

Memo

To: CP-CTNet Colleagues

From: CP-CTNet Steering Committee

Date: October 28, 2022

Subject: Quarterly Steering Committee Information Dissemination

1. NCI Update

- Dr. Szabo shared that Monica Bertagnolli, M.D., began work as the 16th director of the National Cancer Institute (NCI) on October 3, 2022. Dr. Bertagnolli began her early career in Cancer Prevention. We are optimistic that she will be an advocate for cancer prevention.

<https://www.cancer.gov/about-nci/leadership/director>

2. DMACC Update

- **Updated SVAR Review Process**
 - Final SVAR approval has been granted on V3.0 or earlier, indicating that this updated process is getting SVARs approved more quickly.
- **Virtual Specimen Repository**
 - Sample expectancy reports deployed to production in October 2022 and will be utilized/shared by data management staff (as appropriate) beginning in November 2022.
- **Auditing Criteria Algorithm Changes**
 - Allows audits to occur earlier in the study and to identify any problematic areas in a timelier fashion.

3. CP-CTNet Steering Committee Chair

- Powel Brown, MD, PhD (MDA) completed his role as SC Chair. We thank him for his service.
- Dean Brenner, MD (UMI) was appointed the new chair of the CP-CTNet Steering Committee and will serve through October 2023.

4. I-SCORE 2023

- Dates for the next I-SCORE meeting are 3/30/23-3/31/23. The meeting will be a hybrid format (in-person in Rockville, MD and virtual).
 - Howard Bailey, MD (UWI) was elected chair of I-SCORE 2023. Lisa Bengtson, RN, MSN, OCN is the DCP representative.

5. CP-CTNet Committee Updates

- **EDI Committee Update**
 - EDI subcommittee for Education
 - Dr. Adam Murphy delivered a CP-CTNet Equity, Diversity, and Inclusion Webinar on August 2, 2022.
 - EDI subcommittee for Staffing
 - The survey results confirmed that our staffing does not reflect our patient population.
 - We will work on ways to improve EDI within CP-CTNet organizations.
 - EDI subcommittee for Clinical Trials
 - We will meet with the team developing the Community (or Participant) Engagement Advisory Board to determine how best to engage patient advocates to be part of the CP-CTNet protocol life cycle.
- **Cross-Network Trial Working Group**
 - This group has been meeting monthly to update the existing REFGD06 CP-CTNet Cross-Network Trials Guidelines and provide more granularity to the roles and responsibilities of key partners in cross-network trials.

6. Cross-Network Trial Updates

- **Data and Safety Monitoring Board (DSMB) for the cross-network studies.**
 - The first meeting was held on October 11, 2022.
 - The DSMB will serve a very important role in assuring participant safety and the quality of our cross-network trials. The DSMB will regularly monitor the data from the studies, review and assess the performance of its operations, and make recommendations, as appropriate, to NCI/DCP.
 - The DSMB members are:
 - Ana Maria Lopez, MD (Chair), Thomas Jefferson University
 - Carmen Allegra, MD, University of Florida
 - Elizabeth Jaffee, MD, Johns Hopkins University
 - Taofeek Owonikoko, MD, PhD, University of Pittsburgh
 - Lindsay Renfro, PhD, University of Southern California

- **INT21-05-01 Tri-Ad5/N-803 Vaccine for Lynch Syndrome**
 - An amendment was just recently submitted, and a target date of December 1st has been set to hopefully start enrollment.
- **INT22-09-01 Randomized Trial of Apalutamide in Non-Muscle Invasive Bladder Cancer**
 - Four LAOs are committed to this study and hopefully will have an efficient accrual.
 - We are awaiting news from the pharmaceutical company about supplying drug.

7. New Topics.

- **Challenges to study activation and accrual**
 - Discussed the need to better define prescreen and screen.
 - Discussed how coordinators would like to see eCRFs prior to putting the first subject data in RAVE.
- **Auditing Findings / Audit Earlier**
 - Allows audits to occur earlier in the study and to identify any problematic areas in a timelier fashion.
- **SOP Sign-off**
 - Proposed plan to bundle the SOPs into a combined manual to ease burden on the sites.
- **Letters to study participants after study closes**
 - The CP-CTNet Steering Committee will support continued communication with study participants after a study closes.
- **Proposed centralized model for capturing participant reported outcomes.**
 - Dr. Eva Szabo, Dr. Powel Brown, Dr. KyungMann Kim and Sue Siminski will be meeting to discuss options, including a centralized model, for the LAOs to use.

8. Future Topics

- Dr. Julie Bauman discussed future capture of demographic data to include: sexual and gender orientation.

9. Concept Solicitation #13-17

Cycle #	Steering Committee Date	Concept Solicitation Date	Concept Due Date
13	Oct. 28, 2022	Nov. 4, 2022	Jan. 9, 2023

14	Jan. 27, 2023	Feb. 3, 2023	Apr. 7, 2023
15	Mar. 30, 2023	Apr. 7, 2023	Jun. 9, 2023
16	Jul. 28, 2023	Aug. 4, 2023	Oct. 6, 2023
17	Oct. 27, 2023	Nov. 3, 2023	Jan. 9, 2024

Next Steering Committee Meeting is January 27, 2023.