Vivli

CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Vivli Clinical Research Data Sharing: Share. Discover. Innovate.

September 2019

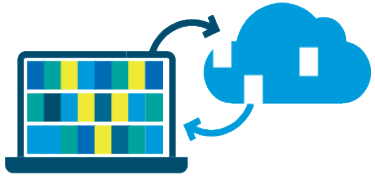
REBECCA LI

VIVLI SOLUTION

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

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Introducing Vivli

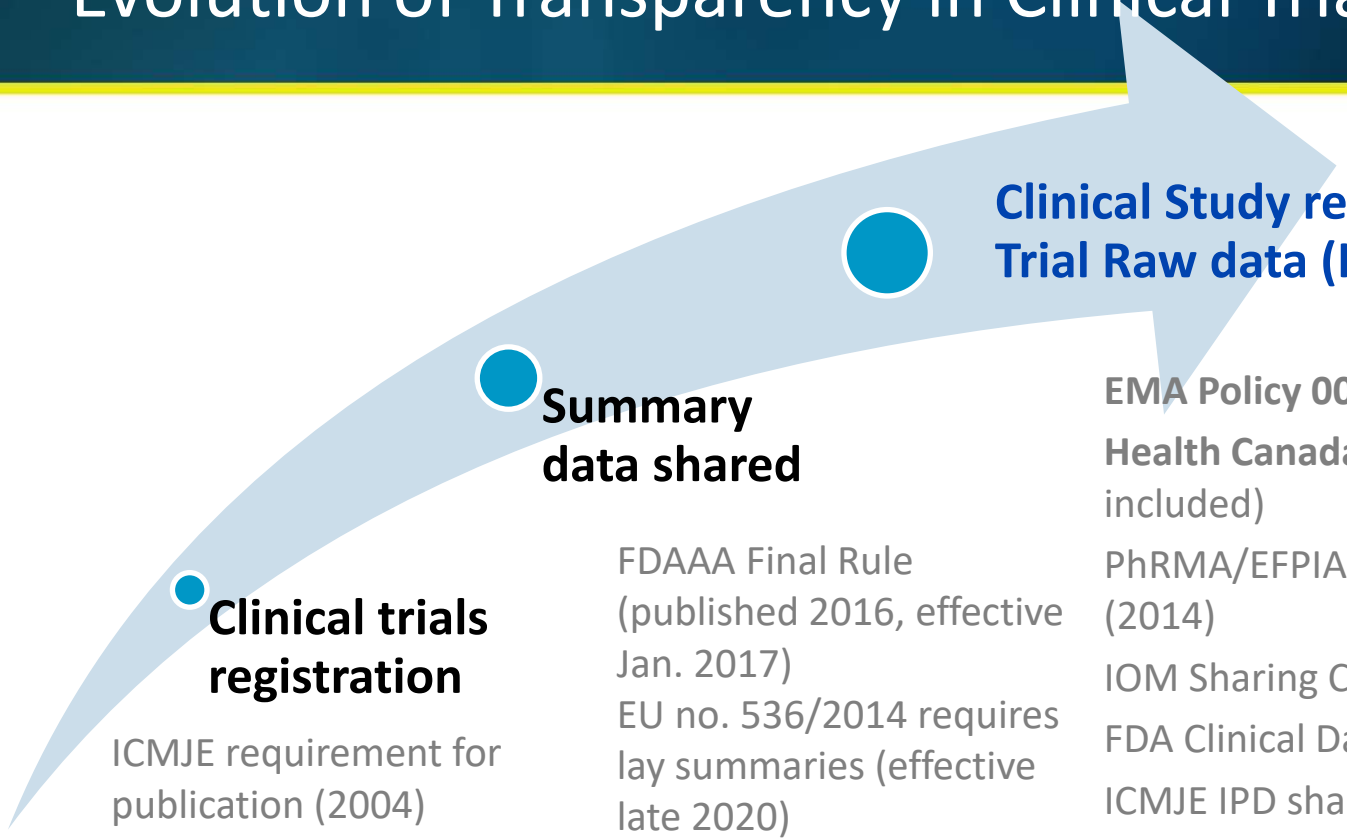
THE ENTITY

- 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

FDAAA Final Rule (published 2016, effective Jan. 2017)
EU no. 536/2014 requires lay summaries (effective late 2020)

Clinical Study reports - CSRs & Trial Raw data (IPD) shared

EMA Policy 0070 (2014), Policy 0043 (2010)
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)

