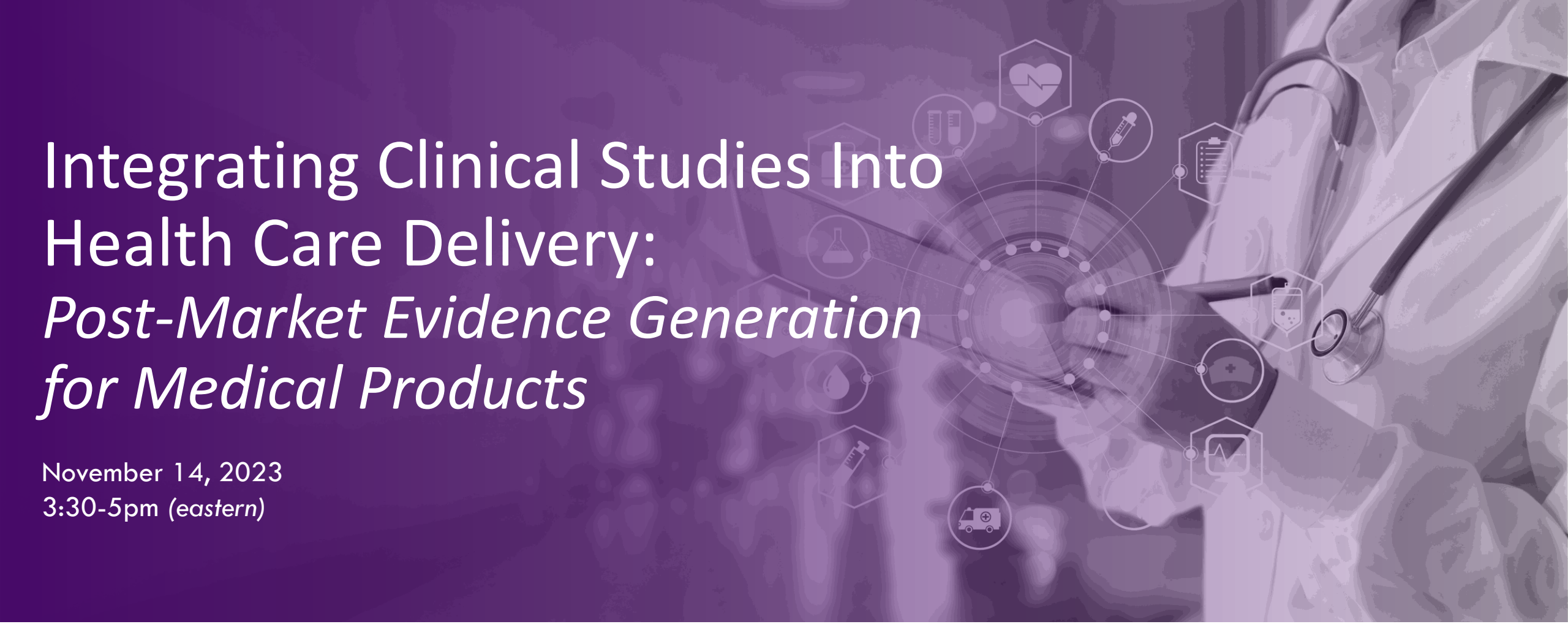


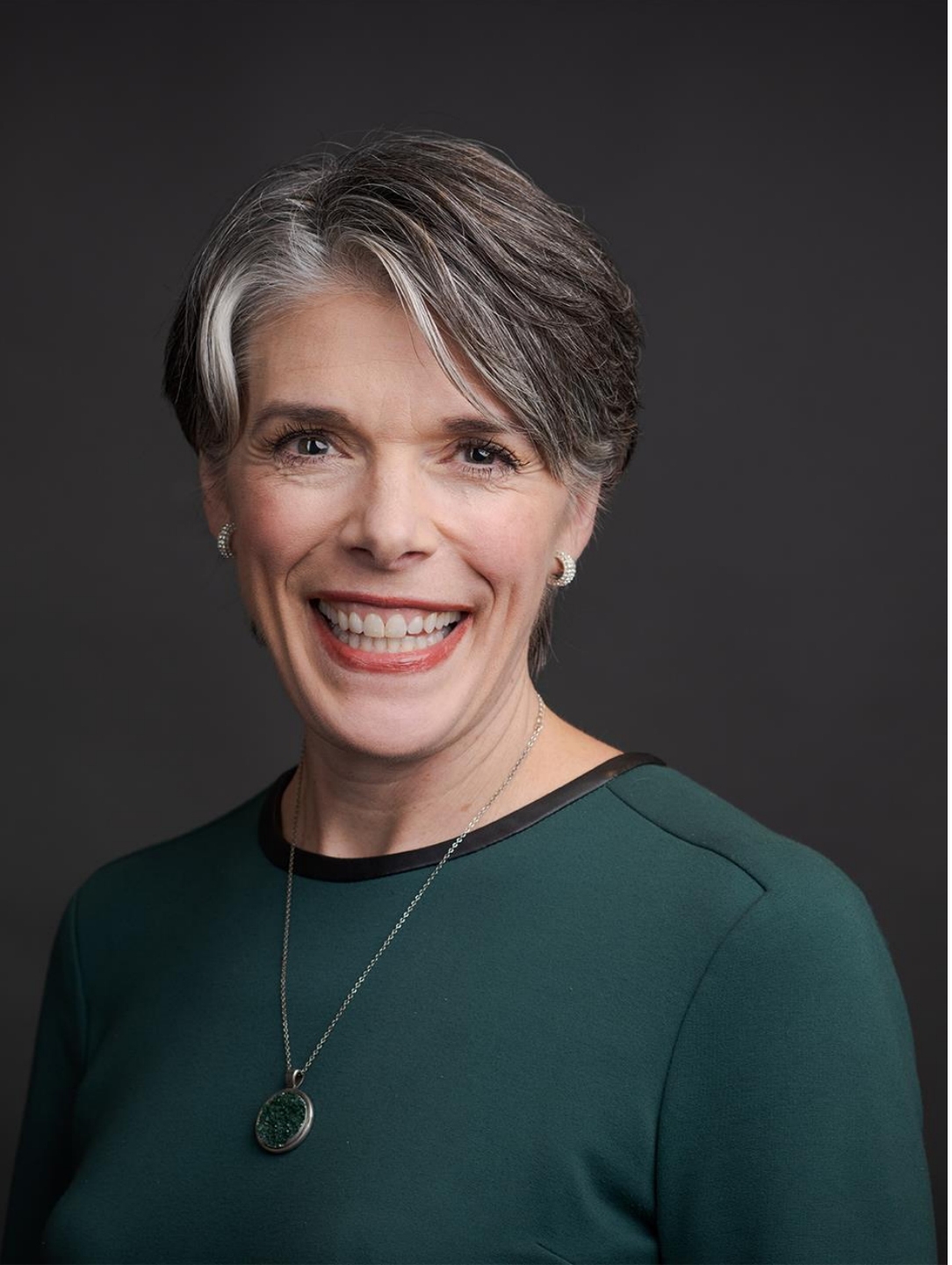
Integrating Clinical Studies Into Health Care Delivery: *Post-Market Evidence Generation for Medical Products*

November 14, 2023
3:30-5pm *(eastern)*

The public meeting will begin shortly

REAGAN-UDALL FOUNDATION FOR THE FDA

This project is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of an award of $399,966 in federal funds (100% of the project). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA, HHS, or the U.S. Government. For more information, please visit FDA.gov.



REAGAN-UDALL FOUNDATION FOR THE FDA

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

Housekeeping

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For the best view of the speakers, click on “View” at the top and then “Hide Non-Video Participants.”

This event is being recorded for notetaking accuracy. The slides, transcript, and video recording will be available on the Foundation’s website soon after the meeting.

Please share your questions and comments using the chat function at the bottom of your screen.

