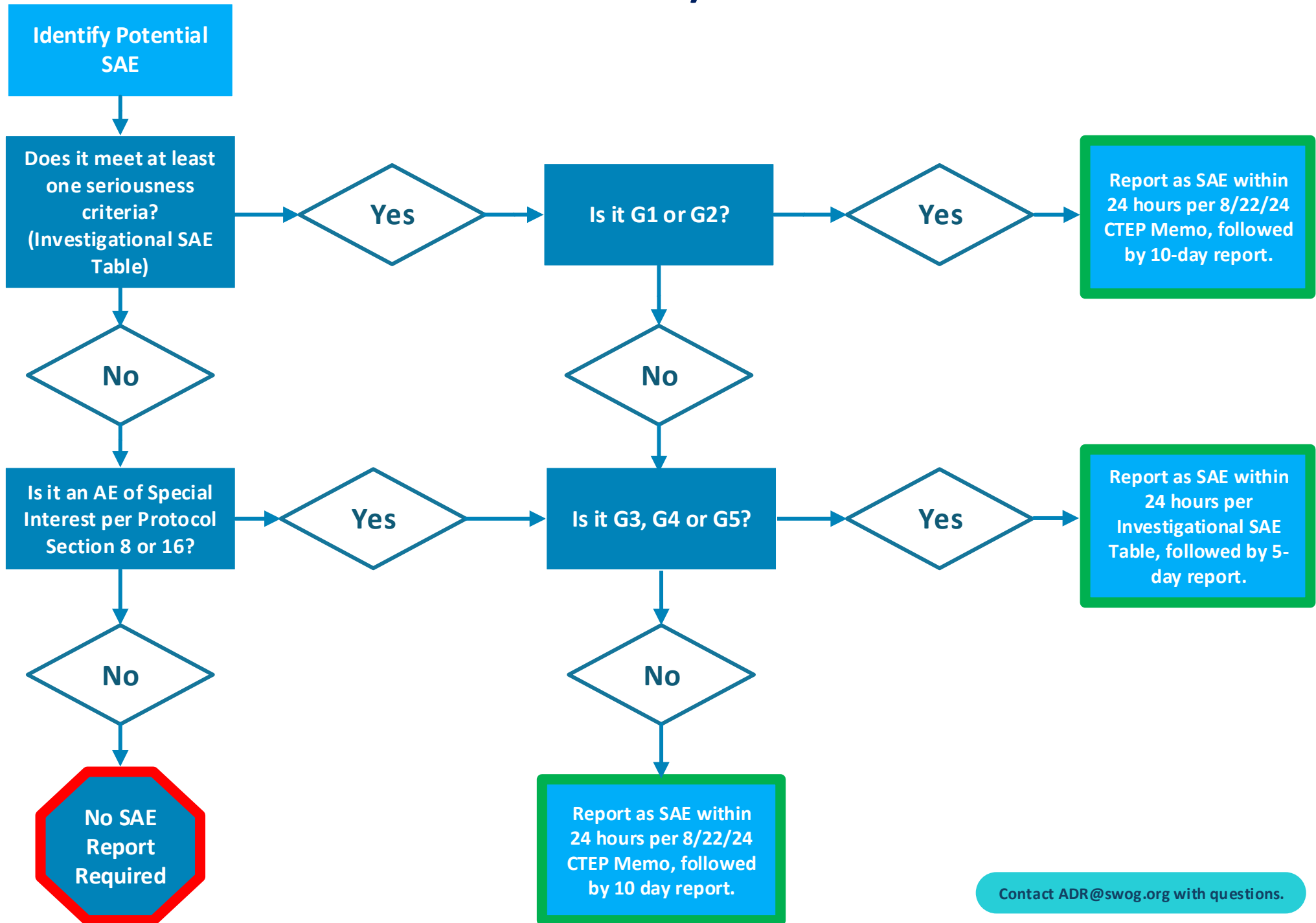
