Global Harmonization for Data Access & Exchange

HYBRID PUBLIC MEETING

November 5, 2026 | 1–4 PM (Eastern)

REAGAN-UDALL FOUNDATION for the Food and Drug Administration

1Day Sooner, Amgen, Bayer, Lilly, and PhRMA provided funding for this meeting



REAGAN-UDALL FOUNDATION FOR THE FDA

WELCOME

Susan C. Winckler, RPh, Esq.

CEO, Reagan-Udall Foundation for the FDA

Housekeeping

REAGAN-UDALL FOUNDATION FOR THE FDA

Cameras & microphones off

Because of the size of the meeting, virtual attendee cameras and mics will remain off

Exception: commenters confirmed in advance will be able to unmute and show video during the public comment period

Questions

Virtual: submit your questions using Zoom's Q&A function

In person: index cards are available

Recording & slides

This event is being recorded, and will be posted on the Foundation website next week

Today's slides are available on our event page

Joining us in person?

Please do not join the virtual transmission and embrace the in-person interaction within the room

Agenda

All Times Eastern

REAGAN-UDALL FOUNDATION FOR THE FDA

1pm	**Welcome** Susan C. Winckler, RPh, Esq., Reagan-Udall Foundation for the FDA
1:05pm	**Overview of 'Modernizing Global Data Access and Exchange' Report** Patrick Crooks, PhD, Accumulus Synergy
1:25pm	**Where Is Cloud-Based Data Exchange Already Working; Where Is New Adoption Best Suited?**
2:30pm	**Public Comment**
3pm	**Pivoting From "Digital Paper" Exchange To A Trusted, Cloud-Enabled Regulatory Data Ecosystem…What Will It Take?**
3:55pm	**Closing Remarks**
4pm	**Adjourn**



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Overview of Report
Modernizing Global Data Access and Exchange

Patrick Crooks, PhD

Senior Manager, Regulatory Innovation

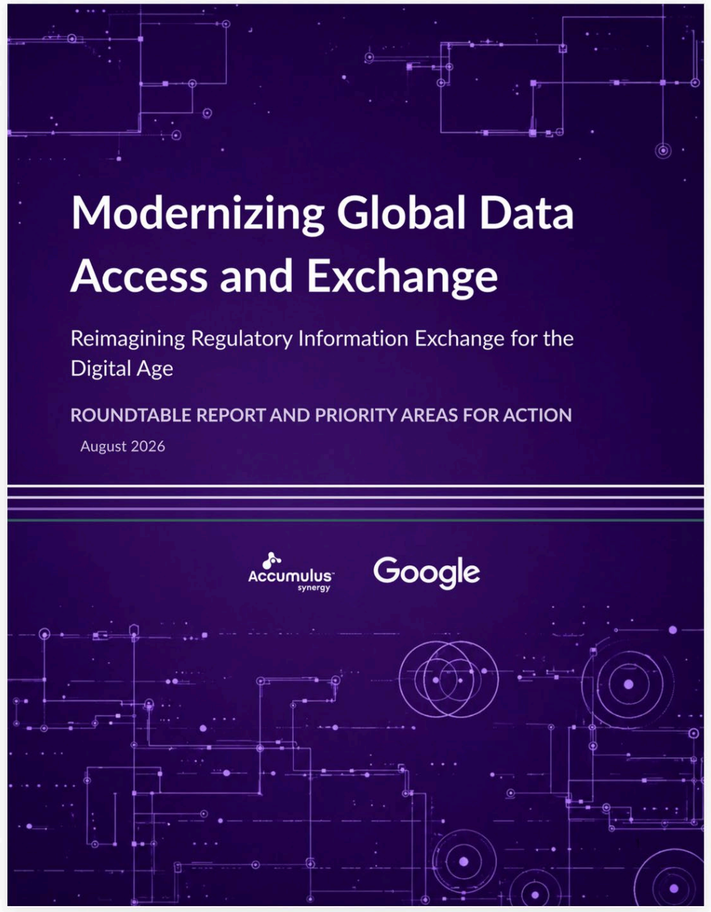
Accumulus Synergy

Modernizing Global Data Access and Exchange

November 5, 2026

Roundtable Report

- On May 14, 2026, Accumulus Synergy, in collaboration with Google, convened an invitation-only Roundtable that brought together global regulators, biopharmaceutical industry leaders, technology developers, and academic experts.
- Participants examined the barriers that limit the efficiency of multiregional clinical trials (MRCTs) and the cross-border use of real-world data (RWD) for regulatory submissions.
- The discussion focused on practical obstacles to data sharing, including fragmented legal bases and transfer mechanisms, inconsistent data governance, and the difficulty of navigating jurisdiction-specific requirements.