Agenda

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3:30 pm	**Welcome & Opening Remarks**
3:35 pm	**The Need for Post-Market Evidence Generation: Patient and Provider Perspectives**
4 pm	**Enhancing Post-Market Evidence Generation for Medical Products**
4:45 pm	**Commissioner Remarks**
5 pm	**Closing Remarks & Adjournment**

The Need for Post-Market Evidence Generation: Patient and Provider Perspectives

REAGAN-UDALL FOUNDATION for the Food and Drug Administration

Moderator

David C. Fajgenbaum, MD

University of Pennsylvania School of Medicine

Panelists

Wanda Brisbane, Four Winds Services

Samuel Brown, MD, Intermountain Health

Jennifer Byrne, Javara Research

Ramita Tandon, Walgreens Boots Alliance

Enhancing Post-Market Evidence Generation for Medical Products

REAGAN-UDALL FOUNDATION for the Food and Drug Administration

Moderator

Richard L. Schilsky, MD, Board Chair
Reagan-Udall Foundation for the FDA

Panelists

Robert A. Harrington, MD, Weill Cornell Medicine

Adrian Hernandez, MD, Duke University School of Medicine

Russell Rothman, MD, Vanderbilt University Medical Center

Joanne Waldstreicher, MD, Independent Board Director and Consultant

Charge to the Expert Panel

Development of a post-market evidence generation framework that

- leverages the U.S. health care system to resolve clinically meaningful evidence gaps for medical products
- supports regulatory submissions for new indications or other revisions to labeling

- Greater clinician engagement
- Broader patient participation
- Design of pragmatic, post-market clinical studies
- Collection of routine clinical data within the context of health care delivery

Expert Panel Members

- Richard L. Schilsky, MD, FACP, FSCT, FASCO (Chair), Reagan-Udall Foundation for the FDA
- Judith Currier, MD, University of California-Los Angeles
- Richard J. Gilfillan, MD, MBA, Trinity Health (retired)
- Robert Harrington, MD, Weill Cornell Medicine
- Adrian Hernandez, MD, MHS, Duke University School of Medicine
- Emily Largent, JD, PhD, RN, University of Pennsylvania Perelman School of Medicine
- Russell Rothman, MD, MPP, Vanderbilt University Medical Center
- Joanne Waldstreicher, MD, Independent Board Director and Consultant

Methodology

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Expert Panel

6 Roundtables

3 Listening Sessions

Final Report

Public Meeting

Overarching Recommendation (#1)

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- Pragmatic evidence generation in the post-market setting needs to be simplified, including
  - Protocol objectives and endpoints
  - Eligibility criteria
  - Adverse event reporting
  - Data collection

Embedded in clinical care

Person-centered research objectives

Simple study design

- Doing so will
  - Reduce administrative requirements
  - Encourage greater participation by both clinicians and patients

Streamlined data collection

Rapid dissemination of findings

Overarching Recommendation (#2)

REAGAN-UDALL FOUNDATION FOR THE FDA

- Establish an inter-agency taskforce, led by FDA and comprised of FDA, NIH, CMS, ONC, and sponsors (e.g., industry, ARPA-H) to establish guiding principles and minimum requirements for post-market studies.

Implementation of Pragmatic Evidence Generation Studies (#5-10)

- Establish a value proposition for health care leaders to incorporate post-market evidence generation studies into routine clinical care.
- Emphasize the importance of stakeholder engagement.
- Simplify site-related documentation and requirements.
- Develop a systematic approach to credentialling investigators.
- Create a centralized database of site credentials and investigators.
- Employ master agreements between sponsors and sites to reduce time to launch.

Data Collection and Algorithms (#11-17)

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- Focus on structured data elements in the electronic health records (EHR) or claims data.
- Simplify inclusion and exclusion criteria and study endpoints.
- Capture key health outcomes in a structured format in EHRs.
- Use validated algorithms to identify endpoints derived from EHR/claims data.
- Develop a library of validated algorithms.
- Pre-specify algorithms to be used in study protocols.
- Perform analyses of most adverse events at the end of the study using EHR and/or claims data rather than real-time reporting during the study.

Study Processes and Data Collection (#18-21)

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- Issue guidance regarding acceptable evidence to expand indications, modify labeling or close evidence gaps.
- Promulgate pragmatic evidence generation principles and processes at all levels within FDA.
- Devise a series of ‘use cases’ that incorporate minimal data collection as examples.
- Develop pilot projects in association with other organizations such as NIH, PCORI, CMS and industry.

