CP-CTNet
Cancer Prevention
Clinical Trials Network

Data Management, Auditing, and Coordinating Center

First Edition / May 2020

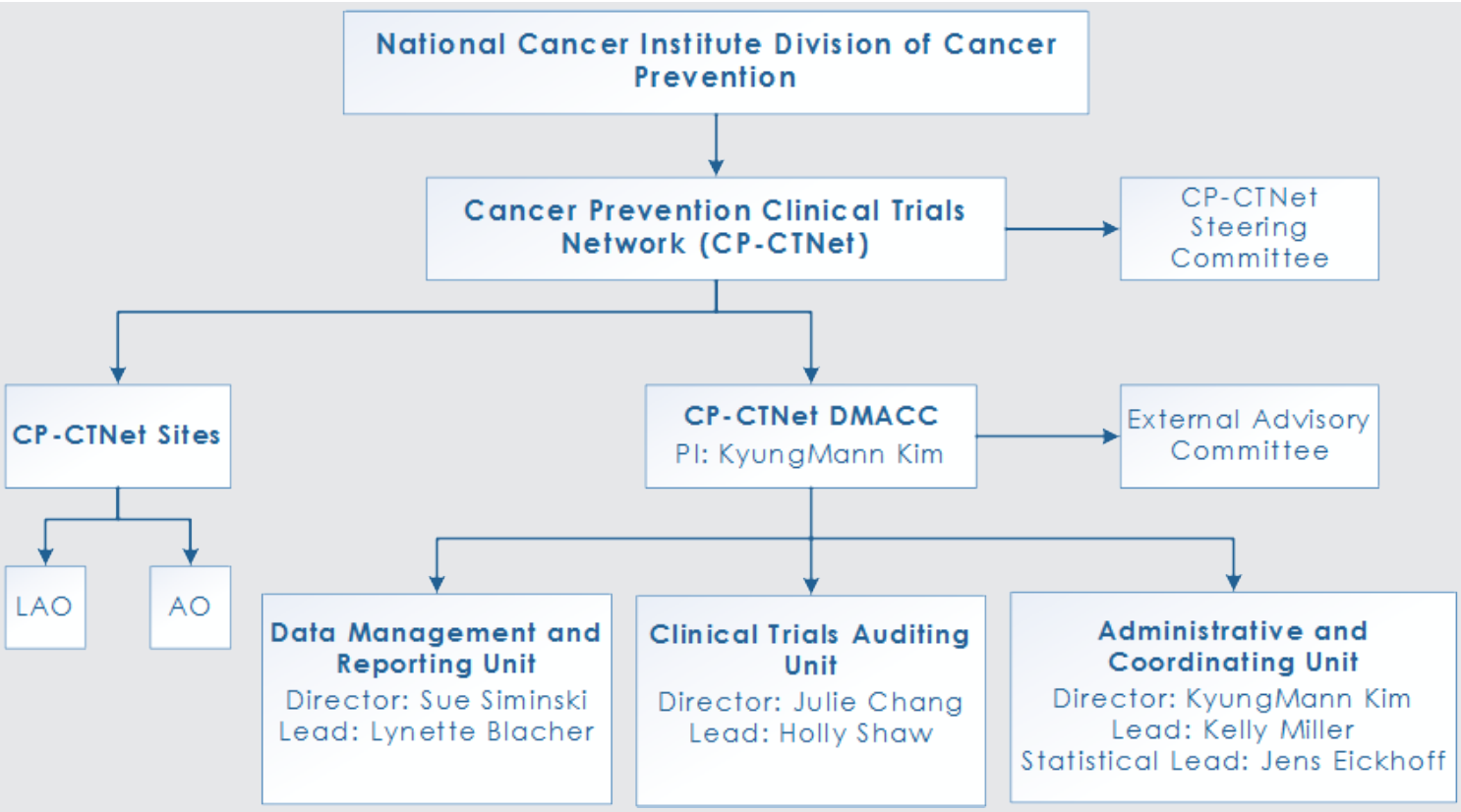
CP-CTNet DMACC Introductory Newsletter

Introduction

The goal of the Cancer Prevention Clinical Trials Network (CP-CTNet) is to identify safe and effective preventive agents and interventions in order to advance their further clinical development for cancer prevention. The CP-CTNet sites will perform these early phase trials with support from the NCI's Division of Cancer Prevention (DCP) and the CP-CTNet Data Management, Auditing, and Coordinating Center (DMACC). These trials include phase 0 (micro-dosing), phase I (dose-finding), and phase II (preliminary efficacy) clinical trials. To support these early phase trials that will be conducted by the CP-CTNet sites, either alone or cross-Network, the CP-CTNet DMACC will coordinate cross-Network activities and provide expertise and resources in centralized data management and reporting, clinical trials auditing, and administrative and logistical coordination, including expertise in clinical trials methodology and biostatistics, across CP-CTNet in partnership with Frontier Science Foundation in Amherst, NY. In addition, the CP-CTNet DMACC will provide an advisory role in early phase cancer prevention trial development for all CP-CTNet trials and a primary statistical role for cross-Network trials. The DMACC is looking forward to collaboration with the DCP and the dedicated research teams at the Lead Academic Organizations (LAOs) and Academic Organizations (AOs) to continue to carry out this important work under this new program.

Dr. Kyungmann Kim,

DMACC, PI



Operational Units

There are three DMACC Operational Units. The first is the **Data Management and Reporting Unit**, which operates out of Frontier Science Foundation, which has over 40 years of expertise in data management and reporting. The Director for the Data Management and Reporting Unit is **Suzanne Siminski**, MS, MBA; the Lead is **Lynette Blacher**, MLS, and the Senior Protocol Data Manager is **Kelly Dunn**, MPH, CCRP. Since its founding, Frontier Science Foundation has been involved with network projects such as the International Breast Cancer Study Group (IBCSG), the AIDS Clinical Trials Group (ACTG), the International Maternal Pediatric Adolescent AIDS Clinical Trial (IMPAACT), and Collaborating Consortium of Cohorts Producing NIDA Opportunities (C3PNO). In addition to the large network projects, Frontier Science Foundation has been involved with other standalone projects, including Olaparib as Adjuvant Treatment in Patients With Germline BRCA Mutated High Risk HER2 Negative Primary Breast Cancer (OlympiA), LDMS support for NIAID/DAIDS Networks managed by SCHARP, the Clinical Pharmacology Quality Assurance (CPQA) and Quality Control Program, and INfluenza Vaccine to Effectively Stop Cardio Thoracic Events and Decompensated heart failure (INVESTED) Data Coordinating Center, for which KyungMann Kim serves as PI.

