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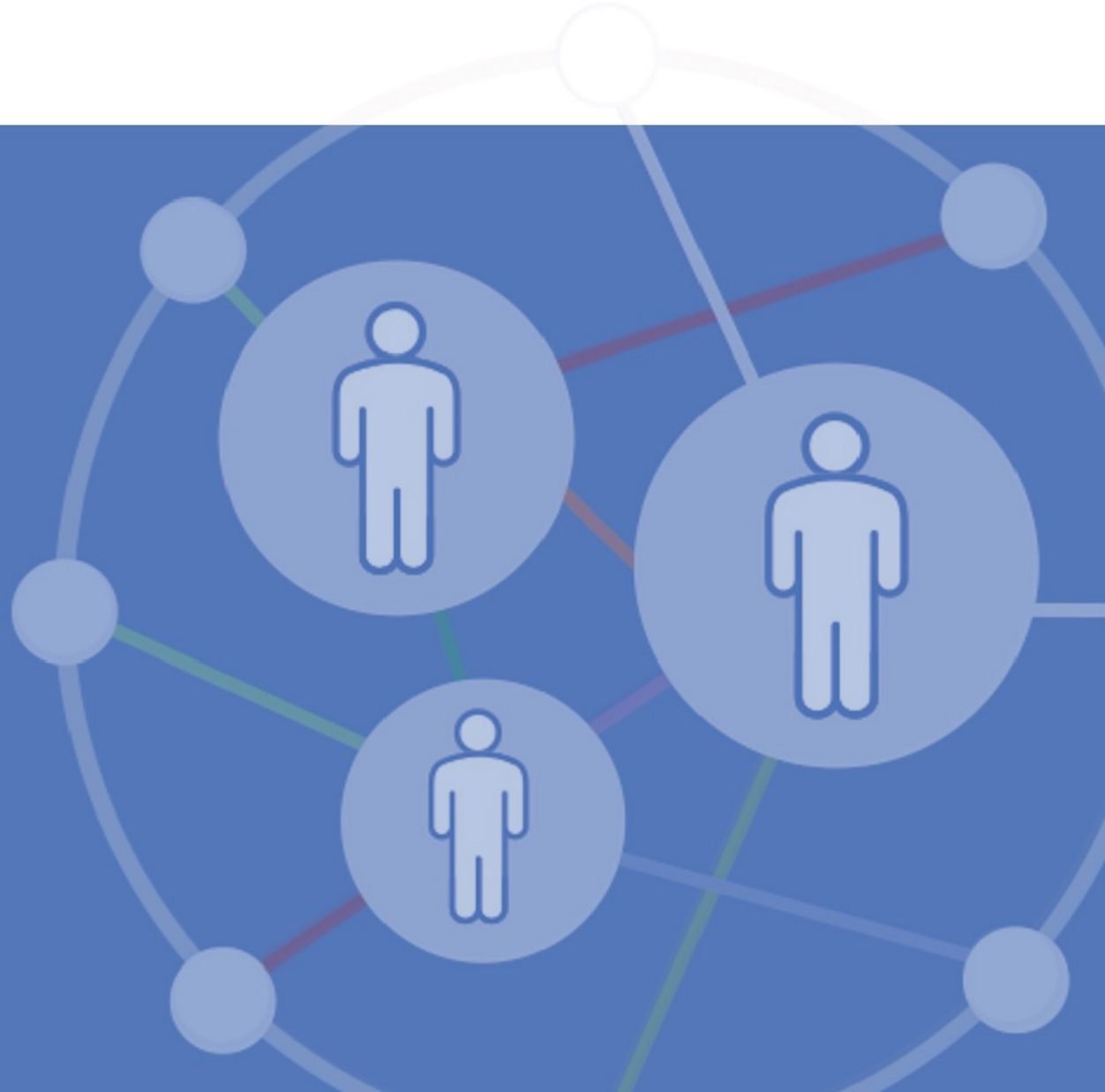
Clinical Research Data Sharing Alliance

Secondary Use Data: What do Researchers Need?

