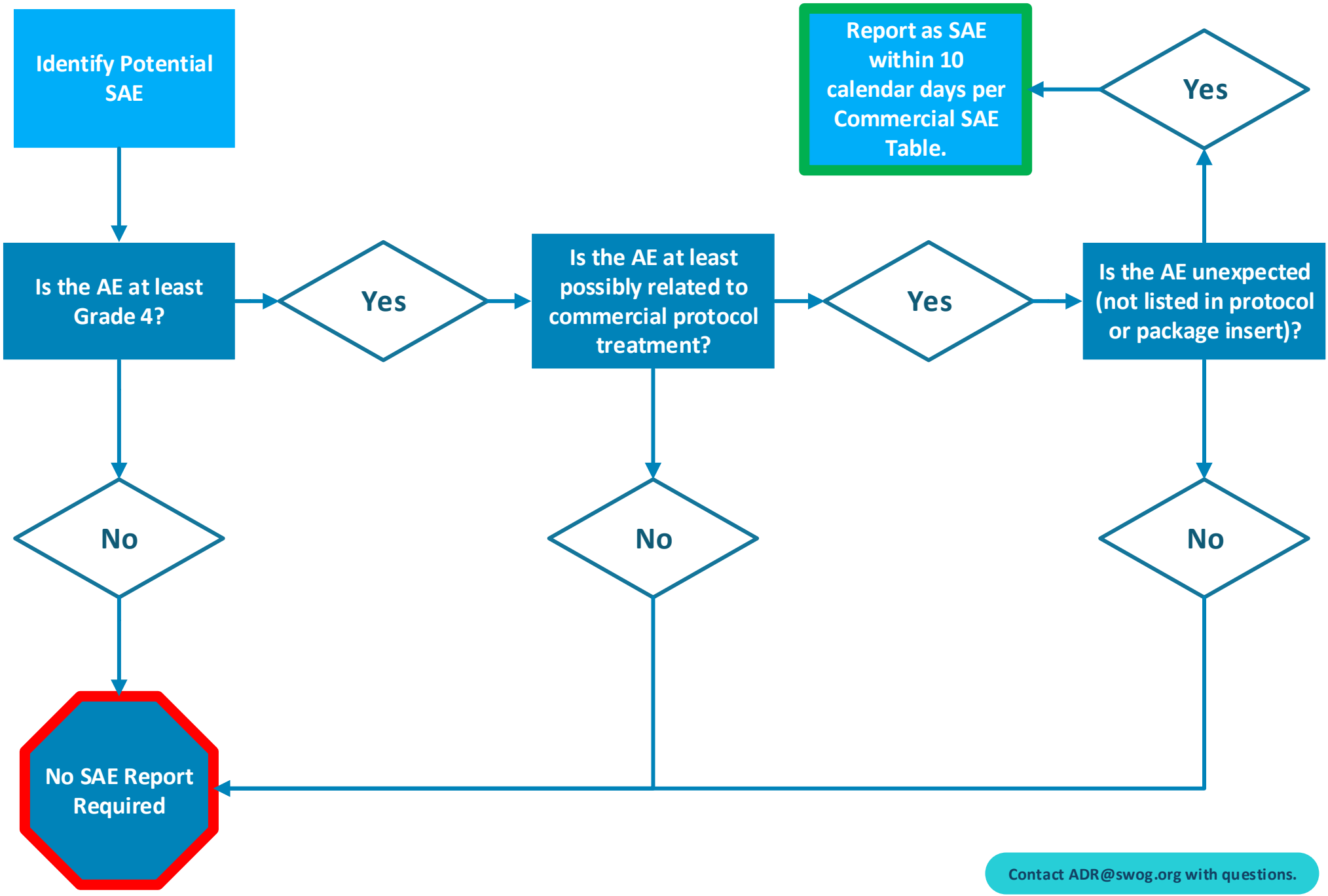


SAE Reporting - Investigational Treatment Arms

