March 2021

CP-CTNet NEWSLETTER

Cancer Prevention Clinical Trials Network

Springtime is Here!

It's synonymous with rejuvenation, renewal, and regrowth. We can all appreciate longer periods of daylight and warmer temperatures after a seemingly endless winter. Hope comes in the form of more COVID-19 vaccines being approved and getting into arms. A return to a somewhat more "normal" life appears within reach. We look forward to a blossoming of ideas from our network colleagues in the coming months and the opening of more trials. The network is flourishing because of the passion and enthusiasm that all of you contribute on a daily basis. Let's keep the momentum going as we SPRING FORWARD!

NCI Cancer Prevention Clinical Trials Network

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

In This Issue

Why Do So Many Chemoprevention Trials Fail to Demonstrate Efficacy?

Jens Eickhoff[1], Jen Birstler[1], Guanhua Chen[1], Zhumin Zhang[1], Vikrant Sahasrabuddhe[2], Eva Szabo[2], and KyungMann Kim[1]

[1]University of Wisconsin-Madison, Madison, WI

[2]National Cancer Institute, Bethesda, MD

The majority of chemoprevention trials fail to demonstrate efficacy. We conducted a systematic review to examine potential causes for failing to detect chemoprevention intervention effects. Chemoprevention trials conducted under the Chemoprevention Consortia Program of the Division of Cancer Prevention, National Cancer Institute between 2003 and 2019 were evaluated. We reviewed study protocols to gather information regarding study design, primary and secondary endpoints, statistical methods, analysis populations and sample size justifications with planned effect sizes. Furthermore, we reviewed corresponding study reports and manuscripts to obtain study results information. Intervention effect differences were standardized by calculating Cohen's d effect sizes. In studies where only p-values without reported effect sizes were reported, we estimated observed effect sizes using p-values and sample size information based on a normal distribution approximation. We compared planned effect sizes to observed effect sizes using correlation analyses and by evaluating concordance measures. Furthermore, we used the observed effect sizes to conduct post-hoc power calculations.

Of a total of 59 chemoprevention trials reviewed, 24 studies were efficacy or biomarker chemoprevention trials with complete information on planned and observed or estimated effect sizes. Primary disease sites of the trials included 5 (21%) breast cancer, 6 (25%) prostate cancer, 4 (17%) lung cancer and 9 (38%) gastrointestinal/other cancer. Seventy-five percent of the trials were multi-arm randomized studies of which 15 trials were blinded. The median planned effect size for detecting an intervention effect was 0.75 (range 0.2-1.14) and the median planned sample size per arm was n=30 (range 11-101). The observed effect sizes, on the other hand, for the majority of studies were small with a median of 0.34 (range 0-0.66). The median difference between planned versus observed effect size was 0.37 and in 88% of the studies, the observed effect sizes were smaller than the corresponding planned effect sizes. A low level of concordance between planned versus observed effect size was observed with an intra-class correlation coefficient 0.18 (95% CI: -0.1-0.50) and Lin's concordance correlation coefficient of 0.18 (95% CI: -0.02-0.35). The median post-hoc power for detecting the observed effect sizes was only 0.29, (range 0.03-0.93). For single arm studies (n=6), the differences between planned versus observed effect sizes were significantly smaller than for multi-arm randomized studies with mean differences (± SD) of 0.15 ± 0.30 vs. 0.45 ± 0.22 (p=0.021). There were no significant differences detected in the comparisons between planned versus observed effect sizes when stratified by accrual goal (≥ 80% accrual goal achieved versus <80% achieved) or analysis population (intent-to-treat versus per-protocol population).

The results indicate that the majority of early phase chemoprevention trials have much smaller observed effect sizes than planned. Sample size calculations for such trials need to balance the known attributes of the study endpoints, e.g. the potential detectable effect sizes in populations that can be realistically and cost-effectively accrued, with the need to detect only effect sizes large enough to justify subsequent phase III trials. Utilization of interim analyses for futility should be considered.

Coordinator Corner

Susan Vanzzini – Study Coordinator for the University of Arizona CP-CTNet

Susan Vanzzini began as a medical assistant in 1980 and spent the first part of her career working in OB/GYN and Rheumatology. She became intrigued when she learned of a job opening for a research coordinator in women's health at the University of Arizona with Dr. Francisco Garcia. She enjoyed the work from the beginning and continued to work with Dr. Garcia for 17 years doing primarily HPV related studies for cervical cancer prevention. In 2017 Susan joined Dr. Sherry Chow's University of Arizona Phase I/II Cancer Prevention Consortium team as the study coordinator for the HPV vaccine delayed booster trial. The HPV vaccine delayed booster trial was our first pediatric cancer prevention trial, and Susan took the recruitment and retention challenges head on by developing a strong rapport with providers for referring patients and establishing close relationships with the study participants and their families. Susan enrolled over 100 participants into the trial in just over one year.

