

# **SWOG Statistical Center Update**

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

# Mentoring Workshops

- Four Hour Workshop Addressing the Following Topics:
  - Why Clinical Trials?
  - History of NCI Funded Research
  - Protocol Development within SWOG
  - Regulations and Ethics in Research
  - Quality Data: Variability/Bias/Principles
  - Audits and Monitoring for S1400 and S1404
  - Expectations, Expectation Reports and IPR
  - Site Readiness for an FDA Audit
  - Regulatory/Trial Master File
  - Reporting AE/SAEs
  - CRA Tools: Source Documents, EPIC smart phrases etc.

# Mentoring Workshops

- Workshops were conducted at the following SWOG Institutions this past year:

➤ U of Utah/Huntsman	May 04	Attendees: 39
➤ MAVERIC VA/Boston	Oct 27	Attendees: 24
➤ Fred Hutchinson/Seattle	Jan 24	Attendees: 33
➤ U of Hawaii	Feb 17	Attendees: 27
➤ PCRC NCORP/Seattle	Feb 29	Attendees: 22

- Upcoming:

➤ U of Colorado	June 05
➤ Oregon Health Sciences	TBD

# Mentoring Workshops

- Criteria:
  - Site Request
  - High Accruing Site
  - IPR Statistics
- Facility Requirements:
  - Minimum of 12-15 attendees (may invite components or other SWOG sites within the area if you have lower numbers)
  - Facility/room large enough to accommodate all attendees
  - AV equipment (accommodate power point presentations)
  - Internet connection
- Contact:
  - Dona Marrah ([donam@crab.org](mailto:donam@crab.org))


# SWOG Training Retreat

- Held in Chicago – April 13
  - What training is currently provided
  - Future training objectives
  - Strengths/weaknesses
  - What resources are needed
- SWOG Training Needs Assessment Survey
  - 557 Nurse, CRA, other site staff responses
    - ☐ Training Mechanisms Used? CTTC
    - ☐ Current trainings are helpful & accurate? 83% yes
    - ☐ Training preference? 52% online, 22% in person, 26% NP
- Suggested Topics
  - Study-specific training
  - Rave, data-entry

# SWOG Training Retreat

- Next Steps
  - Get the word out
  - Update current training modules
  - Utilize more functionality the LMS offers
  - Continue to engage and collect training needs
  - Design new training based on member feedback
- Suggestions? Please forward your ideas!
  - Dana Sparks ([dsparks@swog.org](mailto:dsparks@swog.org))
  - Rodney Sutter ([rodneys@crab.org](mailto:rodneys@crab.org))
  - Mark Schofield ([mschofield@swog.org](mailto:mschofield@swog.org))

# Online Training – CTTC

**SWOG**  Leading cancer research. **Together.**

**MEMBERS SECTION**

- Other Sections ▶
- Quicklinks ▶
- My Favorites ▶
- My Protocols ▶
- Website Index
- Clinical Trials ▶
- Membership ▶

**Workbenches**

- CRA Workbench**
- Member Roster
- SC Workbench
- Training
- SELECT Workbench
- Policies & Manuals
- Administrative Forms
- Miscellaneous

For technical assistance, contact Mark Schofield:  
[MSchofield@swog.org](mailto:MSchofield@swog.org)