Link to Report: https://accumulussynergy.org/resource-cms/modernizing-global-data-access-and-exchange/

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Background, Challenges, and Goals

- ***Regulatory modernization is lagging scientific and technological innovation***. Despite advances in cloud computing, interoperability, and AI, regulatory submissions and reviews remain largely document-centric, creating "digital paper" rather than realizing the full benefits of digital transformation.
- ***Fragmented frameworks limit global data exchange***. Differences in policies, governance, data standards, privacy, consent, and legal requirements create barriers to cross-border collaboration and evidence reuse.
- ***Existing collaborative models improve efficiency, but barriers remain***. Initiatives such as Project Orbis and the ACCESS Consortium demonstrate the value of joint reviews, yet sponsors still face multiple submissions, administrative burden, and country-specific requirements.

Roundtable Goal

Identify practical, near-term actions and foundations for longer-term structural change within existing legal frameworks that can be advanced in the next 1–3 years.

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Summary of Priority Areas for Action

Twelve priority areas for action across ***four categories*** emerged from the discussion, spanning near-term actions and the foundations for longer-term structural change.

1. Sponsor-to-Regulator Data Sharing: Recommendations focused on modernization of submissions and the data-generation pipeline.

2. Regulator-to-Regulator Collaboration: Recommendations focused on collaborative review, capacity building, and federated data access.

3. Data Reuse: Recommendations focused on consent, AI transparency, incentives, and designing data for reuse.

4. Cross-Cutting: Recommendations focused on governance, building the evidence base, and amplifying patient-centered engagement.

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1. Sponsor-to-Regular Data Sharing

#	Priority Area	Focus
1	Establish a Unified Industry Vision and Value Proposition for Regulatory Modernization	Align stakeholders around a common vision and strategic objectives for regulatory modernization, ensuring a shared understanding of the benefits, opportunities, and desired future state.
2	Modernize Processes from Documents to Structured Data	Transition from document-centric submissions to structured, machine-readable, reusable data.
3	Extend Modernization to Clinical Trial Sites and the Data Pipeline	Bring trial sites and upstream data generation into the modernization agenda.

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2. Regulator-to-Regulator Collaboration

#	Priority Area	Focus
4	Advance Collaborative Review Through Targeted Pilots that Define and Demonstrate Value	Use focused pilot programs to demonstrate collaborative review in practice.
5	Develop a Collaboration Framework Supporting Capacity Building	Define collaboration that also strengthens less-resourced authorities.
6	Promote Federated Data Access Models	Enable analysis where data resides to preserve data sovereignty.

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3. Data Reuse

#	Priority Area	Focus
7	Create Harmonized Frameworks for Consent, Reuse, and Transparency	Align consent, data-reuse, and transparency expectations across jurisdictions.
8	Establish Shared AI Terminology and Require Transparency into AI	Adopt a common AI vocabulary and require transparency into regulatory AI architecture.
9	Create Incentives and Design Data for Reuse from Inception	Reward reusable data and design it for reuse from the point of collection.

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4. Cross-Cutting

#	Priority Area	Focus
10	Establish a Multi-Stakeholder Governance Structure	Create durable governance to coordinate long-term change across industry, regulators, and technology partners.
11	Establish a Global Evidence Base	Build shared metrics and evidence that demonstrate the value and impact of modernization.
12	Amplify Patient-Centered Messaging and Convene Expanded Stakeholders	Communicate value in patient terms and broaden participation.

