



# Clinical Trials Training Course

Spring 2023



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# Clinical Trials and Protocol Development

Dana Sparks, M.A.T.



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# Agenda

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



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Preclinical Background



SWOG Southwest Oncology Group SWOG - CTTC Community Clinical Oncology Program **NCI** National Cancer Institute **NCI** Community Clinical Oncology Program

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Types of Clinical Trials



SWOG Southwest Oncology Group SWOG - CTTC Community Clinical Oncology Program **NCI** National Cancer Institute **NCI** Community Clinical Oncology Program

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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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Protocol Development



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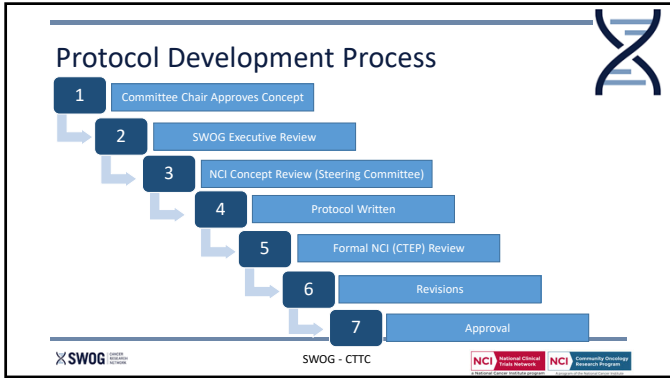
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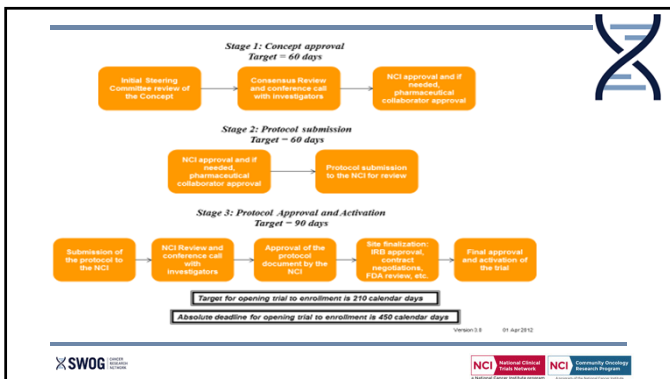
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**Phase 3 Concepts  
OEWG Timeline**

**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.)

Version 3.0 01 Apr 2012

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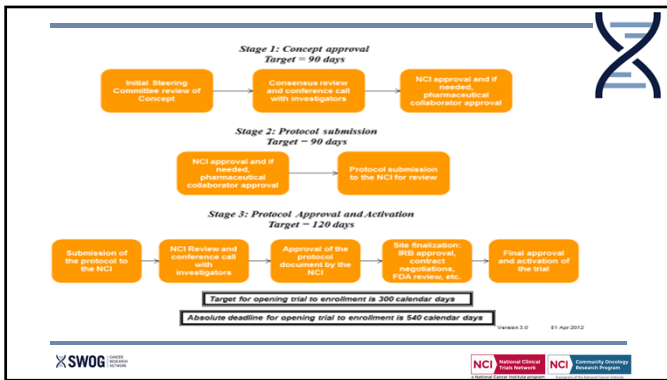
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**Key Protocol Sections**

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Key Protocol Sections



Schema	Section 5 – Eligibility Criteria
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SWOG Southwest Oncology Group NCI National Cancer Institute NCI National Cancer Institute

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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
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Protocol Actions



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Protocol Actions



Activation	Amendment	Revision
Memorandum	Temporary Closure	Permanent Closure

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# National Clinical Trials Network (NCTN)

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

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  National Clinical Trials Network
  Community Oncology Research Program

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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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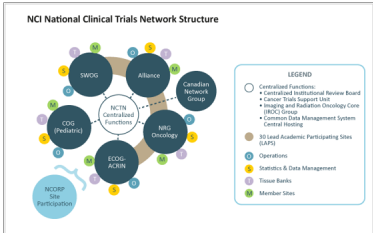
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# NCTN Network Structure