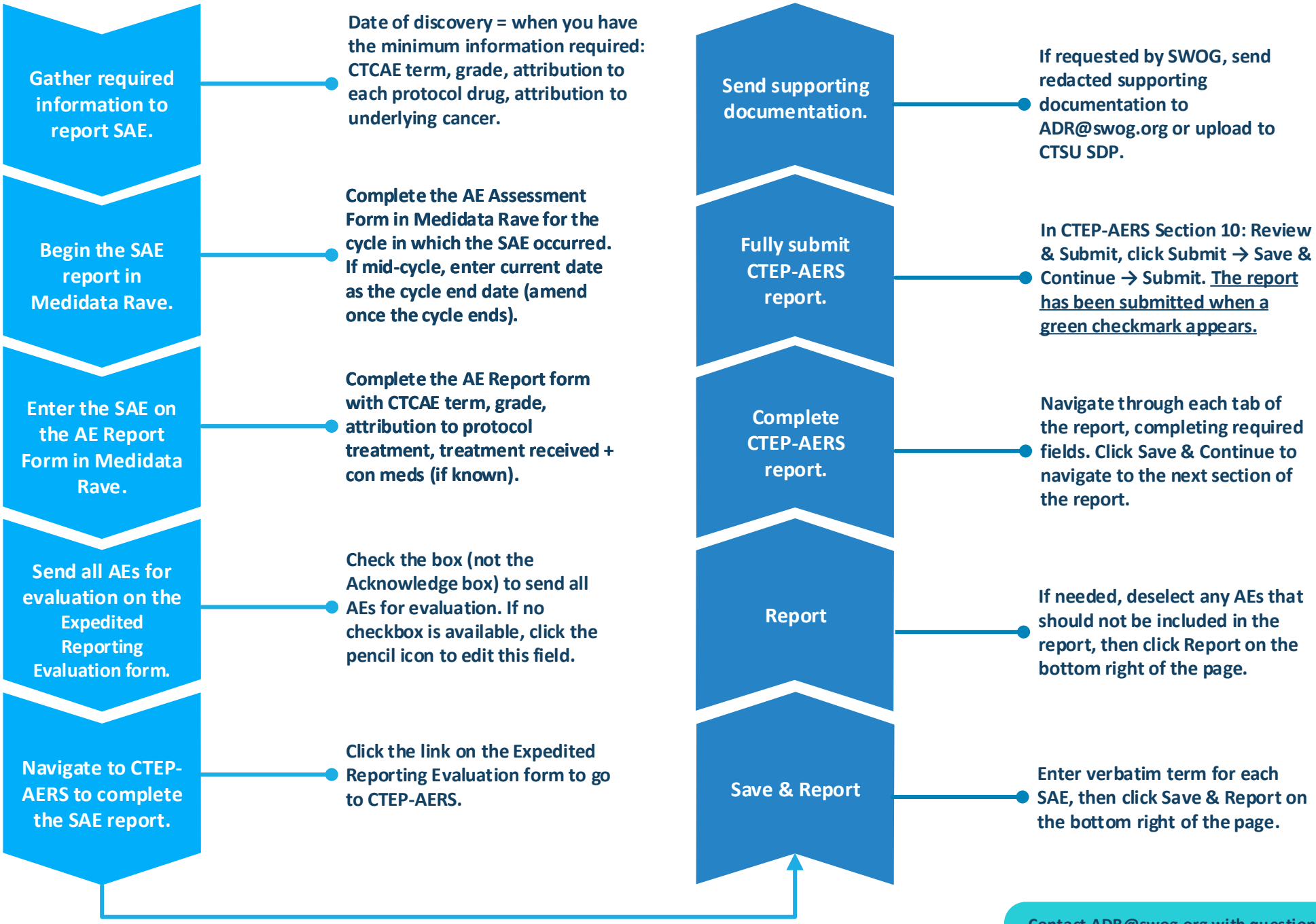


Contact ADR@swog.org with questions.