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Key Takeaways from the Roundtable Report

- ✓ ***Barriers are no longer technological.*** Progress depends on aligning policy, governance, incentives, legal frameworks, organizational readiness, and trust.
- ✓ ***Build a shared vision.*** Regulators, industry, technology providers, patients, academia, and policymakers must work together to establish trusted, practical approaches to data exchange.
- ✓ ***Move beyond "digital paper."*** Modernize document-centric workflows toward structured, interoperable, reusable data that supports more efficient regulatory review.
- ✓ ***Turn pilots into sustained implementation.*** Build on existing capabilities through targeted pilots, collaborative review initiatives, and standards development that enable incremental progress and long-term transformation.
- ✓ ***Leadership is the catalyst for change.*** The priority is to convene stakeholders, align interests, and translate existing capabilities into coordinated action. ***Who should lead these efforts?***
- ✓ ***North Star: Accelerating patient access.*** Leverage a reusable core dossier, coordinated regulatory review, and locally accountable decisions to accelerate access to patients.

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What Comes Next? A Call to Action

- Meaningful regulatory modernization requires coordinated action across the broader ecosystem. ***Progress can begin now!***
- Industry has an important role as a ***catalyst for change*** by articulating a shared vision, identifying practical opportunities, investing in innovative approaches, and demonstrating value through targeted pilots and collaborative initiatives.
- Sustainable transformation cannot be achieved by any single stakeholder and will ***require partnership*** among regulators, industry, technology providers, patient organizations, academic institutions, and international standards bodies.
- ***Regulatory authorities remain essential partners*** in shaping future-state approaches, providing regulatory alignment, and enabling adoption of solutions that advance shared goals.

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Where Is Cloud-Based Data Exchange Already Working? Where Is New Adoption Best Suited?

REAGAN-UDALL FOUNDATION FOR THE FDA

Panelists



Julian Beach
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Medicines and Healthcare products Regulatory Agency (MHRA)



Rich Brennan
MA
Vice President of Federal Affairs

The ALS Association



Rebecca Nebel
PhD
Director of Regulatory Policy & Intelligence

Amgen



Raju Rayavarapu
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Senior Regulatory Director

DNAnexus



Sachin Shah
MBA
Project Manager in the Office of Data Platform Engineering

U.S. Food and Drug Administration

Public Comment

For those who requested during registration

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Public Comment Process

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9

confirmed public commenters

3 min

maximum per commenter

1. **Organized by topic**
   We begin with virtual commenters and proceed primarily in alphabetical order by last name.

2. **Rolling list of three**
   You will hear your name twice before you are called on to present your remarks.

3. **Joining virtually?**
   Accept the prompt to join as a panelist. When the commenter before you finishes, unmute and turn on your camera.

4. **In the room?**
   Staff will direct you to the podium on stage.

The Foundation, the FDA, nor today's speakers will respond to public comment. This time is for members of the public to share their perspectives.

Public Comment Topics

1

What is the value of global data harmonization?

2

What are the primary barriers and potential solutions?

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NOW SPEAKING

PUBLIC COMMENT · TOPIC 1

Rupjani Bhattacharya

NOW SPEAKING

PUBLIC COMMENT · TOPIC 1

Upendo Chenya

THE VALUE OF GLOBAL DATA HARMONIZATION

In regulation of controlled medicines and precursor chemicals to achieve public safety

The objective is not simply to exchange more data, but to ensure that information is **comparable, reliable, timely, and actionable across borders**.

01

CONTROLLED MEDICINES

Match product, strength, quantity, potency, permits and shipment data to detect irregularities while protecting legitimate medical access.

02

PRECURSOR CHEMICALS

Standardize chemical identifiers and shipment records to flag suspicious trade, prevent diversion and support timely cross-border verification.

03

SYNTHETIC DRUGS

Share comparable incident, trends, seizure and laboratory data to identify emerging substances and alert partners quickly.

VALUE OF DATA HARMONIZATION:

- **Eary detect drug-related threats**
- **Verify legitimate trades**
- **Recognize new trends and suspicious transactions**
- **Prevent diversion more effectively**
- **Strengthen collective international responses**
- **Protect legitimate access to medicines**

CALL FOR ACTION

- **Agree minimum data standards**
- **Enable secure exchange**
- **Protect privacy**
- **Build capacity in countries**

Harmonized data turns isolated national signals into coordinated global action—without compromising lawful access.

Sources: INCB : WHO, Harmonization of technical requirements for medicines regulation.

