OPEN FORUM – Fall 2023

Site Operations:
Tips and Tricks for Research Managers

Facilitators

- Kira Pavlik -- kira.pavlik@yale.edu
- Connie Szczepanek – connie.szczepanek@crcwm.org

SWOG | CANCER RESEARCH NETWORK

LIVE WEBINAR SERIES

Educational presentation hosted by the SWOG Quality Assurance Department

October 2023: Quality Assurance Audits – Preparing for Success

~ Overview presentation followed by interactive Q&A
Bring general Audit / Audit Process questions!

Presented by:
Laura Gonzales, BSN, MA, RN, OCN
Rose Ermete RN, BSN, OCN, CRN-BC, CCRP

Upcoming 90-Minute Webinar:	
Friday, October 20, 2023	**11:00am-12:30pm Central Time**

- **NEW Participants (who did not register for the July webinars): Register by October 19, 2023**
  - **Login with CTEP credentials and "Enroll" to the SWOG Quality Assurance Live Webinar Series: SWOG Audits Class. After enrolling, you will receive a system-generated calendar invite.**

REGISTRATION LINK

(https://swog.exphosted.com/coursepage/85_enUS/ExpertusONE_27)

- **Participants who previously registered to the QA webinar sessions were automatically enrolled to the October 2023 webinar via the SWOG ExpertusOne Learning Management System (LMS).**
- **On 10/20/23: Join via the SWOG ExpertusOne LMS course link here (or in calendar invite).**
  - **Login with your CTEP credentials required.**
  - **VA participants: On 10/20/23, you will receive a VA-specific join link via email from training@swog.org.**
- **For questions pertaining to webinar access or registration: Contact training@swog.org.**

SWOG CANCER RESEARCH NETWORK

September 15, 2023

TO: ALL NATIONAL CLINICAL TRIALS NETWORK MEMBERS; CTSU

FROM: SWOG Quality Assurance Department (qamail@swog.org)

RE: SWOG Delegation of Task Log (DTL) Template Updates

MEMORANDUM – Delegation of Task Log (DTL) Template Updates

The purpose of this memorandum is to inform sites that the Delegation of Task Log (DTL) Templates for SWOG Studies in CTSU have been updated to include Non-Physician Investigator (NPIVR) for Eligibility Assessment and End Point Assessment.

The following is a summary of the changes:

1. Updated the allowed registration types for Eligibility and End Point Assessment tasks on all DTL templates. Note that the version date for the templates will not change.
2. Updated DTL will include a comment at the bottom of each template, “CTSU expanded allowed registration types for the Eligibility and End Point Assessment tasks to included NPIVR per SWOG request and CTEP approval.”
3. All newly created DTLs will allow Eligibility Assessment and End Point Assessment to be assigned to NPIVRs.

Sites will not be required to take any action; they can leave their site-level DTLs as they are. If sites do want to make new assignments to NPIVRs, they may do so, and they will need to obtain Clinical Investigator sign-off per the usual procedure for these two tasks.

For any questions, please review the DTL help pages or contact CTSU.

This memorandum serves to notify the NCI, and SWOG Statistics and Data Management Center.

cc: PROTOCOL & INFORMATION OFFICE

The following is a brief description of the content of each section contained in a SWOG protocol.

