December 2020

CP-CTNet NEWSLETTER

Cancer Prevention Clinical Trials Network

Happy Holidays from the DMACC

As 2020 draws to a close we take this time to thank all of you for the patience, flexibility, and resilience you've displayed as we've navigated the uncertain times presented by COVID-19. Many challenges have been overcome by working together, albeit virtually, and truly have made us a stronger team. Your unwavering dedication, perseverance and commitment have led to many successes thus far in building the Cancer Prevention Clinical Trials Network.

As we reflect on the past year and look ahead to 2021, the vaccine news is very encouraging as is the possibility of many more exciting research studies on the horizon. We remain hopeful for brighter days in the coming months and in the spirit of the holidays hope you can appreciate your family and friends and find joy in the little things life has to offer.

NCI Cancer Prevention Clinical Trials Network

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

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Interview with Vikrant Sahasrabuddhe, MBBS, MPH, DrPH

Program Director, Breast and Gynecologic Cancer Group

What sparked your interest in cancer prevention?

As an early career public health researcher, I initially worked in the area of global HIV/AIDS prevention and care prior to becoming focused on cancer prevention. With increasing access to antiretroviral therapy for HIV globally in the early 2000s, lifespans of women living with HIV were increasing; yet their access to setting-appropriate and cost-effective cancer prevention interventions such as cervical cancer screening was either minimal or non-existent. I was fortunate to be able to undertake my graduate dissertation work with a multidisciplinary group of committed clinicians and public health professionals with whom I worked in Zambia to develop the first ever (and now one of the largest) cervical cancer prevention programs nested within HIV/AIDS care settings in sub-Saharan Africa. This graduate-level work exposed me to the opportunity for reducing morbidity and mortality by improved application of knowledge and prevention clinical interventions at a population level, which sparked and has sustained my interest and motivation to work in the field of cancer prevention.

How did you become involved with DCP?

I worked for several years as a faculty researcher at the Vanderbilt University School of Medicine while being based in the NCI's intramural Division of Cancer Epidemiology and Genetics (DCEG). During this time, I was also affiliated with colleagues in DCP on various trans-NCI research initiatives. Coincidentally at that time, DCP was seeking to fill the position of program director overseeing HPV and cervical cancer prevention clinical trials. My training and experience in medicine and public health, and my skills in leading large multidisciplinary teams to conduct clinical, epidemiologic, and implementation research on infection-associated cancers were valued highly enough to be considered and selected for this position. Over the past five years since joining DCP, I have provided scientific direction and strategic guidance for efforts on optimization of clinic-based and population-based precision prevention strategies for cervical cancer and HPV-related cancers, and building the evidence base for their implementation in the United States and globally. In addition to my work with the CP-CTNet and the Early Phase Clinical Trials Consortia Program, I direct the U.S.-Latin American-Caribbean Clinical Trials Network (ULACNet) focused on prevention of HPV-related cancers in people with HIV, and provide leadership to several trans-DCP and trans-NCI initiatives focused on innovations in HPV/cervical cancer prevention research and efforts to address cancer health disparities.

How did the CP-CTNet Program come about?

DCP's Early Phase Consortia Clinical Trials Program ('Consortia') has been one of the only publicly funded clinical trials network efforts to evaluate and advance cancer prevention interventions from bench to the bedside. The Consortia program was funded between 2003-2012, and then again between 2012-2019 via separate Research and Development (R&D) Contracts to five individual lead organizations, each responsible for 'mini-networks' of affiliated institutions. When the new program was being renewed in 2019, it was felt by both DCP Program Staff and Leadership that it would be beneficial to re-conceptualize this program into a single network of five lead academic organizations and their affiliated organizations, while centralizing functions of data management, auditing, and coordination. This led to the current disposition, which is very favorably poised for leading cancer prevention research into the next decade and beyond.

What is your role within CP-CTNet?

I have two roles in CP-CTNet. First, I serve as the NCI DCP Project Scientist for the U24 Data Management, Auditing, and Coordinating Center (DMACC) (led by the University of Wisconsin-Madison and Frontier Sciences). My responsibilities include scientific oversight of activities related to data management/reporting, auditing, and coordination of CP-CTNet clinical trials, as well as ensuring their relevance to the

state-of-the-science, NIH/NCI priorities, resources, and availability of funding. In this role, I serve as one of the two NCI voting members (along with CP-CTNet Director, Dr. Eva Szabo) on the CP-CTNet Steering Committee, as well as participate in several other network management and oversight activities. My second role in CP-CTNet is serving as the Scientific Lead to develop and oversee trials evaluating early phase clinical prevention interventions for cervical and HPV-related cancers.

