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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

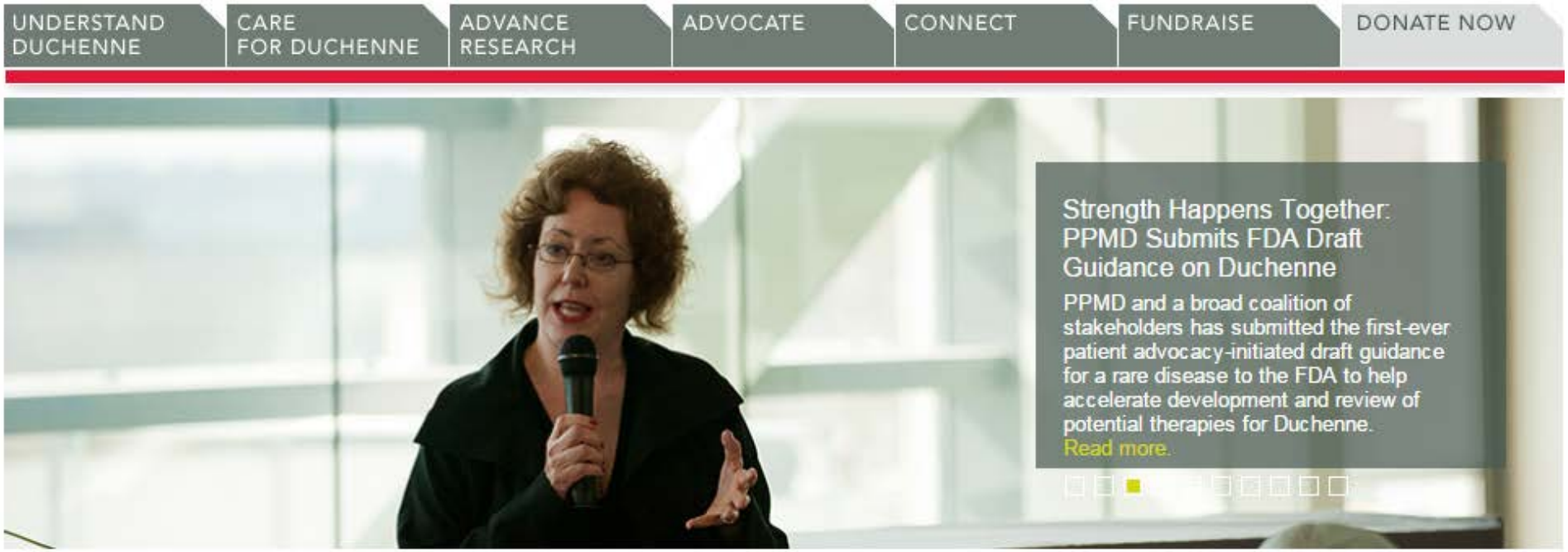
Landscape of Data Sharing Initiatives

- 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



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Data Sharing Landscape

Project Data Sphere

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▸ HOME ABOUT ACCESS DATA SHARE DATA RESOURCES CONTACT US

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?