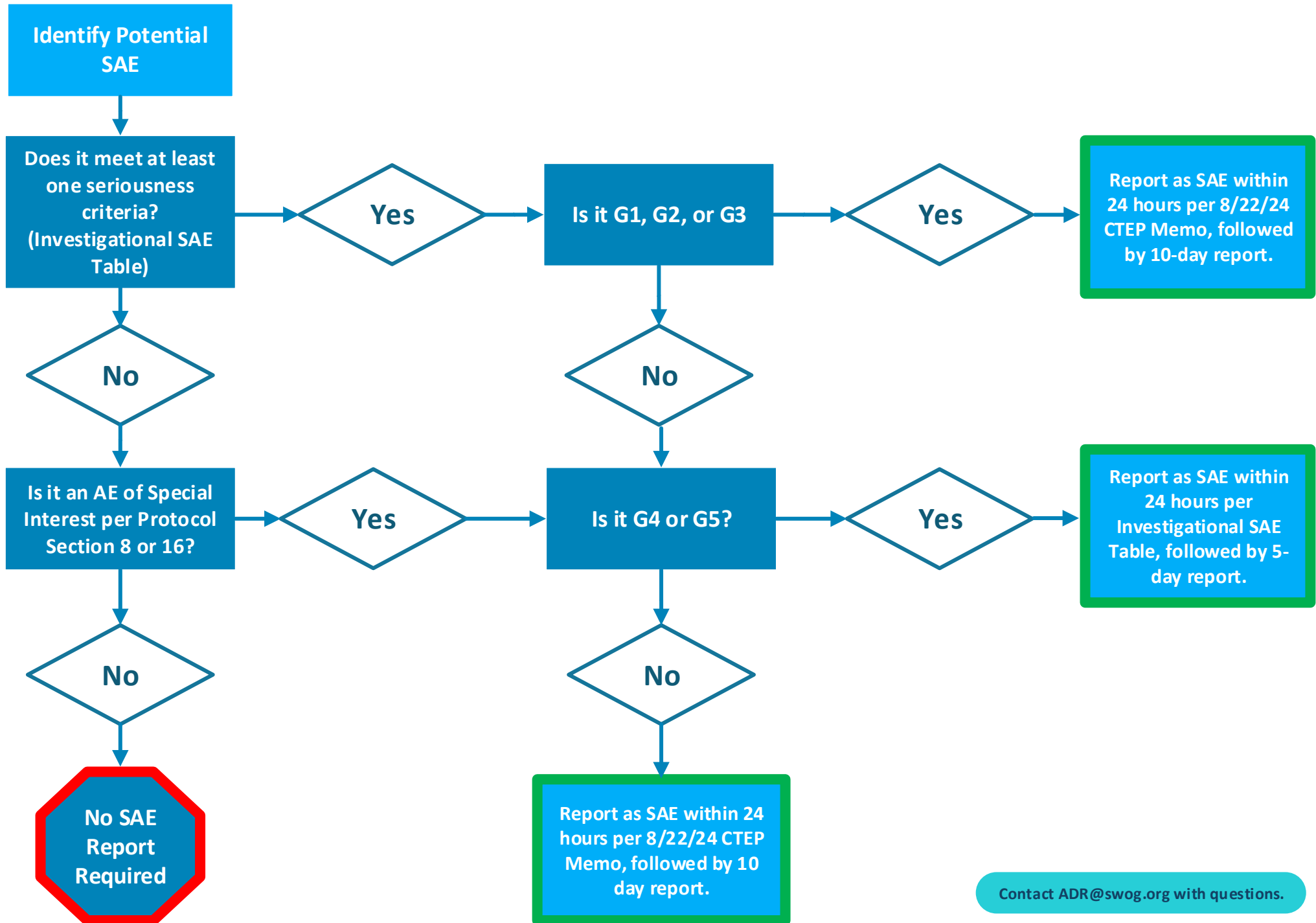


