

September 2021

CP-CTNet NEWSLETTER

Cancer Prevention Clinical Trials Network



WELCOME FALL!

The first day of autumn was September 22nd. Fall reminds us that change can be a beautiful process. It's the season that conjures up memories of heading back to school, visits to the pumpkin patch, jumping in piles of colorful leaves, picking apples at the orchard, drinking apple cider, and making apple crisp and apple pie. The sun begins to rise later and night-fall comes sooner. The clocks may have us falling back soon, but certainly not behind. We wish a colorful, cool, cozy autumn to all our CP-CTNet colleagues!

Fun Fact

The best bit of trivia surrounding the autumnal equinox involves its relationship with the full moon. Curiously, the full moon that occurs nearest to the autumnal equinox is always called the Harvest Moon. Do you know why?

Surprise, surprise—it has to do with farming! Around the fall equinox, the moon rises around sunset for several nights in a row, which traditionally provides farmers with just enough extra light to finish their harvests before the late fall frost begins.

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DMACC Updates

DATA MANAGEMENT AND REPORTING UNIT



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The Data Management and Reporting Unit has finalized and implemented the following initiatives and procedures:

Protocol Deviation Process

As announced in our June newsletter, a **Protocol Deviation Notification** electronic case report form (eCRF) will soon be added to all studies to allow sites to report deviations directly in Medidata Rave. This eCRF will be replacing the previously used PDF form and will help facilitate a more streamlined review process, whereby the Lead Academic Organization (LAO) and Medical Monitor/Nurse Consultant are notified by email when their review is required. LAOs and Medical Monitors/Nurse Consultants will also be able to enter queries in Rave for the Affiliated Organization (AO) to resolve. Medical Monitors/Nurse Consultants can then enter any review comments directly to the eCRF and assign a grade for the deviation. We are pleased to announce that this eCRF update will be available in Rave by the end of October. Stay tuned, the DMACC will provide training on this new process to all applicable National Cancer Institute (NCI) Division of Cancer Prevention (DCP), LAO, and AO staff prior to this implementation.

SVAR Process

The DMACC has begun working with the LAOs to implement the new **System Variable Attribute Report (SVAR)** development and review process for upcoming studies. The DMACC is partnering with the LAO team to create the initial draft version of the SVAR to submit to the DCP's Protocol Information Office (PIO). The collaboration has been going extremely well, and together we are able to identify inconsistencies early on, thereby increasing the efficiency of the development process. As we continue to open more

studies, we have found commonalities and started to develop a set of eCRFs to add to our SVAR template. This new process is allowing us to streamline SVAR development and collect data consistently across the network.

Study Builds in Rave

Since our previous newsletter, two new study builds have been completed in Medidata Rave: NWU20-02-01 (Megestrol/Metformin – Endometrium) and NWU20-02-02 (Atorvastatin – Colon). Both studies were opened to accrual in September. Four additional studies have SVARs near finalization, and preparation for these study builds is in process. Work is also underway to incorporate several updates to the study builds for studies that are currently in production.

COVID-19 eCRFs

Two COVID-19 questionnaires have been developed for use in all CP-CTNet studies. Their purpose is to collect information about infections and the vaccination status of participants. The **Baseline and Follow-up Assessment** eCRFs are now live in our two most recently opened studies and study build updates are being planned to add these eCRFs to studies that are already enrolling for completion at future visits.

New CNC Meeting

The very first Cross-Network Collaboration (CNC) Meeting was held between the DCP, the DMACC, and the LAOs in July 2021. The purpose of these ongoing meetings is to provide a forum for open communication, discussion, and cross-network collaboration between these groups. The CNC meetings provide a dedicated time to not only share

information with and from the DMACC and the DCP, including LAO and AO concerns, questions, and ideas; but, also to engender collective, early, problem identification and solutions, and to support increased collaboration and shared learning across the LAOs.

Topics discussed during the first meeting included: the finalization of the CNC Charter, posting LAO study tools on the CP-CTNet Portal Gateway, revising the Study Initiation Template to clarify responsibilities, creating a user request access log, and collecting pre-screen race, ethnicity, and demographics data. We are pleased to confirm that these initiatives are all underway. The next meeting will be held in November.

Other Meetings

This quarter, the DMACC has also participated in two Study Initiation Meetings (SIMs) with AOs for the UAZ20-01-01 (Apalutamide- Prostate) study, as they become ready for site activation. The DMACC portion of these meetings covered topics such as: study start-up, CP-CTNet website & Portal Gateway access, user access, DMACC systems, demos & training requirements for Stars and Rave, data management & quality control, auditing, documentation & SOPs, and communication. Per LAO request, we have also created a video training of the DMACC SIM topics.

Virtual Specimen Repository Group

We are pleased to announce the formation of the new *Virtual Specimen Repository Group*, a working group comprised of team members from the DCP, DMACC, and LAOs. The stated purpose of this newly formed group is to provide general consultation; oversight and strategic direction for the CP-CTNet DMACC; and, eventually to streamline processes for the optimization of workflows for centralized specimen management and tracking. The overriding goal at this time is to centralize receipt of specimen inventory listings from the LAOs/AOs to the DMACC for storage in the CP-CTNet central database, which may entail discussions for tailoring receipt of specimens from different entities and systems. In the future, the group will be able to make explicit recommendations for a virtual specimen repository that will greatly benefit all entities involved. To date, the group has started efforts by creating a detailed schematic of workflows at each LAO so that it can be better

visualized, broken down, discussed, and analyzed. Currently, the *Virtual Specimen Repository Group* aims to:

- Establish appropriate and clearly-written policies, processes, and procedures that set high standards, based on all known industry best practices, for the current and future tracking of specimen collections at the LAOs/AOs. These efforts will better ensure data integrity is of the highest standards while ensuring easier transfer and tracking for participating entities.
- Evaluate the effectiveness of Frontier Science's Laboratory Data Management System (LDMS) implemented at the LAOs/AOs for use of electronic tracking, labelling, storing, and specimen shipping. If required, additional functionality will be integrated into the LDMS to further promote the vision of the group in these efforts.
- Evaluate the progress of established workflows for how specimen inventory will be submitted to the CP-CTNet central database, which is hosted at Frontier Science, and will include periodic assessments to ascertain data quality and timeliness of data submission given the current conditions under which inventory is submitted.
- As noted, efforts will also include explicit recommendations for a more robust design, presentation, and layout for a virtual specimen repository website (portal) to be easily accessed by all pertinent members.

