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

RFA-CA-24-024

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NIH NATIONAL CANCER INSTITUTE

Information Webinar
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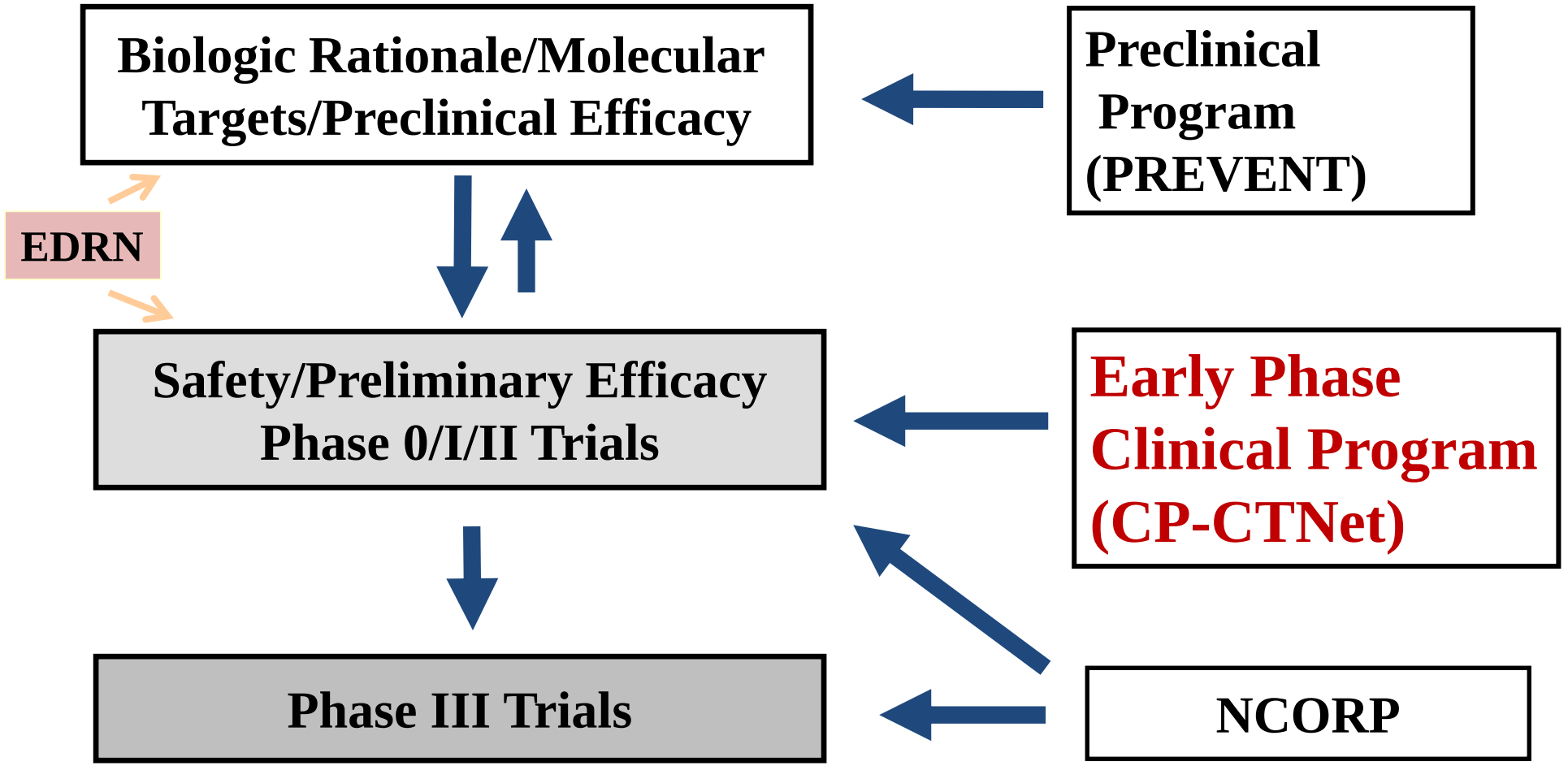
Outline

