Potential Applicant Webinar: Cancer Prevention Clinical Trials Network (CP-CTNet): CP-CTNet Sites

RFA-CA-18-029

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Using WebEx and Webinar Logistics

- Submit questions at any time by typing into the Q&A feature on the right of the WebEx interface.
  - Select Host and a moderator will ask the questions on your behalf
- Closed captioning available by selecting the Media Viewer Panel
- This webinar is being recorded
- Questions following the webinar can be directed to CPCTNet@mail.nih.gov
Outline

- Background and Overview of RFA
- Question and Answer Session
  - *Questions about applicant’s Specific Aims or individual grant applications will not be addressed*
Critical Components of Systematic Preventive Agent Development

Preclinical/tox

Early phase trials

Phase III
Division of Cancer Prevention (DCP)
Drug Development Programs

- Biologic Rationale/Molecular Targets/Preclinical Efficacy
- Safety/Preliminary Efficacy
  - Phase 0/I/II Trials
- Phase III Trials

Preclinical Program (PREVENT)
Clinical Program (focus of this RFA)
NCORP
EDRN
Cancer Prevention Clinical Trials Network
CP-CTNet Program Objectives

• To qualify cancer preventive agents for further clinical development via the conduct of phase 0, I, & II clinical trials assessing preliminary efficacy and safety

• Additional goals:
  – Optimize clinical trial designs
  – Develop surrogate and intermediate endpoint biomarkers
  – Test novel imaging technologies
  – Develop further insights into mechanisms of cancer prevention by agents

Current Program
• 5 contractors
• >100 member sites

To be replaced by:
• 5 UG1-funded CP-CTNet Sites (Lead Academic Organizations and Affiliated Organizations)
• U24-funded Data Management, Auditing, and Coordinating Center
Types of Studies

- Phase 0 micro-dosing, biomarker modulation trials
- Phase I pharmacokinetic, safety trials
- Phase II preliminary efficacy trials (often placebo-controlled)
  - Premalignancy endpoint trials - require screening/biopsy to identify individuals with lesions
  - Molecular endpoint trials
  - Presurgical (window-of-opportunity) trials
Areas of Emphasis for Clinical Trials Program

• New scientific areas
  – Immunoprevention

• Strategies to Optimize Risk/Benefit
  – Regional drug delivery (topical-topical breast; inhaled-lung)
  – Alternative dosing schedules (e.g., intermittent)
  – Combinations

• Repurposing old drugs for prevention
  – Emphasis on drugs affecting multiple chronic diseases (e.g., ASA, NSAIDs, metformin)

Note: these areas of interest should not be viewed as limiting to any proposed applications
RFA Purpose: New Network Structure (Cooperative Agreement)

**DCP**
- study ideas, LOI/protocol/document review, IND sponsor, drug distribution, oversight and compliance

**Lead Academic Organizations (UG1, 5 anticipated grants)**
- study ideas/development/conduct, statistics, enrollment, fiscal management

**Coordinating Center (U24)**
- (1 Grant)
- data management, auditing, clinical operations

**Network Members**
- (Affiliated Organizations, AOs)
- study ideas/development/conduct, participant enrollment, data entry

**Key Program Changes**
- Funding – grant mechanism (UG1, U24)
- Centralized coordination
- One data management system
- Restricted funds for inter-consortia & high priority new studies
CP-CTNet Sites (UG1)

• Role: design, perform, and report the results of early phase (phase 0-II) cancer prevention clinical trials
  – LAO will serve as the main infrastructure to support performance of clinical trials
    • Constitute a network of AOs to perform trials
    • Provide administrative support and oversight to trial performance by AOs
    • Also perform clinical trials at own (LAO) institution
  – Clinical trial ideas and trial performance can occur at LAO, AO(s), and any combination thereof
  – LAOs and AOs may participate in trial arising at their CP-CTNet site as well as other CP-CTNet sites

• DMACC will house database of record, audit sites, and provide coordination across CP-CTNet sites
CP-CTNet Sites

**Requirements**

- Develop 1-3 new clinical trials per year
- Enroll minimum of 10-40 participants per year (10 year 1, 40/yr in years 2-5)
- Evaluate translational endpoints in biospecimens obtained from participants
- Collect, process, store biospecimens
- Evaluate novel technologies (e.g., imaging, blood based, etc.) for assessing the effects of interventions, as appropriate
Agents to be studied

- Agents to be developed will be announced twice yearly via NCI solicitations for Letters of Intent (LOIs)
  - NCI will review and approve selected LOIs for further development
- Agents may be developed by individual CP-CTNet Sites or jointly by more than one Site
- Sites are expected to propose unsolicited LOIs using agents or interventions available to their investigators
- RFA requests 2 sample LOIs using 2 different agents in 2 different target organs. These LOIs are meant to illustrate the Site’s approach and capabilities. They may or may not be approved for full protocol development.

- “Agent” means an “intervention”, including a drug, vaccine, other immune intervention, ablative modality (e.g., surgery, laser or light ablation, etc.), etc.
Trans-Network Activities

All CT-CTNet Sites will be expected to work jointly toward CP-CTNet network goals by:

• Interacting with the DMACC
• Participating in trans-network clinical trials and high priority ancillary studies

Steering Committee:

Representatives of CP-CTNet awardees (UG1 and U24), with NCI participation, will be expected to form a Steering Committee as a self-governing body for the Network
Additional NCI Support (beyond scope of the two CP-CTNet FOAs)

- Regulatory support (inc. IND applications and FDA reporting)
- Agent acquisition, packaging, distribution
- Central Institutional Review Board (CIRB) Review
- Protocol receipt, review, and approval process and study document submissions and management (DCP Protocol Information Office)
Award Mechanism: UG1- Clinical Research
Cooperative Agreement-Single Project (Clinical Trial Required)

- **Clinical research** is defined by NIH and, in brief, involves direct interaction with human subjects to study mechanisms of human disease, therapeutic interventions, clinical trials, or development of new technologies ([https://grants.nih.gov/policy/clinical-trials/glossary-ct.htm#ClinicalResearch](https://grants.nih.gov/policy/clinical-trials/glossary-ct.htm#ClinicalResearch))

- **Cooperative agreement** means that, after award, NCI scientific or program staff will assist, guide, coordinate, or participate in project activities

- **Single project** refers to all CP-CTNet activities

- **Clinical Trial Required** indicates these grants include the conduct of studies that meet the NIH clinical trials definition
Reminders

- Application budgets are limited ($625,000 direct costs year 1; $1,250,000 direct costs years 2-5)
- Request a 5-year project period
- Letter of Intent is requested but not required
- Applicants must follow instructions
- Note: PD/PIs on this application must not be named Senior/Key Personnel or Other Significant Contributors on applications to companion FOA, RFA-CA-030
Timeline for CP-CTNet Applications

- RFA Released: Sept. 14, 2018
- Letters of Intent Due (not required): Oct. 15, 2018
- Applications Due: Nov. 15, 2018
- Scientific Merit Review: Feb.-March 2019
- Awards Made: August 2019

Anticipated Period of Performance: August 1, 2019-July 31, 2024
Additional Resources

- NIH Grants and Funding
  http://grants.nih.gov/grants

- SF424 Instructions

- CP-CTNet site for potential applicants
  Note: recorded CP-CTNet RFA webinars and Frequently Asked Questions (FAQs) will be posted on this site in the near future and the FAQs will be updated as new questions are received

- CP-CTNet Program Staff email
  CPCTNet@mail.nih.gov
Question and Answer Session

Submit questions by typing into the Q&A feature on the right of the WebEx interface

CP-CTNet Sites (RFA-CA-18-029)