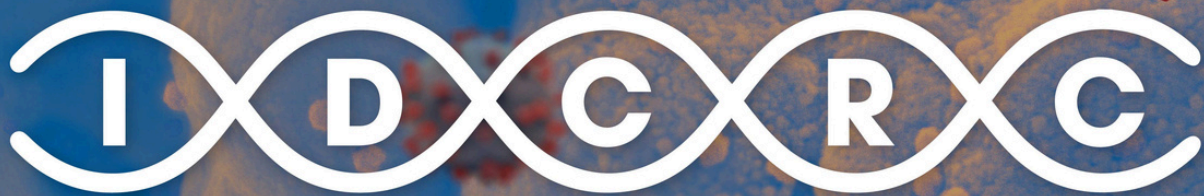


VTEU HIGHLIGHTS



Infectious Diseases Clinical Research Consortium

The following pages include infographics for each VTEU, highlighting some of their accomplishments over the past year. These were created by the IDCRC Leadership Operations Center and are not intended to be comprehensive. Each VTEU will also have an opportunity to highlight their accomplishments throughout the meeting.

Current Projects

DMID 24-0003
PROMISE

Key Stats

- 16 Total VTEU studies
- 10 VTEU Investigators
- 3 Early Stage Investigators
- 71 VTEU publications
- 16 VTEU Invited Talks

Recruitment
Database
Participants

3000+



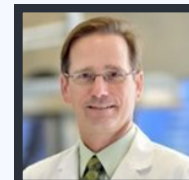
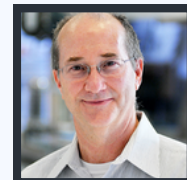
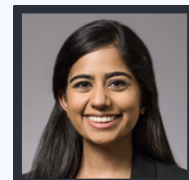
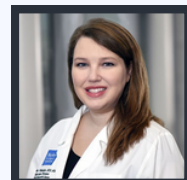
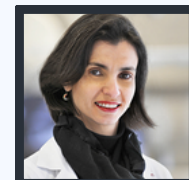
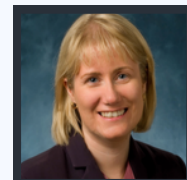
Leadership Reflections

The previous 12-month period had a Jekyll and Hyde persona. The blow of reduced clinical research activity and the relocation of a key investigator were counteracted by expanded research type portfolio, awards, and new trainees. The span of research in which our team is currently engaged includes respiratory viral surveillance, laboratory assays supporting clinical trials, basic and translational virology, clinical vaccine development, controlled human infections, and improving vaccine uptake in the community.



Key Accomplishments

- Vaccinology Course, launched by Drs. Jennifer Whitaker and Sashi Ramani, was voted best course in the Graduate School at BCM.
- Dr. Hana El Sahly led the "Safety and Immunogenicity Trial of MPV/S-2P SARS-CoV-2 Vaccine in Adults" as the 1st study in the NEXTGEN Covid-19 vaccine USG effort.
- Dr. C. Mary Healy joined the IDCRC Leadership Group as co-director of the Clinical Operations Unit.



Current Projects

DMID 23-0006
ETEC

DMID 24-0003
PROMISE

DMID 19-0003
Campy

Key Stats

- 8 Total VTEU studies
- 25 VTEU Investigators
- 6 Early Stage Investigators
- 21 VTEU publications

VTEU
Enrollments 835

Recruitment
Database
Participants 12000+

Leadership Reflections

Over the past year, our site has transitioned to a completely electronic platform that is Part 11 compliant. Our site has worked with other VTEUs to demonstrate our electronic system and assist in other sites implementing an electronic platform. We have been at the forefront on direct data entry (DDE), a pilot project of Emmes and DMID to allow data entry in "real time". Over the next year, we will complete the clinical portion of our ETEC vaccine/challenge trial and continue to submit concepts for future protocol development and implementation.



Key Accomplishments

- Completed Phase 1 trial of Campylobacter jejuni conjugate vaccine trial. Database is locked and awaiting CSR completion
- Completed protocol development for ETEC vaccine/challenge study and are now beginning enrollment
- Initiated protocol development for a Phase 1 trial to evaluate vaccine against Leishmaniasis



Current Projects

DMID 22-0019
Doxy

DMID 24-0003
PROMISE

DMID 23-1101
Next Gen MPV/ S-
2P Phase 1

DMID 24-1102
Ocugen

Key Stats

- 16 Total VTEU studies
- 10 VTEU Investigators
- 4 Early Stage Investigators
- 71 VTEU publications

VTEU
Enrollments

1740

Recruitment
Database
Participants

35000+



EMORY
UNIVERSITY
SCHOOL OF
MEDICINE

Leadership Reflections

Over the past year, the Emory VTEU has made significant strides in mentorship, training, capacity building, and collaborative research.