The group plans to continue to meet monthly to ensure continued progress in reviewing current strategies and procedures, discussing future enhancements to laboratory workflows, and reviewing the submission of specimen inventory data to the CP-CTNet central database. A charter has been devised to formally establish the objectives of the *Virtual Specimen Repository Group*. This will assist in the eventual creation of project plans and other administrative tasks to help keep the group committed to all proposed goals. The group has recently provided a demonstration of current LDMS functionality to the University of Arizona (UAZ) and is continuing efforts by devising a new specimen collection template. It is anticipated that by garnering

feedback from all entities involved, the DMACC will be successful in developing an informative and intuitive virtual repository for specimen tracking in the CP-CTNet.

Documentation

CP-CTNet staff have been working under the guidelines provided by our CP-CTNet standard operating procedures (SOPs) since the implementation of the program. We are constantly evaluating our procedures and inviting LAO feedback. Using this process, we have been able to fine-tune several SOPs to make procedures more efficient. Some recent examples include:

- **SOP 02-04 Participant Recruitment, Retention, Adherence and Reporting Requirements & the Recruitment, Retention, and Adherence Plan.** This SOP has been restructured and updated with additional examples to guide the process of planning and monitoring recruitment, retention, and adherence performance for CP-CTNet trials.
- **SOP 01-02 Study Initiation Meeting and CP-CTNet Study Initiation Meeting Report Template.** This document clarifies the topics covered in each SIM, identifies which CP-CTNet group presents each topic, and provides guidance about SIM recordings and action item follow-up.
- **SOP 01-01 Regulatory Documents** provides additional information about CTEP-IAM and clarification of delegation of task log requirements.
- **REFGD05 CP-CTNet Genomic Data Sharing Guidance** clarifies the responsibility of LAO Principal Investigators in relation to sharing genomic data.

Additionally, you can look forward to seeing three more SOP updates soon:

- **SOP 01-03 Study and Site Activation.** This will be a revision of the Site Activation SOP and will now include information on study activation as well, as these two processes can run in parallel.
- **SOP 03-02 Site Preparations for Quality Assurance Audits.** This update will include new information on scheduling timelines and the risk assessment tool.

- **SOP 04-02 Study Closeout.** This will be a new SOP detailing the steps involved in closing out a study, including communication procedures, database lock and analyses, data deliverables, and manuscripts/publication.

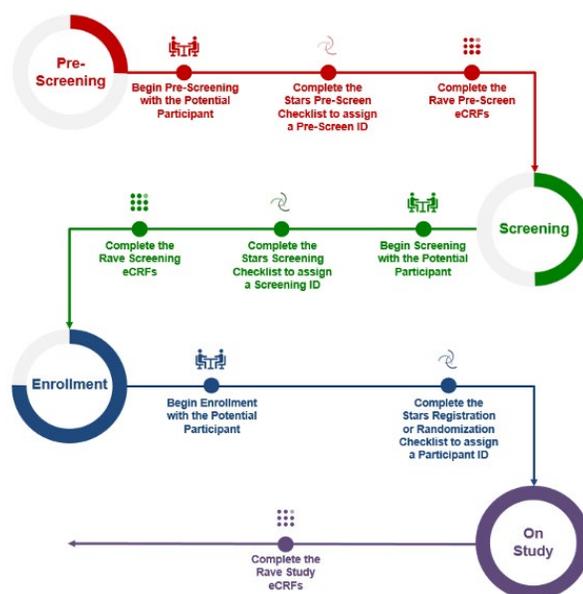
Educational and Training Content

New and updated educational materials and training content has been added to the CP-CTNet public website and Portal Gateway, including:

- **A recording of the CP-CTNet Auditing and Monitoring Webinar for LAOs.** This includes a training presentation on using Medidata Rave reports to monitor data and query status.
- **Updates to documentation for the Stars Registration and Randomization System.** *CP-CTNet QKREFGD02 Summary of Enrollment Process*, *CP-CTNet USRMAN01 Stars User Guide*, and *CP-CTNet Treatment ID Information*.
- **Recruitment Journal Training Materials.** A new *Recruitment Journal Form in Rave* video tutorial and the *Rave Recruitment Journal Quick Reference Guide* (shown below) have also been added.

Completing the Enrollment Process in Stars and Rave

Pre-Screen, Screening, and Participant IDs should be assigned by Stars and data should be entered in Rave on the date that each phase of the enrollment process begins. Stars and Rave exchange data in real time so that enrollment information can be entered while meeting with a potential participant. The infographic below details the steps of each phase of the enrollment process.



All study participants **must** be pre-screened, screened, and enrolled in studies through Stars and data must be entered in Rave prior to conducting study evaluations and dispensing study drugs.

Key Takeaway

Enter potential participants into Stars and Rave to document each enrollment phase in real time.

CLINICAL TRIALS AUDITING UNIT



Julie Chang, MD – Director of the Auditing Unit
Holly Shaw, MS, CCRP – DMACC Auditing Unit Co-Manager
Barbara Wollmer, BSN, RN – Auditing Unit Co-Manager
Meredith Kissel, MPH – DMACC Clinical Trials Auditor

The DMACC Auditing Unit is very happy to announce that we have our first two CP-CTNet audits scheduled. Audits for UAZ 01-02: An Extended Follow-up Study of the HPV Vaccine Delayed Booster Trial are scheduled for UCLA (an AO on this protocol) on October 26-27 and for UAZ (the LAO) on November 2-3. These audits will be performed remotely due to COVID-19 restrictions.

