

December 2021

CP-CTNet NEWSLETTER

Cancer Prevention Clinical Trials Network

HOLIDAY GREETINGS FROM DMACC

As the sound of falling leaves slowly turns to the solitude of dancing snowflakes, we take pause to reflect on the challenges that 2021 presented and celebrate the victories great and small. The Cancer Prevention Clinical Trials Network continues to thrive because of the passion and drive of its members. We look forward to longer days of sunlight and more exciting projects on the horizon.

We wish all of you health and happiness in the New Year!

Winter Fun Facts

- Every winter, at least one septillion (that's 1 followed by 24 zeros) snow crystals fall from the sky!
- Every snowflake has six sides.
- Guinness World Records reports the largest snowflake (15" in diameter and 8" thick) fell during a storm in January 1887 in Fort Keogh, Montana.
- The average snowflake ranges from a size of slightly smaller than a penny to the width of a human hair.

Contents

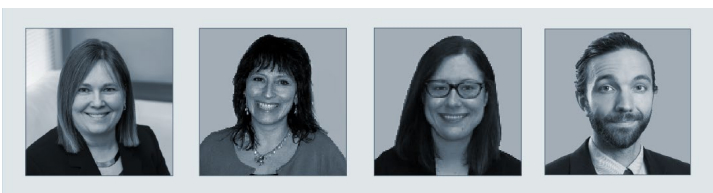
- 2-4 DMACC Unit Updates
- 4 Website and Portal Gateway
- 5-6 LAO Resources Page
- 6-7 Specimen Repository Update
- 8 Equity, Diversity, and Inclusion
- 9 Research Opportunities
- 9 Upcoming Events
- 10 Active Studies
- 10-11 Studies in the Pipeline
- 11 How to Reach Us



DMACC Updates



DATA MANAGEMENT & REPORTING UNIT



Sue Siminski, MS, MBA - Unit Director (DM) and DMACC sub-PI
Lynette Blacher, MLS - DMACC Project Lead, Unit Manager (DM)
Kayla Denson, PhD, MBA - DMACC Senior Data Manager
Alex Krolikowski, MS - Training Specialist

Protocol Deviation Process

In October, DMACC provided four DCP and LAO trainings on reporting and reviewing protocol deviations in Rave. CP-CTNet Protocol Deviation Notification eCRFs are being added to existing studies during December 2021 and all new studies will include these eCRFs in Rave. Additionally, new documentation, educational materials, and training sessions will be offered throughout 2022.

SVAR Process

DMACC is working with the LAOs to create SVARs for seven studies in development:

- UMI21-05-01: Obeticholic Acid-Barrett's Esophagus
- INT21-05-01: Tri-Ad5-Colon to Lynch Syndrome
- UWI20-04-01: RG1-VLP
- UWI21-06-01: GCC Agonists-Duodenum
- UAZ21-06-01: BSSE-Lung
- UAZ21-07-01: Metformin-Oral Cancer
- MDA21-06-01: Nous209-Lynch Syndrome

Studies in the DCP/PIO eCRF review process include:

- MDA20-01-01: Obeticholic Acid-FAP
- MDA20-02-01: Metformin-Breast/TEAMS
- NWU20-04-01: Metformin-Lung

Study Builds in Rave

Work is ongoing on study builds for UWI20-00-01, MDA20-01-01, MDA20-02-01, and NWU20-04-01.

COVID-19 eCRFs

CP-CTNet COVID-19 eCRFs are being added to existing studies throughout December 2021. All new studies will include these eCRFs in Rave.

Meetings

In September and October, several training sessions occurred with CP-CTNet LAOs and DMACC Statisticians to review the Stars Registration and Randomization System specification files circulated before study implementation. DMACC met with UWI on November 9 to discuss the CP-CTNet study initiation and activation process.

The second Cross-Network Collaboration meeting was held on November 22. DCP, LAOs, and DMACC discussed several topics including GDSP posting, the *LAO Resources* page, protocol deviation trainings, the SOP sign-off process, the new pre-screen data collection process, SIM structure, RCR Site Coordinators, and future enhancements to the AQuIP Toolkit. DMACC circulated an invitation to schedule the next Cross-Network Collaboration meeting on February 28.

