Vivli

CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Responsible data-sharing to improve research integrity

November 2020

Julie Wood, Vivli

Vivli: The Difference Data Re-Use Can Make

Balancing Risks and Benefits

Openness

Maximizing the value of the data collected respects participants' contributions

Privacy

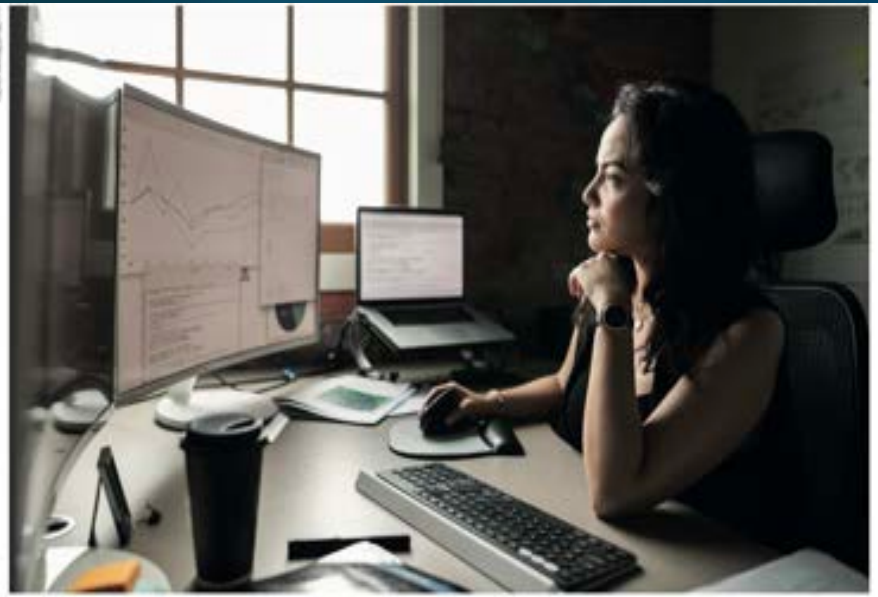
Protecting participant privacy, particularly when sharing individual patient-level data (IPD)

Approaches to Sharing Human Data

Type	Key Features	Examples
Open access	Anyone can access, simple account creation, simple on-line Data Use Agreement (DUA)	Health CAN, EMA, Project Datasphere
Managed access	• for scientific purposes only (standard request form) • (independent) review process • secure environment for data access • clear legal framework	**Vivli, CSDR, SOAR, VISTA**
Restricted access	Invitation only, access only to those who provide data	DataCelerate, IBD Plexus

Challenges with Data Sharing

Vivli



Data sharing can be complex for scientists to navigate, but the rewards are often career-enhancing.

OPEN SCIENCE

Setting your data free

As science becomes more open, researchers who share data are reaping the benefits.

BY GABRIEL POPKIN

Ecologist Thomas Crowther knew that scientists had already collected a vast amount of field data on forests worldwide. But almost all of those data were sequestered in researchers' notebooks or per-

in CSV files (plain-text files that contain a list of data) on servers at Crowther's present laboratory at the Swiss Federal Institute of Technology in Zurich and on those of a collaborator at Purdue University in West Lafayette, Indiana; he hopes to outsource database storage to a third-party organization with expertise

current state of science: partly open, partly closed, and with unclear and inconsistent policies and expectations on data sharing that are still in flux. High-level bodies such as the US National Academies of Sciences, Engineering, and Medicine and the European Commission have called for science

Caiaimage/Rafal Rodzoch

"A love letter to your future self": What scientists need to know about FAIR data

Nature May 2019

Challenges with Data Sharing

- “The secondary requester will be unfamiliar with the data set structure or analysis unduly alarm the public or hinder science rather than advance science”
- “What if they find something a mistake in my trial dataset?”
- Providing academic credit
- Clinical trials take years to design, conduct and analyze is this fair?
- “Won’t this stifle innovation and new science?”

Vivli

Developing a data sharing program

1. Why should we share?
2. What are the key components of a data sharing program?
3. When should we begin a program?
4. How can we manage a data sharing program?
5. What is the role of a partner such as Vivli?