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

Even in its first year of existence, and despite the challenges posed by the COVID-19 pandemic, CP-CTNet has already acquired a true network feel, which was less pronounced in its scope and expanse in the Consortia program. The DMACC has been a key catalyst to drive this transformation, and their leadership in applying several best practices (that they previously developed and utilized in other NIH- and non-NIH networks) has been especially useful for many new network-wide activities and efforts. Additionally, this early phase clinical trials network now feels much more synchronized with other NCI-wide clinical trials networks that have long been funded by similar mechanisms.

What goals do you have for CP-CTNet?

My personal goal for CP-CTNet is to work collaboratively to ensure that the advantages offered by the program's new cooperative agreement structure and the new network-wide initiatives actually transform the speed in initiating and flexibility in conducting early phase prevention clinical trials, thereby reliably and rapidly advancing clinical prevention interventions to phase III environments. Personally, I also would like to see CP-CTNet provide leadership to the entire cancer prevention research community by innovating and experimenting with trial designs for seamless advancements of agents/interventions through the clinical development pathways.

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

The COVID-19 pandemic has posed a major barrier for the past few months in the conduct of most areas of medical research, and this will be a key continuing challenge in the progress and implementation of CP-CTNet clinical trials in the coming months and years. More generally, cancer prevention clinical researchers often have to try hard to balance competing considerations around safety versus efficacy, and these equations will continue to pose challenges in the selection and prioritization of agents as well as the design and conduct of cancer prevention clinical trials.

How do you feel COVID-19 will affect CP-CTNet studies?

The COVID-19 pandemic has delayed and will likely continue to delay and modify schedules around the initiation and conduct of clinical trials in CP-CTNet. On the positive side, though, this pandemic will open up hitherto unknown opportunities for improvements and refinements in the conduct of prevention-oriented clinical trials, such as increased use of home-based visits and remote data collection and monitoring, as well as the need for considering novel innovations in clinical trial design for accelerating agent/intervention development.

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

I hope CP-CTNet substantially accelerates progress in cancer prevention agent/intervention development through coordinated, multidisciplinary, and innovative efforts now made even easier to undertake through the creation of a large cooperative agreement-funded network.

Where did you go to college? Medical School?

I went to college and completed my medical education at the University of Pune in India. Subsequently I pursued my Master's and Doctorate degrees in Public Health at the University of Alabama at Birmingham. I also completed fellowship training in epidemiology at the Johns Hopkins University and at the National Cancer Institute.

CP-CTNet INVESTIGATOR SPOTLIGHT

Sara Centuori, PhD - University of Arizona Investigator

Background

The University of Arizona, a CP-CTNet site, applied for and received a diversity supplement to support an early stage investigator, Dr. Sara Centuori. Dr. Centuori, a Hispanic woman from Arizona, has a BS in Physiology, and a PhD in Cancer Biology from the University of Arizona. Her research background is in tumor immunology and immunotherapy and is also an expert in flow cytometry and immune monitoring. During her postdoctoral career she worked with a team of experts in NSCLC to develop a gene expression signature for risk stratification of early stage tumors. The signature, although not directed this way, emerged as a largely immune signature. Dr. Centuori seized this opportunity to begin working on a project to determine differences in the immune contexture of long- and short-term survivors of NSCLC. This research led to the discovery that distinct immune cell populations that seemed to be essential for long term survival on NSCLC. It was also clear based on the data that advantageous immune cell populations were only detectable in early stage tumors and that not all patients were capable of mounting this type of immune response. Driven by these findings Dr. Centuori became interested in Cancer Prevention Research with a focus on Immunoprevention strategies that could be leveraged in high-risk populations to prevent disease. Upon completion of her postdoctoral studies she begin a position with Dr. Chow in the area of cancer prevention and early phase clinical trials. This position combined her background in basic tumor immunology and cancer biology with the opportunity to develop expertise in conducting early phase clinical trials guide chemoprevention approaches into clinical practice to prevent cancer.

