2022

ANNUAL REPORT

Evidence to Impact

REAGAN-UDALL FOUNDATION FOR THE FDA

About the FDA Foundation

The Reagan-Udall Foundation for the Food and Drug Administration is an independent 501(c)(3) organization created by Congress to advance the mission of the FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety.

The Foundation embodies FDA's vision of collaborative innovation to address regulatory science challenges of the 21st century and assist in the creation of new, applied scientific knowledge, tools, standards, and approaches the FDA needs to evaluate products more effectively, predictably, and efficiently, and thereby enhance the FDA's ability to protect and promote the health of the American public. The Foundation serves as a crucial conduit between FDA and the public, providing a means for FDA to interact directly with stakeholders, including industry and consumers. The Foundation does not participate in regulatory decision-making or offer advice to FDA on policy matters.

From the CEO

In 2022, the Reagan-Udall Foundation for the FDA continued to expand into new areas, creating the opportunity to engage with stakeholders and help advance the mission of the FDA.

The Foundation achieved several milestones this past year. Translating evidence into impact, we became a 'funding foundation' providing research support focused on the Real-World Performance of In Vitro Diagnostics, and the two funded projects are poised to provide insights into the use of real-world data and real-world evidence. We facilitated the operational evaluations of the FDA's Human Foods and Tobacco programs by two Independent Expert Panels, a project which provided the FDA with recommendations to better position its work for the future. We concluded our COVID-19 Evidence Accelerator, which helped elevate the discussion on the use of real-world data and real-world evidence and published the *COVID-19 Real-World Evidence Primer*, contributing to the growing knowledge of real-world evidence and providing an overview of available real-world data sources and appropriate methods for study conduct.

The Foundation applied the "Accelerator" model in new areas with the Real-World Accelerator to Improve the Standard of collection and curation of race and Ethnicity data in health care (RAISE). We also began work on an Accelerator for regulatory science, initiated a project to improve public understanding of FDA and FDA-regulated products, and moved into a new sector, veterinary medicine, with a collaboration to improve data collection regarding anti-microbial use in food-producing animals.

I am particularly proud that we piloted a fellowship program in 2022 to strengthen diversity in the regulatory science workforce. With start-up funding from BeiGene, we provided a hands-on learning experience for a graduate student this year and built a framework for our Fellowship in Regulatory Science, Innovation, and Health Equity that will officially launch in summer 2023.

We are so grateful to our many partners, both old and new, who joined us in 2022 for this significant and valuable work. We cherish your insight and guidance to advance our work. Together, we play a vital role in promoting and protecting the public's health.

Susan C. Winckler, RPh, Esq.
Chief Executive Officer
Reagan-Udall Foundation for the FDA

> We are gratified to have the Foundation as a partner in building a community of stakeholders that leverage health data to inform regulatory decisions, advance innovation, and improve health outcomes.

From the FDA Commissioner

For a decade and a half, the FDA has worked closely with the Reagan-Udall Foundation for the FDA. Our unique relationship has allowed us to engage with stakeholders across the health and regulatory ecosystems to explore new avenues of research and foster meaningful collaborations. Like the FDA, the Foundation prioritizes the value and application of rigorous science and good data to solve the challenges of public health. Consequently, the work they do supports our mission to protect and promote the health of the American public.

Over the years of its existence, the Reagan-Udall Foundation for the FDA has been an important partner, allowing the agency to better meet the continuing challenges we face. The Foundation helps us fill holes in our ability to meet the demands placed on us, whether involving the continuing extraordinary advances in science or the limits on our time and resources.

The FDA, for example, has partnered with the Foundation to highlight the voice of patients and caregivers through our patient listening sessions. We've worked together to instigate dialogue and expand the sources, quality, and types of data we use to address health challenges. This past year, the Foundation was instrumental in facilitating the assessment of the structures and procedures of FDA's Human Foods Program and the Tobacco Program by two Independent Expert Panels. The Panels' work was a vital contribution that will help the agency adapt and position ourselves for the future.

We are gratified to have the Foundation as a partner in building a community of stakeholders that leverage health data to inform regulatory decisions, advance innovation, and improve health outcomes. The support of the FDA by Reagan-Udall allows us to use our resources more efficiently and effectively, to be able to apply regulatory science in new and creative ways, and to better focus on what we should be doing — data-driven decision-making. We look forward to our continued collaboration in support of the agency's mission.

Sincerely,

Robert M. Califf, MD
Commissioner of Food and Drugs

Research Portfolio

In 2022, the Reagan-Udall Foundation for the FDA's research activities demonstrated how we, as an organization, are uniquely situated to develop public/private partnerships and engage throughout the regulatory process to examine the state of real-world data and how they can be used to improve research.

