

CTEP Early Career Investigator Meeting

Charles Kunos, M.D., Ph.D.

Percy Ivy, M.D.

Jeffrey Moscow, M.D.



Investigational Drug Branch
Cancer Therapy Evaluation Program
Division of Cancer Treatment and Diagnosis
National Cancer Institute, National Institutes of Health

- Provide Overview of the Cancer Therapy Evaluation Program (CTEP)
- Discuss CTEP Project Team Basics
- Discuss CTEP Clinical Trials Network Basics
- Discuss Elements of a Career Development Letter of Intent (LOI)
- Describe the CTEP Externship

Overview

Cancer Therapy Evaluation Program (CTEP)

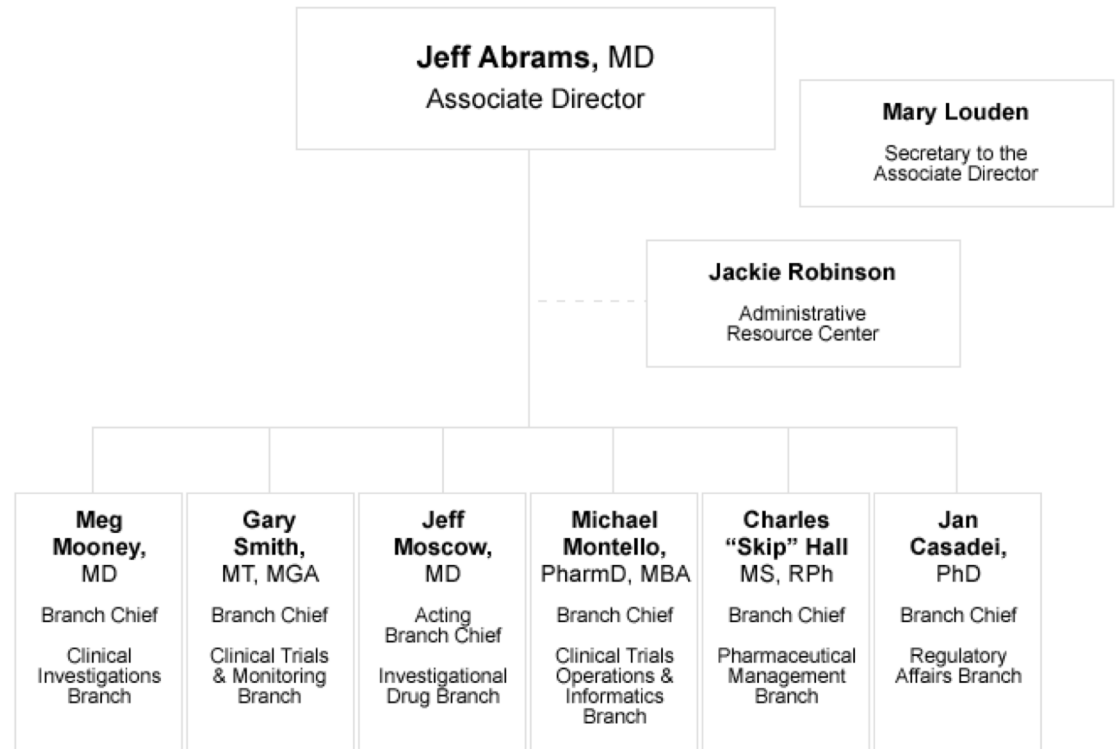
To improve the lives of cancer patients by finding better ways to treat, control, and cure cancer.