Webinar:
April 20, 2023



Agenda and Presenters

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Agenda:

- Introduction
- Why did we conduct the survey?
- Who answered?
- What did we learn?
- Where do we go from here?
- Panel Discussion / Audience Q&A

Presenters / Panel:

Ernest Odame, Takeda
Director, Global Evidence & Outcomes, Oncology

Ramona Walls, Critical Path Institute
Executive Director of Data Science

Luk Arbuckle, Privacy Analytics
Chief Methodologist

Andrew Freeman, CRDSA
Senior Advisor, Standards Development

Aaron Mann, CRDSA
CEO

"Establishing a Basis for Secondary Use Standards for Clinical Trials," was published March 2023 in Applied Clinical Trials Online

Leading Through Multi-Stakeholder Collaboration

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AMGEN
AstraZeneca
GSK
NOVARTIS
Roche
Takeda
ucb
Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA
HDRUK
Health Data Research UK
Project Data Sphere
CRITICAL PATH INSTITUTE
Duke Clinical Research Institute
THE UNIVERSITY OF CHICAGO
PEDIATRIC CANCER DATA COMMONS
Flinders University
TEXAS eHEALTH ALLIANCE
ASCO CancerLinQ
KNOWLEDGE CONQUERS CANCER
THE MICHAEL J. FOX FOUNDATION
FOR PARKINSON'S RESEARCH
ANONOS
atorus
Your Complete Data Solution
COTA
Cytel
d-wise
An Instem Company
EQUIDEUM HEALTH
parexel
PRIVACY ANALYTICS
an IQVIA company
Real Life Sciences
Replica Analytics

Our 2023 Initiatives

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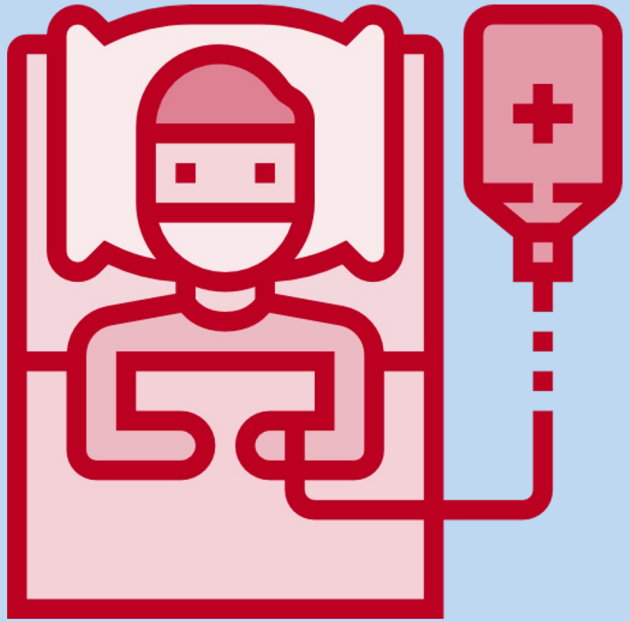
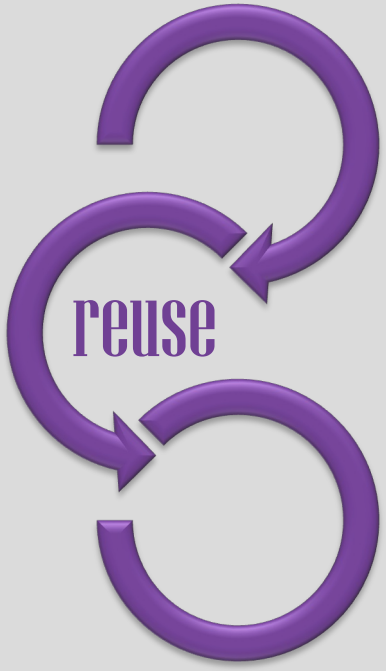
	Contribution	Access	Data Mgt. & Analysis	Output / Use
Principal Actor(s)	Data Contributor	Data Sharing Platform and Researcher	Researcher	Researcher
Desired Outcomes / Future State	Codify and harmonize best practices/standards; promulgate across sponsors; improve contribution logistics	Improve access efficiency; reduce the time to analysis; provide researchers the right information at the right time	Ensure responsible data use; reduce data management burden; accelerate time to research output or use	Expansion of applications, use cases, and regulatory acceptance/use of diverse data types
2023 Initiatives	**Data Contribution Standards**			**NSCLC Supplemental Controls Demonstration Project**
	Data Protection Policy Guide	**Secondary Use Research Standards**		
	Information Loss Framework			
	Enabling Platform Trial Data Sharing			