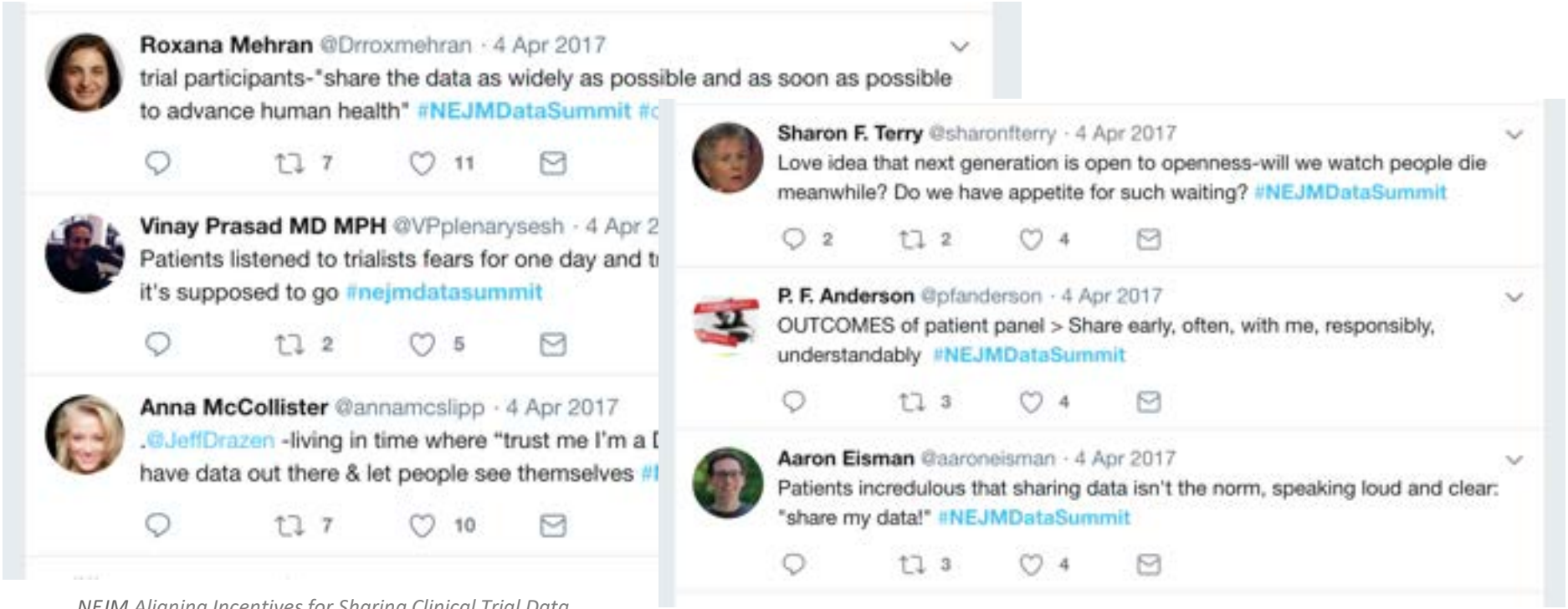
CONFIDENTIAL - Not for distribution

1. Why Should My Organization Share Its Data?

- Ethical obligations to trial participants
- Journal requirements
- BIO, EFPIA, PhRMA, IFPMA publicly stated commitments for members