Goals

Dr. Centuori's research interest lies in examining potential immunoprevention approaches that can be used to mobilize effective immune responses in at risk individuals. Currently, there is limited information surrounding the immunomodulatory effects of many prevention strategies. There is an unmet need to better understand how putative prevention agents may impact immune function in clinical studies before effective immunoprevention approaches can be implemented. Another limitation in this field is the lack of minority populations enrolled in early phase clinical studies leading to a gap in understating of potentially diverse responses to putative chemoprevention/ immuneprevention agents. As a minority herself, one of Dr. Centuori's goals is to enhance minority recruitment within the University of Arizona's CP-CTNet program to ensure comprehensive evaluation of novel prevention agents across all populations. The specific goals for this diversity supplement are designed to address these specific issues: 1) Examine the feasibility of novel technologies to improve assessing immunomodulatory effects of study agents and immune signatures associated with response, 2) Explore new strategies to improve recruitment and retention of study participants, especially minorities, to participate in CP-CTNet prevention trials, 3) Provide training opportunities to an underrepresented early-stage investigator, myself, in clinical and translational chemoprevention/ immunoprevention research. Through these studies we expect to determine the feasibility of the novel approaches and apply them to future UAZ CP-CTNet trials, enhance the understanding of complex immune responses associated with cancer prevention and generate highly relevant data to define the immunomodulatory potential of putative study agents. Furthermore, by imploring new recruitment and retention strategies specifically aimed at minority recruitment we expect that these findings will be greatly applicable to minority populations. Through participation in the proposed research and training activities, Dr. Centuori will gain fundamental expertise in the performance of successful early phase cancer prevention trials, as well as develop expertise in minority recruitment and community outreach to help her achieve her ultimate career goal of continuing to perform impactful clinical research in chemoprevention/immunoprevention and biomarker development in a manner which best serves diversity populations and reduces cancer health disparities by providing precision prevention to all.

DMACC Updates

Data Management and Reporting Unit

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

The focus of the Data Management and Reporting Unit since the last newsletter has been on support for the studies and LAOs. DMACC has completed the study build, validation and testing in Medidata Rave for the first CP-CTNet study, UAZ20-01-02 (HPV Extended Study). Study build and testing is now underway for UAZ20-01-01 (Apalutamide-Prostate), and System Variable Attribute Reports (SVARs) are in development for five additional studies.

DMACC has conducted an Introductory Meeting with Northwestern University, and has provided training and guidance to the LAOs via attendance at two Study Initiation Meetings (UAZ20-01-02 and NWU20-01-03 (Lisinopril-NAFLD). Topics included study start-up, CP-CTNet website/DMACC Portal Gateway, user access to the Gateway and DMACC systems, demos and training requirements for the Stars Registration / Randomization system and Rave, data management and quality control, auditing, SOPs/documentation, and communication.

Discussions were held between DMACC, DCP and the LAOs to determine a Participant ID format that could be used across all studies and sites. This format will be in place prior to the activation of the next study, and will ensure consistency for data collection. Additionally, a treatment ID proposal is also in process.

Reporting has also been initiated at the DMACC. The first Minimum Data Set submission was completed for the UAZ20-01-02 Study. Reports in Medidata Rave were activated for the LAOs and AOs. These reports will aide in monitoring status and performance of the trial in areas such as enrollment, data submission and query response.

DMACC, in conjunction with DCP, is investigating ways to improve the efficiency of both the protocol deviation process, and the SVAR review process. You can expect to see updates on this in the next newsletter!

Clinical Trials Auditing Unit

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

Since our last update, the Auditing Team continues to work on documentation, internal procedures, and our web-based auditing system. We have participated in two Site Investigator Meetings for CP-CTNet's first trials. We really enjoyed the presentations and virtually "meeting" the study teams at the LAOs, and AOs.

The DMACC Auditing Unit has been building our infrastructure to be ready to conduct audits as we now have a study open, with more to be opened in the next few months. Since the first CP-CTNet study is already accruing quite quickly, we anticipate our first audits will be in the first quarter of 2021. In light of the many challenges presented by COVID-19 on conducting clinical trials, some LAOs and AOs may have restricted capabilities for on-site or remote auditing. DMACC is in the process of preparing contingency plans if we are not able to conduct on-site audits as initially anticipated. We would like to gather some information from the LAOs and AOs regarding the sites' capabilities for EMR access procedures, source data, and capacity for remote auditing. Our goal is to be prepared as we may need to temporarily adapt to a fully remote auditing process. We have drafted a survey that will soon be sent to the LAOs, more to come on this soon!

We are excited to welcome Barbara Wollmer, RN, BSN to the DMACC Auditing Unit. Barbara worked for the University of Wisconsin School of Medicine and Public Health for 34 years before retiring in April of 2019. She is no stranger to CP-CTNet. She spent her final 12 years at the UW Carbone Cancer Center as a protocol project manager, study coordinator and study monitor for the Chemoprevention Research Program under the first and second DCP Chemoprevention Consortium contracts. Barbara will be working on a part time basis, assisting Dr. Julie Chang, DMACC Auditing Unit Director, at the UW and we look forward to collaborating with her!

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 meeting planning is underway for another virtual meeting on April 29-30, 2021. It is being spearheaded by Dr. Howard Parnes from the DCP; Dr. Powel Brown from MD Anderson; and Maggie House, RN, BSN from the DCP.

