September 2020

CP-CTNet NEWSLETTER

Cancer Prevention Clinical Trials Network

Pictured: University of Wisconsin, Madison Campus where PI of the DMACC is based

Introduction to the Project

The Cancer Prevention Clinical Trials Network (CP-CTNet) is a major program of the National Cancer Institute (NCI) Division of Cancer Prevention (DCP). The purpose of CP-CTNet is to perform and provide clinical trial support for the efficient conduct of early-phase clinical trials, evaluate the biologic effects of preventive agents and interventions, and determine clinically relevant correlates in order to advance their development for cancer prevention.

The key components of CP-CTNet are the CP-CTNet sites and the CP-CTNet Data Management, Auditing, and Coordinating Center (DMACC). Each CP-CTNet site consists of a Lead Academic Organization (LAO) and Affiliated Organizations (AOs) that work together to perform cancer prevention clinical trials.

NCI Cancer Prevention Clinical Trials Network

A program of the National Cancer Institute of the National Institutes of Health

In This Issue

Save the Date

Sep 2020: 1st CP-CTNet trial starts enrollment
23-Oct-2020: Steering Committee Meeting
29-Apr - 30-Apr, 2021: I-SCORE Meeting

Interview with Eva Szabo

What sparked your interest in cancer prevention and how did it lead to your involvement with the DCP?

I did not take a direct route to cancer prevention. After my clinical year of the oncology fellowship at the NCI, I became a laboratory-based investigator studying the induction of differentiation as a therapeutic modality. It became clear that this kind of approach is much more likely to be feasible during earlier stages of carcinogenesis (before the acquisition of multiple mutations that make cancers refractory to treatment). Our lab became part of what is now the Division of Cancer Prevention during a reorganization and I stayed on as an independent investigator. Transitioning to study how 'normal' differentiation was abrogated during carcinogenesis flowed naturally from my early studies and I became interested in moving some of these preclinical studies to clinical trials targeting premalignancy instead of invasive malignancy. Eventually I moved to a clinical position at DCP and have been overseeing the early phase drug development program since the early 2000's.

How did the CP-CTNet Program come about?

DCP has had a clinical program for the development of preventive agents for several decades. Initially the studies were based only on ideas arising within DCP. Each trial was funded separately via a contract with NCI, as the field of clinical cancer prevention was very new and the clinical trial models were just being developed. In the early 2000's, I was asked to oversee the program and develop a nimbler mechanism for performing multiple early phase trials – the result was the Consortia program. The Consortia were multiple independent networks, each funded by a separate contract, that allowed us to fund ideas arising both within DCP and from academia. With continuing maturation of the field, the transition to the grant-funded CP-CTNet was the next logical step.

What is your role within CP-CTNet?

As the Director, I have responsibilities for the scientific and administrative oversight for CP-CTNet. That includes the long term vision for the program, the scientific directions for the clinical trials, and anticipation of the next steps in continuing the program in the next funding cycle. In the short term, I oversee the day-to-day activities that include building the administrative structure to support the clinical activities, oversight of agent solicitations and review of concepts and protocols, establishment of guidelines to support the program's function, and integration of all the activities to ensure relative uniformity across the LAOs and DCP. I am also a Medical/Scientific Monitor on trials for lung or head and neck cancer prevention, so I am constantly searching for interventions for prevention of cancers arising in these organs and for new clinical trials models to test such interventions.

What do you feel is the biggest change between the Consortia & CP-CTNet?

There are several changes that make the two programs considerably different, primarily due to the funding mechanism, which impacts on "who does what and how". What we are most excited about is the opportunity to be a true network incorporating all the grantees. With the support of the DMACC, there is one database of record, centralized monitoring (which used to be the responsibility of the lead sites in the Consortia program), and, therefore, a path to easily perform cross-network clinical trials. This was quite a challenge in the Consortia program and required somewhat awkward work-arounds. The ability to pool our collective resources to perform high impact studies is one of the major goals of CP-CTNet.

Although the changes to the funding mechanism (cooperative agreement vs. contract) will invariably result in some 'growing pains' (e.g., whereas DCP had close control over budgets in the Consortia, now the responsibility is with the grantees), I am confident that our new network will be able to take the best from the Consortia program and use the less restrictive grant mechanism to make major contributions to cancer prevention.

What goals do you have for CP-CTNet?

I sincerely hope that the excitement we all have for this new program will propel the science of cancer prevention forward in a significant way. Our goals are to perform high quality studies that clearly answer questions about the suitability of

specific interventions to move forward for further drug development, eventually resulting in phase III clinical trials that change standard practice. We hope to develop effective mini-networks of clinical sites that have access to and ability to accrue specific high risk individuals to quickly perform trials in these special cohorts. CP-CTNet has the potential to develop new clinical trial models, using the latest technologies and high-throughput methodologies to answer mechanistic questions about the interventions under investigation. Our goal is for CP-CTNet to provide the foundation for trials that make cancer prevention a viable component of the care of individuals at risk for cancer.

What do you see as the greatest challenge for the CP-CTNet program and how will this challenge affect the CP-CTNet studies?

