Potential Applicant Webinar:
Cancer Prevention Clinical Trials Network (CP-CTNet): Data Management, Auditing, and Statistical Center (DMASC)

RFA-CA-24-025

Eva Szabo, MD
Chief, Lung and Upper Aerodigestive Cancer Research Group
Director, Cancer Prevention Clinical Trials Network
Division of Cancer Prevention, National Cancer Institute

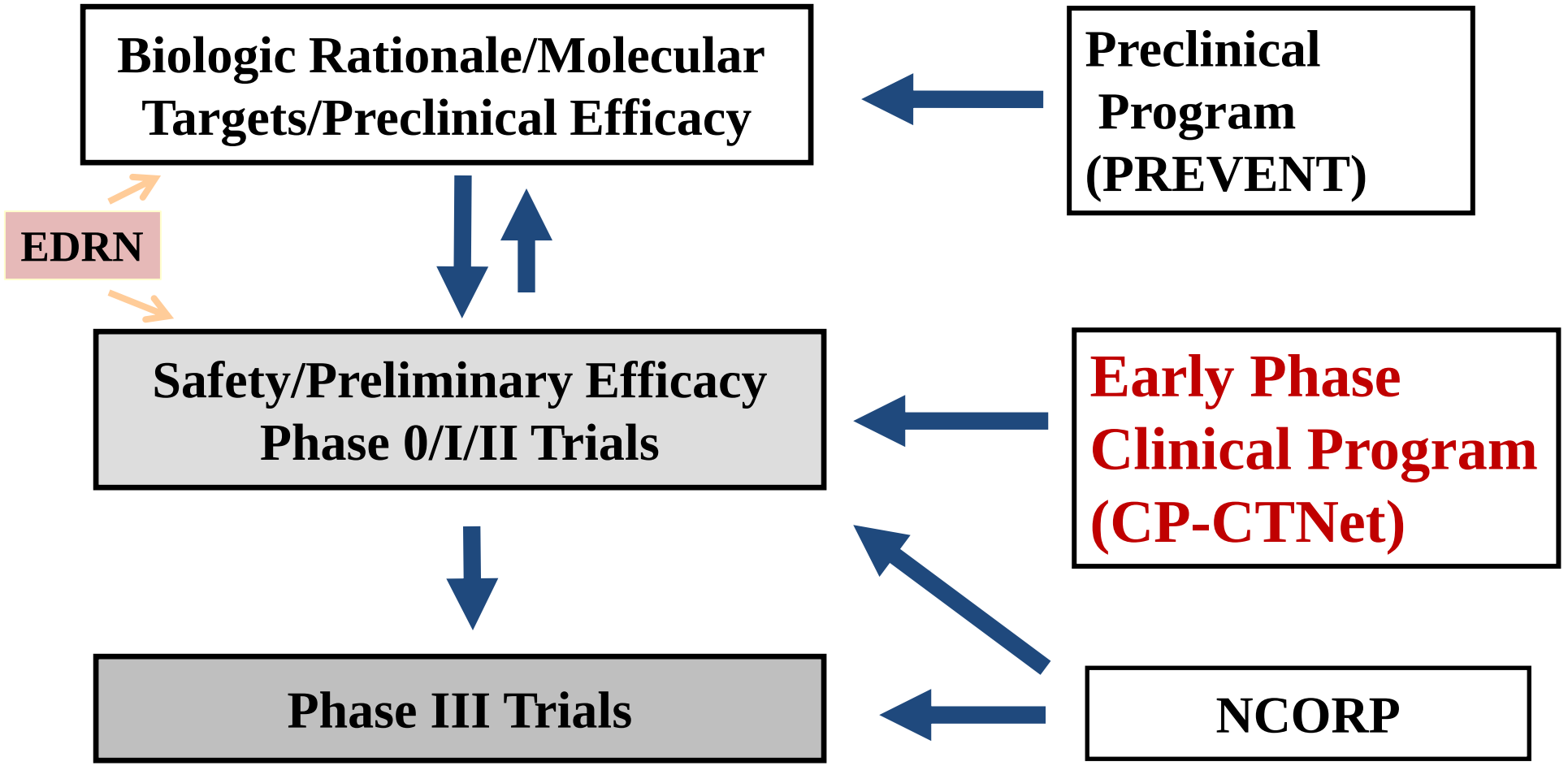
