



Clinical Trials Training Course

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

Welcome to San Francisco!



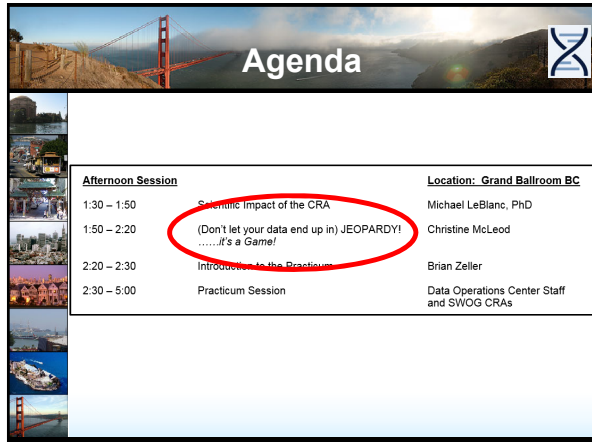
Goals of the CTTC

- 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.



Agenda

Morning Session		Location: Grand Ballroom A
7:00 – 7:30	Registration (<i>continental breakfast provided</i>)	
7:30 – 7:40	Introduction	Rodney Sutter, CCRP
7:40 – 8:05	Clinical Trials and Protocol Development	Dana Sparks, MAT
8:05 – 8:45	Data Submission	Vicky Kim, BS, BA Joseph Sanchez, BS
8:45 – 8:55	Patient Reported Outcomes Questionnaires	Jamie Myers, PhD, RN, AOCNS
8:55 – 9:20	The Expectation Report	Phyllis Goodman, MS
9:20 – 9:40	BREAK	
9:40 – 10:05	Long Term Follow-Up	Keisha Humphries, RN, BSN, MHCL, OCN
10:05 – 10:30	Adverse Event Reporting	Louise Highleyman, BA
10:30 – 11:00	Serious Adverse Events	Kari Williams, RN
11:00 – 11:25	Audits/Quality Assurance	Elaine Armstrong, MS
11:25 – 11:50	Specimen Tracking System	Sevan Gurung, BS
11:50 – 12:00	Tips for Specimen Submission	Hannah Brown, BS
12:00 – 1:30	LUNCH (on your own)	



Agenda

Afternoon Session	Location: Grand Ballroom BC
1:30 – 1:50 Scientific Impact of the CRA	Michael LeBlanc, PhD
1:50 – 2:20 (Don't let your data end up in) JEOPARDY!It's a Game!	Christine McLeod
2:20 – 2:30 Introduction to the Practicum	Brian Zeller
2:30 – 5:00 Practicum Session	Data Operations Center Staff and SWOG CRAs



