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CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

March 13, 2018

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Sharing Clinical Research Data Creates New Value

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.

Institute of Medicine (IOM). 2015. *Sharing clinical trial data: Maximizing benefits, minimizing risk.* Washington, DC: The National Academies Press.

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The NEW ENGLAND JOURNAL of MEDICINE

SOUNDING BOARD

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.

n engl j med 377;20 nejm.org November 16, 2017

Current Gaps

Insufficient capacity to host data

Duplication of effort

Limited analytic tools and environments

Global neutral data sharing and analytics platform

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The Opportunity for the Vivli 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

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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

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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

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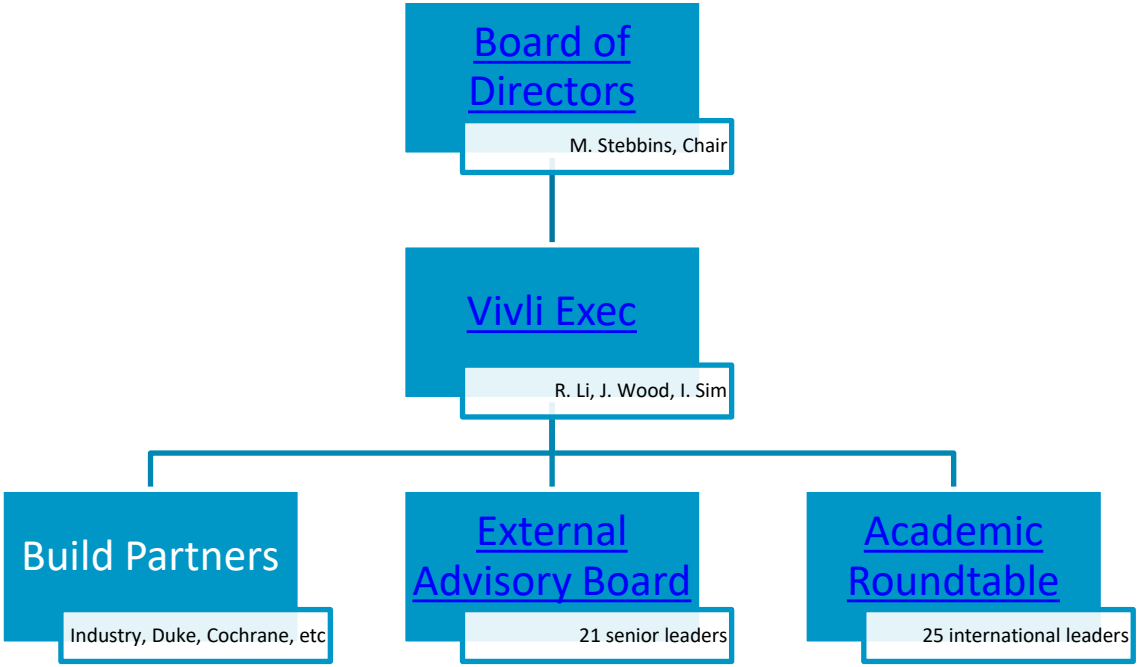
Governance

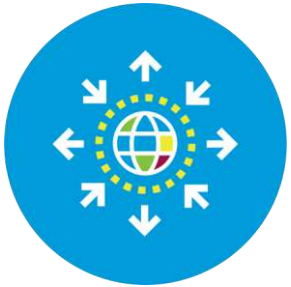

Board of Directors
M. Stebbins, Chair
Vivli Exec
R. Li, J. Wood, I. Sim
Build Partners
Industry, Duke, Cochrane, etc
External Advisory Board
21 senior leaders
Academic Roundtable
25 international leaders

