# Potential Applicant Webinar:
# **Cancer Prevention Clinical Trials Network (CP-CTNet): CP-CTNet DMACC**

*RFA-CA-18-030*

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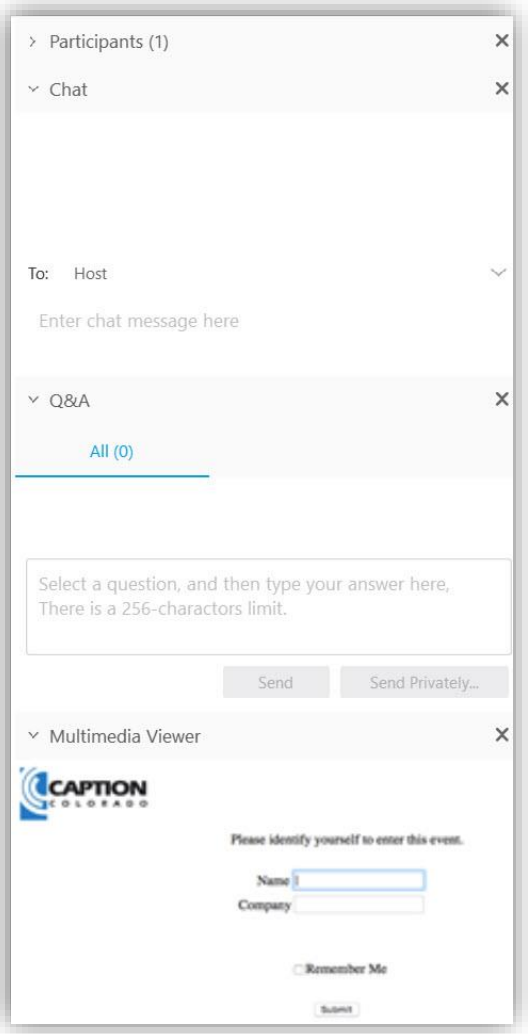
NIH NATIONAL CANCER INSTITUTE