Vivli

Patients Expect Data Sharing and Reuse



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

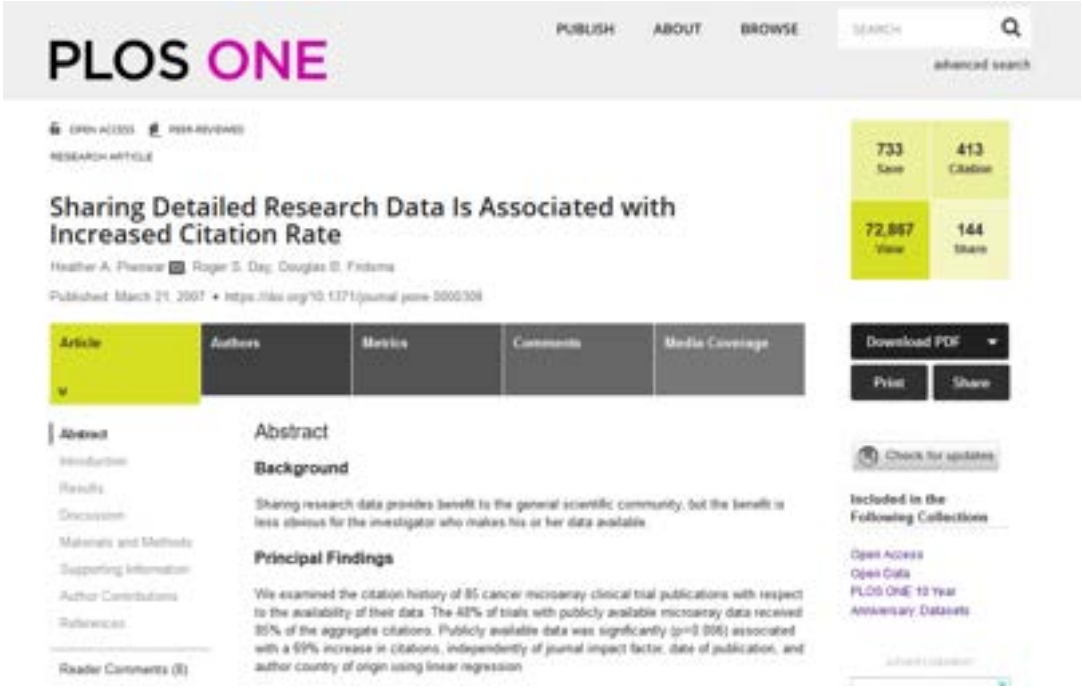
What Do Surveys Show Regarding Patient and Participant Preference Regarding Data Sharing?

- High levels of support for data sharing; however, patients are reluctant to have their data “commodified” purely for commercial gain [1]
- If adequate safeguards were in place, trial participants are willing to share their data[2]

[1] Davidson S, McLean C, Treanor S, Aitken M, Cunningham-Burley S, Laurie G, et al. Public acceptability of data sharing between the public, private and third sectors for research purposes. Edinburgh: Scottish Government Social Research; 2013.Google Scholar

[2] Mello, Michelle M., Van Lieou, and Steven N. Goodman. "Clinical trial participants’ views of the risks and benefits of data sharing." *New England Journal of Medicine* 378.23 (2018): 2202-2211.

Not only is it the right thing to do, it also helps increase citation rate

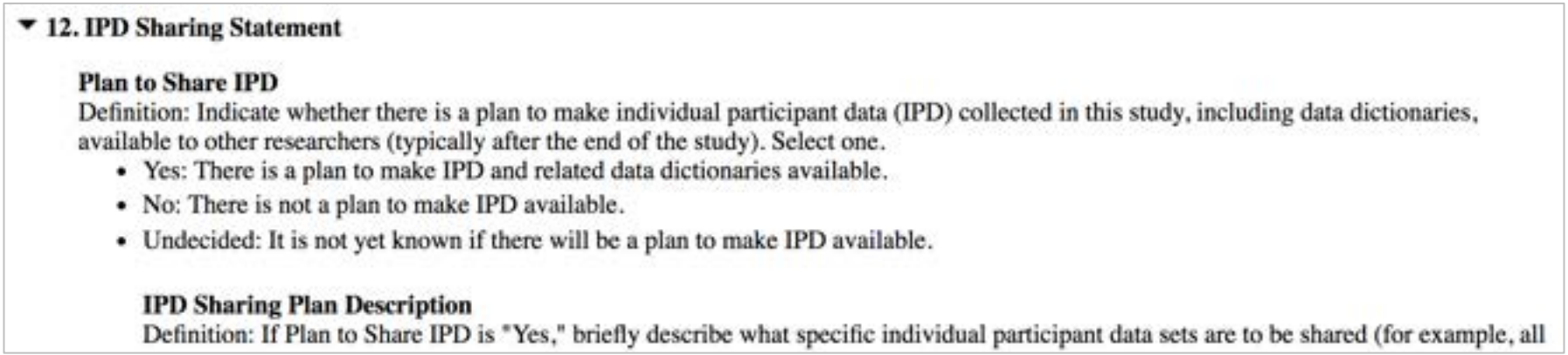


"The 48% of trials with publicly available microarray data received 85% of the aggregate citations. Publicly available data was significantly ($p = 0.006$) associated with a 69% increase in citations"

https://doi.org/10.1371/journal.pne.0000308

Trial Registration

- Data sharing plan is part of the ClinicalTrials.gov registration record



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.