CP-CTNet Clinical Trials Simplification Committee

The DCP formed this committee which will be co-chaired by Maggie House, RN, BSN from the DCP and DMACC, as well as Dr. Eduardo Vilar-Sanchez, MD from MD Anderson. The committee is comprised of staff from the DCP and the DMACC as well as from the LAOs. The goal is to identify lessons learned from the Consortia Program and the COVID era, and to provide recommendations to CP-CTNet for clinical trial simplification moving forward. The first meeting occurred on October 6, 2020. There are three subgroups of the committee to facilitate its charge. Each subgroup meets separately and then presents their findings to the larger committee.

1) Trial Design and Implementation Issues, which covers the burden to the participant, staffing and international sites, budgetary limitations and agent acquisition and distribution. Presented to the committee on November 17, 2020.

2) Participant Safety & Convenience, which covers travel, remote consenting, telehealth and lab collection. Presented to the committee on December 1, 2020.

3) Trial Oversight and Regulatory Issues, which covers AE and deviation reporting, trial monitoring and auditing, and FDA/CIRB/IRB compliance. This presentation is scheduled for January 5, 2021.

These subgroups meet separately and then present their finding to the larger committee. The committee will compile all the work presented to share with this network.

Study and Site Activation Process

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

Several CP-CTNet protocols are in process and we are all looking forward to opening the trials to enrollment! Before enrollment can take place, both the study and site activation steps must be completed.

Steps to Study Activation:

Approval Requirements Met

- IRB/CIRB approval
- Regulatory documents in place
- Agent availability confirmed
- System Variable Attributes Report (SVAR)/ eCRFs final and approved by DCP
- Study Initiation Meeting (SIM) conducted, etc.

PIO issues a Final Approval Letter to the LAO and DMACC

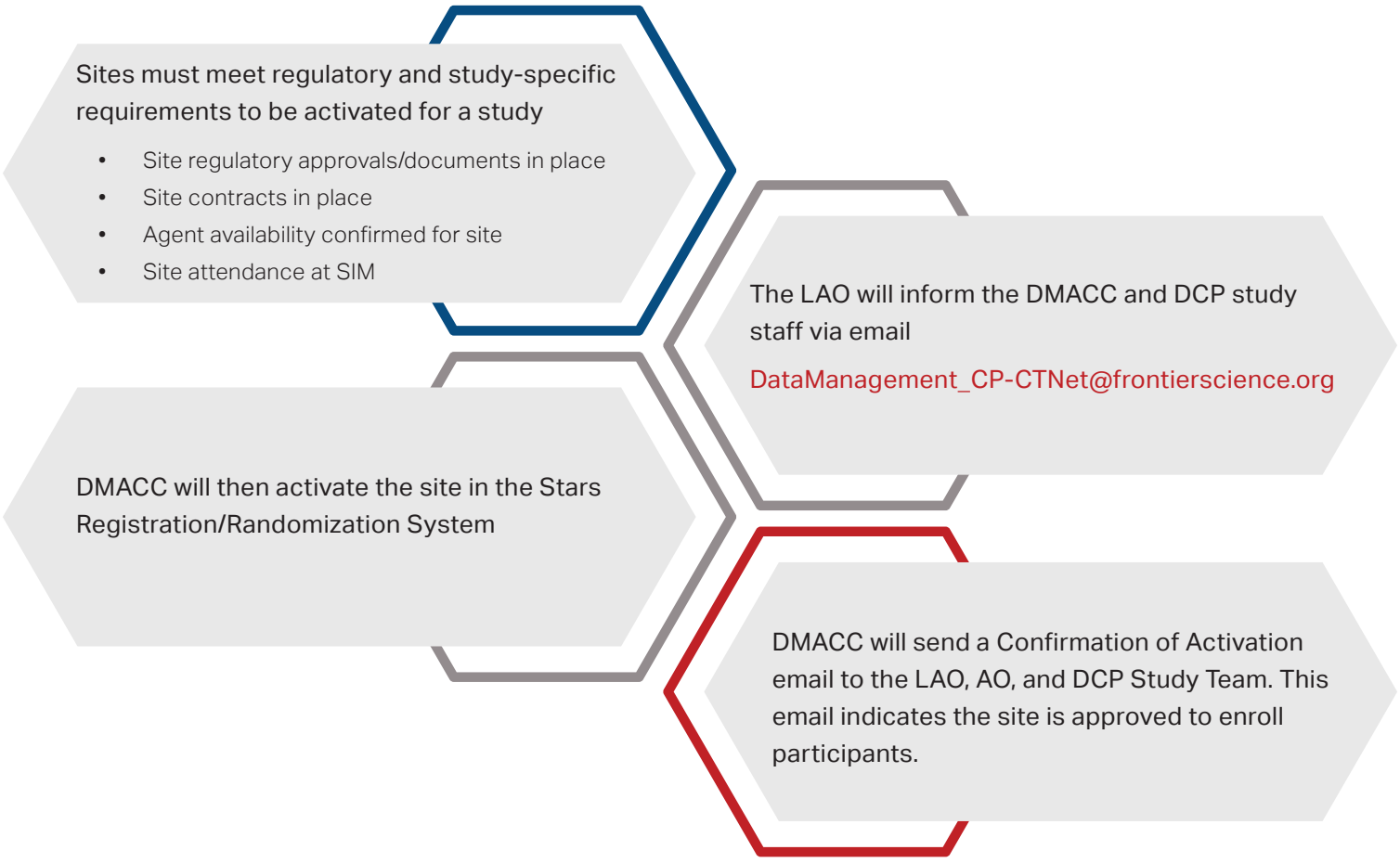
DMACC will record the study as active in internal systems