Perhaps the greatest challenge currently is the COVID-19 pandemic, which affects everyone and everything, from willingness to participate in clinical trials (or even leave one's home) to the ability of providers to focus on prevention research. Since accrual is the bedrock of clinical trials, COVID-19 is an existential threat to everything we do. We are all learning how to function in the context of this new understanding of the world and how to deliver quality healthcare and perform clinical research. We and others have worked hard to simplify the performance and oversight of clinical trials in the Consortia program in response to COVID-19 (e.g., telehealth, use of outside labs for routine safety monitoring, relaxed reporting requirements for minor inconsequential deviations, etc.). We plan to convene a working group to identify the lessons learned and to strategize how we can further maximally support the trials without compromising safety and trial integrity. While there aren't easy answers on how to do clinical trials in a more nimble, flexible fashion, we trust that the partnership with the experienced research teams in CP-CTNet will provide a viable path forward.

What do you hope the CP-CTNet accomplishes over the next 4 years?

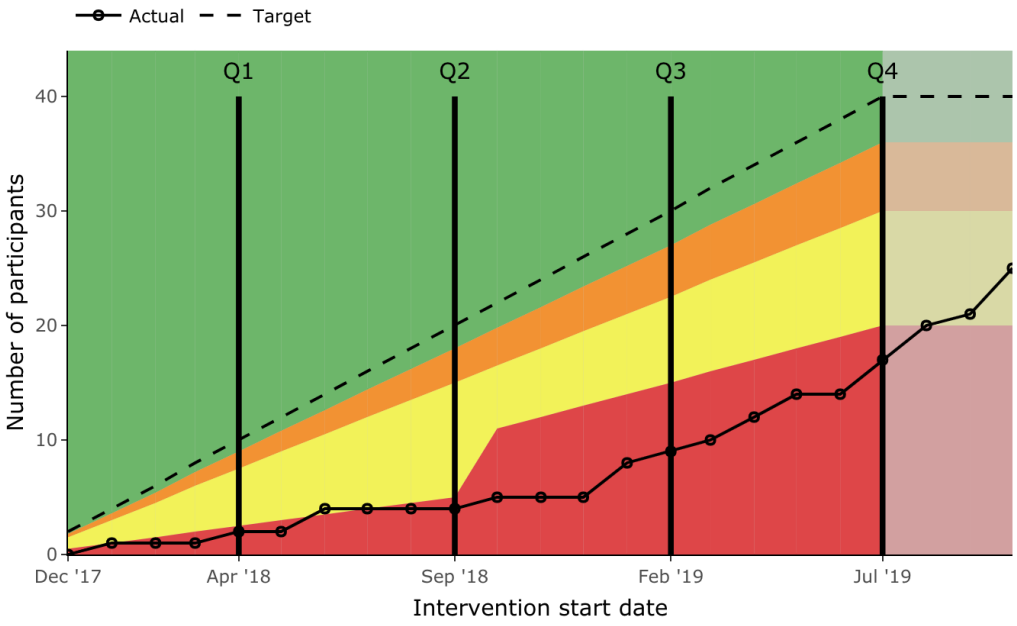
Our mandate is straightforward – to qualify agents (interventions) for phase III definitive efficacy clinical trials. We hope to identify at least two different interventions that can give rise to such trials and eventually lead to changes to clinical practice. To get there, we need to develop new clinical trial models to more expeditiously identify the efficacy of interventions and to harness new technologies to learn more about mechanisms of action of preventive agents. I hope that we develop into a vibrant network that shares ideas and works together to become the driver of cancer prevention science. I also hope that we develop best practices for performance of cancer prevention clinical trials that impact not only the field of prevention, but clinical trials across the spectrum.

Where did you go to college and medical school?

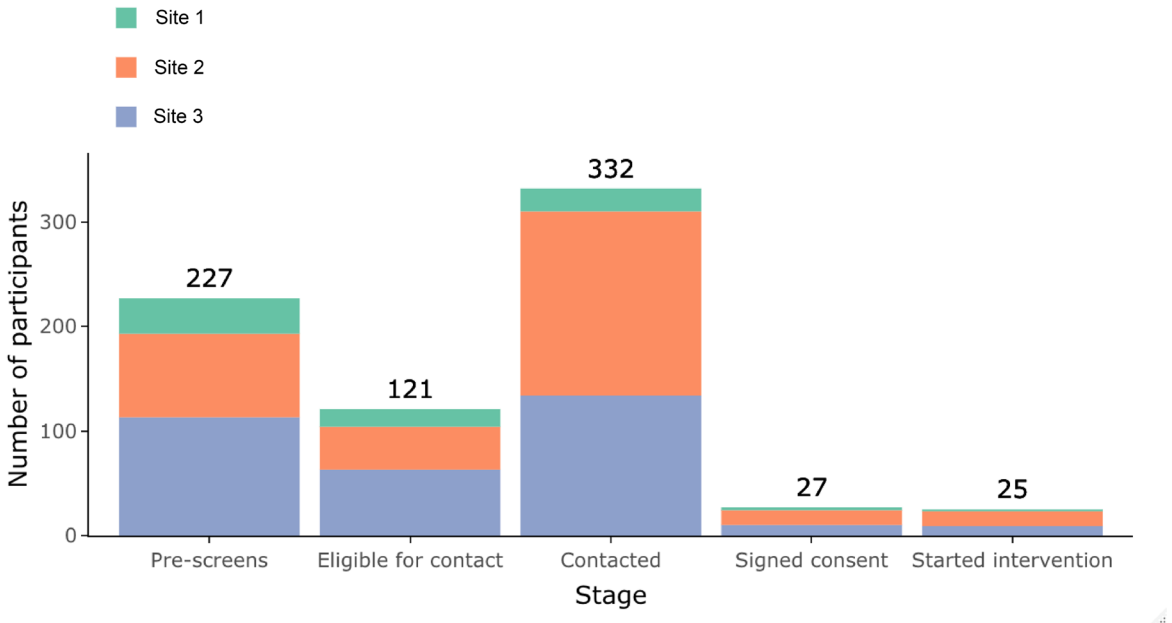
Yale University for college (major Molecular Biophysics and Biochemistry); Duke University Medical School