IPD Sharing Plan Description

Definition: If Plan to Share IPD is "Yes," briefly describe what specific individual participant data sets are to be shared (for example, all

- As of 1 January 2019, ICMJE requires registration of your data sharing plan at time of trial registration

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
- 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

Providing Access to IPD Generates Value

- **Honors** the commitments of participants
- **Strengthens trust** in the clinical research enterprise
- **Prevents repetitive trials** and putting additional patients at risk
- **Enables new discovery** and scientific insights through by combining data from disparate sources

CONFIDENTIAL - Not for distribution

Perhaps most importantly for participants if the data is not shared…

It is used only one time to answer one question (the primary endpoint) rather than leveraging participants' contributions to answer multiple scientific lines of inquiry thereby advancing science

Vivli

Developing a data sharing program

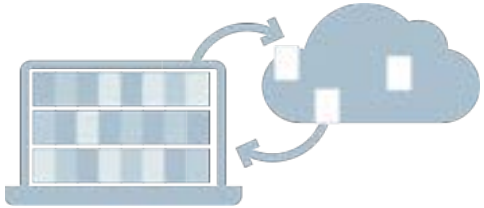
1. Why should we share?
2. **What are the key components of a data sharing program?**
3. When should we begin a program?
4. How can we manage a data sharing program?
5. What is the role of a partner?

CONFIDENTIAL - Not for distribution

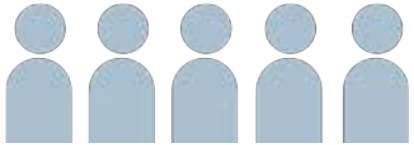
3. How to Share: 3 key elements to consider

POLICY

MECHANISM



RESOURCES



CONFIDENTIAL - Not for distribution

Data sharing governance

Key considerations when formulating your policy

- In data sharing, transparent decision-making equals good public policy
- Data Sharing Policies vary based on a sponsor or funders current portfolio, experience with data sharing and risk tolerance

Vivli

Data sharing governance

Key considerations when formulating your policy

1. Which studies will you share?
2. Are there exceptions to sharing?
3. On a specific request, who makes the final decision on whether to share?

Vivli

Data sharing governance

Key considerations when formulating your policy

1. What studies will you share?
   - **From when? (Date)**
   - **Which Phases?**
   - **Both Submitted and Approved products?**

Vivli

Data sharing governance

Key considerations when formulating your policy

1. What studies will you share?

- **From when?**
- **Which Phases?**
- **Both Submitted and Approved products?**

Example 1: we will share interventional clinical trials conducted in patients (Phase I-IV) for products and indications submitted and approved, since 2002 will be shared.

Example 2: Company-sponsored studies supporting indications approved in both the United States and European Union after January 1, 2013 will be considered for sharing.

Vivli

Data sharing governance

Key considerations when formulating your policy

2. Exceptions to sharing

- **Practical constraints**
- **Legal or contractual constraints**
- **Language**
- **Anonymization**

Vivli

Data sharing governance

Key considerations when formulating your policy

2. Exceptions to sharing

- **Practical constraints**
- **Legal or contractual constraints**
- **Language**
- **Anonymization**

Examples:

- Studies where there is reasonable likelihood that patients' anonymity cannot be maintained. For example in very rare diseases, studies with very low patient numbers or studies performed at a single center.
- There are practical constraints to providing the data (for example, issues related to the format of the databases, and/or resources (costs) are considerable to retrieve data)
- Study documentation is not in English.

