

## Clinical Trials Training Course

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

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NCI

## CTTC Sponsors



**THE HOPE**  
FOUNDATION  
FOR CANCER RESEARCH

**CRAB**  
CANCER RESEARCH  
AND BIostatISTICS

**SWOG** | CANCER  
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NETWORK

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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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## 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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## Agenda

### Morning Session

7:20 – 7:30  
7:30 – 7:55  
7:55 – 8:20  
8:20 – 8:30  
8:30 – 8:55  
**8:55 – 9:10**  
9:10 – 9:35  
9:35 – 10:00  
10:00 – 10:25  
**10:25 – 10:40**  
10:40 – 11:05  
11:05 – 11:30  
11:30 – 11:40  
11:40 – 12:00

### Afternoon Session

2:00 – 2:35  
2:35 – 5:00

### (Hybrid – On Site & Remote Attendees)

Introduction  
Clinical Trials and Protocol Development  
Data Submission  
Patient Reported Outcomes  
Reports to Support Quality Data  
**BREAK**  
Long Term Follow-Up  
Adverse Event Reporting  
Serious Adverse Events  
**BREAK**  
Audits/Quality Assurance  
Specimen Tracking System  
Tips for Specimen Submission  
Scientific Impact of the CRA

### (On-Site Attendees Only)

**JEOPARDY! .....It's a Game!**  
Practicum Session

### 7:20 a.m. – 12:00 p.m.

Rodney Sutter, CCRP  
Dana Sparks, MAT  
Alex Rangel, BA  
Monica Yee, BA, CCRP  
Cathy Rankin, MS

Lisa Stoppenhagen, BS, CCRP  
Pasarfai Ahmadzai, MD, MPH  
Maggie Spillers, BSN, RN

Laura Gonzales, BSN, MA, RN, OCN  
Amy Johnson, BA, CCRP  
Hannah Brown, BS  
Michael LeBlanc, PhD

### 2:00 p.m. – 5:00 p.m.

Christine Magner  
Data Operations Center Staff & SWOG CRAs

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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 of the top has been updated so that you can filter by the specimen status. A list of updates is displayed. We are happy that this will make it easier to identify and select the correct specimen. Also, to avoid potential confusion, we have updated the "Patient" field to "Patient ID" and we have updated the "Patient" field to "Patient ID".  
For more information, see the May 27, 2024 [Data Update](#) email for more information. (1/10/2024)


**SWOG Biorepository Bank Kit Management URL**  
The Kit Management URL has changed. Please update your bookmarks with the new URL:  
<https://biobank.swog.nci.nih.gov/>. If you try to access the old URL, there is a redirect on the server supporting the old URL, so all of the old pages will continue to work as expected. (3/13/2024)

**ORP Manual**

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## CRA Workbench



**Useful Tools**

- Popular Resources
- CRF Data Submission
- Specimen Tracking
- SWOG QR - Audit / Monitoring
- SWOG Best Practices
- New CRM Training
- Tools
- Resources
- CRA Manual for Oncology
- Resource Professional
- External Reports - Data Quality
- Study Reports
- External Management - Data Quality
- Training
- Contact Us
- Internal News (Blog)

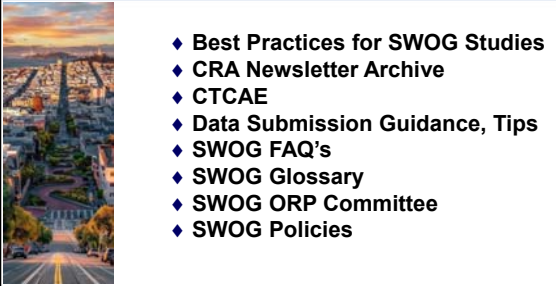
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**SWOG EMR to EDC Project Webinar Recording**  
Introduction information regarding the project being developed by the SWOG using the eCRF platform can be viewed [here](#). See the May 27, 2014 [Data Quality](#) for more information. (11/11/2014)

**SWOG Bioprescription Bank Kit Management URL**  
The Kit Management URL has changed. Please make certain to update your bookmarks with the new URL: <https://bioprescriptionbank.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. (8/19/2017)