Title page	Lists the study number, title, the current version date, the NCT number, the agent(s) used in the study and their commercial vs investigational status, the study chairs(s), and statistician(s). In addition, if it is a registration study, this would also be listed here.
Protocol Contact Information	Provides contact information for questions about eligibility, data submission, specimens, medical queries, CTEP-IAM, OPEN, patient transfers, SAEs, and the CTSU Helpdesk.
Schema	Provides a diagrammatic overview of a protocol from registration to the end of the protocol treatment.
1.0 Objectives	States the study purpose, a brief outline of the therapy under evaluation and the endpoints of interest (survival, response, time to progression, etc.)
2.0 Background	Supplies justification for conducting the study and cites results of similar studies or pilot data. This section provides a detailed explanation of why it is felt that this approach is potentially better than the current standard of care.
3.0 Drug Information	Describes the drugs used in the study, their known toxicities, storage requirements, drug stability, administration, and supply information. CAEPR table with exceptions to SAE reporting (SPEER).
4.0 Staging Criteria	When required, this section details staging criteria used in the study. Diagnostic criteria may also be included in this section, as appropriate.
5.0 Eligibility Criteria	Outlines participant and disease characteristics required or excluded for participation in the study. There are **NO WAIVERS** to these criteria.
6.0 Stratification Factors	Stratification factors are pre-treatment participant characteristics which are balanced across treatment arms. These factors must be documented PRIOR to randomization.
7.0 Treatment Plan	Provides a description of the treatment or study plan, including precautions, prohibited medications, pre-medications, dose, schedules, number of cycles, study specific procedures for disease assessment, and reasons for discontinuing treatment. Pre-medication and supportive care are also included, as appropriate.
8.0 Toxicities Monitored & Dosage Modifications	Lists the anticipated toxicities and guidelines for dosage adjustment and serious adverse event reporting requirements, including additional events to be reported that fall outside of the reporting requirement tables.

9.0 Study Calendar	General snapshot of study requirements for all tests, procedures, and treatment administration required while the participant is on study.
10.0 Criteria for Evaluation & Endpoint Definitions	Provides instructions for measuring disease response, participant performance status, and study endpoints.
11.0 Statistical Considerations	Reiterates the study objectives, defines accrual goals and describes the study design used to address the objectives of the study. Guidelines for early closure and data and safety monitoring will also be outlined.
12.0 Discipline Review	Includes information regarding pathology, radiation therapy, imaging or surgery review requirements and, when required, includes details regarding submission of materials.
13.0 Registration Guidelines	Provides detailed patient registration instructions including when and how to register, how many registration steps are required for the study, registration policies, the requirement for the Registration Worksheet to be completed.
14.0 Data Submission Schedule	Provides a detailed schedule for all required data submission, and how to submit them. Generally, source documentation is uploaded in RAVE and radiology scan images are submitted to TRIAD.
15.0 Special Instructions	Outlines other aspects of protocol participation, including special instructions or protocol specific training, specimen shipping or handling procedures or other materials, if applicable.
16.0 Ethical and Regulatory	Describes ethical and regulatory issues for the study. Informed consent, IRB, and drug accountability information are presented.
17.0 Bibliography	Lists references used in the protocol.
18.0 Appendices	Contain all appendices referenced in the text. Examples of Appendices: – Instructions for the SWOG Biospecimen Bank – Participant Diaries – Quality Assurance Audit/Monitoring plans – New York Heart Association Criteria – Drug Interaction Examples – Live Vaccine Examples – Participant Drug Information Handout and Wallet Card – Algorithms for Immune Related Reactions

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PROTOCOL CONTACT INFORMATION

Regulatory, Protocol, Informed Consent:	protocols@swog.org
Medical Queries/Dose Modifications	**Email the contact(s) listed in Protocol Section 8 or Study Chairs.**
Specimen Tracking System/CRA Workbench:	technicalquestion@crab.org
CTEP-IAM:	https://ctepcore.nci.nih.gov/iam/index.jsp
OPEN:	**888-823-5923 or** ctsucontact@westat.com
Patient Transfers:	patienttransfer@crab.org
AEs/SAEs:	adr@swog.org
Quality Assurance/Audits:	qamail@swog.org
Eligibility, RAVE, and Data Submission: SWOG Data Operations Center: 206-652-2267	• breastquestion@crab.org • cancercontrolquestion@crab.org • giquestion@crab.org • guquestion@crab.org • leukemiaquestion@crab.org • LUNGMAPquestion@crab.org • lungquestion@crab.org • lymphomaquestion@crab.org • melanomaquestion@crab.org • myelomaquestion@crab.org • raretumors@crab.org • SWOGComboMATCHQuestion@crab.org • **For MyeloMATCH and iMATCH protocols, refer to the protocol contact page.**

