A beneficiary is attended to at the community health center in Darhara, Uttar Pradesh, India on September 16, 2020. The center caters to the community with regards to health issues.

Photo: Saumya Khandelwal
All lives have equal value

The Bill & Melinda Gates MRI

We are a diverse group of creative innovators and advocates. We are committed to the development and use of biomedical interventions to address global health concerns.

Who We Are

The Bill & Melinda Gates Medical Research Institute is a non-profit organization dedicated to the development and effective use of novel biomedical interventions addressing substantial global health concerns, for which investment incentives are limited.

The institute works through collaborating partners and organizations, coordinating and driving the full spectrum of biopharmaceutical development activities, including pre-clinical development, full clinical development (from phase 1 through to and including phase 3), and global regulatory interactions.

What We Do

The institute focuses on programs aimed at reducing the burden of TB, malaria, diarrheal diseases, and maternal, newborn, and child illnesses worldwide.

As an affiliate of the Bill & Melinda Gates Foundation, the institute’s programs are focused on disease and health areas of primary focus at the foundation. The interventions under study and development are derived from sources both within and external to the foundation.
Michael Dunne, MD, FIDSA

Over the course of his career, Michael has played an integral role in global and local anti-infective drug development. Prior to joining Gates MRI, Michael was the founder and Chief Scientific Officer at Iterum Therapeutics, where he led the development of the antibiotic sulopenem. From 2014 to 2015, he was Vice President of Research and Development at Actavis. Michael earlier served as a founder and Chief Medical Officer at Durata Therapeutics beginning in 2009, where he was responsible for the development and successful global registration of dalbavancin. Prior to joining Durata, Michael worked at Pfizer for 17 years, where he was the Therapeutic Area Head for Infectious Diseases leading the development and registration of several antibacterial, antifungal, antiviral, and HIV therapeutics. Michael was a member of the Scientific Advisory Committee for the Global Alliance for TB Drug Development and a member of the Expert Scientific Advisory Committee for the Medicines for Malaria Venture. He earned his M.D. from the State University of New York Health Science Center at Brooklyn and completed his residency in internal medicine and fellowship training in pulmonary medicine and infectious diseases at Yale University.

Janie Parrino, MD

Janie is a Clinical Development Leader for Maternal, Newborn, and Child Health product development at Gates MRI which she joined in January 2022 after 8 years leading clinical and regulatory activities at Regeneron Pharmaceuticals. At Regeneron, she supported immunology, cardiovascular/metabolism, and infectious diseases development programs and led the initial registration of an approved treatment for Zaire ebolavirus and the emergency use authorization of a COVID-19 therapeutic. From 2007 to 2013, she led clinical vaccine development for shingles vaccine programs at Merck. Janie received her MD from the State University of New York at Stony Brook, completed her residency training in internal medicine at Lahey Clinic Medical Center and an allergy and immunology fellowship at the National institute of Allergy and Infectious Diseases (NIAID), U.S. National institutes of Health (NIH).
The people behind the science

Alex Schmidt, MD, PhD

Alex is the Head of Vaccine Development at Gates MRI. He joined Gates MRI in 2018, after seven years with GSK Vaccines, where he led clinical vaccine development programs for dengue, RSV, and influenza virus vaccines. Prior to joining industry, he spent ten years in the Laboratory of Infectious Diseases, NIAID, U.S. National institutes of Health, and five years in academic medicine in Berlin, Germany. Alex is a member of the American Society for Microbiology, the American Society of Virology and the American Society for Tropical Medicine and Hygiene. He is a recipient of the NIH Director's Award and several NIAID awards. Alex received his MD from Freie Universität Berlin, trained in pediatrics at Charité and at The German Heart Center in Berlin, and held a faculty position in pediatrics at Charité.

Charles Wells, MD

Charles currently serves as Head of Therapeutics Development at Gates MRI which he joined in May 2019. Previously, he served as Executive Vice President for Global Health and Development for Infectious Diseases at Evotec carrying forward in this role with the transfer of the Infectious Diseases Therapeutics R&D group from Sanofi to Evotec in July 2018. During his time at Sanofi and Evotec he oversaw development programs for malaria therapeutics and antibacterial development, as well as biologics development for HIV and viral tropical disease prevention. From 2007 to 2015, he served as Senior Medical Director for the development and initial registration of delamanid (Deltyba) for treatment of multidrug resistant tuberculosis at Otsuka Pharmaceuticals. Before Otsuka, he served as Chief of the International Research and Programs Branch of the Division of Tuberculosis Elimination at the U.S. Centers for Disease Control and Prevention (CDC) during 2000-2007. Charles completed his medical studies at the University of North Carolina at Chapel Hill in 1992 and then his post-graduate medical training in internal medicine and infectious diseases at Emory University in 1998, as well as the Epidemic Intelligence Service at CDC.
The institute is supporting and investing in multiple vaccines and therapeutics programs. These include the development of novel vaccine interventions to prevent TB and the establishment of global clinical trial capabilities to support future novel approaches to TB control. We are a member of the Project to Accelerate New Treatments for Tuberculosis (PANTB) collaboration, in which we will conduct clinical studies intended to evaluate promising new drug regimens designed to simplify TB treatment and cure. We are starting a clinical evaluation of a probiotic supplement to assess its potential to positively impact weight gain in underweight children. We are developing a monoclonal antibody with the potential of providing seasonal protection in children against *Plasmodium falciparum* malaria, and vaccine candidates for protection against life threatening *Shigella* dysentery in young at-risk children. We are conducting a phase 1 RSV polyclonal antibody study in adult, healthy volunteers.
Gates MRI offers a unique fellowship:

• **All lives have equal value:** Work at Gates MRI is humbling – we are inspired by our mission and driven by the opportunity to serve those in greatest need. We take on the most intractable public health challenges; our science touches the lives of millions.

• **Environment:** The institute is unique; we have a special place in the world of global health. We have outstanding people, leaders who collaborate with global teams in exciting and fulfilling work, working in service of others. We are passionate, driven and disciplined as we strive to make a difference.

• **The institute is fast paced:** We are a small team taking on big challenges. Our work matters.

• **Growth:** We are each experts in our disciplines and functions, experienced but constantly learning and highly engaged. We hire exceptional individuals; their dedication and work in service to our mission reflects its importance. We create, we innovate and we are fortunate to be well supported and resourced. We show up for each other, we find ways to get the job done, using our skills for good.

Our culture thrives on our five mantras:

• **Innovation:** Build on the known, uncover the new, achieve the unprecedented.

• **Rigor:** Drive the science, focus on the details, and execute with the highest quality.

• **Courage:** Dare to confront the world’s most significant global health challenges.

• **Collaboration:** Establish empowered teams to drive our bottom line: lives saved.

• **Urgency:** Execute with excellence to maximize impact.
Objectives

The goal of this training program is to support development of global public health physicians by providing training and experience in product development from target selection to regulatory approvals and policy generation.

Candidate profile

This program is designed for individuals in Boston-area ACGME accredited adult and pediatric Infectious Diseases fellowship programs who have completed their core clinical care responsibilities. Fellows will continue to meet clinical and other requirements (e.g., outpatient continuity clinic or limited inpatient consult time) at their home institution during their time in the Gates MRI clinical research fellowship program. One fellow will be selected each academic year for a two-year term. There is no US citizenship requirement for this fellowship; fellows on US visas are eligible to apply. The program is best suited for fellows who may have an interest in:

- **Clinical Research**
  - Basic principles of study design
  - Hands on experience in execution of clinical trials
  - Research experience in a highly regulated environment focused on new product development, in addition to addressing important clinical questions of our day

- **Global Health**
  - Motivated to build a career focused on developing products to address diseases in low and middle income countries (LMICs)

Additionally, fellows should be able to commit to ~50% time onsite at the Gates MRI Cambridge, MA office.

Details of the fellowship

This fellowship offers a unique opportunity to apply scientific expertise to develop pharmaceutical products and to go from an academic setting, to serve those in greatest need. The participating fellows will gain a foundational skill set in clinical development through hands-on, practical experience as well as through didactic learning.
**Practical Experience**

Each participating fellow will be paired with a Gates MRI clinical development mentor who will provide oversight for the fellow and monitor the fellow’s experience. The fellow will work alongside the Gates MRI physicians as a clinician on the project team and directly contribute to project work. The fellow will be part of a multidisciplinary team and gain experience across many functions:

- Clinical Development
- Regulatory Affairs
- Statistics and data management
- Pharmacovigilance
- Bioassay development
- Translational medicine
- Pharmacometrics
- Clinical Operations
- CMC (Chemistry, Manufacturing and Controls)

- Protocol and supportive document development
- Study site management
- Safety data reviews
- Data interpretation
- Publication Development

To further enhance understanding of clinical trials and gain the investigator perspective, fellows are encouraged to travel outside the US and visit trial sites with their study teams for their assigned programs.

**Didactic Experience**

Didactic training will be accessed through already available coursework at the fellows’ home institutions and/or through online resources sponsored by other institutions. The topics to be covered include:

- Experimental design and analytical methods
- Statistics
- Regulatory framework for clinical research and product approvals and generation of policy recommendations
Interested fellows can apply to one of the following areas:

Click each icon to learn more:

**Tuberculosis**
- TB vaccines
- TB Therapeutics

**Malaria**
- Monoclonal antibodies

**Maternal, Newborn and Child Health**
- Probiotics
- RSV

**Shigella**
- Vaccines

Participating fellows are expected to present at team meetings and share their experiences at Gates MRI-wide seminars. Ideally, participating fellows will also have the opportunity to be an author on at least one manuscript and/or an oral or poster presentation at a recognized conference in the area of interest.

**Clinical Research Fellowship Application**
- Applications accepted online from October 1, 2023 through January 15, 2024.
- Applications will be reviewed on a rolling basis. Following submission of your application, please allow 1 to 2 months for review and interviews.