In mentorship and training, we established a dedicated Hope Clinic Associate Director for Mentorship and Training (Wiley) and secured the Emory T32 Vaccinology renewal (Rouphael, Sep 2024). Additionally, our junior team members have been selected to the third mentee cohort (Graciaa, Grimsley Ackerley) or received the IDCRC pilot award (Gromer), with multiple staff presenting at institutional, regional, national, and international conferences (ECC-VRC and Hope Clinic).

In capacity and relationship building, we have strengthened key collaborations, particularly through the ECC-VRC (Rostad, Kamidani) growing partnership between Emory VTEU and Emory OBGYN, with Badell (OBGYN) joining as a new VTEU co-investigator. We also established a dedicated Hope Clinic Associate Director for Healthcare-Based Clinical Research (Rebolledo), who is working closely with ECC-VRC (Rostad). Furthermore, we have expanded our tissue immunology program, now integrating expertise from ID/Hematology, Radiology, Interventional Pulmonary, and ENT, broadening our research impact and capabilities.



Key Accomplishments

- Leadership of DMID 24-0003 PROMISE by Dr. Rostad.
- Drs. Workowski and Cantos led the highest enrolling domestic sites for DMID 22-0019 Doxy.
- Participation and leadership within the NextGen program by Drs. Rouphael and Rostad.



Current Projects

DMID 24-1102
Ocugen

DMID 24-1104
Capricor

DMID 18-0018
Schistoschild

Key Stats

8 Total VTEU studies

1 VTEU Investigators

27 VTEU publications

VTEU
Enrollments
586

Recruitment
Database
Participants
347

Leadership Reflections

The completion of follow up in the Phase 1 18-0018 trial and the finalized CSR allowed preparation and submission of a manuscript reporting the primary findings. Drs Jackson (Kaiser) and Babu (UW) have been developing the protocol and ICF for the 24-1104 Capricor Next Gen trial. This year we retired the Kaiser vaccine trial registry started in 2020 that was more focused on recruitment specifically for COVID-19 vaccine trials and started up a new registry for vaccine trials in general and thus far have invited 15,000 KP members to join and have 347 registered. The Coler lab has developed humoral endpoint assays (ELISA and neutralization assays) utilized in IDCRC vaccine trials.



Key Accomplishments

- Dr. Jackson's service on the Next Gen protocol development committee, co-chairing, with Dr. Babu, the initial development of the 24-1102 Ocugen trial and full development of the 24-1104 Capricor trial.
- The Kaiser team completed the 18-0018 trial and Dr. Jackson is the primary author of a manuscript that has been submitted for review.
- The Coler lab has developed humoral endpoint assays for IDCRC trials, including the 21-0004 MOMIVAX trial, and members of the lab co-authored two MOMIVAX study publications in 2024.

Current Projects

DMID 24-0003
PROMISE

DMID 23-1101
Next Gen MPV/ S-
2P Phase 1

Key Stats

- 6 Total VTEU studies
- 10 VTEU Investigators
- 6 Early Stage Investigators
- 39 VTEU publications

VTEU
Enrollments

1327

Recruitment
Database
Participants

1806

Leadership Reflections

This past year has been transformative for our VTEU site. The opening of our new space within our main Manhattan Midtown hospital has not only provided us with state-of-the-art facilities but also fostered greater collaboration among our researchers. Looking ahead, we are excited to further our research initiatives and expand our community outreach. Our team remains committed to advancing medical science and improving public health outcomes. Kudos to our PROMISE study team, especially Kathryn Jano, our research coordinator, and Dr. Lalitha Parameswaran, for coordinating and overseeing this complex study that required the involvement of our network of physicians and the implementation of new workflows.



Key Accomplishments

- Grand opening of the NYU Vaccine Center on the Midtown Manhattan campus. Our clinic, investigational pharmacy, and processing lab are now co-located within our hospital, significantly enhancing our collaborative efforts. This strategic move will allow us to increase our reach and expedite the development of lifesaving interventions.
- Successfully implemented DMID 24-0003 PROMISE. Our extensive recruitment process included recruitment at OB clinics, and coordination with the L&D unit for successful study enrollment.
- Successfully implemented a Phase 1 trial, DMID 23-1101, NextGen: MPV/S-2P, in collaboration with Emory and Baylor. This trial, the first under the Next Generation COVID-19 Vaccine Development Program, was developed and operationalized by Dr. Bäcker and our team. The study was officially activated on July 2, 2024. We successfully screened 30 and vaccinated 16 participants by August 2024. Dr. Mulligan is now leading the trial.

