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Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk

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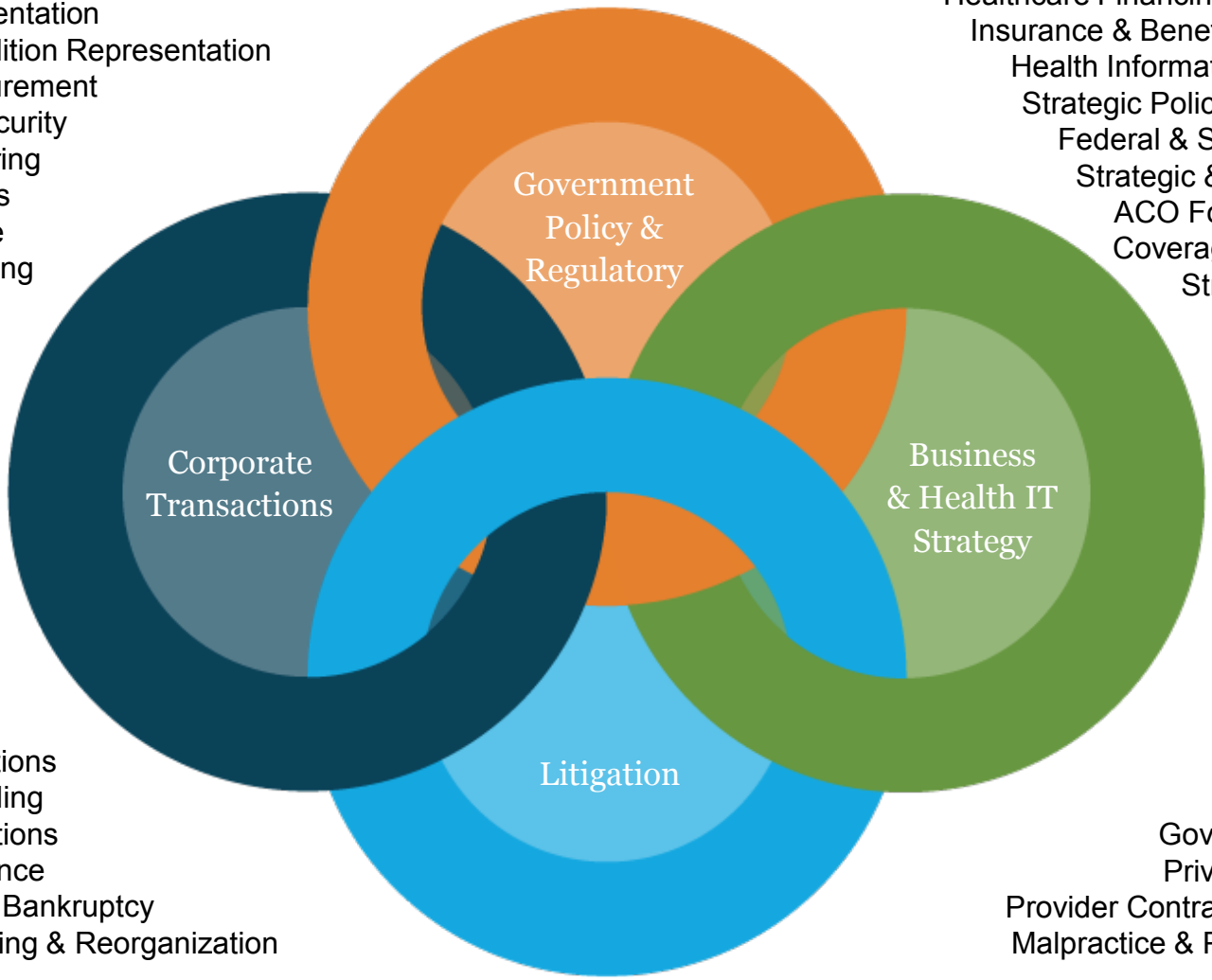
Our Mission is to be a practice whose multidisciplinary professionals, through excellence, deep substantive knowledge and teamwork, support clients seeking to transform America's health system by expanding coverage, increasing access and creating new ways of organizing, paying for and delivering care.

