2014 Annual Report

Improving Public Health through Partnership

The Reagan-Udall Foundation for the Food and Drug Administration embodies the FDA's vision of collaborative innovation to address regulatory science challenges of the 21st century. Pursuant to the unique, statutory relationship between the Foundation and FDA, its central focus is assisting the creation of new, applied scientific knowledge, tools, standards, and approaches that FDA needs to evaluate products more effectively, predictably, and efficiently, thereby enhancing the agency's ability to protect and promote the health of the American public.

Critical Path for Tuberculosis Drug Regimens. In 2014, the Bill and Melinda Gates Foundation bestowed a $1.23 million grant to the Foundation to expand its role in the Critical Path for Tuberculous Drug Regimes (CPTR) — a consortium of leading pharmaceutical and diagnostic companies, public health experts, nongovernment organizations and regulatory authorities that together accelerate the development and impact of new combination therapy regimes — to overcome obstacles to new TB treatment options. The Gates Foundation previously provided seed money for this program in 2011. With this continuation grant, the Foundation substantially expanded its role in 2014 by:

- Leading the **Stakeholder and Community Engagement Workgroup**, which enlists stakeholders and community organizations to increase awareness of CPTR efforts and innovations. By producing resources, like webinars and trainings, that encourage participatory approaches and community engagement, the Foundation initiated early, effective, and appropriate collaboration.
- Promoting CPTR innovations to an international audience via presentations at the 2014 Union Conference in Spain and International Conference of Drug Regulatory Authorities in Brazil.
- Managing the **Global Regulatory Pathway Workgroup**, which not only identified TB clinical trial challenges and barriers to affect drug or regimen approvals but also facilitated TB drug development by identifying more efficient regulatory pathways.
- Creating a **fellowship** for a mid- to senior-level fellow in the relevant FDA division, the Division of Anti-Infective Products, to work on specific regulatory science challenges in TB drug and drug regimens.

Systems Toxicology Project. As treatments for cancer improve and patients live longer, the incidence of chronic adverse effects associated with some of its treatments have increased. To address this emergent problem, the Foundation began the Systems Toxicology Project. Begun in 2011 with a grant from the Susan G. Komen for the Cure., this project strives to better understand treatment toxicity. Specifically, the Foundation worked with FDA and other stakeholders to launch a biology-based pilot project to examine the cardiac side effects of tyrosine kinase inhibitors, a common, beneficial class of cancer drugs.

IMEDS. The Foundation received several grants in 2014 to conclude the transition of the Observational Medical Outcomes Partnership (OMOP)

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— a public-private partnership involving FDA, pharmaceutical companies, and healthcare providers that informs the appropriate use of observational healthcare databases for studying the effects of medical products — to the Foundation's Innovation in Medical Evidence Development and Surveillance (IMEDS) system. This new pillar program broadens the stakeholder audience to receive and use FDA data for ongoing public health and safety uses and methods for using observational electronic health care data for post-market evidence generation.

After the Foundation recruited a data partner and selected a data warehouse vendor in 2014, the IMEDS team and its data partners prepared a 2015 pilot project launch.

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