NATIONAL
CANCER
INSTITUTE

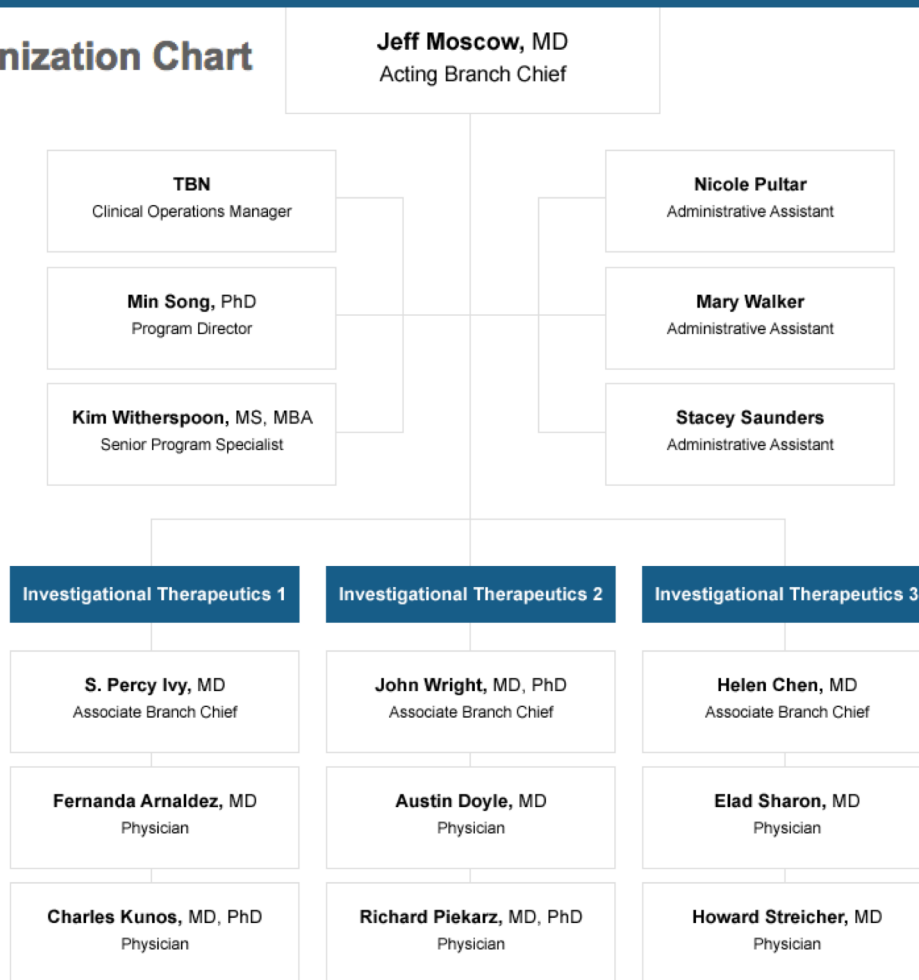


- Tests high priority targeted agents in clinical trials
 - More than 885 clinical trials initiated since 2010
 - Facilitates broad CTEP-Pharmaceutical Collaborator agreements of unique agent combinations
- Interrogates agent mechanism of action and pharmacodynamic biomarkers
 - Reviews clinical assay platforms and performance
 - Identifies proof-of-principle biology
 - Evaluates early pharmacodynamic surrogates for patient clinical outcomes
- Broadens clinical development among less commonly studied cancers
 - Expands industry usual focus upon marketable agent indications to other cancers