NIH NATIONAL CANCER INSTITUTE

Information Webinar
August 27, 2024

Outline

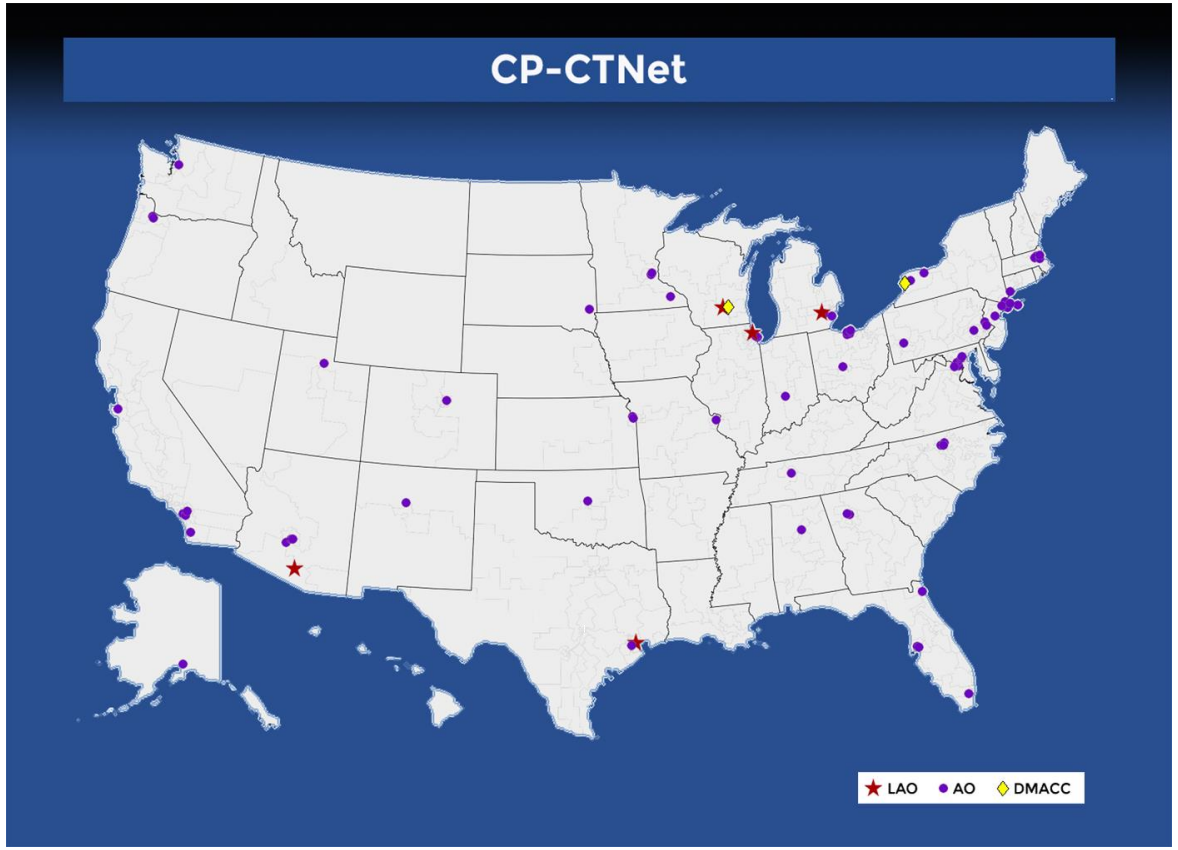
- **Background and Overview of RFA**
- **Question and Answer Session**
  - *Questions about applicant's Specific Aims or individual grant applications will not be addressed*

Early Phase Clinical Trials are a Critical Component of DCP's Drug Development Pipeline