Documentation

The following SOPs have been updated on the *Program Resources* page:

- [SOP 02-01 Reporting Serious Adverse Events:](#) Updated information based on the FDA's 2021 safety guidance documents that outline responsibilities for sponsors and investigators
- [SOP 03-02 Site Preparations for Quality Assurance Audits:](#) New information on scheduling timelines and the risk assessment tool

Documentation to increase efficiency of activation and closeout procedures is being fine-tuned, including: **SOP 01-03 Site Activation** and **SOP 04-02 Study Closeout**.

As mentioned above, we've also been working with DCP to update the AQuIP Toolkit. A project plan was developed, which includes prioritized tasks, responsible parties, and timelines for review and completion. Members of DMACC and DCP meet periodically to discuss the progress.

Educational and Training Content

DMACC launched the [Training Registration](#) dashboard item in October 2021 and used it to facilitate the registration process for LAO and DCP protocol deviation training.

We're currently developing regular training sessions for LAOs, AOs, and DCP on CP-CTNet procedures and systems via the [Training Registration](#) page on the Portal Gateway.

Topics include: the *Stars and Rave Enrollment Flow*, *Rave Reports for Quality Assurance*, *Reporting and Reviewing Protocol Deviations in Rave*, *Audit System Functionality*, *Recruitment Journal in Rave*, and more.

If you have ideas for new training sessions or materials, please email Training_CP-CTNet@frontierscience.org.

CLINICAL TRIALS AUDITING UNIT



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

The first remote audits were held on October 26-27 for UCLA and November 2-3 for UAZ for UAZ20-01-02. The remaining LAO audits will be scheduled starting in Winter/Spring 2022.

The Targeted Source Data Verification (TSDV) module in Rave is being configured for all studies (presently configured for UAZ20-01-02). This module will be incorporated into all future study builds.

Several SOPs were recently updated to support auditing activities and the new *Audit System* application was released at the end of October 2021.

DMACC is currently compiling a report of the Auditing Survey. The Auditing Survey collected information from CP-CTNet sites about various systems, documentation, policies and pharmacy provisions that are in place to support on-site and/or remote audits.

The Stars Registration/Randomization User Manual is available here. Welcome: AuditSystem Site 02 Project: CP-CTNet (CPCTNET Database)

Portal Home Help Support Options Logout

Audit System Overview

Overview Audits

My Tasks		Upcoming Audits	
12 Oct	No current task MEDICAL UNIVERSITY VIENNA VIEW	08 Dec	University of Arizona Cancer Center - Prevention Research Clinic KROLIK , AUDITSYSTEM_AUDITOR_01 , AUDITSYSTEM_AUDITOR_02 VIEW
08 Dec	Complete response form UNIVERSITY OF ARIZONA CANCER CENTER - PREVENTION RESEARCH CLINIC COMPLETE	13 Dec	Mount Sinai Hospital AUDITSYSTEM_AUDITOR_02 VIEW
13 Dec	View audit MOUNT SINAI HOSPITAL VIEW	13 Dec	UM Sylvester Comprehensive Cancer Center at Coral Gables AUDITSYSTEM_AUDITOR_02 VIEW
13 Dec	View audit UM SYLVESTER COMPREHENSIVE CANCER CENTER AT CORAL GABLES VIEW		

ADMINISTRATIVE & COORDINATING UNIT



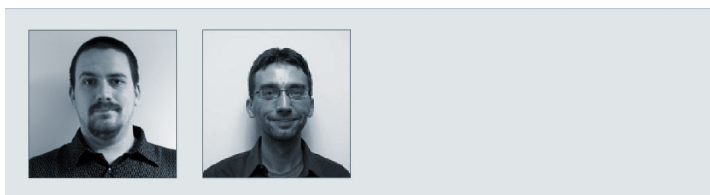
KyungMann Kim, PhD – Unit Director (Administrative) and DMACC PI
Kelly Miller, BS, CCRC – Unit Manager (Administrative)
Bridget Dermody, BS – Administrative Specialist

Planning for the 2022 I-SCORE Meeting began with a virtual kick-off meeting on November 3. The planning team consists of Dean Brenner (UMI), Goli Samimi (NCI DCP), Eileen Dimond (NCI DCP), Mela Asefa (NCI DCP), Perquita Perry (NCI DCP), Bridget Dermody (DMACC), and Kelly Miller (DMACC). The team meets every two weeks to brainstorm about potential speakers, moderators, and topics of interest to be covered at the annual meeting.