Data Sharing Policies and Procedures

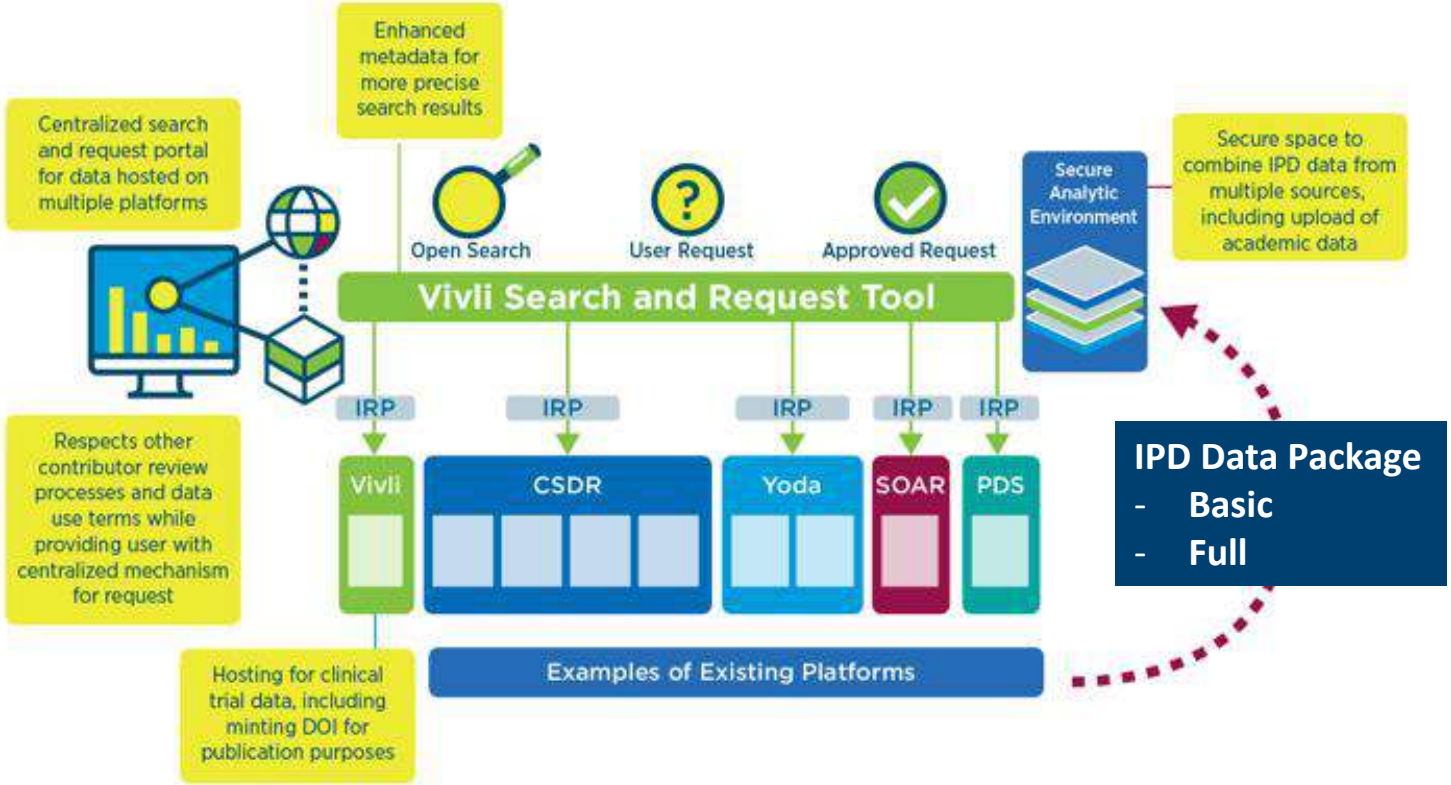
Adaptable: Vivli respects existing processes and has built flexibility to accommodate various stakeholder processes into the current system.

