

Clinical Trials Training Course




Rodney Sutter, CCRP
 Program Director, Therapeutic Studies
 SWOG Data Operations Center
 Seattle, WA

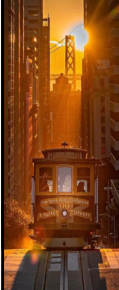







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Goals of the CTTC





- 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>WED. 05/10</p> <p>7:20 – 7:30 7:30 – 7:55 7:55 – 8:20 8:20 – 8:30 8:30 – 8:55</p> <p>8:55 – 9:10</p> <p>9:10 – 9:35 9:35 – 10:00 10:00 – 10:25</p> <p>10:25 – 10:40</p> <p>10:40 – 11:05 11:05 – 11:30 11:30 – 11:40 11:40 – 12:00</p> <p>WED. 05/10</p> <p>1:45 – 2:20 2:20 – 2:30 2:30 – 5:00</p>	<p>Morning Session</p> <p>Introduction Clinical Trials and Protocol Development Data Submission Patient Reported Outcomes Reports to Support Quality Data</p> <p>BREAK</p> <p>Long Term Follow-Up Adverse Event Reporting Serious Adverse Events</p> <p>BREAK</p> <p>Audits/Quality Assurance Specimen Tracking System Tips for Specimen Submission Scientific Impact of the CRA</p> <p>Afternoon Session</p> <p>(Don't let your data end up in) JEOPARDY! It's a Game! Introduction to the Practicum Practicum Session</p>	<p>7:20 a.m. – 12:00 p.m.</p> <p>Rodney Sutter, CCRP Dana Sparks, MAT Michele Counts, BS Monica Yee, BA, CCRP Phyllis Goodman, MS</p> <p>Connie Szczepanek, RN, BSN Gabi Herbert, MS, BS Maggie Spillers, BSN, RN</p> <p>Laura Gonzales, BSN, MA, RN, OCN Laura Wells, BA Hannah Brown, BS Michael LeBlanc, PhD</p> <p>1:45 p.m. – 5:00 p.m.</p> <p>Christine Magner</p> <p>Christine Magner Data Operations Center Staff and SWOG CRAs</p>
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CTTC Sponsors

THE HOPE FOUNDATION FOR CANCER RESEARCH

CRAB CANCER RESEARCH AND BIOSTATISTICS

SWOG CANCER RESEARCH NETWORK

SWOG | NCI | NCI | NCI

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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.

SWOG | NCI | NCI | NCI

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CRA Workbench

CRA Workbench

Your resource headquarters for SWOG clinical trial patient management.

Announcements

Updates to Specimen Tracking

A couple of updates have been made to the Specimen Tracking interface in Step 2 of Logging a Specimen, the "Filter" at the top has been updated so that view at least one key filter is required before a list of specimens is displayed. We are hopeful that this will make it easier to identify and select the correct specimen. Also, to avert potential problems for users in the environment to choose bookmarking, we have moved the "Set" button to the right side of the [bookmarking interface](#). If you have updated the banner and got a watermark on the bookmarking interface, please refresh the page. For more details, (12/11/2022)

SWOG Specimen Bank Kit Management URL

The Kit Management URL has changed. Please make a plan to update your bookmarks with the new URL: <https://www.swog.nci.nih.gov/kitmanagement/>. If you try to access the old URL, there is no redirect as the server supporting the old URL is not on line and users will receive an error message. (05/20/2023)

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SWOG EMR to EDC Project Webinar Recording
Introductory information regarding the project being developed by the SWOG using the iCARTS platform can be viewed [here](#). See the May 27, 2022 [Twitter](#) post for more information. (11/7/2022)

SWOG Bioprescreen Bank Kit Management URL
The Kit Management URL has changed. Please make certain to update your bookmarks with the new URL: <https://data.bioprescreen.org/>. If you try to access the old URL, there is no redirect as the server supporting the old URL is end of life and users will receive an error message. (8/29/2021)

Useful Tools

Popular Resources
 CRF Patient Registration
 Raw Data Submission
 Specimen Tracking
 SWOG-QA / Audit / Monitoring
 SWOG Best Practices
 New CRA Training
 Tools
 Resources
 CRA Manual for Oncology Research Professionals
 Patient Reports / Data Quality
 Study Reports
 Patient Management (Non-Rare Studies)
 Training
 Contact Us
 Internal Users Only

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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


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 Training
 Contact Us
 Internal Users Only

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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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A major update has been made to the Specimen Tracking interface. In Step 2 of Logging a Specimen, the "Filter" at the top has been updated so that now at least one Key Filter is required before a list of samples is displayed. We are hopeful that this will help to reduce the number of incorrect specimens. Also, to prevent potential problems for when the Test environment is chosen (currently, we have moved the "Test" button to the right side of the page and within the Test environment we have updated the button and put a watermark on the tracking list. The upcoming Winter CRA Newsletter will have more details. (2/1/2022)

SWOG Patient Reports, Data Quality (highlighted with red arrow)



SWOG, using the iCare platform can be seen (3/17/2022)

The KR Management URL has changed. Please make certain to update your bookmarks with the new URL: <https://dataquality.cra.swog.org/>. If you try to access the old URL, there is no redirect as the server supporting the old URL is not set up and you will receive an error message (3/2/2022).




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Patient Reports – Data Quality

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



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SWOG EARN to EDC Project Webstar Recording
Introductory information regarding the project being developed by the SWOG using the eCartes platform can be viewed [here](#). See the May 27, 2022 [EARN Live](#) post for more information. (11/17/2022)

SWOG Respecimen Bank Kit Management URL
The Kit Management URL has been updated. Please update your bookmarks with the new URL: <https://kit.medsys.com/kit/>. There is no redirect as the server supporting the old URL is end of life and users will receive an error message. (3/25/2023)

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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Contact Us

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Email Distribution Lists

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CTTC Evaluation Form

2023 SWOG CTTC | Course Evaluation

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

Please Note: Although some of our presenters are professional speakers, we do not pay them. All of our speakers. They have accepted financial interest conflicts. Please do not give them a "5" unless you can explain why they are better than the other speakers. Please do not give them a "5" unless you can explain why they are better than the other speakers.

1. Evaluate the quality of the presentation on a scale of 1-5

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

2. Evaluate the clinical relevance of the presentation on a scale of 1-5

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

3. Comments pertaining to particular presentations
Please be specific and write your comments as clearly as possible.

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Clinical Trials and Protocol Development

Dana Sparks, MAT
Director of Operations and Protocols
SWOG Operations Office
San Antonio, TX

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