MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Optimizing Public-Private Partnerships for Clinical Cancer Research: A Workshop

The Role of the Research Institution in Data Sharing and Data Governance

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The Multi-Regional Clinical Trials Center (MRCT Center)

The MRCT Center is a research and policy center focused on addressing the conduct, oversight, ethics, and regulatory environment of clinical trials.

Our Vision

Improve the integrity, safety, and rigor of global clinical trials.

Our Mission

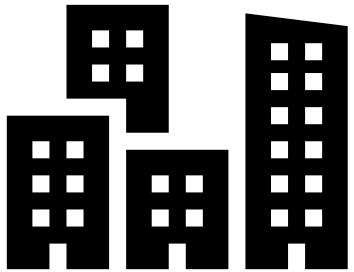
Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.

Brigham and Women's Hospital
Founding Member, Mass General Brigham

HARVARD UNIVERSITY

Data sharing, investigators, and research Institutions

Institutions



Reputation, competitive advantage
Potential revenue from IP/licensing

Required policies and processes
Required systems to support (including anonymization, platform to host, provisions for access)
Compliance and oversight
Costs for unclear gain

Investigators

Reputation
Potential revenue from licensing

Unfunded mandate and expectation
No academic reward
Foreclosing the ability of future trainees to publish
Reuse uncertain for a significant effort

Investigators are not usually data scientists

Data sharing, investigators, and research Institutions

- A continuum from modest enthusiasm to absolute resistance
- Highly dependent on the type of data and the perception of risk:
  basic research → translational research → clinical research
  - Perceived legal restrictions to sharing
  - Privacy protections and confidentiality of participants
    - Risk of HIPAA breach
    - Unanticipated reidentification
  - IP and possible licensing revenue
  - Fear of potential irreproducibility
- For the investigator:
  - The promise of papers to come: point to their trainees and future work
  - Lack of academic credit for data sharing

Moving the needle:

Policies that require data sharing: **Funder requirements**

Gf | Open Access Policy

Not elective
Costs of data sharing are provided
Expectations clear
Oversight exists

Approved repositories, but use is elective
Costs of compliance an issue
Institutions late to the party
    Policies variable
Outcomes assessment important

Moving the needle:

Incentivizing data sharing: **Credit for Data Sharing**

- Evidence-based incentive: Open data badge*

Data

Materials

Analytic Code

Papers

Supplements

COS 10 YEARS
CENTER FOR OPEN SCIENCE
Science Works Best in the Open

https://www.cos.io/blog/badges-for-open-research-practices-available-on-osf-registrations

*Kidwell MC, et al. PLoS Biol. 2016;14(5):e1002456.

Moving the needle:

Incentivizing data sharing: **Credit for Data Sharing**

- Evidence-based incentive: Open data badge
- Incentive structure for investigators
  - Further development of a closed system needed
    - DOI of dataset
    - Attribution for creation
    - Close the loop so DOI, contributor, and downstream use are findable
    - Citation and altmetrics
  - Valued as a promotion criterion
  - Valued as a contribution to grant and other funding applications
- Translate into a traceable system to evaluate investigator contributions and funding portfolio

Moving the needle:

Incentivizing data sharing: **Institutional support**

- Culture and leadership
- Clarify needs to enable FAIR data sharing
  - FAIR: findable, accessible, interoperable, and reusable
  - Data dictionary
  - Data described with shared metadata that is registered and searchable
- Infrastructure to support data sharing (personnel, data management, etc.)
- Support for planning research appropriately: it is way harder to do this well at the end of a study

https://www.go-fair.org

Moving the needle:

Incentivizing data sharing: **Institutional transparency**

- Consent for data sharing is understandable and clear
  - *Not* page 4 of 7 of a hospital consent
  - For clinical data, opt-out (with best efforts to withdraw if consent is withdrawn later)
  - For clinical research data, opt-in optimally (though challenging for reproducibility and concerns for representativeness)

- IT redesign
- Real consequences for misuse

Moving the needle:

Incentivizing data sharing: **Continued research**

- Blockchain platforms for security and user control
- Other differential privacy technologies
- Public and participant opinions pre- and post-education and explanation

Incentivizing data sharing: **Public and community engagement**

Thank you
Questions and Discussion