SAE Reporting - Investigational Treatment Arms Phase 1 and Early Phase 2 IND

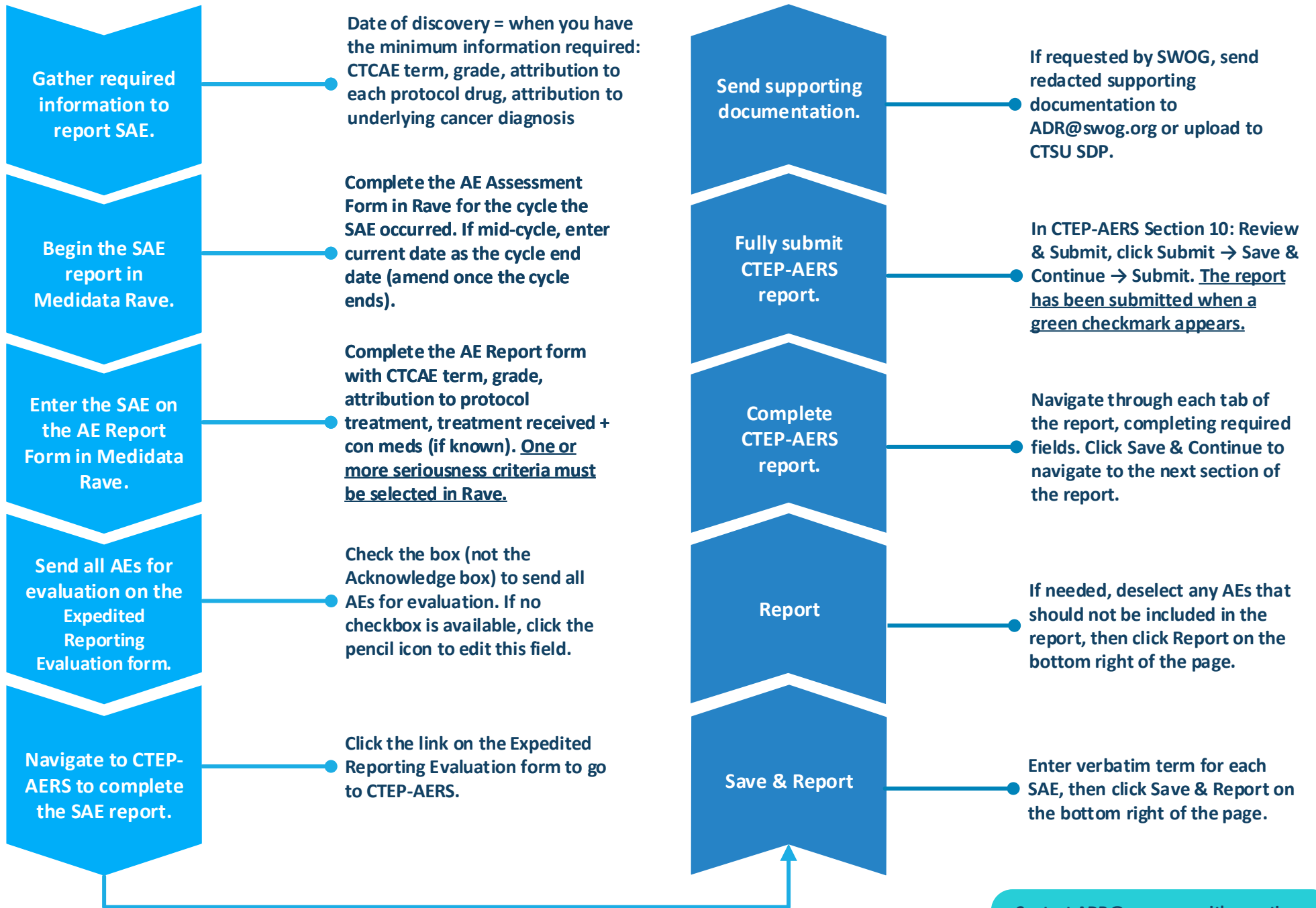