Patient-Participant Recruitment and Enrollment (#22-28)

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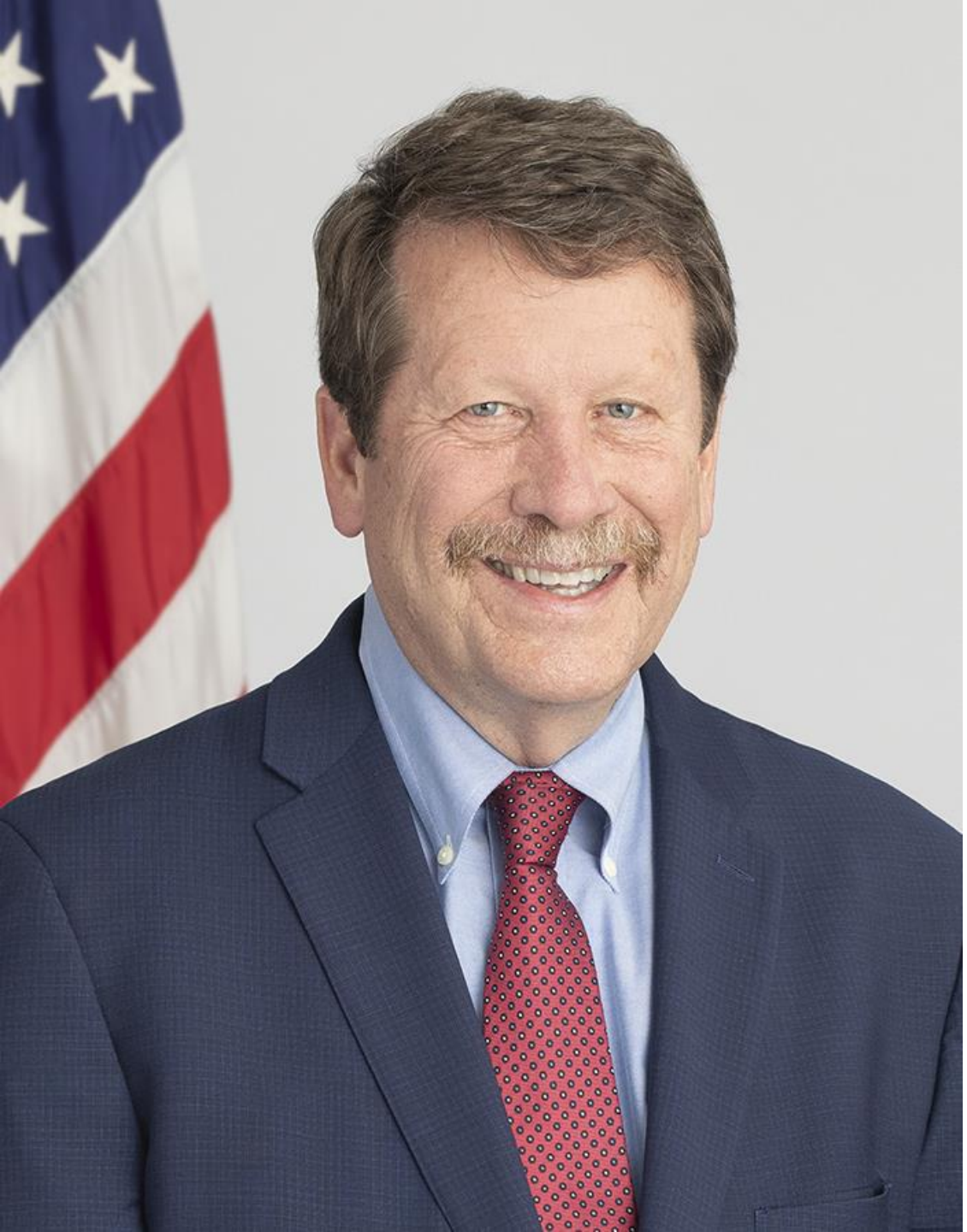
- Reduce barriers to patient participation.
- Reduce cost of participation to patients.
- Incorporate community sites to increase diversity of participants.
- Provide clarification on necessary elements of informed consent.
- Explore alternative methods of consenting.
- Explore separating provision of institutional liability language to shorten consent documents.
- Share learnings on what works in consent forms via ClinicalTrials.gov.