**Information Webinar**
**Oct. 2, 2018**

# Using WebEx and Webinar Logistics

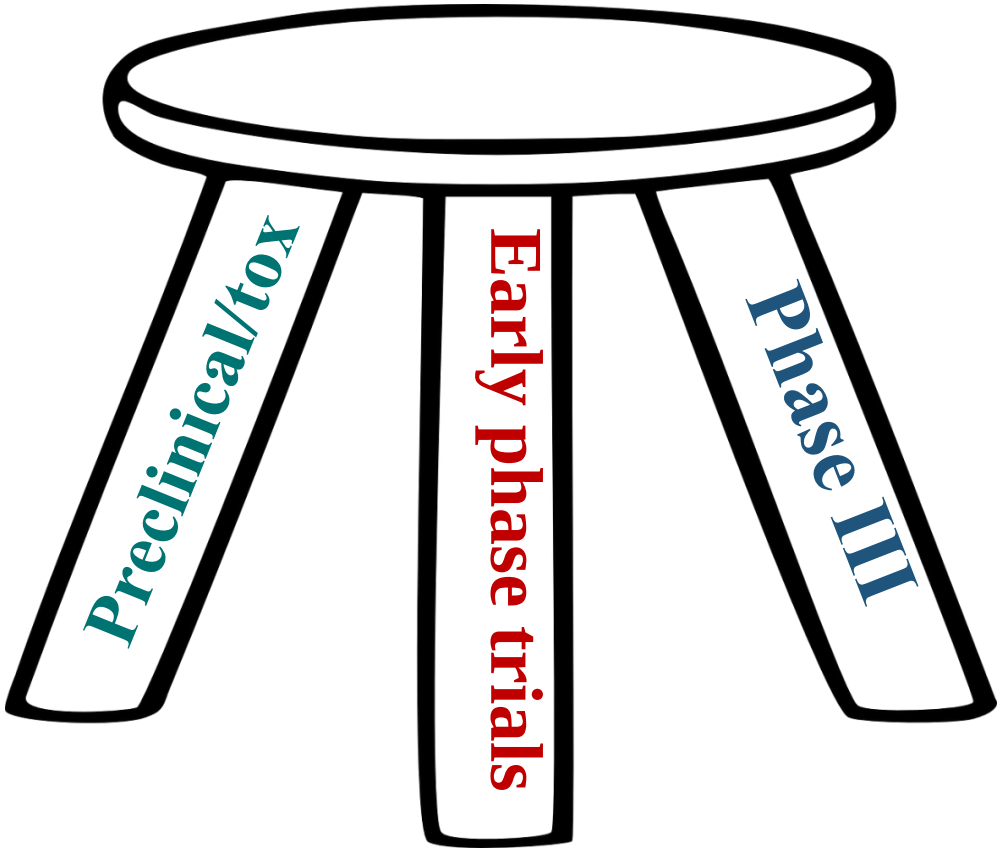



- Submit questions at any time by typing into the Q&A feature on the right of the WebEx interface.
  - Select Host and a moderator will ask the questions on your behalf
- Closed captioning available by selecting the Media Viewer Panel
- This webinar is being recorded
- Questions following the webinar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