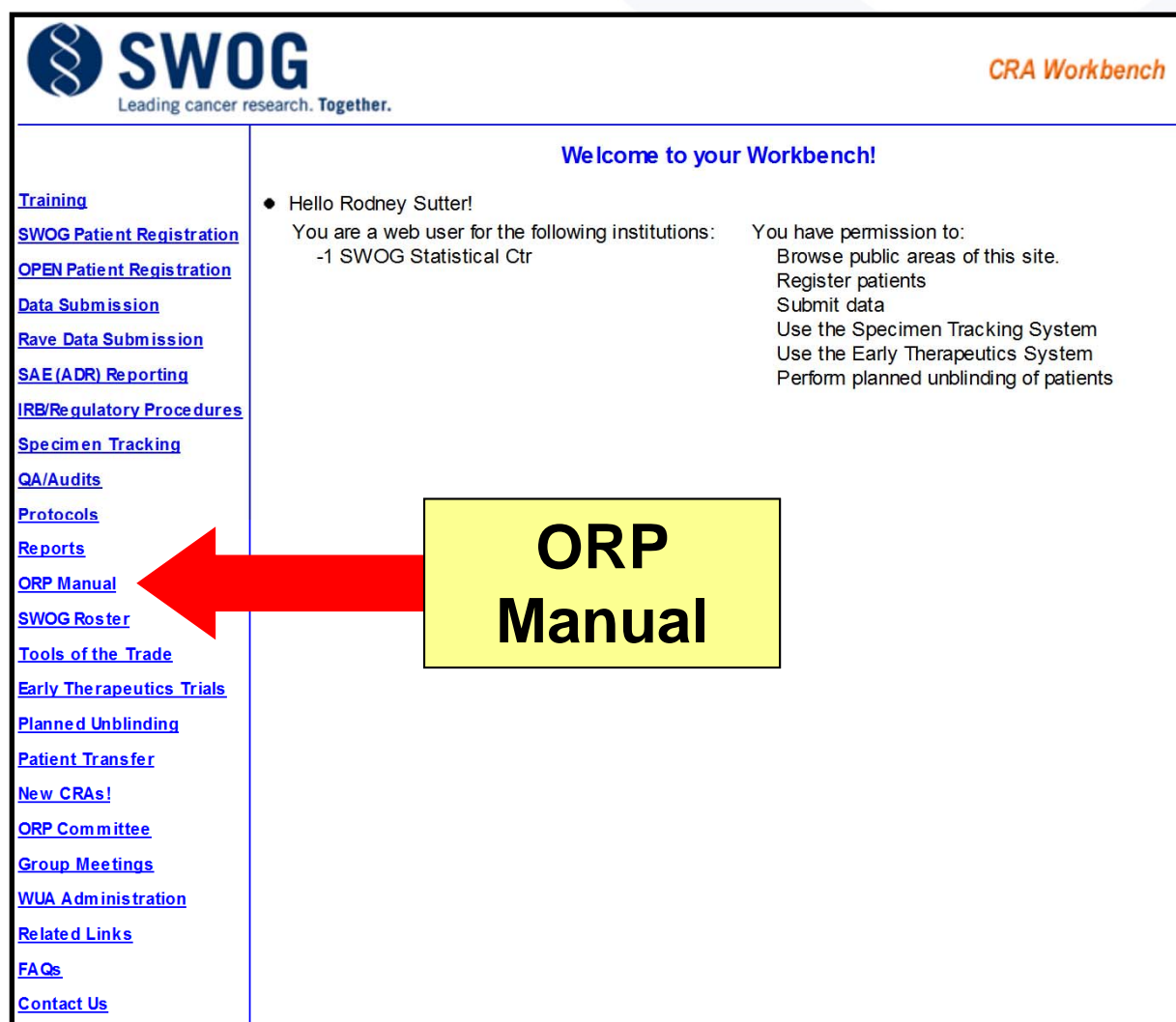
**Latest SWOG News**

- [Spring Group Meeting Registration Now Closed](#)  
On-line Registration for the Spring Group Meeting has now closed. The on-site registration desk will open at 1:00 PM on Wednesday, April 26.

The Spring 2017 [Report of Studies](#) and [Meeting Agenda Book](#) are available on the [Spring Meeting](#) page.

Members section you can build your own menus of frequently-used pages, My Favorites and My Protocols. For help with the My Favorites and My Protocols, go to the help pages for each under their links in the navigation bar at left. If you need help finding something, try the Website Index in the header of every page. Please send any comments you have about swog.org, including additional features you would like to see, to the [Web Manager](#).

# Resources – ORP Manual



The screenshot shows the SWOG CRA Workbench interface. The top left features the SWOG logo and tagline "Leading cancer research. Together." The top right says "CRA Workbench". The main content area is titled "Welcome to your Workbench!" and includes a greeting "Hello Rodney Sutter!", a list of institutions ("You are a web user for the following institutions: -1 SWOG Statistical Ctr"), and a list of permissions ("You have permission to: Browse public areas of this site, Register patients, Submit data, Use the Specimen Tracking System, Use the Early Therapeutics System, Perform planned unblinding of patients"). A left sidebar contains a list of links: Training, SWOG Patient Registration, OPEN Patient Registration, Data Submission, Rave Data Submission, SAE (ADR) Reporting, IRB/Regulatory Procedures, Specimen Tracking, QA/Audits, Protocols, Reports, ORP Manual, SWOG Roster, Tools of the Trade, Early Therapeutics Trials, Planned Unblinding, Patient Transfer, New CRAs!, ORP Committee, Group Meetings, WUA Administration, Related Links, FAQs, and Contact Us. A red arrow points from a yellow box labeled "ORP Manual" to the "ORP Manual" link in the sidebar.

**SWOG**  
Leading cancer research. Together.

**CRA Workbench**

**Welcome to your Workbench!**

- Hello Rodney Sutter!

You are a web user for the following institutions:  
-1 SWOG Statistical Ctr


You have permission to:  
Browse public areas of this site.  
Register patients  
Submit data  
Use the Specimen Tracking System  
Use the Early Therapeutics System  
Perform planned unblinding of patients

**ORP Manual**

[Training](#)  
[SWOG Patient Registration](#)  
[OPEN Patient Registration](#)  
[Data Submission](#)  
[Rave Data Submission](#)  
[SAE \(ADR\) Reporting](#)  
[IRB/Regulatory Procedures](#)  
[Specimen Tracking](#)  
[QA/Audits](#)  
[Protocols](#)  
[Reports](#)  
[ORP Manual](#)  
[SWOG Roster](#)  
[Tools of the Trade](#)  
[Early Therapeutics Trials](#)  
[Planned Unblinding](#)  
[Patient Transfer](#)  
[New CRAs!](#)  
[ORP Committee](#)  
[Group Meetings](#)  
[WUA Administration](#)  
[Related Links](#)  
[FAQs](#)  
[Contact Us](#)



