“Finding New Solutions to Problems and Concerns in Clinical Data Sharing – Outcomes from Datathon"

Session 7

Rebecca Li, PhD Executive Director, Vivli

Co-Faculty Director Research Ethics,
Center for Bioethics, Harvard Medical School

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Agenda

1. The Vivli Global Platform for data sharing
2. Vivli Datathon sponsored by Microsoft

Why it matters

Reduce duplication of trials

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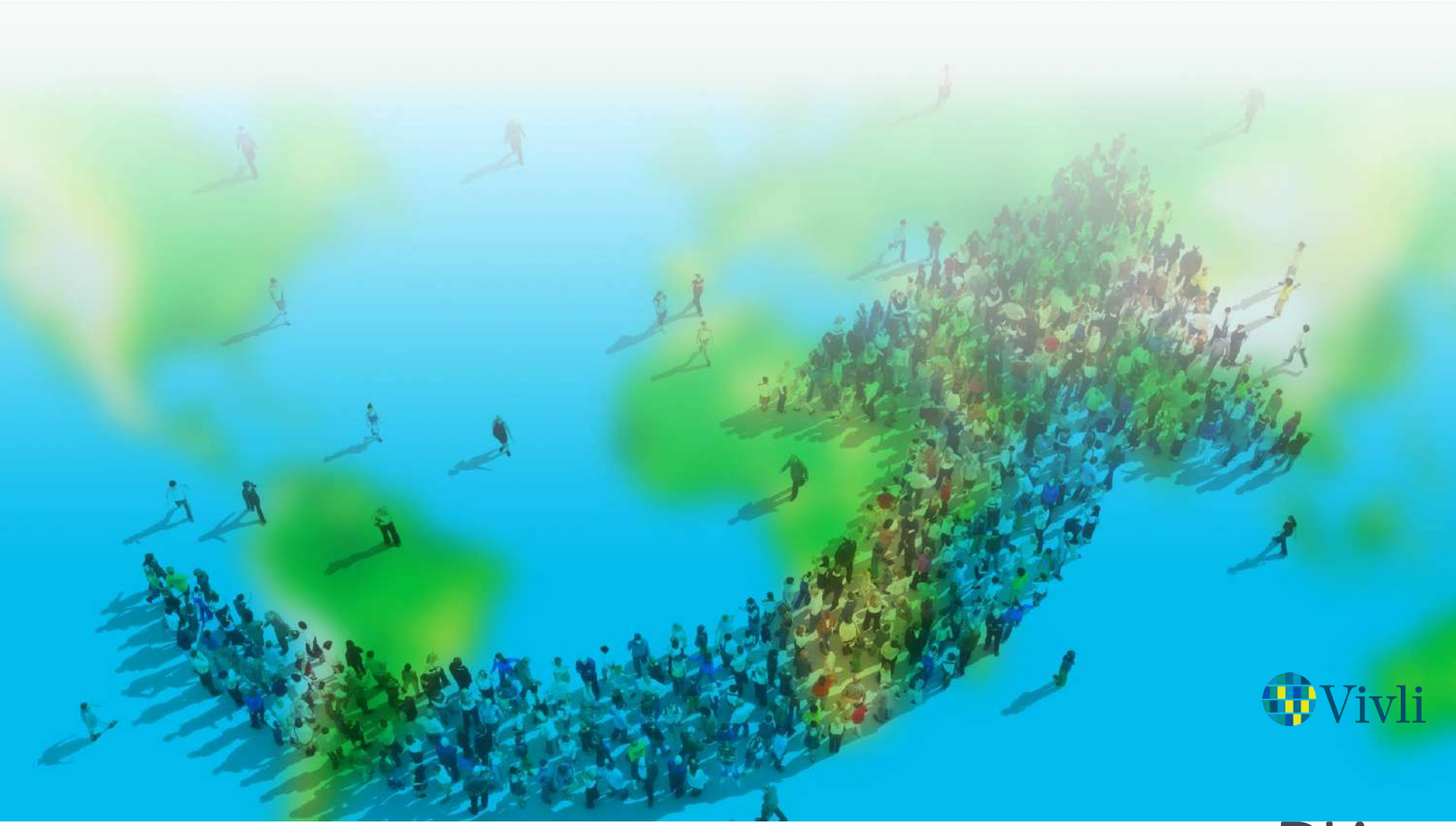
Shape clinical trial design



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Leverage patient contribution

Benefits for Data Contributors

Increase searchability of studies by sharing through a Global Platform

Harmonization for increased efficiency

Reduced workload

Benefits for Researchers

Funder and journal mandates

Analyze and aggregate data

User support services

1. Why Should We Share Our Clinical Research Data

- Funder requirements
- Journal requirements (new as of 2018)
- Publicly stated commitments for industry (BIO, EFPIA, PhRMA)
- Drive new science (integrate data to drive new insights faster)
- Ethical obligations to trial participants
- Enhance and advance your career

What are Journals Requiring as of July 1, 2018?

