**Lilly TB Drug Discovery Initiative**
**IP Guiding Principles**

**This document addresses the intellectual property ("IP") guiding principles of the Lilly TB Drug Discovery Initiative (the "Lilly TB Initiative").**

Eli Lilly and Company ("Lilly"), the Infectious Disease Research Institute ("IDRI"), and the National Institute of Allergy and Infectious Diseases, National Institutes of Health ("NIAID/NIH"), Founding Members of the Initiative, and Academia Sinica, a Contributing Member, share the objectives of supporting research in tuberculosis to create knowledge that will lead to the development of effective therapeutic interventions that may be integrated into domestic and international tuberculosis, including MDR- and XDR-TB (together called "TB") care programs to reduce the transmission of *Mycobacterium tuberculosis*, and burden of Mtb infection and TB disease.

The Lilly TB Initiative is housed within, led by, and "incubated" in IDRI; its operations are located at IDRI's headquarters in Seattle, Washington. The Lilly TB Initiative governance structure consists of a Board of Advisors; a Scientific Steering Committee, which is chaired by Lilly and advised by the Lilly Chemistry and Computational Advisory Committee, among others; a Program Manager (an IDRI employee); and a Technical Expert Group. The Lilly TB Initiative will remain a small, focused alliance. The member representatives will identify and agree on projects to be recommended for the Lilly TB Initiative. The research undertaken by the Lilly TB Initiative will be conducted by personnel located at IDRI in Seattle, Washington, within Lilly or by Lilly contractors, or by NIAID-supported investigators and may be done by personnel of additional members or collaborators joining the Lilly TB Initiative ("Participants in the Lilly TB Initiative").

General IP Principles of the Lilly TB Initiative:

- The Lilly TB Initiative will seek to protect the Intellectual Property of certain inventions discovered during the research and development of molecules for the treatment of tuberculosis, including MDR-TB ("TB").

- Patent applications may be filed in major market countries, mostly members of the OECD (e.g., The United States, Europe, Canada, Japan, Australia, New Zealand, Mexico, etc.); patents may be filed in lesser developed countries after careful cost/benefit consideration.

- Patent applications may be filed on candidate compounds and also on a narrow genus of compounds closely related to the candidate compounds.

- The Lilly TB Initiative will not file patent applications claiming mechanisms of action for broad classes of compounds.

- The Lilly TB Initiative will not file patent applications claiming research tools arising from any of the research results found during research and development of molecules for the treatment of TB.

- Research results will be published as soon as reasonably practical after the filing of the initial priority patent application on each invention.

- In general, initial hits from screening campaigns will not be the subject of patent applications until further information supporting candidacy is obtained.

- Depending on the particular situation, publications may utilize tool compounds in public disclosures instead of hit compounds or compounds that may be included in patent applications.

- A compound library owner will provide blinded compounds to a participant in the Lilly TB Initiative for initial screening work. Structures of compounds resulting in validated hits will be disclosed under confidentiality to the participant after the compound library owner has determined that the disclosure of such structures will not negatively impact the owner's non-TB interests.

- The participants in the Lilly TB Initiative will continue to own all right, title, and interest in any of the participant's existing intellectual property. If necessary, appropriate licenses may be employed to facilitate sufficient access to a participant's existing intellectual property.

- The participants in the Lilly TB Initiative, recognize that institutions employing the inventors are bound by the requirements of the Bayh-Dole Act of 1980, to the extent they have received funding for this invention from the U.S. federal government (including NIH), and any institutional policies regarding technology transfer.

- If the NIH is a participant conducting and contributing research to the Lilly TB Initiative, it may have certain ownership rights in arising inventions. The NIH is an agency of the U.S. federal government and must comply with all applicable U.S. law, regulations, and other governmental provisions as well as internal NIH policies with regard to the allocation of rights for any U.S. government-owned inventions. Therefore, with regard to any inventions arising at NIH, the patent plan will be consistent with these laws and NIH patent and licensing policies.

<u>Scenario 1: Current IP Arrangement between IDRI and Lilly:</u>

- As between the Parties, Lilly retains sole and exclusive ownership of any materials and reagents that Lilly provides to IDRI under a research plan.