CTEP Organization Chart

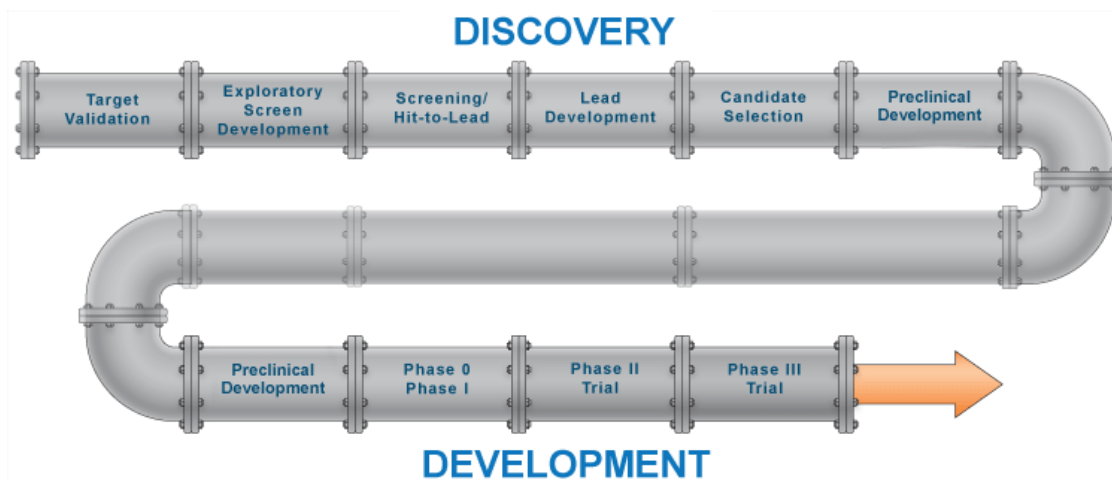


IDB Organization Chart



About NExT

The mission of the NExT Program is to advance clinical practice and bring improved therapies to patients with cancer by supporting the most promising new drug discovery and development projects.