CTTC Sponsors



CANCER
RESEARCH
NETWORK

THE HOPE
FOUNDATION
FOR CANCER RESEARCH

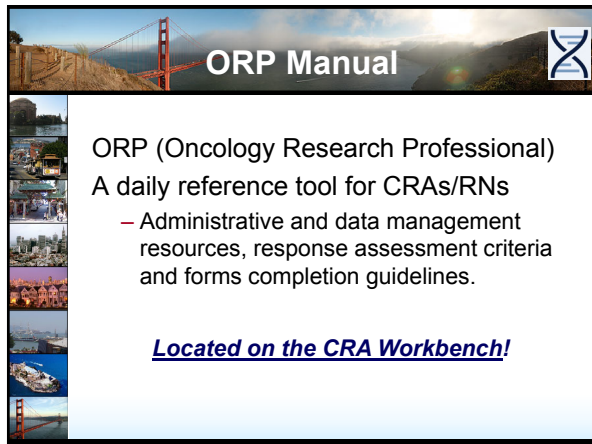


CANCER RESEARCH
AND BIOSTATISTICS



CTTC Collaborators

<p><u>Group Chairs and Operations Office</u></p> <ul style="list-style-type: none"> ◆ Dr. Blanke ◆ Connie Barnes ◆ Courtney Wille ◆ Dana Sparks ◆ Elaine Armstrong ◆ Jo Horn ◆ Kari Williams ◆ Morgan Cox ◆ Nathan Eriksen 	<p><u>Statistics and Data Management Center</u></p> <ul style="list-style-type: none"> ◆ Michael LeBlanc ◆ Phyllis Goodman ◆ Caylene Castagno ◆ Rodney Sutter ◆ Data Operations Staff <p><u>Clinical Research Associates</u></p> <ul style="list-style-type: none"> ◆ Alaina Krone ◆ Clara Dunn ◆ Jamie Myers ◆ Keisha Humphries ◆ Melanie Ozaki
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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.

Located on the CRA Workbench!



CRA Workbench

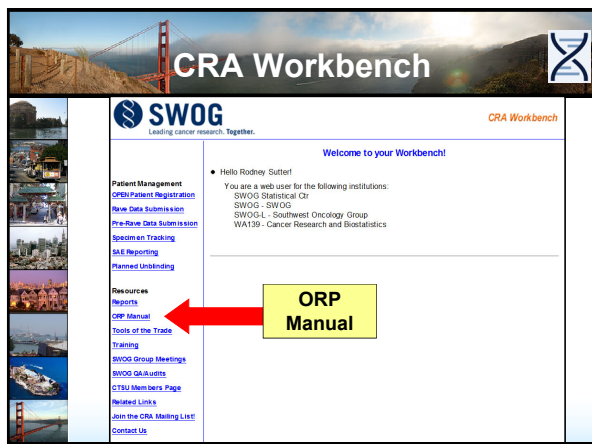
SWOG
Leading cancer research. Together.

Welcome to your Workbench!

- Hello Rodney Suttler!
You are a web user for the following institutions:
SWOG - Statistical Ct
SWOG - SWOG
SWOG-L - Southwest Oncology Group
WAT39 - Cancer Research and Biostatistics

Resources

- Reports
- ORP Manual
- Tools of the Trade
- Training
- SWOG Group Meetings
- SWOG GAIRL edits
- CTSU Members Page
- Related Links
- Join the CRA Meeting List!
- Contact Us



CRA Workbench

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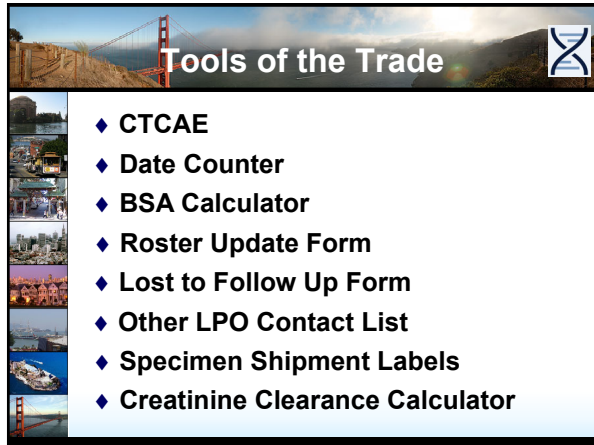
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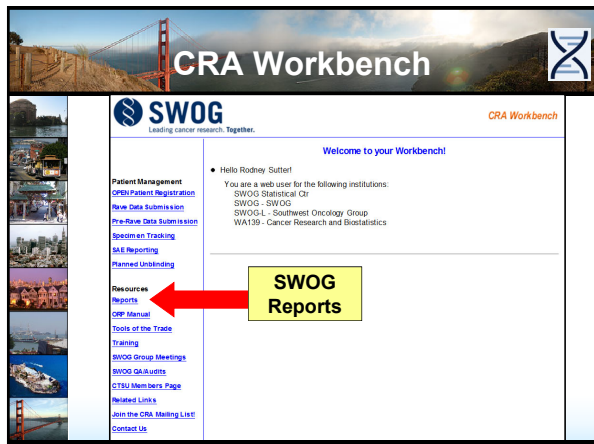
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SWOG Reports

