Abstract

The PreDiCT-TB (Model-based preclinical development of anti-tuberculosis drug combinations) consortium is a 60-month effort from the Innovative Medicines Initiative (IMI) to accelerate the search for new, more effective combinations of treatments to tackle tuberculosis (TB). The consortium’s focus is to address preclinical research barriers to the discovery and development of new TB drug combinations.

Mission

PreDiCT-TB aims to overcome the challenges in TB drug development by creating tools to accelerate pharmacokinetic/pharmacodynamic (PK-PD) analysis that are connected to clinical outcomes. By addressing the gaps in preclinical information, the consortium aims to provide a framework and tools to facilitate the transition of the best combinations of drugs to late phase development.

The aims of the consortium are as follows:
Consortium History

2012: Project launched
July 2012: PreDiCT-TB and Critical Path to TB Drug Regimens (CPTR) announced joint meeting on TB
August 2012: European & Developing Countries Clinical Trials Partnership awarded grant to Stephen Gellespie and other members of the PacACEA and PreDiCT-TB consortia
September 2012: Bedaquiline, an investigational new drug developed by Janssen and scheduled to be included in the second round of PreDiCT-TB, granted accelerated approval by the U.S. Food and Drug Administration (FDA)
March 2013: PreDiCT-TB signed Memorandum of Understanding with Critical Path Institute’s (C-Path’s) CPTR projects to coordinate work
February 2014: Louise Cooper appointed new project manager

Structure & Governance

The governance of the PreDiCT-TB consortium follows the framework for all consortia supported by the IMI. In addition to a Steering Committee, the consortium relies on several working groups and boards, such as an Ethics Advisory Board.

Financing

This project is funded by the IMI, a public-private partnership between the European Union (EU) and the European Federation of Pharmaceutical Industries and Associations (EFPIA), resources of which are composed of financial contribution from the EU Seventh Framework Programme and EFPIA companies’ in kind contribution. Large pharmaceutical companies participating in IMI projects do not receive IMI funding. IMI contributed €14.8 million, EFPIA contributed €9.3 million in kind, and other sources contributed €4.5 million, for a total cost of €28.6 million.

Intellectual Property
The IMI intellectual property (IP) policy governs the IP regime of all projects funded by the IMI Joint Undertaking. To assist with specific IP queries, IMI has set up a dedicated IP Helpdesk, which can be contacted by emailing IMI-IP-Helpdesk@imi.europa.eu. The IMI IP policy can be accessed at http://www.imi.europa.eu/sites/default/files/uploads/documents/imi-ipr-policy01august2007_en.pdf

Data Sharing

According to IMI’s IP policy, the participants undertake to disseminate the data as soon as reasonably practicable but not later than one year after the termination or expiry of the project. The project agreement shall include a description of the material, which must be disseminated in accordance with the IP policy and referenced in the grant agreement. If the participants do not disseminate within such time periods without good reason, then the Executive Office has the right to disseminate such results in a manner consistent with the grant agreement.

Impact/Accomplishment

In 2013, PreDiCT-TB and C-Path’s CPTR project signed a Memorandum of Understanding to coordinate their work in developing new and effective treatment regimens for TB.

Links/Social Media Feed

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