Vivli

Data sharing governance

Key considerations when formulating your policy

1. What studies will you share?
2. Are there exceptions to sharing?
3. **On a specific request, who makes the final decision on whether to share?**

Vivli

Data sharing governance

Key considerations when formulating your policy

3. On a specific request, who makes the final decision on whether to share?

- Internal Approving Entity
- External Review Panel (ERP)
- Independent Review Panel (IRP)

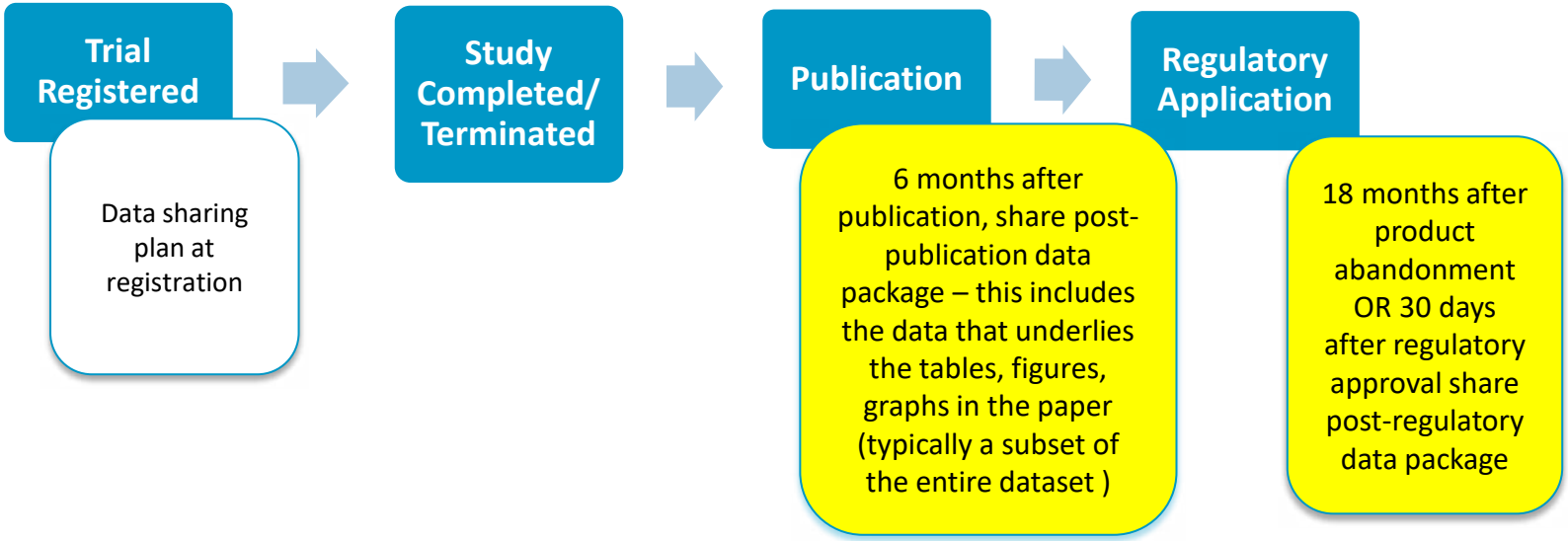
Vivli

Agenda

1. Why should we share?
2. What are the key components of a data sharing program**?**
3. **When should we begin a program?**
4. How can we manage a data sharing program?
5. What is the role of a partner?