Susan is currently the study coordinator for the new extended follow-up study of the HPV vaccine delayed booster trial. She is working to re-enroll participants from the previous trial so that stability and persistent immune response can be evaluated in those who received a single dose of the HPV vaccine with a delayed booster injection at 24 months.

Susan enjoys working in clinical research. She states, "I feel that the most rewarding part of working in clinical research is meeting interesting new people and becoming close to them as they participate in the study. I also am fascinated to be a part of research studies that help to improve medical technology and the health and wellbeing of people".

Interview with Dr. Julie Chang

CP-CTNet DMACC Auditing Director

How long have you been involved in clinical research?

I started my career in clinical research when I first came onto faculty at the University of Wisconsin in 2007. Over this time, I have been involved in large national cooperative group trials, industry-sponsored trials (including early phase and first in human studies), and several multicenter investigator-initiated trials (one for which I am an IND holder).

What sparked your interest in clinical research?

As a physician, I am constantly learning all the gaps we have in understanding disease and the limitations we have in offering effective treatments for patients. The only way most of our modern medical advances have occurred is through clinical research. For example, when I first started my clinical research career in 2007, my focus was in chronic lymphocytic leukemia (CLL), and people thought I was crazy because therapies were so limited in that disease and hadn't really changed in 20+ years. At that time, we had a handful of traditional chemotherapy drugs that were toxic and had limited efficacy, and basically we gave that toxic chemotherapy and prayed that those treatments would work longer than expected for most patients. Fast forward to 2021, and now treatment of CLL is managed almost exclusively with non-chemotherapy approaches with newer targeted oral drugs like ibrutinib and venetoclax. The University of Wisconsin participated in these drug trials that eventually led to FDA approval, and we were on the front-line for understanding and managing toxicity issues and defining appropriate dosing and monitoring. It is inspiring to know that patients with CLL today have a completely different prognosis and profile for therapy compared with just 10 years ago as a direct consequence of clinical research.

What are your fields of interest?

My research focus is in non-Hodgkin lymphomas (NHLs), including chronic lymphocytic leukemia. I am particularly interested in early drug trials in older adults with NHLs, which is an increasing number in the US population.

Interview with Dr. Julie Chang

CP-CTNet DMACC Auditing Director

What are your thoughts on/vision for cancer prevention research?

Cancer prevention is the logical counterpoint to cancer treatment. Cancer treatment exposes patients to risks, side effects and impairments in quality of life that are unfortunately universal. It is only logical that we would want to focus on strategies to reduce cancer risk, much as public health focus has been on prevention of heart disease and diabetes.

What role does auditing play in the clinical research process?

Clinical research is a privilege and a huge responsibility. We are entering into a contract with patients that we will be transparent about the purpose and risks of research, and that patients will be constantly informed of changes to those understood risks and benefits. Without Good Clinical Practice and strict protocol and research compliance, the foundation of this contract with our patients is at risk. Auditing is an important component of ensuring the integrity of this important commitment we have made to patients while participating in a trial. In addition, a robust auditing program is essential for future patients to be assured that data we have about treatment efficacy and safety can be trusted.

What role do you have within the CP-CTNet DMACC?

I am serving as the clinical director for the DMACC auditing unit. My role will be to oversee results of audits, and assist with interpretation and understanding of clinical issues that may arise in an audit with issues such as interpreting eligibility criteria, protocol deviations, etc. The other members of the auditing unit have strong backgrounds in clinical research and bring a breadth of knowledge as we work on developing a plan for effective but efficient auditing strategies.

DMACC Updates

Data Management and Reporting Unit

Lynette Blacher, MLS – Manager of the Data Management and Reporting Unit

A key area of focus for the Data Management and Reporting Unit since the last newsletter has been reviewing trial conduct procedures in order to increase efficiency and alleviate the workload of the LAOs and AOs. DMACC has worked with DCP and the LAOs to identify areas for process improvement. Areas undergoing procedure updates include the reporting of Protocol Deviations, development of study-specific System Variable Attributes Reports (SVARs), Participant ID reservation, and Treatment ID assignment.