Save-the-date calendar invitations have already been distributed to about 200 guests. The format of the meeting will be a virtual model as COVID-19 is still presenting challenges. Look for future updates on the [NCI DCP site](#) and on the [DMACC website](#).

DMACC WEBSITE & PORTAL GATEWAY



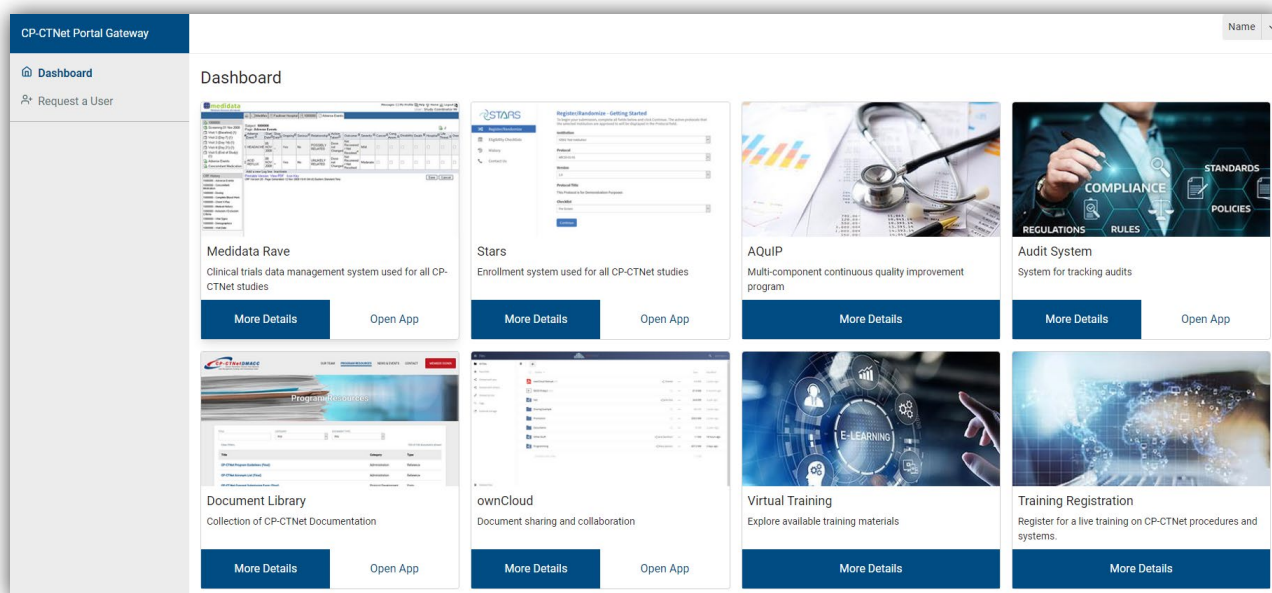
Bob Starkweather, MS – Deputy Director of Software Engineering
David Goss, MA – Software Engineering Business Analyst

DMACC is always working to keep CP-CTNet-DMACC.org updated with the latest information. This quarter, several new funding opportunities, news posts, and document resources have been added.

In December, we added a new page for resources created and shared by LAOs. We are moving forward with plans to update the map on the *Contacts* page to reflect the collaborative effort of LAOs, as well as AOs in the US and abroad. Enhancements are coming to the *Trials* page as well.

We have also progressed with updates to the [Portal Gateway](#), several links and resources have been added since September. The new *Audit System* application has been added to appropriate users' dashboards, as well support for new data visualization reports. As CP-CTNet grows, more data visualization options and reports will be added for study progress and key metrics.