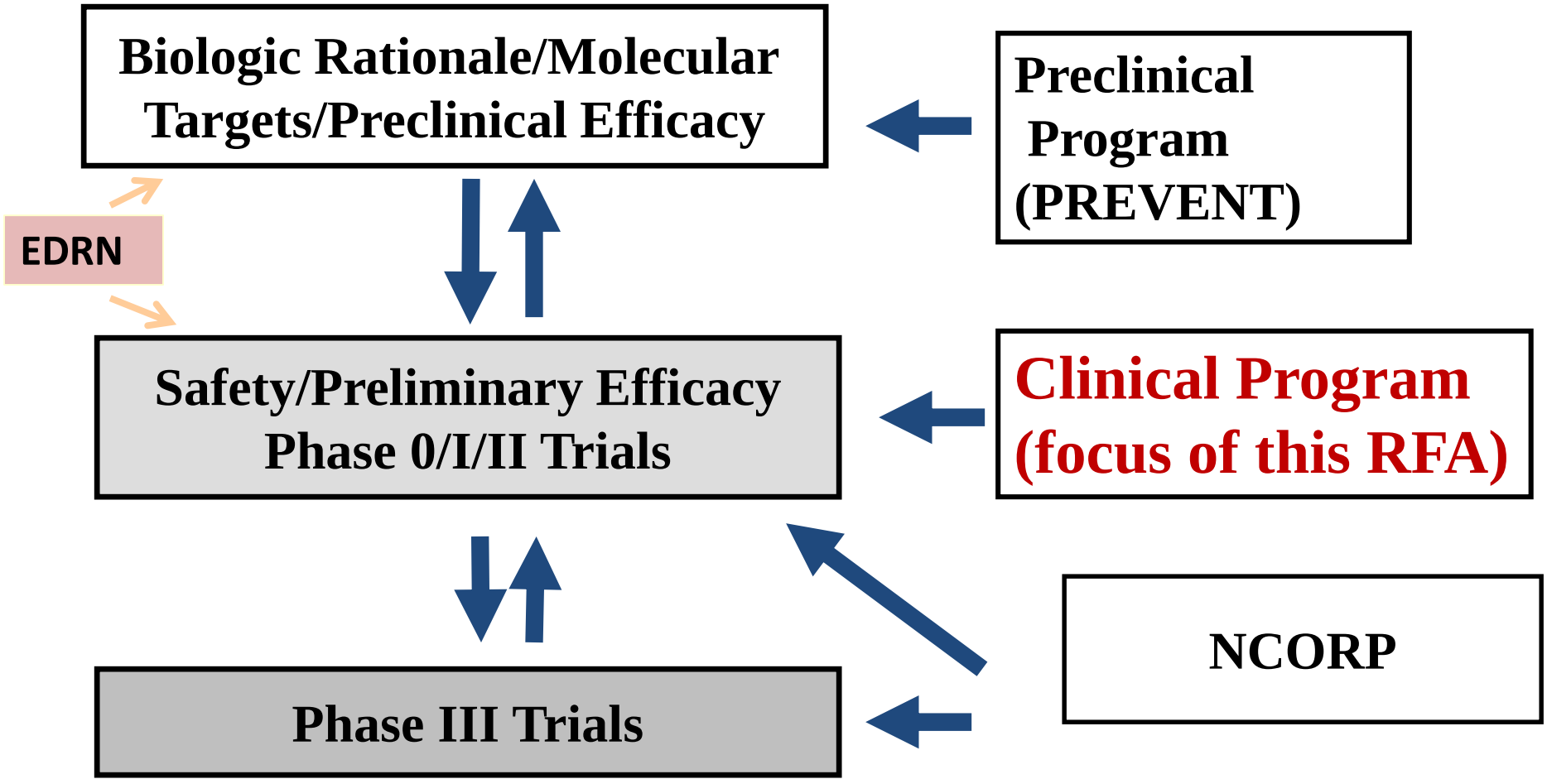
# Outline

- **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



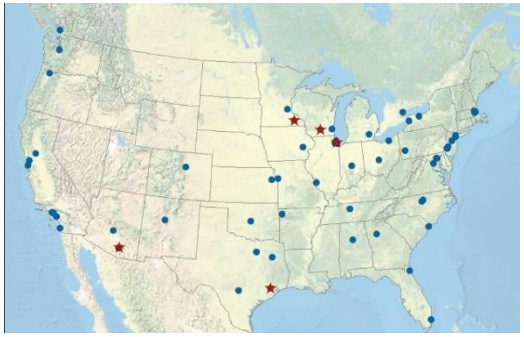
# Division of Cancer Prevention (DCP) Drug Development Programs



