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 1: Stakeholder Responsibilities

• **Regulatory agencies** should develop Clinical Study Report (CSR) templates and harmonize requirements and practices

• **Institutional Review Board (IRBs)** should
  • Consider data sharing when reviewing clinical trials
  • Provide guidance and templates for informed consent
  • Adopt protections for participants
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:

When to Share:

What Data:
Recommendation 2:

**Milestone:**

**When to Share:** At trial registration

**What Data:**

- Data Sharing Plan
- Registration Elements
Recommendation 2 (cont):

Milestone: Study Completion or Termination

When to Share: 12 months after study completion

What Data:
- Summary-level results
- Lay summaries
Recommendation 2 (cont):

Milestone:  

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: With whom are data shared and under what conditions
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
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 ...
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# Study Sponsors

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- Amgen Inc
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- Biogen Idec
- Bristol-Myers Squibb
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- Doris Duke Charitable Foundation
- Eli Lilly and Company
- EMD Serono
- Genentech
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- 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/datasharing.

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Thank you