June 2021

CP-CTNet NEWSLETTER

Cancer Prevention Clinical Trials Network

HAPPY SUMMER!

The summer solstice this June 21st officially marked the start of summer and that always reminds us of running through a sprinkler on a hot day, melting ice cream cones, neighborhood lemonade stands (like Alex's), water balloon fights, trips to the beach, catching fireflies (or "lightning bugs," if you reside in the Midwest or the South), sounds and aromas from our backyard grills, fresh cut grass, sheets drying on the clothesline, and heading out on a bicycle adventure until dusk.

May you all still cherish the memories of sunny summers spent with family and friends. Hopefully, we can make new memories this summer as the world slowly awakens, refreshed from the pandemic.

We look forward to seeing our CP-CTNet colleagues in person in the coming months vs. via Zoom/Webex and eagerly anticipate more participants joining our trials.

Contents

NCI Cancer Prevention Clinical Trials Network

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

DMACC Updates

Data Management and Reporting Unit


Lynette Blacher, MLS – DMACC Project Lead / Manager
Kayla Denson, PhD, MBA – DMACC Senior Data Manager
DMACC Data Management and Reporting Unit

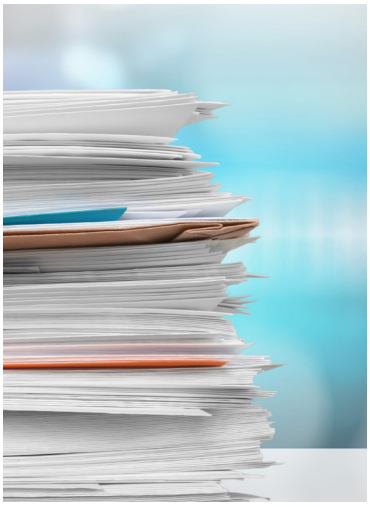
A number of new procedures and initiatives have been finalized and are being implemented by the Data Management and Reporting Unit since our previous newsletter.

Protocol Deviations

A Protocol Deviation Notification eCRF is being added to all studies to allow for the reporting of deviations by an AO directly in Medidata Rave. This is replacing the previously used PDF form and will help facilitate a more streamlined review process, where the LAO and Medical Monitor/Nurse Consultant will be notified by email when their review is required. The LAOs and Medical Monitors/Nurse Consultants will have the ability to enter queries in Rave for the AO to resolve. Medical Monitors/Nurse Consultants will enter any review comments directly on the eCRF and assign a grade for the deviation. Training on this new process will be offered in the coming weeks.

SVAR Development

As of June 2021, a new System Variable Attributes Report (SVAR) development and review process has been implemented. The DMACC will now be responsible for drafting the initial SVAR, with LAO input, for all new studies moving forward. When the DMACC and the LAO determine that the SVAR is ready for wider review, it is submitted to the DCP Regulatory and CDE Contractors. Once all issues are resolved and the SVAR is found to be acceptable by this group, it is submitted to the DCP Study Team for final review and approval. This new process is anticipated to reduce the number of review cycles, allowing the eCRFs to be implemented in the Rave database more quickly. For more details, please refer to the newly updated **SOP 02-03 Electronic Case Report Form Development** and the **SVAR Template**, both of which are available on the **DMACC website**.



Participant ID Reservation

The Reserve PID Module is now available in the Stars Registration/Randomization System. At the time a study receives Approval on Hold from the Protocol Information Office (PIO), DMACC will contact the LAO to confirm which staff will be responsible for reserving Participant IDs, so that the appropriate access can be granted. The LAO will reserve a block of PIDs for each AO participating in the study, which will facilitate the advance creation of labels at the site.

Treatment ID Assignment

The Treatment ID assignment procedure has been finalized for use in CP-CTNet studies that involve study agent. The LAOs will proxy request access to the Treatment Assignments Module in the STARS Registration/Randomization System for AO pharmacists that are involved in dispensing study agent. The site pharmacist uses the Treatment ID Module in Stars to access the Treatment ID List, which maps the Treatment ID to the participant's assigned treatment regimen.

If an over-label needs to be applied to the study agent, the DMACC sends a list of the Treatment IDs assigned to each of the participating sites to MRI Global. MRI Global generates the over-labels for each Treatment ID and ships them to the pharmacy for each site. The pharmacist selects the appropriate over-label, applies the assigned Treatment ID over-labels to the appropriate agent, and writes-in Participant ID and initials before dispensing to the participant.