# 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

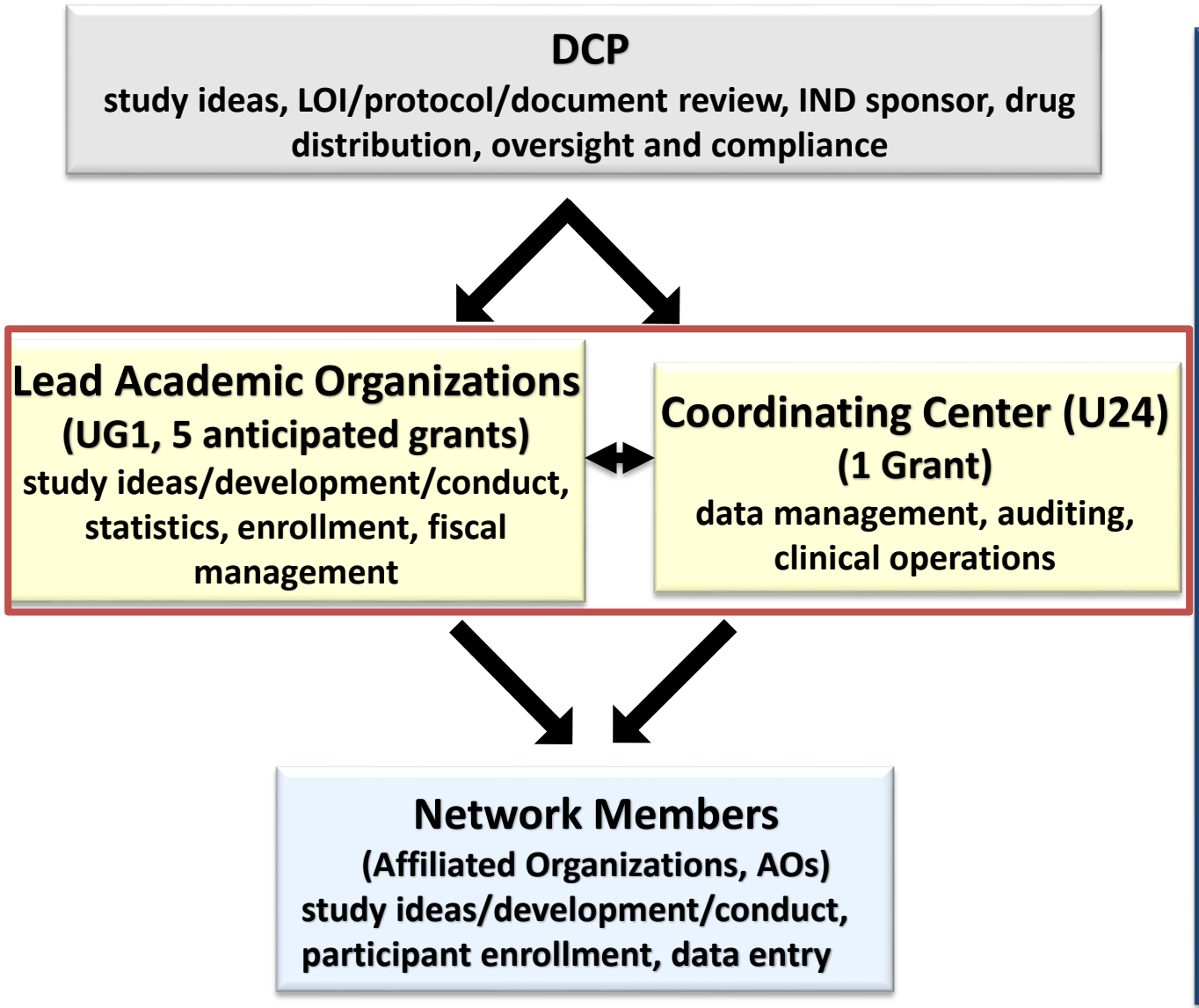
- **Phase 0 micro-dosing, biomarker modulation trials**
- **Phase I pharmacokinetic, safety trials**
- **Phase II preliminary efficacy trials (often placebo-controlled)**
  - **Premalignancy endpoint trials - require screening/biopsy to identify individuals with lesions**
  - **Molecular endpoint trials**
  - **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 Data Management, Auditing, and Coordinating Center (DMACC, U24)

- **Role is to support the CP-CTNet Sites and coordinate trans-Network activities via:**
  - **Centralized data management and data reporting**
  - **Clinical trial auditing**
  - **Administrative and logistical coordination across CP-CTNet**
- **DMACC will provide advisory role in trial development and primary statistical role in cross-network clinical trials**
- **CP-CTNet Sites will develop and conduct clinical trials**

# CP-CTNet DMACC

- **Requirements**
  - **Provide centralized data management using Medidata Rave® as NCI-designated Clinical Data Management System of record**
  - **Provide data management support for tracking improving participant accrual in CP-CTNet trials**
  - **Develop/maintain virtual biospecimen data inventory system**
  - **Conduct independent auditing of clinical trial data and processes at CP-CTNet Sites**
  - **Administrative and logistical coordination across network**
  - **Support development, presentation, and dissemination of educational materials, etc., for CP-CTNEt recruitment and retention activities**

# Trans-Network Activities

**DMACC will be expected to work jointly toward CP-CTNet network goals by:**

- Interacting with CP-CTNet Sites (LAOs and AOs)
- Providing an advisory role for clinical trial development and primary statistical role for cross-network clinical trials

**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: U24 - Resource-Related Research Project - Cooperative Agreement (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
- **U24 definition:** To support research projects contributing to improvement of the capability of resources to serve biomedical research.
- **Clinical Trial Required** indicates these grants include the conduct of studies that meet the NIH clinical trials definition

# Reminders

- **Application budgets are limited ($1,250,000 direct costs year 1; $1,900,000 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-18-030 (https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-18-030.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-029**

# 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-18-030)**

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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