Protocol Deviations

The current process for Protocol Deviations involves reporting deviations on a fillable PDF form and sending this form via email from the AO, to the LAO, to the DCP Medical Monitor and Nurse Consultant. If the LAO and/or Medical Monitor/Nurse Consultant require clarifications, the form will continue to be edited and sent in email between the parties until all is resolved.

With the new process, the Protocol Deviation data and the entire process flow will take place within Medidata Rave. This will ensure all parties see the most recent version of the form, and all changes will be documented within the audit trail in Rave. AOs will enter data directly in Rave, and automatic notifications will be generated to instruct LAOs and Medical Monitors/Nurse Consultants to review. LAOs and Medical Monitors/Nurse Consultants will be able to query, and the AOs will be able to respond, directly in Rave. Medical Monitors/Nurse Consultants can also assign the grade.

SVAR Development

Study-specific SVARs are currently being developed by the LAOs and are submitted with the second submission of the protocol. The SVARs then undergo review by the DCP SVAR Review Coordinator and Study Team, DMACC, and the DCP CDE and Regulatory Contractors. The DCP SVAR Review Coordinator is responsible for sending each version of the SVAR to the reviewers, and DMACC is responsible for coordinating the review.

In order to simplify the process and reduce burden on the LAOs, DMACC will now draft the initial study-specific SVARs upon receipt of the initial version of the protocol. DMACC will then work with the LAO, with input from the DCP CDE and Regulatory Contractors,

DMACC Updates

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until DMACC and the LAO determines the SVAR is acceptable for wider review. At this point, DMACC will send the SVAR to the DCP SVAR Review Coordinator. We anticipate that this update to the process will result in fewer rounds of review, and SVAR finalization taking place more quickly so the eCRFs can be implemented in the Rave database.

A new SVAR Template will be released shortly. This version will contain data items related to the Accrual Quality Improvement Program (AQuIP) data collection.

Patient ID Reservation

At the request of the LAOs, a Reserve PID Module will be available in the Stars Registration/Randomization System, via which LAOs can reserve Participant IDs once a study has received Approval on Hold from PIO. This will allow advance creation of labels containing Participant IDs to occur at the sites.

Treatment ID Assignment

A Treatment ID assignment procedure has been developed to provide Treatment IDs prior to participant enrollment. The Treatment ID corresponds to the treatment that is assigned to a participant based on the randomization scheme for the protocol. A set of Treatment IDs will be reserved in the Stars Registration/Randomization System for each protocol/participating site. The site pharmacist will use the Treatment Module in Stars to access the Treatment ID List, which maps Treatment ID to the participant's assigned intervention, to determine the study agent that should be dispensed to the participant based on the Treatment ID.

If an over-label needs to be applied to the study agent, DMACC will send a list of the Treatment IDs assigned to each of the participating sites to MRI Global. MRI Global will then generate the over-labels for each Treatment ID and ship them to the pharmacy of each site. The pharmacist will select the appropriate over-label, apply the assigned Treatment ID over-label(s) to the appropriate agent, and write-in Participant ID and initials before dispensing to the participant.

The updates to all of these processes are in finalization, and LAOs and AOs will be officially notified of the changes. Training materials will also be provided by DMACC.

DMACC has also been active on the study build and data collection fronts.

Study Builds in Rave

Study build and testing is now underway for NWU20-01-03 (Lisinopril-Liver), and SVARs are in development for six additional studies.

Recruitment Journal

The ability to enter Recruitment Journaling data will soon be available for each study. Sites will now be able to enter site-wide information that affects recruitment (e.g., issue with agent supply for the site, a change of Principle Investigator or Study Coordinator, local regulatory issues, a competing study, etc.) directly in Rave. Previously, sites entered this information in the Online Accrual Reporting System. Sites will be expected to report these data on a monthly basis.

COVID eCRFs

It has been decided by DCP to collect information on COVID-19 testing and vaccination for all CP-CTNet studies. COVID-19 Baseline and Follow-up Assessment eCRFs are in development and will be implemented for all studies, including those that are currently open.

We are excited to facilitate these process improvements and new initiatives, and hope they aid in your trial conduct.

Another area DMACC has been working in is site support, both via meetings and the release of educational materials.

Meetings

DMACC has conducted Introductory Meetings with the MW Chemoprevention Network and the University of Michigan Early Phase Clinical Cancer Prevention Consortium, and has provided training and guidance during the Study Initiation Meetings (SIMs) for the NWU20-02-02 (Atorvastatin-Colon) and NWU20-02-01 (Metformin/Megestrol-Endometrium) studies. Topics included study start-up, CP-CTNet website/DMACC Portal Gateway, user access to the Gateway and

Data Management and Reporting Unit

Lynette Blacher, MLS – Manager of the Data Management and Reporting Unit

DMACC systems, demos and training requirements for the Stars Registration/Randomization system and Rave, data management and quality control, auditing, SOPs/documentation, and communication.

