



## Introducing Vivli

“Data sharing has incredible potential to strengthen academic research, the practice of medicine, and the integrity of the clinical trial system.” – Senator Elizabeth Warren<sup>1</sup>

The Multi-Regional Clinical Trials Center of Brigham and Women’s Hospital and Harvard (MRCT Center) has been involved in multiple efforts to enhance access to clinical trials data by promoting data sharing and transparency since 2013. Working with a group of multi-disciplinary global stakeholders, the MRCT Center is proud to announce the incorporation of Vivli, the Center for Global Clinical Research Data.

### Vision

**To advance human health through clinical trials data sharing, thereby respecting and honoring the contributions of sponsors, funders, investigators and, most essentially, clinical trial participants.**

Vivli was created as an independent not-for-profit entity with the mandate to govern and manage a data-sharing platform that is agnostic to disease, country, sponsor or funding agency.

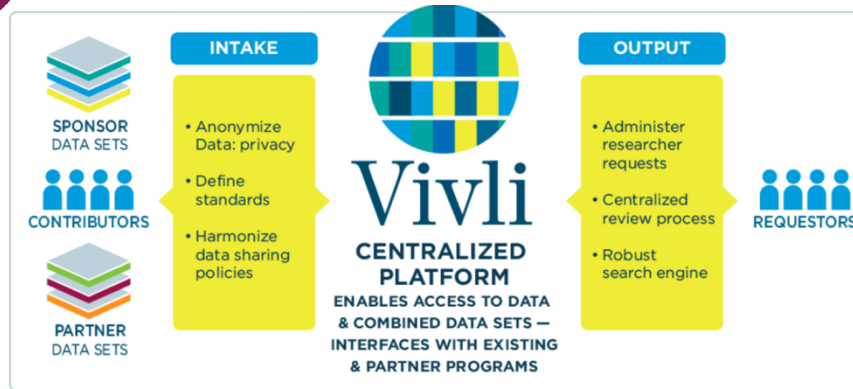
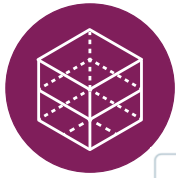
Vivli will establish an independent electronic data repository and search engine to host, share, and access clinical trials data conducted by researchers in academic, industry, foundation and non-profit entities.

In May 2016, the New England Journal of Medicine published a perspective detailing the need for and vision to create a global data-sharing solution, Vivli.<sup>2</sup> Vivli will address many of the current challenges that inhibit greater utilization of participant-level clinical trials data, including the lack of a centralized search engine that can direct precise queries, the lack of data standards to enable true interoperability of data, the lack of harmonized policies and approaches, and the concern over participant privacy and data security. Vivli will facilitate a data requester to combine anonymised individual patient data (IPD) from different hosts, bringing economies of scale to address technical, operational, and policy concerns.

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<sup>1</sup> Warren, E. (2016). Strengthening Research Through Data Sharing. New England Journal of Medicine; 375:401-403  
<http://www.nejm.org/doi/full/10.1056/NEJMp1607282>

<sup>2</sup> Bierer, B. E., Li, R., Barnes, M., & Sim, I., (2016). A Global, Neutral Platform for Sharing Trial Data. New England Journal of Medicine; 374:2411-2413. <http://www.nejm.org/doi/full/10.1056/NEJMp1605348>



## Promoting health science, reducing barriers to data sharing, respecting privacy

A sustainable global enterprise encompassing academia, government, and industry is in our reach. By enhancing the discoverability of data and providing analytical tools, we will complement existing initiatives and promote further collaboration.

Disparate data contributors and data users will benefit from Vivli's efforts to harmonize data sharing practices and policies.

## Enhanced search and discovery

Partnering with existing technologies, Vivli has designed an enhanced search engine to index clinical trial metadata with machine-assisted curation. Vivli's search engine will allow precise query building that is superior to existing platforms, enabling researchers to easily discover data relevant to their research question, regardless of where data are hosted. The robust metadata catalog will also support researchers interested in meta-analysis.

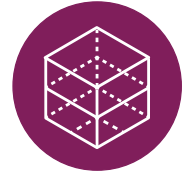
## Support and hosting for academic clinical research

The Vivli platform will provide a secure and cost-effective environment to host academic clinical trials data for the vast majority of academics who do not currently have reliable long-term options. Beyond storage and security, Vivli will also offer a host of services to suit academic research needs: controlled-access, data-sharing, dataset versioning, persistent data citations and unique identifiers (DOI and FORCE11), and anonymization/de-identification services.

## Secure virtual analytic environment

Vivli will provide a secure environment for data requestors to combine anonymized IPD from different hosts and all types of data generators including industry, academia, and biotech. In this controlled-access environment, data security models and export controls can be tightly controlled according to the specifications of each data contributor.

A wide array of analytical tools and benefits will be available through the platform, including anonymization and de-identification.



## Collaboration for a common vision

In partnership with data sharing leaders in industry, academia, patient organizations, government and not-for profit organizations; we can achieve a well balanced approach to lowering barriers to secondary use of clinical trials data.

By fostering collaboration and trust between industry, academia, and government institutions, Vivli will help science move forward and chart a new pathway that will accelerate progress in medicine.

## Current Status

Vivli is established as a US non-profit organization and has applied to be recognized as tax-exempt under IRS section 501(c)(3). The Vivli Board of Directors represents a variety of diverse stakeholders, including representatives from academia, non-profit and for-profit entities, and participant/patient communities. The Vivli Board sets the strategic direction and finances of the organization, will select permanent officers, and will establish partnerships with technology innovators and experts for the Vivli platform build.

## Leading change through policy & advocacy

Vivli will work closely with data sharing leaders in collaboration with MRCT Center and other institutions to promote data sharing by developing guidance and resources for researchers on anonymization, de-identification, and interoperability of data sets using common data elements. Vivli is working to harmonize approaches to data sharing, including a prototype data sharing agreement and data contributor agreement, informed consent language and participant educational tools. Leveraging the expertise and high-level engagement of the MRCT Center stakeholders and partners, Vivli is supporting a new initiative to promote and incentivize data sharing through appropriate academic credit for data generators.

## Join with Vivli

[Vivli.org](http://Vivli.org)

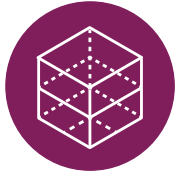
Contribute to Data Sharing

Collaborate with us

Contact Vivli for more information

[Vivli@MRCTcenter.org](mailto:Vivli@MRCTcenter.org)





## Vivli and MRCT Center Data Sharing and Transparency Workgroups

*Members of the MRCT Center workgroups, with the leadership of the co-chairs, contributed to the design of Vivli, the concepts and the content for this document.*

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We would also like to thank:

### The Vivli Project External Advisory Committee