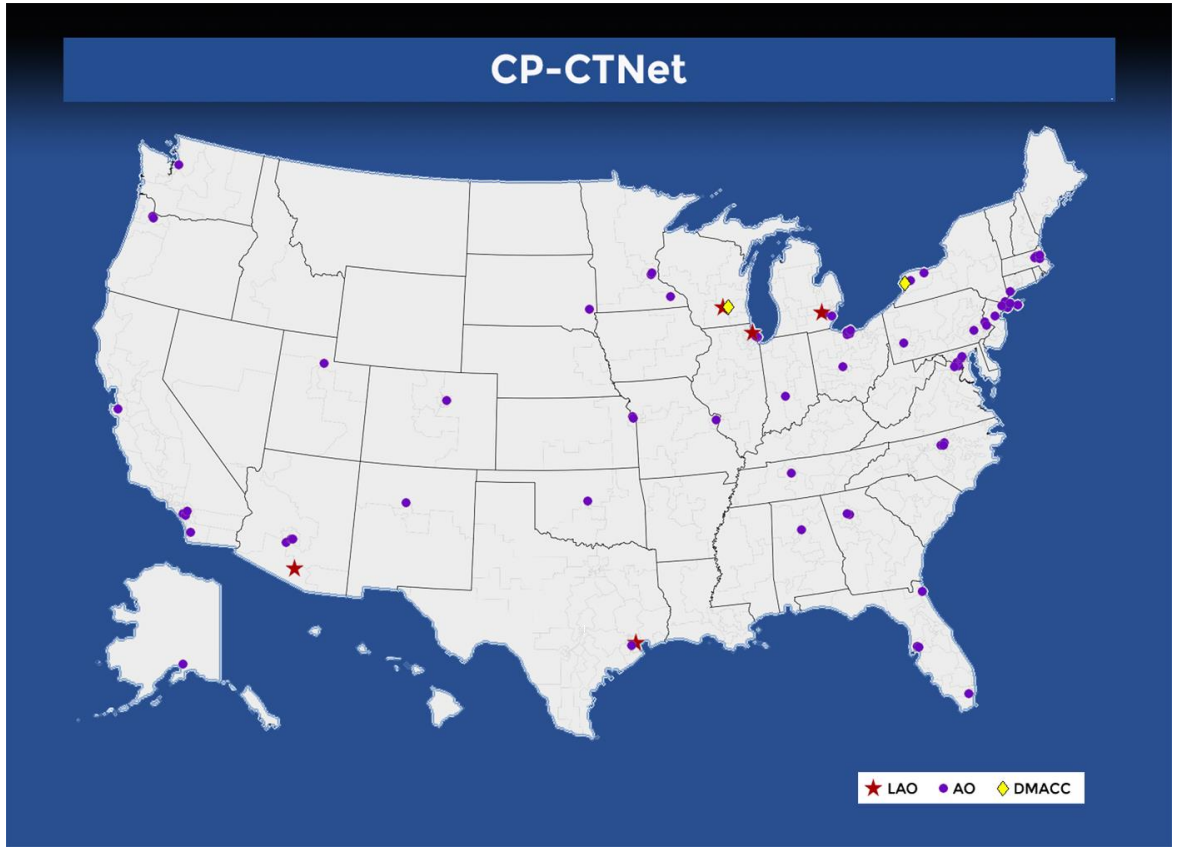
- **Background and Overview of RFA**
- **Question and Answer Session**
  - *Questions about applicant's Specific Aims or individual grant applications will not be addressed*

