

Memo

To: CP-CTNet Colleagues

From: CP-CTNet Steering Committee

Date: January 26, 2024

Subject: Quarterly Steering Committee Information Dissemination

1. NCI Update

- **W. Kimryn Rathmell, MD, PhD, MMHC was sworn in as the 17th NCI Director on December 18, 2023. She previously led the Vanderbilt University Medical Center as physician-in-chief and chair of the Department of Medicine.**
- **A government shutdown is still possible beginning March 8, 2024. If there is a shutdown this could impact the I-SCORE 2024 meeting on March 14, 2024 and March 15, 2024. The I-SCORE Planning Committee will communicate any changes as the date of the meeting approaches.**

2. CP-CTNet Business

- **Due to the I-SCORE 2024 meeting being earlier this year Cycle #19 of the solicitation schedule was changed. Please see the updated solicitation cycle table below.**

3. DMACC Update

- **To date 16 CP-CTNet studies have been open to accrual. Participants have been/are being seen at 32 sites.**
- **Virtual Specimen Repository (VSR)**
 - **Over 3,500 specimen records have been received to date.**
 - **LAO Testimonial regarding VSR – “It turned out to be very user-friendly and helpful for the INT21-05-01 PBMC inventory.”**
 - **Visualizations are now available on the Portal Gateway for more users.**
- **A CP-CTNet Memorandum Repository is now accessible on the Portal Gateway to help keep track of key CP-CTNet memos.**
- **The M-SOP was released in January 2024 with updates to eleven SOPs. The plan is to have biannual M-SOP releases in 2024 and an annual release in 2025.**

4. CP-CTNet Committee Updates

- **EDI Committee Update – The committee continues to look for ways to enhance the network and seek out educational opportunities.**
 - **EDI subcommittee for Education**
 - An upcoming webinar is being planned.
 - **EDI subcommittee for Staffing**
 - No activity to report.
 - **EDI subcommittee for Clinical Trials**
 - No activity to report.
- **Cross-network Trial Working Group**
 - **The group finalized REFGD06 CP-CTNet Cross-Network Trials Guidelines and the Roles and Responsibilities document and both are now posted to the CP-CTNet DMACC website under the Resources tab.**

5. Cross-Network Trial Updates

- **INT21-05-01 Tri-Ad5 and N-803 Vaccines for Lynch Syndrome**
 - Safety Phase I and II have been completed and the study is currently on hold and likely will resume in mid-February when 140 participants are to be enrolled. There have been no unexpected SAEs. AEs/SAEs are being closely monitored for this trial. There may be potential changes to participant distribution across LAOs.
- **INT22-09-01 Randomized Trial of Apalutamide in Non-Muscle Invasive Bladder Cancer**
 - The trial is moving through the appropriate approval/regulatory channels and will open in the next few months.
- **INT23-14-01 Refining Tamoxifen Dose for Premenopausal Breast Cancer Prevention (RENAISSANCE): A Phase II Single Arm Trial**
 - The trial just received CIRB approval. A total of 200 participants will be enrolled. The trial has an expected start date of late April 2024. All five LAOs will be involved with the trial.

6. New Topics

- **Cross-network MTA issues**

- Dean Brenner, MD reported that he will check back with sites for updates on this and provide a report by the next meeting.
- **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.

7. Concept Solicitation Cycles #18-21

Cycle #	Steering Committee Date	Concept Solicitation Date	Concept Due Date
18	Jan. 26, 2024	Feb. 2, 2024	April 5, 2024
19	March 14, 2024	May 6, 2024	July 8, 2024
20	July 26, 2024	Aug. 2, 2024	Oct. 4, 2024
21	Oct. 25, 2024	Nov. 1, 2024	Jan. 10, 2025

8. Next Steering Committee Meeting

- **Date: March 14, 2024 (at I-SCORE 2024 meeting)**