

# PROCESS OVERVIEW OF SWOG-CTP STUDIES (S1919)

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## Overview

- CRA Access
- Site Access
- SAE Process



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## SWOG Way: CRA Access

- CRA Access



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### SWOG-CTP Way: CRA Access

- CRA Access



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### SWOG Way: Site Access

- Site Access



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### SWOG-CTP Way: Site Access

- Site Access



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### SWOG Way: SAE Process

- Reported to SWOG Operations Office using the Cancer Therapy Evaluation Program Adverse Event Reporting System (CTEP-AERS)
- Then SWOG Ops forwards reports and documentation to the appropriate regulatory agencies and drug companies as required




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### SWOG-CTP Way: SAE Process

- Will not use CTEP-AERS
- Report via Medidata Rave
- SWOG Ops will still forward reports and documentation to the appropriate regulatory agencies and drug companies as required




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### SWOG-CTP Way: SAE Process

- SAE Reports
- SAE
  - SAE Report
  - SAE Report Adverse Events
  - SAE Report Source Documentation
  - SAE Report Concomitant Medications
  - SAE Report Additional Information
  - SAE Report Attribution
  - SAE Review - Physician Reviewer
  - SAE Review - SAE Coordinator

- SAE Report
  - Reporter Information
  - Treating Physician
  - Patient Information
  - Cycle/Course Information
  - Description of Event
  - Protocol Agents




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Want to learn more about S1919 (RUSTIC)?

Come to our Training Session + Kick-Off Meeting!

Friday @ 8AM in XXX

Open to all SWOG members

*And light refreshments will be provided!*



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