

Clinical Trials Training Course

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 Program Director, Therapeutic Studies
 SWOG Data Operations Center
 Seattle, WA

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Goals of the CTTC

- Introduce the fundamentals and expectations of SWOG and National Cancer Institute (NCI) policies and procedures to **new** CRAs.
- Illustrate the process for protocol development, data submission, specimen submission, SAE reporting and audits.
- Provide the foundation to efficiently perform your responsibilities as a SWOG CRA.

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Agenda

<p>Morning Session (Hybrid - On Site & Remote Attendees)</p> <p>7:20 - 7:30 Introduction 7:30 - 7:55 Clinical Trials and Protocol Development 7:55 - 8:20 Data Submission 8:20 - 8:30 Patient Reported Outcomes 8:30 - 8:55 Reports to Support Quality Data 8:55 - 9:10 BREAK 9:10 - 9:35 Long Term Follow-Up 9:35 - 10:00 Adverse Event Reporting 10:00 - 10:25 Serious Adverse Events 10:25 - 10:40 BREAK 10:40 - 11:05 Audits/Quality Assurance 11:05 - 11:30 Specimen Tracking System 11:30 - 11:40 Tips for Specimen Submission 11:40 - 12:00 Scientific Impact of the CRA</p> <p>Afternoon Session (On-Site Attendees Only)</p> <p>2:00 - 2:35 JEOPARDY!it's a Game! 2:35 - 5:00 Practicum Session</p>	<p>7:20 a.m. - 12:00 p.m.</p> <p>Rodney Sutter, CCRP Dana Sparks, MAT Laura Wells, BA Monica Yee, BA, CCRP Cathy Rankin, MS</p> <p>Lisa Stoppenhagen, BS, CCRP Gabi Herbert, MS, BS Maggie Spillers, BSN, RN</p> <p>Laura Gonzales, BSN, MA, RN, OCN Christine Magner Hannah Brown, BS Michael LeBlanc, PhD</p> <p>2:00 p.m. - 5:00 p.m.</p> <p>Christine Magner Data Operations Center Staff & SWOG CRAs</p>	
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CTTC Sponsors

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ORP Manual

ORP (Oncology Research Professional)
 A daily reference tool for CRAs/RNs

- Administrative and data management resources, response assessment criteria and forms completion guidelines.

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ORP Workbench

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ORP Workbench

ORP (CRA) Workbench
your resource headquarters for SWOG clinical trial patient management.

Announcements

Useful Tools

CTP Chapter Added to ORP Manual
The ORP Manual has been updated to include details on how CTP trials are different, how to access CRAB Nebula (the EDC), instructions on how to navigate the EDC and how SAE reporting is done. Take the time to read through this address, especially if you are planning to activate one or more of these trials at your site (10/16/2025)

SWOG's Second CTP Trial Activated! - 21CTF0001
SWOG's first CTP trial activated on May 13, 2025 - 21CTF0001. Since then, we have activated the second trial on September 15, 2025 - 21CTF0001 (A Phase II Study of Combined Immunotherapy, Carboplatin and Paclitaxel in Immunotherapy-Locally Recurrent or Metastatic Head and Neck Cancer). (10/16/2025)

All SWOG sites are invited to consider and apply. Questions? Reach out to gsiddick@swog.org
<https://swog.org/ctp/21ctf0001/>

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Useful Tools

- ◆ BSA Calculator
- ◆ Clinical Trial Review Guide
- ◆ Creatinine Clearance Calculator
- ◆ Date Counter
- ◆ Ideal Body Weight Calculator
- ◆ QT Interval (QTc)

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Important Resources

- ◆ Best Practices for SWOG Studies
- ◆ CRA Newsletter Archive
- ◆ CTCAE
- ◆ Data Submission Guidance, Tips
- ◆ SWOG FAQ's
- ◆ SWOG Glossary
- ◆ SWOG ORP Committee
- ◆ SWOG Policies

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Patient Reports, Data Quality

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Patient Reports – Data Quality

- ◆ Expectation Reports
- ◆ IPR Reports
- ◆ Query Reports
- ◆ Patients in Follow Up
- ◆ Ineligible Patients Report
- ◆ Data Quality Portal for Rave Studies

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Fall Group Meeting Presentations
 Recordings from the Fall 2025 Site Operations, Ohio Symposium and NCRP Workshop (among many others) have been updated to the SWOG website. If you were unable to attend or would like to revisit, they can be found here: [Fall 2025 Site Operations](#)

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Study Reports

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Study Reports

- ◆ Accrual by Site
- ◆ Accrual by Race and Sex
- ◆ Accrual by Disease Site
- ◆ BMT and RT Facilities
- ◆ SAEs for a Given Study
- ◆ Studies in Long Term Follow Up
- ◆ Studies with No Required Follow Up

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Email Distribution Lists

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Distribution Lists

- breastquestion@crab.org
- cancercontrolquestion@crab.org
- gquestion@crab.org
- leukemiaquestion@crab.org
- lungquestion@crab.org
- lymphomaquestion@crab.org
- melanomaquestion@crab.org
- myelomaquestion@crab.org
- raretumors@crab.org

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Distribution Lists

- LungMAPquestion@crab.org
- SWOGComboMATCHquestion@crab.org
- SWOGIMATCHquestion@crab.org
- SWOGMyeloMATCHquestion@crab.org
- expectationreportquestion@crab.org
- technicalquestion@crab.org
- ctscontact@westat.com
- datamanagement@crab.org

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CTTC Evaluation Form

2026 SWOG CTTC | Course Evaluation

You must return a completed evaluation to receive your Certificate of Attendance.

Please Note: Although some of our presenters and professional speakers, and the core staff or volunteers who are not, are appreciative of all of our speakers as they have agreed to present beyond their regular workload. Please be sure to let us know if you have any concerns, something was missing, or you feel that there is another issue that we could have explained in a better way. These comments definitely help us improve and prepare for the next course. Thank you!

1. In-person or remote participant?
(for on-site attendees or presenters)

In-Person

Remote

2. Evaluate the Clinical Trials Training Course for its **overall content** on a scale of 1-5
The quality of the information presented (i.e. useful, helpful, relevant)


1 - Poor 2 - Below Average 3 - Average 4 - Good 5 - Excellent

3. Evaluate the Clinical Trials Training Course for its **organization/style** on a scale of 1-5
The degree to which the information presented is clearly, easy, understood



1 - Poor 2 - Below Average 3 - Average 4 - Good 5 - Excellent

Please remember to complete the CTTC Evaluation Form. We are most interested in your assessment of the content and usefulness of the practicum, and your suggestions for improvement.

The CTTC Evaluation Form can be accessed online at <https://www.surveymonkey.com/W888348> or by using the QR code below.



Submission of the CTTC Evaluation Form is required to receive your Certificate of Completion for the CTTC.

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Clinical Trials and Protocol Development




Dana Sparks, MAT
 Director of Operations and Protocols
 Network Operations Center
 San Antonio, TX






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