




Clinical Trials Training Course

Spring 2019








Clinical Trials and Protocol Development

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SWOG - CTTC






Agenda

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



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Preclinical Background

SWOG Southwest Oncology Group **NCI** National Cancer Institute **NCI** National Cancer Institute


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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


Phase III

New Treatment vs Standard Treatment

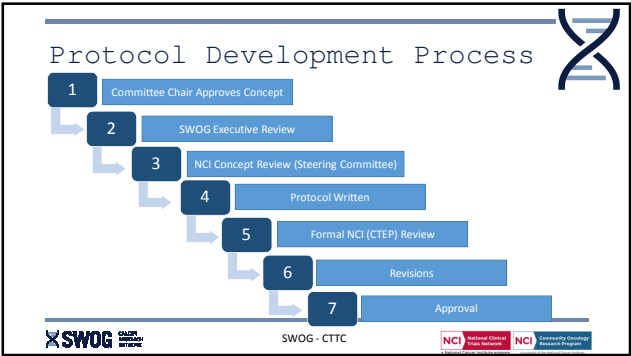




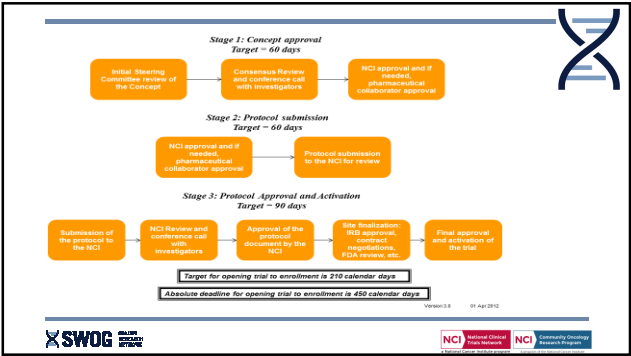

Protocol Development









**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:

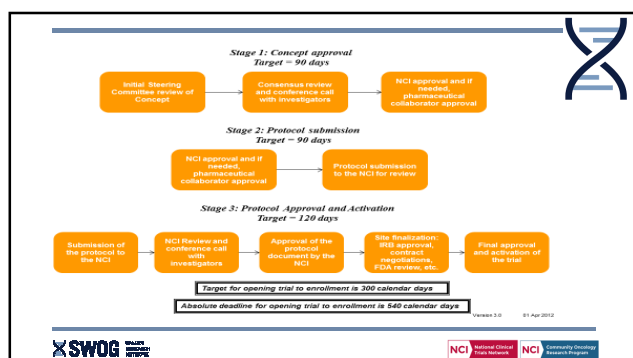
- All Phase 3 Concepts.

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.)

Version 3.0 01 Apr 2012

SWOG **NCI** **National Cancer Institute** **NCI** **National Cancer Institute**



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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Key Protocol Sections

Section 14 - Data Submission Schedule

Master Forms Set

Protocol Actions

Protocol Actions

Activation

Amendment

Revision

Memorandum

Temporary Closure

Permanent Closure

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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NCI

National Clinical Trials Network

NCI

National Cancer Institute

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
 - Biostatistics Core
 - Common Data Management System
 - Central Biostatistics
- Participating Sites:
 - US Lead Academic Participating Sites (APSI)
- Operations:
 - Statistics & Data Management
- Member Sites:
 - Member Sites

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National Clinical Trials Network

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CTSU Website

<http://www.ctsu>

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National Clinical Trials Network

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What Questions Do You Have?


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Your Protocol Coordinators


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