SAE Reporting - Commercial Treatment Arms



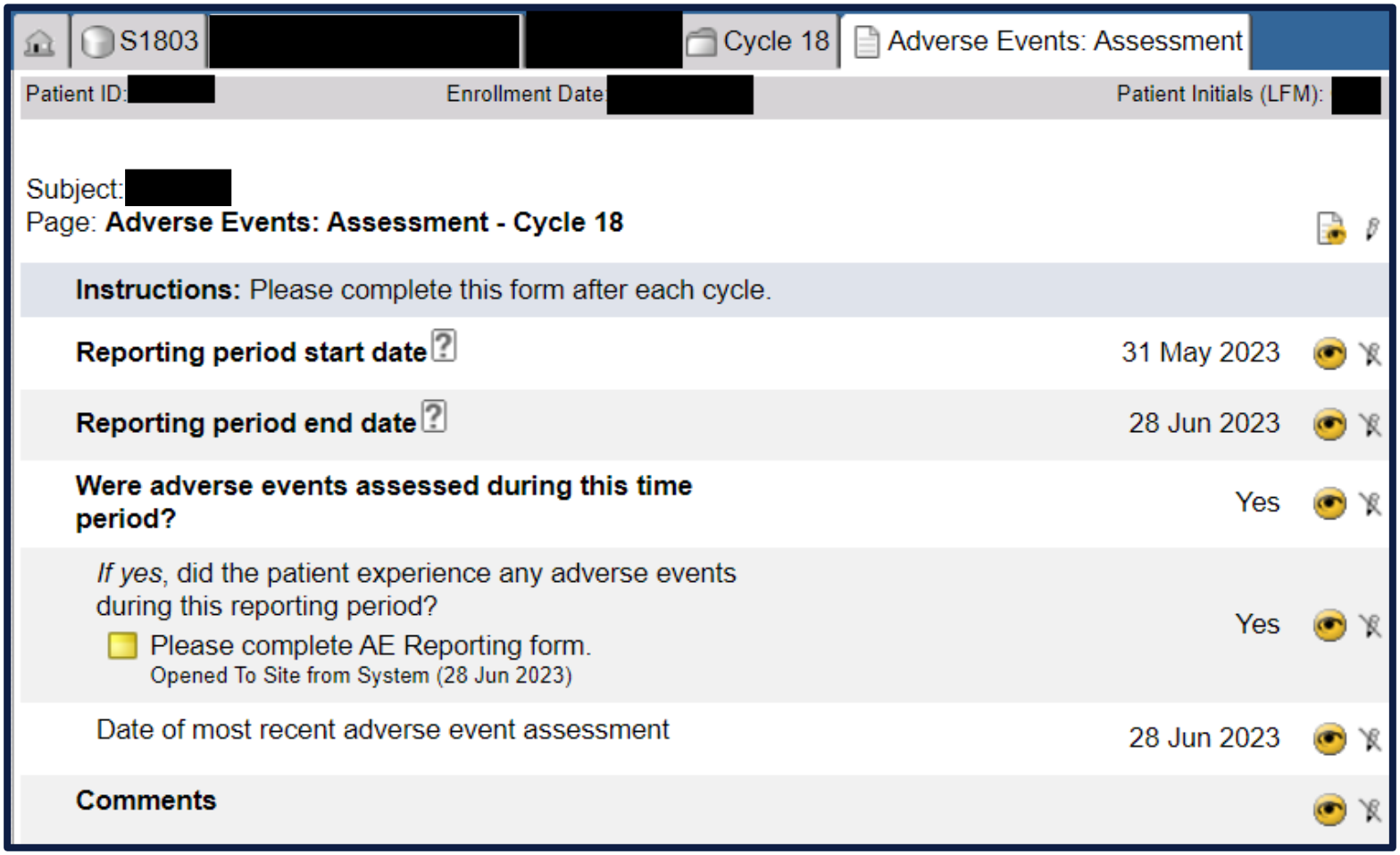
SAE Reporting - Commercial Treatment Arms



Contact ADR@swog.org with questions.

SAE Reporting – Medidata Rave Flowchart

Adverse Events: Assessment Form



- Complete the AE Assessment Form in Medidata Rave for the cycle in which the SAE occurred.
  - If mid-cycle, enter current date as the reporting period end date.
    - Once the cycle ends, please amend to the correct reporting period end date.
- Answer Yes to 'Did the patient experience any adverse events during this reporting period?'
  - This will populate the Adverse Events: Report Form.

