



Clinical Trials Training Course

Spring 2026

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Clinical Trials and Protocol Development

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Agenda




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

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Preclinical Background

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Types of Clinical Trials




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Phase I


Determine Maximum Tolerated Dose (MTD)

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Phase II

Tumor Response



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Phase III

New Treatment vs Standard Treatment



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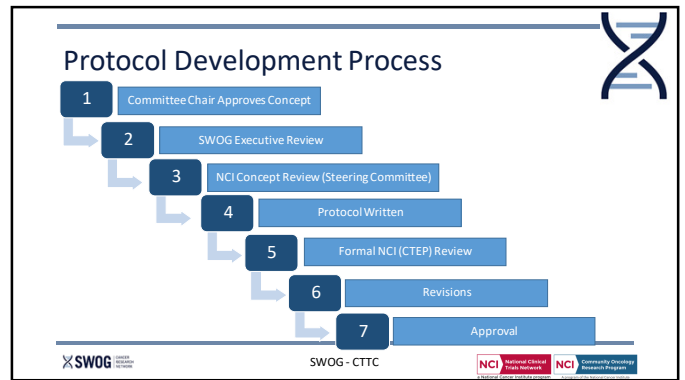
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Protocol Development



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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)

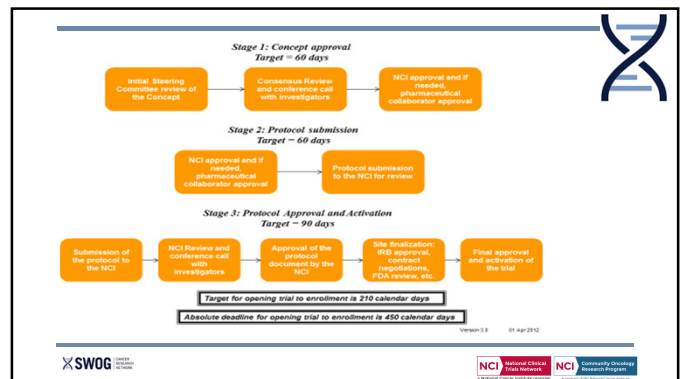
(Please see timeline flowchart on next slide.)

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**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:

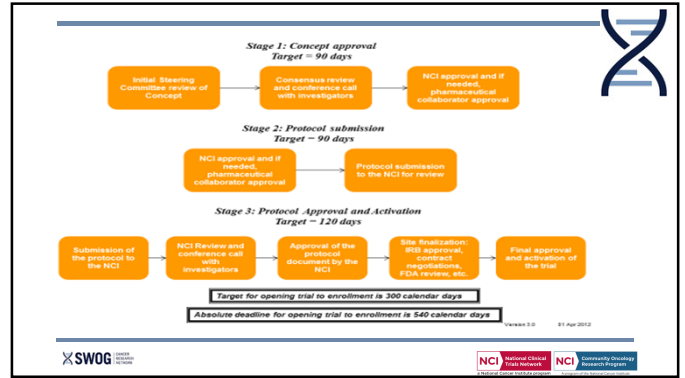
- All Phase 3 Concepts.

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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Key Protocol Sections

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Key Protocol Sections

Schema

Section 5 – Eligibility Criteria

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Key Protocol Sections

Section 7 – Treatment Plan

Section 8 – Toxicities/Dose Modifications

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Key Protocol Sections

Section 9 – Calendar

Section 12 – Discipline Review

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National Clinical Trials Network (NCTN)

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

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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

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NCTN Network Structure

NCI National Clinical Trials Network Structure

LEGEND

- Centralized Functions:
 - Centralized Institutional Review Board
 - Cancer Trials Support Unit
 - Imaging and Radiation Oncology Core
 - Bi-ITC Core
 - Common Data Management System
 - Central Funding
- 33 Lead Academic Participating Sites (LAPIS)
- Operations
- Statistics & Data Management
- Tissue Banks
- Member Sites

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CTSU Website

<http://www.ctsu.org>

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What Questions Do You Have?

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Your Protocol Team

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Laura Gildner

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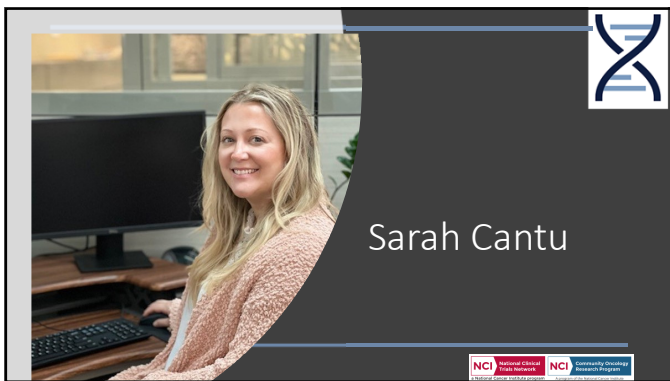
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Catrina Mireles

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Jennifer Beeler

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Chris Kippola

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Megan Keim

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Justine Trevino

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Andrea Garcia

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Amy Doyle

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Erin Rogers

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Gabe Chadwell

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Samantha Bankston

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Elsie Durán

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Brendon Decker

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Robin
Kamucheka



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