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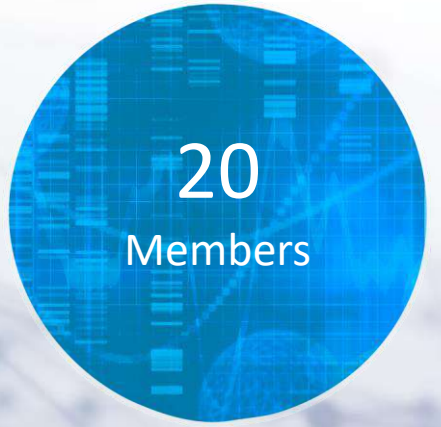
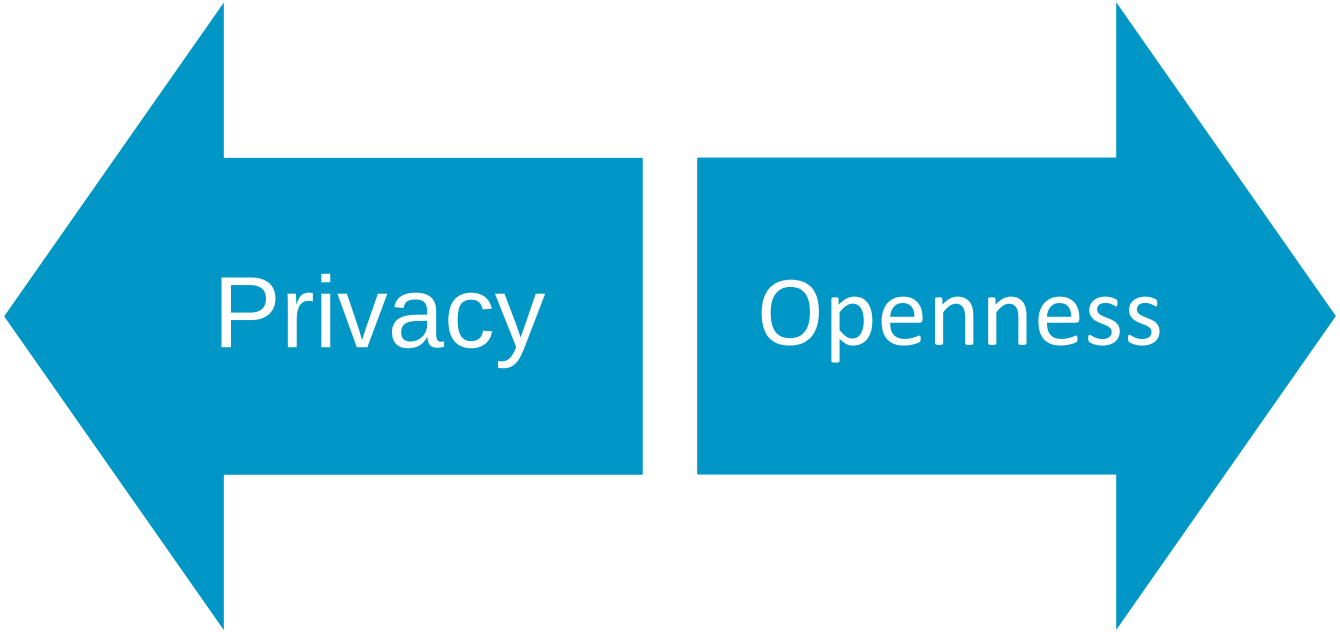
Vivli by the numbers …TODAY



Vivli Members

Balancing Risks and Benefits



Protecting participant privacy

Maximizing the value of the trial data collected respects participants' contributions

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Mechanisms for Sharing - Trial Data sharing platforms

Type	Key Features that may be required	Examples
Open access	None, account creation, simple on-line DUA	Health CAN, EMA, PDS
Managed access	Intermediary, proposal process, specialized expertise, DUA	Vivli, CSDR, SOAR, VISTA
Restricted access	Invitation only, access to those that provide data	DataCelerate, IBD Plexus

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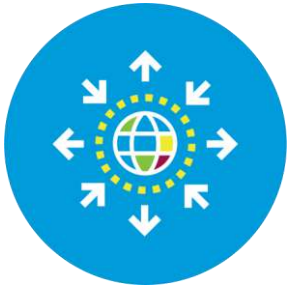
Governance processes flexible and efficient

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.