Work Groups:

Secondary Use Standards (SUS)	
Data Protection (DP)	
Innovative Trial Design (ITD)	
Technology & Innovation (TI)	

Patients Data are valuable





Today's Focus:

Clinical Trial Data Sharing

- Curated, High-Quality Data Collected per Protocol
- Defined Endpoints
- Objective Measurements / Standardized Assessments

Why did we conduct the survey?

Why did we conduct the survey?

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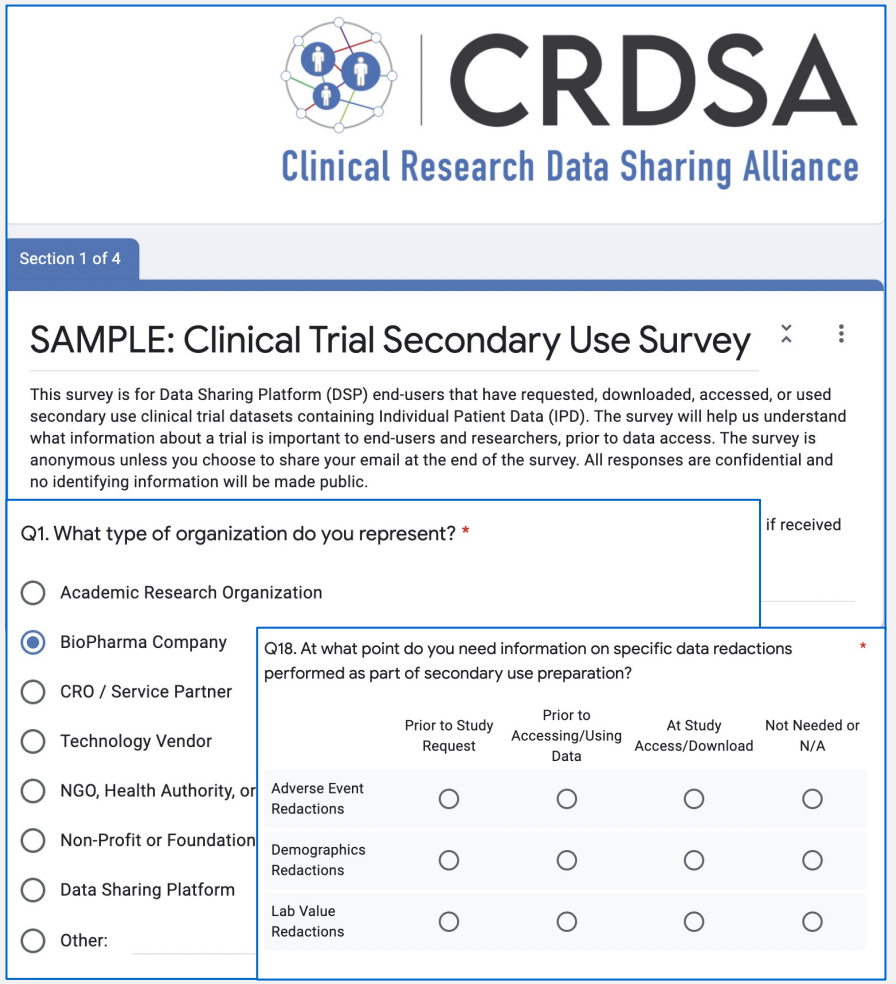
Objectives:

- Understand **key factors of research utility** for users of secondary-use clinical trial datasets containing IPD.
- Determine the **value to researchers** of various types of IPD datasets, supporting documents, and metadata as a basis for future secondary use data standards designed to maximize the research value of clinical trial data.
- **Identify gaps** in researcher or data contributor knowledge that present opportunities for community education.