Educational Materials

DMACC has also posted new educational materials to the CP-CTNet Portal Gateway. These materials are related to the enrollment process and include three video tutorials for the Pre-Screening, Screening, and Enrollment processes. An updated Stars Registration and Randomization System User Guide will soon be posted as well.

Clinical Trials Auditing Unit

Holly Shaw, MS, CCRP – Co-Manager of the Clinical Trials Auditing Unit

The DMACC Auditing Unit has been busy these first few months of 2021 in preparing for launching our auditing program in the coming months. Since the last newsletter, we have participated in meetings with a few LAOs as well as Site Investigator Meetings for trials that will be opening soon. We had a meeting with DCP where we presented a module in Medidata RAVE called Targeted Source Data Verification (TSDV) that we plan to use for participant chart reviews during audits. We also had our first monthly CP-CTNet Auditing Committee meeting with our colleagues at DCP. We are very thankful for their collaboration as we prepare for the first audits in Q2 2021. In addition, our programmers are working hard on our web-based auditing system. It is looking great and we are getting closer to its release. We can't wait to show it to everyone!

At the end of February, you should have received a survey from us about remote auditing. We are trying to gather some information from the LAOs and AOs regarding your sites' capabilities for EHR access procedures, source data, and capacity for remote auditing, especially during these challenging times due to COVID-19. We would be very thankful if you could take a few minutes to complete the survey and send it back to us by email at your earliest convenience: Audit_CP-CTNet@frontierscience.org

Administrative and Coordinating Unit

Kelly Miller, BS, CCRC - Manager of the Administrative and Coordinating Unit

Bridget Dermody, BS - Administrative Specialist

I-SCORE 2021

The I-SCORE 2021 planning committee made up of Howard Parnes, Powel Brown, Maggie House, Mela Asefa, Perquita Perry, Bridget Dermody and Kelly Miller continues to meet weekly leading up to the April 29th and 30th meeting. Registration opened on February 18, 2021. Calendar invites have gone out to those already registered and will go out weekly for newly registered attendees. Speaker and Moderator invitations have been sent. If you haven't already done so please register at https://events.cancer.gov/dcp/iscore by 11:59 PM, EDT, on Wednesday, April 21. Please also consider submitting a poster. If you have questions please contact us at: Admin_CP-CTNet@frontierscience.org

CP-CTNet DMACC Webpage

In collaboration with Frontier staff 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 any further suggestions. The webpage evolves frequently, so please visit it often for up to date news on things happening in the network.