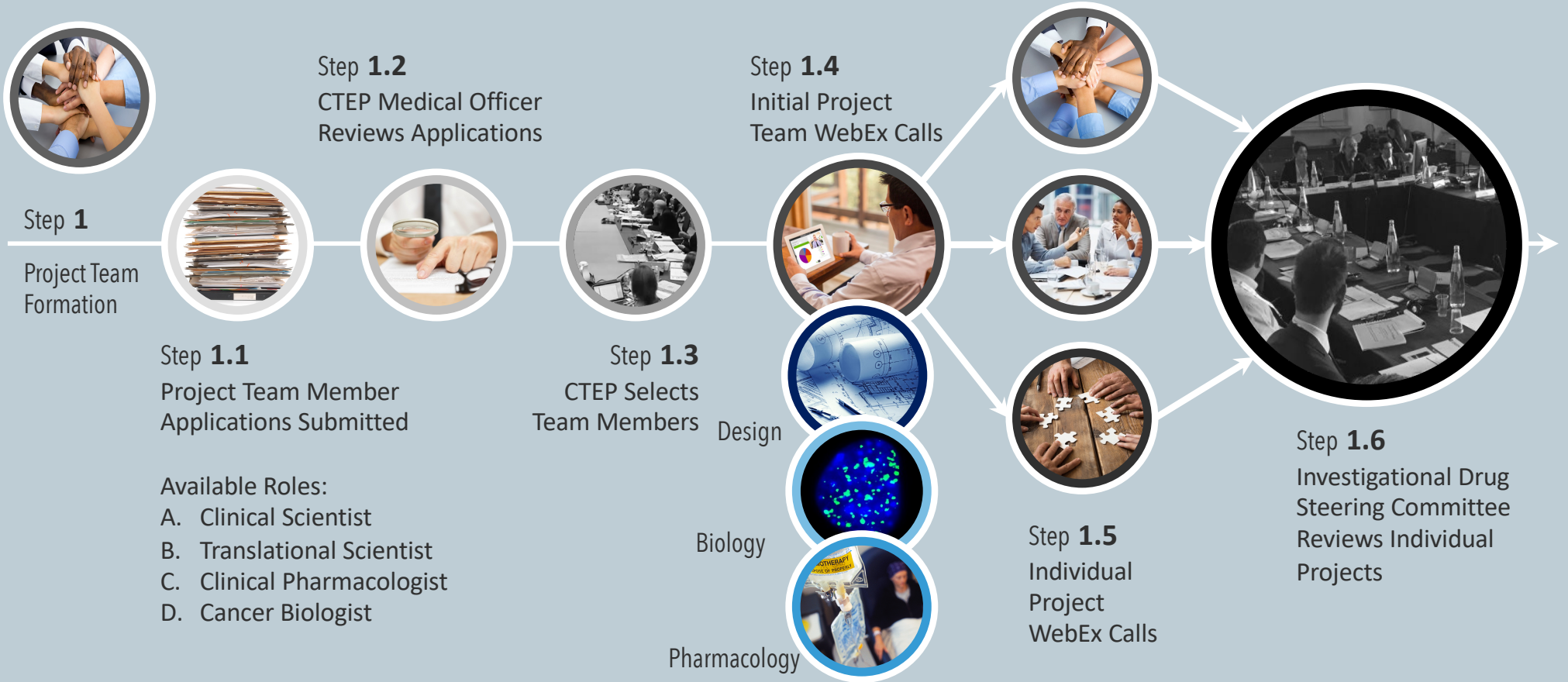


- Introduces novel therapeutics into one of many possible stages of pipeline preclinical or clinical development to NCI infrastructure
- Involves discovery phases (top row of pipeline)
- Expands development phases (bottom row of pipeline)

- Currently sponsors 200 investigational new drug (IND) applications
 - An IND is a request for Food and Drug Administration (FDA) authorization to administer an investigational drug to humans.
- Files 10 or more new INDs each year
- Registers more than 11,000 investigators at over 3,300 institutions
- Has more than 450 active clinical trials
- Accrues up to 20,000 patients per year to its clinical trials

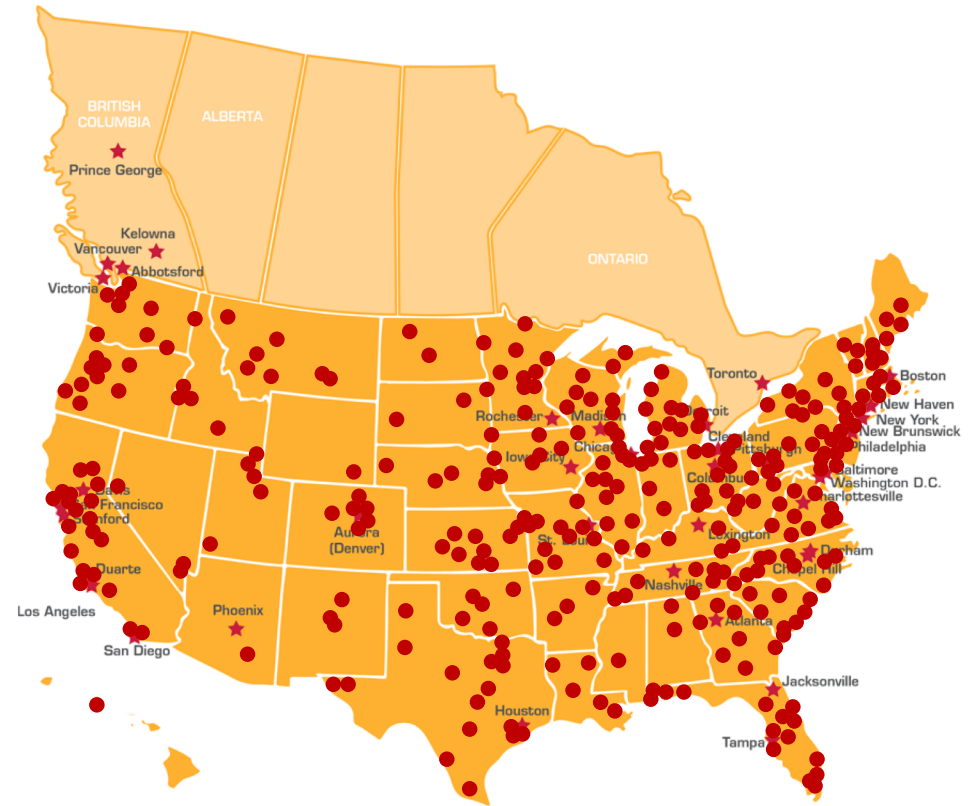
Project Team Basics

Cancer Therapy Evaluation Program (CTEP)



