VTEU HIGHTLIGHTS

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 on Day 2 of the meeting.

BAYLOR COLLEGE OF MEDICINE

Baylor College of Medicine

PROJECTS

DMID 24-0003: Maternal RSV
DMID 20-0034: Gritstone
DMID 21-0004: MOMI-Vax
DMID 21-0012: Mix and Match
mRNA-1273-P204: KidCOVE
DMID 22-0004: COVAIL
DMID 22-0020: DoSES

KEY ACCOMPLISHMENTS

- Dr. Robert Atmar received the Michael E Debakey Excellence in Research Award.
- Dr. C. Mary Healy is now a member of the AAP Committee on Infectious Diseases. Dr. Jennifer Whitaker is a member of the HHS HIV Opportunistic Infections Guidelines Panel, Section on Immunizations.
- Drs. Pedro Piedra and Erin Nicholson launched the Baylor College of Medicine Pandemic Threat Technology Center, which leads and coordinates research and responses to infectious diseases that pose regional and global threats.

4
New Concepts since 2023 Annual Meeting

8
Studies in various stages of development

>75
Peer-reviewed publications added to the medical literature

LEADERSHIP REFLECTIONS

The past 12 months mark a transition phase between the high output of COVID-19 research and resuming a non-pandemic research agenda. BCM VTEU team submitted new study concepts to the VTEU, addressing emerging pathogens clinical vaccine development, and are actively participating in the NEXTGEN Covid-19 vaccine program. We look forward to collaborating with the Leadership Group and other VTEU sites to maintain a robust portfolio of clinical research that addresses public health priorities and orients the young generation of infectious diseases physicians to a career in clinical research.

CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER

PROJECTS

DMID 23-0006: ETEC

DMID 24-0003: Maternal RSV

DMID 19-0003: Campy

DMID 21-0004: MOMI-Vax

DMID 21-0002: Moderna Variant

DMID 21-0012: Mix and Match

mRNA-1273-P204: KidCOVE

KEY ACCOMPLISHMENTS

- Transitioned to "100% electronic" site.
- Completed enrollment and vaccination for DMID 19-0003, Campy.
- Completed participant involvement for DMID 21-0002 Moderna Variant, DMID 21-0004 MOMI-Vax, DMID 21-0012 Mix and Match, and mRNA-1273.

5

IDCRC concepts submitted

5

Fellows and junior faculty in IDCRC Career Development

10

IDCRC cited publications

LEADERSHIP REFLECTIONS

Over the year, the site has been busy completing COVID-19 vaccine trials as well as developing and publishing manuscripts on the trials. We have increased laboratory capacity with the addition of Dr. Gaurav Kwatra as the new Director of our Clinical Research Laboratory (LSCS). Our transition to being "100% electronic" has decreased costs along with increasing participant satisfaction and improving compliance. In the coming year, we will focus on completing the Phase 1 *C. jejuni* vaccine trial as well as initiate our inpatient challenge study to evaluate the efficacy of a candidate vaccine to protect against enterotoxigenic *E. coli* (ETEC).

EMORY UNIVERSITY

EMORY UNIVERSITY SCHOOL OF MEDICINE

PROJECTS

DMID 22-0019: Doxy
DMID 24-0003: Maternal RSV
DMID 19-0015: Neisseria Gonorrhoeae
DMID 20-0034: Gritstone
DMID 22-0004: COVAIL
DMID 21-0004: MOMI-Vax
DMID 21-0002: Moderna Variant
DMID 21-0012: Mix and Match
mRNA-1273-P204: KidCOVE
DMID 22-0020 DoSES

KEY ACCOMPLISHMENTS

- 3 NIH funded mentorship programs (R25, R38 and T32 on vaccinology/infectious diseases/immunology with focus on under-represented minorities) with 5 staff accepted into medical schools in the past year.
- IDCRC mentees as DMID protocol chair (Rostad), EWG co-chairs (Rostad, Rebolledo), CDC-CISA PI (Kamidani), Hope Clinic Associate Director for healthcare based clinical research (Rebolledo), Hope Clinic Associate Director for training and mentorship and Associate Vice Chair of DOM RYSE (DEI) (Wiley).
- Remarkable diversity with up to 58% participants identifying as LatinX or non-White in DoSES (PIs Rebolledo and Rostad).