The NEW ENGLAND JOURNAL of MEDICINE

EDITORIALS

Data Sharing Statements for Clinical Trials — A Requirement of the International Committee of Medical Journal Editors

The International Committee of Medical Journal Editors (ICMJE) believes there is an ethical obligation to responsibly share data generated by

explained at www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html. If the data sharing plan

Taichman DB, et al. N Engl J Med 2017; 376:2277-2279

- Major journals including NEJM, JAMA, The Lancet, BMJ, Annals of Internal Med, PLoS Medicine, and hundreds of others (ICMJE)
- Trial manuscripts must be submitted with a data sharing statement
  - Must describe how you will share your Individual participant-level data (IPD), including who, what, when, where, and why
- IPD sharing is not (yet) required but "editors may take into consideration data sharing statements when making editorial decisions"

Declaring Your Data Re-use Plans as part of the Trial Registration Record… before the 1st patient is enrolled

- Data sharing plan is part of the ClinicalTrials.gov registration record
- **As of 1 January 2019, ICMJE requires registration of your data sharing plan at time of trial registration.**

12. IPD Sharing Statement

Plan to Share IPD

Definition: Indicate whether there is a plan to make individual participant data (IPD) collected in this study, including data dictionaries, available to other researchers (typically after the end of the study). Select one.

- Yes: There is a plan to make IPD and related data dictionaries available.
- No: There is not a plan to make IPD available.
- Undecided: It is not yet known if there will be a plan to make IPD available.

http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html

Note: Undecided is not allowed as a choice for the ICMJE but is a choice in CT.gov

“Patients don’t have patience”

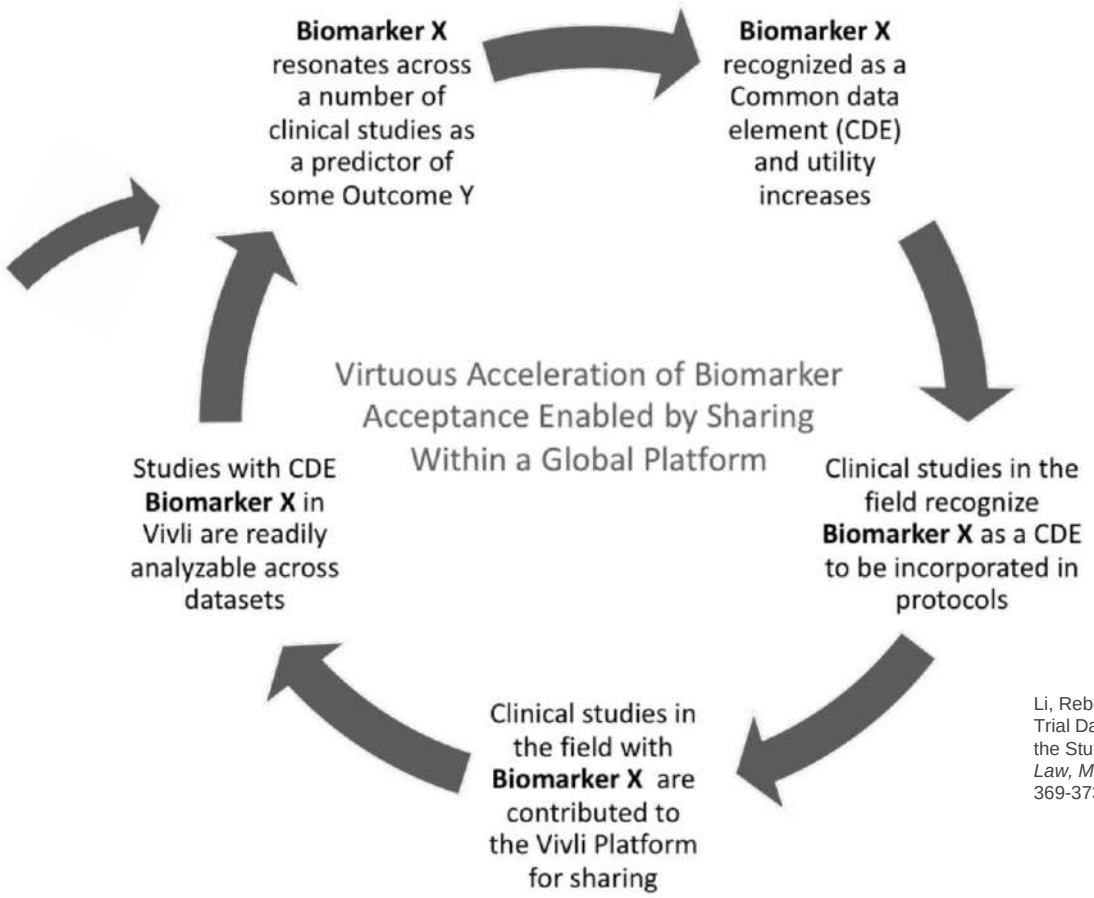
Why is data used only one time to answer one question (the primary endpoint) rather than leveraging participants’ contributions to answer multiple questions to understand disease and find treatments?

