



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

Parent Project
Muscular Dystrophy

LEADING THE FIGHT TO END DUCHENNE

UNDERSTAND
DUCHENNE

CARE
FOR DUCHENNE

ADVANCE
RESEARCH

ADVOCATE

CONNECT

FUNDRAISE

DONATE NOW



Strength Happens Together: PPMD Submits FDA Draft Guidance on Duchenne

PPMD and a broad coalition of stakeholders has submitted the first-ever patient advocacy-initiated draft guidance for a rare disease to the FDA to help accelerate development and review of potential therapies for Duchenne.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



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 Pre-registration for the Prostate Cancer DREAM Challenge is now open; visit: www.synapse.org/#!/Synapse:syn2813558



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



C-PATH ONLINE DATA REPOSITORY



Logout

- CAMD-AD/MCI
- CAMD-PD
- CPTR
- PSTC Clinical-LSSP
- PSTC Non-Clinical
- PSTC Clinical-Kidney
- MSOAC
- PKD

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Coalition Against Major Diseases

Accelerating the development and review of medical products for neurodegenerative diseases.

Tools Collaborators CODR Database AD Trial Simulation

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Programs / CPTR

Critical Path to TB Drug Regimens

Overview Tools Collaborators CPTR: CDC Study Data



- Heart icon
- Clock icon
- Arrow icon
- CAMD
- Introduction
- Recent Highli
- Events

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

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Data Sharing Landscape



[Home](#) [Blog](#) [The Project](#) [eTRIKS services portal](#) [Project Workspace](#) [Jobs](#)

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."

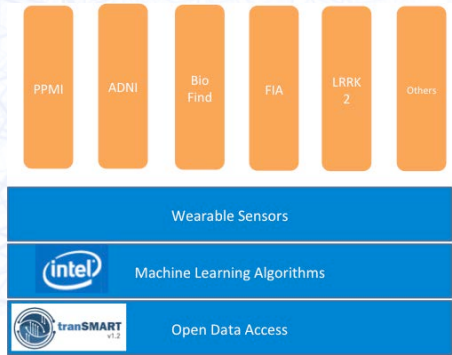
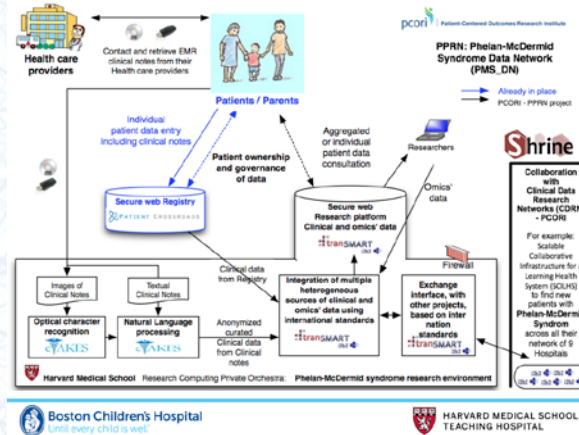
tranSMART Collaborative Data Sharing

Collaborative Data Sharing

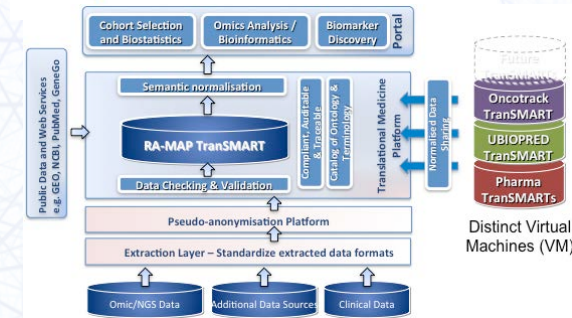
- Open Source Knowledge Management Platform
- Common data formats and interfaces
- Hosted Hackathons and Datathons stimulate collaboration
- Active marketplace and ecosystem

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



THE MICHAEL J. FOX FOUNDATION
FOR PARKINSON'S RESEARCH



You Can Help

Your participation in research makes it possible for researchers to find new treatments, create new studies, and work for the improvement of all our lives.

Information for Patients and Families

Learn about Nephrotic Syndrome Study Network

Get Involved in NEPTUNE

- Join a Study: Find Information About Current Research
- Join the Contact Registry and receive information about research opportunities
- How Can I Help? - Why Your Participation Matters
- Learn more about how NephCure helps families and researchers

Information for Professionals

Physicians, Clinicians, & Researchers

- Nephrotic Syndrome Study Network Description
- Ancillary Study
- Refer patients
- Participating Centers
- Career Development (RAI)
- KDIGO Clinic Glomerulonephritis

neptune Nephrotic Syndrome Study Network	Patients enrolled in the Nephrotic Syndrome Study Network:	504	Patients Currently in Contact Registry:
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next generation sequencing

arrays

non-omics laboratory assays

proteomics (mass spectrometry)

Data Sharing Landscape

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Data Sharing Landscape



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STEP BY STEP

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APPROVED REQUESTS

HELP

About

This site

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.

Next steps

[Study sponsors](#) who have committed to use this site are **Bayer, Boehringer Ingelheim, GSK, Lilly, Novartis, Roche, Sanofi, Takeda, UCB** and **ViiV Healthcare**.

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 [here](#).

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](#)

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

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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