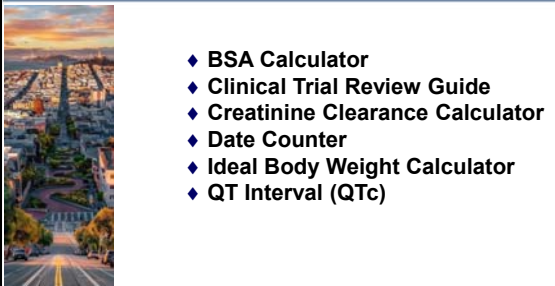
## Important Resources



**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


## Useful Tools



**Useful Tools**

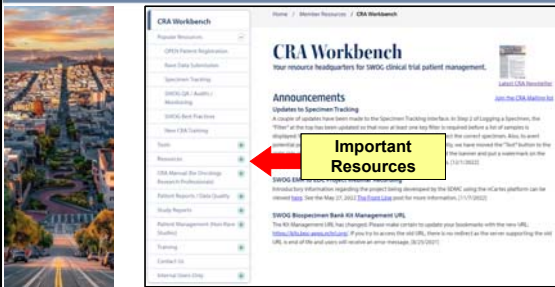
- ◆ BSA Calculator
- ◆ Clinical Trial Review Guide
- ◆ Creatinine Clearance Calculator
- ◆ Date Counter
- ◆ Ideal Body Weight Calculator
- ◆ QT Interval (QTc)

## CRA Workbench



**Patient Reports, Data Quality**

## CRA Workbench



**Important Resources**

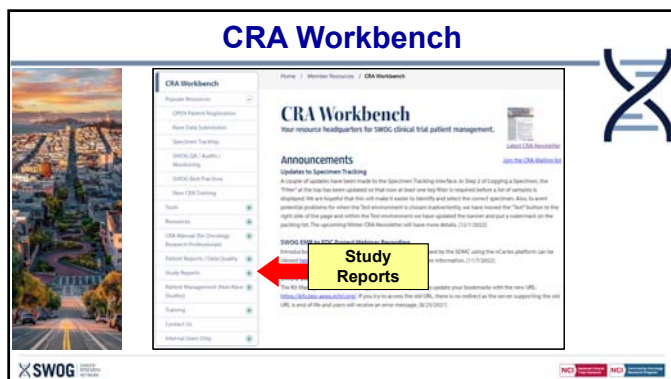
## Patient Reports – Data Quality



**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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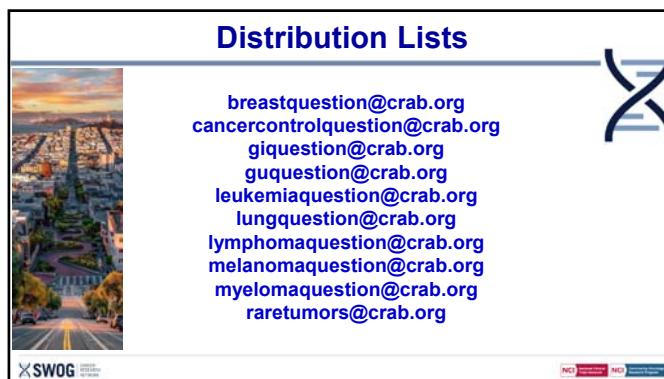
**SWOG Biomarker Bank Kit Management URL**  
Introducing information regarding the project being developed by the SWOG using the vCare platform can be found here: <https://biobank.swog.org/>. If you're to be across the old URL, there is no redbox on the server supporting the old URL, in and of the end users will receive an error message. (8/2/2021)

**Study Reports**

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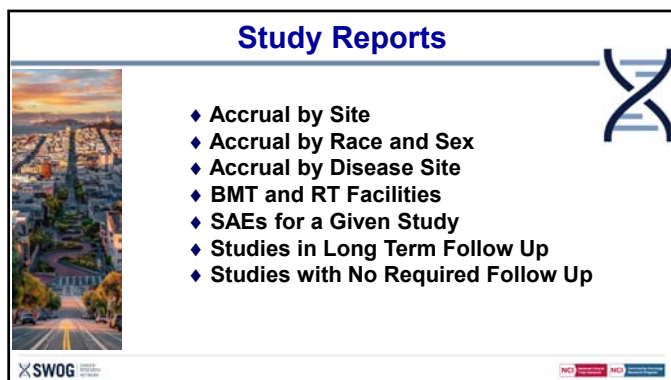
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## Distribution Lists