Note: At this point, only the study is activated - the sites do not have permissions to enroll participants in Stars or enter data in Medidata Rave.

Study and Site Activation Process

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

Steps to Site Activation:



In order to enroll participants in Stars or enter data in Rave, site personnel must have appropriate access to these systems (please see the following article for information on how to request access). Site personnel must also complete the required trainings for the systems:

- Stars: Read and sign off on Stars User Guide, available on the DMACC Portal Gateway
- Rave: Complete required eLearnings directly in Rave:
  - Quality Control Coordinators (e.g., LAOs): Medidata Classic Rave EDC Essentials for Read-Only Users
  - Study Coordinators/Data Managers: Medidata Classic Rave EDC Essentials for Clinical Research Coordinators
  - Investigators: Medidata Classic Rave EDC Essentials for Investigators

For any questions regarding the study or site activation process, please contact:
DataManagement_CP-CTNet@frontierscience.org

How to Request Access for the DMACC Portal Gateway, the Stars Registration/Randomization System, and the Medidata Rave Electronic Data Capture System

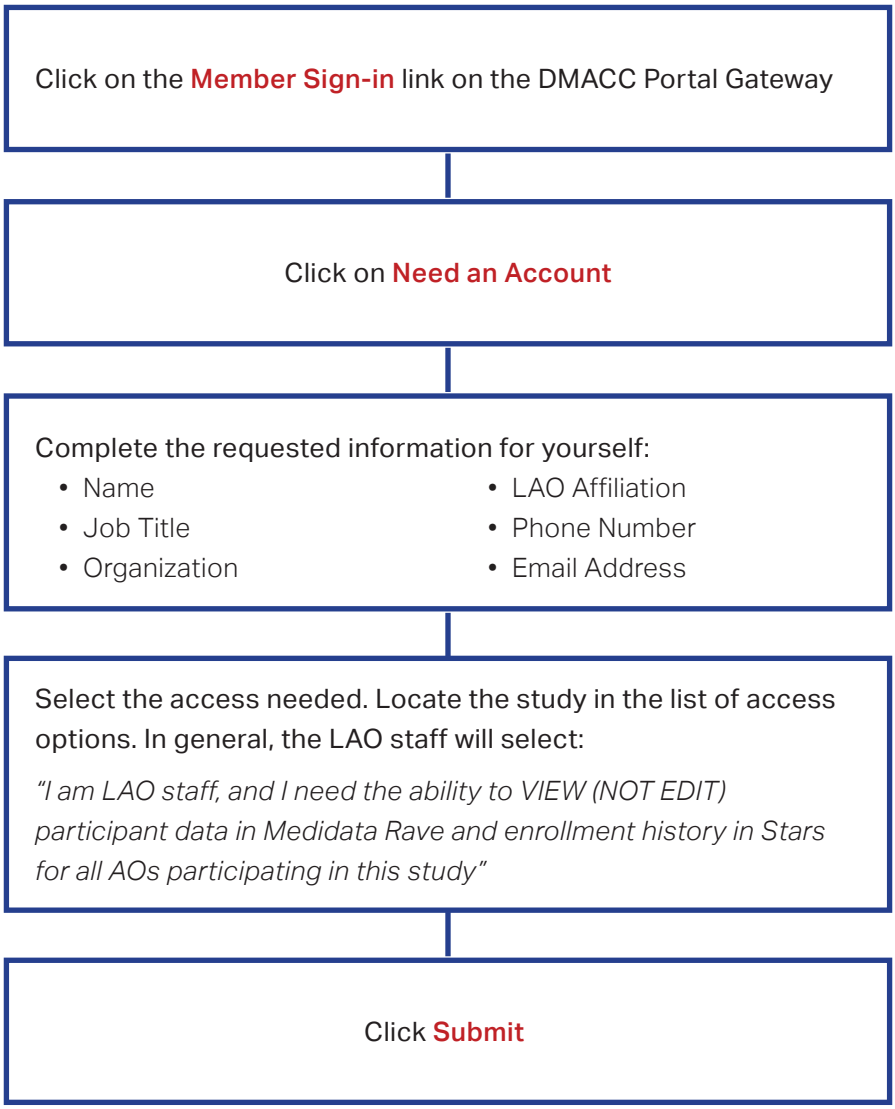
Lynette Blacher, MLS – Manager of the Data Management and Reporting Unit

The DMACC Portal Gateway provides entry points for Stars and Rave, support materials for these systems, project documentation, and other resources. Access to the Gateway, and study-specific access to Stars and Rave can be requested via the CP-CTNet website: cp-ctnet-dmacc.org.

