SWOG NCORP Research Base Clinical Trials Workshop

Wednesday, October 16, 2024, 10:30 am to 2:30 pm CT
Hyatt Regency Chicago

Agenda

General Session (Regency D, Ballroom Level) **(Hybrid)**

Welcome and NCORP Research Base Overview

Mathew Eng, PharmD, Clinical Research Data Coordinator, SWOG Statistics and Data Management Center

NCORP Research Areas

Clinical Trials

Overview of SWOG NCORP Trials

Virginia Sun, PhD, MSN, RN, City of Hope, SWOG Cancer Research Network Executive Officer

Patient Enrollment to Industry-Sponsored versus Federally Sponsored Cancer Clinical Trials

Joseph Unger, PhD, MS, NCORP Research Base Vice Chair, SWOG Statistics and Data Management Center

Outreach to Native Hawaiian/Pacific Islander (NHPI) Communities: A Pilot Project

Jami Fukui, MD, Associate Professor, University of Hawai'i Cancer Center

- Break -

Cancer Disparities: A Panel on Health Literacy, Communicating and Consenting

Plain Talk: Communicating with Participants About Clinical Trials

Lynne Nguyen, MPH, Associate Director, Research Planning and Development, Department of Health Disparities Research, UT MD Anderson Cancer Center

QA Perspective on Informed Consent: A Process, Not a Document

Laura Gonzales, BSN, MA, RN, OCN, Quality Assurance Manager, SWOG Network Operations Office

SWOG Plain Language Tools: Patient-friendly Trial Summaries

Amanda Boyea, MPH, Plain Language Medical Writer, SWOG Network Operations Office

Tips for the Real World

Samantha Wright, MS, CCRP, Clinical Research Coordinator, Carle Cancer Institute/Carle NCORP

So Much Consenting, So Little Time

Erin Fukaya, MS, Clinical Operations Manager, Hawai'i NCORP

Q & A

General Session Close (*In-Person: Transition to Breakout Sessions)*

Monica Yee, CCRP, Program Director, SWOG Statistics and Data Management Center

SWOG CANCER RESEARCH NETWORK

NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

A HOPE FOUNDATION sponsored Clinical Trials Training Course for Studies in Cancer Prevention, Control, Screening and Surveillance and Cancer Care Delivery Research

Breakout Q & A Discussion Sessions (Concourse and Ballroom Levels) **(In-person Only)**

You have the opportunity to attend three Breakout Sessions. Please choose 1 topic for each session time:

	Breakout Room 1 Comiskey (Concourse Level)	Breakout Room 2 Toronto (Ballroom Level)	Breakout Room 3 Hong Kong (Ballroom Level)
Session 1 **1:00 – 1:25 pm**	**NCORP Studies: How can SWOG help sites conduct studies well?**	**The Real World: Consenting and Communication**	**Site and Time Management – Where does the time go?**
Session 2 **1:30 – 1:55 pm**			
Session 3 **2:00 – 2:25 pm**			

Breakout Session Descriptions

Sessions 1 (1:00 pm), 2 (1:30 pm) and 3 (2:00 pm) - Choose 1 topic for each session time

- ☐ **NCORP Studies: How can SWOG help sites conduct studies well?** ***(Comiskey / Concourse Level)***
  Welcome to "information central" about conducting SWOG NCORP studies. Representatives from SWOG's Network Operations Office and the Statistics and Data Management Center invite you to share your questions, suggestions, and feedback with them. Join this informal session to ask about protocols, data submission, participant recruitment and follow-up, training resources, preparing for quality assurance audits, and more. SWOG wants to hear from you!

- ☐ **The Real World: Consenting and Communication** ***(Toronto / Ballroom Level)***
  Communication is a key component to engaging and building trust with our study participants. Join Samantha Wright, CCRP, Clinical Research Coordinator Carle Cancer Institute/Carle NCORP, Lynne Nguyen, MPH, Associate Director, Research Planning and Development, Department of Health Disparities Research, UT MD Anderson Cancer Center and Amanda Boyea, MPH, Plain Language Medical Writer, SWOG Network Operations Office for an interactive conversation about incorporating the practice of communicating effectively, building trust, and consenting various populations of study participants. Bring your questions and insights to share on consenting successes and challenges.