Study Builds in Rave

Study builds are underway for three studies with finalized SVARs. Migrations are also being planned to add the new COVID-19 and Protocol Deviation eCRFs to studies that are already in production and will be available in the coming weeks. SVARs are currently in development for five additional studies. NWU20-01-03 (Lisinopril-Liver) and UAZ20-01-01 (Apalutamide-Prostate) were deployed to production and have now begun enrolling.

Recruitment Journal

The ability to enter Recruitment Journaling data is now available in Medidata Rave for active studies. Sites are expected to: enter site-specific events that affect accrual into the Recruitment Journal – Site-Specific Events eCRF and ensure these data are updated by the last business day of each month, so they may accurately be reflected in the AQuIP Reports. Access to this eCRF will become available when a site pre-screens their first participant for a study. The site-specific events are defined in the SVAR Template and training materials for the Recruitment Journal are forthcoming. The DMACC is now responsible for reporting overall protocol information and the events that affect the study as a whole.

COVID-19 eCRFs

The DCP will now be requiring COVID-19 testing and vaccination questionnaires to be included in every CP-CTNet study's set of eCRFs. Baseline and Follow-up Assessment eCRFs have been developed and incorporated into each new study's SVAR. Studies that are currently in production will undergo migrations in the coming weeks to add these two eCRFs to the Rave database. Data will be collected moving forward and sites will not be expected to retroactively report information at participant visits that have already occurred.

Meetings

Since the last newsletter, the DMACC has participated in the Study Initiation Meeting (SIM) for the UAZ20-01-01 (Apalutamide-Prostate) study. Topics included: study start-up, CP-CTNet website and portal gateway access, user access, DMACC systems, demos and training requirements for the STARS Registration/Randomization system and Rave, data management and quality control, auditing, SOPs and documentation, and communication.

Educational Materials and Training

Recently added content to the CP-CTNet website includes: several training materials (including video tutorials on Reserving Participant IDs and Determining Treatment Assignments), reference guides for Rave Reports and the Participant Enrollment Process, and updates to the STARS User Manual and the STARS/Medidata slide presentation. You will additionally notice updates to: the Regulatory Documents and Electronic Case Report Form Development, the Master Data Management Plan, the SVAR Template, and the Delegation of Tasks Logs. You can also look forward to upcoming webinars on the Protocol Deviation eCRF and using the reports in Medidata Rave to monitor data and query status.

Clinical Trials Auditing Unit


Holly Shaw, MS, CCRP
Barbara Wollmer, BSN, RN
DMACC Auditing Unit
Co-Managers

It has been a busy few months for the DMACC Auditing Unit! Thank you to the LAOs and AOs that completed the DMACC Auditing Survey regarding your sites' capabilities for EHR access procedures, source data, and capacity for remote auditing. We are happy to see that COVID-19 restrictions are beginning to relax at some institutions. We also learned a lot about the various systems and policies sites have in place. In total, we received 35 surveys.

We have spent a lot of time recently collaborating with the DCP to finalize a Protocol Risk Assessment tool. The purpose of protocol risk assessment is to help determine the level and focus of source data verification (SDV) required during an audit. This tool describes the criteria and process used to assign a risk level to a CP-CTNet protocol. The protocol risk level is assigned by the DCP study team during the protocol review process and documented on the Consensus Review of the first submission of a protocol, after concept approval. Risk (low, intermediate, or high) is assessed for seven categories: agent approval status, toxicity, administration and storage, clinical procedures, health status of the study population, and participant's ability to provide informed consent. The protocol risk level is a key part of the algorithm that determines the level of SDV that will occur for each participant chart selected for review during an audit. We will utilize a module in Medidata RAVE called Targeted Source Data Verification (TSDV) for participant chart reviews during audits.

Our web-based auditing system is nearly ready for Phase I release and we're working closely with programmers to conduct user testing and validation. We anticipate conducting our first CP-CTNet audits in late summer for the HPV extension study.

On June 29th, at the LAO auditing webinar, we discussed auditing guidelines, auditing versus monitoring, LAO responsibilities, and RAVE reports. We will provide a summary of the meeting in our next newsletter.

Administrative and Coordinating Unit


Kelly Miller, BS, CCRC
Administrative and Coordinating Unit Manager
Bridget Dermody, BS
Administrative Specialist

I-SCORE 2021 Meeting Recap

A much-deserved thank you to all the organizers, presenters, and participants that attended the 2021 Investigators' and Site Coordinators' Opportunity for Research Excellence (I-SCORE) meeting on April 29th and 30th! Despite another virtual format, we hosted over 140 people globally! This meeting provided a great opportunity for collaboration and information-sharing between the DCP staff, program staff, and Consortia/CP-CTNet members. Dr. Philip Castle introduced himself as the new Director of the Division of Cancer Prevention and expressed his excitement about future advances in the field of cancer prevention. 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. Sza-bo reviewed infrastructure, and approved concepts and program logistics.