QCARD

Our Oncology Quality, Characterization, and Assessment of Real-World Data (QCARD) initiative, a collaboration with FDA's Oncology Center of Excellence, identified key elements of data quality and solicited feedback from international experts to explore the feasibility of implementing a summary tool for current and future sponsors to explain how real-world data might be used in regulatory submissions.

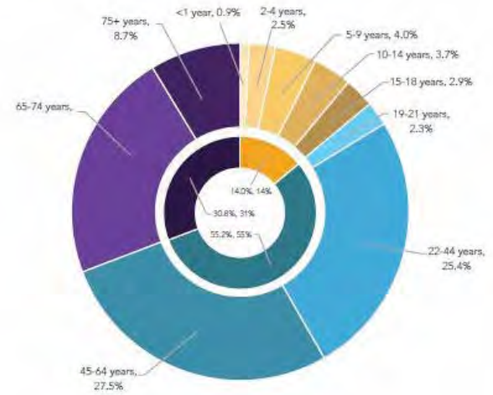
Algorithm Evaluation

The Foundation's development of the Algorithm CErtaInty Tool (ACE-IT) provides greater transparency for regulators to assess the accuracy of a researcher's endpoint. In 2022, we discussed algorithm evaluation at the Rare Disease Summit, the American Public Health Association, the International Society for Pharmacoepidemiology annual conference, and in the keynote address for the Harvard-MIT Center for Excellence in Regulatory Science and Innovation Global Meeting. Through these events, the Foundation spurred dialogue on the ability to generate evidence from real-world data.

Top photo: Dr. Carla Rodriguez-Watson with Deputy Surgeon General RADM Denise Hinton at the American Public Health Association meeting. Bottom photo: Dr. Carla Rodriguez-Watson (second from left) at the International Society of Pharmacoepidemiology Annual Meeting in Copenhagen, Denmark, led a roundtable discussion with experts in the use of real-world data for studies in pregnancy and lactation.

These projects were supported in part or in total through a cooperative agreement with the Food and Drug Administration

DEMOGRAPHIC BREAKDOWN OF IMEDS NETWORK PARTNER DATA



MALE
48.86%
40,364,354

FEMALE
51.14%
42,242,833

IMEDS

The Foundation continued to conduct research to advance evidence generation on post-market regulated products through the Innovation in Medical Evidence Development and Surveillance (IMEDS) program. IMEDS launched new phases of work on several ongoing projects, started new projects with existing sponsors, and began work on a manuscript for one of its finished projects we expect to release in 2023.

IMEDS NETWORK PARTNERS

CVS Health Clinical Trial Services LLC

Harvard Pilgrim Health Care Institute

HealthCore; Carelon Research

HealthPartners Institute

Humana Healthcare Research, Inc.

Kaiser Permanente Washington Health Research Institute

Marshfield Clinic Health System/Marshfield Clinic Research Institute

University of Massachusetts Chan Medical School Division of Health Systems Science

Vanderbilt University Medical Center

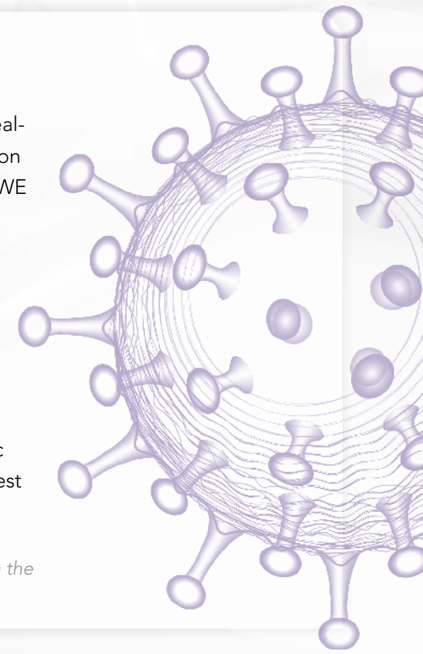
PIVD

The Foundation launched its first research funding project, to evaluate the Real-World Performance of In Vitro Diagnostics (PIVD). The funded projects focus on two types of diagnostic tests (antigen and molecular) to explore how RWD/RWE can be leveraged for Emergency Use Authorizations or full market approvals. In total, $1.8 million was awarded for two projects:

- Beth Israel Deaconess Medical Center studied antigen and molecular COVID-19 tests using real-world patient data
- IDx20 compared the performance of COVID-19 antigen tests in clinical settings versus real-world data collection

Research results are expected to increase knowledge of real-world diagnostic test performance while informing a framework for in vitro diagnostic device test developers to collect and analyze data for regulatory submissions.