Accrual Quality Improvement Program (AQuIP)

The Accrual Quality Improvement Program (AQuIP) is a multi-component system that supports the DCP early phase cancer prevention trials. AQuIP is a dynamic clinical trial accrual improvement program based on systematic planning, detailed accrual-related data collection and frequent monitoring using data visualizations for analysis to inform responsive interventions that lead to measurable improvement in accrual. The program was developed by Ellen Richmond who also leads the DCP AQuIP effort. Ellen is a Nurse Consultant and Program Director in the Gastrointestinal and Other Cancers Research Group (GOCRG) in the NCI's Division of Cancer Prevention (DCP).



The DMACC is excited to collaborate with the entire DCP AQuIP Clinical Team (Ellen Richmond, Lisa Bengtson, Eileen Dimond, Maggie House and Anne Ryan) to build on this already robust program! Data related to AQuIP was previously entered by sites into the Online Accrual Reporting System under the Consortia. For CP-CTNet, data will be captured by the Stars Randomization System and Medidata Rave as part of routine enrollment and electronic case report form (eCRF) data entry, thereby eliminating duplication of data entry. DMACC's Jen Birstler, MS, in conjunction with DCP, has drawn on her expertise to enhance AQuIP graphic reports to support the CP-CTNet. These reports, available to all via the secure DMACC Portal Gateway (cp-ctnet-dmacc.org), will augment accrual by providing visual accrual targets for study staff, enabling prompt identification of opportunities for continuous improvement, providing guidance for responsive interventions to address shortfalls in accrual for current studies; and will inform realistic recruitment rate projections for studies in the future.



DMACC Updates

Data Management and Reporting Unit

As new protocol concepts have been pouring in from the Lead Academic Organizations (LAOs), the Data Management and Reporting Unit has been preparing the infrastructure to support trial conduct for the network.

The unit's Senior Data Managers have worked with the Division of Cancer Prevention (DCP) Team to revise the System Variable Attribute Report (SVAR) Template for use in developing Electronic Case Report Forms (eCRFs) for new protocols. Utilizing the template will reduce workload for the sites, and ensure consistency in data collection across studies. The Senior Data Managers along with DMACC statisticians from the UW have also played a key role in the SVAR review for new protocols, both by reviewing the forms for implementation in the clinical database, and by coordinating the review between the DCP and their Regulatory and Common Data Element (CDE) Contractors.

Both the Medidata Rave Electronic Data Capture (EDC) system and the bespoke Stars enrollment system have been configured, tested and validated for the CP-CTNet program. Once the SVAR is finalized for the first protocol, the Data Management and Reporting Unit will create the study build in Medidata.

The Data Management and Reporting Unit has also worked with the DCP to revise the 2012 Consortia Standard Operating Procedures (SOPs) and 24 related documents in order to provide a smooth transition to the CP-CTNet procedures. The goal of this endeavor is to ensure LAOs and Affiliated Organizations (AOs) have clear guidance to enable trial conduct, and to collaborate together with DCP and DMACC. DMACC solicited feedback from the LAOs, as experts in trial conduct, and received very constructive comments, which were incorporated in a revision of the SOPs.

One of the guiding quality documents that was created is the Master Data Management Plan (DMP), which is applicable across all sites and studies, and replaces the individual LAO DMPs. The purpose of the Master DMP is to ensure the consistency, authenticity, integrity, and confidentiality of study data, and the protection of human subjects participating in CP-CTNet studies.

These documents were approved at the Steering Committee meeting on July 31st. As DCP and DMACC continue to evaluate each area of trial conduct with LAO input, SOPs and related documents will evolve to reflect revised procedures and the systems that support these procedures.

The Data Management and Reporting Unit created a custom website, the DMACC Portal Gateway, to be used as a tool for communication and a resource for all CP-CTNet needs, including accessing the documentation referenced above, Stars, Medidata Rave, official announcements, and the latest news.

As communication is critical in the success of any program, DMACC held six webinars for CP-CTNet Site staff, NCI Contractors and DCP staff to serve as an introduction to the role of the DMACC in CP-CTNet. DMACC is in process of holding virtual visits with LAOs to discuss our collaboration, and to solicit ideas from LAOs on how DMACC can help facilitate their work. DMACC will also be involved in the Study Initiation Meetings for new protocols, to provide information on Stars, Rave, data management, and answer any questions from the sites.

Clinical Trials Auditing Unit

During the first year of CP-CTNet, the Auditing Unit has spent a lot of time planning and preparing for our eventual first audits. It is planned to do both remote and on-site audits (when they can be done safely!). An integral component of our work during year 1 was to outline and define the specifications for our web-based Audit System. The Audit System will enhance and improve CP-CTNet by identifying opportunities for continuous improvement and will lead to increased communication, collaboration, as well as site education and training between the CP-CTNet Sites, DCP, and the DMACC. Some exciting features of the Audit System include scheduling tools & automated reminders, incorporating electronic sign-off, and the ability to view, retrieve or print audit reports. The auditors will use the system to directly create, review, and finalize audit reports and Site Action Response Forms (SARF) within the system. Any issues or opportunities identified in a site will be reviewed to determine if they could affect all sites so that we can develop best practices to be shared across all CP-CTNet Sites.