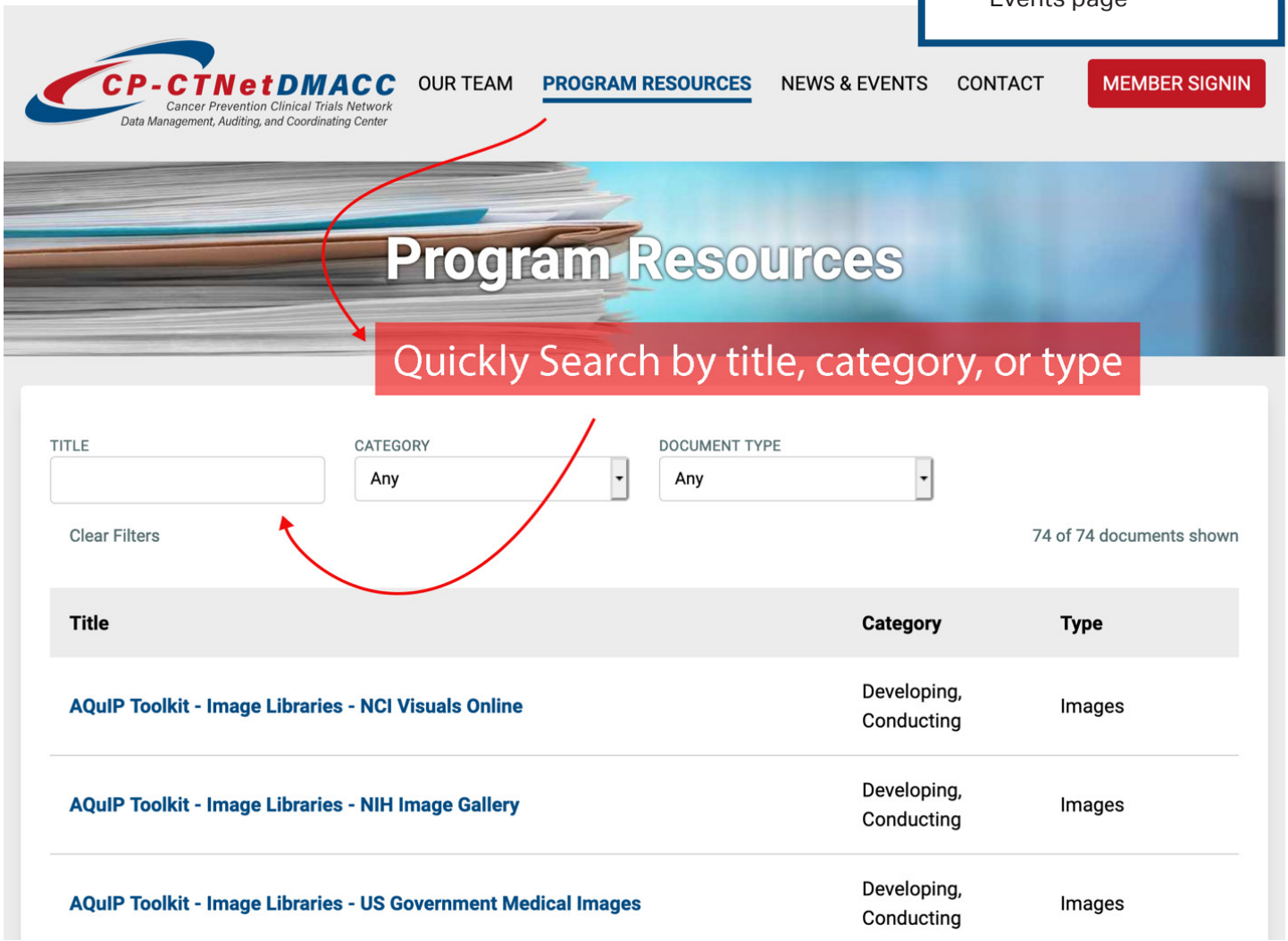
CP-CTNet DMACC Website Updates

The CP-CTNet DMACC website (https://www.cp-ctnet-dmacc.org) is a single destination for LAOs and AOs to get information about CP-CTNet initiatives, view CP-CTNet documentation, and access project tools and resources.

Many CP-CTNet resources are available on the CP-CTNet DMACC website without needing to sign in. You can find documents templates, project news, and contact information for key CP-CTNet personnel.

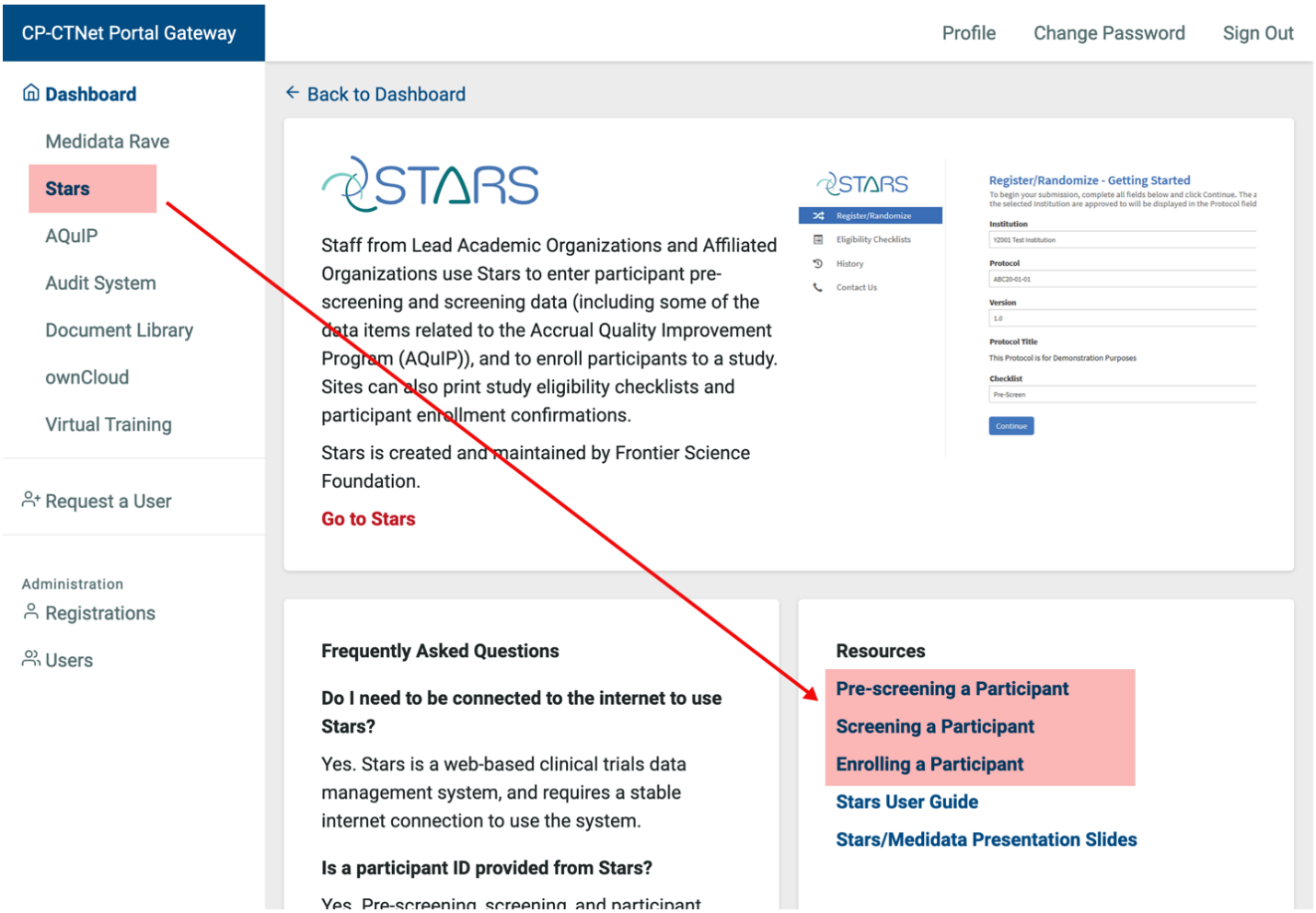
What's New:

- New documents on the Program Resources page
- New Stars video tutorials on the Portal Gateway
- Steering Committee memos now on News & Events page



CP-CTNet DMACC Website Updates

By signing into the CP-CTNet Portal Gateway, additional project resources can be accessed. This includes new video tutorials on pre-screening, screening, and enrolling participants in Stars.



Recent changes to the Portal Gateway will allow more items and resources to be made available to users. AQuIP reports will be made available directly from the Portal Gateway. In the coming months, look for exciting new features such as a directory of CP-CTNet trials and a contact directory. Check the CP-CTNet DMACC website frequently for the latest news and information.

Active Studies

University of Arizona, University of Arizona Cancer Prevention Clinical Trials Network (UA CP-CTNet)

UAZ20-01-02

Title of Study: An Extended Follow-up Study of the HPV Vaccine Delayed Booster Trial
LAO – UAZ
AO – UCLA

Studies in the Pipeline

University of Arizona, University of Arizona Cancer Prevention Clinical Trials Network (UA CP-CTNet)

UAZ20-01-01

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

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

NWU20-01-03

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

NWU20-02-01

Title of Study: Surgical Window of Opportunity Study of Megesterol Acetate and Metformin for Endometrial Intraepithelial Neoplasia

NWU20-02-02

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

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

MDA20-01-01

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

MDA20-02-01

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

University of Wisconsin, The MW Chemoprevention Network

UWI20-00-01

Title of Study: 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

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

UMI21-05-01

Title of Study: Obeticholic Acid for Chemoprevention in Barrett's Esophagus

CP-CTNet Cross-Network Study

INT21-05-01

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

Cancer Vaccine Trial Challenges During the COVID Pandemic

William Gwin, Jennifer Childs, Kris Kauno, Doreen Higgins, Kellie Burton, and Mary Disis, University of Washington

The COVID pandemic has created a ripple effect across the entire healthcare spectrum, affecting many facets of clinical practice beyond diagnosis and treatment of the COVID virus infection itself. The negative impact in oncology has been multifactorial. One area that has been significantly affected has been cancer clinical trials, where a notable decrease in enrollment in National Cancer Institute–sponsored clinical trials has been reported[1]. This decline in enrollment was significantly more pronounced in cancer control and prevention trials compared to therapeutic trials (odds ratio, 0.38; 95% CI, 0.29-0.50; P < .001)[2]. The drop in clinical trial enrollment was due to many factors. Initially, to prevent the spread of COVID, temporary pauses in enrollment were mandated by governmental, institutional, and sponsor organizations[3]. In addition, investigations of patient attitudes found that many patients with cancer were less likely to participate in clinical trials due to concerns about the pandemic[4]. Our Cancer Vaccine Institute (CVI) at the University of Washington in Seattle had several cancer vaccine trials open to enrollment at the time COVID was first reported in the United States, with the first reported case in our local Seattle metropolitan area. Our CVI experience was initially temporary holds on clinical trial enrollment as mandated by our institution. When these holds were lifted we then found that patients from out of state were hesitant to travel due to the concern of exposure to COVID. Patients were also confronted with state specific self-quarantining requirements imposed on individuals traveling across state lines, placing another barrier to patients seeking clinical trials. With the availability of three COVID vaccines in the US, we have now seen more patients willing to travel once they have received a COVID vaccine regimen. We have many patients waiting to enroll on our prevention vaccine studies until after they have received their COVID vaccinations.

