Session 3:
Maximizing the Value of Data
Shared by Multiple Organizations
Agenda

- Introduction of Panel Members
- Landscape of Data Sharing Initiatives
- Themes and Challenges
- Discussion Topics
- Initial Comments by Panel Members
- Panel Discussion
- Q & A Session
Panel Members

- Kald Abdallah (Project DataSphere) – Chief Project Data Sphere Officer
- Ed Bowen (Pfizer) – TransCelerate Placebo / Standard Of Care Executive Leader
- Keith Elliston (tranSMART) – CEO, tranSMART Foundation
- Sharon Hesterlee (Parent Project Muscular Dystrophy) – VP of Research
- Bron Kisler (Clinical Data Interchange Standards Consortium) – VP, Strategic Initiatives
- Mary Ann Slack (FDA) – Deputy Director, Office of Strategic Programs, (OSP) CDER
Landscape of Data Sharing Initiatives

• Tremendous potential for new insights from existing and newly generated data
• Many active projects for sharing of clinical data
• Varied objectives, at times multiple objectives
• Multiple platforms in use
• Common themes and challenges
Data Sharing Landscape

EndDuchenne.org

Strength Happens Together: PPMD Submits FDA Draft Guidance on Duchenne

PPMD and a broad coalition of stakeholders has submitted the first-ever patient advocacy-initiated draft guidance for a rare disease to the FDA to help accelerate development and review of potential therapies for Duchenne.

Read more.
Data Sharing Landscape

Researchers are working tirelessly and new advances are constantly being discovered, yet every day, tens of thousands of our loved ones lose their battle with cancer. Sadly, we’re losing nearly the same number of people today as we were 40 years ago. With researchers working independently, we’re simply not finding solutions quickly enough.

What if we could share, integrate, and analyze our collective historical cancer research data in a single location?
Data Sharing Landscape

Placebo & Standard of Care Data Sharing
An industry collaboration leveraging TransCelerate

Relevance of Pooled Control-Arm Data: Disease Modeling, Biomarker Development, New Tool for Rare Diseases, Historical Controls (fewer enrolled patients) → Better Patient Experience, Millions of dollars in cost avoidance, Enhanced Clinical Trial Design

Feasibility Assessment - 2012

Vaccines Pilot - 2013
- 40,000+ patients
- Supported multiple AE reports for phase II & III programs
- Manuscript developed and planned for submission

Environmental Scan - 2013

2014 - TransCelerate Project
- RFP will issued in Oct 2014
- 600 trials across 5 DAs ID’d
- Planned database by 2Q 2015
- Mapped data in top 3 DAs by 2Q 2016
Data Sharing Landscape

What is eTRIKS?

It is a collaborative project focused on increasing the efficiency of translational research by:

- Reducing the cost of translational research data & knowledge management
- Enabling non-statisticians to perform exploratory analyses
- Facilitating cross study analyses

"eTRIKS is more than just tranSMART. We aim to support projects with different types of open source software, standards, hosted content, business analysis, curation processes and training."

CRITICAL PATH INSTITUTE
tranSMART Collaborative Data Sharing

- Collaborative Data Sharing
  - Open Source Knowledge Management Platform
  - Common data formats and interfaces
  - Hosted Hackathons and Datathons stimulate collaboration
  - Active marketplace and ecosystem

- Examples
  - Michael J. Fox Foundation
    - Neurodegeneration
  - eTRIKS
    - 50+ IMI projects incl. UBIOPRED
  - PCORI / Harvard
    - Phelan-McDermid Syndrome
  - Neptune / U Michigan
    - Kidney disease
  - CTMM/TraIT
    - Oncology
# Data Sharing Landscape

**ClinicalStudy**

[DataRequest.com](https://www.datarequest.com)

Registered Users, Please Login

## About

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<th>Next steps</th>
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<td>Access to the underlying (patient level) data that are collected in clinical trials provides opportunities to conduct further research that can help advance medical science or improve patient care. This helps ensure the data provided by research participants are used to maximum effect in the creation of knowledge and understanding. Researchers can use this site to request access to anonymised patient level data and supporting documents from clinical studies to conduct further research.</td>
<td>Study sponsors who have committed to use this site are <strong>Bayer, Boehringer Ingelheim, GSK, Lilly, Novartis, Roche, Sanofi, Takeda, UCB and Viiv Healthcare.</strong> Other clinical trial sponsors and funders are invited to join with the aim of transitioning to a fully independent system which allows access to data from clinical trials conducted by multiple companies and organisations. It is hoped that such a system will be put in place as soon as possible. If you are a study sponsor interested in listing studies on this site, contact information is provided <a href="#">here</a>.</td>
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Data Sharing Landscape

⚠️ We’re in beta! openFDA is a beta research project and not for clinical use. We may limit or otherwise restrict your access to the API in line with our Terms of Service. Need help? Try StackExchange.

Open data for easier and better access to FDA datasets. APIs, raw data, and documentation for high value public datasets.

Open source code and documentation. Shared on GitHub for community contribution.

Open community to share examples, apps, and ideas. Developers, researchers, and FDA on GitHub, StackExchange, and Twitter.

Making public FDA datasets more accessible

openFDA provides open APIs, raw data downloads, documentation and examples, and a developer community for an important collection of FDA public datasets.

About openFDA »
Themes and Challenges

• Range of objectives for data sharing drives differences in implementation
• Competing requirements need to be addressed
  • Need to comply with all applicable regulations
  • Need to protect patient privacy
  • Need to respect sponsor confidential information and intellectual property
  • Need to optimize utility of shared data
• Complicated by access and use of data from multiple sources
• A wide range of data types need to be handled
  • Clinical trial data, observational study data, registry data
  • Comprising genotypic, phenotypic, treatment, outcome data
• With the ability to share the organized and curated data with a wide range of researchers.
Initial Comments by Panel Members
Topics for discussion

• What are the best methods to maximize the research utility of data contributed by multiple organizations to a collaborative effort

• Success stories in analyzing and pooling data to yield new insights and tools

• Harmonization of approaches to data sharing/aggregating of data

• How to increase collaboration across existing data sharing initiatives

• Integrating Electronic Health Records into Clinical Trial databases
Q & A Session
Thanks!
Thank you for participating!

Good-bye
Au Revoir
Auf Wiedersehen
Adios
Ciao