Vivli: A Global Secure Data-Sharing Platform for Participant-Level Clinical Trial Data

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Clinical trials registration

ICMJE requirement for publication (2004)
FDAAA requirement for applicable trials (2007)

Summary data shared

FDAAA Final Rule (2016)
EU no. 536/2014 requires lay summaries

Raw data (IPD) shared

EMA Policy 0070 (2014), Policy 0043 (TBD)
PhRMA principles for data sharing (2014)
IOM Sharing Clinical Trial Data report (2015)
ICMJE IPD sharing statement requirement (July 2018)
Draft NIH IPD sharing requirements (2019)
Barriers to IPD Sharing 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 and data sharing 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
  - disease-specific data sharing platforms limit cross-disciplinary data discovery
  - limited range of analytic tools available
<table>
<thead>
<tr>
<th>Data Contributors</th>
<th>IPD Sharing Requirements</th>
<th>Figshare &amp; Dryad</th>
<th>University Repository</th>
<th>CT.gov</th>
<th>Vivli</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IPD can be stored and securely hosted</td>
<td>✔️</td>
<td>✔️</td>
<td></td>
<td>✔️</td>
</tr>
<tr>
<td></td>
<td>Harmonized data contributor and data use agreements</td>
<td>✔️</td>
<td></td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td></td>
<td>IPD can be shared securely to anyone in the world</td>
<td></td>
<td></td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td></td>
<td>Independent review available</td>
<td></td>
<td></td>
<td></td>
<td>✔️</td>
</tr>
</tbody>
</table>
Vivli By the Numbers

- 3200+ Trials
- 1.5M Participants from 100 countries
- 16 Members
Vivli Members
Data Sharing Timeline

- **Grant Submission**: Data sharing plan in proposal
- **Trial Registration**: Data sharing plan in registration
- **Trial Completion**: Archive IPD Data Package in Vivli
- **Publication**: Data sharing plan to journal
- **12 Months Later**: Summary results to CT.gov
- **Searchable**: Listed on Vivli
- **Requestable**: Available for requests
- **Shared**: IPD reused, tracked

Supported by Vivli
The Vivli Platform
The Vivli Platform

Harmonized data request and streamlined request review

Centralized search and request portal for data hosted on multiple platforms

Enhanced metadata for more precise search results

Open Search

User Request

Vivli Search and Request Tool

Examples of Existing Platforms

Hosting for clinical trial data, including minting DOI for publication purposes

Vivli
Harmonized data request and streamlined request review
Demo of Search, Request, Access
Summary: Benefits of Requesting Data through Vivli

- **One-stop search** – find individual-level participant data from more than 3,200 completed clinical trials
- **Harmonized request form** – use a single data request form for all studies
- **Bridges platforms** – can bring together data sets from Vivli and multiple other platforms
- **Secure yet customizable** – bring in your own data, tools and scripts to a secure research environment
Summary: Benefits of Sharing through Vivli

- **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
Questions?

Vivli.org

• Explore the ~7,000 trials available via the Vivli platform
• Begin your search
• Contact support@vivli.org with questions
### Data Sharing Cost Per Study for Academics

<table>
<thead>
<tr>
<th>Study Metadata Curated and Listed on Vivli</th>
<th>De-Identified/ an anonymized IPD Storage</th>
<th>Independent Review Panel</th>
<th>One-Time Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study ready for sharing and needs Storage</td>
<td>✓</td>
<td>✓</td>
<td>Free for UCSF (otherwise $2,000*)</td>
</tr>
<tr>
<td>Study ready for sharing and needs Storage and Independent Review Panel</td>
<td>✓</td>
<td>✓ ✓</td>
<td>$4,500</td>
</tr>
<tr>
<td>De-identification/ an anonymization</td>
<td>✓</td>
<td>✓ ✓</td>
<td>Provided by Privacy Analytics (additional $2,000-$5000 / dataset)</td>
</tr>
</tbody>
</table>

*De-identified data and documentation must be shared at the time of curating and listing the study Contributors must sign Data Contributor Agreement*
## Secure Research Environment Options

<table>
<thead>
<tr>
<th>Environment Type</th>
<th>Size</th>
<th>Tools Available</th>
<th>Platform Access</th>
<th>Compute Charge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Research Environment</td>
<td>2CPUx7GB</td>
<td>Office 365, STATA, Jupyter Notebook, Python, R</td>
<td>Unlimited user accounts, 2 concurrent logins</td>
<td>No charge for 365 days, $12/day after 365 days</td>
</tr>
<tr>
<td>Premium Research Environment</td>
<td>4CPUx14GB</td>
<td>Office 365, STATA, Jupyter Notebook, Python, R, SAS</td>
<td>Unlimited user accounts, 2 concurrent logins</td>
<td>No charge for 90 days, $25/day after first 90 days</td>
</tr>
</tbody>
</table>

* Custom environments available upon request
## Contents of the IPD Package

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Required</strong></td>
<td></td>
</tr>
<tr>
<td>Study protocol</td>
<td>Final protocol with all amendments</td>
</tr>
<tr>
<td>Informed consent form</td>
<td>Final approved informed consent form</td>
</tr>
<tr>
<td>Data dictionary</td>
<td>Detailed descriptions of each variable in the dataset, including the definition, source, coding, etc. of the variable</td>
</tr>
<tr>
<td>Statistical Analysis Plan</td>
<td>Description of the principal features of the analyses described in the protocol</td>
</tr>
<tr>
<td>IPD dataset</td>
<td>Final cleaned individual participant-level data, de-identified</td>
</tr>
<tr>
<td><strong>Optional</strong></td>
<td></td>
</tr>
<tr>
<td>Analytic code</td>
<td>Software code used to carry out prespecified and additional analyses</td>
</tr>
<tr>
<td>Case report forms</td>
<td>Forms used to collect the data that is described in the protocol for each trial participant</td>
</tr>
<tr>
<td>Clinical Study Report (CSR)</td>
<td>Report that summarizes the efficacy and safety data from the study (after regulatory decision)</td>
</tr>
</tbody>
</table>