In the winter of 2020-2021, a new challenge was arising for chemoprevention vaccine trials - how will COVID vaccines impact trials of cancer associated preventative vaccines? This was particularly salient for our cancer population who are both at risk for worse outcomes with COVID infection[5], yet in need of additional interventions to reduce their risk of cancer recurrence. The first two COVID vaccines available in the US for the general public were the mRNA vaccines BNT162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna) targeting the spike protein of the COVID virus. It has been recognized that vaccine induced antibodies able to bind to the spike protein at its receptor-binding domain (RBD), prevent its attachment to the host cell and neutralize the virus[6]. These vaccines were developed to induce robust cellular and humoral immunity. Both vaccines also utilized a homologous prime-boost strategy to maximize immune response. A prime-boost immunization strategy is defined as a regimen of immunization with the same immunogen during the initial prime and subsequent booster doses. The primary objective of this approach is to develop more robust humoral and cellular immunity compared to the immune response achieved by a single vaccination. We also utilize this prime-boost strategy in cancer vaccine development to maximize T-cell responses to cancer associated antigens. One immunologic concern of simultaneous cancer vaccine and COVID vaccine administration is that COVID vaccines are priming the immune system against a foreign antigen and have the potential to elicit a robust systemic immune response which may overwhelm an evolving immune response elicited against immunogenic tumor associated antigens (which are self-antigens or mutated self-antigens). Another immunogenic concern is discerning COVID vaccine vs. cancer vaccine adverse events which can be similar in nature but quite different in the grade of severity.

The next challenge became scheduling our cancer vaccine doses while patients were also being scheduled for COVID vaccines. There currently are no data on the safety and efficacy of any FDA authorized COVID vaccines administered with any other vaccine. For this reason, the CDC advises that a COVID "vaccine series should be administered alone with a minimum of 14 days before or after administration with any other vaccine". In addition, the schedule of various COVID vaccines are different with one being two vaccinations three weeks apart (Pfizer) and the other four weeks apart (Moderna). Lastly, the limited

Cancer Vaccine Trial Challenges During the COVID Pandemic

William Gwin, Jennifer Childs, Kris Kauno, Doreen Higgins, Kellie Burton, and Mary Disis, University of Washington

initial supply of the COVID vaccines posed another challenge as patients enrolled on cancer vaccine trials were offered COVID vaccines and then we were faced with working to achieve the 14-day separation of vaccines yet staying within the trial protocols, while not limiting our patients' access to the COVID vaccine supply.

Of particular relevance to our clinical trial patients with a history of breast cancer, the COVID vaccines have been recently reported to induce unilateral axillary adenopathy[7]. Such a response has been reported with prior vaccines and represents a robust local-regional immune response, but certainly can be alarming to a breast cancer patient concerned about recurrence of disease. Such a potential side effect requires close monitoring and follow-up. From an adverse event standpoint, the COVID vaccine associated side effects are very similar to the side effects we have reported with our cancer vaccines, including pain at the injection site, fatigue, and fever. The side effect profile of a COVID vaccine can be much more severe and of a longer duration, so when sequencing COVID immunization with cancer vaccination one will expect the number and grade of adverse events to increase. Differentiating the side effects elicited by a cancer vaccine and those associated with the COVID vaccines are indistinguishable. We must list all of these side effects as potentially related to the cancer vaccine. The common side effects from the COVID vaccines occur within the first 7 days after vaccination, as we are working to schedule patients >14 days after they complete their COVID vaccine series – we anticipate that this break between vaccines will help in differentiating side effects between vaccines. Yet, we still anticipate seeing many more side effects on our current studies than we would have expected previously.