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TRAINING RESOURCES

SWOG Learning Management System https://swog.exphosted.com	• Clinical Trials Training Course • Live Webinars • Head CRA Training • Central Monitoring	• Regulatory Workshops • APP Workshops • Investigational Agents • TeamScience Training
SWOG Website https://www.swog.org	• FAQs • Quality Assurance/Audits • SWOG Policies	• Clinical Research Resources • SAE Resources • Continuing Education
SWOG CRA Workbench https://txwb.crab.org/TXWB/Logon.aspx	• Tools of the Trade • CRA Newsletter • Best Practices	• CRA Manual • Your First Group Meeting • SWOG Glossary
CTSU CLASS Learning Management System https://classlms.org/#/dashboard	• Study-Specific Training • RECIST Training • Source Document Portal	• Neuropen Training • Tuning Fork Training • Timed Get Up and Go
NCI Pharmaceutical Management Branch https://ctep.cancer.gov/branches/pmb/default.htm	• Ordering Agents • DARF Training • AURORA Training	• Agent Storage • Local Agent Destruction • Agent Returns/Transfers

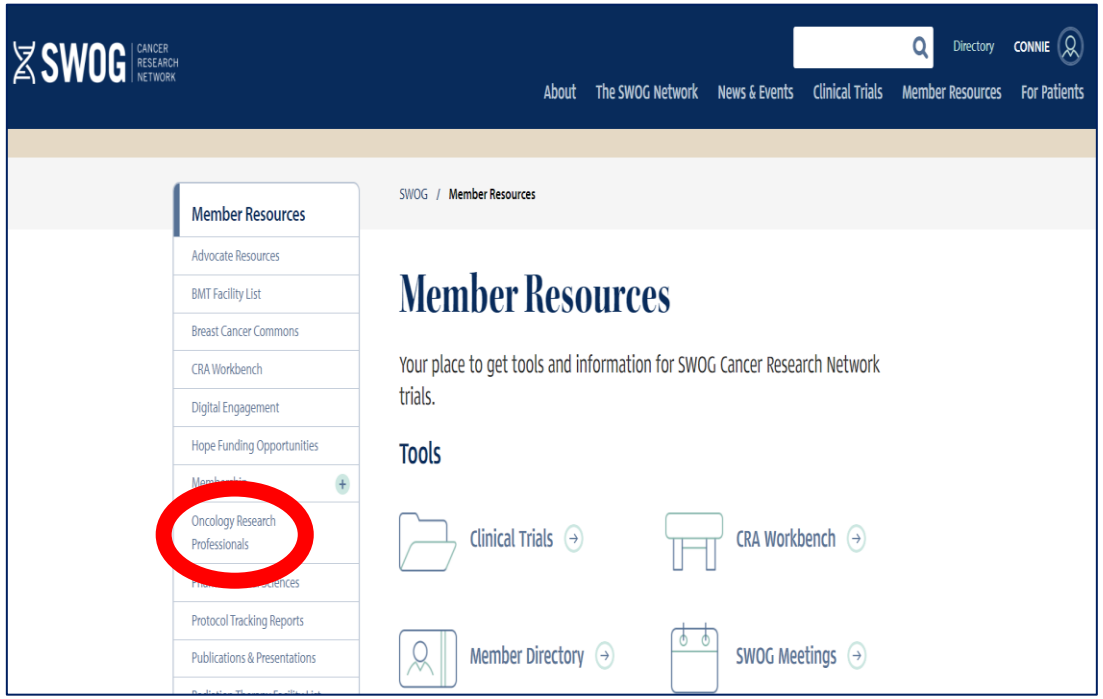
EXTERNALLY AVAILABLE RESOURCES

Additional Trainings and Helpful Resources

Utility for Education, Training, Career Ladder Development and more

ACRP Core Competency Guidelines for Clinical Research Coordinators	First industry-standard competency guidelines for Clinical Research Coordinators. https://acrpnet.org/employer-resources/our-services/acrp-partners-advancing-the-clinical-research-workforce/core-competency-guidelines-clinical-research-coordinators-crcs/
Joint Task Force for Clinical Trial Competency	Developed the framework for standard competencies across eight domains for clinical research professionals. https://mrctcenter.org/clinical-trial-competency/
Domains and Leveled Core Competencies	https://mrctcenter.org/clinical-trial-competency/framework/domains/
ONLINE COMPETENCY-BASED TRAININGS	Available through Tufts University, online courses are available addressing the competency areas highlighted above. Users must create an account. https://ilearn.tuftsctsi.org/catalog?pagename=Skills-Domain

“NEW” Lead ORP Training Found at ORP Page in Member Resources



New Resources

Check out the resources shared at the SWOG Spring 2023 Group Meeting Open Forum Meeting. The Site Operations Meeting and Jeri & Noburu Oishi Symposium Meeting (full meeting and individual presentation) recordings are also now accessible from: Spring 2023 Oncology Research Professionals Resources.

