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.
DMACC Updates

DATA MANAGEMENT & REPORTING UNIT

DMACC Updates

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.

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
- UW120-04-01: RG1-VLP
- UW121-06-01: 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 UW120-00-01, MDA20-01-01, MDA20-02-01, and NWU20-04-01.
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

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.
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 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](https://cp-ctnet-dmacc.org). 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](https://cp-ctnet-dmacc.org).

**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](https://cp-ctnet-dmacc.org). 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.

![LAO Resources Page Screenshot](Image)

**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.

1. Provides general and request-specific information in the LAO Resource Submission and Update Form
2. Emails the requested resource to WebsiteResources_CP-CTNet@frontierscience.org
3. Reviews and vets the resource to ensure that it is de-identified, 508-compliant, and CIRB- and DCP-approved (as applicable)
4. Uploads the resource to the LAO Resources page based on the LAO request
5. Notifies the LAO that the resource has been updated on the LAO Resources page
6. Verifies that the resource has been updated as requested
7. Notifies all LAOs that the resource is available on the LAO Resources page
8. Regularly reviews their posted resources to ensure that they are current and correct

---

**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.

Viewing Specimen Inventory Data

Data will be displayed in the Virtual Specimen Repository (VSR) on the [CP-CTNet DMACC Portal Gateway](https://cp-ctnet.portal.mdacc.edu). 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.

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

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)
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

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec 31</td>
<td>Annual FFR Due</td>
</tr>
<tr>
<td>Jan 28</td>
<td>Quarterly CP-CTNet Steering Committee Meeting (virtual)</td>
</tr>
<tr>
<td>Feb 28</td>
<td>Cross-Network Collaboration Meeting (virtual)</td>
</tr>
<tr>
<td>Mar 31</td>
<td>Quarterly CP-CTNet Steering Committee Meeting (virtual)</td>
</tr>
<tr>
<td></td>
<td>I-SCORE Meeting (virtual)</td>
</tr>
<tr>
<td></td>
<td>March 31 - April 1, 2022</td>
</tr>
<tr>
<td>Apr 8</td>
<td>American Association for Cancer Research in New Orleans, LA (hybrid) April 8-13, 2022</td>
</tr>
<tr>
<td>Jun 3</td>
<td>American Society of Clinical Oncology in Chicago, IL (hybrid) June 3-7, 2022</td>
</tr>
<tr>
<td>Jul 29</td>
<td>Quarterly CP-CTNet Steering Committee Meeting</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cycle #</th>
<th>Steering Committee Date</th>
<th>Concept Solicitation Date</th>
<th>Concept Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>October 29, 2021</td>
<td>November 5, 2021</td>
<td>January 7, 2022</td>
</tr>
<tr>
<td>10</td>
<td>January 28, 2022</td>
<td>February 4, 2022</td>
<td>April 4, 2022</td>
</tr>
<tr>
<td>11</td>
<td>March 31, 2022</td>
<td>April 20, 2022</td>
<td>June 20, 2022</td>
</tr>
<tr>
<td>12</td>
<td>July 29, 2022</td>
<td>August 5, 2022</td>
<td>October 5, 2022</td>
</tr>
<tr>
<td>13</td>
<td>October 28, 2022</td>
<td>November 4, 2022</td>
<td>January 9, 2023</td>
</tr>
</tbody>
</table>
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 Ia, 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 Ib, Window of Opportunity PreSurgical Trial. (TEAM Trial)

• **MDA21-06-01.** A Phase Ib Clinical Trial of Nous-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.

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.