Vivli

CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Clinical Trial Data Sharing and Reuse
A New Reality for Researchers

Ida Sim, MD, PhD, Professor of Medicine, UCSF and Vivli Co-Founder

Rebecca Li, Vivli Executive Director
Faculty Co-Director of Research Ethics, Harvard Center for Bioethics
Harvard Medical School

October 2019

Agenda

1. Why share data?
2. What is the role of data standards in data sharing and reuse?
3. The Vivli Global Platform for Clinical Data sharing and Reuse as a use case

Vivli

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

Vivli

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"

Vivli

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

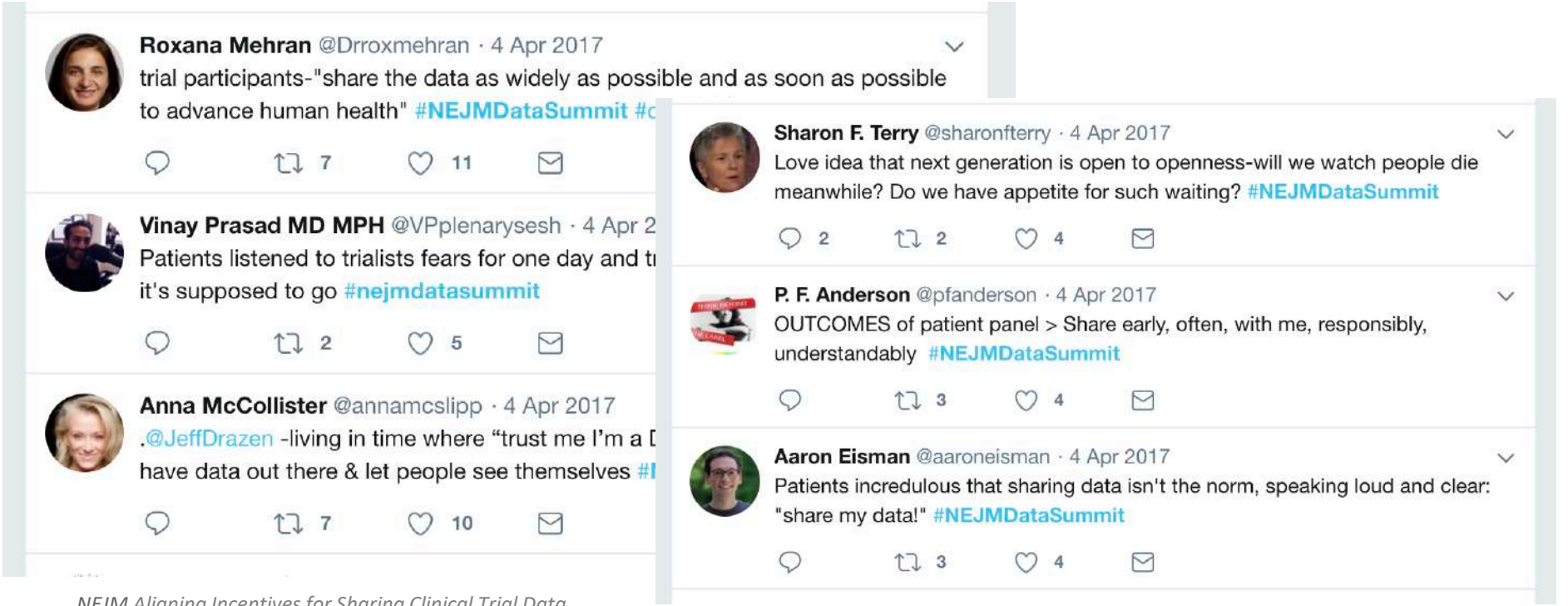
Definition: Indicate whether there is a plan to make individual participant data (IPD) collected in this study, including data dictionaries, available to other researchers (typically after the end of the study). Select one.

- 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.

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

Vivli

Many Patients Expect Data Sharing and Reuse



NEJM Aligning Incentives for Sharing Clinical Trial Data Summit, Boston, MA. April 2017

Vivli

“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?

Vivli

Barriers to Data Sharing (IPD) for Academics

- For most academic trialists (Data Contributors)
  - secure data hosting and sharing platforms not available or limited to within the institution
  - no standard data use agreements
  - no independent review process available to adjudicate data requests
  - cost and difficulty of de-identifying IPD and making it available
  - **All this makes it difficult to meet data sharing requirements**
- For Data Users
  - difficult to discover what IPD is available for sharing
  - **combining datasets from different platforms is resource- and time-intensive**
  - **different data standards, data requirements, security standards, policies**

The Role of Data Standards in Data Sharing and Reuse

- Increasing the number of datasets that use data standards will allow meta-analysts to more easily harmonize and integrate studies and perform analyses such as:
  - Conducting new subgroup analyses
  - Model prognostic or diagnostic data
  - Aggregate studies with time to event outcomes such as survival

What Data is Shared Through Vivli?