Clinical Trial Networks

Cancer Therapy Evaluation Program (CTEP)



• Experimental Therapeutics Clinical Trials Network (ETCTN)

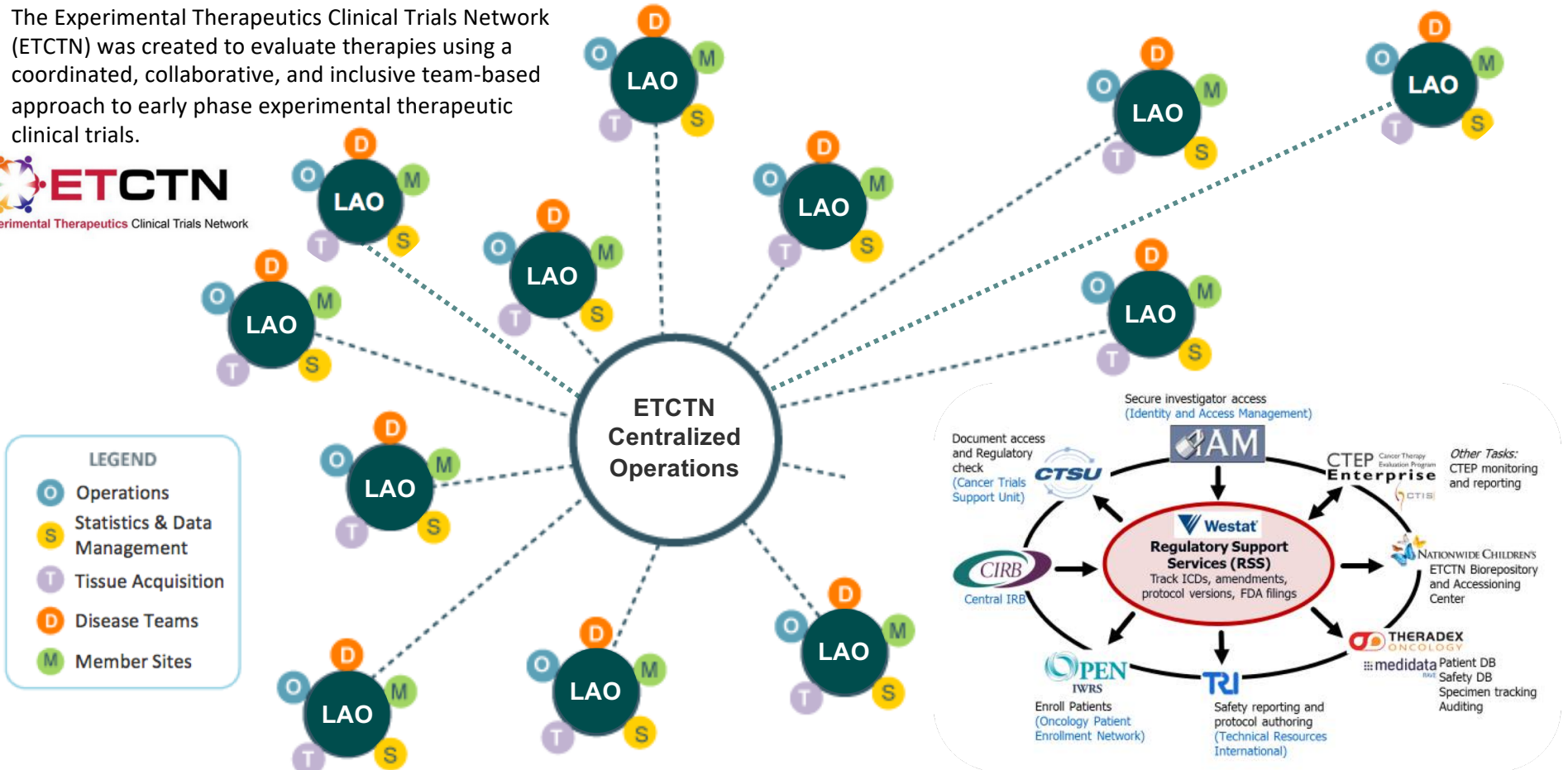
- Studies phase 0, 1, or 2 clinical trials with biologic endpoints