Survey Scope

- **Datasets and Supporting Documentation:**
  - What patient-level datasets are needed by researchers?
  - What trial-specific supporting documents do researchers need to enable secondary use and maximize research value?
- **Metadata:**
  - What information about the trial is needed to provide sufficient context for dataset access and use?
- **Timing:**
  - When is the provision of selected supporting documents and metadata needed to facilitate process efficiency for both data contributors and researchers?



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Section 1 of 4

SAMPLE: Clinical Trial Secondary Use Survey

This survey is for Data Sharing Platform (DSP) end-users that have requested, downloaded, accessed, or used secondary use clinical trial datasets containing Individual Patient Data (IPD). The survey will help us understand what information about a trial is important to end-users and researchers, prior to data access. The survey is anonymous unless you choose to share your email at the end of the survey. All responses are confidential and no identifying information will be made public.

Q1. What type of organization do you represent? *

- Academic Research Organization
- BioPharma Company
- CRO / Service Partner
- Technology Vendor
- NGO, Health Authority, or
- Non-Profit or Foundation
- Data Sharing Platform
- Other:

if received

Q18. At what point do you need information on specific data redactions performed as part of secondary use preparation? *

	Prior to Study Request	Prior to Accessing/Using Data	At Study Access/Download	Not Needed or N/A
Adverse Event Redactions				
Demographics Redactions				
Lab Value Redactions				

Distribution and Limitations

Distribution:

- The survey was distributed to relevant research communities through multiple Data Sharing Platforms, Non-Profit organizations, and BioPharma companies.
  - Other distribution included CRDSA newsletters, social posts (LinkedIn), and conference presentations

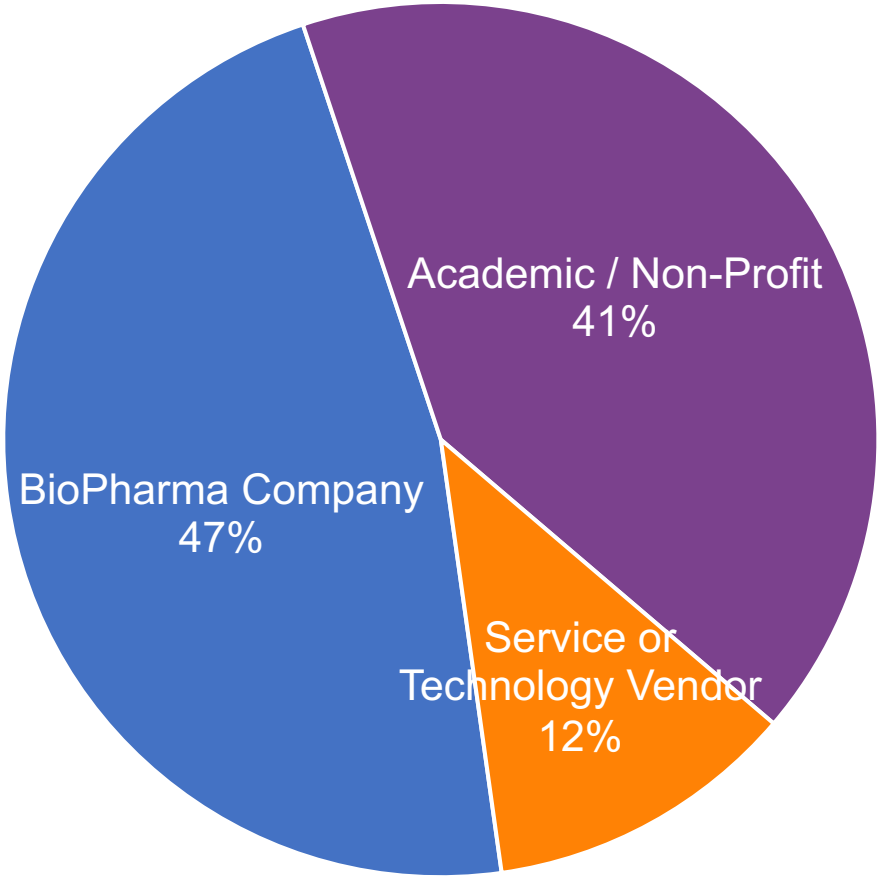
Limitations:

1. Survey distribution was limited by the contacts and reach available to the authors.
2. Survey response rates varied by distribution source and organization type, which may bias responses toward those most engaged in the data-sharing ecosystem.
3. The survey did not explore additional data sharing elements that can impact research use and/or data contributions. These include (but aren't limited to):
   a) Data Access and use policies
   b) Intellectual property and competitive considerations
   c) Data contribution resourcing

Who answered?

Overview

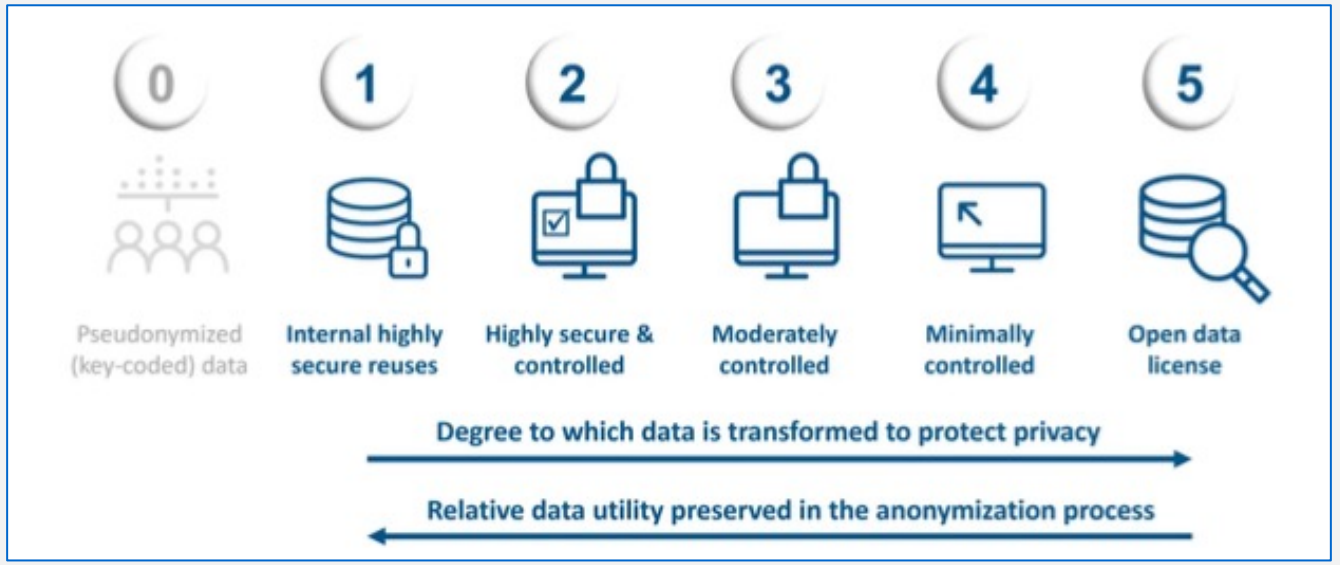
Total Respondents = 104



95% engaged with data sharing platforms one or more times per year

Over 2/3rds considered themselves moderately experienced, very experienced, or a power user.