In the coming weeks, new access request features will be made available to Portal Gateway users. More information about these exciting features will be announced soon.

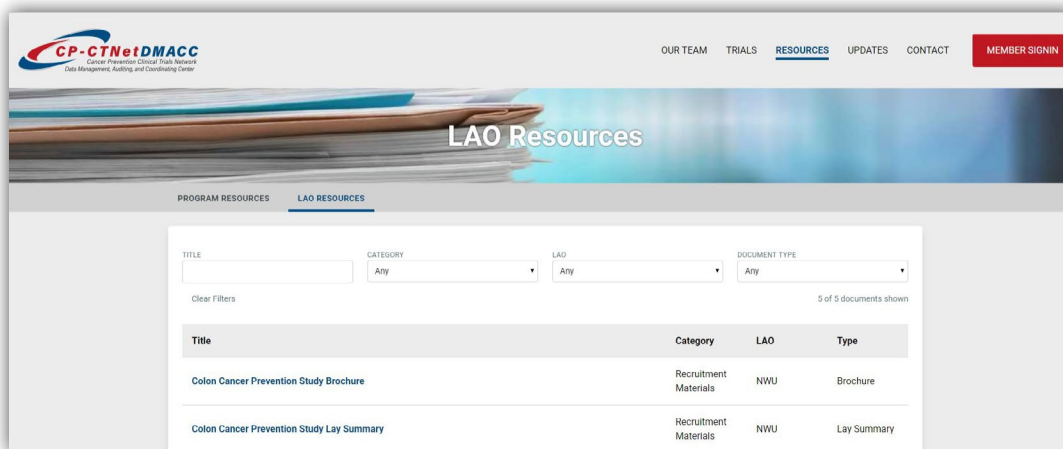


THE LAO RESOURCES PAGE

DMACC is excited to introduce the new [LAO Resources](#) page on the [CP-CTNet DMACC Public Website](#). This page is designed to encourage collaboration between LAOs involved in CP-CTNet and host resources that may be beneficial to LAOs and the wider cancer prevention community. The resources that are shared via this page include resources designed to facilitate daily trial conduct, accrual, administrative processes, and other CP-CTNet activities as needed. The development of this page has been an ongoing collaboration between DCP, LAOs, and DMACC since the idea's conception during a Think Tank discussion at the 2021 I-SCORE Meeting. The [LAO Resources](#) page is now available on the [CP-CTNet DMACC Public Website](#).