Current Projects

DMID 22-0011
BCG Challenge

DMID 24-0008
West Nile Virus

Key Stats

- 11 Total VTEU studies
- 13 VTEU Investigators
- 3 Early Stage Investigators
- 9 VTEU publications

VTEU
Enrollments

5046

Recruitment
Database
Participants

7500+



Leadership Reflections

We have been recruiting new CVD/VTEU investigators (Dr. Krishna Vankayalapati, TB immunologist and PI of RePORT India clinical trial site), and have more physician scientist positions open currently. We have gone through an External Review of our CVD/VTEU providing important recommendations to SLU on how to best support our group, including the investment in a new CHIM facility for respiratory viral challenges. Azra Blazevic has done an outstanding job of overseeing the move of our CVD sample repository containing hundreds of thousands of samples stored from VTEU and other trials done over the past 40 years. Karla Mosby has done a fantastic job of supervising 5-10 nurse coordinators leading a complex and highly diverse combination of VTEU, other NIH and industry funded vaccination trials. Tammy Grant has led our CVD/VTEU financials for 30 years and frequently advises others within SLU, DMID and other VTEUs on grants management issues. Carol Duane has done an outstanding job of leading our CVD/VTEU regulatory efforts from VTEU studies, investigator-initiated studies and investigator sponsor trials.



Key Accomplishments

- SLU Patents filed for 3 novel vaccines (TB, Influenza & HCV)
- Development of qualified mpox immune assays.
- Launching 2 investigator-initiated IDCRC funded trials (West Nile Virus vaccine phase I trial; BCG Challenge Model Development)



Current Projects

DMID 23-0005
AFM/EV68-228-N

DMID 20-0024
Mening Mali

DMID 19-0007
Malaria Uganda

DMID 24-0003
PROMISE

DMID 23-0006
ETEC

DMID 24-0034
C Diff

DMID 23-0021
NextGen Mucosal
Sampling Consortium

Key Stats

18 Total VTEU studies

12 VTEU Investigators

5 Early Stage Investigators

50 VTEU publications

VTEU
Enrollments
2916

Recruitment
Database
Participants
14959

Leadership Reflections

CVD investigators published a total of 22 VTEU-related papers during this period including 3 papers for which mentored junior investigators served as first author. Two VTEU protocols successfully completed participant enrollment and are in follow-up: DMID 23-0005 and DMID 19-0007, which evaluated interventions for enterovirus serotype 68 and severe malaria, respectively. In the coming year, three awards will be active: DMID 23-0006, DMID 24-0034, and DMID 24-0003 to evaluate interventions for ETEC, C. difficile, and RSV, respectively. Jim Campbell, MD, MS, was named IDCRC LG Vice-Chair.



Key Accomplishments

- SNIFF (DMID 21-0011), a remote ancillary study to the phase 3 trial of NVX-CoV2373 using twice weekly self-collected nasal swabs, demonstrated high vaccine efficacy against subclinical SARS-CoV-2 infection (Deming M Lancet Microbe 2025).
- DMID 20-0024 demonstrated pentavalent meningococcal ACWYX conjugate vaccine safety and immunogenicity, resulting in a WHO recommendation for routine use in children ages 9–18 months in the African meningitis belt, and for mass vaccination of people aged 1–19 years (Diallo F and Haidara F Lancet 2025).
- Leveraging CVD's library of specimens from participants living in malaria-endemic areas, CVD investigators and collaborators performed whole genome sieve analyses, uncovering a powerful tool to identify novel protective targets in whole organism-based malaria vaccines (Dwivedi A, MedRxiv 2025).
- In a cross-VTEU collaboration (DMID 13-0013), CVD Investigators demonstrated strong and long-lasting systemic and mucosal immunity to ETEC dmlT administered intradermally to adults in a phase 1 trial conducted at the Cincinnati VTEU site, supporting further evaluation of dmlT as a stand-alone or multivalent ETEC vaccine or as a vaccine adjuvant (Pasetti MF NPJ Vaccines 2025).