This unit will provide full data management support for all CP-CTNet studies. This support includes areas such as study build and validation, Medidata Rave support, and quality assurance. Additionally, Frontier Science Foundation will maintain the document repository which includes all CP-CTNet SOPs and DMACC Manual of Procedures. Other areas of support will include web services for data exchange, support for routine and ad hoc reporting to sites and the NCI/DCP, educational support for Medidata Rave, support for virtual biospecimen repository tracking, and the LDMS laboratory information management system.

Operational Units

The second **Operational Unit is the Clinical Trials Auditing Unit**, which operates out of both the University of Wisconsin-Madison and Frontier Science Foundation. The Director is **Julie Chang**, MD, from University of Wisconsin-Madison and the Lead is **Holly Shaw**, MS, CCRP from Frontier Science Foundation. The Clinical Trials Auditing Unit will audit data and processes in order to ensure protocol compliance, proper study documentation, compliance with Good Clinical Practices, the protection of human subjects, and the quality and integrity of data across the CP-CTNet studies. To do this, the unit will perform virtual audits to supplement on-site auditing. This will require proactive planning based on statistical predictive modeling, which is an exciting new take on auditing services, and will provide continuous systemic and policy-level improvements, thereby increasing efficiency and compliance based on risk-based assessments. The third Operational Unit is the **Administrative and Coordinating Unit**, which operates out of the University of Wisconsin-Madison. **KyungMann Kim**, PhD serves as the Director, with **Kelly Miller**, BS, CCRC as Lead and **Jens Eickhoff**, PhD as Statistical Lead. This unit will offer expertise to CP-CTNet site investigators and statisticians in a consulting capacity. The unit will assume responsibility for clinical trials methodology and biostatistics for CP-CTNet cross-Network studies utilizing their expertise in biomarket studies, biomarker-driven adaptive trials, and precision oncology. Other operational management items will include maintenance of the CP-CTNet web portal, development of SOPs and Manuals of Procedures in coordination with the steering committee, provision of support for committees and annual I-SCORE meetings, and maintenance of the CP-CTNet administrative database items such as site personnel and authentication, publications and presentations, and the calendar of events.