The auditing unit has been creating documentation, including the CP-CTNet Site Preparations for Audit SOP, internal DMACC Auditing procedures, audit plans, and report templates. We have also participated in continuing education for the auditing unit staff. We are very excited that the first few CP-CTNet studies will be opening soon. We look forward to meeting and building strong relationships with each LAO and AO in the coming months and year 2!

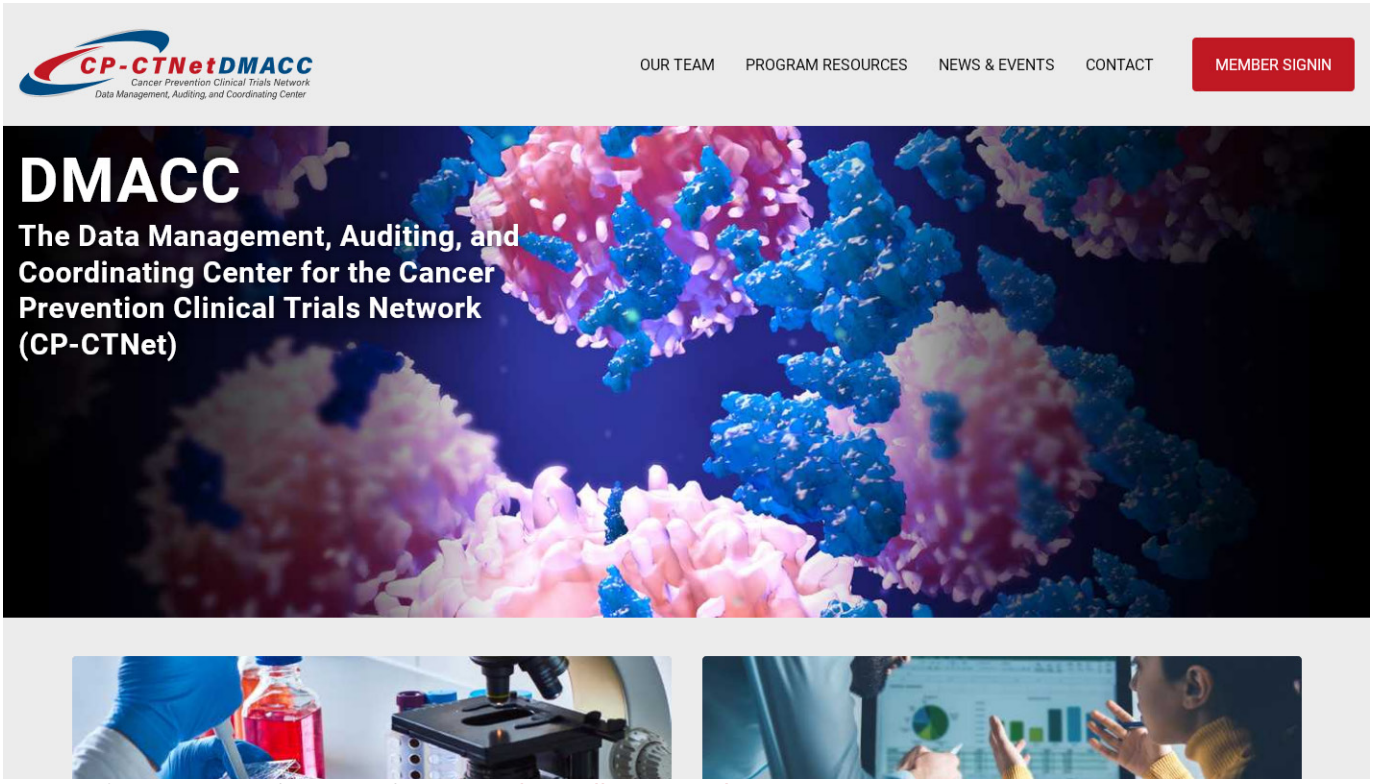
Administrative and Coordinating Unit

The Administrative and Coordinating Unit certainly has been busy since funding began on September 20, 2019. As year one wrapped up on July 31, 2020 we look back with great pride on all of our accomplishments and look forward with anticipation and excitement for what is to come. The Operations Management Subunit has provided administrative support and logistical coordination for CP-CPNet to include: meeting support, budget management and preparation of the annual report to the NCI. We look forward to hopefully coordinating the next in-person I-SCORE meeting in April 2021! We also are in the process of developing educational and training materials to support clinical and CP-CTNet operations in recruitment and retention at all CP-CTNet Sites. The Statistics Subunit has provided support reporting for the Data Management and Reporting Unit including the reports for the Accrual Quality Improvement Program (AQuIP), and provided reviews of CP-CTNet trials electronic Case Report Forms (CRFs) and System Variable and Attribute Reports (SVARs) to DCP. It is available to CP-CTNet Site investigators and statisticians in a consulting capacity and is responsible for clinical trials methodology

and biostatistics for CP-CTNet cross-network studies. The Statistics Subunit has been reviewing all comparative trials conducted under the 2003 and 2012 Consortia Program to understand what the gap is between the design of these comparative trials and their findings in terms of planned vs realized sample size, planned vs estimated effect size, and planned vs post-hoc power. In collaboration with the DCP investigators, the Statistics Subunit plans to present and publish the findings. It will play a key role in biomarker studies, biomarker-driven adaptive trials and precision oncology for cancer prevention trials.