11
IDCRC Publications

27
Active Studies

96
Staff (79) and Faculty (17)

LEADERSHIP REFLECTIONS

The mission of the Emory VTEU is to address global public health threats by translating basic research discoveries into clinical advances. We achieve our mission by conducting clinical trials for vaccines and therapeutics and translational immunology studies. We take pride in training the next generation of vaccinologists and our community engagement.

KAISER PERMANENTE WASHINGTON HEALTH RESEARCH INSTITUTE

PROJECTS

DMID 18-0018: SchistoShield
DMID 22-0020: DoSES
DMID 21-0002: Moderna Variant
DMID 21-0012: Mix and Match
DMID 22-0004: COVAIL
DMID 24-1102: ChAd36 COVID vaccine given IN and inhaled

KEY ACCOMPLISHMENTS

- Completion of DMID 18-0018, SchistoShield.
- Dr. Jackson served as a co-chair on the Next Gen protocol development committee and for the 24-1102 Ocugen trial, in protocol development.
- Dr. Coler's lab completed the IgG ELISA assays for the DMID 18-0018 protocol using the assay developed and validated in their SCRI lab.

3
Number of IDCRC studies for which the Coler lab is serving as an end-point lab

10
Published citations in past 12 months involving Kaiser WA VTEU investigators

>1000
Participants in vaccine studies registry

LEADERSHIP REFLECTIONS

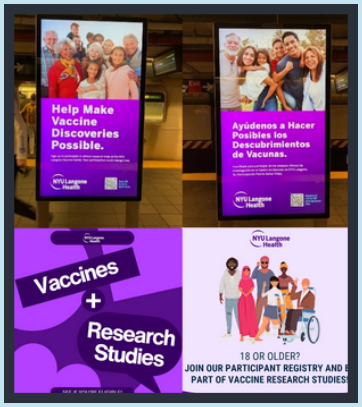
The completion of follow up in the Phase 1 DMID 18-0018 trial has allowed initiation of a phase 1b trial in adults in Burkina Faso and Madagascar sponsored by the International Vaccine Institute (NCT05762393). DMID 18-0018 was also the first trial using direct data entry to allow streamlining of recording of study visit information. We are in the early stages of preparing for 24-1102 which will involve use of a novel method of administration of inhaled vaccine.

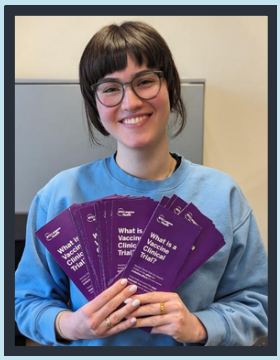
NEW YORK UNIVERSITY

NYU Grossman School of Medicine

PROJECTS

DMID 24-0003: Maternal RSV
DMID 23-1101: Next Gen MPV/S-2P Phase 1
DMID 22-0004: COVAIL
DMID 21-0004: MOMI-Vax
DMID 21-0012: Mix and Match





KEY ACCOMPLISHMENTS

- Successfully completed all visits for MOMI-Vax and Mix and Match studies across all locations, maintaining high retention.
- Dr. Martin Bäcker was chosen as a PI for the first Phase 1 Trial, DMID 23-1101, conducted by NYU, Emory, and Baylor. This trial is the inaugural project of the program, with Dr. Bäcker contributing to development and operational readiness.
- The NYU Vaccine Center has been running the NYC OSMI study, Protocol 22-01338, to assess immune responses to MVA JYNNEOS vaccines and mpox infection. We have shared samples with the network and our findings with the IDCRC and CDC, suggesting the need for additional vaccination for protection. The first results were also published in the *NEJM*. An mpox booster study concept was proposed to the IDCRC following our initial observations.

30%

Participants identifying as races and ethnicities other than Non-Hispanic White

96%

Site retention for MOMI-Vax.