SAE Reporting – Medidata Rave Flowchart

Adverse Events: Report Form

S1803 [redacted] Cycle 18 | Adverse Events: Report

Form Instructions

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

* Start date of this course/cycle: 31 May 2023

* Start date of first course/cycle *(derived)*: 02 Feb 2022

#	*Adverse event term (CTCAE v5.0)	*Adverse event grade description *(first 120 characters)*	Attribution to study intervention	Treatment received for this AE	If yes, concomitant agent name	None	Hospitalization	Life-threatening	Death	Disability	Congenital anomaly/birth defect	Required intervention	Other	SAE report recommended *(derived)*
4	Lung infection	(3) IV antibiotic, antifungal, or antiviral intervention indicated; invasive intervention indicated	Possible	Yes	Vantin, steroids	☐	☑	☐	☐	☐	☐	☐	☐	Yes
1	Dyspnea	(2) Shortness of breath with minimal exertion; limiting instrumental ADL	Unrelated	Yes	Nebulizer, albuterol	☐	☑	☐	☐	☐	☐	☐	☐	Yes

Complete the AE Report form with the following information:

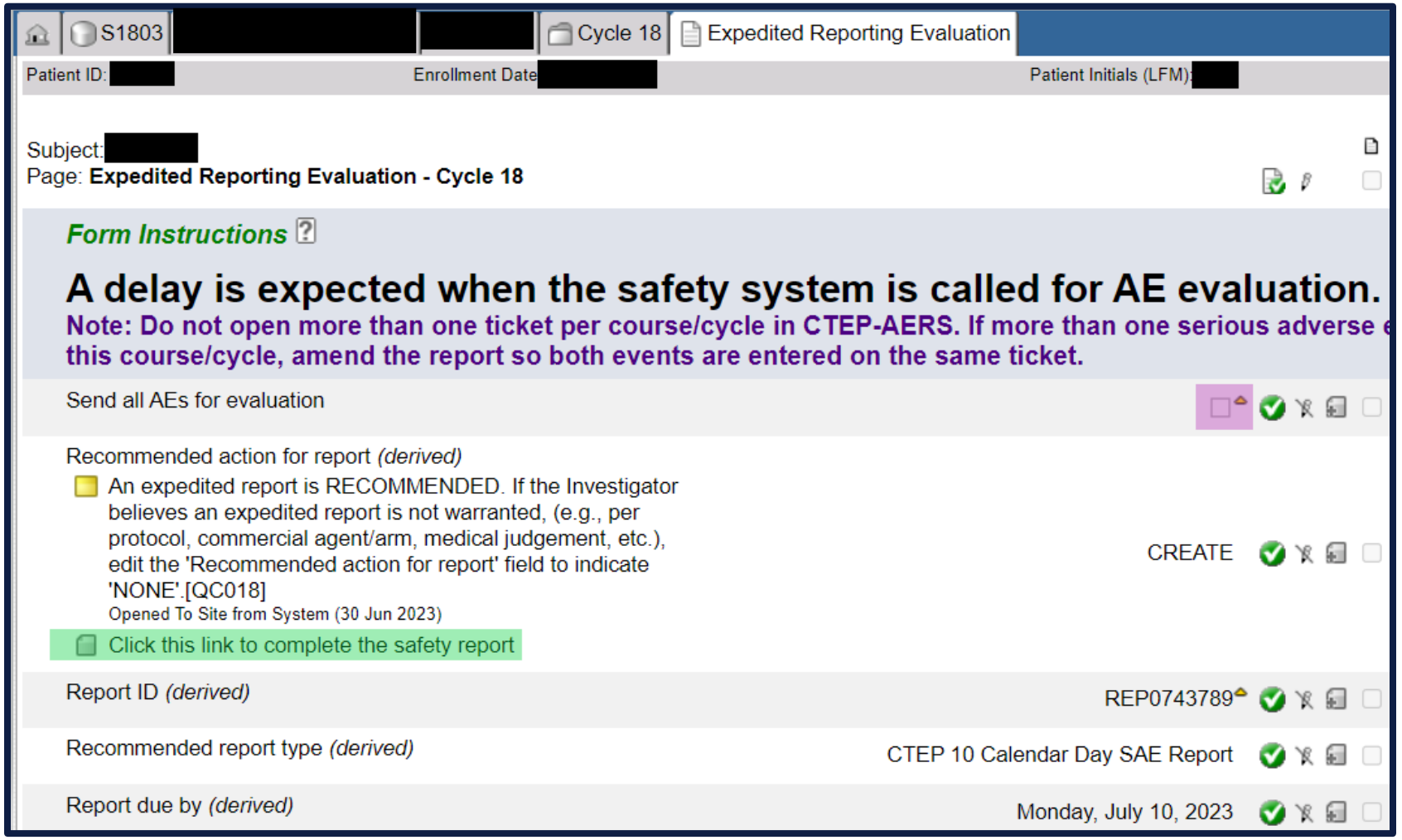
- **CTCAE term**
- **Grade**
- **Attribution to protocol treatment**
- **Treatment received for AE (Yes/No)**
- **Concomitant medications used to treat AE (if known)**