- Interdisciplinary team with over 80 professionals:
- Pharmaceutical strategy: health reform, pricing, Medicare reimbursement, regulation of research, approval, manufacturing and marketing of medicines
- Provider strategy: IDNs, academic medical centers, children's health, ACO formation
- Privacy and security
- Mergers, acquisitions, joint ventures
- Corporate structure and governance
- Medicaid program evaluation and redesign
- Payer strategy: provider-sponsored plans
- Health information exchange, health IT
- Insurance

Manatt Health: Interdisciplinary Services

Congressional, Federal & State Agency Representation
Association & Coalition Representation
Government Procurement
Data Privacy & Security
Legislative Monitoring
Legislative Analysis
HIPAA Compliance
Language Drafting
Reimbursement
Fraud & Abuse
Lobbying



Healthcare Financing & Reimbursement
Insurance & Benefit Exchange Design
Health Information Exchange (HIE)
Strategic Policy & Market Analysis
Federal & State Policy Advisory
Strategic & Financial Planning
ACO Formation & Planning
Coverage & Access Design
Strategic Partnerships
Health IT Strategy
Business Strategy

Contracts
Antitrust
Compliance
Accreditation
Joint Ventures
Tax Exemption
Corporate Finance
Mergers & Acquisitions
Investment & Funding
Physician Transactions
Nonprofit Governance
Credit Recovery & Bankruptcy
Corporate Structuring & Reorganization

Real Estate
Knox-Keene
False Claims
Investigations
Reimbursement
Creditor's Rights
Fiduciary Liability
Contract Disputes
Unfair Competition
Government Regulation
Privacy & Ethics Issues
Provider Contracting Arrangements
Malpractice & Professional Liability

Briefing Overview

- Discuss "Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk," report released by an IOM Committee in January 2015.
  - Study context and background
  - Recommendations
- Slides rely on material developed by the IOM to help disseminate the report.

Study Context

- Responsible clinical trial data sharing is in the public interest
  - Data now not analyzed and published in a timely manner
    - One-third of trials not publish results after 4 years
  - Advance science that is foundation of clinical care
  - Reproduce published findings
  - Maximize contributions of participants
  - Maximize effort and funds invested in trials
- There is momentum for data sharing
- Question is not whether to share, but ***what*** types of clinical trial data to share, ***when*** to share, ***how*** to share

Background

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

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

STEVE GOODMAN, Stanford University School of Medicine

PATRICIA KING, Georgetown University Law Center

TRUDIE LANG, Nuffield Department of Medicine, University of Oxford

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ELIZABETH NABEL, Brigham and Women's Hospital

ARTI RAI, Duke University School of Law

IDA SIM, University of California, San Francisco

SHARON TERRY, Genetic Alliance

JOANNE WALDSTREICHER, Johnson & Johnson

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

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

Poll

- Where is your organization with respect to sharing of clinical trial data? (Select the answer that most closely represents your organization's status.)
  - We are already sharing at least some clinical trial data.
  - We are pursuing how to share clinical trial data.
  - We have not yet considered whether or not we will share clinical trial data.
  - We likely will never share clinical trial data.
  - This question is not applicable to my organization.

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.
  - **Secondary research** includes re-analyses, new de novo analyses, meta-analyses
- **Data include:**

Key Benefits of Data Sharing

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

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.

Stakeholder interests, concerns, perceptions of risk

- 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).

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

Stakeholder Responsibilities

- Stakeholders in clinical trials should foster a **culture** in which data sharing is the **expected norm …**

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.