We have finalized the protocol risk assessment tool. During an audit, DCP study teams will use this tool to inform the depth and breadth of source data verification needed for the audit team to perform on select participant charts. Protocol risk assessment has been integrated into DCP's consensus review process and, for ease of tracking, the result of this assessment (low, intermediate, or high) will be documented on the *Consensus Review Form*. Risk assessment is used only for auditing purposes, it is NOT a value judgement on the merits of a protocol. By the very nature of early phase studies (often of novel agents), most CP-CTNet protocols will be intermediate or high risk.

At the end of June, the Auditing Unit participated in a DCP webinar to address LAO concerns regarding their role in the oversight of CP-CTNet protocols. To summarize:

- **Audits of CP-CTNet protocols are the responsibility of the DMACC Auditing Unit.** They may occur remotely or on-site, and serve as an independent quality assurance function to ensure the protection of study participants, verify the validity of study data, and ensure compliance with regulations governing the conduct of clinical research and the principles of Good Clinical Practice (GCP).

- **Monitoring of a CP-CTNet protocol is performed by the LAO responsible for the protocol.** This is an ongoing day-to-day activity, performed remotely, to ensure the study is conducted and progresses as planned. It includes activities like: AQuIP data review to ensure that accrual remains on track; collecting and submitting regulatory documents to CCSA; ensuring participating sites enter their study data on time, respond to queries, submit protocol deviations and SAE reports; and, ensuring sites are aware of and operate in compliance with the CP-CTNet SOPs as well as the principles of GCP.

Our web-based audit system is nearing its release date and should be available for our first scheduled audits.

We are working in conjunction with the DCP nurse consultants to review and update the Site (LAO/AO) Preparations for Quality Assurance Audits SOP.

If you have any audit-related questions, please reach out to us at Audit_CP-CTNet@frontierscience.org.



ADMINISTRATIVE AND COORDINATING UNIT



KyungMann Kim, PhD – Director of the Administrative and Coordinating Unit,
DMACC Principal Investigator

Kelly Miller, BS, CCRC – Administrative and Coordinating Unit Manager

Bridget Dermody, BS – Administrative Specialist

Our team continues to disseminate important information to the greater CP-CTNet audience via email and updates to the CP-CTNet DMACC website, and to provide administrative and coordinating support to CP-CTNet. Brainstorming new and exciting content for the quarterly CP-CTNet Newsletter also keeps us busy!

In addition, our Statistics Unit is working on several projects with DCP investigators, as well as on the cross-network study: INT21-05-01, A Phase IIb Clinical Trial of the Multitargeted Recombinant Adenovirus 5 (CEA/MUC1/Brachyury) Vaccines (Tri-Ad5) and Il-15 Superagonist N-803 in Lynch Syndrome.

Planning for the next I-SCORE meeting will begin in November. If anyone has any thoughts, ideas, suggested guest speakers, or topics you'd like to discuss for I-SCORE 2022, please email Admin_CP-CTNet@frontierscience.org.

CP-CTNET DMACC WEBSITE & PORTAL GATEWAY



Bob Starkweather, MS – Deputy Director of Software Engineering

David Goss, MA – Software Engineering Business Analyst

Website

We are always working to improve the [DMACC website](#)—particularly ensuring CP-CTNet clinical sites can stay updated about network activities, news, and upcoming network events. Starting in September, the DMACC has started posting information related to NIH Funding Opportunity Announcements (FOAs) of potential interest to CP-CTNet sites. This information includes a short description of each FOA, when applications are due, and links to additional information. You can find this information in the new [Funding Opportunities](#) page, in the Updates section on the DMACC website.

Recent content added to the CP-CTNet website includes: training materials, new and updated reference and user guides, DCP contractor contact information in the Contact Directory, and other resources intended to assist in training site and LAO staff regarding their day-to-day CP-CTNet activities. We make several updates to the website each month, so check back often for the latest project

documents, news, upcoming events, and now – additional funding opportunities!

Portal Gateway

Since the last newsletter, the DMACC has also been working hard on enhancing the functionality offered to users of the CP-CTNet Portal Gateway. These enhancements include a substantial revision to the new user request process, as well as providing an improved mechanism for requesting new and/or modified access to key systems like Rave or Stars. Additionally, Gateway dashboard item functionality is being enhanced to improve how content is organized and made available to Gateway users. There will also be a variety of other backend updates meant to increase performance and improve the end user experience. These updates are expected to be made public soon, so stay tuned! Feel free to reach out to Admin_CP-CTNet@frontierscience.org if you have any questions or suggestions to improve the end user experience with the public website or the Portal Gateway.

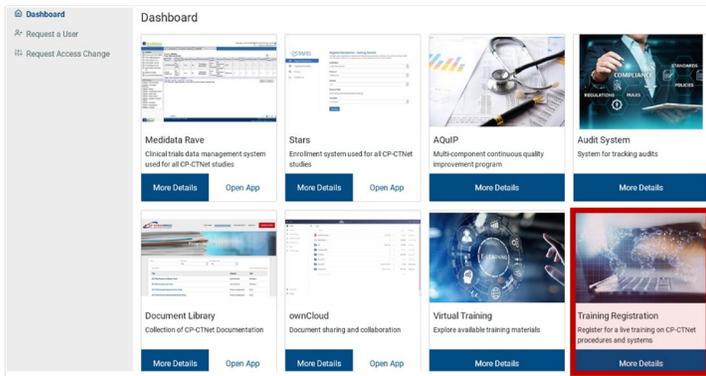
Introducing: Training Registration via the CP-CTNet DMACC Portal Gateway

By: Alex Krolikowski, MS – Training Specialist

The DMACC team is excited to announce the new *Training Registration* dashboard item page on the CP-CTNet DMACC Portal Gateway. This page will be included in the next release of the Portal Gateway and will provide CP-CTNet members with access to information and registration links for upcoming training sessions. This article introduces the *Training Registration* dashboard item page and provides an overview of the registration form that members use to enroll in standalone training sessions.

Accessing Training Registration Links

The *Training Registration* page will be available via the password-protected Portal Gateway. To access the page, CP-CTNet members select the *Training Registration* tile from the Portal Gateway dashboard.



