Potential Applicant Webinar:
Cancer Prevention Clinical Trials Network (CP-CTNet): CP-CTNet Sites
RFA-CA-18-029

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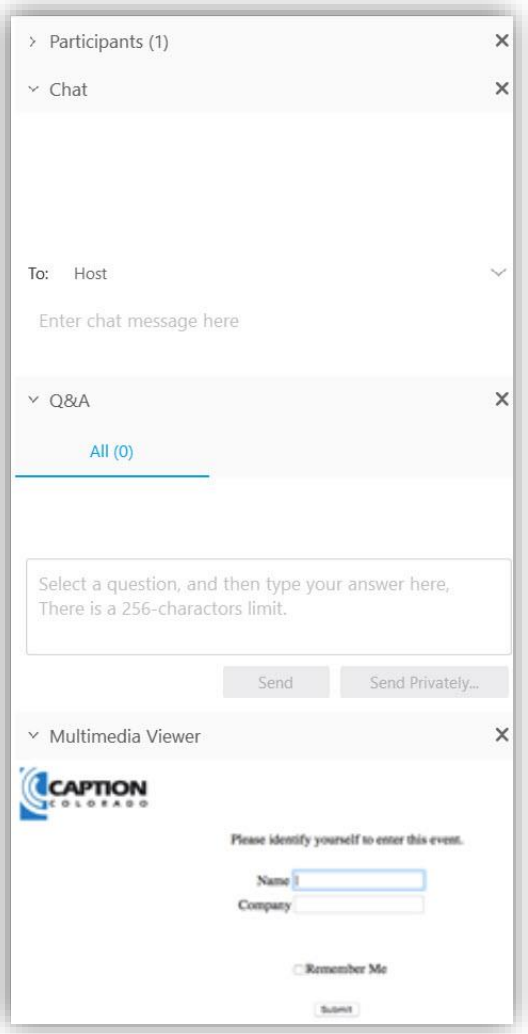
NIH NATIONAL CANCER INSTITUTE

Information Webinar
Oct. 2, 2018

Using WebEx and Webinar Logistics

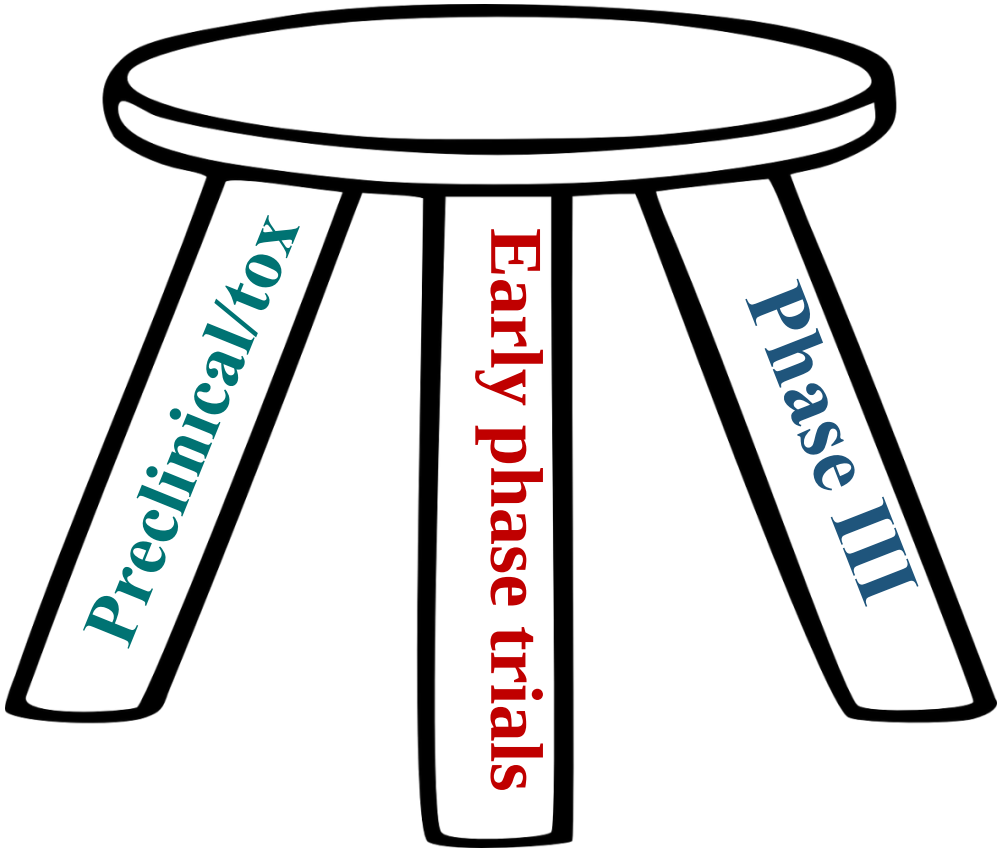


- Submit questions at any time by typing into the Q&A feature on the right of the WebEx interface.
  - Select Host and a moderator will ask the questions on your behalf
- Closed captioning available by selecting the Media Viewer Panel
- This webinar is being recorded
- Questions following the webinar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