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



- *Specimen biorepositories*

Cancer Prevention Clinical Trials Network: Objectives



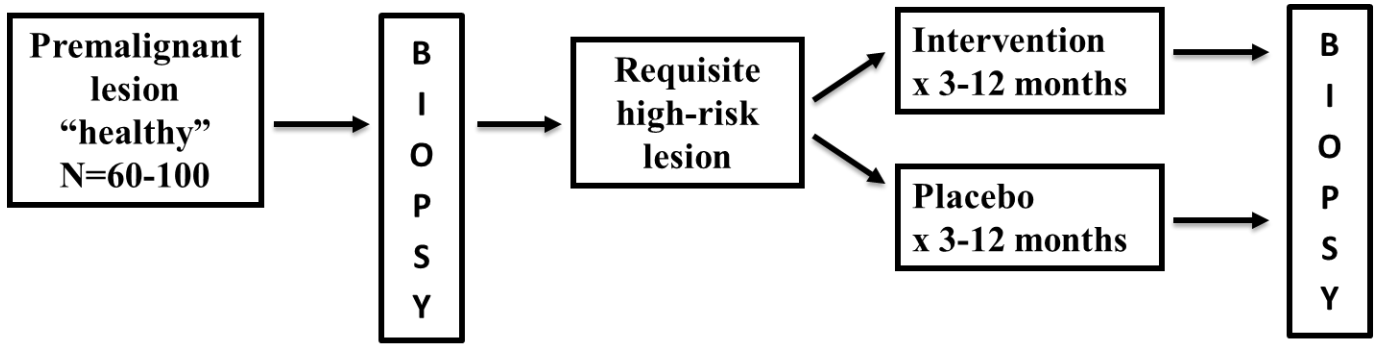
Current Program

- *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**
  - **Presurgical (window-of-opportunity) trials**