The Training Registration Page

The Training Registration page includes registration links for upcoming training sessions and downloadable documentation and educational resources. The training registration links will be updated continuously as new training sessions are scheduled. These training sessions complement the training that DMACC provides as a component of Study Initiation Meetings, topic-specific webinars, and other network meetings. To register for a training, CP-CTNet members click on the desired registration link and then re-enter their Portal Gateway credentials before accessing the registration form.



Completing Training Registration Forms

Each registration form includes general information about the training session (e.g., title, topic, date, and time) and specific questions that must be answered to successfully register for the training session. Once the registration form is complete, the CP-CTNet member selects “Submit” and receives an email to confirm their registration. Reminders for registered training sessions and additional information will be sent by the *DMACC Education and Training Team* prior to the training session.

Requesting New Training Sessions

CP-CTNet members may request training related to any area of study conduct at any time. DMACC will develop educational materials and sessions to ensure that any identified training needs are thoroughly addressed. If you have ideas for training topics that you would like to see offered via the *Training Registration* page on the CP-CTNet DMACC Portal Gateway, please reach out to Training_CP-CTNet@frontierscience.org.

Featured Articles

HOW DO DCP INVESTIGATIONAL AGENTS GET TO THE CLINIC?

By: **Dr. Dan Boring**, RPh, PhD – Contracting Officers Representative for the DCP

As a Medical Monitor for the DCP, you are excited and impatient to start a clinical trial that you have been nurturing for months. The Investigational Agent (IA) has jumped all the scientific, regulatory, and other documentary hurdles and only needs to be dispensed to the subjects.

How will that happen?

Fortunately, a DCP Drug Repository was established some 30 years ago to facilitate this process. This is a contracted service that is currently administered through [MRIGlobal](#), a Kansas City organization. The Drug Repository Program serves as the centralized source of investigational agents and provides development services necessary to support early phase cancer prevention studies. The repository provides logistic organization for the procurement, tracking, labeling, storage, shipping, maintenance, testing, quality control, and distribution of investigational agents.

Who?

Investigational agents come to the DCP from many sources. Internally, the [PREVENT Program](#) serves as a pipeline for IAs from academic and pharmaceutical partners into pre-clinical testing and ultimately into clinical trials. PREVENT provides a structure for introducing new agents, drugs, and vaccines that work to inhibit, delay, or reverse the tumorigenic process. This program was designed to optimize translational opportunities in the clinic and to provide a mechanism to identify and study efficacy and pharmacodynamics of biomarkers that will help in phase II trials to evaluate drug effects.

Additionally, the DCP solicits studies of promising IAs from a consortia of chemoprevention researchers into the CP-CTNet.

The CP-CTNet performs early phase clinical trials to assess the safety, tolerability, and cancer preventive potential of agents and interventions of varying classes. These trials

include phase 0 (micro-dosing), phase I (dose-finding), and phase II (preliminary efficacy) clinical trials. The goal is to identify safe and effective preventive interventions and to advance their further clinical development for cancer prevention. Agent suggestions for the CP-CTNet may come from the PREVENT program, from inside the DCP itself, and from academic researchers or from Pharma companies.



What?

Many different types of dosage forms are proposed for clinical study. Creams, lotions, tablets, capsules, aerosols, and injections (vaccines) have all been used in DCP pre-clinical and clinical studies. These finished dosage forms may be supplied by a pharmaceutical partner, purchased from commercial drug wholesalers, or developed completely through the Repository resources from the beginning drug substance.

If a pharmaceutical company is supplying the IA, many options are available. The company may elect to supply agent from their own supplies through company distribution centers directly to the clinical sites. Alternatively, the company may provide bottled drug to MRIGlobal who will then develop labeling, packaging, and distribution to the clinical center. When the Repository has to re-bottle the drug supply to accommodate the trial design, then the IA is also placed into a stability program of a duration to cover the length of the clinical trial. Almost every combination of drug responsibility has been seen with DCP trials.

When?

Coordinating the availability of drug supply with the clinical trial start date may be complicated. When the drug product is being manufactured and supplied by the DCP, many different factors can influence both the product availability and actual trial start date. There can be manufacturing delays, starting material shortages, packaging and labeling hold ups, documentation delays from the clinical sites, clinical trial agreement problems and a host of other issues. This can be a delicate balancing act and requires careful attention to timelines.

IAs that are manufactured by the DCP are placed into a 3-year stability protocol that will qualify the IA for continued use throughout any length of trial by analytical testing. However, when the IA is a commercially-available, FDA-approved drug product, it will be obtained with a fixed expiration date. The Repository tries to purchase these products with the longest possible expiration dating. But, since there are so many moving parts in a clinical study, it is difficult to have a precise start date. If the Repository purchases IA too soon, it may expire before the trial is finished, requiring a second purchase of material. When a trial is halted early, there will be leftover drug that can only be destroyed. When there is an unforeseen drug shortage in effect, the trial start may be delayed. Again, this is a balancing act that requires good communication and careful attention.

Assuming the IA is being supplied directly by its manufacturer, other factors come into play such as intellectual property rights and level of support needed. Some manufacturers will have their own logistical groups to handle supply demands. Others may want the DCP Repository to provide specific services such as labeling and shipping.

Regardless of the supplier identity, the Repository is equipped to provide an array of services to connect the drug with the subject in a safe and timely manner. It maintains a robust inventory management system that ensures inventory levels are always adequate at the Repository and at the clinical site. They have proper packaging supplies and mailing services to reach sites both domestic and abroad.

Where?

The Repository service contract currently resides with MRIGlobal, a not-for-profit research organization located in Kansas City, Missouri. There are two facilities in Kansas City that MRIGlobal utilizes for servicing the contract.

Their main headquarters is in Kansas City proper with a full array of analytical testing, animal testing, drug synthesis, and formulation services. The actual Repository itself is a few miles away in North Kansas City. The North Kansas City warehouse has 10,000 square feet of storage that provides receiving, storage and shipping areas combined with many different environmental storage areas at controlled temperatures.

