

Critical Path to TB Drug Regimens

Press Release



FDA and Global Partners Join Forces to Speed Development of New TB Drug Combinations

Tucson-Based Critical Path Institute to Coordinate Major World Health Initiative

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Tucson, Arizona, 24 March 2010 – In coordination with World TB Day, US Food and Drug Administration Commissioner Margaret Hamburg last week helped public and private sector partners launch a new collaboration to significantly accelerate the development of combination treatments for tuberculosis - and replace an almost 50-year-old drug regimen. Created by the **Critical Path Institute**, the Global Alliance for TB Drug Development and the Bill & Melinda Gates Foundation, the initiative could potentially reduce the time it takes to introduce new combination TB treatments from as much as a quarter century to as few as six years.

Known as the Critical Path to TB Drug Regimens (CPTR), the initiative will test promising combinations of individual TB drug candidates from different companies early in the development pipeline—and identify the best new treatment regimens. Initial groups engaged in CPTR include scientists from FDA and the pharmaceutical companies Johnson & Johnson, sanofi-aventis, Pfizer, AstraZeneca, GlaxoSmithKline, Bayer, Otsuka, Novartis, Sequella and Anacor Pharmaceuticals, Inc. The World Health Organization (WHO) has expressed its support for the initiative.

“CPTR will be coordinated by the Critical Path Institute—a Tucson, Arizona based independent, non-profit organization whose mission is to create innovative collaborations in regulatory science that enable the most efficient and safe medical product development. The collaboration will welcome participation from any company with a promising TB drug candidate in development, as well as other companies and organizations with the technical expertise or resources to help develop new TB regimens.

“By working together, CPTR partners can take years off the drug development timeline for safer new TB drug regimens,” said Dr. Raymond Woosley, President and CEO of the Critical Path Institute. **“The commitments of FDA and regulators in Europe helping to develop new and improved testing methods, and of companies making their compounds and expertise available, show leadership and flexibility that could benefit millions of patients.”**

FDA is absolutely committed to working with partners to speed access to new, safe and highly-effective treatments for TB, which continues to mutate and spread," said Dr. Hamburg. "I've seen first-hand the public health impact and personal tragedy of drug-resistant TB. This creative approach mirrors FDA's own investments in innovative regulatory science that ensures the best new medical technologies—including combination therapies—reach patients as soon as possible."

Currently, obtaining regulatory approval for completely new TB regimens could take 24 years as individual candidates are developed and registered separately and substituted, one at a time, into existing combination therapies. The CPTR initiative has the commitment of the FDA and regulatory authorities in Europe to help develop and validate improved, safe, and accurate regulatory pathways to test and register combination TB treatments.

"This type of collaboration between the public and the private sector is exactly what's needed to help speed the availability of a shorter and more effective treatment for TB," said Dr. Tachi Yamada, president of the Global Health Program, Bill & Melinda Gates Foundation. "A successful drug combination regimen to fight TB could save millions of lives."

Although it is often thought of as a disease of the past, TB remains one of the world's deadliest infectious diseases. TB kills approximately 1.8 million people each year, mainly in developing countries. The standard four-drug course of treatment requires patients to take pills for six months or longer. These drawbacks contribute to the rise of drug resistance. In 2007 there were more than 500,000 cases of drug-resistant TB globally.

"No single company or institution can do it alone," said Dr. Paul Stoffels, Global Head, Pharmaceuticals Research and Development, Johnson & Johnson. "Industry has to continue to focus on innovation and accelerate the discovery and development of new compounds with new mechanisms of action, and at the same time work in collaboration with regulators, non-profit organizations, and other partners to accelerate testing of new combination regimens as early as possible in development."

Nine promising TB compounds from at least six antibiotic classes are currently in clinical trials or late preclinical development, offering an unprecedented opportunity for collaboration. New TB drug combinations could sharply reduce treatment time and prove effective against both drug-susceptible and drug-resistant TB strains. However, given the resilient nature of the TB bacterium and its ability to become resistant to single drugs, TB treatment will still require a combination of antibiotics.

"TB drug development needs these innovations if we are to offer countries better and shorter treatments," said Dr. Mario Raviglione, Director, WHO Stop TB Department. "This initiative has the potential to break new ground and change the TB landscape radically. WHO is pleased to be a partner in this effort."

"With its leadership on TB, FDA is poised to repeat its creative regulatory approach to AIDS drugs in the 1990s, which helped save the lives of millions without compromising drug quality," added Mark Harrington, Executive Director of Treatment Action Group. "It's encouraging that drug companies, FDA, the Gates Foundation and partners are all collaborating to speed faster, more effective TB regimens to approval and to patients."

To facilitate clinical research of combination TB therapies, collaboration partners are also exploring creative funding mechanisms and potential trial site support for Phase IIB and Phase III clinical trials.

“New TB drug regimens could simplify the number of pills patients have to take, shorten the amount of time they have to take them, and be effective against drug-resistant strains,” said Dr. Mel Spigelman, President and CEO of the TB Alliance. “Donor governments, industry, and other research funders should support these efforts and help ensure new, more effective TB treatments are developed as quickly as possible.”

About Critical Path Institute

Critical Path Institute (C-Path) is an independent, non-profit organization whose mission is to serve as the impartial facilitator of collaborative efforts among scientists from government, academia, patient advocacy organizations and the private sector to support the U.S. Food and Drug Administration’s regulatory science initiatives. This involves creating faster, safer and smarter pathways for innovative new drugs, diagnostics and devices that will significantly improve public health.

Support from Southern Arizona and Science Foundation Arizona has enabled C-Path to develop collaborations with the Gates Foundation and the TB Alliance that not only address serious global health problems, but which will make it possible to speed the development of medical products for many other diseases such as Alzheimer’s, cancer and others. Established in 2005, C-Path is headquartered in Tucson, Arizona, with offices in Phoenix, Arizona, and Rockville, Maryland. Visit www.c-path.org for more information.

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