DMACC Portal Gateway

DMACC is pleased to announce the release of the DMACC Website and Portal Gateway! This truly has been a labor of love. The DMACC staff have devoted many hours/weeks/months (attempting to see this through the eyes of busy coordinators, PIs, and DCP staff) into getting this just right so that it is a user-friendly environment. This custom website was designed to serve as a "one-stop-shop" for all your CP-CTNet needs. The site consists of three areas:



Pictured: DMACC Portal Gateway homepage https://cp-ctnet-dmacc.org

- Public site: general information about the project, its progress, publications, leaders, cores, meetings, etc.
- Private site (for site staff access): restricted access to various resources and systems, including project documentation, gateway entry points for systems like Medidata Rave, the subject enrollment system (Stars), recruitment information, support material for those systems, etc.
- Private site (for DMACC and DCP access): protected access to data retrieval tools for statisticians, administrative information, and support to collaborators, such as email lists and various team reports.

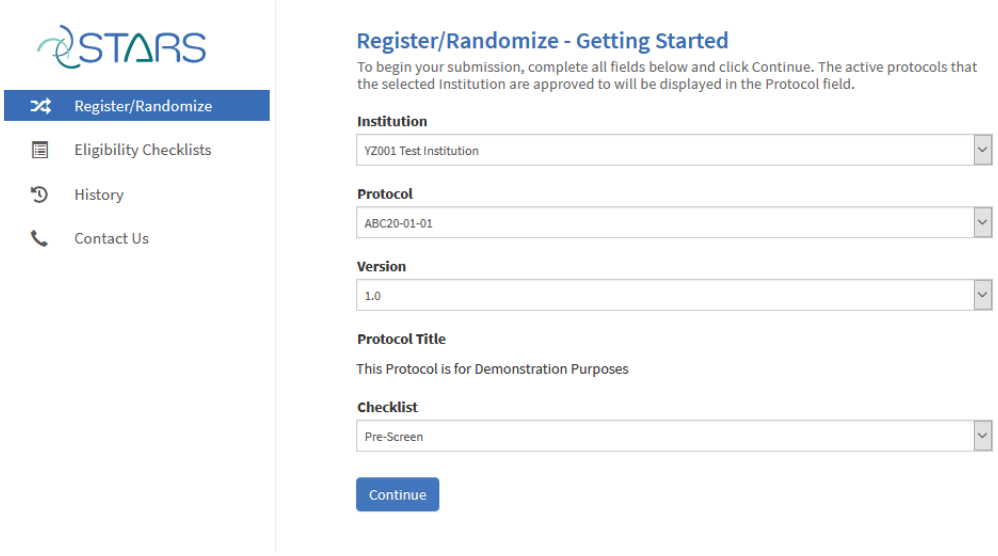
Please visit the website frequently and bookmark it! If you would like to see any additional features or components that would be helpful to you, please don't hesitate to reach out to us, Admin_CP-CTNet@frontierscience.org. This website will be ever evolving and we certainly welcome your input to improve upon its functionality.

Introduction to Stars and Rave

There are two primary systems used to collect data for CP-CTNet protocols:

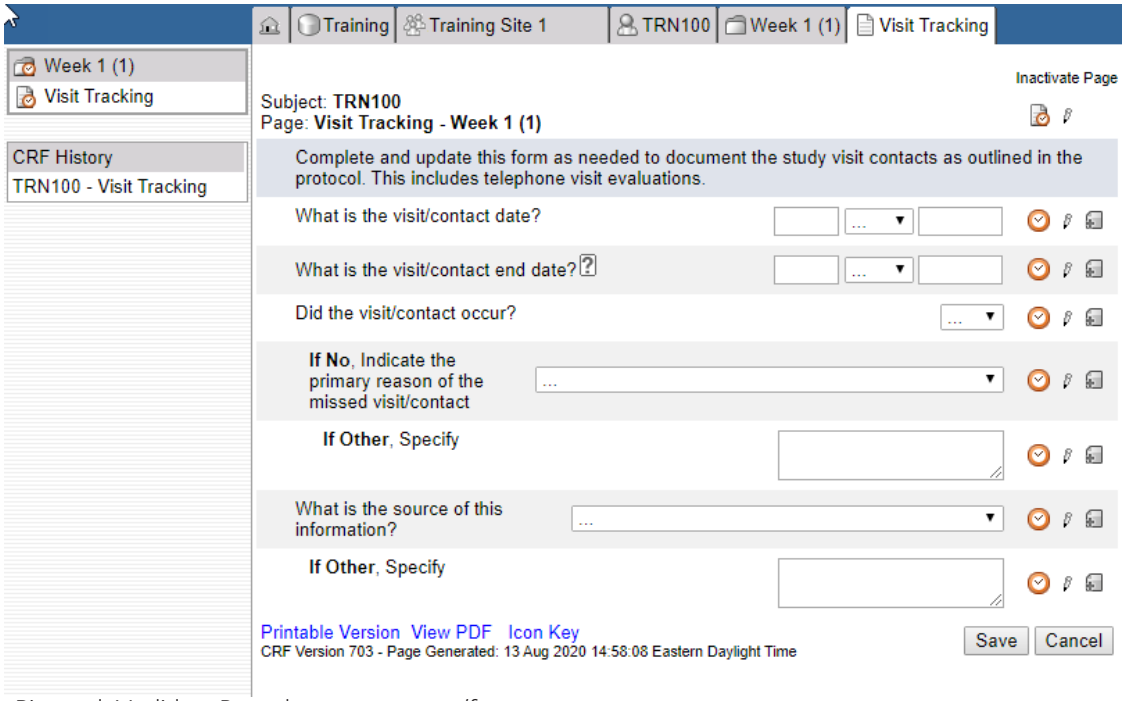
Stars is the enrollment system developed by DMACC that sites will use to obtain Participant IDs, for pre-screening, screening and registration/randomization. Sites may also download Eligibility Checklists and a History of completed enrollments.