External Advisory Committee

The External Advisory Committee (EAC) will meet annually via web-conference, with occasional in-person meetings to advise the DMACC leadership on its operational and programmatic issues. The EAC consists of Ernest Hawk, MD, MPH, University of Texas MD Anderson Cancer Center; Catherine Tangen, Dr.PH, Fred Hutchinson Cancer Research Center; and Eleanor McFadden, MA, Frontier Science (Scotland) Ltd. The EAC members are highly recognized experts in the areas of cancer prevention clinical trials and coordinating center operations. Dr. Hawk is Vice President and Head of the Division of Cancer Prevention and Population Sciences, Boone Pickens Distinguished Chair for Early Prevention of Cancer, and Professor in the Department of Clinical Cancer Prevention Sciences at the University of Texas MD Anderson Cancer Center. Dr. Tangen is Member of the Public Health Sciences Division of Fred Hutchinson Cancer Research Center, Deputy Director of the Southwest Oncology Group Statistical Center, and has served as statistician for several large-scale landmark cancer prevention clinical trials. Ms. McFadden is Managing Director of Frontier Science (Scotland) Ltd., and former Director of the Eastern Cooperative Oncology Group's Coordinating Center.

Meet the DMACC Staff

Project PIs

KyungMann Kim, PhD is the DMACC PI and Director of the Administrative and Coordinating Unit. Dr. Kim is currently Professor of Biostatistics and Medical Informatics at the University of Wisconsin-Madison. He is an elected Fellow of the American Association for the Advancement of Science and the Society for Clinical Trials as well as the American Statistical Association.

Sue Siminski, MS, MBA is the DMACC Sub-PI and Director of the Data Management and Reporting Unit. She has been working in clinical trials data management and related research activities for more than 30 years and currently serves as the Chief Executive Officer of Frontier Science Foundation.

University of Wisconsin

Jens Eichkoff, PhD is a Co-Investigator on the project and Statistical Lead of the Administrative and Coordinating Unit. He is a senior level statistician and will work with Dr. Kim as his deputy. Dr. Eickhoff will participate in advising the early phase cancer prevention clinical trial development at the CP-CTNet sites and will work with the statisticians. In addition, he will serve as an unblinded statistician for cross-Network clinical trials and will support the data monitoring committee responsible for CP-CTNet cross-Network clinical trials.

Julie Chang, MD is the Director of the Clinical Trials Auditing Unit. Dr. Chang treats a wide range of cancers, but has special interest in lymphoma and complications of cancer involving the central nervous system. She is actively participating in further developing the Lymphoma Research Program at the University of Wisconsin Carbone Cancer Center.

Guanhua Chen, PhD is a Co-Investigator on the project. Dr. Chen conducts research with a focus on precision medicine. He will contribute statistical expertise in the development of CP-CTNet protocols, especially as they may involve precision oncology.

Jen Birstler, MS is a Master's level statistician who will work with Dr. Kim on quality assurance and preparation and transfer of the limited data set. She will serve as Statistical Data Manager and Analyst for cross-Network trials and will assist the Clinical Trials Auditing Unit with sampling of cases for Patient Case Review.

Zhumin Zhang, PhD in Nutrition is a Master's level statistician who will work with Dr. Kim on quality assurance and preparation and transfer of the limited data set. She will serve as Statistical Data Manager and Analyst for cross-Network trials and will assist the Clinical Trials Auditing Unit with sampling of cases for Patient Case Review.

Kelly Miller, BS, CCRC is the Lead of the Administrative and Coordinating Unit. She has 19 years of experience conducting, managing, and coordinating clinical trials sponsored by the NIH. She will provide support for administrative and logistical coordination across CP-CTNet operations including organizing and supporting the annual I-SCORE meetings.