# Resources – Best Practices

**SWOG**  
Leading cancer research. Together.

<a href="#">CRA Workbench Home</a>	<b>Please select from the following:</b>
<a href="#">Training</a>	
<a href="#">SWOG Patient Registration</a>	<a href="#">Best Practices for SWOG Studies</a>
<a href="#">OPEN Patient Registration</a>	This document provides current information related to expectations for SWOG studies.
<a href="#">Data Submission</a>	<a href="#">Calculated Creatinine Clearance Formula and Calculator</a>
<a href="#">Save Data Submission</a>	<a href="#">Clinical Trials in Oncology</a>
<a href="#">SAE (ADR) Reporting</a>	At recent CRA Plenary Sessions, Jackie Benedetti has given a series of topics are available in <i>Clinical Trials in Oncology</i> (by Green, Benedetti, and the Oncology Group studies. For more information and to purchase the book, please contact the Group.
<a href="#">IRB/Regulatory Procedures</a>	<a href="#">Conflict of Interest (Financial and Affiliation Declaration Form)</a>
<a href="#">Specimen Tracking</a>	Prior to developing a protocol or serving in a leadership role in Research, all primary and secondarily responsible investigators, all Group Coordinators (as listed on the title page of the protocol), the Group Statisticians, all Committee Chairs, co-chairs and members of the Board of Governors, members of Data and Safety Monitoring Committees and the Director of The Hope Foundation are required to complete the COI form.
<a href="#">QA/Audits</a>	
<a href="#">Protocols</a>	
<a href="#">Reports</a>	
<a href="#">ORP Manual</a>	
<a href="#">SWOG Roster</a>	
<a href="#">Tools of the Trade</a>	
<a href="#">Early Therapeutics Trials</a>	
<a href="#">Planned Unblinding</a>	

# Rave Image Upload Feature

- Uploading Source Documents
  - Sites without a scanner available
- Released in 2014

**Instructions:** Use this form to upload reports from all Baseline procedures performed, as required per protocol.

Please ensure all source documents are properly and completely redacted and free of PHI before uploading to Rave. Using a black pen or marker only works when the image is photocopied and the photocopy is then scanned and uploaded. Other ways to redact: electronic redacting tools, covering PHI with labels or opaque tape, black correction tape, white-out or cutting out the identifiers and shred the clippings. Queries will be generated to replace images where PHI is still visible.

#	Date of procedure	Type of procedure	Upload document?	Comments
1	15 Mar 2017	PET Scan		

**Upload document**

☐ Please use the following cover sheet if you intend to fax the document to CTSU. [Click here to Print Cover Sheet](#)

[Add a new Log line](#) [Inactivate](#)

Comments

# NCORP Workshop – Fall

SAVE THE  
DATE!

3<sup>rd</sup> Annual

## NCORP Research Base Clinical Trials Workshop

*For Clinical Research Professionals and Investigators at  
NCORP, Member and LAPS Institutions and Affiliates*

*A HOPE FOUNDATION sponsored Clinical Trials Training Course*

**WEDNESDAY,  
OCTOBER 11**

**Fall 2017  
SWOG Group  
Meeting**

**Chicago**

NCORP studies in the following SWOG research areas will be discussed:

- **Cancer Survivorship**
- **Prevention & Epidemiology**
- **Cancer Care Delivery Research**
- **Symptom Control and Quality of Life**

**New agenda and topics  
at each Workshop!**

The workshop consists of didactic presentations and breakout sessions for information sharing.

# NCORP Workshop – Fall

- NCORP studies specific to the following research areas will be discussed:
  - Cancer Survivorship
  - Prevention & Epidemiology
  - Cancer Care Delivery Research
  - Symptom Control and Quality of Life
- Topics will be specific to the unique administration of these studies such as:
  - Patient Recruitment
  - Patient Follow-Up
  - Data Collection

*Submit suggestions for topics to: [cancercontrolquestion@crab.org](mailto:cancercontrolquestion@crab.org)*

# Statistical Center Training

- Active SWOG FDA Registration Trials
  - S1400 (Lung-MAP)
  - S1404 (Melanoma)
  - S1418 (Breast)
  - S1605 (GU)
- Implications
  - Study Set-Up
  - Data Submission
  - Monitoring
  - Analysis
  - Reporting
  - Resources

# Statistical Center Training

8:25 – 8:50	S1404 – Immunotherapy Clinical Trials	Megan Othus
8:50 – 9:10	Data Management for FDA Registration Trials	Diana Heaney Louise Highleyman
9:10 – 9:25	S0777 – Lessons Learned and Moving Forward	Evonne Lackey Cathy Rankin
9:25 – 9:40	How to Navigate Expectations and the new Data Quality Portal (DQP)	Phyllis Goodman
9:40 – 9:45	Q and A	



# Questions?



# Please Welcome,

***Charles D. Blanke, MD***  
*SWOG Chair*

**Group Chairs Office**  
Oregon Health & Science University  
Portland, OR