The fields highlighted in green represent seriousness criteria.

- **These fields designate an AE as an SAE.**
- **One or more of these fields must be checked for each SAE.**
- **Required intervention is only used for device trials.**

SAE Reporting – Medidata Rave Flowchart

Expedited Reporting Evaluation Form



- **Check the box (highlighted in purple) and save the form to send all AEs for evaluation.**
  - **If no checkbox is available, click the pencil icon to edit this field.**
- **Click the link (highlighted in green) on the Expedited Reporting Evaluation form to go to CTEP-AERS.**
- **Detailed instructions for completing the CTEP-AERS report are found:**
  - https://ctepcore.nci.nih.gov/ctepaers/help/webhelp/welcome/help%20-%20welcome%20to%20ctepaers%20help.htm

SAE Reporting – Tips and Resources

SWOG SAE TEAM (Contact first with all SAE questions, including technical support issues.)

- SAE Email: ADR@swog.org
- SAE Phone: 210-614-8808

TIPS

- CTEP-AERS requires each SAE to have an attribution of possible/probable/definite to *something*. If unrelated to protocol treatment and underlying cancer diagnosis, an 'other' cause may be added in *CTEP-AERS Section 7: Other Causes*. Unknown may be added as an 'other' cause if necessary, and an attribution of possible/probable/definite may be assigned to that.
- The seriousness criteria 'required intervention' (found in Rave) is only applicable to device trials and should not be selected for drug trials.

FREQUENTLY ASKED QUESTIONS

- I'm not sure if this AE requires SAE reporting, should I submit a report just in case?
  - If unsure, the SWOG SAE Team would prefer that you contact us by email or phone to confirm the need to report before spending time submitting an unnecessary report.
- Rave is recommending an SAE report, but the recommendation does not match the SAE reporting requirements in the protocol. Should an SAE report be submitted based on the recommendations in Rave?
  - The Rave recommendations are based on very basic rules and are often incorrect. SAEs should be submitted per protocol guidelines. ADR@swog.org can be contacted anytime for guidance.
- What is the deadline for submitting an SAE report to SWOG?
  - Reporting timeframes are found in the SAE reporting tables within the protocol. SAE tables are found in Section 8 or Section 16 of the protocol.
  - It is important to note that the 'submission due dates' in Rave or in the automated CTEP-AERS emails are not true deadlines; these dates only reflect the date after which CTEP-AERS will automatically delete unsubmitted reports.
  - SWOG makes every effort to notify sites if they have a pending report that will soon be deleted, but sites are responsible for reporting within protocol-specified timeframes.

RESOURCES

- Help resources for the CTEP-AERS application:
  - https://ctepcore.nci.nih.gov/ctepaers/help/webhelp/welcome/help%20-%20welcome%20to%20ctepaers%20help.htm
- NCI Guidelines for Investigators: Adverse Event Reporting Requirements
  - https://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/aeguidelines.pdf