Where did respondents go to find data?



11.6%

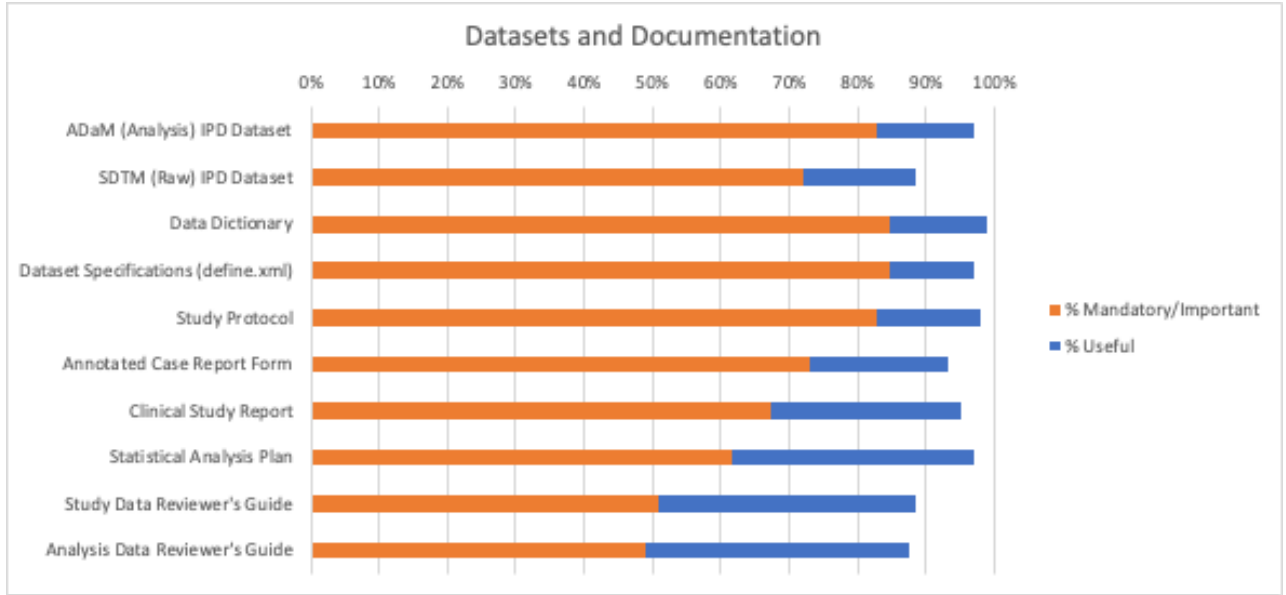
66.3%