The Repository has defined areas for storage, inventory management, importation activities, shipping, supply management, receipt, and distribution, restocking, stability studies, disposal, clinical label design and production, custom kitting, and preparation of blind samples. In the past eight years, the Repository has shipped over 1,500 drug orders without incident. The Repository will ship drug orders Monday through Thursday, but not over weekends (to avoid no one being present to accept a shipment). The Repository is the last link in the chain from Investigator, to the DCP, and finally to the clinical subject.

How?

Let's assume the Repository has received an IA and is storing the released and labeled agent pending a site order. What needs to happen for the material to be shipped?

Prior to any shipment, the Repository must receive a Drug Shipment Authorization (DSA) from the DCP Regulatory Affairs contractor, CCS Associates (CCSA). The CCSA is charged with compiling and filing regulatory documents needed for a trial to begin. When the CCSA has satisfied the documentary requirements for a study site, it sends MRIGlobal the DSA for that specific site. Each site in a multicenter trial receives its own DSA. Usually, the investigational pharmacy at the site will contact MRIGlobal with a shipment order for the IA.

Each IA is unique in terms of its shipping configuration. Some may be very stable and will be simply packed in

bubble-wrap and a cardboard box. Others may have a defined cold storage temperature and must be packed with ice packs or dry ice within insulated boxes. These shipments will have a TempTale® monitoring device to ensure that no temperature excursions happen during shipment to the site. Other IAs may be in sophisticated kits that need additional processing to place specific agents in specific packaging containers. Some shipments may be going overseas and have import/export laws to satisfy. They all arrive safely in a timely manner.

Why?

The DCP is the global leader in making life-saving cancer prevention and care possible through rigorous, highly valued research and training. The DCP provides funding and administrative support to clinical and laboratory researchers, community and multidisciplinary teams, and collaborative scientific networks. This is the mission of the DCP and the Repository is a critical component of that mission. Together, we make it happen.



ABOUT THE AUTHOR

Dr. Dan Boring graduated in 1989 with a doctorate of Medicinal Chemistry from the University of Mississippi and went on to the NIH for post-doctoral research studies

on new blood pressure medications.

In 1991, Dr. Boring joined the Food and Drug Administration (FDA) as a chemist. He reviewed the chemistry sections of Investigational New Drug applications (INDs) and New Drug Applications (NDAs).

In 2003, Dr. Boring left the FDA to join the NCI in the DCP. He is the Contracting Officers Representative for the DCP's Repository and Regulatory Affairs contracts.

For the Repository, he oversees the procurement and logistical management of investigational agents needed for the DCP's pre-clinical and clinical programs.

For Regulatory Affairs, he directs the preparation and submission of INDs and other required filings as needed for proper regulatory compliance.

Call for Nominations 2022 ODP Early-Stage Investigator Lecture



SEEKING NOMINATIONS FOR THE 2022 ODP ESIL AWARD

The Office of Disease Prevention (ODP) is seeking nominations for their [2022 Early-Stage Investigator Lecture](#). The award is made annually to early-career scientists who have made significant research contributions in disease prevention but who have not yet successfully competed for an [R01 or R01-equivalent](#) National Institutes of Health (NIH) research grant.

The award winner will be invited to give a lecture at the NIH in 2022. The awardee will also have the opportunity to meet and network with NIH program directors and scientists. Due to the coronavirus pandemic, the date and in-person status of the lecture will depend on travel and meeting guidance provided by the NIH. Nominees should have:

- Innovative and significant research accomplishments in applied prevention research in humans, in areas that are relevant to the ODP's mission.
- Evidence of highly collaborative research projects, especially those that bridge disciplines to offer new approaches and ways of thinking in disease prevention research.

Nominations Due: October 29, 2021

Winner Notified: January 14, 2022

Please email prevention@mail.nih.gov with any questions.

DIVERSITY, EQUITY, AND INCLUSION (DEI)

DEI in Clinical Trials: Framework, Evidence, and Steps Forward

By: **Joseph M. Unger**, PhD, MS - Associate Professor at Fred Hutchinson Cancer Research Center

Clinical trials represent a critical final step in developing new therapies for cancer patients. Yet few adult cancer patients participate in clinical treatment trials, even as most cancer patients have expressed a willingness to do so.[1] Estimates of adult cancer trial participation rates have ranged from 2%-8%, highlighting the large gap between the willingness to participate versus actual participation. [2, 3] Research that aims to improve understanding about barriers to trial participation and disparities in access to trials is therefore critical, since the entire clinical trial system hinges on the availability of patients who participate. A patient's decision about treatment is complex and personal, and the prospect of incorporating clinical trial treatment into a patient's care adds another level of complexity. In this multi-factorial decision-making environment, patients may face many barriers to trial participation. To understand trial barriers/disparities in access as a system, it is useful to establish a framework.

A recent study delineated the structural, clinical, physician, and patient barrier domains that prohibit trial participation for most patients.[3] Structural barriers are characterized by the burden and investment required to conduct cancer clinical trials.[4] Clinical trial conduct requires a substantial institutional commitment, representing considerable administrative, financial, and organizational challenges. For this reason, clinical trials are much more commonly conducted at major academic centers.[5] This limits access to a locally available trial for many patients, who must find the resources for transportation and travel, care for their children, and to cover other direct or indirect costs, in order to simply access a trial.

Even if a trial is available, patients may not be eligible, representing another domain of clinical barriers. Trial eligibility attempt to satisfy opposing factors; they must be sufficiently narrow so that the treatment effect is approximately constant across subgroups, but also must be sufficiently broad so trial results apply to a meaningful

population of patients.[6] Trials are often criticized for having overly narrow eligibility criteria, sacrificing generalizability and reducing access for patients. Importantly, the American Society of Clinical Oncology, Friends of Cancer Research, and the U.S. Food and Drug Administration are currently engaged in a years-long effort to "modernize" clinical trial eligibility and broaden access for patients by reducing exclusions due to such conditions as a preexisting cancer diagnosis or brain metastases.[7]

Even if the patient is eligible for an available trial, there is no certainty that a treating physician will offer a patient the opportunity to participate. In their role guiding patients care, physicians may prefer a specific treatment. Alternatively, trial participation can interfere with physician-patient relationship. Practical considerations of reimbursement and the time and effort to conduct a trial can also be burdensome for the treating team.

