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Vivli: The Difference Data Re-Use Can Make
Patients Expect Data Sharing and Reuse

Roxana Mehran @Drroxmehran · 4 Apr 2017
trial participants-"share the data as widely as possible and as soon as possible to advance human health" #NEJMDatasummit #NEJMDataSummit

Vinay Prasad MD MPH @VPplenarysesh · 4 Apr 2017
Patients listened to trialists fears for one day and then it’s supposed to go #nejmdatasummit

Anna McCollister @annamcslipp · 4 Apr 2017
@JeffDrazen -living in time where “trust me I’m a doctor” have data out there & let people see themselves #IHEM

Sharon F. Terry @sharonferry · 4 Apr 2017
Love idea that next generation is open to openness-will we watch people die meanwhile? Do we have appetite for such waiting? #NEJMDatasummit

P. F. Anderson @pfanderson · 4 Apr 2017
OUTCOMES of patient panel > Share early, often, with me, responsibly, understandably #NEJMDatasummit

Aaron Eisman @aaroneisman · 4 Apr 2017
Patients incredulous that sharing data isn’t the norm, speaking loud and clear: “share my data!” #NEJMDatasummit

NEJM Aligning Incentives for Sharing Clinical Trial Data Summit, Boston, MA. April 2017
Balancing Risks and Benefits

Openness

Maximizing the value of the data collected respects participants' contributions

Privacy

Protecting participant privacy
# Approaches to Sharing Human Data

<table>
<thead>
<tr>
<th>Type</th>
<th>Key Features</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open access</td>
<td>Anyone can access, simple account creation, simple on-line data use agreement (DUA)</td>
<td>Health CAN, EMA, Project Datasphere</td>
</tr>
<tr>
<td><strong>Managed access</strong></td>
<td>• for scientific purposes only (standard request form)</td>
<td>Vivli, CSDR, SOAR, VISTA</td>
</tr>
<tr>
<td></td>
<td>• (independent) review process</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• secure environment for data access</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• clear legal framework</td>
<td></td>
</tr>
<tr>
<td>Restricted access</td>
<td>Invitation only, access only to those who provide data</td>
<td>DataCelerate, IBD Plexus</td>
</tr>
</tbody>
</table>
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 by the numbers ...TODAY

4,800+ Trials

2.3M Participants from 111 countries

23 Members
Vivli is a Global Data Platform – Agnostic to Disease, Funder or Data Contributor
Search Vivli platform for information about available studies.

Request IPD Data sets.
Each Data Request will be reviewed according to contributors' publicly stated requirements.

Data from approved requests can be accessed in Vivli's secure research environment or downloaded with permission.

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

Completed research results will be assigned a DOI.
Researchers may use the Vivli platform to meet their publication requirements.
Secure Environment Bridges Multiple Platforms

Vivli Secure Environment

30+ packages
- STATA
- MS Office
- R
- Jupyter Notebook
- Python
- SAS

BYO data, scripts, software on request
Harmonization based on wide stakeholder consultation reduces friction for both data contributors and data users:

- Harmonized Data Request Form
- Harmonized Data Use Agreement
- Harmonized Data Contributor Agreement
## Usage Metrics (as of January 1, 2020)

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global Hits to Vivli</td>
<td>57,030</td>
</tr>
<tr>
<td>Studies Available for Sharing</td>
<td>4,788</td>
</tr>
<tr>
<td>Data Contributors</td>
<td>22</td>
</tr>
<tr>
<td>Data Requests Submitted</td>
<td>91</td>
</tr>
</tbody>
</table>
Vivli FAIR Data Sharing

• Findable
  - metadata model, annotated using Cochrane vocabulary (SNOMED, WHO ATC, MedDRA)
  - Dataset DOIs minted by DataCite

• Accessible
  - from fully downloadable to available only in secure MS Azure environment

• Interoperable, Reusable
  - SDTM format recommended but not required
  - No requirement for common variables
Explore Vivli

Log on to Vivli.org

To explore the ~4,800 trials and begin the search