Item	Description
Recommended Set	
Study protocol	**Final protocol with all amendments**
Data dictionary	**Detailed descriptions of each variable in the dataset, including the definition, source, coding, etc. of the variable**
Statistical Analysis Plan	**Description of the principal features of the analyses described in the protocol**
Clinical Study Report (CSR)	**Report that summarizes the efficacy and safety data from the study (after regulatory decision)**
IPD dataset	**Final cleaned individual participant-level data, de-identified/anonymized**
Optional	
Analytic code	Software code used to carry out prespecified and additional analyses
Analysis ready IPD dataset	Dataset in a format used to carry out a sponsor's analyses
Case report forms	Forms used to collect the data that is described in the protocol for each trial participant

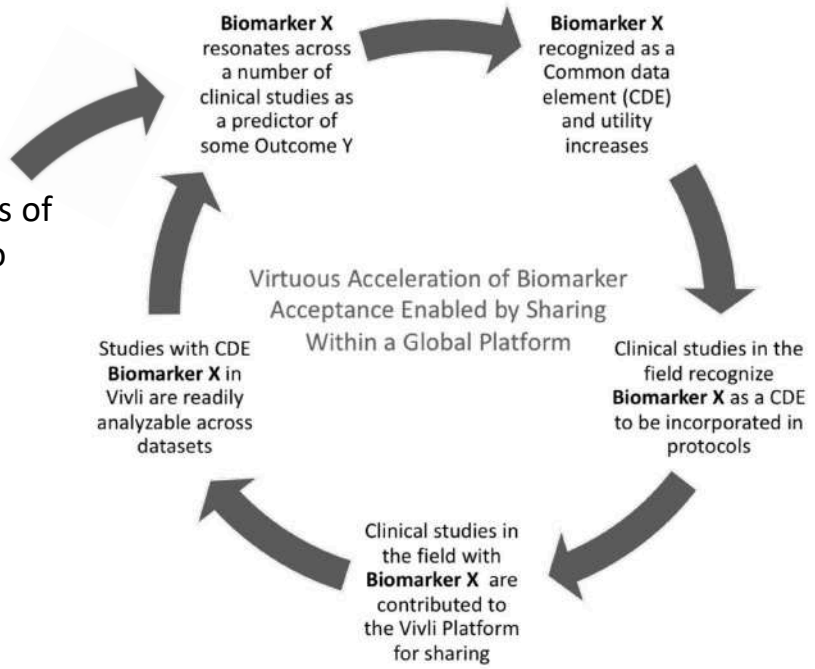
NOTE: *this is a subset of the entire full data package and includes the data that underlies the publication findings (tables, figures)

VIVLI

Data Sharing May Drive Adoption of CDEs

Figure 1

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



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

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.

Vivli

Agenda

1. Why share data?
2. What is the role of data standards in data sharing and reuse?
3. **The Vivli Global Platform for Clinical Data sharing and Reuse as a use case**

Vivli

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 Solution Models for Data Sharing

Institutional Sharing

- Institutional membership
- Ensures all researchers at an institution or division have access to a central sharing resource
- DOI minted for credit and citation

Individual Researcher/ Team Sharing and Reuse

- Covers single publication or trial
- Recognizes life cycle of grant is not the same as life cycle of sharing
- DOI minted for credit and citation

Vivli Diverse Membership

Summary: Benefits of Sharing through Vivli

- **Ease of sharing** - Sharing de-identified data is facilitated through either institutional memberships in Vivli or individually per dataset
- **Citation** – DOIs allow for citation and credit of your research data
- **Metrics** – Yearly metrics on number of data requests, resulting publications, etc.
- **Long-term archiving** – Archive your trials on Vivli (at least 25 years)
- **Post-grant data sharing** – Management of IPD sharing that continues even after grant funds end
- **Funder and journal mandates** – Easily fulfill requirements for data sharing plans

Vivli

Vivli

CENTER FOR GLOBAL CLINICAL RESEARCH DATA

How to Access Data in Vivli?

Secure Environment Bridges Multiple Platforms

BioLINCC
Biologic Specimen and Data Repository Information Coordinating Center

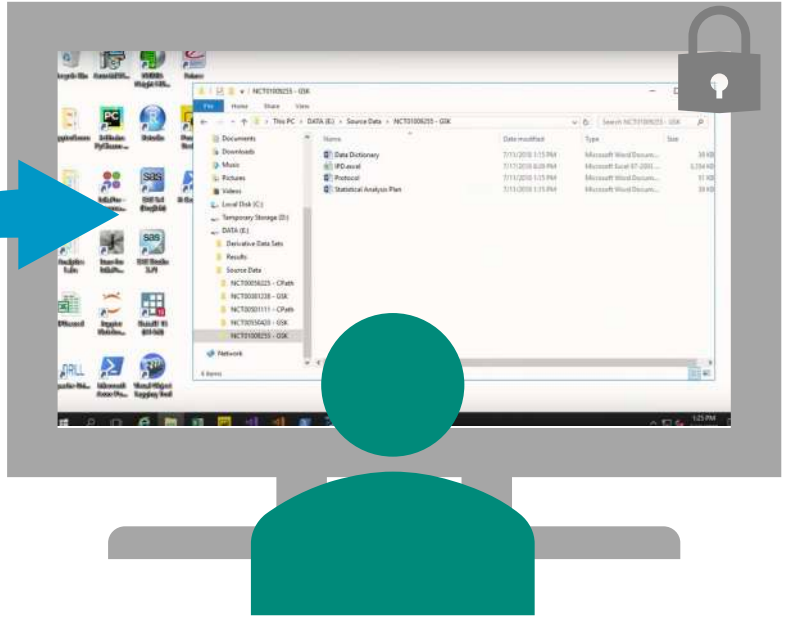
Johnson & Johnson

ImmPort
Bioinformatics For The Future Of Immunology

Project Data Sphere®

gsk do more feel better live longer

Vivli Secure Environment



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

Vivli

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

Vivli

Data Request and Access Process

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

Log on to

Vivli.org

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

Vivli