Sharing Clinical Trial Data
MAXIMIZING BENEFITS, MINIMIZING RISK

Study Context
- Responsible clinical trial data sharing is in the public interest
- Data not analyzed and published in a timely manner
- Advances science that is foundation of clinical care
- Reproduce published findings
- Maximize contributions of participants
- Maximize effort and funds invested in trials
- Momentum for data sharing

Study Context
- Question is not whether to share, but what types of clinical trial data to share, when to share, how to share

Briefing Overview
- Study context and background
- Conceptual framework
- Recommendations

Background
- 23 public and private sponsors
- Committee with diverse expertise, balance
- IOM peer review

Charge to Committee
- Describe types of data, when data are shared, with or without restrictions
- Identify benefits, risks, challenges of sharing for stakeholders
- Make recommendations to enhance responsible sharing of clinical trial data
Key Definitions

• **Data Sharing** is the practice of making data from clinical trials available for secondary research. Data may be shared either proactively or after request.

• **Data include:**
  - Summary data
  - Individual participant data
  - Metadata

• **Secondary research** includes re-analyses, new de novo analyses, meta-analyses.

Key Benefits of Data Sharing

• Other investigators can reproduce published findings, carry out additional analyses
• Strengthens evidence base for regulatory and clinical decisions
• Leads to new ideas for research
• Increases contributions of participants and avoids unnecessary duplicative trials
• Increases scientific knowledge gained from work of clinical trialists, investments by funders

Guiding principles for data sharing

• Maximize the benefits of sharing data while minimizing the risks.
• Respect individual participants whose data are shared.
• Increase public trust in clinical trials and the sharing of trial data.
• Conduct the data sharing in a fair manner.

Multiple stakeholder interests and concerns must be balanced

• Protect participants and maximize contributions
• Clinical trialists publish analyses and get credit for sharing data
• Other investigators analyze data and reproduce findings
• Reduce risk of invalid secondary analyses
• Protect intellectual property and commercially confidential information (CCI)

A Vision for Data Sharing: Advancing the science that is the foundation of medical care

• Culture of sharing with effective incentives and protections
• Multiple interoperable platforms with different models of data sharing
• Best practices for sharing identified and modified in response to evidence
• Sustainable, equitable funding model

Recommendation 1: Stakeholder Responsibilities

Stakeholders in clinical trials should foster a culture in which data sharing is the expected norm...
Recommendation 1: Stakeholder Responsibilities

- **Funders and Sponsors** should require data sharing and provide appropriate support.
- **Investigators** should share data.
- **Journals** should require sharing of analytic data set supporting the published results of a trial.
- **Universities** should require data sharing and consider in promotions.
- **Disease Advocacy Organizations** should educate participants and consider when supporting trials.

Recommendation 2: What data should be shared When

Sponsors and investigators should share the various types of clinical trial data no later than the times specified.

Overview of Clinical Trial Life Cycle

**Milestone:** At trial registration

**What Data:**

- Trial design & registration

**When to Share:** At trial registration

**Milestone:** 12 months after study completion

**What Data:**

- Summary-level results
- Lay summaries

**When to Share:** 12 months after study completion

**Milestone:** Study completion or termination

**What Data:**

- Study completion report
- Lay summary

**When to Share:** Study completion or termination

**Milestone:** Final data sharing

**What Data:**

- Data sharing plan
- Registration elements

**When to Share:** Final data sharing
Recommendation 2 (cont):

Milestone: Publication

When to Share: No later than 6 months after publication

What Data:
- Subset of the analyzable data set supporting the findings, tables, and figures in the publication
- Full protocol, full statistical analysis plan, analytic code

Recommendation 2 (cont):

Milestone:

When to Share: 18 months after study completion

What Data:
- Full analyzable data set
- Full protocol, full statistical analysis plan, analytic code

Recommendation 2 (cont):

Milestone:

When to Share: 30 days after regulatory approval or 18 months after abandonment

What Data:
- Full analyzable data set
- Redacted CSR
- Full protocol, full statistical analysis plan, analytic code

Recommendation 3:

Holders of clinical trial data should
- Employ data use agreements
- Reduce risks
- Enhance scientific value of secondary analyses
- Protect public health
- Independent review panel that includes members of the public should review data requests
- Make public data sharing policies and procedures
- Learn from experience by collecting data on outcomes and sharing information / lessons learned

Recommendation 4:

Stakeholders Should Work Together on Key Challenges Toward a Vision for Data Sharing
Key Challenges

- **Infrastructure**: insufficient platforms to store and manage data
- **Technological**: current platforms are not discoverable, searchable, and interoperable
- **Workforce**: shortage of skills and knowledge to manage operational and technical aspects
- **Sustainability**: small subset of sponsors, funders and trialists cannot continue to bear costs. Those who benefit from sharing should pay fair share.

Recommendation 4:
Stakeholders Should Work Together on Key Challenges Toward a Vision for Data Sharing

The sponsors of this study should take the lead, together with or via a trusted impartial organization(s), to convene a multistakeholder body with global reach and broad representation to address ... [these] challenges ...

Committee Members

- BERNARD LO (Chair), The Greenwall Foundation
- TIM COETZEE, National Multiple Sclerosis Society
- DAVE DEMETS, University of Wisconsin
- JEFFREY DRAZEN, New England Journal of Medicine
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- JOANNE WALDSTREICHER, Johnson & Johnson

Study Sponsors

- National Institutes of Health
- U.S. Food and Drug Administration
- AbbVie Inc.
- Ameba Inc
- AstraZeneca Pharmaceuticals
- Bayer
- Biogen Idec
- Bristol-Myers Squibb
- Burroughs Wellcome Fund
- Doris Duke Charitable Foundation
- Eli Lilly and Company
- EMD Serono
- Genentech
- GlaxoSmithKline
- Johnson & Johnson
- Medical Research Council (UK)
- Merck & Co., Inc.
- Novartis Pharmaceuticals Corporation
- Novo Nordisk
- Pfizer Inc.
- Sanofi-Aventis
- Takeda
- Wellcome Trust

Report and Additional Resources are available for download at: www.iom.edu/datasaring.
Thank you