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Secure Environment Bridges Multiple Platforms

BioLINCC
Biologic Specimen and Data Repository Information Coordinating Center

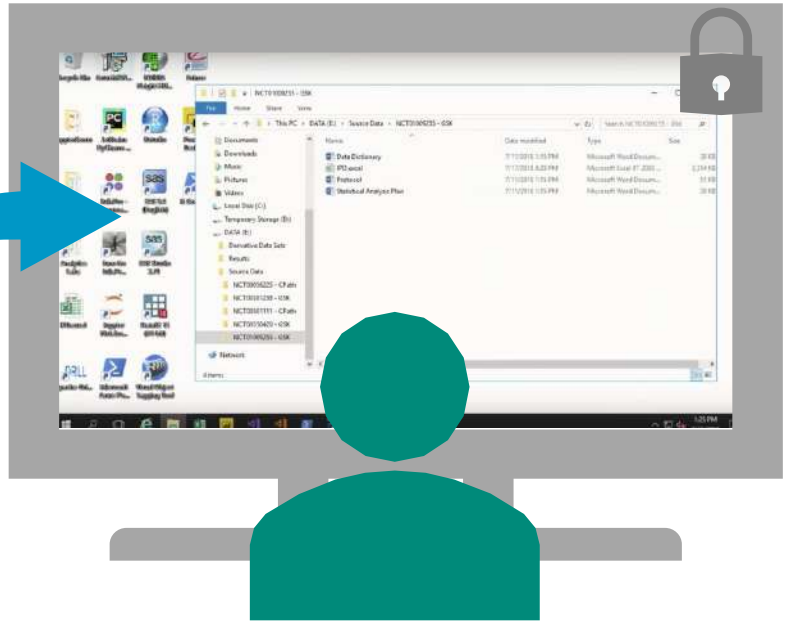
Pfizer

IMMPORT
BIOINFORMATICS FOR THE FUTURE OF IMMUNOLOGY

Project Data Sphere®

gsk
do more
feel better
live longer

Vivli Secure Environment



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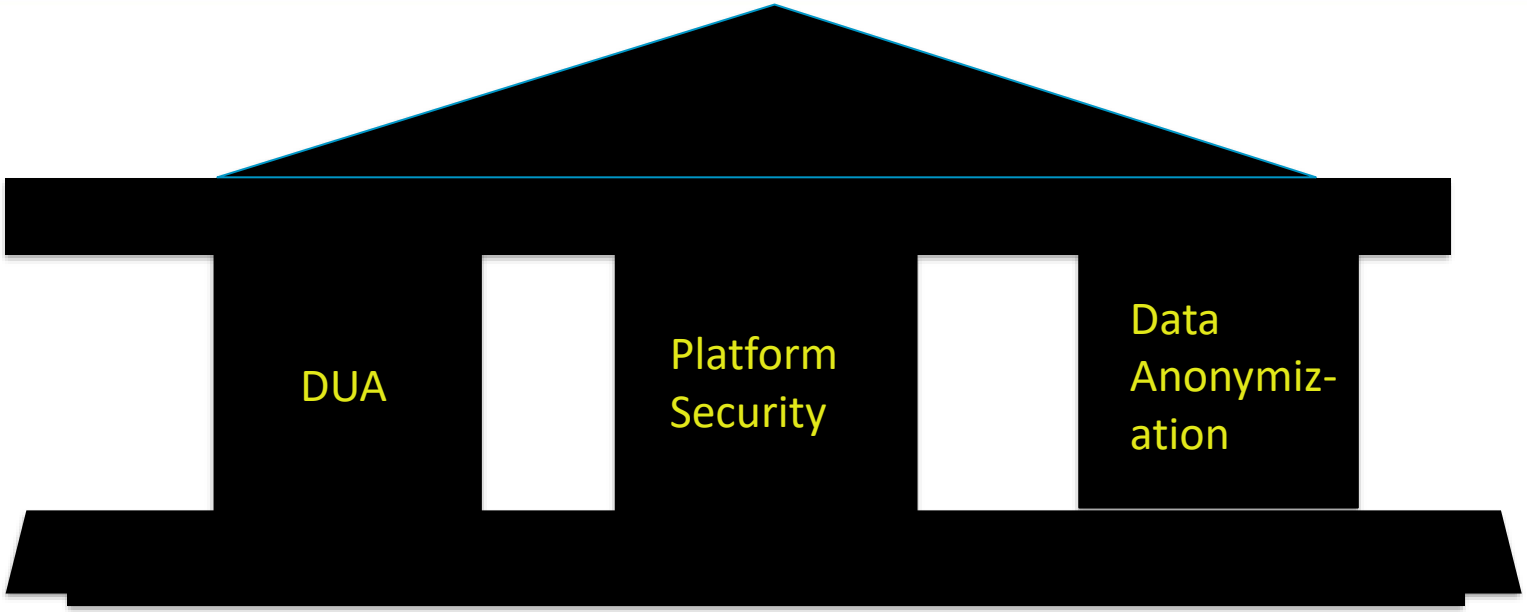
Data Use Agreement – Key provisions

- 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



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Thank you

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