- ☐ **Site and Time Management – Where does the time go?** ***(Hong Kong / Ballroom Level)***
  It's so easy to get overwhelmed with tasks, especially in research where attention to detail and juggling multiple duties is crucial. We've batched work tasks, prioritized activities, and blocked time on our calendars for productivity. We have a plan for the day and that plan is usually scrapped by lunchtime – if we even have time to take a break to eat! Erin Fukaya, Clinical Operations Manager, Hawaii NCORP and Ken Matheus, Research Program Manager, Swedish Cancer Institute/Pacific Cancer Research Consortium NCORP, will lead this session where we can collectively share and discuss our strategies for time management while ensuring time intensive processes, like consenting, are provided the attention they deserve. It's a balancing act so let's not navigate this alone. Join us to learn and connect with other research professionals and share your best strategies for time management.

Please turn in your completed Feedback Form at the last Breakout Session you attend.
We welcome you to submit topics for future SWOG NCORP Clinical Trials Workshops.

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SWOG NCORP Research Base Clinical Trials Workshop

Wednesday, October 16, 2024
Chicago, Illinois

General Session: 10:30 am – 1:00 pm CT
Breakout Sessions: 1:00 pm – 2:30 pm CT

Certification of Attendance:

I certify that I attended _____ hours of this meeting. The topics of the meeting contribute to the education and professional advancement in clinical research.

Attendee Name _____
Attendee Signature _____
Date _____

Program Director, SWOG NCORP Data Management:
Monica Yee, CCRP — monicay@crab.org

A HOPE FOUNDATION sponsored Clinical Trials Training Course for Studies in
Cancer Prevention, Screening, Supportive Care and Symptom Management, Surveillance, HR-QOL and Cancer Care Delivery

SWOG NCORP Research Base Clinical Trials
Active and Upcoming Studies

Study #	Study Title	Activation / Status	Accrual	Follow-up (from Reg Date)	Participating Sites
Cancer Care Delivery Research Committee					
S1703	Randomized Non-Inferiority Trial Comparing Overall Survival of Patients Monitored with Serum Tumor Marker Directed Disease Monitoring (STMDDM) versus Usual Care in Patients with Metastatic Hormone Receptor Positive HER-2 Negative Breast Cancer	July 2018	359 of 739 **49%**	6 years from Step 2 rando date	NCTN and NCORP
S1912CD	A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT)	July 2021	301 of 326 **92%**	1 year	NCORP Only
S2108CD	A Cluster Randomized Trial Comparing An Educationally Enhanced Genomic Tumor Board (EGTB) Intervention to Usual Practice to Increase Evidence-Based Genome-Informed Therapy	August 2022	1205 of 1282 **94%**	2 years	NCORP Only Limited Institution
S2417CD	A Pragmatic Randomized Controlled Trial to Evaluate the Effectiveness of an Intervention to Promote Guideline-Concordant Colorectal Cancer Surveillance	2025 IN DEVELOPMENT	654	1.5 years	NCORP Only
Palliative Care Committee					
S1501	Prospective Evaluation of Carvedilol vs No treatment in Prevention of Cardiac Dysfunction in Patients with Metastatic HER-2+ Breast Cancer	September 2017 **TEMP CLOSURE**	310 of 491 **63%**	2 years	NCTN and NCORP
S2408	A Randomized Phase III Blinded Trial of Lanreotide For The Prevention of Postoperative Pancreatic Fistula	Est. Q4 2024 IN DEVELOPMENT	274	1 year (post-surgery date)	NCTN and NCORP
Prevention, Screening and Surveillance Committee					
	Accrual recently completed on trials; New concepts are under development				
Symptom Management and Survivorship Committee					
S2010	A Randomized Phase III Trial Comparing Active Symptom Monitoring Plus Patient Education Versus Patient Education Alone To Improve Persistence With Endocrine Therapy In Young Women With Stage I-III Breast Cancer (ASPEN)	January 2023	439 of 540 **81%**	1.5 years	NCTN and NCORP
S2013	Immune Checkpoint Inhibitor Toxicity (I-CHECKIT): A Prospective Observational Study	August 2021 **TEMP CLOSURE**	2084 of 4124 **51%**	1 year	NCTN and NCORP
S2205	Ice Compress: Randomized Trial of Limb Cryocompression Versus Continuous Compression Versus Low Cyclic Compression for the Prevention of Taxane-Induced Peripheral Neuropathy	March 2023	227 of 777 **29%**	1 year	NCTN and NCORP Limited institution