This project was supported in part or in total through a cooperative agreement with the Food and Drug Administration



COVID-19 Evidence Accelerator

The COVID-19 Evidence Accelerator, launched at the start of 2020 in collaboration with Friends of Cancer Research (Friends), was a forum for key players across the health care ecosystem to share real-world data (RWD) and help evaluate new diagnostics, treatments, and vaccines for COVID-19. The Evidence Accelerator provided a unique framework for sharing ideas and advancing understanding of RWD to inform the nation's pandemic response.

Clockwise from top left: Jeff Allen, PhD, Friends of Cancer Research, moderates a discussion with FDA panelists: Sarah Brenner, MD, MPH; Jacqueline Corrigan-Curay, JD, MD; and Peter Marks, MD, PhD

After a successful two-and-a-half years of collaborating on research, sharing learnings, and highlighting outcomes, the Foundation and Friends closed out the COVID-19 Evidence Accelerator with an October 2022 meeting that highlighted the many achievements of the project, including several published articles, notable presentations, and the release of the *COVID-19 Real-World Evidence Primer*. Produced in collaboration with the International Society of Pharmacoepidemiology, the Primer provides an overview of types of RWD sources and an introductory level insight in core pharmacoepidemiologic methods for RWE study conduct.

2022 PUBLICATIONS FROM THE COVID-19 EVIDENCE ACCELERATOR

COVID-19 is associated with higher risk of venous thrombosis, but not arterial thrombosis, compared with influenza: Insights from a large US cohort.
PLoS ONE 17(1): e0261786
January 2022

Sharing Health Data: The Why, the Will, and the Way Forward
A Special Publication from the National Academy of Medicine
January 2022

8000 total attendees

from **>200** organizations

delivering **275** expert presentations

in **>200** virtual meetings

With the success of the Evidence Accelerator, it was clear that this innovative collaborative approach might have applicability in other health and regulatory topics. In 2022, the Foundation laid the groundwork for two new Accelerators.

RAISE (The Real-World Accelerator to Improve the Standard of collection and curation of race and Ethnicity data in health care)

Capturing race and ethnicity data in the course of health care delivery and payment is essential to strengthening the presence of this information in real-world data, where it can then be used to facilitate understanding of FDA-regulated products. In RAISE, the Foundation, in collaboration with FDA's Office of Minority Health and Health Equity, is convening a series of workshops with leaders across the health care ecosystem to create opportunities to share, learn, and build capacity to advance solutions to improve the capture, curation, and exchange of race and ethnicity data. Through the workshops, participant input will help develop a multi-dimensional tool that will help prioritize strategies to improve the capture and curation of race and ethnicity data, based on the barriers and solutions discussed.

Regulatory Science Accelerator

In 2023, the Foundation, working with FDA's Office of Regulatory Science and Innovation, will engage leading experts in the scientific community to build a **regulatory science road map** to examine emerging technologies and methodologies. The Regulatory Science Accelerator will identify the most pressing scientific gaps as well as help develop a research agenda for addressing those gaps.

Evidence Generation

The Evidence Generation project is a new workstream initiated in 2022 for execution in 2023. The initiative will bring stakeholders together to identify the issues and obstacles that hinder evidence generation and provide FDA and others with recommendations for addressing those obstacles. Specifically, the project should articulate what actions should be taken to help capture data of sufficient quality to support regulatory decision-making with regard to medical products and food safety and nutrition.

The Evidence Generation project will engage two expert panels who will help draft recommendations for FDA and other stakeholders on how to encourage evidence generation. One panel will be dedicated to medical products (drugs, biologics, and medical devices), and the second to food safety and nutrition.

These projects were supported in part or in total through cooperative agreements with the Food and Drug Administration

FDA Operational Evaluations

At the request of Commissioner Robert Califf, the Foundation facilitated external operational evaluations of FDA's Human Foods Program and, separately, of certain components of the Center for Tobacco Products.

The Foundation facilitated virtual and in-person meetings and listening sessions for the Independent Expert Panels. Throughout the evaluations, the panels conducted interviews, solicited public comments through an online portal, and compiled a series of recommendations that were submitted to the FDA.

The reports of both the Human Foods and Tobacco Programs were the result of an intensive effort to obtain input from governmental and non-governmental stakeholders. The reports offer practical and constructive advice based on information gathering and synthesis, and the recognition of the challenges and opportunities inherent in public health regulation.