★ Lead Academic Organization (LAO, 12) or affiliate (41) ● Early Drug Development Opportunity Program (15)

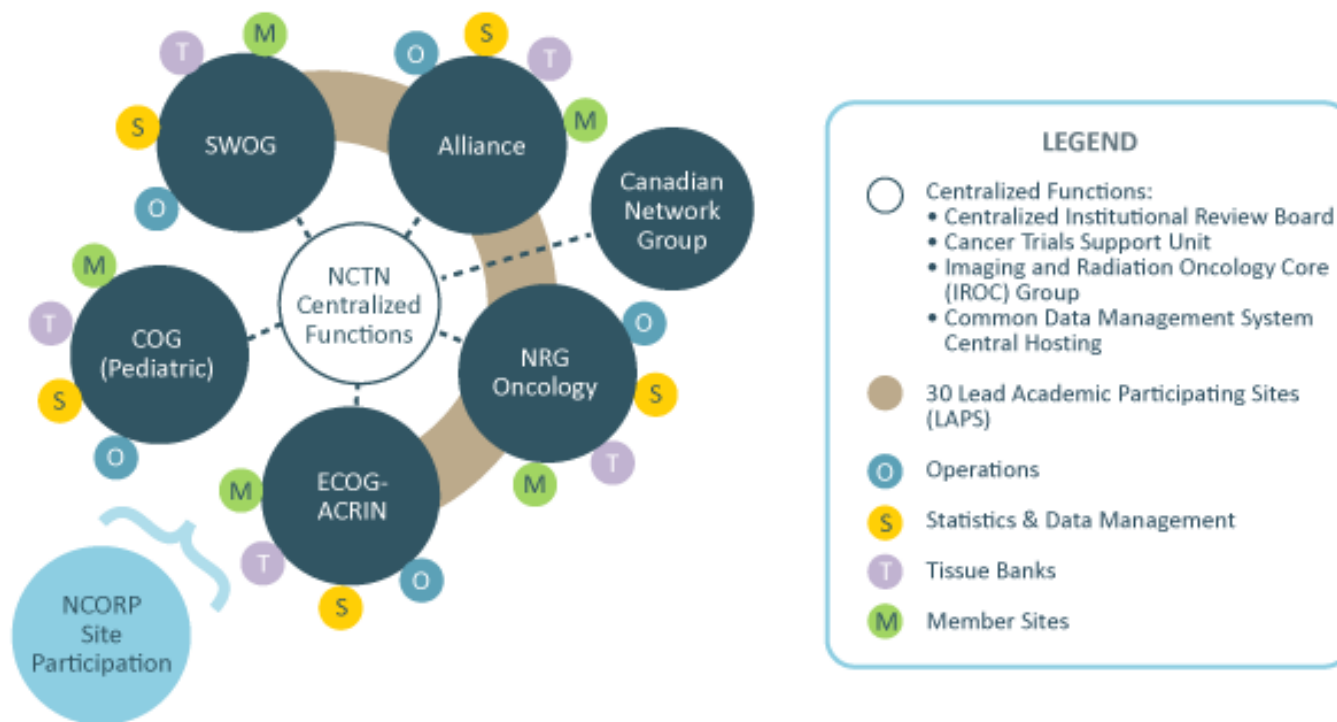
• National Clinical Trials Network (NCTN) – cooperative groups

- Studies randomized phase 2 or 3 clinical trials with clinical endpoints

- The Experimental Therapeutics Clinical Trials Network (ETCTN) was created to evaluate therapies using a coordinated, collaborative, and inclusive team-based approach to early phase experimental therapeutic clinical trials.