SAE Reporting - Investigational Treatment Arms

Late Phase 2 and Phase 3 IND

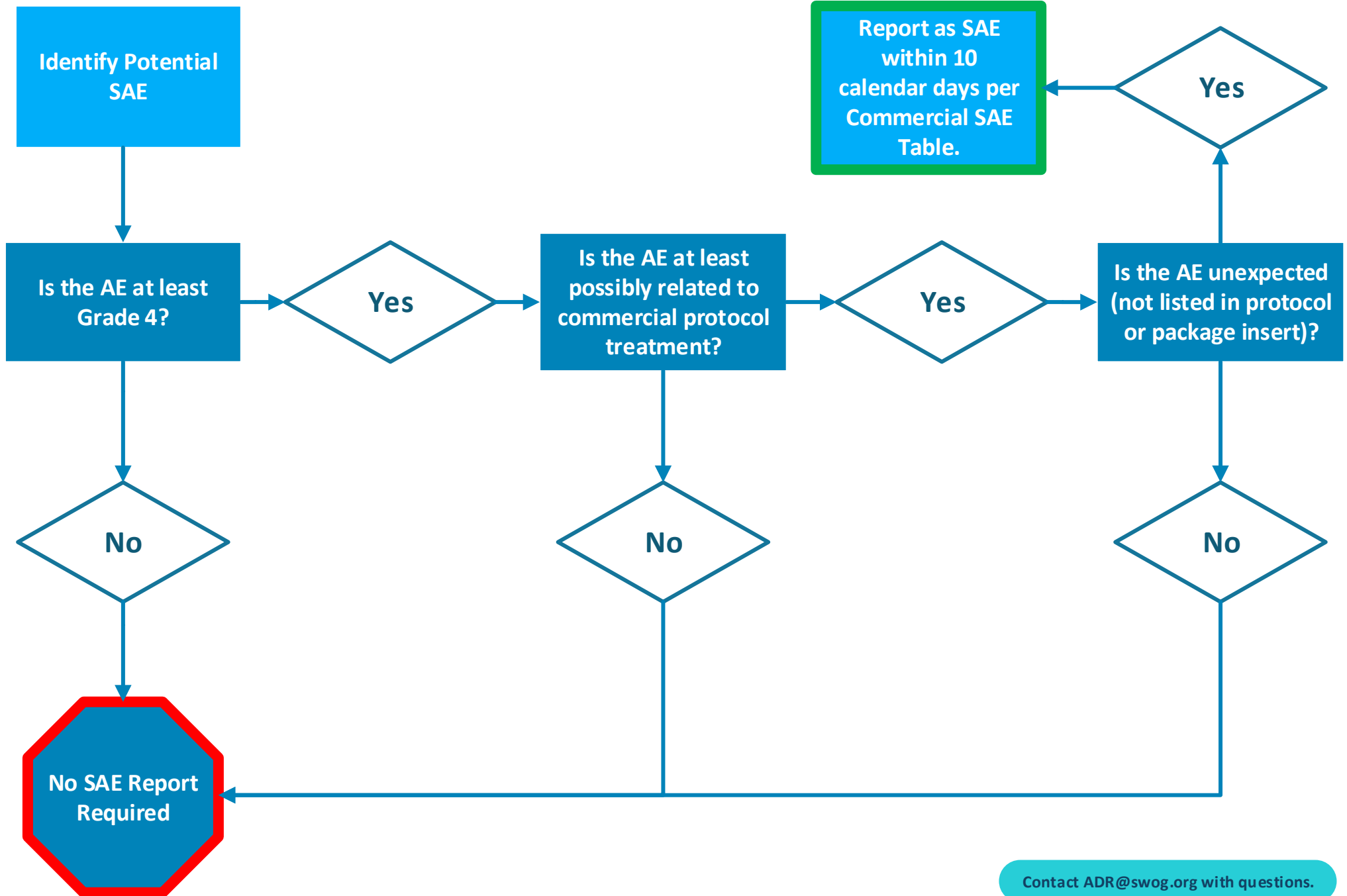