This project was supported in part or in total through a cooperative agreement with the Food and Drug Administration

Human Foods Program

An Independent Expert Panel, chaired by former FDA Commissioner Jane Henney, MD, presented FDA with recommendations addressing culture, structure/leadership, resources, and authorities of the Agency's Human Foods Program to help equip FDA to fulfill its regulatory responsibilities, strengthen its relationships with state and local governments, and secure the nation's food supply for the future.

INDEPENDENT EXPERT PANEL

Jane Henney, MD (Chair)

Francisco Diez-Gonzalez, PhD

James Jones

Barbara Kowalcyk, PhD

Shiriki Kumanyika, PhD, MS, MPH

John Taylor, JD

Tobacco Program

The Tobacco evaluation, led by former FDA Chief of Staff Lauren Silvis, JD, focused on recommendations to help modernize the structure and organization of the Center for Tobacco Products and improve its regulatory processes and functions, including premarket review, and compliance and enforcement efforts.

INDEPENDENT EXPERT PANEL

Lauren Silvis, JD (Chair)

Jane Axelrad, JD

Keith Flanagan, JD

Charlene Frizzera

Alberto Gutierrez, PhD

BY THE NUMBERS

FDA Operational Evaluations

77	40	323	16,280	1.4 BILLION
PUBLIC SESSION SPEAKERS	EXPERT INTERVIEWS	PUBLIC COMMENTS	REPORT VIEWS	MEDIA IMPRESSIONS

The Foundation extends its deepest thanks to the members of the Independent Expert Panels for their countless hours of work on these evaluations.

Convenings

The Foundation routinely supports the FDA's mission by bringing stakeholders together in small roundtables or large public meetings to spur dialogue and foster real-world understanding of FDA pathways and how FDA-regulated products are used.

SNAPSHOT 2022: A Changing Environment for FDA-Regulated Consumer Products

The Foundation, with support from the Consumer Healthcare Products Association, brought together stakeholders from patient advocacy, health care practice, industry, academia, and Federal agencies to examine the current environment for FDA-regulated consumer products. Topics included how technology has changed consumer access to health care, understanding consumer expectation and capacity for over-the-counter-products, and potential improvements to the regulatory process. In August of 2022, the Foundation broadly disseminated a report summarizing learnings from the symposium.

Snapshot 2022 was underwritten by the Consumer Healthcare Products Association

Snapshot 2022 was the Foundation's return to in-person events.

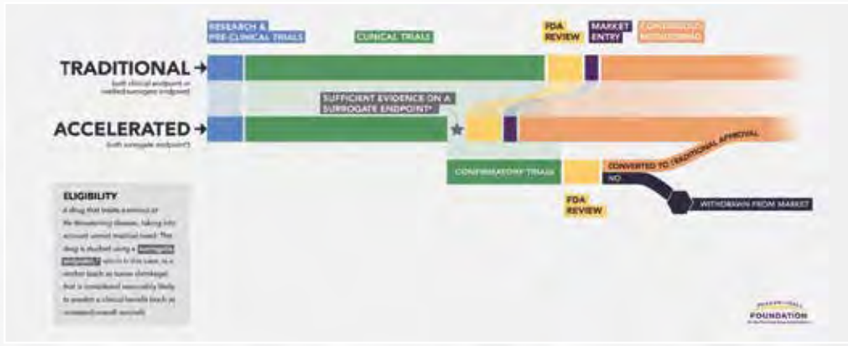
Real-World Evidence Webinars

Working with the FDA, the Foundation continued a series of public webinars to discuss the FDA guidance documents related to real-world evidence in regulatory submissions. Topics included assessing registries to support regulatory decision-making and considerations for the use of real-world data and real-world evidence. The Foundation provided the opportunity for stakeholders to pose questions about the draft guidances.

FDA Foundation CEO Susan Winckler, RPh, Esq., facilitates a discussion on Accelerated Approval with patient panel.

Accelerated Approval Pathway

The Accelerated Approval Program allows for earlier approval of of drugs that treat serious conditions and fill an unmet medical need based on a surrogate endpoint. To mark the 30th anniversary of the Accelerated Approval Program, the Foundation brought together patients, providers, payors, researchers, advocates, and federal agencies to explore the evolution of the pathway, clarify the process for Accelerated Approval, and discuss its future potential. An important part of the conversation was clarifying how the Accelerated Approval pathway differs from the traditional drug approval route.