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



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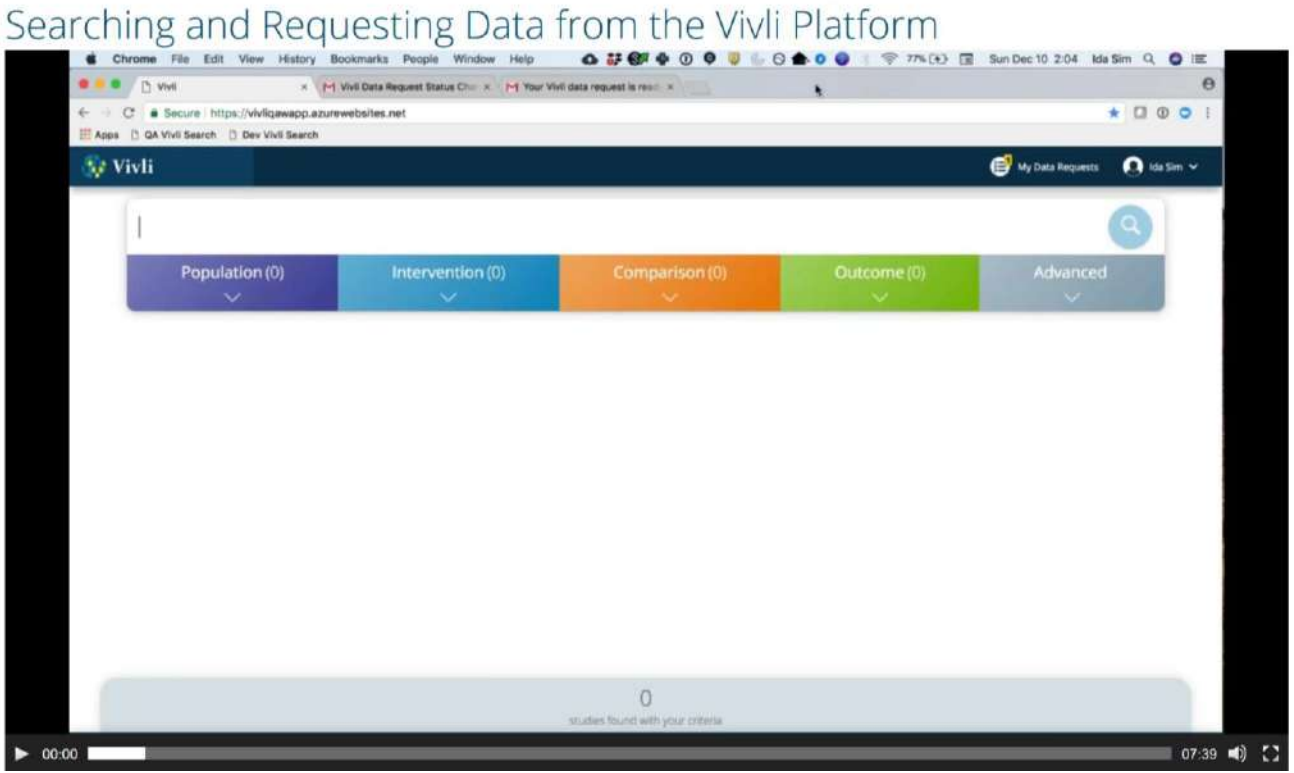
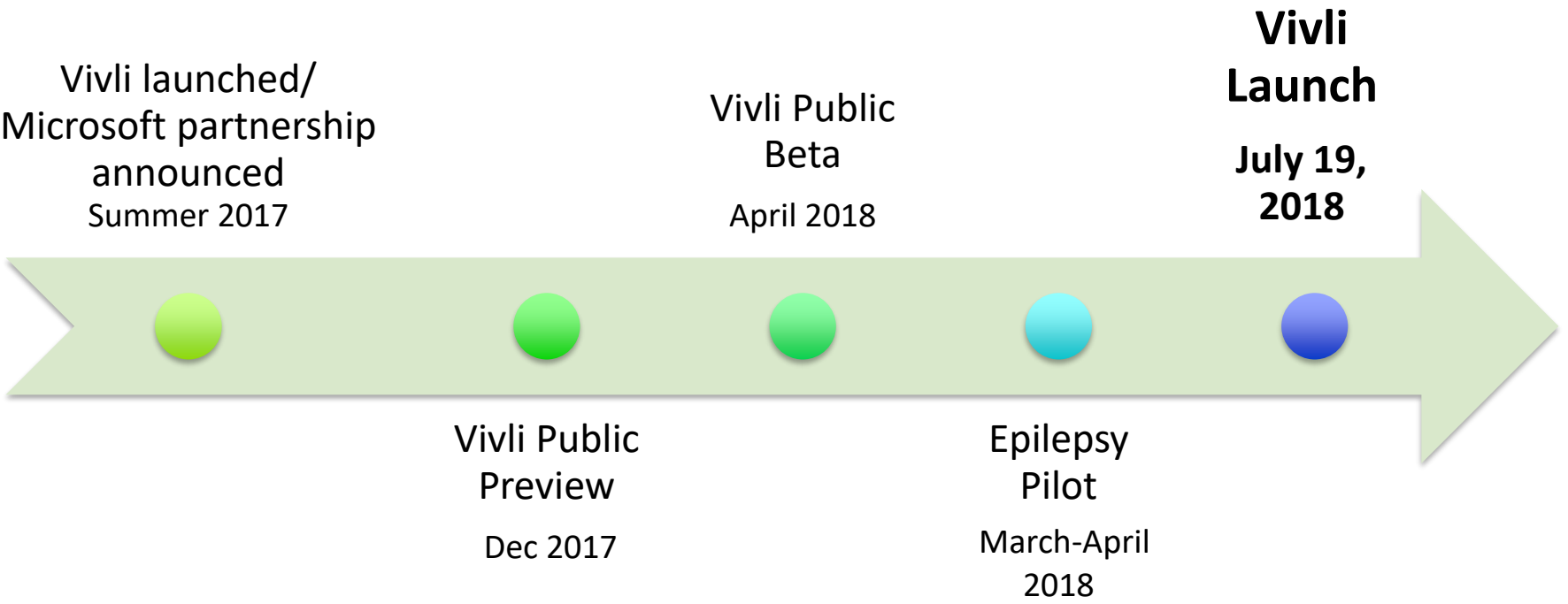
Platform Demo: Search, Request, Analyze