SAE Reporting - Investigational Treatment Arms

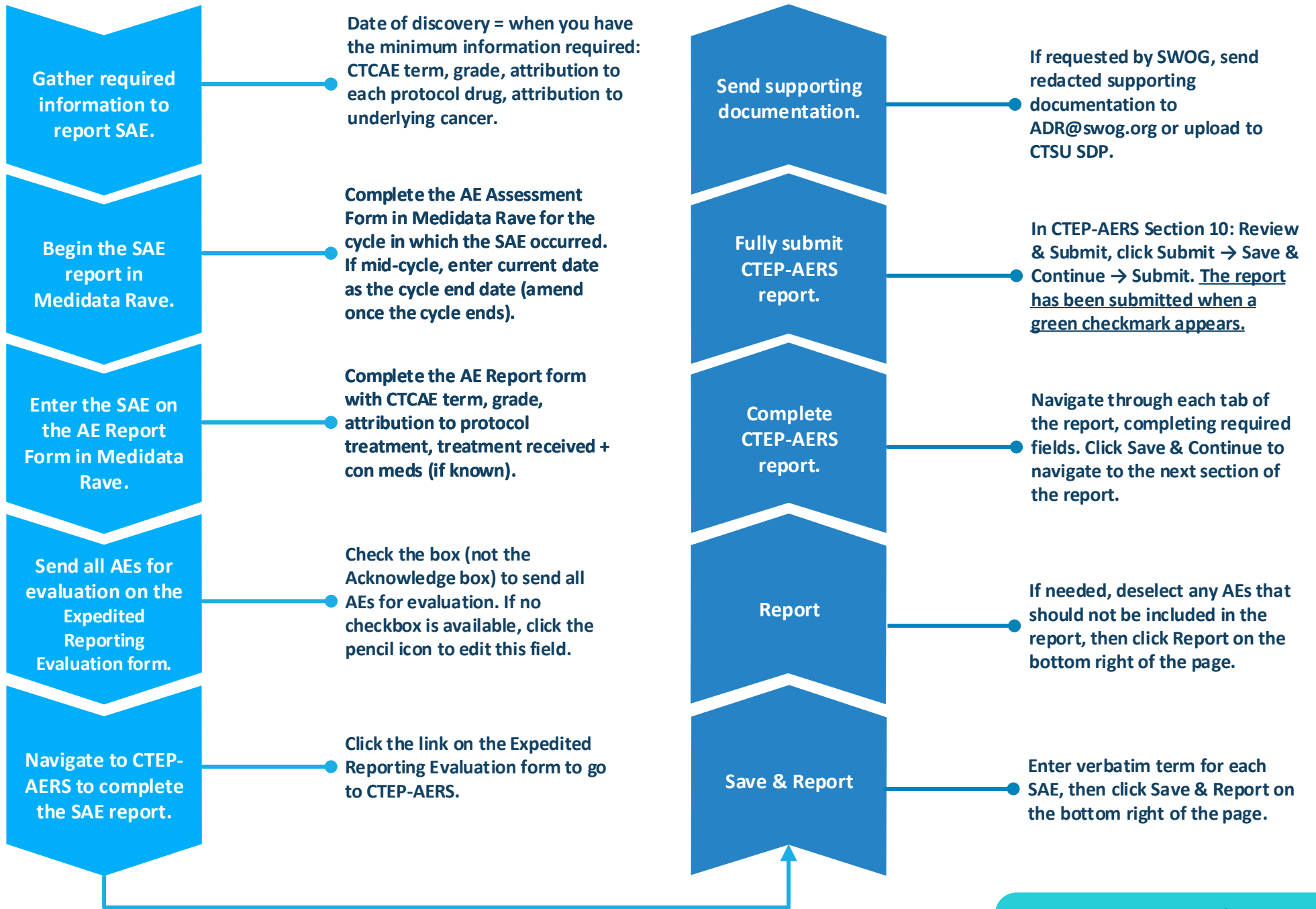


Contact ADR@swog.org with questions.

