Clinical Trials Training Course

Spring 2025

Preclinical Background

Clinical Trials and Protocol Development

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Types of Clinical Trials

Agenda

- Preclinical Background
- Types of Clinical Trials
- Protocol Development
- Key Protocol Sections
- Protocol Actions

Phase I

Determine Maximum Tolerated Dose (MTD)

Phase II

Tumor Response

Protocol Development Process

1. Committee Chair Approves Concept
2. SWOG Executive Review
3. NCI Concept Review (Steering Committee)
4. Protocol Written
5. Formal NCI (CTEP) Review
6. Revisions
7. Approval

Phase III

New Treatment vs Standard Treatment

National Cancer Institute

Cooperative Group Phase 2 (and 1/2) Concepts OEWG Timeline

OEWG timeline for opening a trial to enrollment, for Cooperative Group Phase 2 (and 1/2) Concepts:

Target timeline: 210 days

Absolute deadline: 450 days

Cooperative Group Phase 2 (and 1/2) Concepts include the following:

- Cooperative Group phase 2 (or 1/2) Concepts ≥ 100 patients **not** in response to a LOI mass solicitation.

Phase 2 concept approval stage: 60 days (Day 1 – 60)

Protocol authoring stage: 60 days (Day 60 – 120)

Protocol approval and open to enrollment: 90 days (Day 120 – 210)

(Please see timeline flowchart on next slide.)

Version 3.8 01 Apr 2012

Protocol Development

Stage 1: Concept approval
Target = 60 days

Initial Steering Committee review of the Concept → Consensus Review and conference call with investigators → NCI approval and if needed, pharmaceutical collaborator approval

Stage 2: Protocol submission
Target = 60 days

NCI approval and if needed, pharmaceutical collaborator approval → Protocol submission to the NCI for review

Stage 3: Protocol Approval and Activation
Target = 90 days

Submission of the protocol to the NCI → NCI Review and conference call with investigators → Approval of the protocol document by the NCI → Site finalization: IRB approval, contract negotiations, FDA review, etc. → Final approval and activation of the trial

Target for opening trial to enrollment is 210 calendar days

Absolute deadline for opening trial to enrollment is 450 calendar days

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National Cancer Institute

Phase 3 Concepts OEWG Timeline

OEWG timeline for opening a trial to enrollment, for Phase 3 Concepts:

Target timeline: 300 days

Absolute deadline: 540 days

Phase 3 Concepts include the following:

- All Phase 3 Concepts.

Concept approval stage: 90 days (Day 1 – 90)
Protocol authoring stage: 90 days (Day 90 – 180)
Protocol approval and open to enrollment: 120 days (Day 180 – 300)

(Please see flowchart timeline on next slide.)

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SWOG

Key Protocol Sections

Schema	Section 5 – Eligibility Criteria

SWOG - CTTC

Stage 1: Concept approval
Target = 90 days

Initial Steering Committee review of Concept → Consensus review and conference call with investigators → NCI approval and if needed, pharmaceutical collaborator approval

Stage 2: Protocol submission
Target ~ 90 days

NCI approval and if needed, pharmaceutical collaborator approval → Protocol submission to the NCI for review

Stage 3: Protocol Approval and Activation
Target ~ 120 days

Submission of the protocol to the NCI → NCI Review and conference call with investigators → Approval of the protocol document by the NCI → Site finalization: IRB approval, contract negotiations, FDA review, etc. → Final approval and activation of the trial

Target for opening trial to enrollment is 300 calendar days

Absolute deadline for opening trial to enrollment is 540 calendar days

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SWOG

Key Protocol Sections

Section 7 – Treatment Plan	Section 8 – Toxicities/Dose Modifications

SWOG - CTTC

Key Protocol Sections

SWOG - CTTC

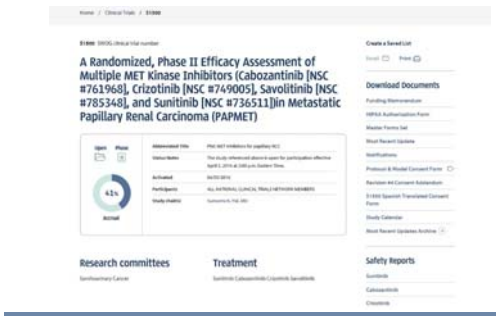
Key Protocol Sections

Section 9 – Calendar	Section 12 – Discipline Review

SWOG - CTTC

Key Protocol Sections

Section 14 – Data Submission Schedule	Master Forms Set



Protocol Actions

Protocol Actions

Activation	Amendment	Revision
Memorandum	Temporary Closure	Permanent Closure

Confidentiality of Protocol Information

- Please note that the information contained in the protocol is considered confidential and should not be used or shared beyond the purposes of completing protocol requirements until or unless additional permission is obtained.
- Confidentiality of study results through publication is a principal of good research. We have an ethical obligation to inform patients of study results as soon as we can, but investigators and study staff must be conscious that information may be shared with patients prior to its release and should not be released to the public or to social media until after publication.

National Clinical Trials Network (NCTN)

https://ctep.cancer.gov/initiativesPrograms/nctn.htm

CTSU Website

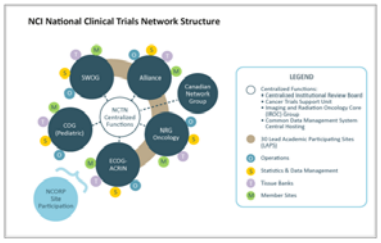
http://www.ctsu.org

NCTN

- ALLIANCE / Alliance for Clinical Trials in Oncology
- ECOG-ACRIN / ECOG-ACRIN Cancer Research Group
- NRG / NRG Oncology
- SWOG / SWOG
- CCTG / Canadian Clinical Trials Group
- COG / Children's Oncology Group

What Questions Do You Have?

NCTN Network Structure



Your Protocol Team

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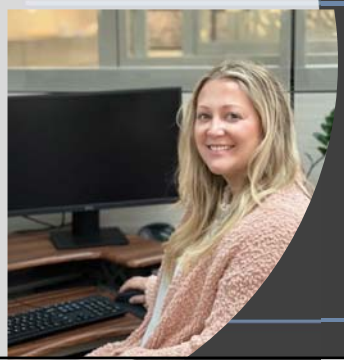

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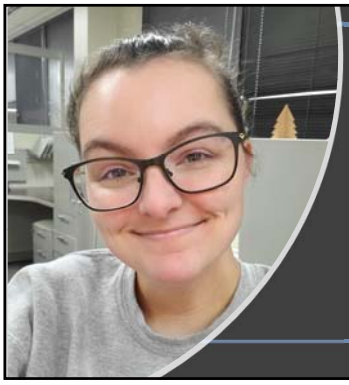

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