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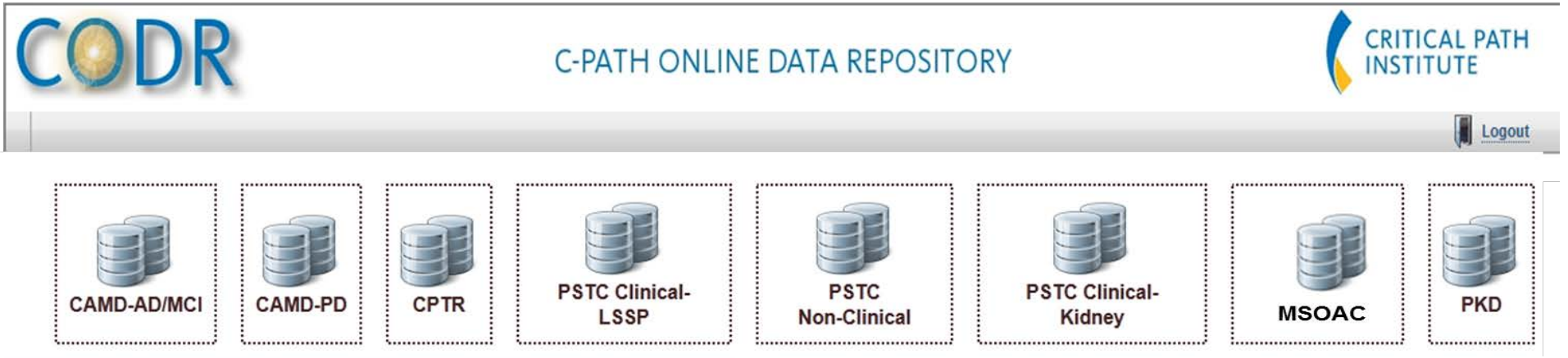
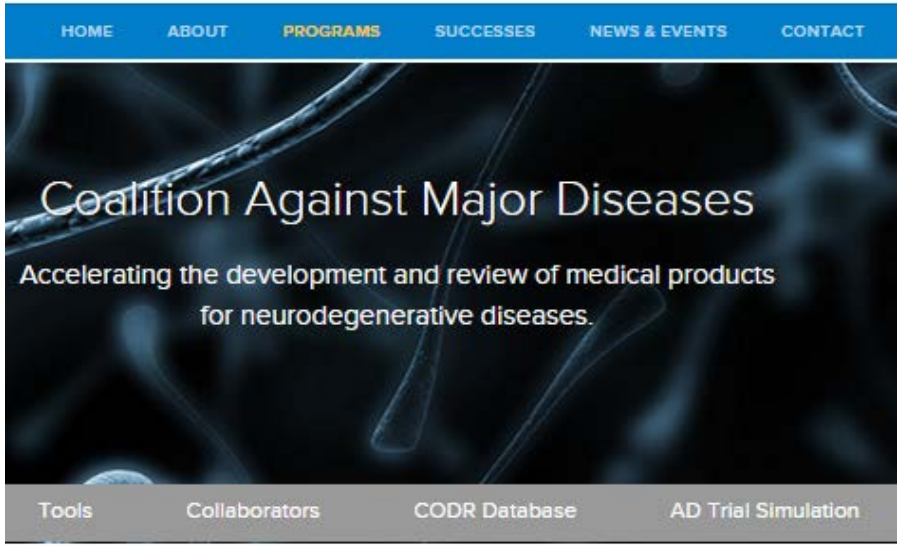
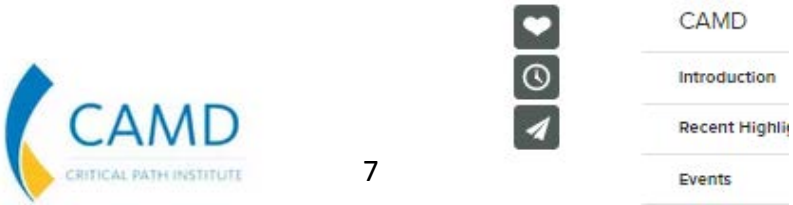
Data Sharing Landscape







Data Sharing Landscape

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

Pfizer BUSINESS TECHNOLOGY

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

JAMIA

Vaccines Pilot - 2013

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

Environmental Scan - 2013

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TransCelerate BIOPHARMA INC.

Project Data Sphere

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

abbvie

AstraZeneca

Johnson & Johnson

Pfizer

gsk GlaxoSmithKline

Lilly

TransCelerate BIOPHARMA INC.

Bristol-Myers Squibb

SHIONOGI

Actavis

Boehringer Ingelheim

astellas

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

eTRIKS

European Translational Information and Knowledge Management Services

efpia

imi

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."