Feedback was quite positive following the meeting, with many expressing how smoothly it went and that the topics discussed were very relevant and showcased strong science. We look forward to gathering more feedback after the 2022 meeting in order to provide the best experience possible. Read the 2021 agenda here.

The meeting was a great success in collaboration and we are already looking forward to next year's I-SCORE 2022 meeting, when we're hopeful to visit in-person again in Rockville, MD on March 31st to April 1st! Check the News & Events tab on the DMACC webpage for upcoming information regarding the 2022 meeting as it becomes available.

If you have questions, please contact us at: Admin_CP-CTNet@frontierscience.org

Upcoming Events

July 28
External Advisory Committee Meeting with the DMACC

July 30
Quarterly Steering Committee Meeting (Virtual)

September 13-14
TACPAD Virtual Workshop

TBD Fall 2021
Fall Retreat at Frontier Science Foundation

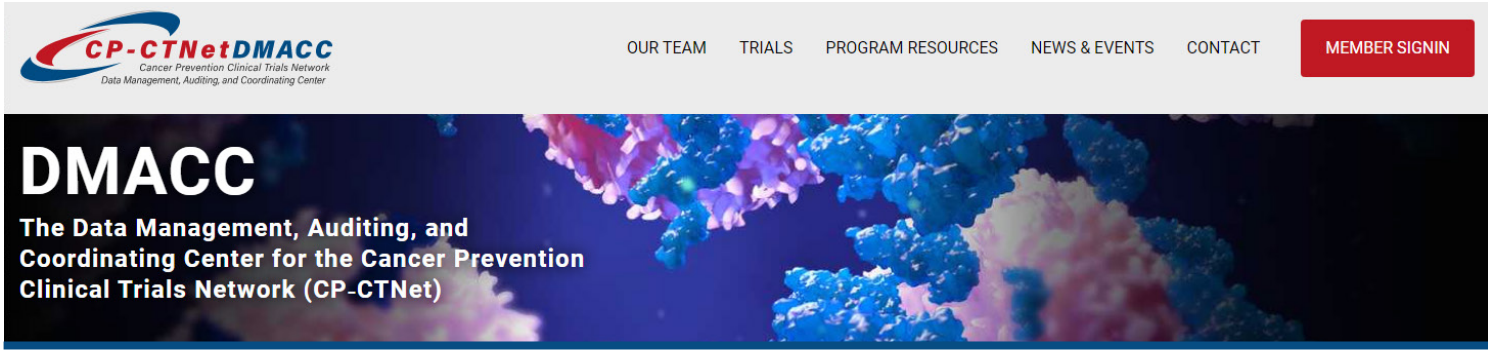
2022:
March 31 & April 1
I-SCORE 2022 in Rockville, MD

DMACC Website Updates

A CP-CTNet *Website Review Committee* was formed recently and meetings were held in March and April of 2021 with another meeting planned for the end of June 2021. The purpose of the *Website Review Committee* is to provide oversight and strategic direction for the CP-CTNet DMACC Portal Gateway including the following:

- Review and make recommendations for website design, presentation, and layout
- Discuss, plan, and prioritize requests from the LAOs, AOs, and other network members
- Ensure the DCP CP-CTNet website and CP-CTNet DMACC portal gateway operate as complementing websites

The committee has representation currently from the DMACC and the DCP. The committee will plan to meet about four times per year to review current website requests and discuss future enhancements. We continue to implement suggestions from our colleagues in the network to improve the user experience with the page. Feel free to reach out to us at Admin_CP-CTNet@frontierscience.org if you have further suggestions. The webpage evolves frequently, so please visit often for up-to-date news on things happening in the network.



