

Overview of Product Development Consultative Services Support provided by the Collaboration for TB Vaccine Discovery (CTVD)

The Collaboration for TB Vaccine Discovery ([CTVD](#)) is an international network of scientists and experts dedicated to fostering innovation, cooperation, and collaboration in the up-stream TB vaccine discovery, translational research and development space, funded by the Gates Foundation.

The International AIDS Vaccine Initiative (IAVI) and TuBerculosis Vaccine Initiative (TBVI), two well established and knowledgeable, not for profit, TB vaccine development organizations, received grants from the Gates Foundation to provide consultative services to investigators who have novel TB vaccine concepts or candidates but little direct product development experience.

With support from these grants, TBVI and IAVI provide consulting services on:

- Product development planning, including development of Product Development Plans and Target Product Profiles and provision of tools for monitoring objectives vs. deliverables
- Regulatory strategy and related filings, e.g. pre-IND, IND (FDA, EMA and regulatory bodies in low- and middle-income countries)
- Requirements regarding and design of preclinical studies, e.g. Toxicology, immunogenicity in suitable animal models
- How to identify and manage manufacturing partners for process development, clinical manufacturing and distribution of clinical materials
- Clinical study protocol development planning, including clinical assay development
- Adherence to GXP requirements
- Quality assurance across entire process

This consulting service is tailored to meet individual Principal Investigator (PI) needs where these are aligned with the objectives of CTVD. Consulting costs associated with the service are covered through the foundation grants.

Who Should Apply? How to Apply:

If you currently have a novel TB vaccine concept or candidate and would like to apply for product development consultative services please contact ksenia.koon@gatesfoundation.org. CTVD members may apply [here](#) although CTVD membership is not a requirement.

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**About International AIDS Vaccine Initiative (IAVI):** <https://www.iavi.org/> IAVI is a nonprofit organization dedicated to developing vaccines and antibodies for HIV, tuberculosis, emerging infectious diseases, and neglected diseases. Their mission is to translate scientific discoveries into affordable, globally accessible public health solutions.

**About TuBerculosis Vaccine Initiative (TBVI):** <https://www.tbvi.eu/> The TuBerculosis Vaccine Initiative (TBVI) is a Research and Innovation partnership that facilitates the discovery and development of new, safe and effective TB vaccines that are accessible and affordable for all people.