

Clinical Development Leader—Tuberculosis Vaccines
Bill & Melinda Gates Medical Research Institute
Cambridge, MA

We are focused on results. Those that can be measured. And those measured in ways beyond numbers.

We see individuals, not issues. We are inspired by passion, and compassion for the wellbeing of people. Our methods are based on logic, driven by rigor, results, issues, and outcomes. Our innovation means trying new things, learning from our mistakes, and consistently refining our approach. Our strategies help us define our path to success, but our effectiveness is based in the aggregate power of our initiatives to impact holistic change.

-Bill and Melinda Gates

BILL & MELINDA GATES MEDICAL RESEARCH INSTITUTE

The Bill & Melinda Gates Medical Research Institute (“Gates MRI”) is dedicated to translating findings from basic science into potential solutions that will fill the product pipeline for malaria, tuberculosis, enteric and diarrheal diseases and major causes of neonatal mortality. It is committed to saving lives by improving the pace and predictability of translational medicine and product development in global health. The Gates MRI will relentlessly seek out innovative strategies to develop the best drugs, biologics, and vaccines to fight some of the toughest, most complex disease problems in the world.

The Gates MRI is bringing together top talent from diverse scientific backgrounds and work across a range of disease areas and modalities to build upon the best work being done in scientific discovery and product development, constantly pushing the envelope and embracing new methodologies. Unlike the private sector in biotech and pharma, the Gates MRI has the unique luxury of operating outside a traditional for-profit delivery model to enable rapid innovation and agile decision-making. Imagine never having to raise capital, having the freedom to take scientific risks, and being solely focused on finding solutions for diseases that take the lives of more than 3 million people per year.

The institute anticipates and accepts that some of these approaches will fail. However, it will fail fast and iterate quickly, in order to rapidly identify the most promising candidates for development. To enable a fast to decision mindset, the institute will operate using small teams and a flat structure with the understanding that it is essential to break out of silos and embrace unconventional approaches across modalities. The five core mantras that will permeate across the organization and drive progress at every level are:

- **Urgency:** *Strive every day to do better than your last best accomplishment.*
- **Collaboration:** *Solving the world’s most complex disease burdens is a team effort.*

- **Innovation:** *Uncover new methods, approaches and solutions to achieve unprecedented results.*
- **Rigor:** *Follow the science with passion and perseverance.*
- **Courage** – *Pursue progress boldly to deliver on our bottom line: lives saved.*

Though the institute will be a diverse group of passionate change-makers, creative fixers and relentless advocates, these five core values will be universally adopted by all who join the Gates MRI and strive to improve the health and wellness of the world's most vulnerable populations.

THE POSITION

The **Clinical Development Leader** for TB Vaccines will take on a pivotal leadership role in advancing the M72/AS01E candidate TB vaccine from Phase 2b into Phase 3 development and through registration, should Phase 3 data be supportive. The individual will help build the organization, including modeling and driving the desired culture, helping to guide epidemiology and clinical development strategy, and building a robust network of external partnerships.

The successful individual will initially have responsibility for the Institute's late stage tuberculosis vaccine program, and potentially for other programs as the institute and the role evolves. These activities will be aligned with the priorities of the Tuberculosis Program Strategy Team at the Gates Foundation. The CDL will play a critical role in preparing for and conducting a large Phase 3 TB vaccine efficacy study in low income countries, mainly in Africa and Asia. This work will be conducted in close collaboration with a variety of partners and stakeholders, and the CDL will play a central role in building and maintaining programmatic and strategic partnerships. In addition, the CDL will play a key role in guiding the capacity building for the Phase 3 trial and he/she will work closely with clinical investigators and teams in-country. Preparation for Phase 3 will also include a large epidemiology study to assess the burden of TB at site-level and to train site teams on TB surveillance.

The CDL will be expected to lead and oversee protocol design, protocol writing and clinical study execution in close collaboration with the matrix team. The CDL will work in partnership with leading academics, nonprofits, supranational organizations and regulatory authorities to ensure global alignment on the program goals and best-in-class trial design and execution. Working closely with the biostatistics, assay development and exploratory biomarker teams within the Institute, the CDL will also contribute to biomarker discovery and correlates of protection work for TB vaccines.

QUALIFICATIONS

The successful candidate will be an innovative, experienced, and highly creative individual who thrives in a "get it done" type of environment with a strong track record of hands on experience in clinical trials and clinical development. (S)he will have the following mix of personal and professional characteristics:

- MD with 5+ years of leadership experience in clinical trials and clinical development across strategic and operational roles, as demonstrated by serving as principal investigator or clinical development leader
- Experience designing and executing clinical trials in low- and middle-income countries is highly preferred, along with the demonstrable insight and awareness of the complexities of this important work

- Training and/or experience in infectious diseases and/or immunology and/or epidemiology desired
- Comfortable working across disease areas and able to shift gears quickly. Must be open to change and the unknown with a creative and resourceful nature; a self-starter, proactive and results-oriented with high performance standards
- Strong interpersonal skills with the ability to influence others at all levels and lead in a highly matrixed organization
- Personal leadership style that inspires trust, confidence, and collaboration
- Passionate, persistent and tenacious. Strong ability to prioritize and operate with a sense of urgency
- Demonstrable history of intellectual rigor and high aptitude with a highly strategic nature but also balanced with a biotech mindset and a hands-on, roll-up-the-sleeves style that gets things done
- Trustworthy with highest integrity, committed to ethics and scientific standards
- Outstanding communication skills; ability to work well with a wide range of internal and external stakeholders and build strong partnerships and alliances inside and outside the organization
- Experience building capability, both internally within own organization and externally with a range of partners is desired
- Experience in pioneering the start-up of new organizations or functions is a significant plus
- Demonstrated passion for the Institute's values with a commitment to deliver results against our mission