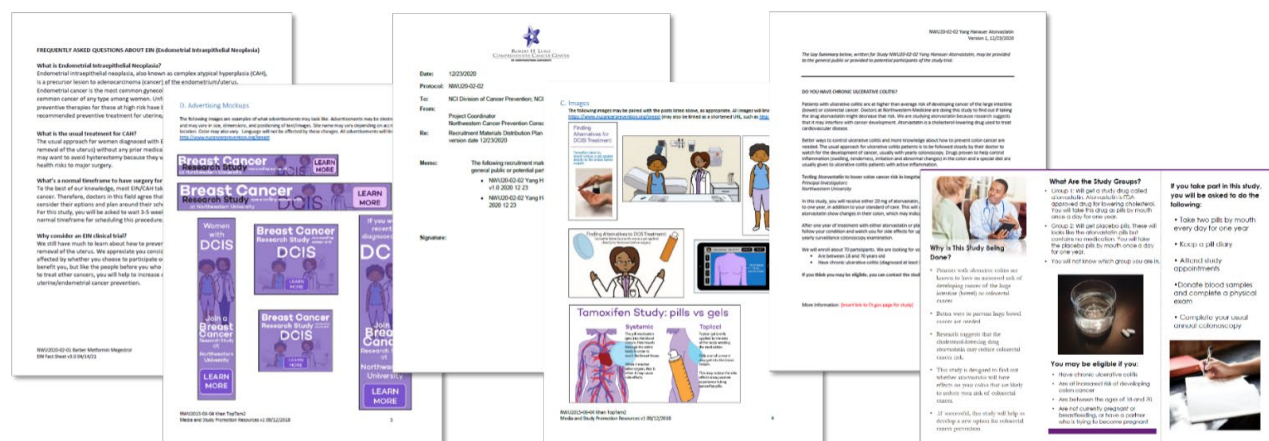
Accessing the LAO Resources Page

Resources that are created and shared by LAOs are publicly available on the [LAO Resources](#) page. This page is a subsection of the *Program Resources* page, which can be accessed from the *Resources* tab on the [CP-CTNet DMACC Public Website](#). The *Program Resources* page is split into two tabbed subsections, including *Program Resources* and *LAO Resources*. The *Program Resources* tab includes an extensive list of publicly available documents that are used to support LAOs and AOs from concept development to study closeout. The *LAO Resources* tab is limited to publicly available resources created and shared by LAOs. The resources displayed in the table can be sorted using the filters above the table, including Title, LAO, Category and Document Type. These filters correspond directly to the columns included in the table of LAO resources.



Featured LAO Resources: NWU

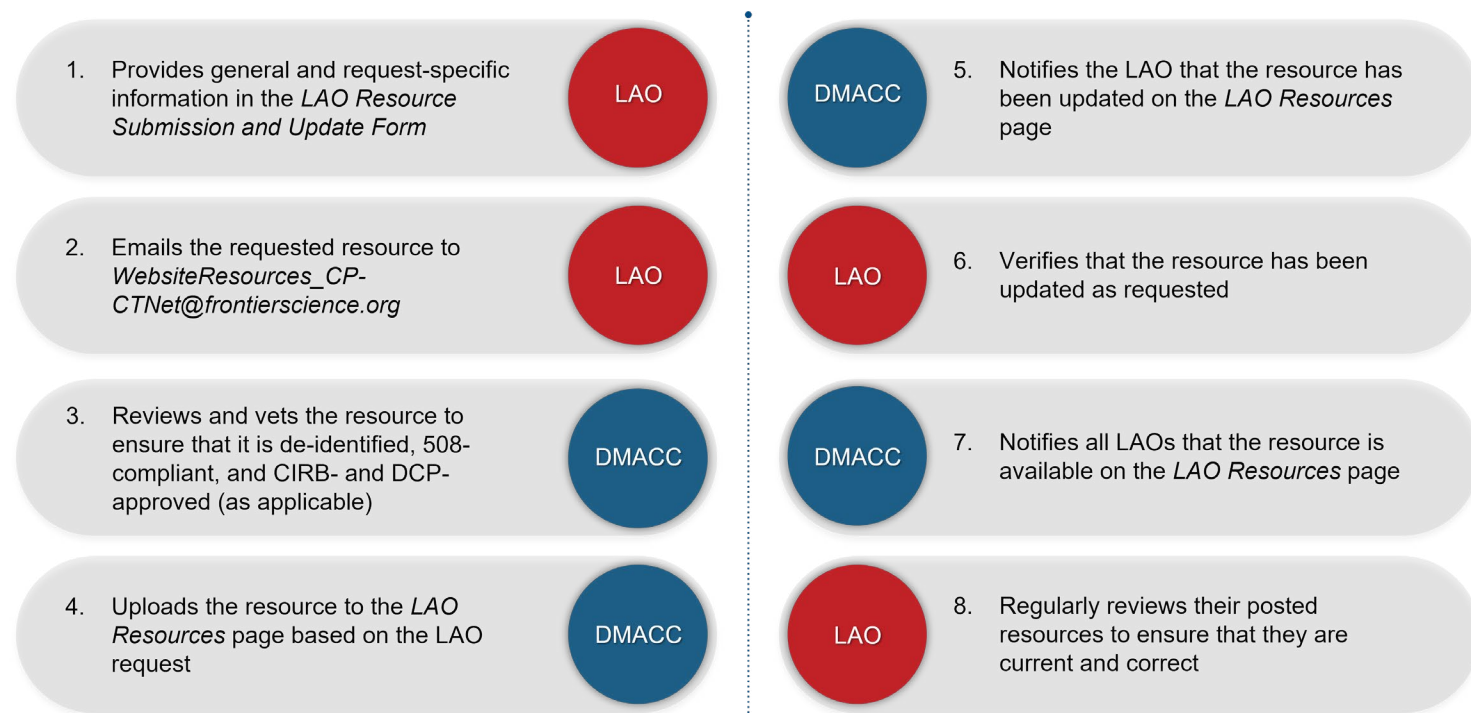
LAO Coordinator, Kelly Benante, and her team at the Robert H. Lurie Comprehensive Cancer Center of Northwestern University, Northwestern Cancer Prevention Consortium shared five resources, which are now available on the [LAO Resources](#) page. These resources have been reviewed and vetted by DMACC and include a brochure, fact sheet, lay summary, media strategies guide, and a recruitment materials distribution memo.