[breastquestion@crab.org](mailto:breastquestion@crab.org)  
[cancercontrolquestion@crab.org](mailto:cancercontrolquestion@crab.org)  
[giquestion@crab.org](mailto:giquestion@crab.org)  
[guquestion@crab.org](mailto:guquestion@crab.org)  
[leukemiaquestion@crab.org](mailto:leukemiaquestion@crab.org)  
[lungquestion@crab.org](mailto:lungquestion@crab.org)  
[lymphomaquestion@crab.org](mailto:lymphomaquestion@crab.org)  
[melanomaquestion@crab.org](mailto:melanomaquestion@crab.org)  
[myelomaquestion@crab.org](mailto:myelomaquestion@crab.org)  
[raretumors@crab.org](mailto:raretumors@crab.org)

## Study Reports



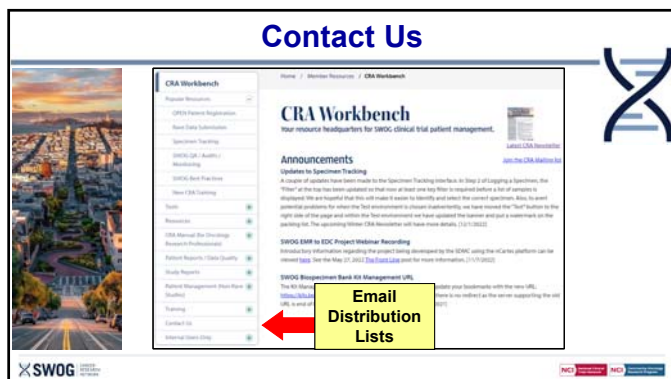
- ◆ Accrual by Site
- ◆ Accrual by Race and Sex
- ◆ Accrual by Disease Site
- ◆ BMT and RT Facilities
- ◆ SAEs for a Given Study
- ◆ Studies in Long Term Follow Up
- ◆ Studies with No Required Follow Up

## Distribution Lists



[LungMAPquestion@crab.org](mailto:LungMAPquestion@crab.org)  
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[expectationreportquestion@crab.org](mailto:expectationreportquestion@crab.org)  
[technicalquestion@crab.org](mailto:technicalquestion@crab.org)  
[ctscontact@westat.com](mailto:ctscontact@westat.com)  
[datamanagement@crab.org](mailto:datamanagement@crab.org)

## Contact Us



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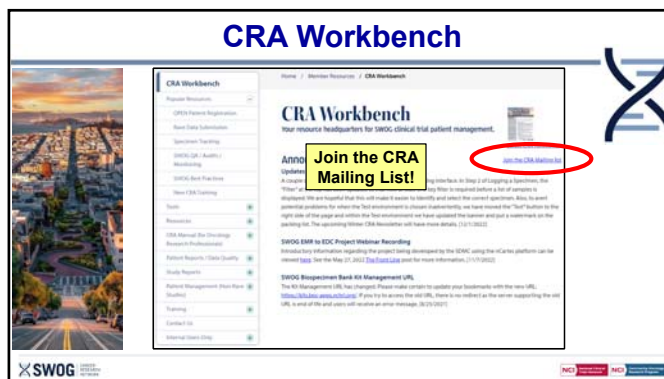
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**Email Distribution Lists**

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**Join the CRA Mailing List!**

## CTTC Evaluation Form




**2025 SWOG CTTC | Course Evaluation**

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


Please Note: Although some of our presenters are professional speakers, we do ask staff or volunteers who are not. We appreciate all of our speakers. They have worked beyond their regular workload. Please let us know if content was unclear, 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!

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

The CTTC Evaluation Form can be accessed online at <https://www.surveymonkey.com/2625CTTC> or by using the QR code below.



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





**1. In-person or remote participant?**  
(Did you attend remotely or in-person?)

☐ In-Person

☐ Remote

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

## Clinical Trials and Protocol Development

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