Stakeholder Responsibilities

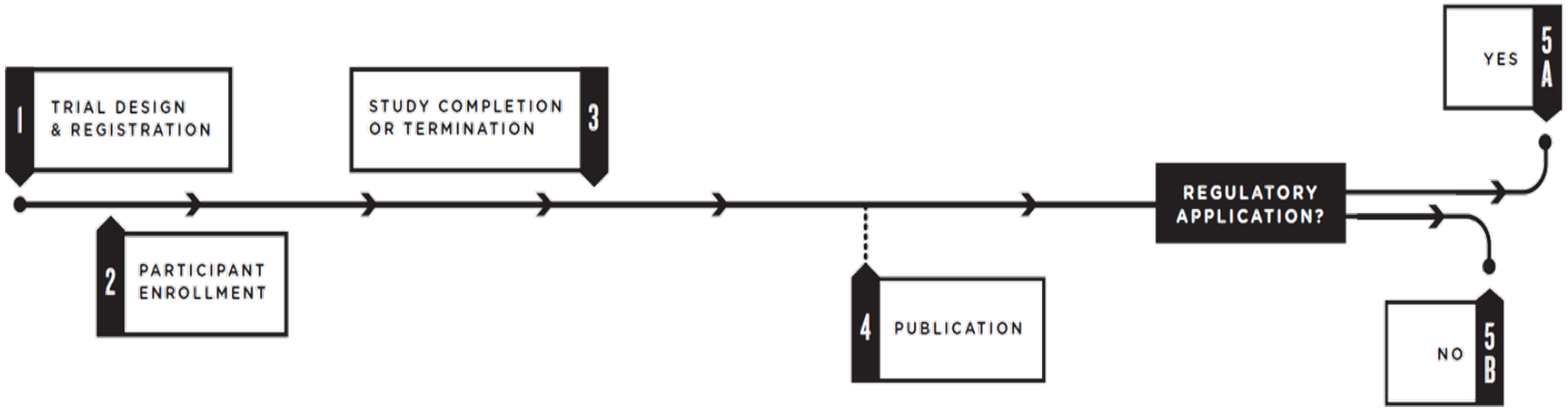
- **Regulatory agencies** should develop Clinical Study Report (CSR) templates and harmonize requirements and practices.
- **Institutional Review Board (IRBs)** should
  - Consider data sharing when reviewing clinical trials.
  - Provide guidance and templates for informed consent.
  - Adopt protections for participants.
- **Membership and professional societies** should require data sharing as a condition for submitting abstracts and promote use of common data elements.

What data should be shared and *When*?

- Sponsors and investigators should share the various types of clinical trial data no later than the times specified. Sponsors and investigators who decide to make data available for sharing before these times are encouraged to do so.

Overview of Clinical Trial Life Cycle

Milestone:



When to Share:

What Data:

Recommendation 2:

Milestone:

When to Share: At trial registration

What Data:

Recommendation 2 (cont):

Milestone:

When to Share: 12 months after study completion

What Data:

SUMMARY-LEVEL RESULTS

LAY SUMMARIES

Recommendation 2 (cont):

Milestone:

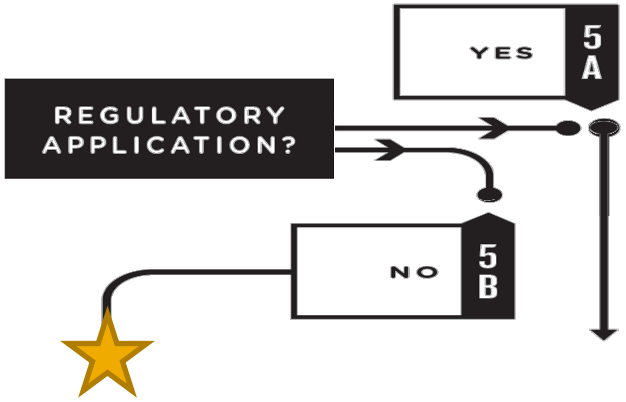
When to Share: *No later than* 6 months after publication

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:



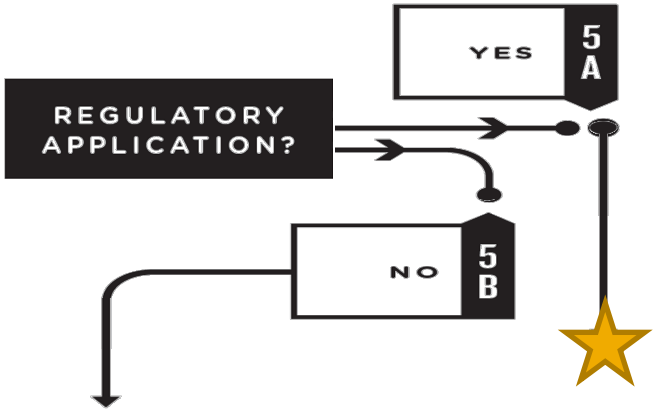
When to Share: 18 months after study completion

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:

POST-REGULATORY DATA PACKAGE

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

Recommendation 3:

With whom should data be shared and under what conditions?

Holders of clinical trial data should mitigate the risks and enhance the benefits of sharing sensitive clinical trial data by implementing operational strategies that include:

- **Employing data use agreements:**
  - Reduces risks
  - Enhances scientific value of secondary analyses
  - Protects public health
- **Employing appropriate privacy protections**, in addition to de-identification and data security
- **Designating an independent review panel, including members of the lay public**
- **Making access to clinical trial data transparent**

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 trusted impartial organization(s), to convene a multistakeholder body with global reach and broad representation to address, in an ongoing process, the key infrastructure, technological, sustainability, and workforce challenges associated with the sharing of clinical trial data.

- **Infrastructure:**
  - Insufficient platforms to store and manage data
  - Bring query to data
- **Technological:**
  - Current platforms not discoverable, searchable, and interoperable
  - Common data model
  - Common data elements
- **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.

Poll

- What do you think is the biggest challenge to clinical trial data sharing?
  - Financial sustainability
  - Privacy of data subjects
  - Risks to intellectual property
  - Insufficient incentives to share
  - Other

Dissemination of Report

- Sponsor briefings held January 9-14, 2015
- Public release event and webinar January 15, 2015
- Committee briefings to OSTP and Senate HELP Committee February 5, 2015
- Genetic Alliance webinar
- AAAS annual meeting and AMIA Joint Summit session on report (upcoming)
- Meetings with AAHC, AAMC

Next Steps

- Continue to pursue dissemination activities.
- Work with other IOM Roundtables to form a Cross Forum Action Collaborative that could:
  - Provide support and venue for coordination among stakeholders engaged in activities.
  - Identify priority issues, convene stakeholders, or otherwise support implementation activities where appropriate.

Report and Additional Resources are available for download at:

www.iom.edu/datasharing

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Questions and Answers

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Education

- **Georgetown University Law Center, J.D., magna cum laude, and L.L.M.**
- **Johns Hopkins School of Hygiene and Public Health, M.P.H.**
- **University of Maryland, B.A., magna cum laude.**

About

Ms. McGraw provides legal, regulatory and strategic policy and business counsel to healthcare providers, payers and other healthcare organizations with respect to the adoption and implementation of health IT and electronic health information exchange. Her areas of focus include HIPAA/privacy advice and compliance, data security, data governance, research and health data analytics, health IT policy, and patient engagement.

Previously, Ms. McGraw was the Director of the Health Privacy Project at the Center for Democracy & Technology (CDT). In this role she led efforts to develop and promote workable privacy and security protections for electronic personal health information. Ms. McGraw's background includes service on a number of committees established by the U.S. Department of Health and Human Services (HHS) and other workgroups to provide guidance on a wide array of health IT, privacy and security policy and business issues. She was one of three persons appointed by former HHS Secretary Kathleen Sebelius to serve on the HIT Policy Committee. Within the committee, she serves on the Meaningful Use workgroup, chairs the Privacy and Security Tiger Team and is cochair of the Information Exchange workgroup. She has also served on two key workgroups of the American Health Information Community (AHIC), the federal advisory body established by HHS in the Bush Administration, and on the Policy Steering Committee of the eHealth Initiative and currently serves on its Leadership Committee. She serves on the Steering Committee of the Electronic Data Methods Forum and leads policy work for the Patient-Centered Outcomes Research Network.