The ultimate decision rests with the patient. Although altruism is one motivation, a primary concern for patients is finding the best treatment for their disease.[8] Patients report being uneasy and fearful about participating in an experiment. Residual mistrust of medical science due to past abuses (such as the Tuskegee Syphilis Study or human experimentation with radiation after World War II), have adversely impacted the willingness of patients to participate in research for generations, although modern attention to patient protections and informed consent has likely reduced fears for many.[9]

Under this framework, patient agency in the trial decision-making process only arrives at the end of a very long pathway. Moreover, along the pathway, numerous demographics, socioeconomic, and geographic disparities may arise that result in reduced trial participation for certain patient groups. These disparities have adverse consequences both for the patients interested in trials for their cancer care and for the science of clinical research.

Older patients are dramatically underrepresented in trials. One seminal study showed that while patients 65 or older comprised about 2/3 of the U.S. cancer population, only around one in three patients in trials are 65 or older.[10] Observations such as this motivated a policy change for Medicare, which in the year 2000 began covering the routine care costs of clinical trial participation. Socioeconomic disparities in access to trials have also become apparent. Studies have demonstrated that patients with household income <\$50,000/year are as much as 30% less likely to participate in trials.[8, 11] In particular, lower income patients report being much more concerned about how to pay for clinical trial treatment, with 53% of patients with household income <\$20k/year expressing concern about how to pay for trial participation, compared to only 24% expressing a similar concern among those with household income >\$100k/year.[8] The recent passage of the Clinical Treatment Act, which mandates that all state Medicaid programs must cover the routine care costs of trial participation for life-threatening illness, including cancer, may help alleviate this disparity for some patients.[12]

The representation of Black patients in cancer clinical trials has been a long-standing concern. In a recent landmark study by Loree et al., investigators examined how often Black patients participate in clinical trials leading to new FDA oncology drug approvals. They found that Black patients comprised only 3.1% of all trial enrollments, compared to an expected rate of 14.1% in a similar set of cancers.[13] Of note, 97% of the trials in the dataset were sponsored by pharmaceutical companies. In contrast, enrollment of Black patients in trials sponsored by the NCI's National Clinical Trials Network has historically been much better. A follow-up study to that of Loree et al., showed that in a similar set of cancers over the same time period, Black participation was 9% in NCI-sponsored network group trials, three times greater than for pharmaceutical company sponsored trials leading to FDA drug approvals.[14]

Why the vast disparity in enrollment of Black patients to pharmaceutical company sponsored trials compared to NCI sponsored trials? Although recruitment at international sites for pharmaceutical company trials is one issue, another likely culprit is differing enrollment strategies. Pharmaceutical company sponsored trials primarily enroll



patients from large academic centers.[5] In contrast, trials from the NCI's network groups have a particular focus on outreach to community and minority/underserved sites through the mechanism of the NCI's Community Oncology Outreach Program (NCORP). More proof of the success of the NCORP program in reaching out to less accessible patient groups is the recruitment of rural patients, who represent 20% of patients in network group trials, the same proportion as in the US population.[15]

The FDA, in partnership with the American Association for Cancer Research, is currently examining ways to improve representation of Black patients in FDA registration trials. [16] Although the focus is on trials for myeloma, given the high prevalence of myeloma in the Black population, models for improving minority participation could be extended to other cancer settings. The recommendations of the working group include an emphasis on prospective recruitment and outreach strategies; in this context, the NCORP program could serve as a model for the recruitment of minority and underserved patients to pharmaceutical company sponsored trials.

It is critical to recognize more than half of patients cannot access a trial because no trial is locally available and another quarter are clinically ineligible.[3] Thus, for 3 out of 4 cancer patients, these structural and clinical barriers preclude patients from even having a chance to consider trial participation with their physician. Therefore, the conventional refrain that about 5% of adult cancer patients participate in trials does not provide the appropriate context to understand the willingness of cancer patients to participate in trials. A recent systematic review and meta-analysis addressed this particular question by evaluating how often patients who are actually offered trial participation do

participate.[17] The findings were surprising; more than 50% of the time, patients agreed to participate. Moreover, Black, Hispanic, and Asian patients agreed to participate at least as often as white patients. These results dramatically underscore the willingness of cancer patients to participate in a trial *if one is offered*.

Considering these considerations, we see that the root cause of low trial participation rates in adults with cancer is a clinical trial system beset with structural and clinical barriers, rather than patient lack of interest. Thus, research, interventions, and policies to improve trial participation should focus more on these systemic structural and clinical barriers, and importantly, the disparities that these barrier domains drive. In so doing, we may be better able to achieve a more ideal, demographically, socioeconomically, and geographically open and inclusive clinical trial system, to the ultimate benefit of all patients with cancer.



ABOUT THE AUTHOR

Dr. Joseph Unger is a biostatistician and health services researcher. He uses big data to understand more about cancer patients' treatment outcomes and disparities,

especially as they pertain to barriers to participating in clinical trials. He has been at the forefront of efforts to link Medicare claims data to clinical-trial records to address novel research questions. Dr. Unger also has extensive expertise in the design and analysis of prospective clinical trials that examine disease symptoms and treatment side effects, patient quality of life and delivery of cancer care. His research has revealed that factors such as annual household income and having multiple simultaneous health conditions, or comorbidities, can affect patients' participation in clinical trials, as can structural and logistical issues such as the availability of a trial at the center where the patient is receiving treatment.

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THE NCI'S COMMITMENT TO DIVERSITY

The NCI is committed to increasing the diversity of the cancer research workforce by building a more inclusive and equitable NCI community. To learn more about NCI's commitment to DEI, visit the [NCI Equity and Inclusion Program website](#).

DEI was discussed at length at the July 29th CP-CTNet Steering Committee Meeting. All the LAOs highlighted their ongoing and planned efforts at each of their institutions with respect to the topic of DEI.

