Study Activation – Best Practices

Introduction

Activating a study at your institution can be an overwhelming process so the SWOG Network Operations Center would like to call-out several "best practices" for sites to refer to when activating SWOG trials. Please refer to the details below.

Opening an NCTN (National Clinical Trials Network) clinical trial at your site involves several steps and typically requires collaboration with the Cooperative Group, NCI, and institutional review board (IRB). Here's a general outline of the process:

1. **Identify Trials**: Determine which NCTN clinical trials are suitable for your site based on the participating countries, trial's eligibility criteria, patient population, available resources, and expertise.
2. **Membership and NCI Registration:** Investigators and associates/clinical site staff must be registered members of a Cooperative Group with a Cancer Therapy Evaluation Program (CTEP) Identity and Access Management (IAM) number and maintain an active CTEP-IAM account status. Refer to SWOG Policy Memorandum N0. 7 (Individual Membership Process) for further information.
3. **Site Activation Documents:** Prior to study activation, sites must complete the CTEP and CTSU registration procedures outlined in Section 13 of all SWOG protocols. For studies that require additional site training prior to activation there will be a Protocol-Specific Requirements (PSR) sub-section within Section 13 with details related to those training requirements.
4. **IRB Approval**:
    a. **NCI CIRB:** As of March 1, 2019, all U.S.-based sites must be members of the NCI Central Institutional Review Board (NCI CIRB) in order to participate in Cancer Therapy Evaluation Program (CTEP) and Division of Cancer Prevention (DCP) studies open to the National Clinical Trials Network (NCTN) and NCI Community Oncology Research Program (NCORP) Research Bases. Additionally, U.S.-based sites must accept the NCI CIRB review to activate new studies at the site after March 1, 2019. Sites participating through the NCI CIRB must submit the Study Specific Worksheet (SSW) for Local Context to the CIRB using IRBManager to indicate their intent to open the study locally.
    b. **Local IRB:** Local IRB review will continue to be accepted for studies that are not reviewed by the CIRB, or if the study was previously open at the site under the local IRB.
5. **SWOG Training and Credentialing:** Ensure that all investigators and research staff involved in the trial are properly trained and credentialed according to the study requirements. This may include completion of specific training modules or certifications. Section 13 and 15 of SWOG protocols will state if there are any optional or mandatory trainings for the specific trial and how to access these.
6. **Activate Trial:** After successful completion of the Site Initiation Visit (SIV) and any additional requirements, your site will be activated to start enrolling patients in the NCTN clinical trial.

7. **Patient Recruitment and Enrollment:** Begin recruiting eligible patients according to the trial protocol. Ensure that all procedures are conducted in accordance with the protocol and regulatory requirements. Study specific patient recruitment materials can be accessed under the CIRB Approved Documents tab on the CTSU protocol webpage.
8. **Study Conduct and Monitoring:** Throughout the trial, adhere to the study protocol, collect data accurately, and report any adverse events or protocol deviations as required. The sponsoring organization may conduct monitoring visits to ensure compliance and data quality.

Referencing CTSU for Protocol Related Documents

To access active SWOG protocols and protocol related documents, please refer to the Protocols tab on the CTSU website. The protocol specific pages provide information and materials related to individual protocols. A protocol-specific webpage exists for each protocol listed on the CTSU website. You will only be able to see protocols in which you are able to participate, meaning that you must be a member of the lead protocol organization (LPO) or participating organization. Protocols that are open cross-network will contain all materials needed for protocol participation. Protocols that are not open cross-network may have more limited postings such as CIRB and funding documents only, but no supplemental LPO documents. Further information on the protocol-specific webpages can be found here on the CTSU website.

SWOG Protocol: Section 13.0 (Registration Guidelines)

When activating a SWOG trial at your site, refer to Section 13.0 (Registration Guidelines) of the protocol which contains information for sites related to the following activation processes:

- Registration Timing
- Investigator & Site Registration
- CTEP & CTSU Registration Procedures
- IRB Approval Status
- Study Specific Worksheet (SSW)
- Protocol Specific Requirements (PSR) – *when applicable*
- Delegation of Task Log

Additional training materials and other resources (including user-friendly modules) are available for interested SWOG members via the SWOG Oncology Research Professionals (ORP) page on SWOG / Member-Resources website.

Additional Resources & Contact Information

SWOG Protocol, Consent & Regulatory Questions For questions related to protocol, informed consent content and regulatory processes.	**SWOG Network Operations Center** E-mail: protocols@swog.org
SWOG Membership Questions For questions related to site and personnel membership.	**SWOG Membership** Email: member@swog.org
Quality Assurance Questions For questions related to protocol compliance, site audits and process verification.	**SWOG Quality Assurance** Email: qamail@swog.org
CTSU OPEN Portal System or RAVE Questions For questions dealing with access to the OPEN or RAVE systems.	**Contact** Email: ctsucontact@westat.com
CTSU Regulatory Office For questions related to the CTSU registration procedures.	**Contact** Email: CTSURegPref@ctsu.coccg.org
CIRB Regulatory Office For questions related to the CIRB procedures.	**Contact** Email: support@ncicirbcontact.zendesk.com