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

1. The Vivli Global Platform for data sharing
2. Vivli Datathon sponsored by Microsoft
Why it matters
Reduce duplication of trials
Shape clinical trial design
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?

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 1\textsuperscript{st} patient is enrolled

- Data sharing plan is part of the ClinicalTrials.gov registration record
- \underline{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
“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?
Datasets with variations of Biomarker X mapped to e.g., a common CDISC variable.
## 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
How to Access Data in Vivli?

- 4600+ Trials
- 2M Participants from 100+ countries
Secure Environment Bridges Multiple Platforms

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

Vivli Secure Environment
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.
Datathon Video

Vivli and Microsoft Data Challenge
Log on to

Vivli.org

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