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

The screenshot shows the Medidata Rave interface for the 'Adverse Events: Assessment' form. The top navigation bar includes a home icon, a patient ID 'S1803', a cycle identifier 'Cycle 18', and the form title 'Adverse Events: Assessment'. Below the navigation bar, there are fields for 'Patient ID', 'Enrollment Date', and 'Patient Initials (LFM)'. The main content area displays the 'Subject' and 'Page: Adverse Events: Assessment - Cycle 18'. A light blue instruction box states: 'Instructions: Please complete this form after each cycle.' The form contains several data entry rows, each with a label, a value, and a visibility icon (eye with slash). The rows are: 'Reporting period start date' (31 May 2023), 'Reporting period end date' (28 Jun 2023), 'Were adverse events assessed during this time period?' (Yes), a question 'If yes, did the patient experience any adverse events during this reporting period?' (Yes) with a yellow warning icon and a note 'Please complete AE Reporting form. Opened To Site from System (28 Jun 2023)', and 'Date of most recent adverse event assessment' (28 Jun 2023). At the bottom, there is a 'Comments' section with a visibility icon.

Field	Value	Visibility
Reporting period start date	31 May 2023	Visible
Reporting period end date	28 Jun 2023	Visible
Were adverse events assessed during this time period?	Yes	Visible
If yes, did the patient experience any adverse events during this reporting period?	Yes	Visible
Date of most recent adverse event assessment	28 Jun 2023	Visible
Comments		Visible

- 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	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Yes
1	Dyspnea	(2) Shortness of breath with minimal exertion; limiting instrumental ADL	Unrelated	Yes	Nebulizer, albuterol	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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

The screenshot shows the 'Expedited Reporting Evaluation' form in Medidata Rave. At the top, there are tabs for 'S1803', 'Cycle 18', and 'Expedited Reporting Evaluation'. Below the tabs, patient information is displayed: Patient ID, Enrollment Date, and Patient Initials (LFM). The subject is identified as 'Expedited Reporting Evaluation - Cycle 18'. A section titled 'Form Instructions' contains a warning: '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 in this course/cycle, amend the report so both events are entered on the same ticket.' Below this, there is a checkbox labeled 'Send all AEs for evaluation', which is highlighted in purple. A 'Recommended action for report (derived)' section contains a yellow box with text: 'An expedited report is RECOMMENDED. If the Investigator believes an expedited report is not warranted, (e.g., per protocol, commercial agent/arm, medical judgement, etc.), edit the 'Recommended action for report' field to indicate 'NONE'. [QC018] Opened To Site from System (30 Jun 2023)'. A green box contains a link: 'Click this link to complete the safety report'. At the bottom, a table of derived fields is shown:

Report ID (derived)	REP0743789
Recommended report type (derived)	CTEP 10 Calendar Day SAE Report
Report due by (derived)	Monday, July 10, 2023

- 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>

SWOG SAE RESOURCES

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

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

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 or the [8/22/2024 Global Safety CTEP Memo](#).
 - 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.
- What is the SPEER?
 - SPEER = Specific Protocol Exceptions to Expedited Reporting
 - The SPEER is simply a list of AEs that will never require SAE reporting.
 - Absence of an AE on the SPEER is not a mandate to report as an SAE.

RESOURCES

- **For information on the CTEP-AERS application**
 - <https://ctepcore.nci.nih.gov/ctepaers/help/webhelp/welcome/help%20-%20welcome%20to%20ctepaers%20help.htm>
 - https://ctep.cancer.gov/protocolDevelopment/adverse_effects.htm
- **For information on the Rave/CTEP-AERS integration**
 - <https://ctepcore.nci.nih.gov/ctepaers/help/webhelp/rave%20users/rave-overview.htm>
- **NCI Guidelines for Investigators: Adverse Event Reporting Requirements**
 - https://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/aeguidelines.pdf