It is recommended to request access to Stars and Rave after a study has been activated by the DMACC, as passwords cannot be sent until the study is activated.

The LAO Study Coordinators are responsible for proxy requesting access for study personnel at the LAO and AOs. In this way, the LAOs are able to vet that the appropriate staff are granted access. The LAO Study Coordinator should first request access for themselves.

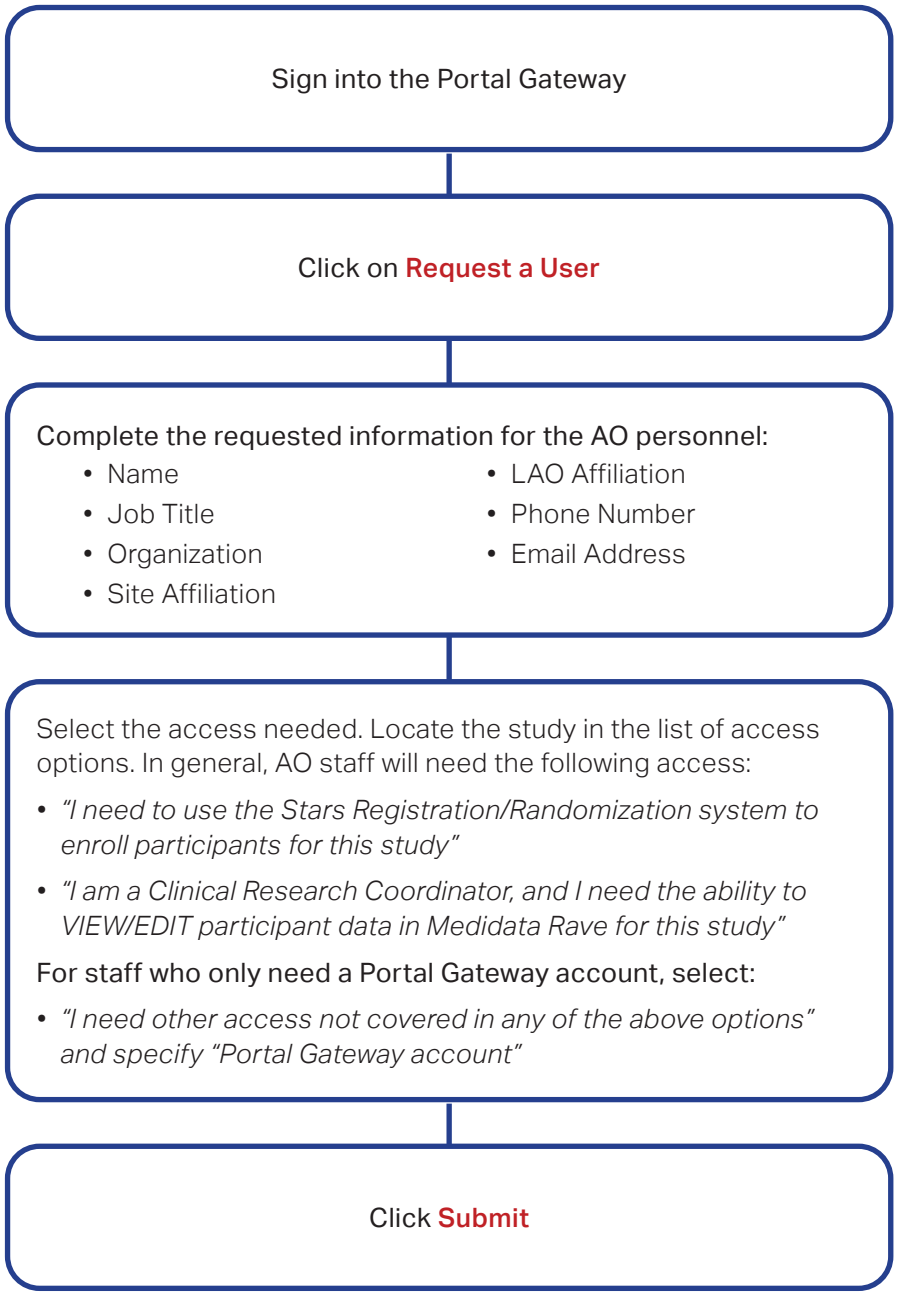
LAO Access Request:



How to Request Access for the DMACC Portal Gateway, the Stars Registration/Randomization System, and the Medidata Rave Electronic Data Capture System

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

LAO Proxy Access Request for AO Staff:



If you have any issues requesting access, our User Support department is happy to help and can be reached at UserSupport_CP-CTNet@frontierscience.org.