If you are an LAO and are interested in sharing resources with the other LAOs in the network, the next section provides everything that you need to know about submitting resources for posting on the [LAO Resources](#) page.

Resources Submission & Updates

When LAOs have resources that they would like to share via the [LAO Resources](#) page, they start the submission process by completing the [LAO Resource Submission and Update Form](#) and emailing the requested resource to WebsiteResources_CP-CTNet@frontierscience.org. The figure below outlines the steps that LAOs and DMACC follow to complete resource submission and update requests.



Virtual Specimen Repository Update

DMACC is excited to announce that four LAOs will be implementing the Laboratory Data Management System (LDMS) at their sites, including:

- University of Arizona, University of Arizona Cancer Prevention Clinical Trials Network (LDMS database #939)
- University of Texas MD Anderson Cancer Center, iCAN-PREVENT: International Cancer Prevention Clinical Trial Consortium (LDMS database #941)
- University of Wisconsin, The MW Chemoprevention Network (LDMS database #942), and
- Robert H. Lurie Comprehensive Cancer Center of Northwestern University, Northwestern Cancer Prevention Consortium (LDMS database #943)

The LDMS will be used for ongoing sample inventory management, storage, and tracking shipments of samples to Frederick Repository.

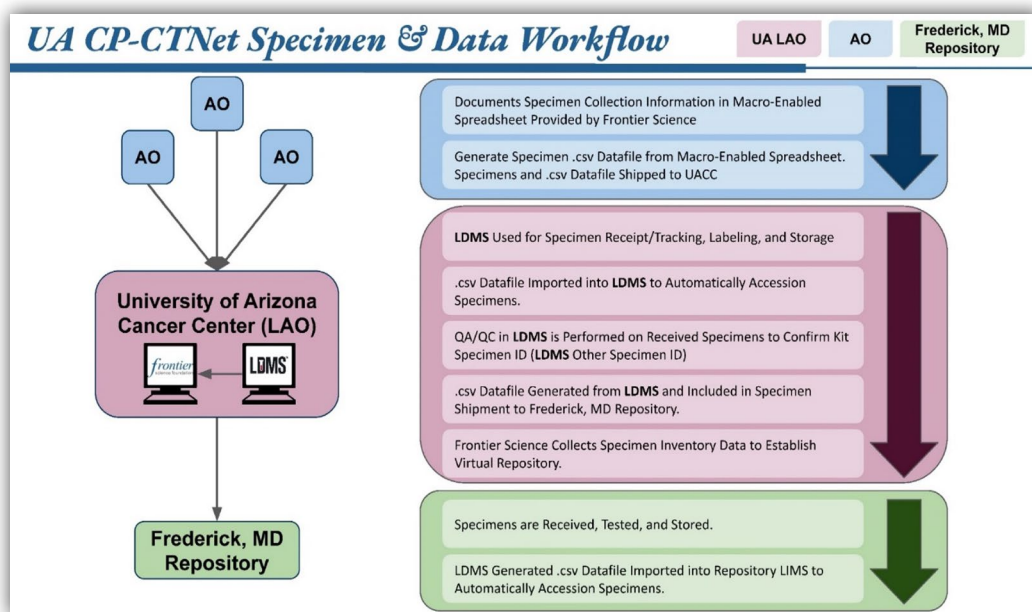
Transferring Specimen Inventory Data

All specimen inventory data at each LAO will be loaded into the CP-CTNet DMACC central database. LDMS data from each LAO will be loaded automatically each day, while non-LDMS specimen inventory data will be processed and loaded as the updated Excel inventory data file is received. The frequency and workflow for submitting this specimen inventory data file is in development.

