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.

  - SUMMARY DATA
  - INDIVIDUAL PARTICIPANT DATA
  - METADATA

• **Data include:**

• **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.
- **Membership and professional societies** should require data sharing as a condition for submitting abstracts and promote use of common data elements.
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:

1. Trial Design & Registration
2. Participant Enrollment
3. Study Completion or Termination
4. Publication
5. Regulatory Application?
   - Yes 5A
   - No 5B

When to Share:

What Data:
Recommendation 2:

**Milestone:**

**When to Share:** At trial registration

**What Data:**

1. Trial Design & Registration
2. Data Sharing Plan
3. Registration Elements
Recommendation 2 (cont):

**Milestone:**

**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

- National Institutes of Health
- U.S. Food and Drug Administration
- AbbVie Inc.
- Amgen 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/datasharing.

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Thank you