CONFIDENTIAL - Not for distribution

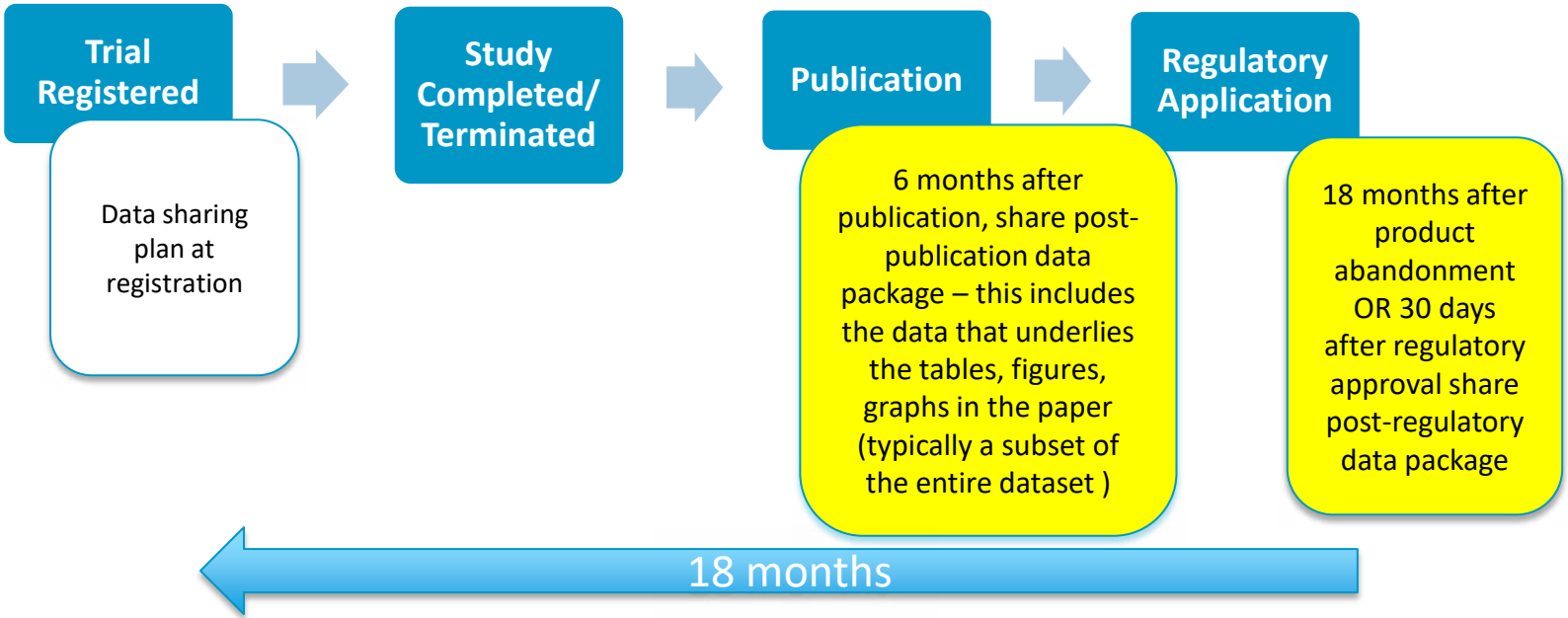
3. Recommendation - When to share what



Recommendations based upon IOM report *Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk*, Jan. 2015

Vivli

3. Recommendation - When to share what



At least 18 months before regulatory submission or a major publication is when institutions should begin their data sharing program planning

Recommendations based upon IOM report *Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk*, Jan. 2015

Vivli

What data will be shared?

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

Vivli

4. How can we manage a data sharing program?

- **Manage in-house:**
  - *Mechanism for sharing* – build, management and updating of a platform
  - *Team* – internal resources to maintain the platform; negotiate legal agreements; user queries, generate metrics, data anonymization and data preparation
  - *Policy* – draft and manage data sharing policies

- **Trusted partner to manage and assist with:**
  - Mechanism
  - Team
  - Policy

