REAGAN-UDALL FOUNDATION FOR THE FDA

Global Harmonization for Data Access & Exchange

A hybrid public meeting hosted by the Reagan-Udall Foundation for the FDA on behalf of Accumulus Synergy

1333 New Hampshire Ave NW, Washington, DC 20036
November 5, 2026

1 PM **Welcome**

- Susan C. Winckler, RPh, Esq. | Reagan-Udall Foundation for the FDA

1:05 PM **Overview of 'Modernizing Global Data Access and Exchange' Report**

- Patrick Crooks, PhD | Accumulus Synergy

1:25 PM **Discussion #1: Where Is Cloud-Based Data Exchange Already Working; Where Is New Adoption Best Suited?**

Variability in data governance requirements, inconsistent data quality frameworks, and divergent interpretations of consent and secondary use are barriers to harmonized data exchange and reuse across jurisdictions. Panel participants will discuss a current use case (chemistry, manufacturing, and controls (CMC) post-approval space) and potential use case (rare disease clinical review).

PANELISTS:

- *Julian Beach, MBA | Medicines and Healthcare products Regulatory Agency (MHRA)*
- *Rich Brennan, MA | The ALS Association*
- *Rebecca Nebel, PhD | Amgen*
- *Raju Rayavarapu, PhD | DNAnexus*
- *Sachin Shah, MBA | U.S. Food and Drug Administration (FDA)*

2:30 PM **Public Comment**

- What is the value of global data harmonization? What are the primary barriers and potential solutions?

3 PM **Discussion #2: Pivoting From "Digital Paper" Exchange to a Trusted, Cloud-Enabled Regulatory Data Ecosystem…What Will It Take?**

Panelists will discuss and recommend prioritized next steps to accelerate movement to a cloud-enabled regulatory data ecosystem

PANELISTS:

- *Crystal Allard, MSIT | Veeva Systems Inc*
- *Hussein Ezzeldin, PhD | U.S. Food and Drug Administration (FDA)*
- *Sandra Krogulski, MA | Bristol Meyers Squibb*
- *Rebecca Li, PhD | Vivli*
- *Andrew Robertson, PhD, JD | Denali Therapeutics*
- *Mariann Yeager, MBA | The Sequoia Project*

3:55 PM **Closing Remarks**

- Winckler

4 PM **Adjourn**

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