

Memo

To: CP-CTNet Colleagues

From: CP-CTNet Steering Committee

Date: July 26, 2024

Subject: Quarterly Steering Committee Information Dissemination

1. NCI Update

- Dr. Szabo stated that she recently presented CP-CTNet to the External Review Panel and it went well. The panel was especially pleased with accrual rates in the network.

2. CP-CTNet Business

- Dr. Szabo thanked Dr. Brenner for his contributions to the field of chemoprevention over his 50-year career and wished him well in his upcoming retirement. His official last day is 8/2/2024.
- CP-CTNet Data Sharing Timeline
 - Committee members agreed to continue implementing the data sharing timelines used in the Consortia and will plan to submit final clinical data sets to IMS (NCI contractor) within 6 months of study completion.
 - This process will need to be reevaluated with the upcoming grant renewal as NIH issued a new [Data Management and Sharing \(DMS\) policy](#) effective for applications submitted on/after January 25, 2023.
- Dr. Szabo stressed how critical AO PI oversight/involvement is in the success of trials in the network and noted that some AO PIs have been absent from important meetings like Auditing Exit Interview Meetings. She also indicated that AE interpretation may initially start with a coordinator that may not necessarily have a medical background. PIs are responsible for final evaluation and sign off of all AEs.
- Don Johnsey noted that he is working on Notice of Awards and appreciates the assistance of team members to facilitate grantees receiving them in a timely manner.

3. DMACC Update

- **ePRO (Medidata eCOA)**
 - **DMACC continues with efforts towards adopting an appropriate ePRO solution for the network but likely a formalized solution will not be adopted until after the renewal.**
- **Report Requests**
 - **DMACC continues to work on several newly requested reports/updates to existing reports and encourages LAOs to reach out when they may need specialized reports.**
- **Statistical Sub-Unit Activity**
 - **The statistical team conducted internal statistical monitoring of CP-CTNet trials with the analysis of elapsed time between enrollment and intervention and the number of protocol/SVAR revisions.**

4. CP-CTNet Committee Updates

- **EDI Committee Update**
 - **The full committee is taking a break until the new program is renewed.**
 - **EDI subcommittee for Education**
 - **A webinar is being planned for Fall 2024.**
 - **EDI subcommittee for Staffing**
 - **A follow up climate survey will go out in August.**
 - **EDI subcommittee for Clinical Trials**
 - **Principles and best practices for social media accrual packets is being reviewed.**

5. Cross-Network Trial Updates

- **INT21-05-01 Tri-Ad5 and N-803 Vaccines for Lynch Syndrome**
 - **Dr.Szabo reported that the study is doing well overall. They are currently in the randomized-controlled phase and have 42 participants enrolled, of which, 1-2 will not go on to intervention. The PBMC collection problems are resolved and a new amendment is approved.**
- **The INT22-09-01 Randomized Trial of Apalutamide in Non-Muscle Invasive Bladder Cancer**
 - **Dr. Barroilhet reported that they have CIRB approval and the Study Initiation Meeting is planned for the end of September.**

Howard Parnes said that the New Zealand company, Pacific Edge, agreed to do the analysis of a urine test, which will be a secondary endpoint.

- INT23-14-01 Refining Tamoxifen Dose for Premenopausal Breast Cancer Prevention (RENAISSANCE): A Phase II Single Arm Trial
- Dr. Chow reported that they had the Study Initiation Meeting in early July and are waiting on the completion of the study build database. She added that the agent is already available.

6. New Topics

- None

7. Concept Solicitation Cycles #20-21

Cycle #	Steering Committee Date	Concept Solicitation Date	Concept Due Date
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: October 25, 2024