Medical Countermeasures Master Files

The Foundation spearheaded a roundtable discussion on medical countermeasures master files (MCMs) that may be used in a public health emergency. Master files are submissions to the FDA that may be used to provide confidential, detailed information about the facilities, processes, or articles used in the manufacture, processing, packaging, or storing of one or more regulated products. The discussion centered on how to improve MCM awareness, development, preparedness, and response in the event of future emergencies.

Antimicrobial Use in Food Producing Animals

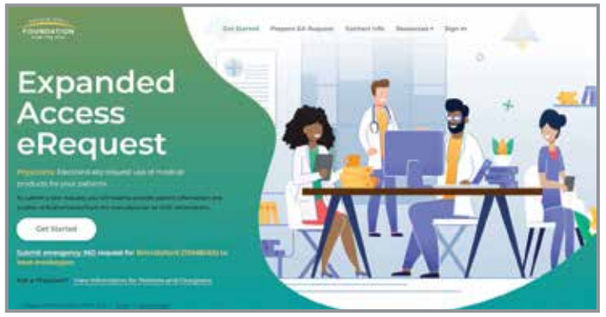
The Foundation, partnering with the FDA's Center for Veterinary Medicine, held a series of meetings to explore the development of a public-private partnership for collecting and analyzing real-world data regarding antimicrobial use in food-producing animals. Antimicrobial resistance is recognized as a growing global threat requiring action in product research and development and greater stewardship of antimicrobial use in human and animal health. Learnings from the series were published in a Summary Report released in September.

These projects were supported in part or in total through a cooperative agreement with the Food and Drug Administration

Expanded Access

Core to the Foundation's work is helping patients and other stakeholders navigate the benefits and risks of FDA pathways as well as FDA-regulated products. Expanded access is one such opportunity, potentially connecting seriously ill patients to investigational medical products outside of a clinical trial when FDA-approved treatment options have been exhausted.

With supports and resources tailored to each stakeholders' unique needs, the Foundation's web-based Expanded Access Navigator leads patients, caregivers, health care providers, and industry through the expanded access process. Providing custom user guides, links to open clinical trials, and detailed information on company expanded access policies, the Navigator also features the easy-to-use eRequest app that allows prescribers to complete and immediately submit expanded access requests online to FDA. In 2022, as the nation faced a new public health emergency, the Foundation worked closely with FDA to add a direct eRequest pathway to access brincidofovir for the treatment of monkeypox. The app enhancements not only met the immediate need, but established capacity for eRequest to quickly adapt to future emergency uses.



A popular component of the Navigator is its company directory, where users can search for potential therapies, identify companies, and find active expanded access programs and contact information. Thirty companies joined the directory in 2022 and provider use of the eRequest app more than doubled.

More than **17,000 people** visited the Expanded Access Navigator and Company Directory in 2022

This project was supported in part or in total through a cooperative agreement with the Food and Drug Administration

Food & Nutrition

Consistent with the 2022 White House Conference on Hunger, Nutrition, and Health, the Foundation's work in this space focused on the intersection of nutrition and chronic disease.

The Foundation's Food and Nutrition partnership brought traditional nutrition experts together with groups that are often absent from nutrition conversations. Our June 2022 roundtable added health insurers, social service organizations, and economic development specialists to the conversation to spark new thinking on strategies for moving toward a healthier population through improved dietary patterns.

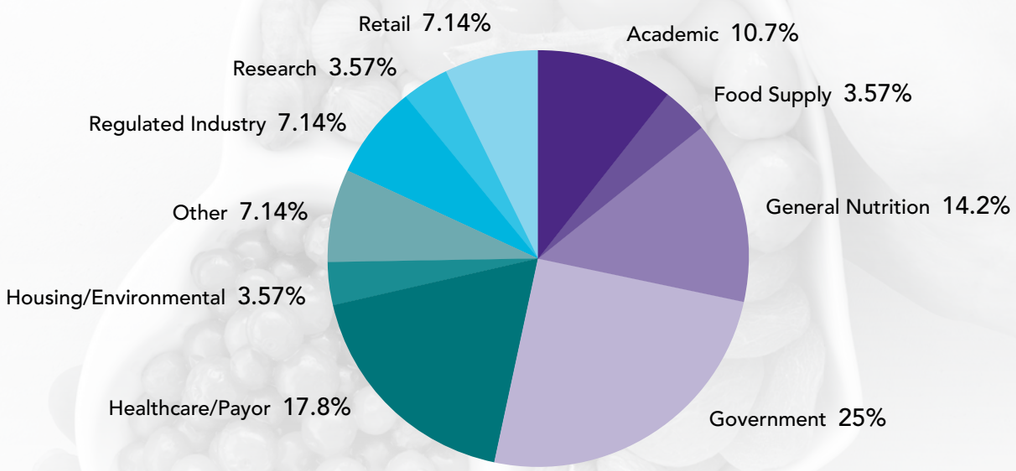
We continued to expand our Nutrition Communications Network — comprised of consumer, patient advocacy, industry, and government groups who disseminate coordinated nutrition messages. We increased our network by 10% over the past year and began incorporating more infographics and visual content into our nutrition message guides built largely around the Nutrition Facts label.