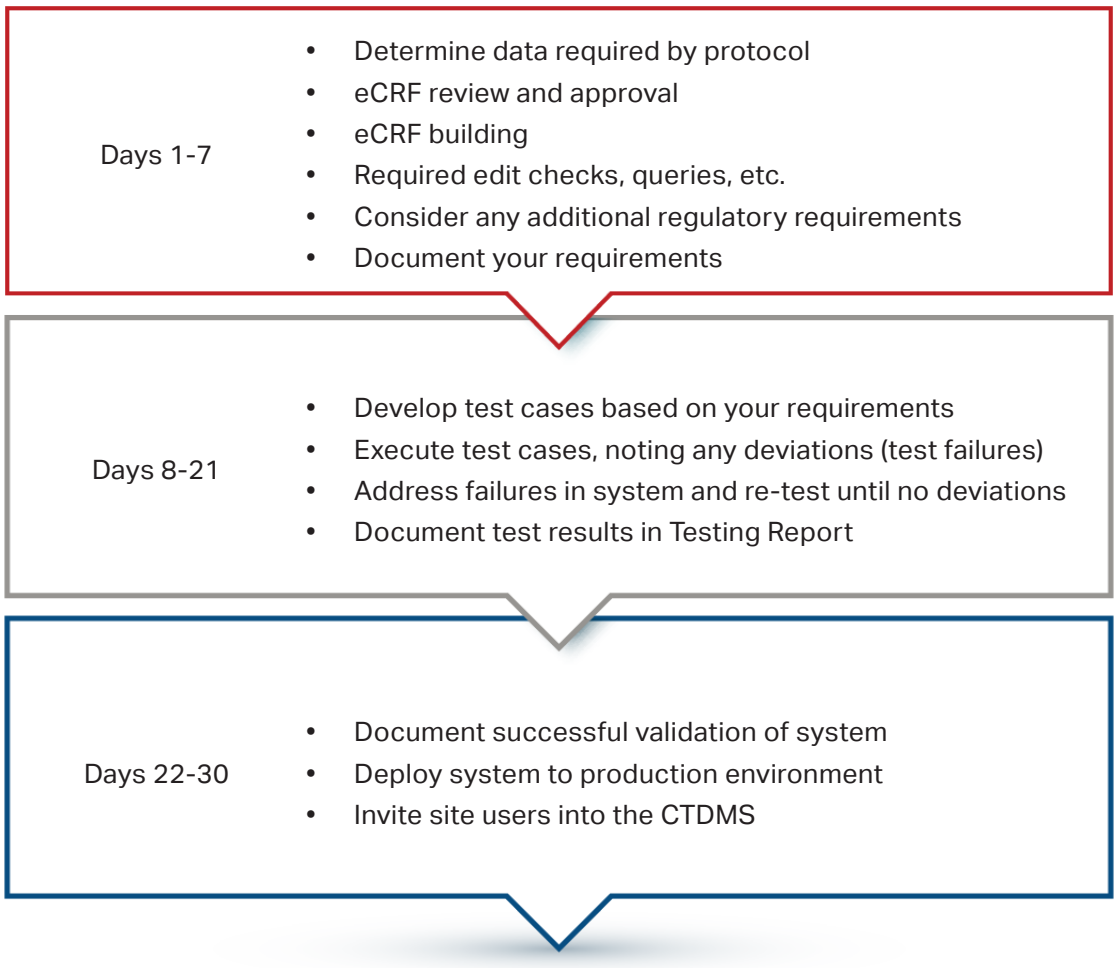
Ensuring the Integrity of the Clinical Database During Study Build in Medidata Rave

By Colleen Woodworth, JD, Compliance Officer, Frontier Science

The requirements of 21 CFR Part 11 (often just called "Part 11"), first promulgated by the FDA in 1997, are well known in the context of the clinical trial industry. Part 11 is the requirement that states that all computer systems should be validated, tested and verified to ensure that they are fit for use. Another lesser recognized requirement is that all study builds must also be tested and validated. This is one of the tasks delegated to the DMACC, and guides the process and timelines required to get a study fully ready in Medidata Rave.