Website & Portal Gateway Update

David Goss, MA – Software Engineering Business Analyst

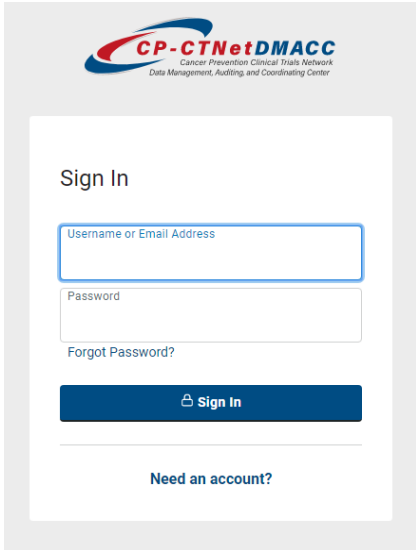
We are always working to improve the DMACC website at cp-ctnet-dmacc.org. Since the last newsletter, there have been a number of exciting updates aimed at helping CP-CTNet colleagues find information.

A new Contact Directory has been added to the Contacts page. The Contact Directory is a searchable list of the DMACC, the DCP, and LAO staff. You can use this tool to quickly reach project staff.

A new Trials page shows active and upcoming trials. This page pulls data from ClinicalTrials.gov for select CP-CTNet studies. Since the data are pulled from ClinicalTrials.gov, make sure that the

information for your study is up-to-date and accurate. Note that not all studies may appear here right away. If you are expecting to see a study that is not listed, please contact us at Admin_CP-CTNet@frontierscience.org to let us know.

Recent content added to the CP-CTNet Website includes training videos, reference/user guides, informative presentations, and other resources intended to assist in training site and LAO staff in regards to their day-to-day CP-CTNet activities (please refer to the DMACC Data Management and Reporting Unit Updates starting on page 2 for more details). We make several updates to the website each month. Check back often for the latest project documents, news, and upcoming events.



Functionality of the CP-CTNet DMACC Public Website and Portal Gateway

Alex Krolikowski, MS – Training Specialist

The DMACC website provides an innovative one-stop shop where CP-CTNet colleagues can access a variety of systems and resources to support their work. This website was custom-built for CP-CTNet and is continuously updated to stay current with network activities and provide timely resources to staff as the project evolves. The project website is divided into two access areas: the public section and the member section (aka the Portal Gateway). This article describes the functionality and key features of both sections of the CP-CTNet DMACC website.

Public Website

The public section of the website contains generally-available information about the project and provides administrative support to collaborators. Publicly-available information about the network can be accessed via the navigation links at the top of the public website homepage.

Navigation Links on the CP-CTNet DMACC Website

Our Team

Provides an overview of the organizational structure of CP-CTNet and information about the collaborative institutions and operational units that make up the DMACC.

Trials

Includes a directory of CP-CTNet clinical trials that are currently active and approved by the DCP. Click the trial name to access trial-specific details such as the trial description, eligibility criteria, or outcomes.

Program Resources

Provides an extensive list of publicly-available documents that are used to support LAOs and AOs from concept development to study close-out. Enter criteria into one or more filters to limit the resources displayed in the table. The available resources are updated as the project progresses.

News & Events

Access network news updates, upcoming events, newsletters, and memos from key Steering Committee meetings.

Contact

Provides a list of the DMACC, DCP, and LAO organizational contacts as well as a searchable CP-CTNet contact directory.