The impact of the COVID pandemic has been multifactorial on cancer control and prevention trials with specific challenges associated with patient enrollment, vaccine timing, and overlapping side effects. Despite these obstacles we believe that it remains critical to the health of our cancer patients that we continue our work in the development of new cancer prevention approaches. Toward this end the University of Washington CVI has continued to advance our vaccine and immunotherapy programs and have opened three new clinical trials in the past 12 months. The lessons learned from the COVID pandemic and related clinical trial challenges has driven our clinical trial program and the clinical cancer research community as a whole to be more flexible in confronting the obstacles that a future public health crisis would create.

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CP-CTNet DMACC Staff Updates/Spotlight

Alex Krolikowski

Alex Krolikowski is a Training Specialist and will be responsible for the development, coordination, and presentation of documentation and training materials for studies in the CP-CTNet program. He has B.S. degrees in Psychology and Communications and an M.S. in Educational Psychology and Methodology. Prior to joining Frontier Science, Alex worked in the fields of learning and development, clinical research, and nonprofit management.

Nicole Freitag

Nicole Freitag is a Data Manager and will be responsible for communication with participating sites, and quality control and data management of participant data for the CP-CTNet studies to ensure accurate and timely data. She earned a B.S in Biochemistry from Rochester Institute of Technology and joined Frontier Science in 2021. Prior to joining Frontier Science, she served as a Laboratory Technician at the University of Rochester School of Medicine and Dentistry, working on various projects focused on the use of stem cells and their role in the progression and treatment of neurodegenerative diseases.

Yvonne Woolwine-Cunningham

Yvonne Woolwine-Cunningham is a Data Manager and will be responsible for eCRF/SVAR review and coordination, eCRF building, and data management. She has a BA in Biology, is a certified phlebotomist, and is completing her MS degree this spring; her thesis work focuses on electrophysiological study of the structure and function of human gap junction channels. She has worked as a Research Coordinator with the University at Buffalo for 6 years on vascular surgery, pulmonology, endocrinology, hepatic, and infectious disease studies. She worked at Frontier Science as a Data Manager for the IMPAACT Network for 2.5 years in pediatric HIV studies sponsored by the Division of AIDS, NIAID, NIH.

Yeonhee Park

Yeonhee Park is a Co-investigator on the project. Dr. Park completed her PhD in Statistics from University of Florida in 2015 and had a postdoc training in Biostatistics at MD Anderson Cancer Center. After spending almost three years as postdoc, she joined as an assistant professor the Department of Public health sciences at Medical University of South Carolina (MUSC) in 2018. She is currently an assistant professor in the Department of Biostatistics and Medical Informatics at University of Wisconsin-Madison after working for two years in MUSC. Her primary areas of research interest are the development of innovative statistical designs, statistical methods and data analysis tools with application to biomedical studies. Her statistical expertise includes adaptive clinical trial designs, Bayesian methods, multivariate analysis for complex observational study, and statistical designs for precision medicine. Dr. Park has collaborated with oncology investigators across the cancer research continuum, including those in the basic, clinical, and population sciences. Also, Dr. Park was a member of Hollings Cancer Center's Protocol Review Committee at Medical University of South Carolina to assist with the scientific review of investigator-initiated trials, protocols initiated by outside investigators, and industry-sponsored trials.

Upcoming Events

April 10-15 and May 17-21, 2021

American Association for Cancer Research
https://www.aacr.org/meeting/aacr-annual-meeting-2021/

AACR Annual Meeting

April 29-30, 2021

I-SCORE – Virtual Meeting
https://prevention.cancer.gov/news-and-events/meetings-and-events/investigators-and-site
** **Registration open until April 21, 2021** Please** submit posters

April 29, 2021

Quarterly Steering Committee Meeting- Virtual

May 20, 2021

Clinical Trials Day – The International Clinical Trials Day is a yearly event and celebration held to commemorate and honor the industry of clinical research especially the professionals in it by recognizing their greatest contributions to medicine and public health. Specifically, the Clinical Trials Day is held on the 20th of May each year to commemorate the first randomized clinical trial done by James Lind in 1747.
https://dayfinders.com/clinical-trials-day/

June 4-8, 2021

American Society of Clinical Oncology Annual Meeting
https://meetings.asco.org/am/attend

How to Reach Us

Data Management Contact

Lynette Blacher, DataManagement_CP-CTNet@frontierscience.org

Auditing Contact

Holly Shaw, Audit_CP-CTNet@frontierscience.org

Administrative Contact

Kelly Miller, Admin_CP-CTNet@frontierscience.org

DMACC Website

https://www.cp-ctnet-dmacc.org/public/

CP-CTNet Website

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

Do you have questions, comments, or content suggestions? Email Admin_CP-CTNet@frontierscience.org

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