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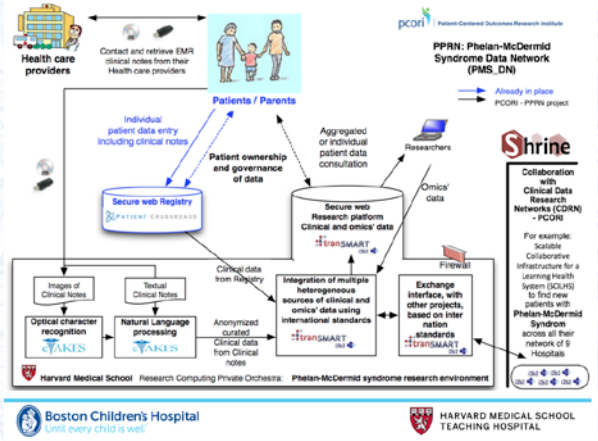
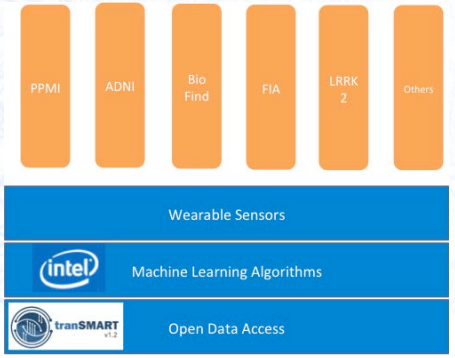
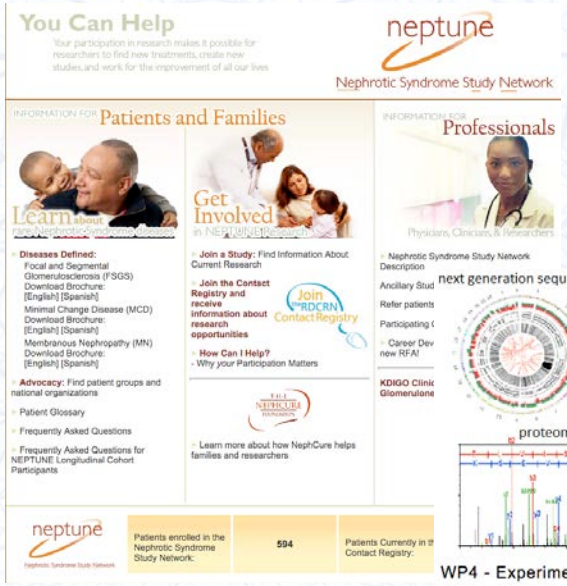
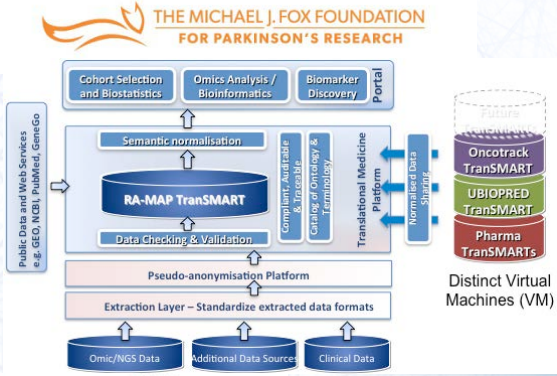
tranSMART Collaborative Data Sharing

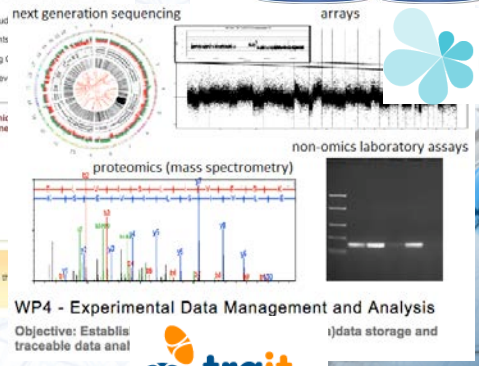
- **Collaborative Data Sharing**
  - Open Source Knowledge Management Platform
  - Common data formats and interfaces
  - Hosted Hackathons and Datathons stimulate collaboration
  - Active marketplace and ecosystem
- **Examples**
  - Michael J. Fox Foundation
    - Neurodegeneration
  - eTRIKS
    - 50+ IMI projects incl. UBIOPRED
  - PCORI / Harvard
    - Phelan-McDermid Syndrome
  - Neptune / U Michigan
    - Kidney disease
  - CTMM/TraIT
    - Oncology