The Stars enrollment system transfers the data it collects to the Rave system to initialize the participant in the system so clinical data collection can begin. This automatic data exchange to Rave occurs within a few minutes of entry, which eliminates data duplication and allows for one central database.



Pictured: Stars registration page

Medidata Rave is the Electronic Data Capture system (EDC) that sites will use to enter protocol-specific Electronic Case Report Form (eCRF) data, including data related to the Accrual Quality Improvement Program (AQuIP), such as pre-screening/ screening strategies and outcome, and Recruitment Journaling information –events that occur at the study or site level that may affect participant enrollment. Rave also provides several reports within the system to assist LAOs and AOs in monitoring study status in relation to data submission, queries, and enrollment.



Pictured: Medidata Rave data entry screen/form

Why Quality? Aspects of Quality in the CP-CTNet Project

By Colleen Woodworth, JD, Compliance Officer, Frontier Science

What comes to mind when you hear "quality"? Does it sound like a vague, somewhat meaningless concept, something that might be nice in theory but doesn't bear much weight in the real world? If so, you certainly aren't alone. It is common for people to think of simply performing their work first, as the most critical priority, and then thinking about things like quality later. However, by acknowledging the role and requirements of quality and by utilizing a quality management system (QMS), you can actually decrease time spent on work, reduce mistakes, find more efficient work flows, and most importantly, ensure that study participants are kept safe and the data provided are as accurate and complete as possible, which after all is the reason that we conduct research in the first place. The Clinical Trials Transformation Initiative (CTTI) has defined quality as "the ability to effectively answer the intended benefits and risk of a medical product (therapeutic or diagnostic) or procedure, while assuring the protection of human subjects". Thus, there is a clear link between quality and participant well-being, as well as between quality and sound research.

The CP-CTNet DMACC has been established on the principles of quality, using a defined quality management system which will ensure that work flows are standardized, mistakes are quickly caught, deviations effectively managed, and that the data are accurate. One component of the QMS is a quality management plan (QMP), which guides how quality control

The Reporting and Data Management Unit of the DMACC is based out of Frontier Science's New York office, just outside of Buffalo.

and assurance will be implemented, and is based on project collaborators' and organizational leaders' determination of the values that are critical to the trial and program, and how those might be achieved. Quality management is being implemented in CP-CTNet through various guidance documents, including the CP-CTNet Program Guidelines, SOPs, reference documents, and a single Master Data Management Plan to apply across all studies and sites (replacing LAO-specific plans), with the goal of ensuring consistent procedures and a standard level of quality control. These documents can be found on the CP-CTNet Portal Gateway. Please be sure to review these documents and make sure that your staff is likewise aware of their existence.

In addition to this, the DMACC has created a host of other guidance documents to map out its internal workflows and therefore ensure a consistent approach to quality. These documents will inform current staff and also act as onboarding material for future employees. The Manual of Operations Table of Contents was created and approved by DCP and the CP-CTNet Steering Committee. Several more detailed SOPs and procedural documents are also under development to ensure full compliance of the DMACC with project requirements as well as regulatory requirements (e.g., DMACC Data Management Plan, Site Training SOP, etc.) while also ensuring audit readiness.

Another important component of a robust QMS is training. This goes somewhat hand in hand with the documentation described above; the ultimate goal being to ensure that all project staff are aware of their required work flows and are capable to conduct their duties with full attention to detail. For example, a tutorial was created to provide an overview and demo of how Stars and Rave will be used within CP-CTNet, which was presented during the I-SCORE Meeting and is currently

(Continued on next page)

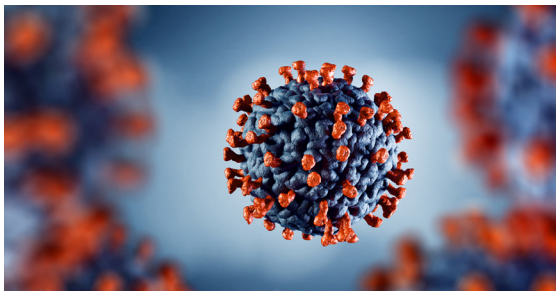
available to all sites. Additional tutorials will be developed for the benefit of all project staff and announcements will be sent to sites, indicating the location on the CP-CTNet DMACC Portal Gateway. Internal training is likewise important; all sites should be sure that their staff are familiar with their own standard operating procedures and work flow requirements.

