Sharing Clinical Trial Data

MAXIMIZING BENEFITS, MINIMIZING RISK

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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

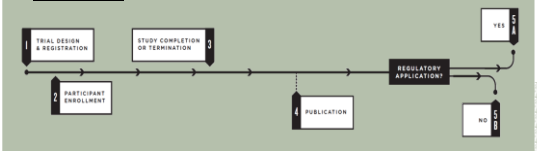
- **Regulatory agencies** should develop Clinical Study Report (CSR) templates and harmonize requirements and practices
- **Institutional Review Board (IRBs)** should
  - Consider data sharing when reviewing clinical trials
  - Provide guidance and templates for informed consent
  - Adopt protections for participants
- **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:



When to Share:

What Data:

Recommendation 2:

Milestone: 1 TRIAL DESIGN & REGISTRATION

When to Share: At trial registration

What Data:

Recommendation 2 (cont):

Milestone: STUDY COMPLETION OR TERMINATION 3

When to Share: 12 months after study completion

What Data:

Recommendation 2 (cont):

Milestone:

When to Share: *No later than* 6 months after publication

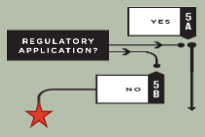
What Data:

POST-PUBLICATION DATA PACKAGE

- 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

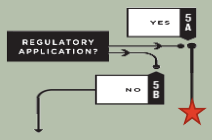
What Data:

FULL DATA PACKAGE

- 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:

POST-REGULATORY DATA PACKAGE

- 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

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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