Member Sign In

Access the Portal Gateway via the Member Signin button

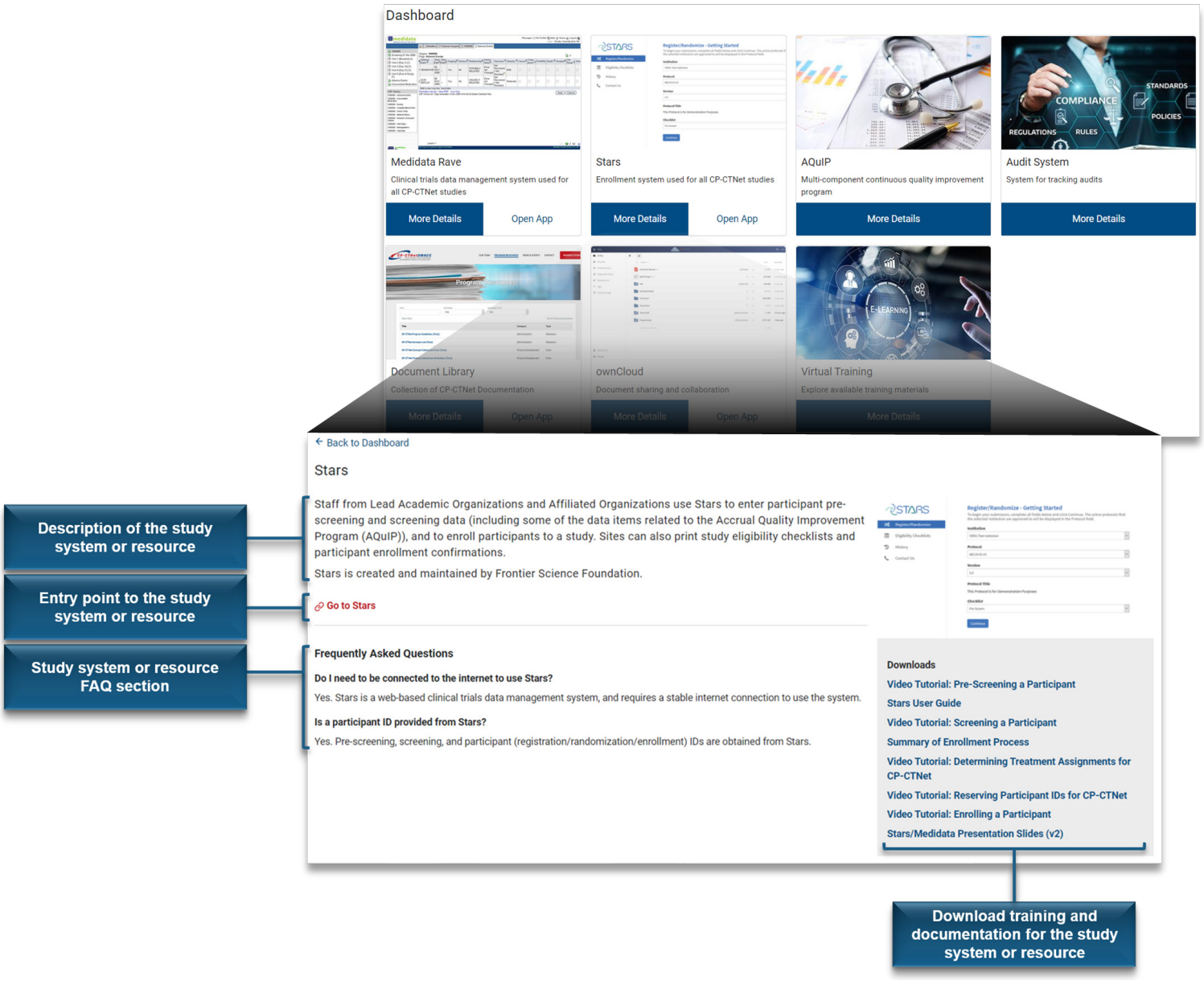
CP-CTNet DMACC Portal Gateway

The Portal Gateway provides member-only access to the Portal Gateway Dashboard, which houses a wide variety of applications and tools for facilitating the progress of CP-CTNet. These resources are continuously updated and include entry points and support for study systems, program resources, training materials, and secure access into the CP-CTNet Central Database via Medidata Rave.

Accessing the CP-CTNet DMACC Portal Gateway

Portal Gateway access is requested by an LAO designee (usually the Study Coordinator) via Member Sign-in on the CP-CTNet DMACC website. They select Need an account? to requests access. The LAO designee proxy requests access for LAO and AO staff based on their study role via Request a User on their Portal Gateway Dashboard.

Site	No. Registered
Frontier Science Foundation	25
NIH/NCI	31
University of Wisconsin	11
Northwestern University	3
UCLA	3
University of Arizona	11
Cedars-Sinai Medical Center	3
University of Michigan	1
Mayo Clinic/MW Consortium	1
Mayo Clinic Rochester	1
MD Anderson Cancer Center	3
USC Norris Cancer Center	2
John/Hopkins / SK CC	2
Duke University	1
University of Wisconsin/WI020	1
TOTAL	**99**



Portal Gateway Dashboard

Users are taken to the Portal Gateway Dashboard A signing into the Portal Gateway. The Portal Gateway Dashboard is organized using tiles that provide a link to a webpage designed for each study system or resource, including:

1. Medidata Rave
2. Stars
3. Accrual Quality Improvement Program (AQuIP)
4. Audit System
5. Document Library (Program Resources)
6. ownCloud
7. Virtual Training

Next Steps

1. Bookmark the CP-CTNet DMACC website in your browser for quick access to the latest CP-CTNet information, documentation, and resources in one, central location.
2. Access network news, events, resources, directories, and a secure sign-in to the Portal Gateway via the public website.
3. Explore member-only resources (AQuIP, Virtual Training, ownCloud) and network systems (Medidata Rave, Stars, etc.) designed to support CP-CTNet research activities via the Portal Gateway.
4. Please reach out to us at with any suggestions to improve the user experience with the public website and/or Portal Gateway.