**LEGEND**

- Centralized Functions:
  - Centralized International Review Board
  - Cancer Trials Support Unit
  - Imaging and Radiation Oncology Core (IROC) Group
  - Common Data Management System
  - Clinical Trials
- 30 Lead Academic Participating Sites (LAPS)
- Operational
- Statistics & Data Management
- Tissue Banks
- Member Sites

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  National Clinical Trials Network
  Community Oncology Research Program

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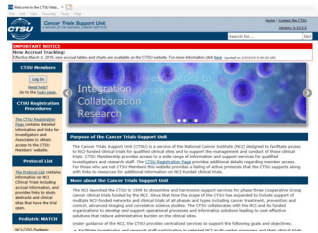
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CTSU Website



<http://www.ctsu.org>

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NCI National Clinical Trials Network

NCI Community Oncology Research Program

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What Questions Do You Have?

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NCI Community Oncology Research Program

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Your Protocol Team

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NCI National Clinical Trials Network

NCI Community Oncology Research Program

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Mariah Norman



NCI National Clinical Trials Network NCI Community Oncology Research Program

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Patricia O'Kane



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Catrina Mireles



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Christy Klepetko



NSWOG

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Chrissy Laubach



NSWOG

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Jennifer Beeler



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A video call slide for Chris Kippola. On the left is a circular video feed of a man with a beard wearing a plaid shirt. To the right of the video feed, the name "Chris Kippola" is written in white text. In the top right corner is a blue DNA double helix icon. At the bottom, there are logos for "XSWOG" and "NCI National Clinical Trials Network Community Oncology Research Program".

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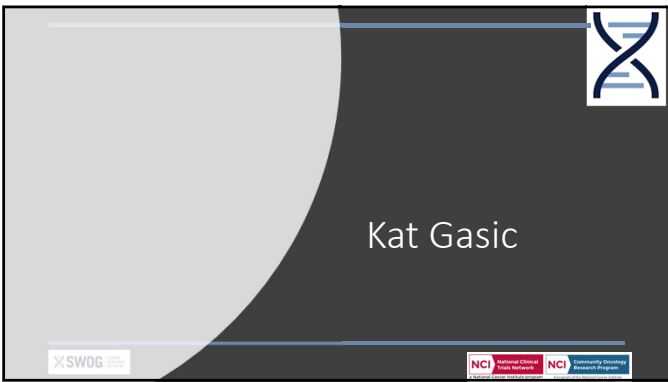
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A video call slide for Kat Gasic. The left side of the slide is a large grey semi-circle. To the right, the name "Kat Gasic" is written in white text. In the top right corner is a blue DNA double helix icon. At the bottom, there are logos for "XSWOG" and "NCI National Clinical Trials Network Community Oncology Research Program".

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A video call slide for Megan Keim. On the left is a circular video feed of a woman with glasses and a grey shirt. To the right of the video feed, the name "Megan Keim" is written in white text. In the top right corner is a blue DNA double helix icon. At the bottom, there are logos for "XSWOG" and "NCI National Clinical Trials Network Community Oncology Research Program".

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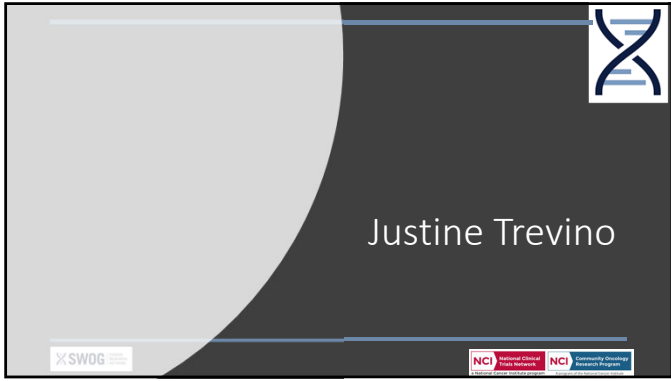
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