tranSMART FOUNDATION

trait a ctmm project

Data Sharing Landscape

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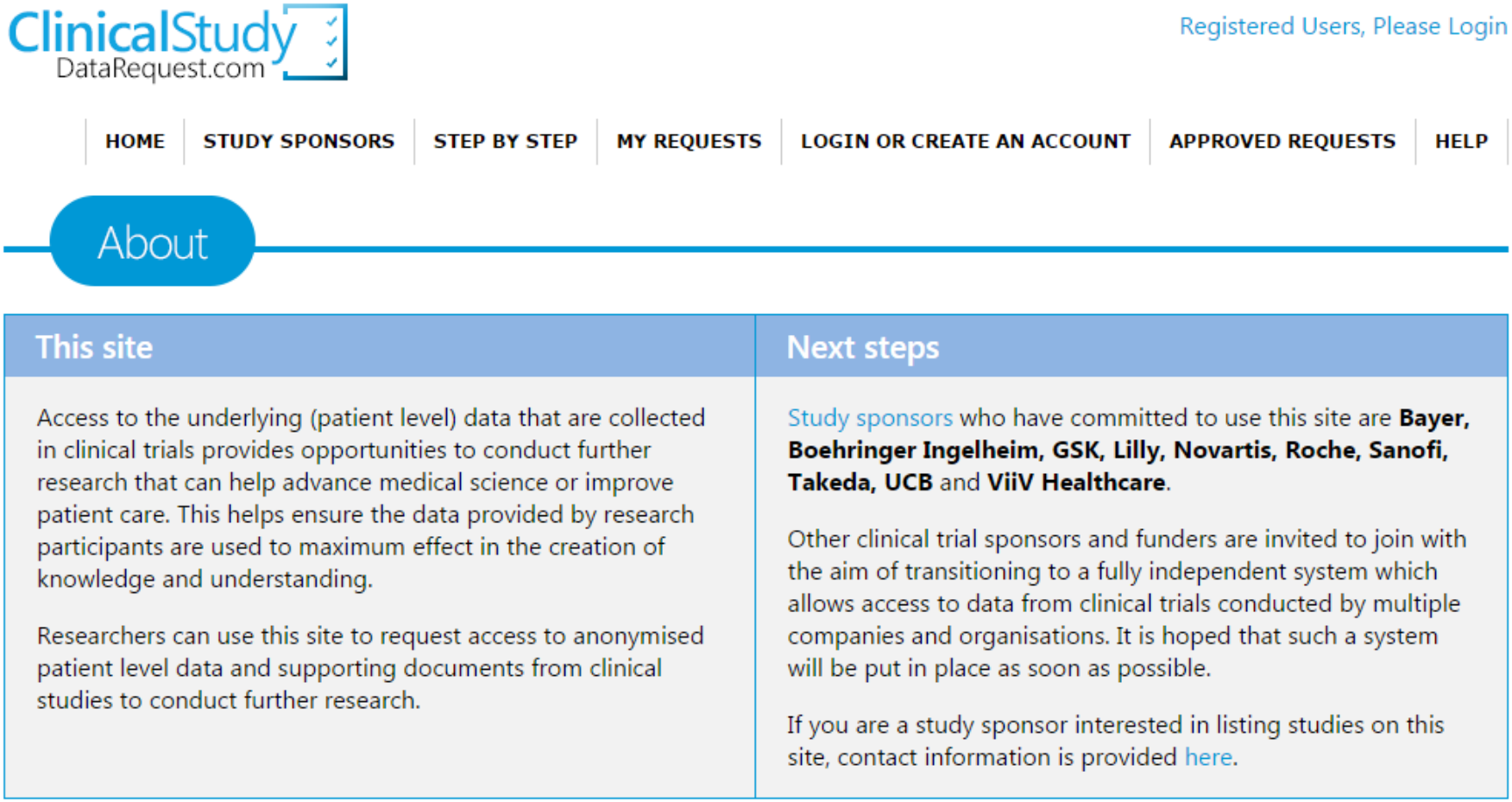

