2015 Annual Report

Partnering for Patient Health

An independent nonprofit organization created by Congress, the Reagan-Udall Foundation for the Food and Drug Administration advances the FDA scientific mission through progressive regulatory science and research. With a purpose of improving public health, the Foundation provides a unique opportunity to bring all parties to the table — such as FDA and other government entities, patient groups, academia and industry — to create new regulatory science.

REAGAN - UDALL FOUNDATION FOR THE Food and Drug Administration

INNOVATION IN MEDICAL EVIDENCE DEVELOPMENT AND SURVEILLANCE (IMEDS)

Innovation in Medical Evidence Development and Surveillance

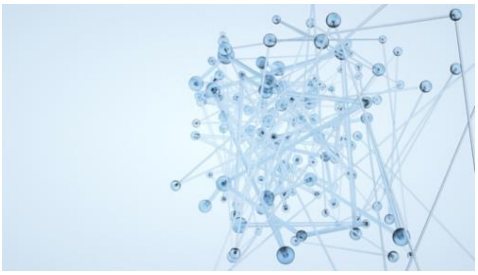
IMEDS provides industry and researchers access to extensive healthcare data and FDA-quality analytic tools to study post-market medical products' safety. IMEDS centers around critical needs such as developing ways to use electronic health data for safety assessments and broader purposes; establishing a long-term research agenda and governance structure to address stakeholders' methodological needs; leveraging FDA tools to answer important questions about safety and effectiveness; and equipping new scientists with the knowledge and expertise to conduct safety assessments.

Notable 2015 Accomplishments

- Launched and completed an inaugural pilot program, enabling IMEDS to evaluate non-FDA entities' use of the FDA data system and tools.
- Expanded IMEDS' research capacity to use various common data resources (e.g., FDA and Patient-Centered Outcomes Research Institute health data).
- Set an actionable research agenda with FDA.
- Investigated using IMEDS to conduct experiments on computational and hardware improvements to the FDA data system.

"We need a rapid way to find out what's happening with drugs, especially safety of drugs, after they're approved and on the market." — Janet Woodcock, MD, Director, FDA Center for Drug Evaluation & Research

BIG DATA FOR PATIENTS (BD4P)



In medicine, "big data" refers to patient data, and, thus, patient participation is pivotal to advancing patient-centered research initiatives. To serve as the first regulatory science training program developed for patients and advocates, the Foundation launched Big Data for Patients (BD4P). This novel approach introduces the concepts of big data, familiarizes participants with necessary vocabulary, teaches appraisal skills and empowers patients, and advocates to actively participate in and contribute to current data science efforts in health and medicine. After completing a BD4P training, participants use their new skills and knowledge to engage in FDA, National Institute for Health, Patient-Centered Outcomes Research Institute (PCORI) and pharmaceutical industry advisory boards and committees.

A two-year grant from PCORI and industry sponsors enabled the Foundation to create this important data science program to further develop the patient community's regulatory science capacity.

Notable 2015 Accomplishments

- Enhanced patient advocates' data science literacy and appraisal skills through empowering training workshops.
- Developed curriculum (e.g., online training modules, community supports, continuing education) to educate patient advocates on how to use big data and data science advances that directly affect their treatment options, and ultimately encouraging more effective and efficient treatments, better care and patient-centered outcomes.

EXPANDED ACCESS

In 2015, the Foundation established a program to track patients' requests for expanded access, often called "compassionate use," to help physicians and patients navigate the process by which a person with an immediately life-threatening condition may gain access to an investigational medical product for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options exist.

The Foundation's new program will develop a user-friendly, instructional roadmap for providers and patients to navigate expanded access requests. This novel approach will significantly streamline the expanded access process and serve as the go-to resource for those seeking direction.

Notable 2015 Accomplishment: Organized an initial stakeholder meeting to gain insight and explore the feasibility of an expanded access program for patients and advocates to help them with expanded access requests.

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The Reagan-Udall Foundation makes its audited financials and 990 forms publicly available.