Funding Pragmatic Evidence Generation (#29-30)

- Sponsors, payers, federal agencies and health care systems all benefit from post-market evidence generation, and all should be expected to contribute significantly to support such studies.
- Funding post-market evidence generation studies will need to extend beyond typical sponsors. Federal government agencies may need to establish a precedent.



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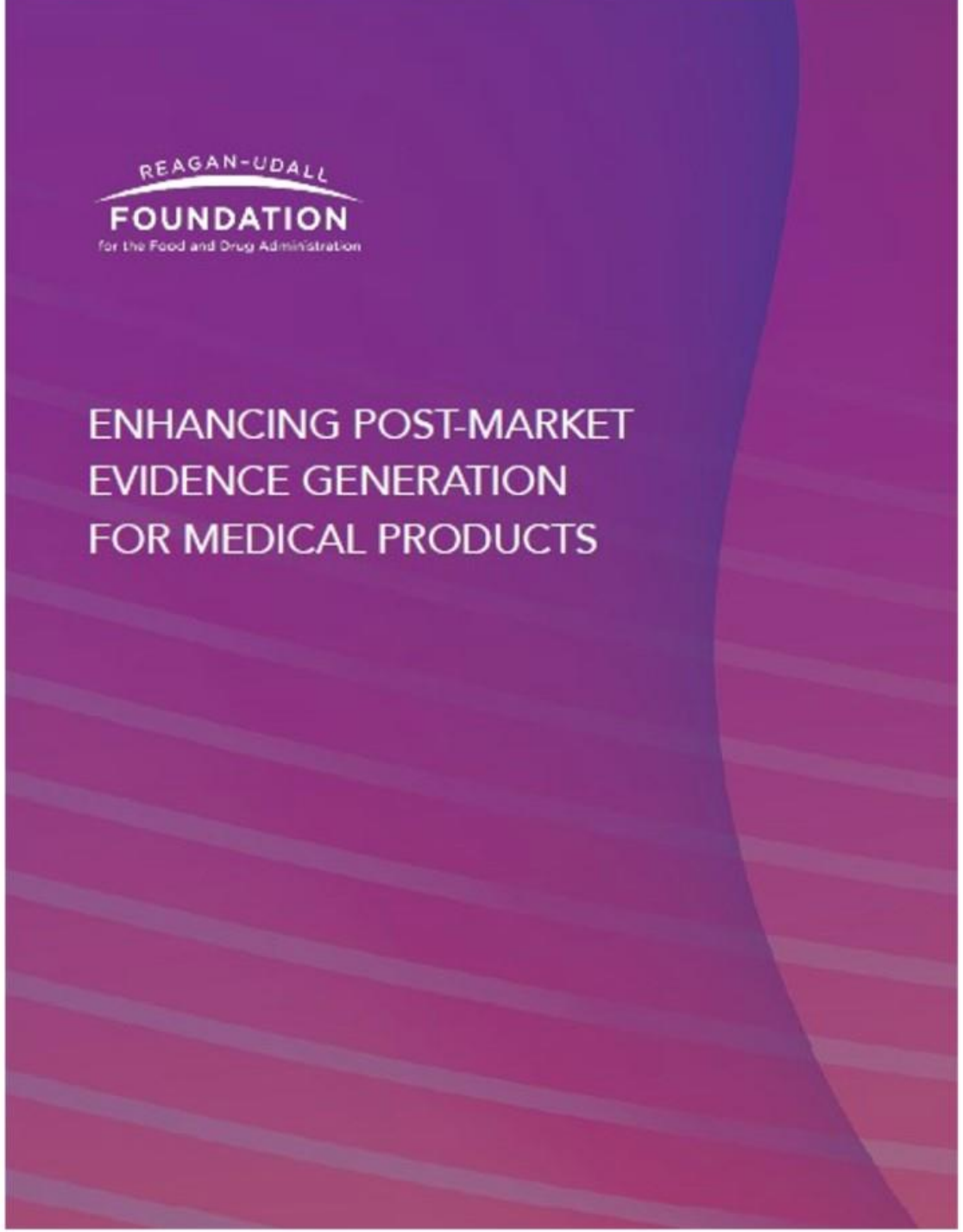
Robert M. Califf, MD, MACC

Commissioner of Food and Drugs

U.S. Food and Drug Administration



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Thank you for joining us.

Download the report at ReaganUdall.org

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