MRCT Multi-Regional Clinical Trials

The MRCT Center of Harvard and Brigham and Women's Hospital

Multi-Regional Clinical Trials Center – FDLI Webinar, November 10, 2015

Building A Learning Community Among Key Stakeholders

Collaborating to Improve Multi-Regional Clinical Trials

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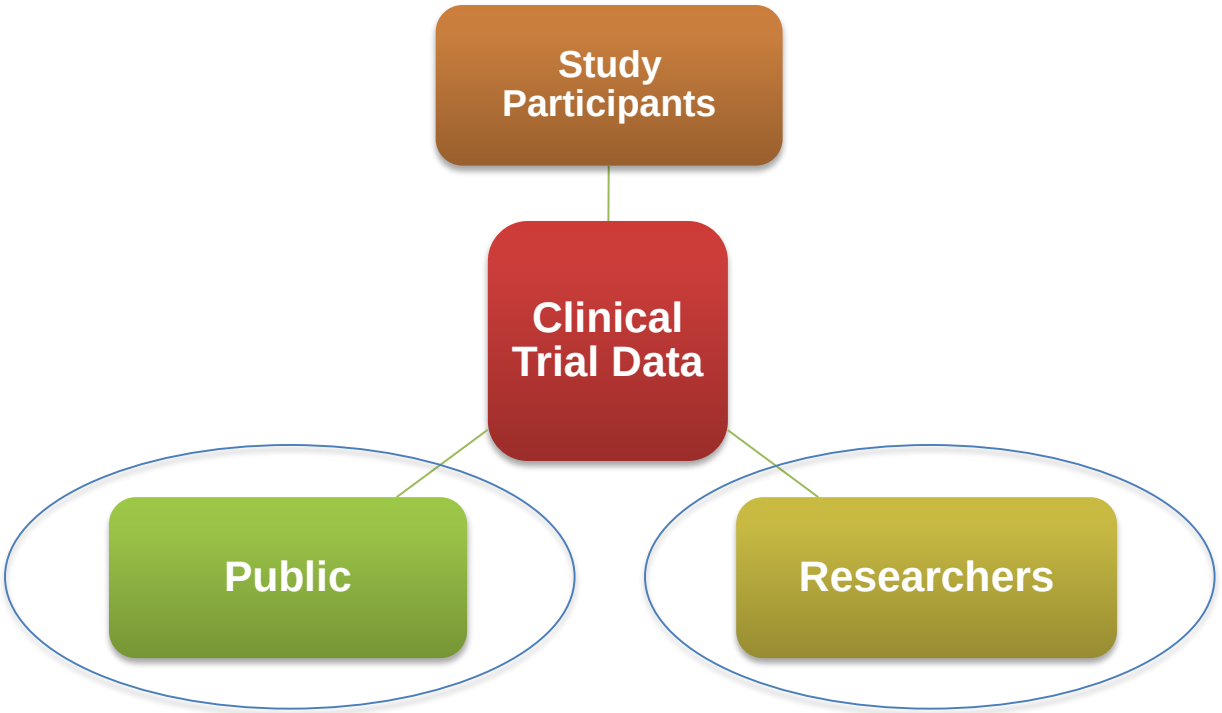
To improve the integrity, safety, and rigor of global clinical trials

Engage diverse stakeholders to define emerging issues in global clinical trials and to create ethical, actionable, and practical solutions.

HARVARD

Clinical Trial Data Sharing and Transparency Project

Data Sharing and Transparency Efforts



- MRCT has spearheaded two major initiatives related to sharing of clinical trials data sharing
  - Return of summary results to participants
  - Data sharing and transparency
    - Registration and results reporting
    - Participant-level data sharing

MRCT Center's Focus in Data Sharing

Timeframe	Milestones
February 2013	Working Group launched with 18 stakeholder organizations
March 2013	Convened 4 sub-groups on key issues: - Rationales for clinical trial data sharing - Safeguarding patient privacy, consent principles - Balancing intellectual property interests - Implications of patient-level data shared in public domain
May 2013	Co-hosted a conference "Issues and Case Studies in Clinical Trial Data Sharing: Lessons and Solutions"

MRCT Center as a Neutral Convener and Implementer of a Consensus Driven Solution

In March of 2015, the MRCT Center hosted a Clinical Trials Data Sharing Conference at Harvard

Attendees included: 70 representatives of pharma, biotech, patient/patient advocates, foundations, academics, journal editors and others for a conference on clinical trials data sharing:

March 2015 Data Sharing Confernece

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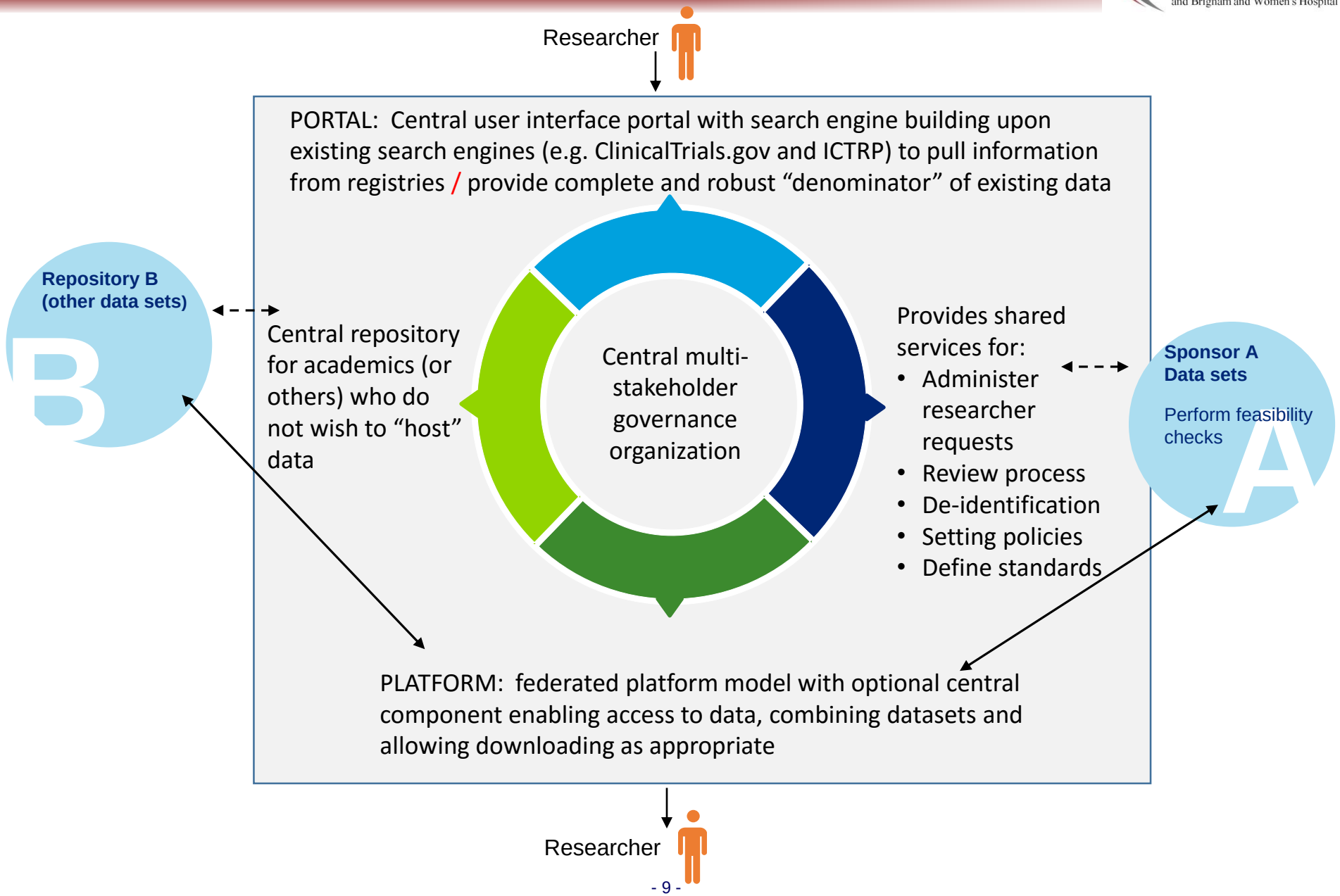
Developed consensus on future strategic vision:

- Expectations and practices of registration and results reporting of all clinical trials would be regularized among industry and academia;
- Greater access to participants-level clinical trial data could be facilitated;
- Researchers would be able to access and combine data across various platforms and sponsors, to multiply opportunities for data analysis; and
- Research participant privacy can be safeguarded

March 2015 Data Sharing Conference: Future Vision

- **Organizational structure and Governance** - A coordinating, centralized, international, not-for-profit organization with accountability;
- **A centralized and single portal** - A central user interface with a robust search engine functionality, including information on trials around the world;
- **Data requirements** – Data standards, definition, data ontology and metadata to allow for and enable the integration of differing datasets for analysis;
- **Shared or common services** – Efficient shared or common services across data generators/sponsors (e.g. policy setting, data de-identification, criteria for independent review panel decisions or reliance, and statistical services); and
- **Flexibility** – Data platform accommodating differing expectations and research needs, including ability to host data for those data generators that do not wish to or cannot do so themselves, access data that is hosted elsewhere, or download data if freely available. Ability to utilize middleware to perform analyses.