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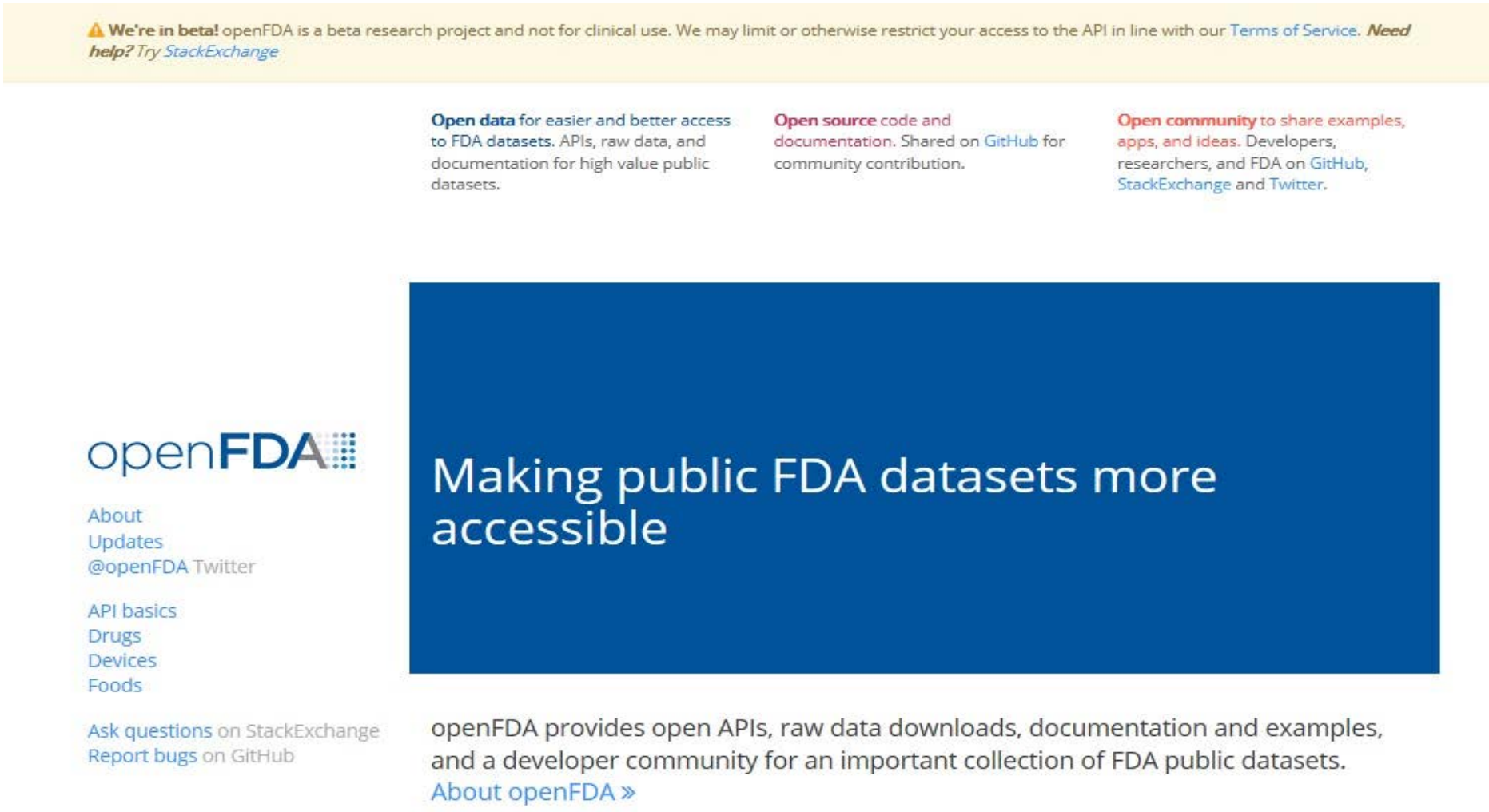
Data Sharing Landscape



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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

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Thanks!

Thank you for participating!

Good-bye

Au Revoir

Auf Wiedersehen

Adios

Ciao