Staff Spotlight

What does a Nurse Consultant do for the CP-CTNet at the NCI Division of Cancer Prevention?

A Nurse Consultant evaluates both overall healthcare delivery systems and individual patient cases. A Clinical Nurse Consultant role includes teaching, researching, and clinical practice.

The CP-CTNet is fortunate to have these wonderful nurse consultants to advise us and collaborate with us as we continue to grow our network. They are committed, diligent, resourceful, and full of heart. Take time to get to know a little bit about each one on the next few pages. Rely on their knowledge and experience to assist with your clinical trial successes.

The Division of Cancer Prevention consists of 18 major programs and 10 research groups. Four of these research groups (Breast and Gynecologic, GI and Other Cancers, Lung and Upper Aerodigestive, and Prostate and Urologic) work together to form and provide oversight for the CP-CTNet Program. At the heart of each of these four groups is a nurse consultant. They serve as the primary liaison between the DCP Research Group, the LAOs that are developing and conducting the cancer prevention trials, and the many services and programs that serve the network. The nurse consultants are an invaluable resource. They have a wealth of knowledge, are problem solvers extraordinaire, and are pillars of support for the Network. Let us introduce you to these 5 amazing nurses that we are so fortunate to work with:

Meet our CP-CTNet Nurse Consultants

What made you want to become a nurse?

Maggie House

"In 5th grade, I was hospitalized for a month with viral meningitis and encephalitis (for supportive care, as there were no antiviral medications); and in 9th grade I was hospitalized for a ruptured appendix. During those experiences, my most vivid memories are of the compassionate and skilled nurses who cared for me. These experiences also contributed to my decision to persue a career in nursing."

"I started out wanting to do psychology. Working as a Nursing Assistant in a nursing home as a teenager, I was quickly drawn to the nursing aspect of patient care. I decided to become a nurse where I could use my interests to help in the field."

Val Dyer

"In high school, I had lots of orthopedic surgery as a child and; thus, spent a lot of time with nurses.

This for sure influenced my choice!"

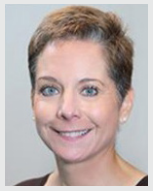
Eileen Dimond

"I was lucky; I was looking for a career change in my mid 20s and picked nursing because of the job security. Who knew it would become my life's work?"

Ellen Richmond

"I have wanted to be a nurse as long as I can remember. I have always taken care of things and people. In high school, I worked as a Candy Striper at a local hospital and that confirmed my career choice."

Lisa Bengtson



What's the most rewarding part about nursing for you?

"I have always worked in Oncology. I find it very rewarding to know that I have made a difference in someone's life, especially when I have been able to help a patient reach a milestone (for example: see a graduation, a wedding or the birth of a grandchild)." -Lisa

"For me, the most rewarding part of nursing has been having the privilege and opportunity to help others." -Maggie

"Being involved in cancer prevention research" -Ellen

"You look at life differently when you see people go through cancer and its treatment. Working with terminal patients and their families was hard but incredibly rewarding, as was helping doctors to consider when it was time to pull back so a patient could have a peaceful death. It's also rewarding to see patients, who were all research participants and now the participants in our prevention trials, give of themselves to advance oncology care, often without reward for themselves. It just gives me continued hope in humanity." -Eileen

"The most rewarding part of nursing for me was when I was doing patient care and had the ability to guide a patient through their cancer journey, inform them about clinical trials, and try and make their participation in a clinical trial less stressful and as smooth as possible. A big part of that included educating patients and their families about all aspects of the clinical trial in which they were being enrolled. Spending quality time with the patients and their families throughout the trial enabled me to really get to know them which lead to a strong bond with the patients." -Val

What is your role within CP-CTNet?

Lisa Bengtson: As a Nurse Consultant with the Lung and Upper Aerodigestive Cancer Research Group, I am actively involved in all phases of the lifecycle of clinical trials. I act as a liaison with Val Dyer, between the LAOs and CCSA (the regulatory contract). Along with the other nurse consultants, I help the sites with the navigation and resolution of issues related to the utilization of the CIRB. I continually work with the other nurse consultants to update SOPs and Templates according to the regulatory requirements.

Ellen Richmond: I am the Nurse Consultant in the GI and Other Cancers Research Group and AQuIP Project Lead.