All parties are already likely aware that one of the most critical components of a solid QMS is an auditing program to ensure both that sites have all the necessary workflows established and are comfortable with what they are doing, and also to ensure audit readiness in the event of audit by a regulatory agency or sponsoring entity. CP-CTNet has its own Auditing Unit who will be responsible for confirming site compliance, and these reviews will be accomplished using an auditing plan and schedule for participating sites. The first round of audits will focus on the evaluation of internal procedures, templates, and SOPs to ensure their accuracy and to suggest any revisions as needed. The Auditing Unit will also work closely with the DMACC UW Statisticians to discuss plans for audit findings to be examined and analyzed statistically for trends and patterns within and across sites and trials. The DMACC plans to release an auditing system to be created by the software development team at Frontier Science, which will assist in tracking audits, corrective and preventative actions, and any other observed gaps or noncompliances. Auditing is a critical tool to ensure that all entities understand their overall mission and are conducting their duties compliantly and per regulatory expectations. These should be used as opportunities to learn from any mistakes, to correct deficient documentation, and to make work flows more efficient. It is better to have an item discovered by the internal Auditing Unit rather than by a regulatory agency!

Last, staying on top of trends in regulations and other industry best practices is always critical to the success of a project and contributes to its overall quality management system by ensuring that best practices are integrated into all work flows. The DMACC will use the CP-CTNet DMACC Portal Gateway to disseminate information about study updates, but will also use it to post new guidance materials and other publications provided by the various regulatory agencies. In addition, this newsletter will act as a means of communication to ensure that all participating entities are on board with any project updates and changes in the compliance/regulatory environment. From time to time, it may be helpful to engage the Audit Team and determine if there are any systemic issues noted as far as compliance, so that all project members are cognizant of potential pitfalls and can correct them in their own institutions.

Remote Auditing Anticipated Due to COVID

Back in December 2019 when we first started hearing reports of a new strain of coronavirus that had not previously been identified in humans little did we know how it would upend the world! Never in our lifetime did we think the words pandemic and shelter in place would we used so frequently. Travel was suspended for most world academic enterprises beginning in March 2020 and we all have pivoted to the new work from home environment. By April 2020 most, if not all, clinical trials came to a screeching halt due to safety concerns for subjects, researchers,and clinical research staff. Trials needed to be adapted and trial sponsors or research organizations needed to be flexible and issue guidance on how to report protocol deviations, record covid-19 as an adverse event, etc. It will be interesting to see how this pandemic impacts analyses and subsequent results of many clinical trials. Fast forward to today and COVID-19 continues to be an emerging, rapidly evolving situation. There might just be a silver lining to the current dire global situation with respect to progress in clinical trials. Remote/Virtual auditing for years has not really had any traction due mostly to the gold standard of auditing in person/on-site. The pandemic certainly has shown how we can persevere by embracing the technology that is accessible from virtually anywhere in the world. Changes are on the horizon in clinical research and likely will be embraced by research staff and subjects alike. In-person subject visits may just become passé. Remote visits (when and where possible) and remote auditing could result in a win-win situation. The burden on subjects, staff, and cost of on-site auditing would all be reduced. A paradigm shift will not happen overnight, but these truly are exciting times of great change. Research organizations are finding new ways to be creative and embracing new technology to still meet the GCP standards and requirements set forth by a protocol, institution, or regulatory agency to ensure high quality clinical trial data.



In Other News ...

We can officially kick off the first study of the CP-CTNet! It is really happening! The inaugural study will be: UAZ20-01-02 *An Extended Follow-up Study of the HPV Vaccine Delayed Booster Trial*, and is anticipated to start in September.

It is a prospective, single-arm, open-label, non-randomized, phase IIA trial of a nonavalent prophylactic HPV vaccine (Gardasil 9) to assess immunogenicity of a prime and deferred-booster dosing schedule among 9-11 year old girls and boys.

This is a follow-up study of the currently ongoing "HPV vaccine delayed booster trial" in the Consortia program (UAZ2015-05-01) examining the nine-valent HPV vaccine (Gardasil 9) in girls and boys aged 9-11 to determine the stability of serologic response after a delayed booster (administered 24 months after the initial vaccine dose). The currently ongoing study has accrued very well, has outstanding retention, and will provide important data on stability of the vaccine response up to 24 months post initial vaccination. A booster (second dose) was given to all participants at 24 months and an option for a third dose to be administered at 30 months. The majority of families in the study refused the third dose. The proposed trial intends to determine the stability of the type-specific serologic response in geometric mean titer (GMT) of HPV16 and HPV18 between 6 vs. 24, 24 vs. 36, and 36 vs. 48 months after the delayed booster of Gardasil 9 (primary endpoint). It is expected that 120 participants will be enrolled. Secondary endpoints are to determine the stability of type-specific serologic GMT for the other HPV types in the vaccine during the same time points.

The Study Initiation Meeting was held August 19, 2020 and included UA staff (LAO), UCLA staff (AO), DCP staff and DMACC staff.

Way to go University of Arizona!

Highlights of I-SCORE Presentations

Thank you to all the presenters and participants who attended the April 2020 I-SCORE Meeting! Despite a change to a virtual format, over 120 people attended. The meeting provided a great opportunity for information-sharing and collaboration between DCP staff, program staff, and Consortia/CP-CTNet members. Highlights of the first half of the program included:

- Dr. Eva Szabo provided an overview of both the Consortia and CP-CTNet Programs, including the science and status of the Consortia studies. For CP-CTNet, Dr. Szabo reviewed the infrastructure, approved concepts, and Program logistics.
- Consortia Clinical Trial Reports were presented by Principal Investigators & Study Coordinators, and included overviews of the trial concept, status, and results, as well as shared experiences of trial conduct.
- Ellen Richmond presented the Accrual Quality Improvement Program (AQuIP), and insights gained from reviewing accrual-related data from 40 studies.