Important Links:

- [NIH UNITE Initiative](#)
- [Ending Structural Racism](#)
- [Enhancing Research to Address Cancer Health Disparities](#)
- [Ensuring Diversity of Thought and Background in the Cancer Research Workforce](#)
- [Promoting an Inclusive and Equitable Community at NCI](#)

CP-CTNet Efforts to Address DEI

A new working group comprised of six to ten members, all of differing career levels and races and ethnicities, will be formed to address DEI in CP-CTNet with respect to participant enrollment and staff (investigators, scientists, coordinators).

The DCP shared that the Central Institutional Review Board (CIRB) Initiative is looking at race and ethnicity data and if we could demonstrate that we prescreen a diverse population and figure out why certain populations don't go on study, it would increase the amount of information we could provide to the CIRB. Race and ethnicity have been added to the pre-screen eCRFs that the sites fill out in Rave.

Staff Spotlight

DON JOHNSEY

What is your role within CP-CTNet?

As a DCP Program Official, I have the overall programmatic stewardship of the individual awards and responsibility of the budget process (e.g., review, oversight, and approval). I work closely with the CP-CTNet Director, Dr. Eva Szabo, Project Scientists, and other DCP staff to ensure consistency in the administration of the program. I work with the Principal Investigators (PI) and their staff to facilitate the award, address concerns, and approve proposed changes. I serve on many committees to contribute to the various aspects of the day-to-day management and operations of the program. I am the liaison between the Office of Grant Administration and the awardees.

What sparked your interest in cancer prevention?

Having heard the term whispered many times in my childhood, I remember in 6th grade looking up “cancer” in a dictionary and then in the Encyclopedia Britannica (Google the term if needed). I learned cancer is a terrible disease with a lot of unknowns that needs more research. My first paper was titled, “What is cancer and why more research is needed.” I lost many family members to this disease and knew one day I would work in or support cancer research. It did not take me long to understand that prevention is better than a cure.

How did you become involved in DCP?

Upon graduation from college, I did what most graduates do, updated my resume and sent it out via the web. My revised resume listed my professional activities in clinical reference research, pharmaceutical database management, and social work with an emphasis on understanding of basic laboratory science, business, and communication. Luckily, someone saw my resume and inspired me to apply for a job with the Cancer Biomarkers Research Group in the DCP as a Program Specialist. I applied, and was offered the job. I functioned as the program manager for



the Early Detection Research Network for many years. I worked closely with the program director, grantees, and DCP program staff through several reissuances. In 2007 my brother-in-law was diagnosed with Acute Myeloid Leukemia and started treatments. I realized then that I wanted to work more closely with clinicians. The timing of my desire to make a change coincided with the consortia’s need for a Program Manager. I’ve enjoyed the many challenges of the Consortia and the development of CP-CTNet.

Please note that after many years of treatment, including two bone marrow transplants, my brother-in-law is still cancer free and living with the long-term complications from treatments.

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

While the underpinnings of the contract and grant mechanisms are the same, there is more flexibility with a grant. The cooperative group mechanism sets the tone of collaboration within CP-CTNet. CP-CTNet established the DMACC with a centralized data management and coordinating center. The program is positioned to unite our resources

and work together to efficiently and successfully build, open, enroll, complete, and publish findings for clinical trials. Although it has taken some time and many conference calls, the first cross-network study is a testimony to the collaborative spirit of CP-CTNet. I am sure other cross-network studies will be proposed.

What goals do you have for CP-CTNet?

One goal for CP-CTNet is to build on what is happening in the news today regarding the rapid approval of vaccines for COVID-19. A positive coming from this unfortunate pandemic is that many more people in mainstream occupations are aware of the need for clinical trials. CP-CTNet has an opportunity to build on this platform. Whether I am riding at home in Virginia, the hills of Tennessee or Kentucky, or across farms in the Carolinas and into Georgia, people are now talking about clinical trials. They are receptive to the processes and understand the terms – inclusion and exclusion criteria, randomization, adverse events, clinical data, and findings. When I share with new friends that I work with the NCI managing prevention clinical trials they listen and ask intelligent questions about new developments in prevention strategies. CP-CTNet can inform the general population of the benefits of participating in prevention clinical trials.

What do you see as the greatest challenge for CP-CTNet?

With the continuation of the COVID-19 pandemic there is a concern that the priority of prevention may not be the focus of health providers and patients. In the spring and early summer, I heard many advertisements reminding patients to keep their appointments for routine health checks, colonoscopies, and screenings. I have not heard as many ads over the last two months. There is a shift in the research community to covidization. As we all know, the number of institutions committed to doing chemoprevention research was limited prior to the pandemic. There is an even larger need for CP-CTNet to establish itself as the leader in prevention clinical trials with successful trials to inform the broader scientific community.

What are your hobbies/interests?

I must look down to see how I am dressed before I answer this question. My main passion is living on a farm,



breeding, raising, and riding horses. I also train horses and occasionally riders. I enjoy gardening, cycling, and hiking.

I am passionate about protecting the natural flora and fauna found in rural Virginia. You always find a colorful display of wildflowers on the farm, starting from the winter blossoms of jasmine, the arrival of spring beauties, bluebells, the summer butterfly weed, and ageratum, to the fall ironweed up to a killing frost. I know where and when to find wild game on my property during each season and enjoy watching the young game explore each spring and mature through the year.

The horse in the picture, Blue Virginia's Blues, is one of over 20 I have bred. He is a Registered Irish Draught Sport Horse, sired by Touch of the Blues (Registered Irish Draught), out of Virginia Sly (Thoroughbred).

What is the best advice you've been given?

1. Never ask a horse, dog, or a person to solve a problem that is impossible. Success and confidence are built one step at a time.
2. Do not provide a permanent solution to a temporary problem.

What advice do you offer to continue the success of CP-CTNet?

Ask questions and use the resources developed for the CP-CTNet. You are not alone, CP-CTNet is a network. We work together to solve the issues around Chemoprevention Clinical Trials.