Val Dyer: I am a Nurse Consultant in the Protocol Information Office (PIO), the central hub for managing all protocol documents. Within CP-CTNet, I work as the PIO liaison with the regulatory contractor and address any regulatory issues as needed. I assist the sites with Registration and Credentialing Repository (RCR) issues. I update various PIO documents such as the CP-CTNet protocol template, the informed consent document, and other documents as needed. I am the DCP SVAR contact. Until recently, I have been responsible for reviewing all CP-CTNet SVAR documents prior to final DCP approval. I am a member of the DCP Safety Assessment Committee which looks at the SAEs associated with CP-CTNet clinical trials. I am also a member of the NCI CTCAE Working Group that is currently working on creating v6.0 of the CTCAE.

Maggie House: I am a Nurse Consultant in the Division of Cancer Prevention's Prostate and Urologic Cancer Research Group (PUCRG). I help to manage the PUCRG clinical trials, work with Lynette B. on developing and maintaining CP-CTNet SOPs, and lead the CP-CTNet Clinical Trials Simplification Committee, among other CP-CTNet responsibilities.

Eileen Dimond: I am a Nurse Consultant for the Breast and GYN Cancer Research Group and thus engage with early phase studies related to breast, endometrial / gyn, and HPV-related cancer prevention. I seek to help the LAOs/PIs in all aspects of the trials we do from concept feasibility to accrual to assisting with challenges along the life of the trial.

In your opinion, what are the most beneficial and the most challenging aspects of CP-CTNet fo the LAOs and AOs?

"The beneficial aspect is the support of the network. They not only have the DCP staff as a resource, but also the DMACC staff and the LAO/AO coordinators at all the sites. I think the most challenging aspect for the LOAs/AOs is that the Consortia 2012 program has not yet been completed. Some of the procedures and processes are different and they are currently managing the two programs in parallel." -Lisa

"The most beneficial aspect is working collectively toward preventing cancer. The most challenging aspect of CP-CTNet is participant accrual, especially minority accrual." -Maggie

"Most beneficial I think is cross-network collaboration." -Ellen

"I think the increased collaboration across the network, and the support of the DMACC will benefit the LAOs, but like anything new, there are growing pains and kinks to get worked out in these early days of opening the first trials at each LAO. I do think all will be well as I prefer to see the glass half full and the bumps do get smoothed out!" -Eileen

"I think the most challenging aspect for the LAOs and AOs will be getting used to new systems and processes associated with the program. One of the most beneficial aspects is having centralized data management through Rave . There are always "growing pains" with a new program, but it's a pleasure to see all the enthusiasm from all involved to make this program a success." -Val

What's your favorite summer memory?

"Summer has always been my favorite season so, it is hard to pick out one memory. I would say all of our SCUBA trips!" -Lisa

Walking to the ice-cream parlor with my grandmother, getting mint-chocolate chip ice cream in a cone and walking back home to sit on her porch and eat it and watch people go by. It was a simple pleasure." -Eileen

"When I was a child, all the neighborhood kids would play outside together for the entire day. One that sticks out is when I went salamander hunting in the creek with my brother and his friends when I was about 6 or 7 years old, and then we crawled through the huge creek drainage pipes from one end of the street to the other!" -Val

"I visited my grandmother every summer in Narragansett, RI for a 2-week cousin free-for-all. My 7 siblings and I would walk to the drug store to by candy and comic books for the 8-hr trip. Much to the dismay of my parents, the bags of goodies entertained us for only a few hours. Invariably, a fight would break-out about the window seat, an unheard request to roll-up a window, someone touching someone else! Since there were no seatbelt laws, we converted the back into a bed with pillows and blankets and all of us crammed in. No matter our arrival time, my grandmother had blondies and homemade bread waiting for us. This was the start of our summers." -Maggie

"Our wedding." -Ellen

New Research Funding Opportunities

NOSI NOT-CA-21-070

NCI Administrative Supplement Opportunity for Strategies to Optimize Recruitment and Retention of Cancer Prevention and Symptom Management Clinical Trial Participants [LINK]

PLCO EEMS & PAR

Upcoming Prostate, Lung, Colorectal and Ovarian (PLCO) Etiologic and Early Marker Studies (EEMS) 2021 Summer Review Cycle (Round 32) and PAR (PAR-18-913) deadlines:

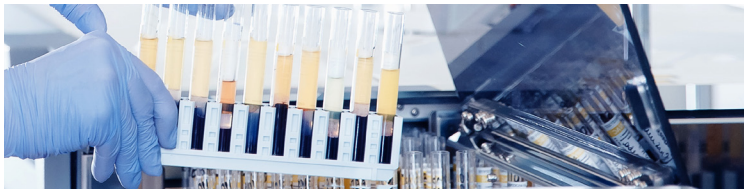
- EEMS preliminary applications will now be accepted on a continuous basis. However, preliminary applications must be completed prior to 8/17/21 to be considered for the next (Round 32) review cycle. Full applications must then be submitted by 10/1/21 to be considered in the Round 32 review cycle.