Participant ID	Visit Identifier	Clinic (AO)	Collection Date	Collection Time	Sample Type	Volume	Unique Specimen ID
100001	V1	101	19-Oct-21	11:00	Plasma	1mL	11011234-01
100001	V1	101	19-Oct-21	11:00	Plasma	1mL	11011234-02
100001	V1	101	19-Oct-21	11:00	Plasma	1mL	11011234-03
100002	V2	101	19-Oct-21	11:30	Serum	10mL	11021234-01
100002	V2	101	19-Oct-21	11:30	Serum	10mL	11021234-02

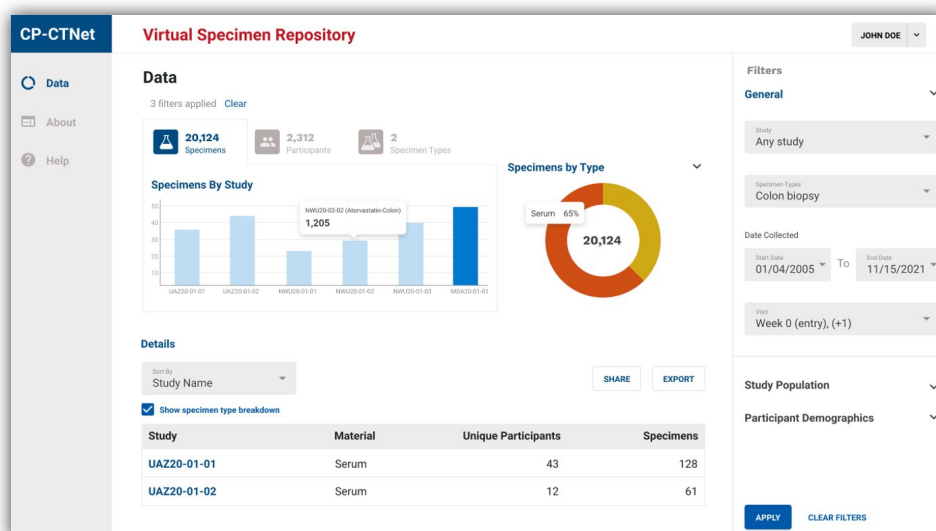
Viewing Specimen Inventory Data

Data will be displayed in the Virtual Specimen Repository (VSR) on the [CP-CTNet DMACC Portal Gateway](#). The VSR's intuitive visual interface will allow users to perform searches rendering aggregate data or more detailed data. Study-specific VSR access will be determined for designated users prior to deployment on the Portal Gateway.



Virtual Specimen Repository Group

The VSR Group continues to meet monthly, with the next meeting scheduled for January 2022. Future discussions aim to define standard practices across the LAOs and AOs for specimen collection to ensure a high standard of specimen completion and data integrity across CP-CTNet clinical trials.



Equity, Diversity, and Inclusion (EDI)

NIH Listening Sessions on Racial Equity

NIH launched the [UNITE initiative](#) in March 2021 to address structural racism in the biomedical research enterprise. Through this initiative, NIH is holding a series of listening sessions to learn from external stakeholders about the full range of issues and challenges in achieving racial equity in biomedical research. Some of these issues include:

- Changing culture to promote equity, inclusivity, and justice
- Improving policies, transparency, and oversight
- Strengthening career pathways, training, mentoring, and the professoriate
- Ensuring fairness in review and funding deliberations
- Enhancing funding and research support for diverse institutions and historically under-resourced research areas, and
- Structural racism in the biomedical research enterprise.

The insights shared during these [listening sessions](#) will help to identify priorities for UNITE and inform the development of an NIH action plan.

