Vivli Clinical Research Data Sharing:

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Ida Sim, MD, PhD
Sharing individual participant-level data (IPD) from completed clinical studies

*Enables new discovery* and new research questions through using and combining existing data with increased statistical power;

*Validates* existing research results by peer review and reanalysis;

*Broadens* research by enabling aggregation of data derived from disparate data generators

*Accelerates* the pace of clinical science;

*Prevents* repetitive trials—that may put additional participants at risk—when data already exists.

Data Sharing from Clinical Trials — A Research Funder’s Perspective

“...collaboration and cooperation among members of the global research community will be essential in maximizing the effect of funded research. It is simply unacceptable that the data from published clinical trials are not made available to researchers and used to their fullest potential to improve health.”

Wellcome Trust, the UK Medical Research Council, Cancer Research UK, and the Bill and Melinda Gates Foundation.
Current Gaps

- > 60 existing sites, different standards, policies, security, access
- Insufficient capacity to host data
- Duplication of effort
- Limited analytic tools and environments

Global neutral data sharing and analytics platform
A trusted platform for clinical trial data, globally:

- For all trials worldwide, for all diseases
- Protects the privacy of patients
- Responds to the needs of researchers
- Provides a user-friendly, secure, state-of-the-art data sharing and computing platform
- Brings together all stakeholders with transparent and inclusive governance
Agenda

• Vivli, the Organization
• Platform Features and Demonstration
• Data Sharing Policies and Procedures
• Sustainability
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
Supporters and Funders of Vivli

- Doris Duke Charitable Foundation
- Helmsley Charitable Trust
- Laura and John Arnold Foundation
- Lyda Hill
- Microsoft*
- PhRMA
- Ropes & Gray*

Vivli was created through a project of the Multi-Regional Clinical Trials Center (MRCT Center) of Brigham and Women’s Hospital and Harvard.

*In-kind contributions
Governance

Board of Directors
- M. Stebbins, Chair

Vivli Exec
- R. Li, J. Wood, I. Sim

Build Partners
- Industry, Duke, Cochrane, etc

External Advisory Board
- 21 senior leaders

Academic Roundtable
- 25 international leaders
Adaptable: Vivli respects existing processes and has built flexibility to accommodate various stakeholder processes into the current system.

In areas where harmonization is critical for the user experience, we will do so:

- Harmonized Data Request Form
- Harmonized Data Use Agreement
- Harmonized Data Contributor Agreement
The Vivli Platform

- IPD Data Package
  - Basic
  - Full
Platform Demo: Search, Request, Analyze

Searching and Requesting Data from the Vivli Platform
Vivli Milestones to Launch

- Vivli launched/Microsoft partnership announced Summer 2017
- Vivli Public Preview Dec 2017
- Vivli Public Beta April 2018
- Epilepsy Pilot March-April 2018
- Vivli Launch July 19, 2018
Meeting ICMJE 2018 data sharing requirements

• Beginning July 1, 2018, clinical trial authors must describe data sharing plans (whether IPD available, when, to whom, for how long, etc)
  
  - Vivli offers a full-featured IPD-sharing platform that balances the needs of Data Contributors and Data Requesters

• With Vivli, researchers have a one-stop shop for FAIR requesting and analyzing IPD
Draft Policies and Procedures for a Culture of Data Sharing
Contribution of IPD and Data Sets

• When does a Data Contributor need to provide the IPD data sets and associated documents?

• Once a Data Request is approved, the Data Contributor(s) will be notified to provide the Basic or Full IPD Package.

• Alternatively, Data Contributors can pay an upfront per-study charge for Vivli to store anonymized IPD and associated documents and to make those datasets available under approved Data Requests.
Can Data Contributors review and reject requests?

Data Contributors are notified of any request for their data.

Data Contributor may require researchers to file a data request with an Independent Review Committee (IRC) or may allow any researcher to access their data.

Data Contributors can review Data Requests and may reject a request, in which case the reason for such rejection will be listed publicly by each data contributor.
• Should the data request be made public? Which parts, to whom, and when?

• The following is made publicly available when a Data Request has been approved and the requested data provided to the Recipient:
  - the title of the Research Plan, the name of the principal investigator and his or her affiliation, funding source(s), potential conflicts of interest, a narrative summary of the proposed research, the studies from which Data Sets have been requested.

• If the request is not approved, it is not shared but is included in the overall statistics of the number of rejected data requests.
Collaboration

• Are there any expectations for researchers who request data (aka “Recipient”) to collaborate with the Data Contributor?

• Data Contributors who are interested in collaborating with Recipients of their data may express their interest in collaborating, but Recipients are under no obligation to contact, inform, or collaborate with Data Contributors.

• For their part, Recipients can contact Data Contributors, but Data Contributors are under no obligation to respond to or collaborate with Recipients.
Should the results of an analysis be made public? If so, what should be the parameters of this disclosure?

Yes, secondary data researchers are under the same obligations for transparency and accountability as primary researchers.

Recipients shall make the results of the Analysis (the “Analysis Results”) available within 1 year of obtaining the requested Data Sets
- Manuscripts will be shared at time of submission with Data Contributors
- Recipients will provide Vivli with citation to publications

Extensions beyond 1 year may be granted
Sustainability
Vivli Sustainability Approach

- Aim to reduce barriers to participation. Both sides contribute.
- Users charged for access to research environment, not for access to data
- Data contributors charged for services to meet data sharing mandates set by funders and journals
(DRAFT) Costs per study for academic data contributors

<table>
<thead>
<tr>
<th>Study Curated and Listed on Vivli</th>
<th>Anonymized IPD Storage</th>
<th>Independent Review Panel</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study ready for sharing and needs storage</td>
<td>✓</td>
<td>✓</td>
<td>$2,000</td>
</tr>
<tr>
<td>Study ready for sharing and needs Storage and Independent Review Panel</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Anonymization</td>
<td></td>
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</tbody>
</table>

Data and documentation must be shared at the time of curating and listing the study. Contributors must sign harmonized Data Contributor Agreement and Data Sharing Agreement.
<table>
<thead>
<tr>
<th>Timing</th>
<th>Compute charge</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-3 months</td>
<td>No charge</td>
<td>Jupyter notebook, Python, R, STATA, Office suite, and SAS analytical tools available</td>
</tr>
</tbody>
</table>
| 3+ months       | $10/day, 2 concurrent logins (user accounts for all team members) | Standard Research environment (2CPUx7GB) size  
Jupyter notebook, Python and R tools available. |
| 3+ months       | $20/day, 2 concurrent logins (user accounts for all team members) | Premium research environment (4CPUx7GB) size  
Jupyter notebook, Python R, STATA and SAS tools are available. |
Conclusion

• Vivli offers a full-featured IPD-sharing platform that balances the needs of Data Contributors and Data Requesters

• Vivli will provide a new global capacity to securely meet emerging data sharing mandates under trusted governance
Thank you.
http://vivli.org/