SWOG Oncology Research Professionals Regulatory Workshop

- The Workshop is posted in the LMS in entirety via above link (login with your CTEP credentials to access the Workshop), OR, you can access the shorter (individual sessions) via the links below.
  - Session 1: Introduction
  - Session 2: Regulatory 101 Panel Discussion
  - Session 3: Understanding the PMB
  - Session 4: Know Your IRBs Panel Discussion
  - Session 5: SWOG Perspectives and Common Challenges Panel Discussion
  - Session 6: Past Accomplishments & Hope for the Future

Lead Oncology Research Professional (formerly Head CRA) Training Materials

The ORP Executive Committee is in the process of developing a library of training materials for SWOG Lead Oncology Research Professionals (formerly Head CRAs) and site leader. The forthcoming SWOG Lead ORP (formerly Head CRA) Workshop will include the following.

Direct links to newly released individual courses that will comprise the complete SWOG Lead Oncology Research Professionals (or Lead ORP) Workshop are included below. Forthcoming course content (in process of development) is not yet linked.

Lead ORP Training ~ Content by Module

- **Introductory Modules**
  - SWOG Lead Oncology Research Professional Workshop Introduction (10 mins)
  - SWOG and NCI: An Introduction
- **Leadership and Site Operations Modules**
  - Leadership Perspective (17 mins)
  - NCI Trials - Site Operations Perspective (forthcoming modules)
    - Site-level feasibility assessment
    - Site-level activation processes
    - Institutional Roles
    - Collaboration with the SWOG Site PI
    - Tips, Tricks, and Tools
- **SWOG and NCI Systems Module**
  - SWOG and NCI Systems Overview Training (14 mins)
- **Data Management and Resource Access Modules**
  - Data Managment and Access Module Introduction for Lead ORPs (1 min)
  - CTSU Website Overview (9 mins)
  - SWOG Website Overview (4 mins)
  - SWOG CRA Workbench Overview (4 mins)
  - iMedidata RAVE Access for Lead ORPs (6 mins)
  - SWOG Specimen Tracking System for Lead ORPs (8 mins)
  - Central Monitoring (5 mins)
- **Funding and Site Payments Modules**
  - NCTN and NCORP Study Funding and Payment Distribution (20 mins)
  - Open Funding (10 mins)
  - National Coverage Analysis Overview (4 mins)
- **Study Activation and Management Modules**
  - Delegation of Tasks Log (2 mins)
  - Adverse Events Training for Lead ORPs (8 mins)
  - Dose Modifications Training for Lead ORPs (1 min)
  - Serious Adverse Event Reporting Training for Lead ORPs (30 mins)
  - SAE Reporting - Specific Exceptions to Expedited Reporting for Lead ORPs (4 mins)
  - Data Entry in Difficult Situations Training for Lead ORPs (2 mins)
  - Record Retention Training for Lead ORPs (3 mins)
- **Reports and Tools for Data Quality Modules**
  - Expectations and Expectation Reports for Lead ORPs (10 mins)
  - Vital Status Expectations Training for Lead ORPs (5 mins)
  - Specimen Expectations Training for Lead ORPs (8 mins)
  - Institution Performance Review Training for Lead ORPs (10 mins)
  - Query Reports Training for Lead ORPs (4 mins)
  - CTSU reports - Data Quality Portal (DQP) Training for Lead ORPs (7 mins)
- **Regulatory Module**
  - Regulatory Expectations from a QA Perspective - Training for Lead ORPs (13 mins)
- **Quality Assurance Modules**
  - Audits and Quality Assurance Program -Training for Lead ORPs (20 mins)
  - Protocol Deviations vs. Deficiencies Training for Lead ORPs (4 mins)
  - When is my Institution's next Audit Due? - Training for Lead ORPs (2 mins)