Vivli Milestones to Launch



Meeting ICMJE 2018 data sharing requirements

Annals of Internal Medicine EDITORIAL

Data Sharing Statements for Clinical Trials: A Requirement of the International Committee of Medical Journal Editors

The International Committee of Medical Journal Editors (ICMJE) believes there is an ethical obligation to responsibly share data generated by interventional clinical trials because trial participants have put themselves at risk. In January 2016 we published a proposal aimed at helping to create an environment in which the sharing of deidentified individual participant data becomes the norm. In response to our request for feedback we received many comments from individuals and groups (1). Some applauded the proposals while others expressed disappointment they did not more quickly create a commitment to data sharing. Many raised valid concerns regarding the feasibility of the proposed requirements, the necessary resources, the real or perceived risks to trial participants, and the need to protect the interests of patients and researchers.

It is encouraging that data sharing is already occurring in some settings. Over the past year, however, we have learned that the challenges are substantial and the requisite mechanisms are not in place to mandate universal data sharing at this time. Although many issues must be addressed for data sharing to become the norm, we remain committed to this goal.

Therefore, ICMJE will require the following as conditions of consideration for publication of a clinical trial report in our member journals:

1. As of 1 July 2018 manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement as described below.

2. Clinical trials that begin enrolling participants on or after 1 January 2019 must include a data sharing plan in the trial's registration. The ICMJE's policy regarding trial registration is explained at www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html. If the data sharing plan changes after registration this should be reflected in the statement submitted and published with the manuscript, and updated in the registry record.

Data sharing statements must indicate the following: whether individual deidentified participant data (including data dictionaries) will be shared; what data in particular will be shared; whether additional, related documents will be available (e.g., study protocol, statistical analysis plan, etc.); when the data will become available and for how long; by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism). Illustrative examples of data sharing statements that would meet these requirements are in the **Table.**

These initial requirements do not yet mandate data sharing, but investigators should be aware that editors may take into consideration data sharing statements when making editorial decisions. These minimum requirements are intended to move the research enterprise closer to fulfilling our ethical obligation to participants. Some ICMJE member journals already maintain, or may choose to adopt, more stringent requirements for data sharing.

