SWOG | CANCER RESEARCH NETWORK

LIVE WEBINAR SERIES

Educational presentation followed by time for open discussion/Q&A.

Quarterly - Beginning July 2023

Hosted by SWOG Quality Assurance

Registration (Requires CTEP-IAM Login):

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

Upcoming 1-Hour Sessions (Choose Your Session):	
Tuesday, July 25, 2023	12:00pm Central
Thursday, July 27, 2023	4:00pm Central

For questions, contact Maggie Spillers at mspiller@swog.org.

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