Bridget Dermody, BS is the admin Program Specialist and is responsible for administrative support for the DMACC.

Keith Wanta, BS is the Senior Programmer Analyst for the project. Mr. Wanta is a 15 year medical software professional with experience in clinical data models, data warehousing, software application development, and automated workflow testing and ontology management. He will work with Dr. Kim on quality assurance of electronic data capture (EDC) workflows.

Meet the DMACC Staff

Frontier Science

Lynette Blacher, MLS is the Lead of the Data Management and Reporting Unit. She has been involved in cancer research for over 20 years and is involved in global collaboration with research groups and networks in six continents to conduct clinical trials in breast cancer.

Bob Starkweather, MS is the Software Project Manager, and will work closely with the project PIs and the Lead of the Data Management and Reporting Unit to define and design the software that is developed for this project, as well as to select existing software to adapt to the needs of this project. He has over 15 years of experience leading software engineering efforts at Frontier Science Foundation.

Holly Shaw, MS, CCRP is the Lead of the Clinical Trials Auditing Unit. She has over 10 years of experience in both AIDS and breast cancer trials, including data management, monitoring, and coordinating. The auditors will conduct independent on-site and remote auditing of clinical trials data and processes at all CP-CTNet LAOs and AOs.

Kelly Dunn, MPH, CCRP is the Senior Protocol Data Manager. Kelly has worked in the clinical trials environment for the past seven years, five of which were specifically in oncology and included working with various EDC systems and coordinating the care of oncology patients on numerous clinical trials.

DMACC Year 1 Activities

Over year 1, we are implementing several major online systems, including a registration/randomization system, electronic data capture (EDC) systems, and a clinical trials auditing program. The DMACC will support the AQuIP program, including providing user-friendly data entry systems to enter recruitment, screening and enrollment data, as well as recruitment journaling information.

Stars is the system that sites will use to generate participant records in the clinical database for the recruitment, screening, and enrollment process. Stars will also support the Accrual Quality Improvement Program (AQuIP).

Medidata Rave is the EDC system for collection of study data and recruitment journaling. Much of the data flow for CP-CTNet will take place within the overall structure of Medidata Rave. This is the locus for data entry at sites, and for queries and responses with regard to clinical data. The Medidata Rave infrastructure, which Frontier Science Foundation has validated and audited, will be responsible for data protection and integrity during transmission for these processes.

The **Audit System** captures the entire audit process. Clinical trials auditing will be based on the following four phases known as P-E-R-C: P for Plan the audit; E for Execute the audit; R for Report the audit findings; and C for Corrective action. This is considered to be best practice in clinical trials auditing, and the Clinical Trials Auditing Unit will build its auditing program based on these four pillars. The resulting auditing program will encompass these components and will enhance and improve the CP-CTNet clinical trials auditing overall through: risk management, policy and standard setting, site education and training, and continuous improvement. Frontier Science Foundation has created a comprehensive online tracking system for one of its large cancer clinical trials to manage audit workflow, record and track activities, store audit reports, and send automatic notifications. This system will be adapted for the CP-CTNet. The system will be expanded to include audit scheduling and tracking of CAPAs as a follow-up to audit findings, and an automatic notification feature will be modified to also include upcoming audit-related tasks/activities, e.g. CAPA response due.

Training, educational materials, and direct support for these systems are available to LAOs and AOs. Additionally, in collaboration with DCP, DMACC has revised the Consortia Standard Operating Procedures (SOPs) to reflect the current CP-CTNet activities and ensure all stakeholders have clear guidance to enable trial conduct. The next important step is providing LAOs the opportunity to review and comment on the SOPs, as it is critical to include the input of those performing the conduct of the trial.

The DMACC has created the CP-CTNet gateway portal, to serve as a one-stop shop for all CP-CTNet needs. The gateway will serve 2 functions, one as a face of the CP-CTNet to the public and the other as a portal for the CP-CTNet sites and DMACC investigators and research staff for access to CP-CTNet information, including all online systems. This will serve as a hub for storage and exchange of CP-CTNet related documents such as CT-CTNet SOPs and DMACC Manual of Operations.