SWOG NCORP Research Base Clinical Trials
Completed Accrual with Participants in Active Follow-up

Study #	Study Title	Activation/ Closure	Accrual	Follow-up Length from Reg Date	Participating Sites
Prevention, Screening and Surveillance Committee					
S0820	A Double Blind Placebo-Controlled Trial of Eflornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon or Rectal Cancer, Phase III - Preventing Adenomas of the Colon with Eflornithine and Sulindac (PACES)	March 2013 **Closed June 2023**	354 of 389	8 years	NCTN and NCORP
S1823	A Prospective Observational Cohort Study to Assess miRNA371 for Outcome Prediction in Patients with Early Stage Germ Cell Tumors	June 2020 **Closed May 2024**	964 of 956	3 years	NCTN and NCORP
S1904	Cluster Randomized Controlled Trial of Patient and Provider Decision Support to Increase Chemoprevention Informed Choice Among Women with Atypical Hyperplasia or Lobular Carcinoma In Situ - Making Informed Choices on Incorporating Chemoprevention into Care (MiCHOICE)	September 2020 **Closed June 14, 2024**	412 of 415	5 years	Limited institution
Symptom Management and Survivorship Committee					
S1600	A Randomized Phase III Double-Blind Clinical Trial Evaluating the Effect of Immune-Enhancing Nutrition on Radical Cystectomy Outcomes	February 2019 **Closed October 2023**	203 of 200	3 years (post-cystectomy date)	NCTN and NCORP
S1714	A Prospective Observational Cohort Study to Develop A Predictive Model of Taxane-Induced Peripheral Neuropathy in Cancer Patients	March 2019 **Closed Nov 2021**	1336 of 1336	3 years	NCTN and NCORP

Questions? Contact cancercontrolquestion@crab.org

Trial Activation and Facilitation Resources

Available online with hyperlinks to the resources listed below.

Identifying Upcoming Studies:

SWOG Protocol Development Tracking Reports and Dashboards (login required)

- These webpages provide real-time status updates on SWOG-led studies in the development pipeline, including targeted activation dates.

Feasibility Assessment Tool: Clinical Trial Review Guide

Getting Started with CTSU and NCI Applications:

CTSU Operations Training Modules, accessible via CTSU.org >> Resources >> CTSU Operations Information >> General Procedures & Training (login required)

Site Rostering:

- CTSU RUMS User Guide (login required) and
- SWOG FAQs: Systems Access and Rostering Maintenance

Site Initiation: Refer to Section 13 of the SWOG-led protocol.

- SWOG FAQs: Funding, Financials, and Study Payments
- The CTSU Site Registration Help Topics (login required)
- NCI CIRB Standard Operating Procedures and Start Guide (login required)
- NCI CIRB How to Open a Study Guide (login required)
- The CTSU Regulatory Submission Portal User Guide (login required)

Participant Enrollment: Refer to Section 13 of the SWOG-led protocol.