[Sign up](#) for future UNITE and Ending Structural Racism updates.

In Recognition of Outstanding Service

For years of dedication to the advancement of science and medicine, we thank you. We wish you both the best of luck in your future adventures and we truly value and appreciate your contributions to CP-CTNet. Congratulations on your retirement, Dan and Valerie!



Dan Boring, RPh, PhD - Contracting Officers Representative for DCP



Valerie Dyer, RN - Nurse Consultant in the Protocol Information Office (PIO)



EIAP Aids Scientists from Diverse Backgrounds

NCI is launching the [Early Investigator Advancement Program](#) (EIAP) to facilitate the advancement of scientists from diverse backgrounds to become independent investigators.

The cancer research enterprise needs a continuous flow of talent through the research career pipeline to thrive. One critical juncture is the transition from junior investigator to independent investigator. Each year, EIAP will support the professional and career development of a cohort of eligible and qualified Early Stage Investigators and New Investigators from institutions across the country.

The program aims to:

- Enhance professional skills
- Guide preparation of an R01 grant application
- Provide access to a mentoring and peer network, and
- Grow a community of emerging independent investigators from diverse backgrounds.

Applications to the EIAP must be submitted by **December 31, 2021**. The target start date is March 1, 2022.

Potential applicants should visit the [EIAP webpage](#) for information about eligibility, application instructions, and the webinar link, which will be available very soon.

NCI values diversity and particularly encourages applicants from populations underrepresented in the biomedical sciences, as noted in NIH's Notice of Interest in Diversity ([NOT-OD-20-031](#)).

Contact: Dr. Alison Lin, EIAP@nih.gov

Research Funding Opportunities

GRANTS & AWARDS

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. **Submission Due Date: December 28, 2021**

- [RFA-CA-21-045](#): Coordinating Center for HIV/Cervical Cancer Prevention 'CASCADE' Clinical Trials Network (U24 Clinical Trial Required)
- [RFA-CA-21-046](#): Research Bases for HIV/Cervical Cancer Prevention 'CASCADE' Clinical Trials Network (UG1 Clinical Trial Required)
- [RFA-CA-21-047](#): Clinical Sites for HIV/Cervical Cancer Prevention 'CASCADE' Clinical Trials Network (UG1 Clinical Trial Required)

UPCOMING EVENTS

Dec 31: Annual FFR Due

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

Feb 28: Cross-Network Collaboration Meeting (virtual)

Mar 31: Quarterly CP-CTNet Steering Committee Meeting (virtual)

I-SCORE Meeting (virtual)
March 31 - April 1, 2022

Apr 8: [American Association for Cancer Research](#) in New Orleans, LA (hybrid) April 8-13, 2022

Jun 3: [American Society of Clinical Oncology](#) in Chicago, IL (hybrid) June 3-7, 2022

Jul 29: Quarterly CP-CTNet Steering Committee Meeting

Cycle #	Steering Committee Date	Concept Solicitation Date	Concept Due Date
9	October 29, 2021	November 5, 2021	January 7, 2022
10	January 28, 2022	February 4, 2022	April 4, 2022
11	March 31, 2022	April 20, 2022	June 20, 2022
12	July 29, 2022	August 5, 2022	October 5, 2022
13	October 28, 2022	November 4, 2022	January 9, 2023





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 - 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)
- **UAZ21-07-01.** M4OC-Prevent 2.0: Phase IIb Trial of Metformin for Oral Cancer Prevention

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

HOW TO REACH US

Principal Investigators

KyungMann Kim - DMACC PI, kyungmann.kim@wisc.edu

Sue Siminski - DMACC sub-PI, siminski@frontierscience.org

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

Other Links

[DMACC website](#)

[DCP CP-CTNet website](#)

THE NAME GAME

Can you name the CP-CTNet colleague in this photo?

Submit your guesses to DMACC_Newsletter_Editors@frontierscience.org. The answer will be revealed in the next newsletter!

Please submit childhood pictures to [Our Editorial Team](#) to be used in future editions.



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

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.