Data Sharing May Drive Adoption of CDEs

Datasets with variations of Biomarker X mapped to e.g., a common CDISC variable

Figure 1

Vision of Virtuous Cycle of Sharing and Advancement of Biomarker Science Using the Vivli Platform



Li, Rebecca, and Ida Sim. "How Clinical Trial Data Sharing Platforms Can Advance the Study of Biomarkers." *The Journal of Law, Medicine & Ethics* 47, no. 3 (2019): 369-373.

Introducing Vivli

THE ENTITY

- Non-profit organization
- Convening function
  - Biomedical industry (pharma, bio, device)
  - Academia
  - Non-profit funders and foundations
  - Government (funders and regulators)
  - Patient/patient advocates
- Governance and policy
  - Harmonizing language & agreements
  - Move culture of data sharing
- Advocacy
  - Lowering barriers
  - Promoting incentives
- Oversight of implementation

THE PLATFORM

- A user-friendly, secure, state-of-the art data sharing and computing platform
- Serving the international community, including trials from any disease, country, sponsor, funder, or investigator
  - Open search
  - Robust security
  - Modern tools and technologies

Vivli's Diverse Membership

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Vivli

CENTER FOR GLOBAL CLINICAL RESEARCH DATA

How to Access Data in Vivli?

Secure Environment Bridges Multiple Platforms

- STATA
- MS Office
- R
- Jupyter Notebook
- Python
- SAS

BioLINCC
Biologic Specimen and Data Repository Information Coordinating Center

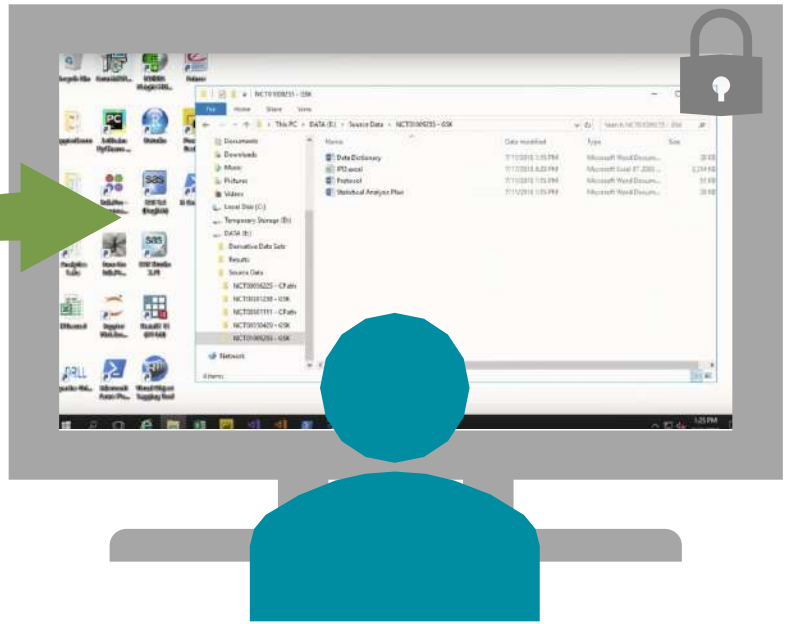
Johnson & Johnson

ImmPort
Bioinformatics For The Future Of Immunology

Project Data Sphere®

gsk do more feel better live longer

Vivli Secure Environment



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Vivli is a Global Data Platform – Agnostic to Disease, Funder or Data Contributor

Data Request and Access Process through Vivli

SEARCH

Search Vivli platform for information about available studies.

REQUEST

Request IPD data package.

Each Data Request **reviewed** according to contributor's publicly stated requirements.

ACCESS

Access data from approved requests in Vivli's secure research environment or **downloaded** with permission.

ANALYZE

Use robust **analytical tools** to combine and analyze multiple data sets.

DISSEMINATE

Completed **research results** assigned a DOI.

Researchers may use the Vivli platform to meet their **publication** requirements.

Vivli-Microsoft Datathon Scientific Objective

- **Background** - More than 60 individuals formed 11 teams and participated in the first Vivli Microsoft Data Challenge. Participants were from universities, hospitals, pharmaceutical, biotech and software companies.

- **Objective** – To find innovative solutions for how to safeguard participant privacy and minimize privacy loss while maintaining the scientific analytic value of the data for rare disease data sets that are more highly identifiable.

Microsoft

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Datathon Video

Log on to

Vivli.org

- Explore the ~thousands of trials available via the Vivli platform
- Begin your search
- Contact support@vivli.org with questions

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