NCI National Clinical Trials Network Structure



- **Phase 1 and 2 LOIs:** Time from Letter of Intent (LOI) receipt (for unsolicited LOIs) or due date of project team solicitation LOIs to opening trial to enrollment:
 - Target timeline: **210 days**
 - Absolute deadline: **300 days**
 - Phase 1 and 2 LOIs include:
 - Unsolicited LOIs — phase 1, 1/2, and 2
 - Project Team solicited LOIs — phase 1, 1/2, and 2, including Cooperative Group mass-solicitation LOIs \geq 100 patients
 - Cooperative Group phase 1, 1/2, 2 LOIs $<$ 100 patients
- **Cooperative Group Phase 1/2 or 2 Concepts \geq 100 patients:** Time from Concept's actual, initial evaluation date by a Steering Committee to opening trial to enrollment:
 - Target timeline: **210 days**
 - Absolute deadline: **300 days**
 - These concepts do not include Cooperative Group phase 1/2 or 2 trials \geq 100 patients that are in response to a LOI mass solicitation.
- **Phase 3 Concepts:** Time Concept's actual, initial evaluation date by Steering Committee to opening trial to enrollment:
 - Target timeline: **300 days**
 - Absolute deadline: **540 days**

Career Development Letters of Intent (LOIs)

Cancer Therapy Evaluation Program (CTEP)

- Career Development LOIs facilitate early career investigator's mentorship toward a long-term translational cancer research career:
 - Provides opportunities to be recruited to a CTEP project team;
 - Provides feedback for the successful development of a competitive CTEP LOI;
 - Promotes professional mentorship and institutional support for career development.
- Overarching goal is to provide early career investigators *a competitive advantage* within the CTEP Project Team process:
 - Enables leadership skill development as principal investigator of prestigious CTEP clinical trial;
 - Develops team building skills and scientific knowledge base to utilize broad scientific resources;
 - Identifies senior faculty mentor;
 - Recognizes disease interest of young investigator;
 - Incentivizes home institution to commit nursing, data management, patient access to the young investigator.

- Early career investigator should be within seven (7) years of final oncology training period.
- Early career investigator should have an interest in clinical research and the intention to develop an oncology-based career.
- Early career investigator's home institution should have a track record of conducting clinical trials with investigational agents or experimental therapeutics.
- Early career investigator should submit a CTEP LOI that meets its evaluation criteria utilizing a CTEP-held investigational new drug (IND) application agent (https://ctep.cancer.gov/industryCollaborations2/agreements_agents.htm).
- Early career investigator should acquire an institutional letter of support pledging trial logistics and resources.
- Early career investigator should identify a senior mentor:
 - that is a faculty member at the home institution;
 - that confirms the feasibility of the trial in the LOI; and
 - that makes every reasonable effort to enable the young investigator able to conduct the proposed clinical trial successfully.

Visiting Physician Externship

Cancer Therapy Evaluation Program (CTEP)

- The Cancer Therapy Evaluation Program (CTEP) welcomes oncology fellows, senior radiation oncology residents, and junior faculty to become involved in its day-to-day operations:
 - Schedule up to a 4-week experience at CTEP;
 - Work in close collaboration with CTEP Medical Officers;
 - Review comprehensive trial designs, trial implementation, and trial monitoring;
 - Provide review of incoming letters of intent (LOIs) for phase 0, 1, or 2 trials, or concepts for randomized phase 2 or 3 trials;
 - Present reviews for internal CTEP meetings for the evaluation of new agents or biomarkers to learn how CTEP prioritization is undertaken;
 - Learn important insights for the preparation of successful LOIs and the conduct of clinical trials.
- Those who are interested in learning more about the externship may contact Charles Kunos, MD, PhD in the CTEP Investigational Drug Branch (charles.kunos@nih.gov).



**NATIONAL
CANCER
INSTITUTE**

www.cancer.gov

www.cancer.gov/espanol