CONVENING PLANNING COMMITTEE

GEORGES BENJAMIN, MD MACP (Chair)
American Public Health Association
Center for Food Safety and Applied Nutrition, Food and Drug Administration
The Kellogg Company
Nestlé USA
Reagan-Udall Foundation for the FDA

NUTRITION CONVENING ATTENDEES

By Organization Type and Percentage



This project was supported in part or in total through a cooperative agreement with the Food and Drug Administration

Substance Use Disorder

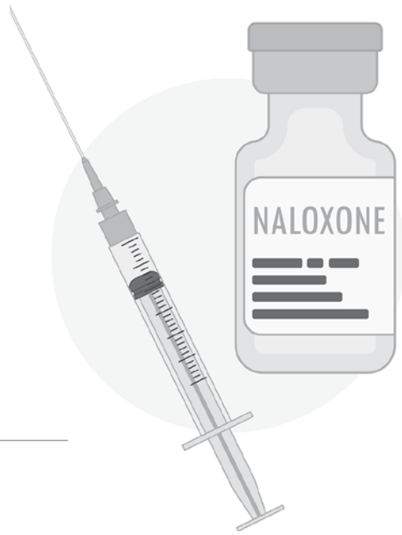
Naloxone

The Foundation initiated work on a suite of projects about access and payment for naloxone, an antidote for heroin, fentanyl, and prescription opioid overdose.

In March 2022, we hosted a virtual public webinar to discuss frequently asked questions related to naloxone access, bringing together harm reduction specialists, physicians, pharmacists, and regulators to share their experiences in increasing the availability of this life-saving medication.

Beginning in the summer of 2022, the Foundation conducted a research project to understand the distribution of naloxone in the U.S. and explore potential economic impacts of a change in the prescription-only status of naloxone. As a part of that project, Foundation staff spoke directly to manufacturers, trade organizations, and academic researchers about the capture of distribution data. We also hosted a closed-door roundtable with payor experts to learn more about how cost, coverage, and patient access might be impacted by the introduction of a nonprescription formulation of naloxone. A report detailing this work and our findings is available on the Foundation website.

Bringing together harm reduction specialists, physicians, pharmacists, and regulators to share their experiences in increasing the availability of this life-saving medication.



Stimulant Use Disorder

The Foundation published several reports to highlight some of its ongoing substance use disorder work. *A Practical Research Agenda for Treatment Development for Stimulant Use Disorder: A Virtual Public Workshop* summarizes the discussion and learnings from an earlier public meeting on endpoints and study design strategies for clinical trials of stimulant use disorder treatments.

Harm Reduction

The Foundation also produced two reports to share perspectives from its Harm Reduction work. Following roundtables in October of 2021 that explored community and clinical perspectives on fentanyl drug checking and screening, the Foundation released reports detailing the unique perspectives of those stakeholder groups on the potential for technology development, research, and practice.

These projects were supported in part or in total through a cooperative agreement with the Food and Drug Administration

Patient Listening Sessions

The Foundation's ongoing collaboration with FDA to host Patient Listening Sessions supports a forum for patients, advocates, and caregivers to interact directly with FDA staff. These sessions are an opportunity for patients to share their experiences and provide invaluable insights to the FDA to help inform clinical trial design, medical product development, and regulatory processes.

In 2022, the Foundation worked with FDA's Office of Patient Affairs to conduct 11 listening sessions on a variety of conditions, including rare diseases and illnesses that affect children and/or adults. One significant outcome from the Patient Listening Sessions is hearing from individuals in various stages of illness to better understand their unique needs: for example, the session on Huntington's disease included those who were diagnosed, but not yet showing symptoms.