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

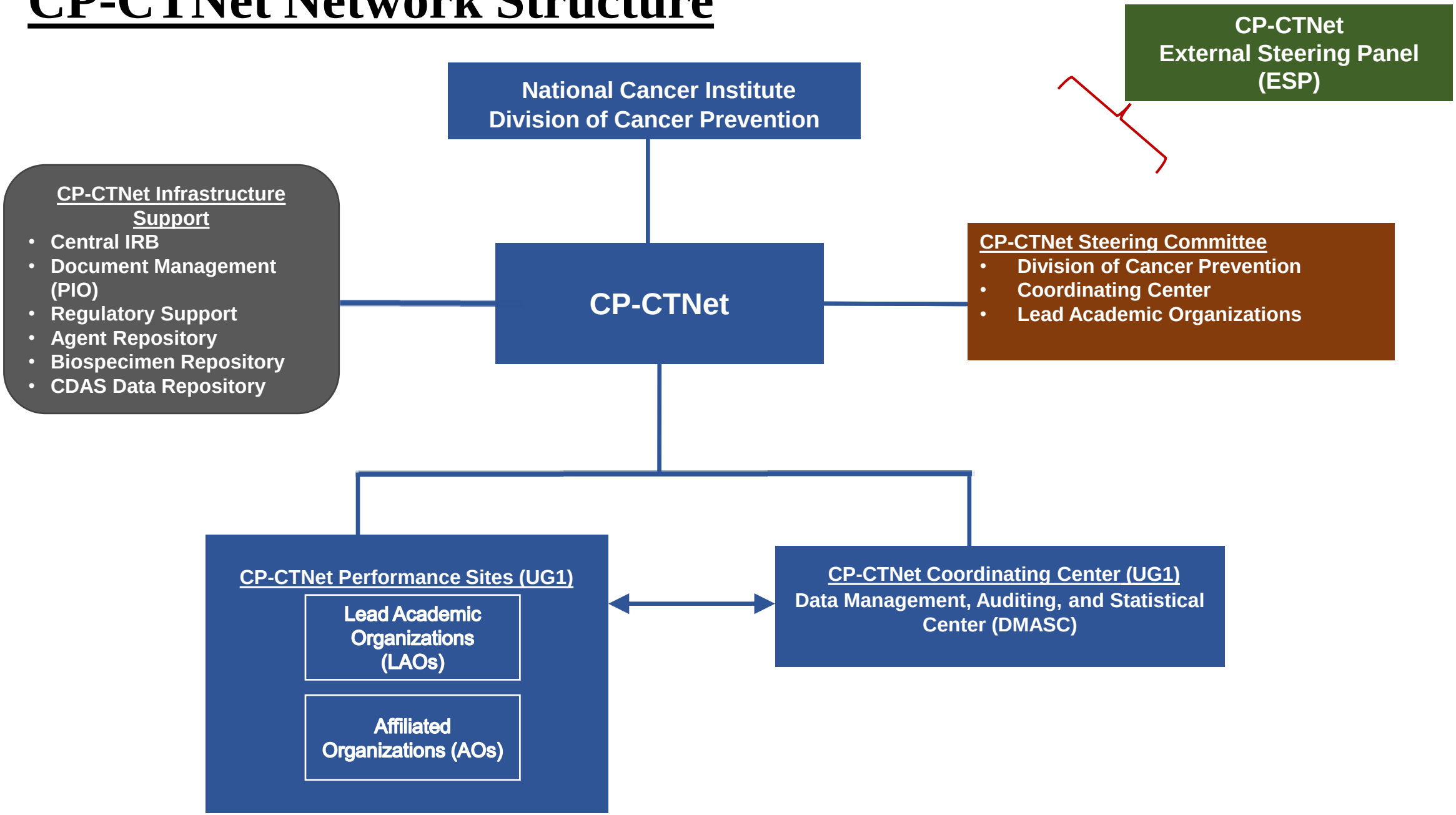
Scientific Areas of Emphasis

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 Sites

- **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**
- **DMASC 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**
  - **Focus on at least 3 different target organs (one must be breast/colon/prostate/lung, one must be from any other organ)**
- **Enroll minimum of 10-40 participants per year**
  - **New sites: 10 participants starting with yr 2, then 40 participants/yr**
  - **Returning sites: 40 participants/yr starting with yr 1**
- **Evaluate biomarker 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**
- ***Emphasis on young investigators (including mentoring plan)***
  - **$125K/yr restricted funds for professional development of young/emerging investigators (faculty, fellows, post-docs)- $25K/person/yr ($ administered by DMASC)**
- ***Patient advocate or community engagement board for each LAO to bring in patient perspective, with allotted funding***
- ***Quality of Life – e.g., PROs; impact of high-risk status on QOL , inc. within context of interventions***

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**
  - **RFA requests 2 sample concepts using 2 different agents in 2 different target organs. These concepts 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.**

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)**
- **Data and specimen access to the research community after study end via the Cancer Data Access System (CDAS)**

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 $1,375,000 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-24-024 (https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-24-024.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-24-025**

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**

*** this was stated incorrectly in the RFA**

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

Questions Already Received

1) **How do we address protocol chair (PI) and lead site coordinator (LSC) salaries for studies that will be designed in the future? Do we need to set up subawards?**

A: Salaries need to be estimated in view of requirement of 1-3 new studies per year for 6 yrs. The 2 submitted concept may not be approved. Subawards will be set up in the future. Individual PIs and LSCs will not be named, but their roles and salaries should be submitted under "Other Personnel". Subawards will be negotiated post award after studies are approved.

2) **Elaborate on what goes into the Clinical Trial Program vs. Site Accrual Program and how to assign direct costs to each.**

A: The Clinical Trial Program encompasses the leadership and infrastructure that supports the clinical trials (such as, but not limited to, LAO salaries, consumables, shipping, operational efficiencies supporting study accrual/recruitment/retention and community engagement activities, trial activation, etc.). The Site Accrual Program encompasses the actual accrual and study conduct (such as, but not limited to, accrual and patient care costs not covered by insurance, obtaining biospecimens, etc.).

3) **Do existing clinical trials rolled over into renewal need to be updated in clinicaltrials.gov?**

A: Existing trials should be updated using the Human Subjects and Clinical Trial Information form in the application and related study records should be included via the Human Subject System (HSS) (completed via ASSIST), without making any changes at this time to the current clinicaltrials.gov record.

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