| POLICY | We provide expertise in policy development and harmonized agreements |
| MECHANISM | We provide the platform to securely share your data |
| RESOURCES | The Vivli team manages researchers’ queries |
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
Evolution of Transparency in Clinical Trial Data

Clinical trials registration
- ICMJE requirement for publication (2004)
- FDAAA requirement for applicable trials (2007)

Summary data shared
- EU no. 536/2014 requires lay summaries (effective late 2020)

Clinical Study reports - CSRs & Trial Raw data (IPD) shared
- Health Canada Regulations (2019) (IPD not included)
- PhRMA/EFPIA principles for data sharing (2014)
- IOM Sharing Clinical Trial Data report (2015)
- FDA Clinical Data Summary Pilot (Jan. 2018)
- ICMJE IPD sharing statement (July 2018)
Vivli by the numbers ...TODAY

- 4,300+ Trials
- 2M Participants from 106 countries
- 20 Members
Vivli Members
Balancing Risks and Benefits

Privacy

Protecting participant privacy

Openness

Maximizing the value of the trial data collected respects participants’ contributions
# Mechanisms for Sharing -
**Trial Data sharing platforms**

<table>
<thead>
<tr>
<th>Type</th>
<th>Key Features that may be required</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Open access</strong></td>
<td>None, account creation, simple on-line DUA</td>
<td>Health CAN, EMA, PDS</td>
</tr>
<tr>
<td><strong>Managed access</strong></td>
<td>Intermediary, proposal process, specialized expertise, DUA</td>
<td>Vivli, CSDR, SOAR, VISTA</td>
</tr>
<tr>
<td><strong>Restricted access</strong></td>
<td>Invitation only, access to those that provide data</td>
<td>DataCelerate, IBD Plexus</td>
</tr>
</tbody>
</table>
Governance processes flexible and efficient

Adaptable: Vivli respects the review process of each data contributor and has built flexibility to accommodate various review processes into the current system.

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

• Harmonized Request Form
• Harmonized Data Use Agreement
• Harmonized Data Contributor Agreement
Data Request and Access Process

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.
Secure Environment Bridges Multiple Platforms
Data Use Agreement – Key provisions

- Vivli manages DUA process for our members who use the Vivli harmonized DUA
- Vivli members who are partner platforms may use their own DUA as long as it does not conflict with the Vivli DUA (cross-platform sharing)

Key Vivli DUA provisions. Researcher agrees:
- To adhere to a research plan
- To make reasonable efforts to publish
- Not to re-identify participants
Platform Pillars of Security

- DUA
- Platform Security
- Data Anonymization
Thank you