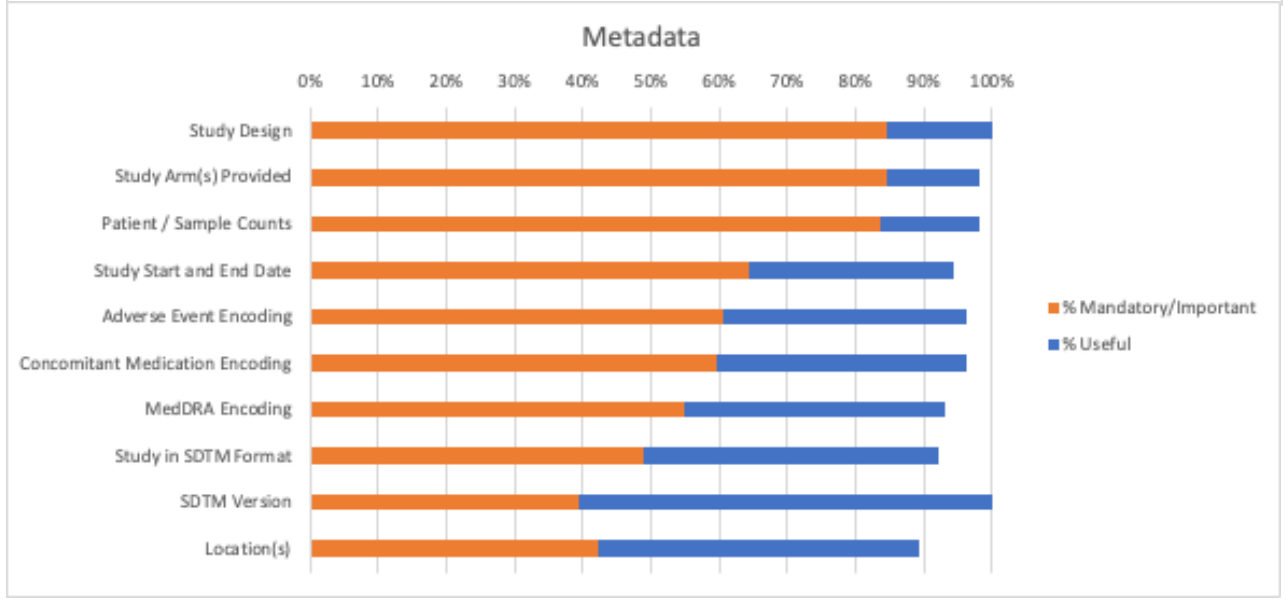
4.8%

19%

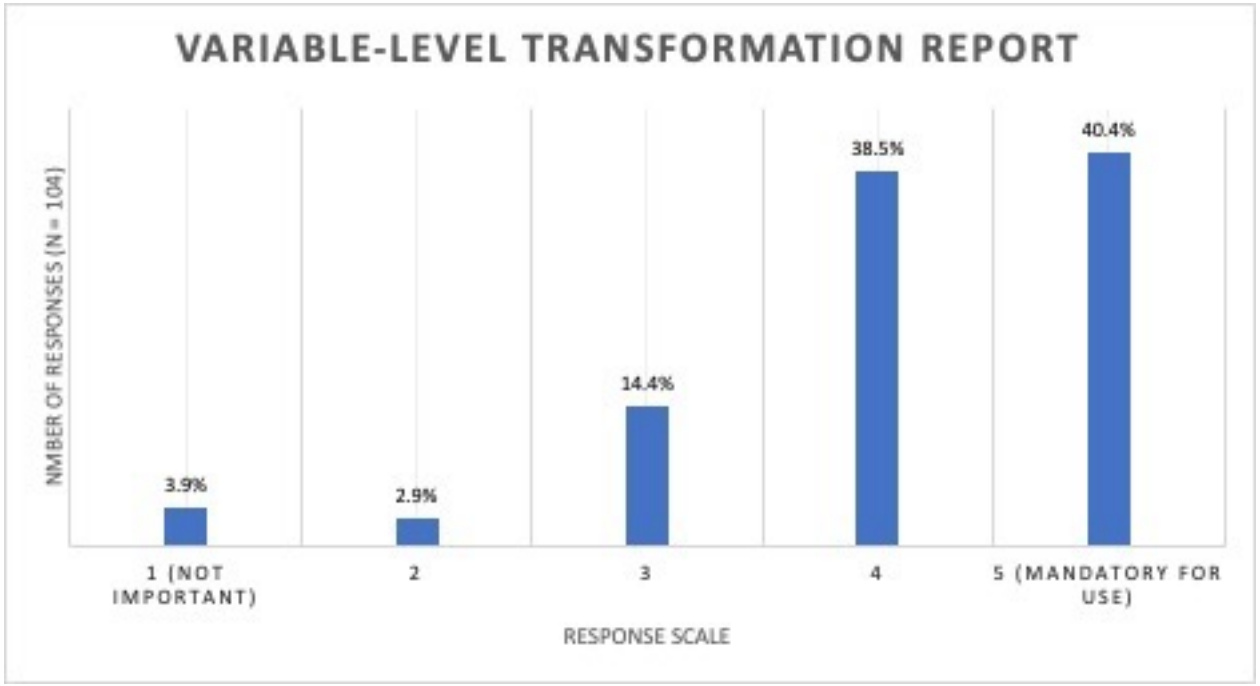
What did we learn?