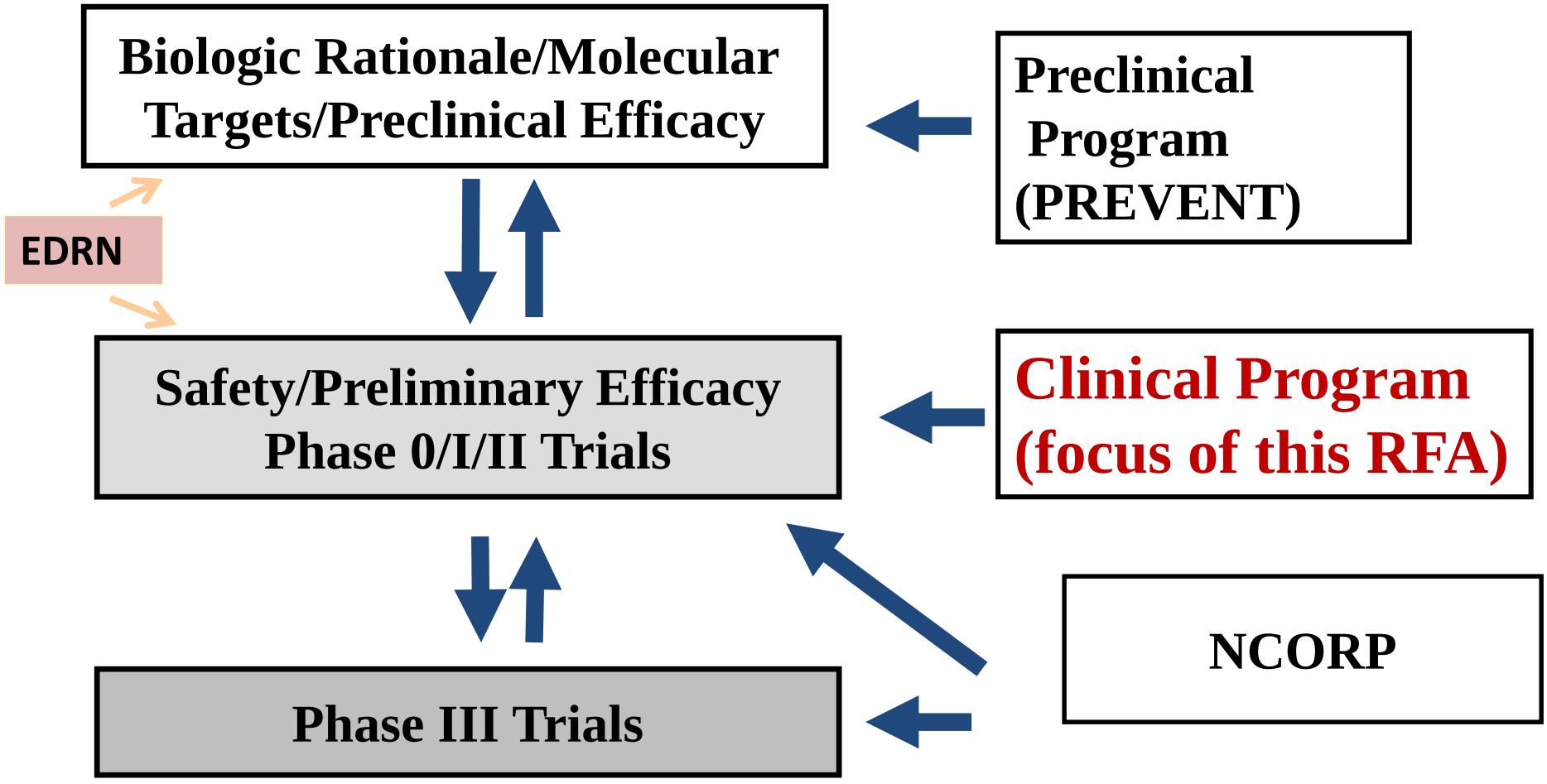
Outline

- **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



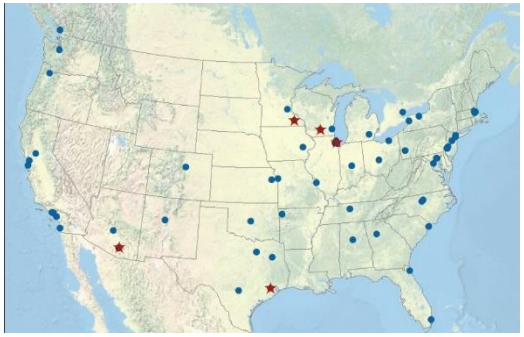
Division of Cancer Prevention (DCP) Drug Development Programs