Data Sharing: Proposed Model Platform



Recap: Overview of New Data Sharing Platform

To create a blueprint for the creation of a new, not-for-profit organization whose goal is to create, direct, implement and oversee a sustainable data-sharing platform

3 Phases of Realization:

Creation of 3 Workgroups

Operational New Steering Committee

Operational New Entity

Partnering with Wellcome Trust, IOM, Industry, Laura and John Arnold Foundation and Deloitte Consulting to ensure collaborative, sustainable, unified approach to common platform and portal

Recap: Progress to Date

MRCT Governance Working Group

- Created Charter with vision + mission statement
- Developed steering committee specifications

Information Technology (IT) Working Group

- Designated commissioned report specifications
- Developed platform use cases
- Identified data sharing policy issues

Business Models Working Group

- Examined existing sustainable business models through an environmental scan

Data Sharing Working Group Members

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Governance Work Stream

Co-Chairs:
MRCT Center
Wellcome Trust
Arnold Foundation

Team Members:
Mark Barnes **(Ropes & Gray/MRCT)**
Barbara Bierer **(BWH/MRCT)**
Stuart Buck **(Arnold Foundation)**
Nina Hill **(Pfizer)**
Rebecca Li **(MRCT Center)**
Nick Lingler **(Deloitte Consulting)**
Justin McCarthy **(Pfizer)**
Heather Marino **(MRCT Center)**
Sandra Morris **(Johnson & Johnson)**
Jennifer O'Callaghan **(Wellcome Trust)**
Nicola Perrin **(Wellcome Trust)**
Jessica Scott **(GlaxoSmithKlein)**
Paul Seligman **(Amgen)**
Caroline Stockwell **(Pfizer)**
Catrin Tudur Smith **(University of Liverpool)**

IT Work Stream

Co-Chairs:
Ida Sim **(UCSF)**
Barbara Bierer **(MRCT)**

Team Members:
George Alter **(U of Michigan)**
Munther Baara **(Pfizer)**
Vivien Bonazzi **(NIH)**
Brian Bot **(Sage Bionetworks)**
Anne Claiborne **(IOM)**
Khaled El Emam **(U of Ottawa)**
Michael Khan **(U of Colorado)**
Ghassan Karam **(WHO)**
Rebecca Kush **(CDISC)**
Rebecca Li **(MRCT)**
Gene Lichtman **(HCRI)**
Michelle Mancher **(IOM)**
Heather Marino **(MRCT)**
Chris Mavergames **(Cochrane)**
Eric Perakslis **(Takeda)**

Business Models Work Stream

Co-Chairs:
Wellcome Trust
MRCT Center

Team Members:
Barbara Bierer **(MRCT)**
Rebecca Li **(MRCT)**
Peter Lyons **(Deloitte Consulting)**
Heather Marino **(MRCT)**
Nicola Perrin **(Wellcome Trust)**
Rohin Rajan **(Deloitte Consulting)**

Recent Progress: Use Case Documents

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Update on Progress of Data Sharing Project

Recent Progress:

- **Use Case Definition** – a methodology detailing how a user will interact with the platform

- **Use Case Documents** – Developing use case documents to define the scope, utility and feature set of new entity IT platform including:

  - Data Analysis Use Cases
  - Data Submission Use Cases

- **Policy Questions** – Developed related data sharing IT policy questions for inter-workgroup discussions

Initial Use Case List

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1. **Analyzing published and unpublished data from more studies**
   - A data requester wishes to analyze both published and unpublished data from several related studies, with a specific analytic plan in mind.

2. **Research Portfolio Analyses**
   - Having both study designs and individual participant-level data (IPD) results in computable form will allow descriptive analyses of clinical trials, e.g., describing the evidence base for a topic, the research portfolio of a sponsor, what queries and data requests are made on which studies, etc.

3. **Secure Access to Pre-Publication Data Set for Peer Review**

4. **Linkage to Administrative and/or Clinical Data to Extend Study Follow Up**

5. **Submitting a Data Package to be hosted by the Platform**
   - The responsible party for a study wishes to submit a Post-Publication or Full Data Package to the Platform, for hosting by the Platform

6. **Others?**

Data Sharing Policy Question Examples

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Related Data Sharing Policy Issues

- Policy questions generated for Governance Working Group

- **Authorization and Authentication** –
  - Who can establish an account on the Platform?
  - Do data requesters need to have a specific analytic question, or can the request be completely exploratory?
- **Quality of Data and Timelines** –
  - Should platform users be held to identical data sharing standards as the original data generator (i.e. should platform users have to share their analysis results and analytic code back with the platform)?
- **Access & Protection** –
  - What are the policies on which datasets can be downloaded?
  - Must all data depositors use the same de-identification approach?

Data Sharing: Endorsement and Implementation

- Conference in March 2016 in London to discuss the blueprint for the new governance structure and IT platform for all stakeholders
- New not-for-profit entity will commence operation of directing, implementing and overseeing broad data-sharing platform.
- Sustainable, cost-sharing business model for use of data sharing platform will be implemented to support new entity longitudinally.

Invitation to Join Our Efforts

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- Timing – many key players are aligned and behind the MRCT Center Project (industry, academia and non-profits) and the regulatory environment is primed for acceptance
- Impact – this project has the potential for broad impact across medicine
- Commit to data as a public good – ability to leverage vast trove of existing clinical trial data for the public good
- **MRCT Center with key partners are creating a new entity which will provide critical infrastructure and mechanisms for data sharing**

Questions and Discussion