Datasets, Documentation, and Metadata





Transformation Report / Redaction Transparency



Data Redaction Transparency

	Adverse Events	Demographics	Laboratory Values
% Mandatory/Important/Useful	89.4%	93.3%	93.3%

Timing

Timing of Protocol Access (N=104)	Critical / Important / Useful
Prior to Data Request	99.1%
Prior to Data Access or Download	97.1%

97%+ of respondents indicated the importance of access to the study protocol **prior to data request or data access/download**

Data Redaction Transparency (N=104)	Adverse Events	Demographics	Laboratory Values
Prior to Data Request	19.4%	24.7%	19.6%
Prior to Data Access or Download	32.3%	26.8%	33.0%

Over **50%** of the respondents indicated the importance of redaction transparency before they access study data

Where do we go from here?

A gap between research need and data provision…

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Findings from CRDSA's 2022 Whitepaper:

"A Review of BioPharma Sponsor Data Sharing Policies and Protection Methodologies"

	Tier 1	Tier 2	Tier 3
Sponsor Tiers (by employee count) Tier 1: 25k+ Tier 2: 5 to 24.99k Tier 3: Under 5k	(n=12)	(n=11)	(n=6)
Datasets and Documentation			
Raw (SDTM)	100%	82%	83%
Analysis (ADaM)	92%	92%	67%
Protocol	100%	82%	83%
Annotated CRF	100%	73%	67%
Reporting and Analysis Plan / SAP	100%	82%	67%
CSR	92%	91%	33%
Dataset Specifications	75%	73%	50%

Publicly available information from **29 biopharma** sponsors

Green - Meets or exceeds survey response level

…results in frustrating data wrangling challenges

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In their most recent data sharing experience, 35% of Moderately/Very Experienced and Power Users (n=71) related that they were able to **use less than 80% of studies** requested/accessed (for 30% it was **less than 60%**).

The top 4 reasons (cited over 80% combined) were:

1. Studies were not suitable for their intended use
2. Could not harmonize for analysis
3. Missing documentation (protocol, etc.)
4. Key information redacted

Data Contribution Standards

Data Contribution Standards can:

- Ensure secondary use contributions include the datasets, documentation, and metadata the research community needs.
- Reduce wasted data management overhead and increase interoperability across platforms.
- Increase the likelihood that contributed data will be effectively used by promoting the provision of key supporting documents and metadata earlier in the data access process.

Accelerating the reuse of trial data, improving clinical trial development, and enabling new innovative medicines to reach patients faster!

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Panel Discussion:

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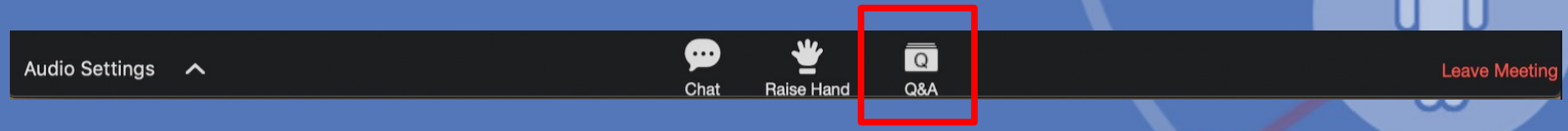
Luk Arbuckle, Privacy Analytics
Andrew Freeman, CRDSA
Aaron Mann, CRDSA (Moderator)



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Thank you!

If you have additional questions, please contact:

aaron.mann@crdsalliance.org or arpana.patel@crdsalliance.org

Slides and a link to today's recording will be circulated via email.

Access the survey results paper at: https://crdsalliance.org/resources