FOUNDATION STAFF SUPPORTED
11 PATIENT LISTENING SESSIONS IN 2022

Thymidine Kinase 2 Deficiency	January 2022
Glycogen Storage Disease 1b	March 2022
Pulmonary Sarcoidosis	April 2022
Adult Dermatomyositis	April 2022
Hypomyelination with atrophy of the basal ganglia and cerebellum	May 2022
Stargardt Disease	June 2022
Short Bowel Syndrome	July 2022
Huntington's Disease	July 2022
Narcolepsy	August 2022
Recurrent Respiratory Papillomatosis	October 2022
Proteus Syndrome	December 2022

Annual Public Meeting

More than 200 patient, consumer, industry, research, and government stakeholders joined the Foundation's Virtual Annual Public Meeting of our Board of Directors on May 16, 2022. It was an opportunity to look back at the Foundation's achievements over the previous year and look ahead to new collaborations in support of the FDA's work.

ROBERT M. CALIFF, MD ELLEN V. SIGAL, PHD

FDA Commissioner Robert M. Califf sat down with our Board Chair, Ellen V. Sigal, PhD, to discuss Agency priorities and the integral role collaboration plays in achieving the FDA's mission. Dr. Califf highlighted several key areas where he anticipated the Foundation would play a significant role: evidence generation, product oversight, and FDA's food portfolio.

SUSAN C. WINCKLER, RPH, ESQ. JACQUELINE O'SHAUGHNESSY, PHD

The event featured candid discussions with senior FDA leadership on topics ranging from data interoperability to food safety and FDA's plans for a return to in-person events. Acting Chief Scientist Jacqueline O'Shaughnessy, PhD, helped round out the discussion with FDA leadership, highlighting the partnership between FDA and the Foundation in advancing regulatory science "to protect and promote the public health."

> "We need to make Americans understand that sharing data, under the right circumstances, can really help people… I hope to work together with Reagan-Udall on this."
>
> — ROBERT M. CALIFF, MD
> Commissioner of Food and Drugs

Innovations in Regulatory Science Awards

The Innovations in Regulatory Science Awards returned to an in-person event in 2022 as more than 220 people gathered to celebrate the honorees and their remarkable contributions to regulatory science.

Leadership Award

Dr. Robert Temple's lifetime commitment to FDA's public health mission is evident from his incredibly influential career at FDA and the tremendous impact he has had on advancing thinking on clinical trials. He has written extensively on this subject, especially on choice of control group in clinical trials, evaluation and active control trials, and enrichment design clinical trials. In his current role as the Senior Advisor in the Office of New Drugs, he advises on policy, guidance, and difficult problems in drug development and regulation.

2022 honorees (from left to right) George Vradenburg; Robert Temple, MD; and Sastry Chilukuri, representing Medidata Link

Advocacy/Policy Award

George Vradenburg has been a tireless advocate for raising awareness and increasing engagement for Alzheimer's and dementia. He was named by then-U.S. Health and Human Services Secretary Kathleen Sebelius to serve on the Advisory Council on Research, Care, and Services established by the National Alzheimer's Project Act and is co-founder and chair of UsAgainstAlzheimer's. Vradenburg has spearheaded an effort to work across sectors to secure $10 billion in annual public funding for Alzheimer's and dementia research and drug development.

Innovation Award

Medidata Link, a product from Medidata, is leading the digital transformation of life sciences and creating hope for millions of patients. Medidata Link works to modernize the clinical trial process, allowing sponsors and regulators to connect and analyze once-disparate data sources to create new insights into patients, and bridge the gap between clinical trial data and the real world. It pioneered its process during Operation Warp Speed, which allowed researchers to identify breakthrough infections more quickly and better understand adverse events while developing the COVID-19 vaccines. It's now being used to connect clinical trial data with real-world evidence in other therapeutic areas such as cardiovascular disease and oncology.

ROBERT M. CALIFF, MD

The evening also featured remarks from FDA Commissioner Robert M. Califf and a panel discussion with three outgoing board members: Helen Darling, MA; Jonathan Leff, MBA; and outgoing Board Chair Ellen V. Sigal, PhD.

HELEN DARLING, MA

JONATHAN LEFF, MBA

ELLEN V. SIGAL, PHD

> "We have a foundation that is able to make huge differences... we have the leaders and we have the staff, we can be of great value to the FDA."
>
> — ELLEN V. SIGAL, PHD
> Reagan-Udall Foundation for the FDA
> Board Chair

2022 AWARDS SELECTION COMMITTEE

Mark Cullen, MD
Chair of the COVID-19 Research Database Scientific Steering Committee
(2021 Innovation Honoree)

Helen Darling, MA
Board Member
Reagan-Udall Foundation for the FDA

Michael Landa, Esq
Former Director
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration

Peter Marks, MD, PhD
Director, Center for Biologics and Research
U.S. Food and Drug Administration
(2021 Leadership Honoree)

