

Memo

To: CP-CTNet Colleagues

From: CP-CTNet Steering Committee

Date: October 27, 2023

Subject: Quarterly Steering Committee Information Dissemination

1. NCI Update

- **Monica Bertagnolli, MD, current director of the NCI, was nominated for the Director of the NIH and testified before the U.S. Senate Committee on October 18, 2023. Her nomination was cleared by the Senate HELP Committee and will now proceed to the Senate floor vote. Most likely Douglas Lowy, MD will become Acting NCI Director again.**
- **A government shutdown is still possible beginning November 17, 2023. NCI always is prepared for this possibility and sites have already been funded so grantees for CP-CTNet should see no interruption.**
- **There will be an open competition for the renewal of the CP-CTNet program at the NCI level. It was recommended by Leslie Ford, MD that current grantees send major/innovative accomplishments in the last 4 years to Eva Szabo, MD to assist with internal preparation for the renewal. Dr. Szabo will email the CP-CTNet PIs as the turnaround time is short.**

2. Steering Committee (SC) Chair Appointment/I-SCORE Chair Election

- **Dean Brenner, MD (UMI) completed his role as SC Chair. He was thanked for his service.**
- **Howard Bailey, MD (UWI) was appointed the new chair of the CP-CTNet Steering Committee and was expected to serve through October 2024. Due to his upcoming retirement in the coming months Lisa Barroilhet, MD, MS will serve as co-chair and fully become chair upon Dr. Bailey's official retirement. Dr. Barroilhet will start attending meetings beginning in January 2024.**
- **Seema Khan, MD (NWU) was appointed chair of I-SCORE 2024. Howard Parnes, MD and Ellen Richmond, MS, GNP-BC are the DCP representatives for the March 14-15, 2024 meeting.**

3. DMACC Update

- To date 14 CP-CTNet studies have been open to accrual. Participants have been/are being seen at 31 sites.
- Virtual Specimen Repository
 - LDMS inventory data is transferred to DMACC in real-time for seven active studies.
- Software for creating LAO datasets was deployed.
- A CP-CTNet Memorandum Repository is being developed and will be housed on the Portal Gateway to help keep track of key CP-CTNet memos.

4. CP-CTNet Committee Updates

- EDI Committee Update
 - EDI subcommittee for Education
 - An upcoming webinar is being planned.
 - EDI subcommittee for Staffing
 - No activity to report.
 - EDI subcommittee for Clinical Trials
 - A meeting is being planned with a patient advocate to learn more about how they may help with clinical trial recruitment.
- Cross-network Trial Working Group
 - The group hopes to finalize the updated version of REFGD06 CP-CTNet Cross-Network Trials Guidelines and the Roles and Responsibilities document by the end of November 2023.

5. Cross-Network Trial Updates

- DSMB Meeting
 - The second CP-CTNet Data and Safety Monitoring Board (DSMB) meeting was held October 6, 2023. Three cross-network trials were presented and safety data was reviewed for INT21-05-01 Tri-Ad5/N-803 Vaccine for Lynch Syndrome. The next meeting will be held in September/October 2024.

6. New Topics

- Cross-network MTA issues
 - Dean Brenner, MD reported that attempts were made to conform to one MTA template but it was not easy and individual legal teams at each LAO are involved.

- **Proposed centralized model for ePRO**
 - Sue Siminski, MS, MBA shared that all the LAOs have REDCap and the current plan is that Frontier Science will build the ePRO in their instance of REDCap; MDACC will serve as the first test LAO. Hopefully we'll have data in a month.
- **Auditing algorithm**
 - The auditing team and members from DCP continue to meet to discuss an algorithm for how often to audit sites and to weigh the pros/cons of auditing onsite vs. remote visits.
- **QA/QC procedures for laboratory/biomarker data in CP-CTNet**
 - Initial discussions were had with many providing input about the importance and challenges involving QA/QC procedures for biomarker data. It was noted that biomarker technology/assays change rapidly; different sites use different assays even for the same biomarker. Howard Bailey, MD asked how the required Biomarker Report could be enhanced so processes could be improved. All agreed that the primary endpoints need to be the focus. Further discussion will need to be had on this important topic.

7. Concept Solicitation Cycles #17-21

Cycle #	Steering Committee Date	Concept Solicitation Date	Concept Due Date
17	Oct. 27, 2023	Nov. 3, 2023	Jan. 9, 2024
18	Jan. 26, 2024	Feb. 2, 2024	Apr. 5, 2024
19	Mar. 14, 2024	Apr. 5, 2024	Jun. 7, 2024
20	Jul. 26, 2024	Aug. 2, 2024	Oct. 4, 2024
21	Oct. 25, 2024	Nov. 1, 2024	Jan. 10, 2025

8. Next Steering Committee Meeting

- **Date: 01.26.2024**