2013 Annual Report

Building Better Science Together

The Reagan-Udall Foundation for the Food and Drug Administration is an independent, nonprofit organization created by Congress to advance the FDA's mission to modernize medical, veterinary, good, food ingredient, and cosmetic product development; accelerate innovation; and ensure product safety.

To ultimately improve America's public health, the Foundation provides a unique opportunity for varying stakeholder sectors — such as FDA, patient groups, academia, industry and other government entities — to work together transparently to create new research projects that advance regulatory science. As a neutral third party, the Foundation helps establish novel, scientific collaborations.

Critical Path for Tuberculosis Drug Regimens

With a grant from the Bill and Melinda Gates Foundation, the Foundation provides leadership and program management to the Critical Path for Tuberculosis Drug Regimes (CPTR), which is comprised of leading pharmaceutical and diagnostic companies, public health experts, non-government organizations and regulatory authorities that work together to accelerate the development and impact of new and improved drug regimens — and overcome obstacles obscuring the way to new TB drug regimens. In this role, the Foundation builds effective stakeholder and community engagement.

Systems Toxicology Project

As treatments for cancer improve and patients live longer, the incidence of chronic adverse effects associated with some of its treatment increase correspondingly. To confront this emergent problem, the Foundation began the Systems Toxicology Project in 2011 with a grant from the Susan G. Komen for the Cure. The project helps stakeholders better understand treatment toxicity. In 2013, the Foundation worked with FDA and other stakeholders to launch a pilot project to examine the cardiac side effects of tyrosine kinase inhibitors, a common, beneficial class of cancer drugs.

Alzheimer's Fellowship

The Foundation, with the support of FDA and the Alzheimer's Association, began developing a two-year regulatory science fellowship for experienced physicians dedicated to treating and studying Alzheimer's disease. This fellowship will train participating physicians in regulatory science at FDA, granting them an unparalleled experience and unique knowledge.[1]

2013 SUPPORTERS

Alzheimer's Association
Bill and Melinda Gates Foundation
AstraZeneca
Biogen IDEC
Eli Lilly and Company
Glaxo Smith Kline
Johnson & Johnson
Merck
Novartis
PhRMA
Pfizer

Innovation in Medical Evidence Development and Surveillance

The Innovation in Medical Evidence Development and Surveillance (IMEDS) program creates methods for cross-industry entities to use electronic health care data for post-market evidence generation, including ongoing safety surveillance. In 2013, the Foundation accrued more than $3 million in grants to bring IMEDS to scale.

[1] Due to legal and logistical challenges, this Fellowship did not launch, and the project concluded.

REAGAN - UDALL FOUNDATION FOR THE Food and Drug Administration

Within the year, the Foundation exceeded even optimistic forecasts for IMEDS' success by mobilizing scientific and healthcare thought leaders to launch IMEDS in less than one year. Key 2013 developments were significant and included:

- Facilitating ongoing research at and transition of the Observational Medical Outcomes Partnership (OMOP) — 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 IMEDS.
- Contracting an Interim Chief Implementation Officer to aid the OMOP-to-IMEDS transition and realization of IMEDS' potential.
- Selecting a 14-person IMEDS Steering Committee comprised of top leadership from the healthcare and scientific communities, with representation across a diverse set of stakeholder groups. The Committee governs IMEDS's research and operations.
- Approving the IMEDS charter, which details mission, vision, governance plan and research policies.
- Completing the transition of OMOP assets and personnel to the Foundation, making OMOP a foundational component of IMEDS.
- Choosing and convening a Scientific Advisory Committee.
- Developing a draft IMEDS research agenda for the Steering Committee's review, with vital input from FDA, legacy OMOP investigators and regulated industry.

2013 BOARD OF DIRECTORS & LEADERSHIP

Chair	Mark McClellan, MD, PhD, 18th FDA Commissioner
Vice Chair	Ellen V. Sigal, PhD, Chair and Founder, Friends of Cancer Research
Treasurer	Georges C. Benjamin, MD, Executive Director, American Public Health Association ,
Secretary	Kay Holcombe, Senior Vice President for Science Policy, Biotechnology Innovation Organization
Director	Pamela G. Bailey, President and CEO, Grocery Manufacturers
Director	Allan Coukell, BScPharm, Senior Director of Health Programs, Pew Charitable Trust
Director	Helen Darling, President, National Business Group on Health
Director	Sally J. Greenberg, JD, Executive Director, National Consumers League
Director	Garry Neil, MD, Corporate Vice President of Science and Technology, Johnson & Johnson
Director	Richard L. Schilsky, MD, Chief Medical Officer, American Society of Clinical Oncology
Director	Robert Tjian, President, Howard Hughes Medical Institute, University of California, Berkeley
Director	Nicholas J. Valeriani, CEO, West Health
Director	Tadataka Yamada, MD, Executive Director, Bill and Melinda Gates Foundation
Director	Diana Zuckerman, PhD, President, National Center for Health Research
Ex officio	Francis S. Collins, MD, PhD, Director, National Institutes of Health
Ex officio	Margaret Hamburg, MD, 21st FDA Commissioner
Executive Director	Jane Reese-Coulbourne

As a 501(c)3, the Reagan-Udall Foundation makes its audited financials and 990 forms publicly available.

Reagan-Udall Foundation for the Food and Drug Administration
1025 Connecticut Avenue NW STE 1000
Washington, DC 20036
www.reaganudall.org