- ◆ Expectation and IPR Reports
- ◆ Query Reports
- ◆ Ineligible Patients Report
- ◆ SAEs for a Given Study
- ◆ Registrations by Race and Sex
- ◆ Registrations for a Given Date Range
- ◆ Patients in Follow Up
- ◆ Protocols with No Required F/U

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Training Opportunities

Training

TRAINING

Please take some time to review the online training opportunities noted below. To access the training modules, JavaScript must be enabled in your browser, and it must have the Adobe Flash Player plugin; if it does not, the program can install it for you. We suggest setting the audio volume on your computer to a moderate level before you begin.

Amendable Forms Training Module
 The opportunity to amend more of your data online was published and released on October 18, 2010! There are some important details about which forms are applicable to online amendments, as well as some changes to the interface of the Data Submission section of the CRA Workbench. Therefore, we highly recommend anyone at your institution responsible for data submission views this training module before submitting new data. Please send any technical issues with the new format to raed@swog.org and any general questions can be directed to your Data Coordinator at 298-652.

CRA Clinical Trials Training Course (CTTC)
 Are you new to the Group and the next formal CTTC at the Group Meeting is far enough away that you'd like to get started now? We have created an online version of the training course that includes audio, short quizzes and evaluation forms to provide feedback to the Data Coordinator. **Complete** Once all modules are completed you will also receive a Certificate of Completion. This is a great opportunity for the new CRA as well as experienced members in the group to take as a refresher.

Medidata Rave: Getting Started
 A primer to what you can expect the first time you logon to Rave.

Medidata Rave Introduction
 All SWOG studies activating April 1, 2012 and later will require use of the **Medidata Rave** application for online submission of the data. These slides were presented at the Fall 2012 Clinical Trials Training Course in Chicago to introduce the attendees to Rave, and to explain how SWOG studies will operate in Rave. This presentation is meant to complement the more formal training modules in Rave that CRAs will also be required to take. Show the Comments pane in Adobe to view the speaker notes.

Contact Us

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Email Distribution Lists

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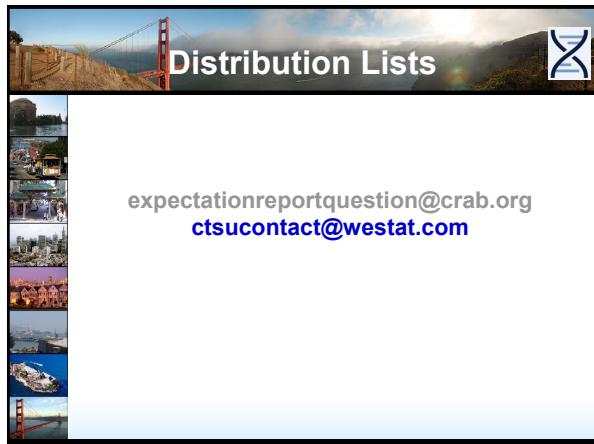
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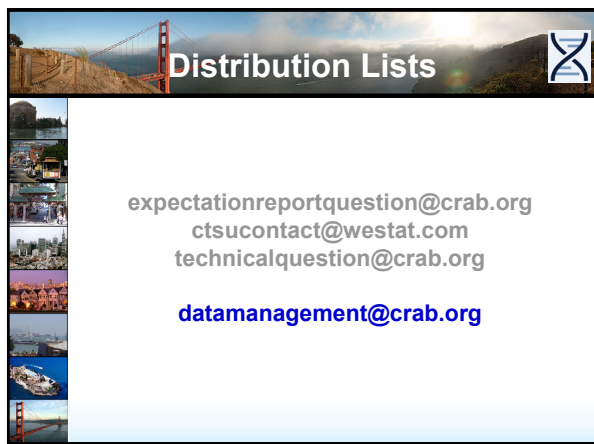
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Please Welcome,

Dana Sparks, MAT
Director of Operations and Protocols

“Clinical Trials and Protocol Development”