The final portion of the agenda focused on the CP-CTNet Data Management, Auditing & Coordinating Center:

- Dr. KyungMann Kim provided an overview of the DMACC & progress made thus far.
- Sue Siminski gave a demonstration & overview of Stars, the Registration/Randomization System, & Medidata Rave, the electronic data collection system, for the CP-CTNet Program.
- Lynette Blacher provided an update on the trial conduct documentation for the CP-CTNet.
- Holly Shaw gave an overview of the audit program & online system which is in development.

The meeting was a great collaboration and we are already looking forward to next year's I-SCORE Meeting!

CP-CTNet Lead Academic Organizations

There are five Lead Academic Organizations along with their Affiliated Organizations (AOs) that make up the CP-CTNet Sites. New to the network are the Early Phase Clinical Cancer Prevention Consortium at the University of Michigan, and the MW Chemoprevention Network at the University of Wisconsin. We are pleased to welcome these academic centers to the network and look forward to continuing our work with all five organizations.

CP-CTNet Lead Academic Organizations:

Robert H. Lurie Comprehensive Cancer Center of Northwestern University, Northwestern Cancer Prevention Consortium, Northwestern Cancer Prevention Consortium, led by Seema A. Khan, M.D.

University of Arizona, University of Arizona Cancer Prevention Clinical Trials Network (UA CP-CTNet), led by H. H. Sherry Chow, Ph.D. and Julie Bauman, M.D., M.P.H.

University of Texas MD Anderson Cancer Center, iCAN-PREVENT: International Cancer Prevention Clinical Trial Consortium, led by Powel H. Brown, M.D. and Eduardo Vilar-Sanchez, M.D., Ph.D.

University of Michigan, Early Phase Clinical Cancer Prevention Consortium, led by Dean Brenner, M.D. and Zora Djuric, Ph.D.

University of Wisconsin, The MW Chemoprevention Network, led by Howard Bailey, M.D.

Projects in the Pipeline

UAZ20-01-02
Title of Study: An Extended Follow-up Study of the HPV Vaccine Delayed Booster Trial

UAZ20-01-01
Title of Study: Clinical Study of Bioactivity of Low Dose Apalutamide in Prostate Cancer Patients Scheduled for Prostatectomy

NWU20-01-03
Title of Study: Role of Lisinopril in Preventing the Progression of Non-Alcoholic Fatty Liver Disease (NAFLD): Relief-NAFLD

NWU20-02-01
Title of Study: Surgical Window of Opportunity Study of Megesterol Acetate and Metformin for Endometrial Intraepithelial Neoplasia

MDA20-01-01
Title of Study: A Phase IIa, Placebo-Controlled, Randomized Study of Daily Obeticholic Acid (OCA) to Reduce Intestinal Polyp Burden in Familial Adenomatous Polyposis (FAP)

NWU20-02-02
Title of Study: A Randomized and Placebo-Controlled Phase II Trial Targeting Dominant-Negative Missense Mutant p53 by Atorvastatin for Reducing the Risk of Longstanding Ulcerative Colitis-Associated Cancer

MDA20-02-01
Title of Study: Time Restricted Eating and Metformin (TEAM) in Breast Cancer (BC) and Adjacent Intraepithelial Neoplasia (IEN). A Randomized, Phase IIb, Window of Opportunity PreSurgical Trial. (TEAM Trial)

Update from the External Advisory Committee

The DMACC convened an External Advisory Committee (EAC) via web conference on July 28 to advise the DMACC leadership on its operation and programmatic issues. EAC members will review the scientific and administrative progress of the DMACC and make recommendations to complement our effectiveness. Members will consider our mission, goals, science, planning, and future directions. The EAC consists of Ernest Hawk, MD, MPH, Catherine Tangen, DrPH, and Eleanor McFadden, MA, pictured below from left to right. The EAC members are highly recognized experts in the area of cancer prevention clinical trials and coordinating center operations. We plan to convene again in person at Frontier Science in Spring 2021 if travel restrictions have lifted.

Message from the DMACC Investigators

We hope that you found this newsletter insightful and useful as we would like to use it as a communication tool for all CP-CTNet members to showcase future information happening across the CP-CTNet. After a successful first year of building an infrastructure to support the CP-CTNet, attending the I-SCORE Meeting, virtually meeting LAO/AO staff and current key contractors, as well as working closely with the DCP to carry out its vision, the DMACC is excited about opening up the first study of the newly structured CP-CTNet. As we enter the opening phase for this project, we would like to take this opportunity to congratulate the entire team on achieving this milestone and look forward to the Network's subsequent studies and advances in cancer prevention. If you have future newsletter ideas and suggestions, please email Admin_CP-CTNet@frontierscience.org.

Thank you,

KyungMann Kim, DMACC PI, University of Wisconsin

Sue Siminski, DMACC SubPI, Frontier Science Foundation

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CP-CTNet Website
https://prevention.cancer.gov/major-programs/cancer-prevention-clinical-trials-network