CONFIDENTIAL - Not for distribution

5. What can partners like Vivli do for us?

CONFIDENTIAL - Not for distribution

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

CONFIDENTIAL - Not for distribution

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 by the numbers …TODAY

5,700+
Trials

3.0M
Participants from
119
countries

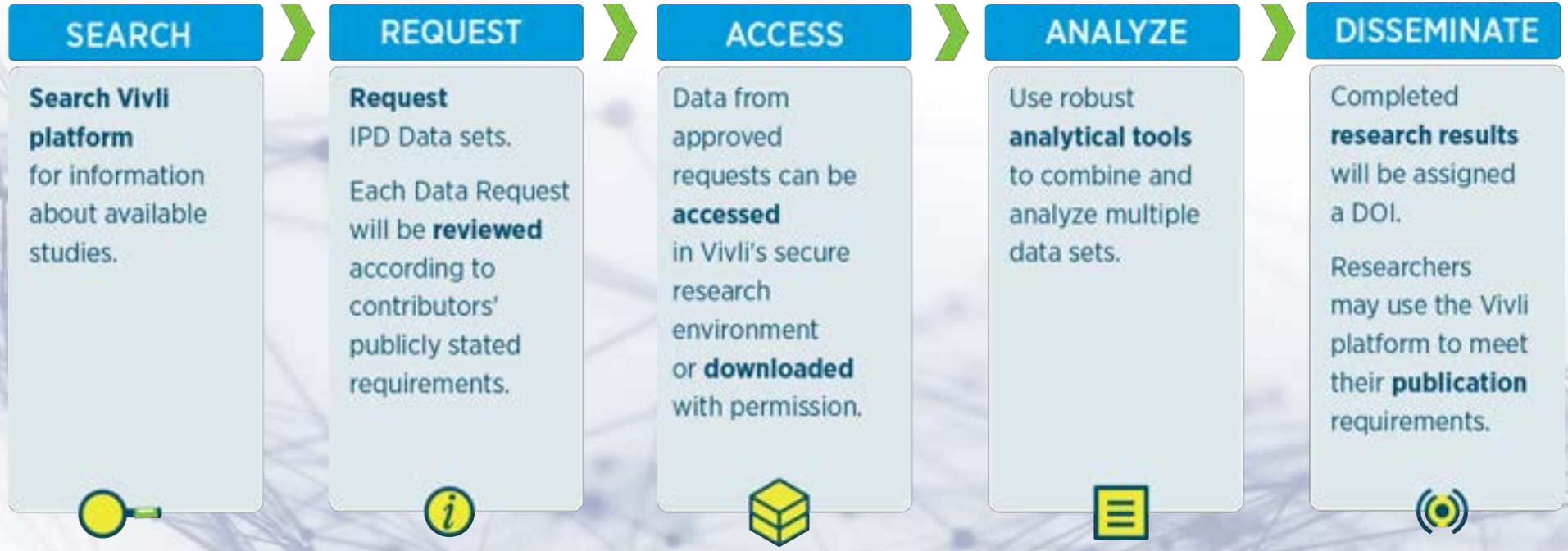
29
Members

Vivli Members

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

Vivli

How Vivli works



Vivli

Vivli's Secure Environment Bridges Multiple Platforms

BioLINCC

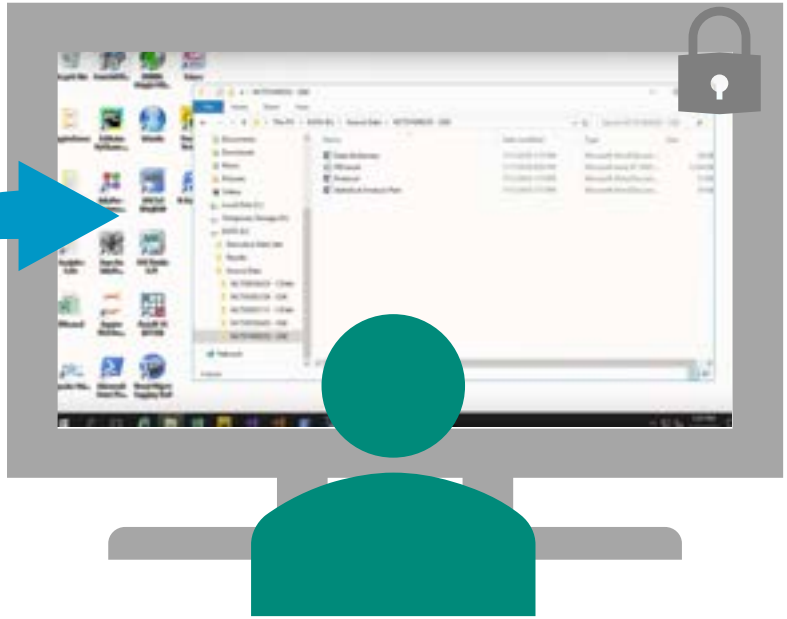
Johnson & Johnson

ImmPort

Project Data Sphere

gsk do more feel better live longer

Vivli Secure Environment



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

Vivli

Explore Vivli

Log on to

Vivli.org

To explore the ~5,800 trials available

Thank you!

Vivli