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

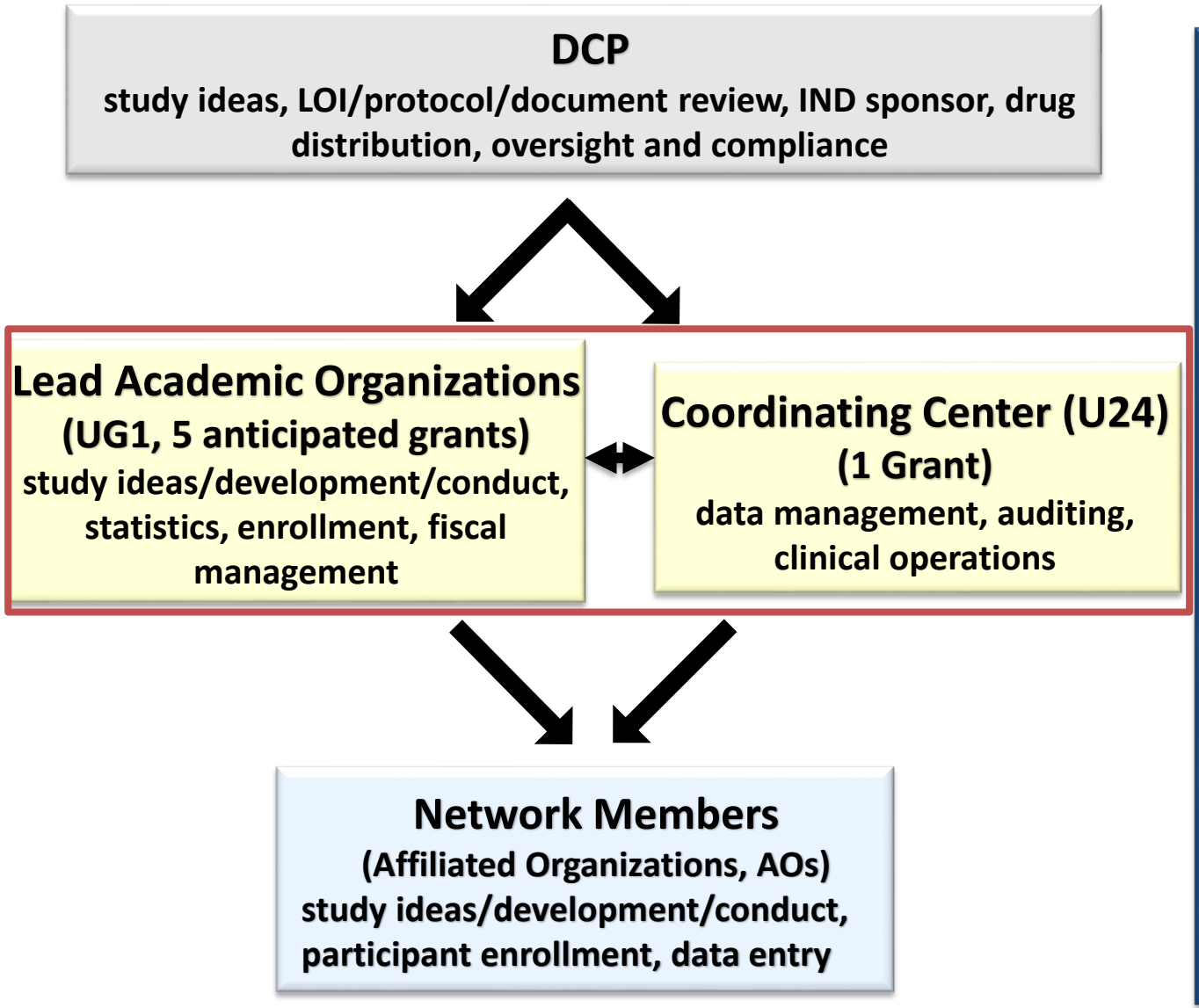
- **Phase 0 micro-dosing, biomarker modulation trials**
- **Phase I pharmacokinetic, safety trials**
- **Phase II preliminary efficacy trials (often placebo-controlled)**
  - **Premalignancy endpoint trials - require screening/biopsy to identify individuals with lesions**
  - **Molecular endpoint trials**
  - **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)



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**

CP-CTNet Sites

- **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)
- **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**
  - **SF424(R&R) Application Guide (https://grants.nih.gov/grants/how-to-apply-application-guide.html)**
  - **RFA-CA-18-029 (https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-18-029.html)**
- **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**

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/research-forms-e.pdf

- **CP-CTNet site for potential applicants**

https://prevention.cancer.gov/major-programs/cancer-prevention-clinical-trials-network-cp-ctnet

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)

U.S. Department of Health and Human Services

National Institutes of Health | National Cancer Institute

https://prevention.cancer.gov/major-programs/cancer-prevention-clinical-trials-network-cp-ctnet

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