REAGAN-UDALL FOUNDATION FOR THE FDA

2016 Annual Report

Changing Lives through Partnership

The Reagan-Udall Foundation for the Food and Drug Administration advances the FDA's mission to modernize product development, accelerate innovation and enhance product safety. An independent, nonprofit organization, the Foundation provides a unique partnership platform and galvanizes FDA, healthcare and advocacy organizations, biopharmaceutical industry and academia to create new science together — ultimately bettering American lives.

Expanded Access Navigator

Expanded access, also known as compassionate or single-patient use, provides some patients living with serious or life-threatening conditions access to investigational treatments not approved by the FDA. In 2015, the Foundation initiated the Expanded Access Navigator Program to guide physicians, patients and caregivers through the process of accessing unapproved treatments shown to have some benefit when other options have been exhausted.

The Expanded Access Navigator marks a unique partnership between the Foundation, FDA, other federal agencies, physicians, patient advocacy organizations, and the biopharmaceutical industry. Built with meaningful input from a broad group of advocacy, federal, nonprofit, and academic entities, the Navigator provides user-friendly, step-by-step guidance through the entire application process. Notably, in late 2016, Congress passed the 21st Century Cures Act, bringing significant reforms meant to expedite the discovery, development and delivery of new treatments. The law includes substantial steps toward easing the expanded use process and creating transparency to help physicians and patients make timely, critical medical decisions.

2016 Highlights

- Completed a landscape analysis to gather requisite input from patient groups and other relevant stakeholders on how the Expanded Access Navigator could best assist those going through the expanded access process.
- Presented a scoping report to the FDA outlining how targeting outreach efforts for healthcare providers to educate them on the expanded access process could benefit patients' lives.
- Secured appropriate resources for a 2017 launch.
- Created a directory of biopharmaceutical companies, with available expanded access policies, for public use.

Innovation in Medical Evidence Development and Surveillance (IMEDS)

The Foundation formed a public-private partnership to provide private sector entities — such as industry, academia and nonprofits — unprecedented access to FDA's extensive post-market data. The Foundation's Innovation in Medical Evidence and Surveillance (IMEDS) program provides data access to researchers outside of the FDA and informs the appropriate use of observational healthcare databases in studying medical product safety and efficacy.

2016 Highlight:

- IMEDS moved away from a subscription-based service model to its fee-for-service model. The Foundation recruited new academic and industry stakeholders to use IMEDS in their research and outcome sharing.

Big Data for Patients Project

In medicine, "big data" is patient data, as such patient participation in big data science efforts is central to advancing patient-centered research initiatives. To introduce the first regulatory science training program specifically for patients and advocates, the Foundation launched the Big Data for Patients (BD4P) program in 2015 and built upon that work in 2016.

This novel training introduces the big data concepts, familiarizes participants with necessary vocabulary, teaches appraisal skills and empowers patients and advocates with the information and context to participate in and contribute to current data science efforts in health and medicine.

After completing BD4P, participants use their new skills and knowledge to participate actively and knowledgably in advisory boards and committees with national leaders such as FDA, National Institutes for Health, Patient-Centered Outcomes Research Institute (PCORI) and industry. BD4P is a powerful tool in building a community of informed, empowered advocates.

2016 Highlights

- Partnered with the University of Maryland to develop BD4P program and curriculum and program and navigate scientific and ethical issues in health data use
- Piloted the nascent curriculum with a multiple-day workshop with patient advocates.

Critical Path to Tuberculosis Drug Regimens Project

The Foundation is a managing partner of the Critical Path to Tuberculosis Drug Regimes (CPTR) global initiative to accelerate the development of new tuberculosis multidrug regimens. In addition to providing leadership and project management, the Foundation oversees two workgroups: Stakeholder & Community Engagement and Global Regularity Pathways.

Namely, the Foundation brings together an array of international stakeholders with diverse perspectives to identify, prioritize and resolve regulatory science issues and challenges to TB drug development and treatments.

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