Site retention for Mix and Match was 85%

1700

Participants enrolled in Pediatric & Adult Registry

LEADERSHIP REFLECTIONS

Over the past year, our site has undergone significant restructuring in terms of staffing and space. In this process, Heekoung (Allison) Youn, our Clinic Operations Manager, has emerged as a pivotal figure. Her vast experience and exceptional mentoring skills have been instrumental in supporting this transition. The mpox epidemic impacted many of our patients in midtown Manhattan. We responded with care, support, education and research. The NYU VTEU is now focusing to expand on its core mission to serve the NYC communities that are most affected by health disparities. Recognizing the pressing need to combat vaccine hesitancy and promote vaccine equity, we are committed to designing and implementing strategies to address these issues.

UNIVERSITY OF MARYLAND

UNIVERSITY of MARYLAND
SCHOOL OF MEDICINE
CENTER FOR VACCINE DEVELOPMENT AND GLOBAL HEALTH

PROJECTS

DMID 23-0005: AFM/EV68-228-N

DMID 24-0003: Maternal RSV

DMID 23-0006: ETEC

DMID 20-0024: Mening Mali

DMID 19-0007: Malaria Uganda

DMID 21-0012: Mix and Match

mRNA-1273-P204: KidCOVE

KEY ACCOMPLISHMENTS

- DMID 20-0024 study led to WHO recommending its use in meningitis-belt countries for routine pediatric vaccination programs and mass immunization campaigns.
- DMID 21-0012 found that a protein based NVX-CoV2373 heterologous booster following mRNA vaccines was safe and immunogenic in recipients of Ad26, COV2.5, mRNA-1273, or BNT162b2 vaccine, resulting in 5 publications in high impact journals, e.g., NEJM and Nature.
- DMID 19-0007 began enrolling in December 2023, targeting 100 children 6mo. to 14 years of age with severe malaria to correlate active drug levels to clinical outcomes to more effectively dose children.

1

2024 IDCRC Mentee

2024 Pilot Award Recipient

3

Concepts Submitted

Concepts Approved

50

Number of years CVD has been developing and testing vaccines. Est 1974.

LEADERSHIP REFLECTIONS

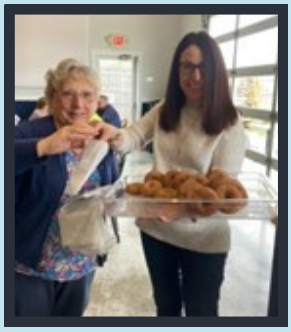
These studies illustrate the most gratifying aspect of working in a VTEU - the ability to impact policy and improve public health.

UNIVERSITY OF ROCHESTER

UNIVERSITY of ROCHESTER MEDICAL CENTER

PROJECTS

DMID 22-0019: Doxy
DMID 24-0003: Maternal RSV
DMID 22-0004: COVAIL
DMID 21-0004: MOMI-Vax
DMID 21-0012: Mix and Match
mRNA-1273-P204: KidCOVE
DMID 22-0020: DoSES



KEY ACCOMPLISHMENTS

- We activated additional research arms, such as the UR VTEU research laboratory which will participate as a reference lab for COVAIL, and our colleagues in sexual health who are leading the Doxy study at our site.
- Though operations were briefly impacted by an unexpected flood of our research clinic and laboratories on December 26, 2022, we resumed normal activities within a few days with little impact on study visits and no loss of clinical data or biological samples.
- The UR VTEU Pilot award program is thriving with 2 pilot grants completed in October 2023 by Dr. Jinjian Pang and Drs. Regina Rowe and Jennifer Nayak, resulting in publications in high impact journals and additional grant applications, including one awarded R01. Two new pilot grants will explore the immunogenicity of mRNA vaccines in patients with advanced COPD and test a novel adjuvant for LAIV in a mouse model.