- *Specimen biorepositories*

Cancer Prevention Clinical Trials Network: Objectives



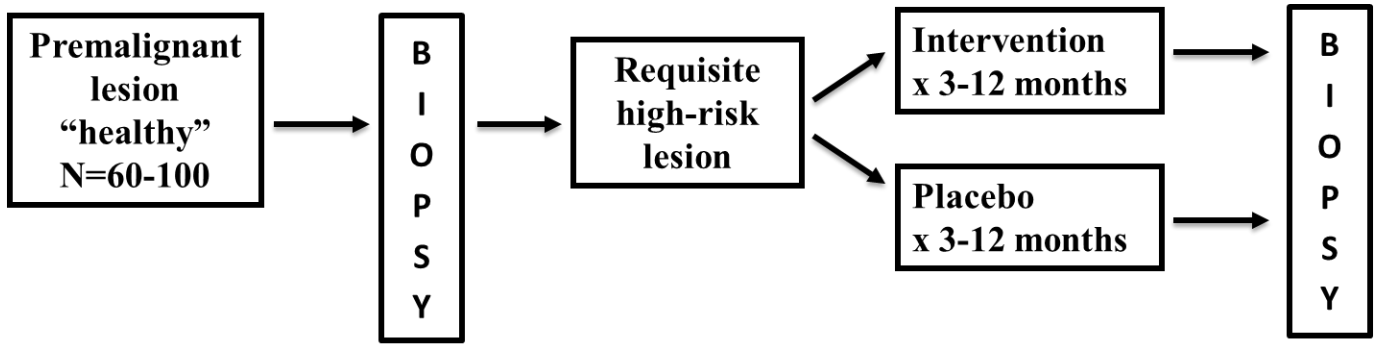
Current Program

- *5 UG1-funded Sites (Lead Academic Organizations and Affiliated Organizations)*
- *U24-funded Data Management, Auditing, and Coordinating Center*

- **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**

Types of Studies

- **Phase 0 microdosing, biomarker modulation trials**
- **Phase I pharmacokinetic, safety trials**
- **Phase II preliminary efficacy trials (usually placebo-controlled)**
  - **Premalignancy endpoint trials - require screening/biopsy to identify individuals with lesions**
  - **Molecular endpoint trials**
  - **Pre-surgical (window-of-opportunity) trials**



1º Endpoint: lesion regression (clinical and histologic)
2º Endpoints: multiple biomarkers (tissue, blood)