NOW SPEAKING

PUBLIC COMMENT · TOPIC 1

Carly McWilliams

NOW SPEAKING

PUBLIC COMMENT · TOPIC 1

Tingting Zhang

NOW SPEAKING

PUBLIC COMMENT · TOPIC 2

Manjari Narayan

NOW SPEAKING

PUBLIC COMMENT · TOPIC 2

Javid Rahaman

GOVERNANCE AS CODE · BARRIERS & SOLUTIONS FOR GLOBAL DATA HARMONIZATION

Encode trust into the data, not around it

BARRIER 1

“Digital paper”

Near-identical dossiers rebuilt for every jurisdiction

SOLUTION

Harmonized data contracts

One versioned core dossier on eCTD 4.0 and IDMP, plus jurisdiction-specific extensions. Prepare once, reuse everywhere.

BARRIER 2

Data sovereignty

Cross-border transfer rules stall collaboration

SOLUTION

Federated access

Move the question to the data, not the data across borders. DARWIN EU already shows it works.

BARRIER 3

Trust in provenance & AI

Regulators must know exactly what was reviewed, and how

SOLUTION

Provenance at the source

Each data element carries lineage, consent basis and audit trail, with a shared vocabulary for AI use.

PROPOSAL

A rare-disease pilot: FDA and two partner regulators review **one core dossier as a data contract**, then publish question-cycle time and time to patient access.

Javid Ur Rahaman · Founder & Head of Applied Intelligence, AAI Applied Agentic Intelligence Research Labs® · Doctorate from Golden Gate University, San Francisco, CA, USA · linkedin.com/in/jrahaman7

NOW SPEAKING

PUBLIC COMMENT · TOPIC 2

Ramona Walls

OPPORTUNITIES FOR A HARMONIZED REGULATORY DATA ECOSYSTEM

The challenge is not simply willingness to share.

BARRIERS / OPPORTUNITIES	HOW C-PATH CAN HELP
1 **Harmonization** Data are heterogeneous and dispersed, and methods remain too manual, expensive, and study-specific to scale.	Build scalable, standards-based methods that integrate heterogeneous data while preserving scientific meaning and provenance.
2 **Evidence interoperability** Immature standards and structures for representing, and reusing evidence across regulatory applications.	Develop evidence structures and standards that support traceability, evaluation, and appropriate reuse across regulatory use cases.
3 **Governance** Cross-organization and -jurisdiction reuse requires trusted rules for access, appropriate use, and decision-making.	Apply decades of neutral, consensus-based governance to allow trusted access and reuse across organizations and jurisdictions.

Build for where regulatory science is going:
An ecosystem that can learn across heterogeneous – even individualized – evidence without creating false uniformity.

NOW SPEAKING

PUBLIC COMMENT · TOPIC 2

Terri Conneran

GLOBAL PROGRESS. HUMAN CHOICE.

GOAL



Every person's data is **precious**.
So is their **right** to choose.

LESSONS FROM THE INTERNET



Unintended **consequences** from
designed solutions

OPPORTUNITY REQUIRES RESPONSIBILITY.

Treatment today, without surrendering my future. Meaningful consent. Enforceable boundaries

Future Generations Deserve Enduring Data Protections.

Terri Conneran | Mom | Cancer Patient | Founder, KRAS Cancer Connect | Terri@KRASKickers.org

Global Data Harmonization Public Meeting, Nov.05.2026

NOW SPEAKING

PUBLIC COMMENT · TOPIC 2

Luca Emili

Pivoting From "Digital Paper" Exchange To A Trusted, Cloud-Enabled Regulatory Data Ecosystem… What Will It Take?

REAGAN-UDALL FOUNDATION FOR THE FDA

Panelists



Crystal Allard
MSIT
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Hussein Ezzeldin
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U.S. Food and Drug Administration



Sandra Krogulski
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Rebecca Li
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CEO
Vivli



Andrew Robertson
PhD, JD
Senior Vice President of Global Regulatory Affairs and Quality
Denali Therapeutics



Mariann Yeager
MBA
CEO
The Sequoia Project

Global Harmonization for Data Access & Exchange

Thank You

Recording and transcript will be posted on our website next week

www.reaganudall.org

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