1
Concept approved in prioritization

8
Junior investigators engaged in the IDCRC

1700
Vaccines administered over the first 4 years of the grant

LEADERSHIP REFLECTIONS

The fouth year of the Rochester VTEU has been characterized by the growth and diversity of our research portfolio. With stable leadership of our team under the guidance of senior project manager Kari Steinmetz, we turned our attention to engaging new junior investigators and activating additional research arms. Plans for future years include developing pilot concepts that would establish Uganda as an international site under the direction of Dr. Paul Bohjanen and potentially a VTEU subsite with the next VTEU grant cycle submission. We also hope to establish the "chalkboard series" to explore potential collaborations between the Center for Vaccine Biology and Immunology (CVBI) and Infectious Diseases Division which can lead to the development of multidisciplinary pilots studies and lab-based concepts in two areas of subject matter expertise: respiratory viral infections and STIs.

UNIVERSITY OF WASHINGTON

UNIVERSITY of WASHINGTON

PROJECTS

DMID 22-0019: Doxy

CoVPN 3005: Sanofi Crossover/Booster

DMID 23-0010: LARC2

DMID NextGen COVID-19

DMID 20-0034: Gritstone

DMID 21-0012: Mix and Match

DMID 22-0004 COVAIL

KEY ACCOMPLISHMENTS

- Launch of the 3-day vs 7-day Doxy Trial (DMID 22-0019) at our parent site in Seattle and two of our Kenyan sub-sites.
- Neurosyphilis ECP trial moving towards protocol development.
- LARC2 (DMID 23-0010) protocol development underway with final protocol estimated for May 2024 and implementation estimated for Sept 2024.

17

ICPs submitted; 7 approved to ECP review

1,142

Participants enrolled in CoVPN at parent site and sub-sites; 67% from historically under-represented minorities

1,530

Participants enrolled in VTEU registry, with 20% from historically underrepresented minorities

LEADERSHIP REFLECTIONS

We wanted to acknowledge Kirsten Hauge, our program manager for the VTEU, who has demonstrated exceptional dedication, attention to detail and enthusiasm for the teamwork that has enabled us to be successful. We are also proud of our VTEU mentees who have been successful in advancing their research and careers in academic medicine. In the future, we would like to continue our collaboration with the Indian Tribes in Washington State that we have developed initially for COVID vaccine trials.

VANDERBILT UNIVERSITY

VANDERBILT UNIVERSITY MEDICAL CENTER

PROJECTS

DMID 23-0005: AFM/EV68-228-N

DMID 24-0003: Maternal RSV

DMID 21-0002: Moderna Variant

mRNA-1273-P204: KidCOVE

DMID 22-0020: DoSES

KEY ACCOMPLISHMENTS

- Stephanie Rolsma, MD, PhD and Shannon Walker, MD are participating in the IDCRC Mentorship Program and developing their independent research careers. Dr. Rolsma continues to explore ways to improve pharmacokinetics of beta-lactam antimicrobials and Dr. Walker is using Artificial Intelligence and Machine Learning to address gaps in the prevention of venous thromboembolic events.
- Recent student trainees are thriving, having presented posters at IDWeek and the St. Jude/PIDS Research Conference in Memphis, TN. Two are now in medical school, and two will be starting medical school this summer.
- Recent publications to highlight include evaluation of immunometabolomic changes after influenza vaccine (Howard et al), popPK of meropenem in ICU patients, ongoing analysis from the mRNA-1273 pediatric trials, and development of a kELISA and reactive B-cell assay for RSV.

4
Active Domestic and International Subsites

12
Active Studies in the VVRP

25
VVRP-affiliated Faculty and Staff

LEADERSHIP REFLECTIONS

The mission of the Vanderbilt Vaccine Research Program and Vanderbilt VTEU is to reduce the burden of infectious diseases worldwide through the discovery, evaluation, and delivery of safe and effective immunizations and therapeutics. Our portfolio is focused principally on influenza, RSV, pertussis, S. aureus, C. difficile, and antimicrobial resistance, with new collaborations forming around alphaviruses, S. pyogenes, and Group B Streptococcus. The team is also exploring new technologies to identify alterations in immunometabolism that may impact immune responsiveness to vaccines and immune readiness in patients with chronic critical illness.