Research Funding Opportunities

GRANTS & AWARDS

NCI Research Specialist Awards

The NCI shared newly-published funding opportunities for [Research Specialist Awards](#) (*R50 clinical trial not allowed). This funding is specifically for clinician scientists supporting NCI-funded clinical trials research. The award is intended to provide salary support and sufficient autonomy, so that individuals are not solely dependent on NCI grants held by others or other sources of support for cancer research career continuity. We encourage CP-CTNet Investigators to apply!

- [PAR-21-285](#). This award is targeted to career scientists; non-tenure track laboratory staff researchers, core facility managers, and data scientists whose salary is currently supported by NCI-funded grants. It is anticipated that only exceptional scientists who want to pursue research within the context of an existing NCI-funded cancer research program, but not serve as independent investigators, will be competitive for this award.
- [PAR-21-286](#). This award is designed for exceptional scientists who want to continue to pursue research within the context of an existing NCI-funded basic, translational, clinical, or population science cancer research program, but not serve as independent investigators.
- [PAR-21-306](#). This award is designed for exceptional clinician scientists who want to participate in the scientific review committees, monitoring committees and other activities, but not serve as principal investigators of research project grants.



CASCADE

The [CASCADE Network](#) seeks to conduct pragmatic clinical trials evaluating the effectiveness of clinically proven interventions to overcome barriers and reduce failures in the cervical cancer screening, management, and precancer treatment cascade for women living with HIV.

- [NOT-CA-21-112](#)
- [NOT-CA-21-113](#)
- [NOT-CA-21-114](#)

NIH Planning Grant Program

This grant program provides support for the initial development of a clinical trial or research project, specifically in planning a large randomized or non-randomized Phase II or later study.

- [R34/U34](#)

Administrative Supplement

This Notice of Special Interest ([NOT-CA-21-070](#)) informs current awardees of NCI cancer prevention and symptom management clinical trial grants of an opportunity for supplemental funding. The NCI is providing this opportunity for support of implementation and evaluation of promising clinical trial recruitment and retention strategies for cancer prevention, cancer control, and care delivery clinical trials, as well as quality-of-life studies embedded within treatment and imaging studies.

The research solicited through this opportunity includes, but is not limited to, strategies that are directed toward NIH-designated U.S. health disparity populations, including Blacks/African Americans, Hispanics/Latinos, American Indians/Alaska Natives, Asian Americans, Native Hawaiians and other Pacific Islanders, socioeconomically disadvantaged populations, underserved rural populations, and sexual and gender minorities, as well as older adult populations.

Diversity in Health-Related Research

The Center to Reduce Cancer Health Disparities (CRCHD) [CURE program](#) offers unique training and career development opportunities to enhance and increase diversity in the cancer and cancer health disparities research workforce. The CURE program supports promising candidates from middle school through junior investigator levels, and provides them with a continuum of competitive funding opportunities.

- [PA-21-071](#). Funds are available for administrative supplements to enhance diversity by recruiting and supporting students, post-doctorates, and eligible investigators from diverse backgrounds, including those from groups that have been shown to be underrepresented in health-related research. (Admin Supp - Clinical Trial Not Allowed)

CAP-IT

The NCI Cancer Prevention-Interception Targeted Agent Discovery Program ([CAP-IT](#)) is a collaborative research network with the overarching goal of discovering molecularly or immunologically targeted agents designed to prevent or intercept the oncogenic process in higher-risk populations.

- [RFA-CA-21-038](#). (U54 clinical trial not allowed)
- [RFA-CA-21-039](#). (U24 clinical trial not allowed)

Please check the [Funding Opportunities](#) page of the DMACC website for up-to-date information on FOAs.



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
Enrolling Sites: LAO – UAZ, AO – UCLA
- **UAZ20-01-01**. Bioactivity of Apalutamide in Prostate Cancer Patients Scheduled for Prostatectomy
Enrolling Sites: LAO – UAZ, AO – Johns Hopkins

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
Enrolling Sites: AO – Cedars Sinai Medical Center, AO – Duke
- **NWU20-02-01**. Surgical Window of Opportunity Study of Megesterol Acetate and Metformin for Endometrial Intraepithelial Neoplasia
Enrolling Sites: LAO - NWU, AO - University of Colorado
- **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
Enrolling Sites: LAO/AO - NWU

View the [complete list of active studies](#) at any time on the DMACC website.

STUDIES IN THE PIPELINE

UAZ: University of Arizona Cancer Prevention Clinical Trials Network

- **UAZ21-06-01.** Phase II Randomized, Placebo-Controlled Trial of Broccoli Seed and Sprout Extract (BSSE) to Evaluate Sustained Detoxication of Tobacco Carcinogens in Heavy Smokers (BSSE)

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

- **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)
- **MDA21-06-01.** A Phase Ib Clinical Trial of Nons-209 for Recurrent Neoantigen Immunogenicity and Cancer Immune Interception in Lynch Syndrome Patients

UWI: MW Chemoprevention Network - University of Wisconsin & 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
- **UWI21-06-01.** Pilot Study of GCC Agonists to Identify a Cyclic-GMP Signal in Duodenal Tissue of Healthy Volunteers

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



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Other Links

- [DMACC website](#)
- [DCP CP-CTNet website](#)

Do you have questions, comments, or newsletter content suggestions? Please [email us](#).

UPCOMING EVENTS

Oct 7: CP-CTNet DMACC Website Review Committee Meeting

Oct 19: CP-CTNet Webinar
Virtual Bio-Repository Meeting

Oct 21: DCP Agent Call Meeting

Oct 29: Quarterly Steering Committee Meeting (Virtual)

Nov 11: Veterans Day

Nov 22: Cross-Network Collaboration Meeting

TBD: Fall/Winter Retreat at Frontier Science

Jan 28: Quarterly CP-CTNet Steering Committee Meeting (Virtual)

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

June 3: American Society of Clinical Oncology (ASCO) June 3-7, 2022

Research reported in this publication is supported by the National Cancer Institute of the National Institutes of Health under Award Number U24CA242637. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.