Concept Preparation for the ClinCap Consortium (version Jan 20, 2022)

Formulation of the concept

- ✓ Discussion of ideas for cancer prevention clinical trials starts with the Organ Group Leaders. ClinCaP primary focus is Phase 1 and 2 trials.
- ✓ Organ Group Leaders will vet trial ideas at ClinCaP Operations Committee meetings and determine whether a 2-page pre-concept summary should be submitted for review. The Operations Committee will make the decision as to whether the concept should proceed based on scientific "fit", competing trials and budget.
- ✓ The Organ Group Leaders participate in the ClinCaP Operations Committee and can facilitate the identification and collaboration of Affiliate Organization (AO) sites for the trial
- ✓ The study design must involve collaboration with a statistician. Regardless of whether the trial PI has their own statistical collaborator, the ClinCap statistician, Dr. Ananda Sen must be consulted early on in concept preparation. Dr. Sen is well aware of DCP requirements for study design, including criteria for the selection of primary, secondary and exploratory endpoints. The interaction with the statistician is iterative until a final, optimized design is achieved.

What is involved with preparing the concept?

- ✓ The formal 10-page Concept Proposal is prepared using the NCI template. The template includes:
    - Scientific rationale, trial objectives (primary, secondary and exploratory), study design, agent availability and participant safety, participant recruitment and reporting requirements
    - Identification of participating clinical sites (AOs) and site PIs, along with their academic qualifications
    - Documented recruitment capability of AOs (clinic cases and accrual to previous prevention trials) and list of competing studies
    - Facilities for recruitment, study conduct and biomarker analysis
    - Budget estimate using the NCI concept budget template. ClinCap administration provides assistance with budget preparation.

The elements of a complete application are:

_____Completed CP-CTNet Concept Proposal Submission Form (10 pages)

_____Completed CP-CTNet Concept Budget Submission Form

_____Signed Letter of Commitment from the protocol PI

_____NIH Biographical Sketch for the protocol PI

_____Cover Letter from ClinCaP PIs

Lesson Learned from DCP Reviews of Concepts

- ✓ The DCP statisticians will rigorously review the trial design and sample size/power calculations.
- ✓ The DCP has an emphasis on development of pharmaceutical agents as opposed to foods or food extracts. Characterized and defined extracts may be considered.
- ✓ The program seeks to develop new agents that can go on to Phase 3 trials. Extensive mechanistic work is more appropriate for a R-type of grant.
- ✓ The concept can be submitted both as a concept and a grant, and that is encouraged.

Budget Notes

- ✓ It is possible to jointly fund prevention trials by ClinCaP and other sources, and this is encouraged.
- ✓ The ClinCaP budget is modest and cannot support extensive mechanistic work
- ✓ Ms. Yarden Ginsburg is the multi-site coordinator at UM. She is familiar with CPCT-Net requirements, procedures, and trial monitoring. She conducts site training and interfaces with sites for trial coordination. Her effort will be included on concept budgets.

Interactions with the NCI Staff leading CPCT-Net

- ✓ CPCT-Net organ group leads can be consulted for planned concepts that are not solicited, and this is encouraged to ensure that the concept is within the purview of the kind of trial they would consider approving.
- ✓ After submission of a concept written in reply to a solicitation, CPCT-Net staff can be engaged for questions regarding solicited concepts.
- ✓ The data management is done by the Data Management, Auditing and Coordinating Center (DMACC) in Wisconsin. Clincal trial data is entered into Medidata RAVE (not REDCap).
- ✓ The data is owned by the lead academic organization (U Michigan) and shared with the trial PI and participating investigators.

Timelines

- ✓ Concepts are due to NCI-DCP every 3 months (first week of Jan, April, July and October). Review takes about 30 days. DCP decides if concept is approved for submission of a full protocol, resubmission is required after revision or concept is disapproved.
- ✓ Concepts are due to ClinCaP administration at least 7 calendar days before the NCI deadline. Administrative review is required to check for completeness. ClinCap leadership may decide to delay applications for the next cycle if a need for revision is identified.