

ABOUT AERAS

Aeras is a nonprofit biotechnology organization developing new, effective tuberculosis (TB) vaccines that are affordable and accessible to all who need them. Aeras works through partnerships in both the public and private sectors, with individuals, research organizations, academic institutions, funders, policymakers and others around the world to advance TB vaccine science and development.

THE URGENT NEED FOR NEW VACCINES

The world's only TB vaccine, now over 90 years old, has failed to halt the global epidemic. In 2015, under the specter of 9.6 million new cases and 1.5 million deaths per year¹, the World Health Organization (WHO) called attention to "the need for prioritization and additional funding for TB vaccine research to develop a more effective vaccine to contribute to tuberculosis control."² A vaccine that prevents adolescents and adults from developing and transmitting the disease is an urgently needed and cost-effective tool to help end this epidemic.



KEY AERAS ACTIVITIES

- Develop criteria for vaccine candidate progression, in collaboration with the TB vaccine research community
- Conduct epidemiological studies
- Evaluate TB vaccines from preclinical testing through post-licensure clinical trials
- Introduce novel study designs to streamline clinical development
- Improve infrastructure and enhance capacity in high-burden countries for lasting impact
- Facilitate community engagement in TB vaccine clinical research
- Conduct TB advocacy and communications

To see the current global TB vaccine clinical portfolio, go to: www.aeras.org/portfolio

ADVANCING VACCINE CANDIDATES

Over the past decade, more than a dozen³ new TB vaccine candidates have been tested in human clinical trials around the world. Serving as a critical translational bridge from the bench to the field, Aeras has sponsored and conducted over 30 clinical and epidemiological studies in 15 different countries. Each of our partnerships is overseen by a joint project team and steering committee with the collaborating organization – an equal partner in all aspects of the product development.

9.6 Million

new TB cases per year

IMPROVING EFFICIENCY

Aeras is working to conduct trials more efficiently and to reduce risk by making strategic portfolio management decisions as early as possible, to focus resources on candidates with the highest probabilities of success. Terminating or proceeding with a candidate uses an objective set of scientific, clinical and business 'Stage Gate' criteria, established in collaboration with the European TB Vaccine Initiative (TBVI) and international experts, enabling transparency into go/no-go decisions.

AERAS AT A GLANCE

- Founded in 1997 as a U.S. 501(c)(3) nonprofit biotechnology organization
- In-house capabilities in translational product development from preclinical research through clinical trials and registration, pharmacovigilance, regulatory, project management, portfolio management, finance, policy, advocacy and resource mobilization
- Offices in Rockville, USA (HQ); Cape Town, South Africa; Beijing, China
- Governed by an independent Board of Directors, with external technical advisory groups incorporating global expertise
- Executive leadership team with decades of experience developing and commercializing new vaccines and biologics

PRECLINICAL RESEARCH: STRENGTH THROUGH DIVERSITY

Preclinical Research: Strength Through Diversity

We work with partners around the world to support the advancement of promising candidates into the clinic. This process is meant to encourage innovation, strengthen the global TB vaccine portfolio and maximize the overall likelihood of success.

ADVANCING VACCINE SCIENCE

There is much to be learned about how TB vaccines need to work. Aeras is helping to develop new and improved human challenge and animal models of disease, and examining correlates of risk and protection to help accelerate vaccine development.

TRANSLATIONAL AND EXPERIMENTAL MEDICINE

Aeras uses innovative, adaptive trial designs with populations specifically selected to reduce trial size and cost. New, experimental medicine studies are also examining key immunological and clinical issues.

ADVOCACY AND RESOURCE MOBILIZATION

Global spending on new TB vaccine development is just 25% of what is needed – part of a US\$1.3 billion funding gap in 2013.⁴ Aeras aims to strengthen political will, and expand and diversify the funding base to help ensure long-term financial support for TB vaccine R&D.

PARTNERSHIPS: ENHANCING KNOWLEDGE AND CAPACITY

No one organization or institution can conduct TB vaccine R&D alone. Aeras has built close partnerships with a variety of African, European, North American and Asian organizations. Aeras fosters the sharing of knowledge and strengthening research capacity in multiple countries, and has recently held more than 10 scientific and product development symposia on key aspects of TB vaccine development.

DONORS

Aeras is primarily funded by The Bill & Melinda Gates Foundation and European donor governments. We also receive support from the U.S. government, and through partnerships and collaborations with universities and pharmaceutical companies around the world.

REFERENCES

1. WHO (2015). Global Tuberculosis Report 2015.
2. WHO (2015). Guidance on how to prioritize globally constrained BCG vaccine supply to countries.
3. The Lancet, 2014. Progress in tuberculosis vaccine development and host-directed therapies – a state of the art review doi:10.1016/S2213-2600(14)70033-5
4. Treatment Action Group, 2014. 2014 Report on Tuberculosis Research Funding Trends, 2005–2013.

Major Progress: Innovation and Impact

Over the past decade, Aeras has made significant contributions to the marked progress of the TB vaccine field. Together with our partners and collaborators, we are advancing the best TB vaccine science and working toward a common goal of ending the threat of TB.