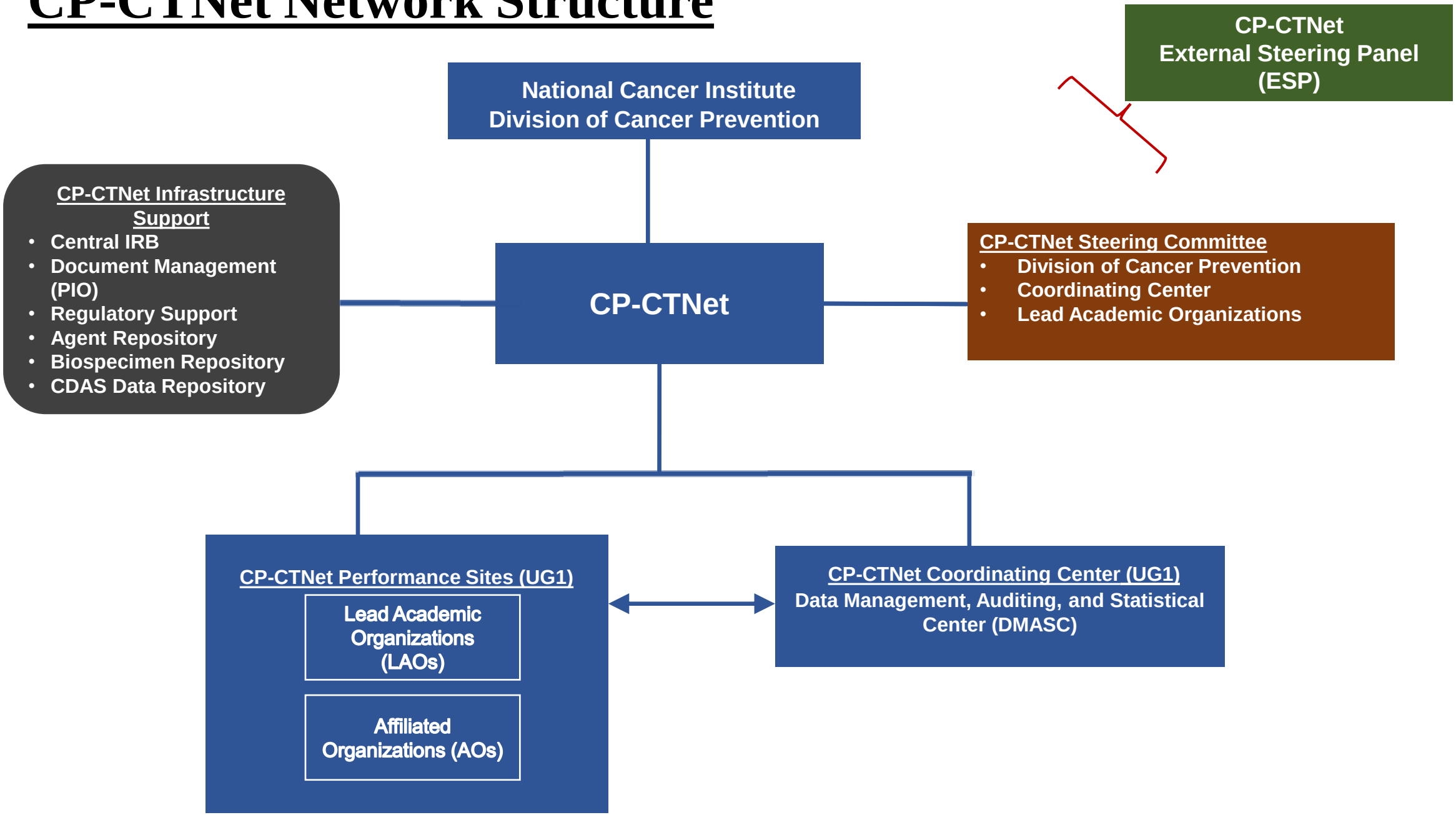
Scientific Areas of Emphasis

Overall Goal: move agents/strategies along the agent development pipeline

- **Targeting the biology of carcinogenesis**
  - **e.g., Immunoprevention**
  - **Focus on (but not limited to) high-risk populations**
- **Strategies to optimize risk/benefit**
  - **Regional drug delivery (e.g., topical-breast; inhaled-lung)**
  - **Alternative dosing schedules (e.g., intermittent)**
  - **Combinations**
- **Re-purposing '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

CP-CTNet Network Structure



CP-CTNet Data Management, Auditing, and Statistical Center (DMASC, UG1)

- **Role: collaborate with and support the CP-CTNet Sites, coordinate cross-Network activities via:**
  - **Centralized data management and data reporting**
  - **Clinical trial auditing**
  - **Statistical support for cross-network trials**
  - **Administrative and logistical coordination across CP-CTNet**
- **DMASC statisticians will be primary for cross network trials and will provide advisory role in trial development of other trials**
- **CP-CTNet Sites will develop and conduct clinical trials**

CP-CTNet DMASC

- **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**
  - **Provide statistical support (clinical trials methodology and biostatistical expertise)**
  - **Conduct independent auditing of clinical trial data and processes at CP-CTNet Sites**
  - **Administrative and logistical coordination across network**
  - **Develop/maintain virtual biospecimen data inventory system**
  - **Support development, presentation, and dissemination of educational materials, etc., for CP-CTNet recruitment and retention activities**

CP-CTNet Sites

- **Agents to be studied**
  - **Agents to be developed will be announced quarterly via NCI solicitations for concept proposals**
    - NCI will review and approve selected concept for further development
  - **Agents may be developed by individual CP-CTNet Sites or jointly by more than one Site (cross-network studies)**
  - **Sites are expected to propose unsolicited concepts using agents or interventions available to their investigators**
  - **“Agent” means an “intervention”, including a drug, vaccine, other immune intervention, ablative modality (e.g., surgery, laser or light ablation, etc.), etc.**

Cross-Network Activities

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

- **Collaborating with the DMASC**
- **Participating in cross-network clinical trials and high priority ancillary studies**

Steering Committee:

Representatives of CP-CTNet awardees (Sites and DMASC), with NCI participation, will form a Steering Committee as a self-governing body for the Network

Additional NCI Support (beyond scope of the two CP-CTNet NOFOs)

- **Regulatory support (inc. IND applications and FDA reporting)**
- **Agent acquisition, packaging, distribution (DCP Drug Repository)**
- **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 to $2,000,000 direct costs per year**
- **Request a 6-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-24-025 (https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-24-025.html)**
- **Multi-PI applications are allowed/encouraged. The 2nd individual designated as MPI may have a primary affiliation at a different US institution**
- **Applicant organizations may only submit one application per institution (this was incorrect in the RFA)**
- **Note: PD/PIs on this application must not be named Senior/Key Personnel or Other Significant Contributors on applications to companion NOFO, RFA-CA-24-024**

Timeline for CP-CTNet Applications

- **RFA Released** **August 12, 2024**
- **Letters of Intent Due (not required):** **October 1, 2024**
- **Applications Due:** **October 31, 2024**
- **Scientific Merit Review:** **February- March 2025**
- **Awards Made:** **July-August 2025**

Anticipated Period of Performance: **August 1, 2025 - July 31, 2031**

Additional Resources

- **NIH Grants and Funding**

https://grants.nih.gov/

- **SF424 Instructions**

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

- **CP-CTNet DCP website for potential applicants**

https://prevention.cancer.gov/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**

CP-CTNet@mail.nih.gov

Question and Answer Session

Submit questions by typing into the Chat function on the bottom of the Zoom interface

Submit question after the webinar to CP-CTNet@mail.nih.gov, all responses will be posted on DCP CP-CTNet website at https://prevention.cancer.gov/cp-ctnet