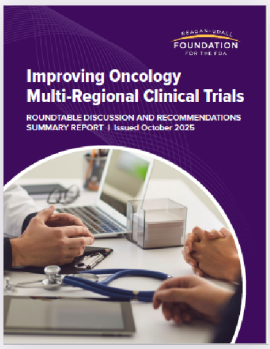
REAGAN-UDALL FOUNDATION FOR THE FDA

The Foundation's Role in Advancing Medical Product Development in the United States

Over the past 12 months, the Reagan-Udall Foundation for the FDA has issued **three roundtable reports** with a total of **44 recommendations** to help advance medical product development in the United States. These stakeholder insights are seen in recent FDA initiatives, including guidance documents, the 2026 Unified Agenda, and the FY 2027 Budget.

ROUNDTABLE REPORTS AND KEY RECOMMENDATIONS



ROUNDTABLE RECOMMENDATIONS INCORPORATED INTO RECENT HHS/FDA INITIATIVES

FY 2027 HHS/FDA Budget Initiatives

- Artificial Intelligence/ Machine Learning
- Rare Disease Innovation Hub Strategic Agenda & Rare Disease Evidence Principles
- Expedited IND / Clinical Trial Notification Pathway
- New Approach Methodologies / Alternatives to Animal Testing R&D
- Advanced Pharmaceutical Manufacturing & CMC Streamlining
- Post-Market Surveillance, Real-World Evidence & Alternative Testing Models

Final Actions and Guidance Documents

- Single IRB Rule
- Cancer Clinical Trial -Laboratory Values
- Cancer Clinical Trial -Performance Status
- Cancer Clinical Trial -Washout Periods and Concomitant Medications
- CMC Flexibilities for Cell and Gene Therapy BLAs

Proposed Agenda Items, Actions, and Guidances

- Sponsor Rule
- E-Submission Rule
- CRL Disclosure Rule
- GLP Modernization