- Oncology Patient Enrollment System (OPEN) user guide (login required)
- Open Funding (login required)

Data Submission and Management:

- CTSU Rave Roles, Training, and Resources (login required)
- CTSU Data Quality Portal (DQP) Help Topics (login required)
- SWOG Patient Reports and Tools for Data Quality (login required)
- SWOG List of Studies with No Required Follow-up (login required)
- SWOG FAQs: Data Submission and Management (login required)

Key Guidance for SWOG-led Study Implementation:

- SWOG CRA Manual for Oncology Research Professionals (login required)
- SWOG Best Practices Document
- SWOG Quality Assurance & Audits, includes essential guidelines.

Key SWOG Policies and Procedures for Study Management:

Policy 12	SWOG Registration and Treatment Policies
Policy 15	Applicability of IND Applications and Investigator Brochures/Support From Pharmaceutical Companies
Policy 18	Data Evaluation Policy and Procedure
Policy 19	Quality Assurance Program
Policy 20	New Agent Studies and Safety Monitoring
Policy 21	Data and Safety Monitoring
Policy 22	Ethical and Regulatory Considerations
Policy 23	Serious Adverse Events
Policy 25	Drug Ordering
Policy 29	Roster of Investigators Maintenance Policies and Procedures
Policy 30	Responsibility for Patient Follow-Up
Policy 33	Institutional Performance Review
Policy 36	Affirmation of Integrity
Policy 38	Research Calculations for Clinical Trials
Policy 39	Acquisition, Maintenance and Use in Research of Tissue and Other Biologic Patient Specimens

General Training and Informational Resources

Getting Started with SWOG:

- Vital Information and Contacts
- SWOG CRA Manual for Oncology Research Professionals (login required)
- CTSU Website Overview (9 mins) (login required)
- SWOG Website Overview (4 mins) (login required)
- SWOG CRA Workbench Overview (4 mins) (login required)
- iMedidata RAVE Access for Lead ORPs (6 mins) (login required)
- SWOG Specimen Tracking System for Lead ORPs (8 mins) (login required)

NCORP-provided materials (accessible via the NCORP-Portal):

- NCORP Administrator Basics, includes NCORP Guidelines walkthrough, Site Orientation, and funding overview information. (login required)
- NCORP Meeting/WebEx Materials, includes helpful resource materials from monthly administrator meetings, study-specific webinars, and prior NCORP annual meeting materials. (login required)

SWOG-led Study Accrual Tracking: Reports & Dashboards (login required)

Tools for Clinical Trial Conduct: SWOG CRA Workbench Tools (login required)

Tools for a Successful Audit: SWOG Quality Assurance & Audits

SWOG Training for Oncology Research Professionals:

Clinical Trials Training Course (login required)

Specimen Submission Training:

- Improving Submissions to the SWOG Biospecimen Bank (login required)
- Biospecimen Quality, Compliance, Tips and Tricks (login required)
- Complete Guidelines for Specimen Submission

SWOG Regulatory Workshop

SWOG Quality Assurance Webinar Series, including:

- Workload Prioritization in Clinical Trials (1.5 CEU contact hours) (login required)
- Best Practices for Informed Consent (1 CEU contact hour) (login required)
- Research Protocol Deviations vs Deficiencies (1 CEU contact hr) (login required)
- Adverse Event Reporting (login required)
- Serious Adverse Event Reporting (login required)
- SWOG Audits: Preparing for Success and Audit Process (login required)
- How to Develop a CAPA Plan (login required)

Additional SWOG-provided Training:

- For more training resources refer to:
  - SWOG Training Resources
  - SWOG CRA Workbench (login required)
  - SWOG Oncology Research Professionals (login required)

Onboarding and Refresher Training:

Compiled Researcher Resources List, now accessible via CTSU.org >> Resources >> Researcher Resources. This is a downloadable / sortable (by Topic area and Source) / editable list that sites can use as a basis for local staff onboarding or continuing education. (login required)

General Research Training and Informational Resources:

SWOG Clinical Research Resources, a clearinghouse of resources and continuing education materials pertinent to the conduct of NCTN, including NCORP trials. In particular, check out the “Announcements and Current Training Opportunities” and “Oncology Research Professionals” sections.