John Taylor, Esq
President and Principal
Compliance and Regulatory Affairs
Greenleaf Health

Andrew von Eschenbach, MD
Board Member
Reagan-Udall Foundation for the FDA
20th Commissioner of the U.S. Food and Drug Administration

Financials

	2022	2021
REVENUE AND SUPPORT		
FDA Direct Funding*	$1,250,000	$1,250,000
Grants and Contributions	3,544,924	1,097,120
Contracts	3,614,197	2,725,836
Fundraising	414,550	428,200
Miscellaneous and Interest Income	23,468	2,092
Total Revenue and Support	**$8,847,139**	**$5,503,248**
EXPENSES AND CHANGES IN NET ASSETS		
Program Services		
Innovation in Medical Evidence Development and Surveillance	3,786,924	3,267,672
Expanded Access Navigator	123,537	47,719
Evidence Accelerator	575,477	575,581
Food & Nutrition	55,815	49,312
Algorithm Evaluation	99,667	101,018
Other	3,610,640	883,834
Total Program Services	**$8,252,060**	**$4,925,136**
Supporting Services		
Management and General	198,798	189,623
Fundraising	285,708	256,671
Total Supporting Services	**$484,506**	**$446,294**
TOTAL EXPENSES	**$8,736,566**	**$5,371,430**
CHANGE IN NET ASSETS	**$110,573**	**$131,818**

**The Reagan-Udall Foundation for the FDA's operations are supported by direct funding from the U.S. Food and Drug Administration. (21 USC Chapter 9, SUBCHAPTER VII, §379dd(n))*

Sponsors & Donors

The Reagan-Udall Foundation for the FDA supports the FDA's vision of collaborative innovation to address regulatory challenges of the 21st century in order to promote and protect the public's health. We are grateful for the financial contributors who help support our efforts.

PROJECT FUNDERS

AbbVie, Inc.
BeiGene USA, Inc.
Consumer Healthcare Products Association
Merck & Co, Inc.
Novartis
U.S. Food and Drug Administration

MAJOR GIFTS

Georges Benjamin, MD, MACP
Danaher Diagnostics
Debra Lappin, JD
Joe Levitt, JD
UsAgainstAlzheimer's

INDIVIDUAL GIFTS

Katherine Corso, MPH
Alec Halsne
Daniel McIntyre
Derek Yach, MPH

INNOVATIONS IN REGULATORY SCIENCE AWARDS

The 505(b)(2) Platform
Alexandria Real Estate Equities, Inc.
Alston & Bird LLP
Amazon
American Society of Clinical Oncology
Amicus Therapeutics, Inc.
Bayer AG
BeiGene USA, Inc.
Georges Benjamin, MD, MACP
Buchanan Ingersoll & Rooney PC
Cerevel Therapeutics
Cooley LLP
Helen Darling, MA
Deloitte Consulting
Eli Lilly & Company
Phil Febbo, MD
Friends of Cancer Research
Genentech
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You have our deepest thanks for your leadership, dedication, and vision through the years.

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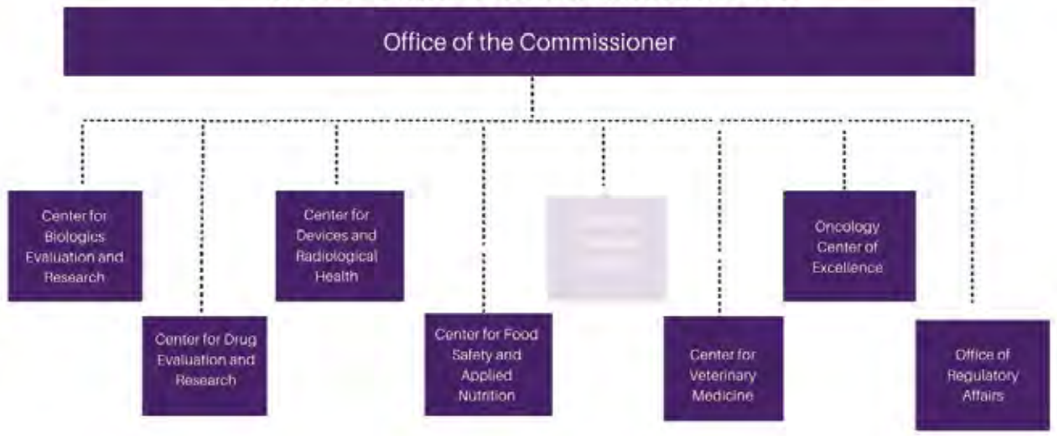

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