  8/17/2021 – 10/1/2021 CDAS open for Round 32 EEMS full application

- PAR: 5/14/2021-7/15/2021 CDAS open for FOA PAR-18-913 requests for specimen verification [LINK]

Find more information below:

- https://cdas.cancer.gov/nlst
- https://cdas.cancer.gov/studies/plco
- Email: cdas-eems@imsweb.com



Coming Soon

CASCADE

Global Clinical Trials Network to Improve Screening and Preventive Therapy Outcomes for Cervical Cancer among Women Living with HIV [LINK]

Planning Grant Program (R34/U34)

A grant opportunity for planning large randomized or non-randomized Phase II or later studies. Dr. Brandy Heckman-Stoddard will be presenting this opportunity at the NCI Board of Scientific Advisors meeting in June 2021. [LINK]

R50 PAR

Concept Clinician Scientist Research Award [LINK]

CAP-IT

NCI Cancer Prevention-Interception Targeted Agent Discovery Program [LINK]

Active Studies

UAZ: University of Arizona Cancer Prevention Clinical Trials Network

- **UAZ20-01-02:** An Extended Follow-up Study of the HPV Vaccine Delayed Booster Trial
  - » LAO – UAZ *currently enrolling site
  - » AO – UCLA *currently enrolling site

- **UAZ20-01-01:** Clinical Study of Bioactivity of Low Dose Apalutamide in Prostate Cancer Patients Scheduled for Prostatectomy
  - » LAO – UAZ *currently enrolling site

NWU: Robert H. Lurie Comprehensive Cancer Center of Northwestern University, Northwestern Cancer Prevention Consortium

- **NWU20-01-03:** Role of Lisinopril in Preventing the Progression of Non-Alcoholic Fatty Liver Disease (NAFLD): Relief-NAFLD
  - » LAO – NWU
  - » AO – Cedars Sinai Medical Center *currently enrolling site

Studies in the Pipeline

NWU: Robert H. Lurie Comprehensive Cancer Center of Northwestern University, Northwestern Cancer Prevention Consortium

- **NWU20-02-01:** Surgical Window of Opportunity Study of Megesterol Acetate and Metformin for Endometrial Intraepithelial Neoplasia
- **NWU20-02-02:** 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
- **NWU20-04-01:** Metformin for Chemoprevention of Lung Cancer in High Risk Obese Individuals

MDA: University of Texas MD Anderson Cancer Center, iCAN-PREVENT: International Cancer Prevention Clinical Trial Consortium

- **MDA20-01-01:** A Phase IIa, Placebo-Controlled, Randomized Study of Daily Obeticholic Acid (OCA) to Reduce Intestinal Polyp Burden in Familial Adenomatous Polyposis (FAP)
- **MDA20-02-01:** 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)

UWI: MW Chemoprevention Network - University of Wisconsin and the Mayo Clinic

- **UWI20-00-01:** A Phase II Trial of the Immunogenicity of a DNA Plasmid Based Vaccine (STEMVAC) Encoding TH1 Selective Epitopes From Five Antigens Associated with Breast Cancer Stem Cells (MDM2, YB1, SOX2, CDC25B, CD105) In Patients with Early Stage Triple Negative Breast Cancer
- **UWI20-04-01:** A Dose Escalation Phase I Trial of the Safety and Immunogenicity of RG1-VLP, A Candidate Broadly Protective Vaccine for the Prevention of HPV-Associated Cancer

UMI: University of Michigan, Early Phase Clinical Cancer Prevention Consortium (ClinCaP)

- **UMI21-05-01:** Obeticholic Acid for Chemoprevention in Barrett's Esophagus

CP-CTNet Cross-Network Study

- **INT21-05-01:** Phase II Clinical Trial of the Multitargeted Recombinant Adenovirus 5 (CEA/MUC1/Brachyury) Vaccine (Tri-Ad5) in Lynch Syndrome

How to Reach Us

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Other Links

- DMACC website
- DCP CP-CTNet website

Do you have questions, comments, or content suggestions? Please don't hesitate to email us.

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