

Memo

To: CP-CTNet Colleagues

From: CP-CTNet Steering Committee

Date: March 27, 2025

Subject: Quarterly Steering Committee Information Dissemination

1. NCI Update

- **Dr. Szabo noted the NIH Director was approved by the Senate and the NCI Director, who is a presidential appointee but not yet Senate approved, will likely be appointed soon.**

2. CP-CTNet Business

- **Dr. Szabo proposed that LAOs hold off on submitting any new concepts until more is known about funding which likely will happen this summer. As soon as funding is approved, LAOs will be notified which previously submitted concepts were approved to move forward. Dr. Szabo asked that if there is an update to previously submitted concepts, LAOs submit the update within 30 days of the solicitation notice that will be going out soon.**
- **Dr. Szabo noted that the nurse consultants asked her to convey to the LAO PIs that all the regulatory documents be up to date at their site. CCSA asks for annual updates to all regulatory documents. Lapses have been discovered during visits to the sites. This is the responsibility of the LAOs during their annual reviews of all their sites.**
- **Don Johnsey stated the importance of getting any pending trials open as soon as the sites are able.**

3. DMACC Update

- **Dr. Kim and Sue Siminski provided updates on the DMACC Data Management and Reporting Unit, Clinical Trials Auditing Unit, and the Administrative and Coordination Unit. Dr. Kim was very proud of the fact that since the prior steering committee meeting (January 17, 2025) the Network has enrolled 62 participants. The Network is doing an outstanding job with accrual.**

- **Discrepancies between information presented on ClinicalTrials.gov and the CP-CTNet DMACC webpage were discussed. PIO is only responsible for updates to ClinicalTrials.gov when DCP is the IND holder and CTRP is the official record holder. LAOs are responsible to update ClinicalTrials.gov when they are the IND holder. Dr. Heckman-Stoddard said that one time of the year all the information should harmonize and that is when RPPRs are due. When RPPRs are submitted, it is imperative that ClinicalTrials.gov be updated and match the HHS entries. Otherwise NOAs could be held up. PIO has the best real time information as the sites submit the Protocol Status Update (PSU) to PIO.**
- **Dr. Khan inquired about the possibility of VSR/LDMS reports being sent back to the sites in efforts to assist in monitoring sites. Biomarker data will be extremely helpful. Dr. Khan recommended a meeting be set up with Frontier Science and the LAOs to discuss samples at the sites (LAOs/AOs). Dr. Sahasrabuddhe indicated it would be beneficial to develop a SOP.**
- **DMACC looked at the number of queries across CP-CTNet and assessed the time to query resolution. Dr. Kim said the DMACC will produce and send query reports by study to the LAOs and DCP.**

4. Cross-Network Trial Updates

- **INT21-05-01 Tri-Ad5 and N-803 Vaccines for Lynch Syndrome**
 - **Dr. Szabo noted that Dr. Bansal presented the trial during the I-SCORE meeting and it has 76% accrued with an anticipated completion date of June/July 2025. Dr. Sahasrabuddhe brought up the PBMC yield and viability issue in the trial and suggested having a focused conversation with vaccine experts at Frederick. Dr. Schlom and his colleagues proposed a solution and problems are no longer being seen. Dr. Szabo and Dr. Vilar-Sanchez stressed the importance of checking the sampling and shipping process early.**
- **The INT22-09-01 Randomized Trial of Bicalutamide in Non-Muscle Invasive Bladder Cancer**
 - **Dr. Parnes shared that the study drug apalutamide was switched to bicalutamide. Dr. Messing sent a revised protocol recently. A start date is anticipated in the Spring of 2025.**

- **INT23-14-01 Refining Tamoxifen Dose for Premenopausal Breast Cancer Prevention (RENAISSANCE): A Phase II Single Arm Trial**
 - **Dr. Khan noted that almost all sites are open. Accrual is going well. Dr. Khan would like to close the trial early if possible if accrual goes as planned. BCRF supplemental funding has been wonderful. Dr. Heckman-Stoddard commended the effort of the administrative/fiscal team at Northwestern on their management of all the complicated contracts associated with this trial.**

5. New Topics

- **Dr. Kim commended the effort of NWU associated with professional development of their staff. Dr. Khan noted supplemental funding from their cancer center makes it possible but that, unfortunately, funding going forward may be challenging. Dr. Kim utilizes PI CapEx funding (indirect cost) to support development of staff and encouraged PIs to consider this investment in their teams.**
- **Dr. Kim announced his upcoming retirement at the end of June 2025.**

6. Concept Solicitation Cycles #22-25

Cycle #	Steering Committee Date	Concept Solicitation Date	Concept Due Date
22	Jan. 17, 2025	Jan. 24, 2025	Apr. 4, 2025
23*	Mar. 27, 2025	Apr. 1, 2025	Apr. 30, 2025
24	Jul. 18, 2025	Jul. 25, 2025	Sep. 26, 2025
25	Oct. 24, 2025	Oct. 31, 2025	Jan. 9, 2026

*No new concepts will be accepted, only new relevant information pertaining to concepts proposed in the LAO renewal grants will be accepted

7. Next Steering Committee Meeting

- **Date: July 18, 2025**