Current Projects

DMID 22-0019
Doxy

DMID 24-0003
PROMISE

Key Stats

- 12 Total VTEU studies
- 26 VTEU Investigators
- 12 Early Stage Investigators
- 42 VTEU publications

VTEU
Enrollments

1147

Recruitment
Database
Participants

19,718

Leadership Reflections

With activation of new clinical trials, we have been able to fully integrate new core faculty to the UR VTEU. Dr. David Dobrzynski, MD is an Associate Professor in the Infectious Diseases Division and has helped lead Mix and Match 21-0012 and COVAIL Trials. He has also become a standing member of the Emerging Infections Expert Working Group and leading efforts through a pilot award to develop capacity for clinical research in Lira Uganda. Dr. Daniela DiMarco is an Assistant Professor in the Division of Infectious Diseases and a recognized national leader in the field of sexually transmitted infections. She serves as the UR VTEU member of the STI EWG and site PI for the Chlamydia Doxycycline Treatment Trial. Dr. Jennifer Nayak is an Associate Professor of Medicine in the division of Pediatric Infectious Diseases and successfully helms the pediatric arm of the UR VTEU, successfully leading both the 22-0020 Doses and 24-0003 Promise studies at our site.



Key Accomplishments

- Launched a malaria observational study assessing in Lira, Uganda to build capacity and establish Lira University as a future VTEU subsite.
- First site to completely enroll for the 24-0003 Promise study
- Developed collaborative research partnerships with three IDCRC VTEUs to define the cause of LRTI in hospitalized adults in the area of respiratory viral and bacterial infections

Current Projects

DMID 22-0019
Doxy

DMID 23-0010
LARC2

DMID NextGen
COVID-19

Key Stats

8 Total VTEU studies

29 VTEU Investigators

7 Early Stage Investigators

19 VTEU publications

VTEU
Enrollments
1251

Recruitment
Database
Participants
1748

Leadership Reflections

We are proud of Dr. Tara Reid, a prior IDCRC mentee, who has successfully obtained a K08 award entitled "Local and systemic immune responses during syphilis infection" that will pursue the development of an immunotherapeutic for syphilis. Kudos to our staff at VRC (Seattle), PRC (Mombasa), and PHRD (Thika) for their launch and continued efforts in implementation of the Doxy Short study. We also wanted to acknowledge the Phase 1 malaria study team - Drs. Sean Murphy, Jim Kublin and Scott McClelland, and Kirsten Hauge, Jessica Heimonen and Meredith Potochnic, who has shown perseverance, creativity and resilience in finalizing the protocol and moving it toward implementation. We appreciate the support we have received from our DMID program officers.



Key Accomplishments

- Version 1.0 of the LARC2 Protocol (DMID 23-0010) was finalized in Sept 2024. The site began pre-implementation activities with an estimated start date of spring 2025. Dr. Sean Murphy and Dr. Jim Kublin serve as protocol co-chairs and Dr. Scott McClelland is the site PI.
- The neurosyphilis protocol (DMID 24-0020) is under protocol development. Dr. Matthew Golden is the protocol chair for the trial.
- Dr. Tia Babu has been selected for the IDCRC Early Career Investigator Award in Grant Year 6.

Current Projects

DMID 23-0005
AFM/EV68-228-N

DMID 24-0003
PROMISE

Key Stats

- 10 Total VTEU studies
- 8 VTEU Investigators
- 5 Early Stage Investigators
- 18 VTEU publications

VTEU
Enrollments 665

Recruitment
Database
Participants 4440

Leadership Reflections

The Vanderbilt VTEU is a collaborative team that brings together sites in Pittsburgh, Philadelphia, St. Louis, and Lima to conduct studies across the lifespan. The Department of Pediatrics at Vanderbilt now ranks first in the nation in NIH funding (>\$80M) and provides a robust infrastructure to conduct the work, including recent investments in a new Clinical Research Unit that will open in Fall 2025. Now as much as ever, the work of the VTEU is critical for our nation's health. We are excited about how we can continue to stand in the gap and promote the wellbeing of children and adults around the world.



Key Accomplishments

- Completion of mpox adolescent vaccine study, leading to EMA approval of MVA-BN in adolescents
- Completion of DMID 23-0005, a phase 1, first-in-human study of a monoclonal antibody that was identified at VUMC, produced in a novel tobacco system, and evaluated in healthy volunteers.
- Multiple staff members achieved SOCRA certification this year.
- Sandra Yoder (Assistant Director, VVRP Laboratory) received the highly prestigious VUMC Award for Excellence in Research Contributing to Multi-Investigator Teams



Newest Member of VVRP (and first grandchild of Dr. Creech)