In order to ensure for data integrity, the way that the study and related questions are configured in Rave, as well as the way that any reports are configured, must all be tested to ensure that the data are being collected correctly. Data Managers and other Study Build experts participate in this process together, by confirming that the final data collection pages reflect the data needs required by the protocol as determined by the LAOs, DCP and DMACC. They must ensure that the questions follow logically and that all data fields are placed in the appropriate location and actually "send" the data to the correct location in the database. Likewise, the team must ensure and test that study visits roll out in the correct order and that specially configured case report forms, such as adverse event forms, are triggered upon the appropriate conditions. During testing, screen shots and other notes are taken during each step to ensure that the study itself has a package of validation deliverables to act as evidence that this testing was completed and that there were no issues discovered during testing. Test data are entered and reviewed in the back-end database to act as a check that the data are loaded correctly and accurately. If there is any kind of change to a data collection instrument during the course of the study, the validation deliverables are up-versioned and testing must start all over again .

This is a time-consuming and laborious process but is extremely critical to ensuring that the system works as expected in relation to the collection and collation of the necessary data elements.



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, 13 participants enrolled as of December 16, 2020.
AO – UCLA

Projects 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, 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

UWI20-00-02

Title of Study: Randomized, Phase II Trial of Aspirin, 81 mg Once Daily +/- Plecanatide, 3 mg Once Daily, to Reduce Duodenal Polyp Burden in Patients with Familial Adenomatous Polyposis

Table of Related Funding Opportunity Announcements (FOAs) that May be of Interest to Prevention Researchers.

Title	Program Announcement	Due	Expires
Cancer Prevention and Control Clinical Trials Grant Program (R01 Clinical Trial Required)	PAR-21-035	Standard Dates	January 8, 2024
PREVENT Cancer Preclinical Drug Development Program	https://prevention.cancer.gov/major-programs/prevent-cancer-preclinical-drug-development-program	Twice per year on the second Monday in January and July	Ongoing
National Cancer Institute Program Project Applications (P01 Clinical Trial Optional)	PAR-20-077	Standard dates	May 8, 2023
NCI Clinical and Translational Exploratory/Developmental Studies (R21 Clinical Trial Optional)	PAR-20-292	February 19, 2021 June 21, 2021 October 20, 2021 February 22, 2022 June 21, 2022	July 21, 2022
Cancer Tissue Engineering Collaborative: Enabling Biomimetic Tissue-Engineered Technologies for Cancer Research (R01 Clinical Trials Optional)	PAR-19-113	Standard dates	January 8, 2022
Basic and Translational Research on Adducts in Cancer Risk Identification and Prevention (R01 and R21 Clinical Trial Optional)	PAR 19-251 PAR 19-252	July 8, 2021 November 8, 2021	November 9, 2021
Notice of Special Interest (NOSI): Single-Cell Proteomics for Interrogating Premalignant and Early Malignant Lesions	NOT-CA-20-044	Companion to various FOAs	May 08, 2023

Optimizing Recruitment to Cancer Prevention Trials

Edward Sauter MD, PhD from the DCP, centers his research on the prevention and early detection of breast cancer using noninvasive and minimally invasive approaches. He shares his own lessons learned for optimizing recruitment to prevention trials; and though these tips are common sense, they can be much-needed reminders when preparing for a study.

1. Minimize visits and visit times.
2. Provide reimbursement for travel/visit.
3. Demonstrate the benefits from participation.
4. Use treatment with minimal side effects.
5. Engage site PIs and nurse coordinators who are truly committed to optimize recruitment and retention. Get a full buy-in from everyone.
6. Have a large pool of potential participants to increase the trial's success.
7. Do not expect to recruit far greater than 10% of potential participants.

An article, Overcoming Barriers to Clinical Trial Enrollment by Ryan Nipp, MD; Kessely Hong, PhD, MPA; and Electra Paskett PhD, is another great resource for PIs and study coordinators to reference. Below are some excerpts from that article.

- Clinical trials are critical for advancing the science of cancer care, yet barriers to clinical trial enrollment contribute to low participation in cancer clinical trials.
- Multiple factors likely play a role in the persistently low rates of trial participation, including financial barriers, logistical concerns, and the lack of resources for patients and clinicians to support clinical trial enrollment and retention.
- Financial Barriers to Clinical Trial Enrollment include routine care costs, such as copayments, coinsurance, or deductibles; time away from work for frequent clinical visits and travel to the site of the clinical trial; lodging, meals, dependent care, and transportation required for clinical trial participation; and unknown adverse effects of investigational agent and therefore unknown expenses relating to treatment of adverse effects.
- Potential Solutions to Address the Financial Burden of Cancer Clinical Trials include clarifying definitions of routine care costs; streamlining prior authorization processes; providing patients with clear and transparent information about potential trial-related financial burden and resources available to help, such as financial navigation and counseling; allowing for ethically appropriate financial assistance for trial-related out-of-pocket expenses; and conducting additional research to help.

The full article can be accessed here: https://doi.org/10.1200/EDBK_243729

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DMACC Website
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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

Best wishes for a happy new year