Sharing clinical trial data is one step in the process articulated by the World Health Organization (WHO) and other professional organizations as best practice for clinical trials: universal prospective registration; public disclosure of results from all clinical trials (including through journal publication); and data sharing. Although universal compliance with the requirement to prospectively register clinical trials has not yet been achieved and requires continued emphasis, we must work toward fulfilling the other steps of best practice as well–including data sharing.

As we move forward into this new norm where data are shared, greater understanding and collaboration among funders, ethics committees, journals, trialists, data analysts, participants, and others will be required. We are currently working with members of the research community to facilitate practical solutions to enable data sharing. The United States Office for Human Research Protections has indicated that provided the appropriate conditions are met by those receiving them, the sharing of deidentified individual participant data from clinical trials does not require separate consent from trial participants (2). Specific elements to enable data sharing statements that meet these requirements have been adopted at ClinicalTrials.gov (https://prsinfo.clinicaltrials.gov/definitions.html#shareData). The WHO also supports the addition of such elements at the primary registries of the International Clinical Trials Registry Platform. Unresolved issues remain, including appropriate scholarly credit to those who share data, and the resources needed for data access, the transparent processing of data requests, and data archiving. We welcome creative solutions to these problems at www.icmje.org.

We envision a global research community in which sharing deidentified data becomes the norm. Working toward this vision will help maximize the knowledge gained from the efforts and sacrifices of clinical trial participants.

This article was published at Annals.org on 6 June 2017.

- 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

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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.

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Data Contributors: handling 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

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Publication of Data Requests

- **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.

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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.

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Transparency

- **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

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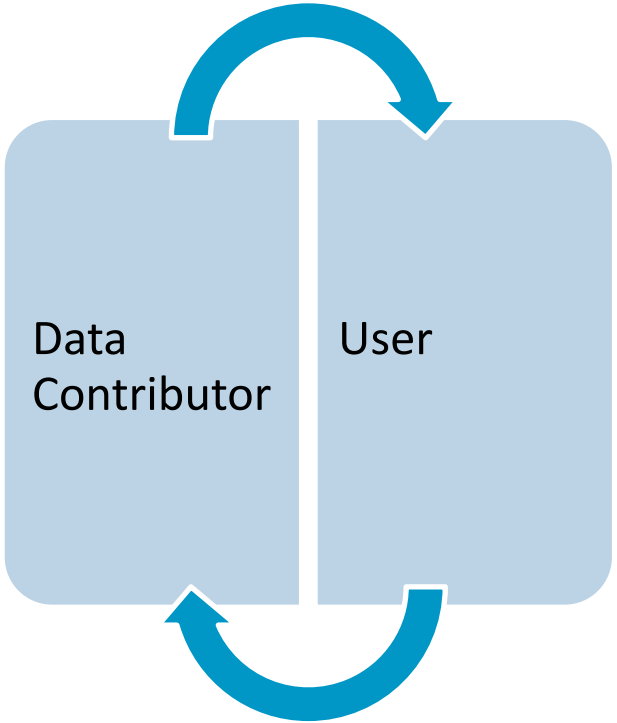
Sustainability

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

	Study Curated and Listed on Vivli	Anonymized IPD Storage	Independent Review Panel	Cost
Study ready for sharing and needs storage	✓	✓		$2,000
Study ready for sharing and needs Storage and Independent Review Panel	✓	✓	✓	$4,500
Anonymization				Vivli does not provide this, but we have partners who can. Please get in touch with us.

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.

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(DRAFT) Charges for research environment

Timing	Compute charge	Details
0-3 months	**No charge**	Jupyter notebook, Python, R, STATA, Office suite, and SAS analytical tools available
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

Larger sizes available upon request. Administrative fee of $500 for loading additional data, tools, scripts

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

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Thank you.
http://vivli.org/