



CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

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February 11, 2020

Vivli: The Difference Data Re-Use Can Make



Patients Expect Data Sharing and Reuse



Roxana Mehran @Drroxmehran · 4 Apr 2017

trial participants-"share the data as widely as possible and as soon as possible to advance human health" #NEJMDataSummit #c



Vinay Prasad MD MPH @VPplenarysesh · 4 Apr 2017

Patients listened to trialists fears for one day and t
it's supposed to go #nejmdatsummit



Anna McCollister @annamcslipp · 4 Apr 2017

.@JeffDrazen -living in time where "trust me I'm a [redacted]
have data out there & let people see themselves #I



Sharon F. Terry @sharonferry · 4 Apr 2017

Love idea that next generation is open to openness-will we watch people die meanwhile? Do we have appetite for such waiting? #NEJMDataSummit



P. F. Anderson @pfanderson · 4 Apr 2017

OUTCOMES of patient panel > Share early, often, with me, responsibly, understandably #NEJMDataSummit



Aaron Eisman @aaroneisman · 4 Apr 2017

Patients incredulous that sharing data isn't the norm, speaking loud and clear: "share my data!" #NEJMDataSummit



Balancing Risks and Benefits

Openness



Maximizing the value of the data collected respects participants' contributions

Privacy



Protecting participant privacy

Approaches to Sharing Human Data

Type	Key Features	Examples
Open access	Anyone can access, simple account creation, simple on-line data use agreement (DUA)	Health CAN, EMA, Project Datasphere
Managed access	<ul style="list-style-type: none">• for scientific purposes only (standard request form)• (independent) review process• secure environment for data access• clear legal framework	Vivli, CSDR, SOAR, VISTA
Restricted access	Invitation only, access only to those who provide data	DataCelerate, IBD Plexus

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

abbvie



Vivli Members



TEMPUS



Vivli by the numbers ...TODAY



Vivli is a Global Data Platform – Agnostic to Disease, Funder or Data Contributor

Irritable Bowel Syndrome
Bacterial Peritonitis Glaucoma Endometriosis
Kidney cancer Non Hodgkins Lymphoma Epilepsy HIV
Breast cancer Cystic Fibrosis Diabetes Mellitus Insomnia
Coronary Artery Bypass Surgery Schizophrenia Bariatric Obesity
Atrial Fibrillation Fibromyalgia Cancer Traumatic Brain injury Trauma
Influenza Crohn's Diabetes Huntington's Disease Dabigatran
Atorvastatin Disease Hypertension Hepatitis CHepatitis Autism
Hidradenitis Myocardial Arthritis
Psoriasis Statin Endometriosis Interleukin-6 Zolofit
Tysabri Tuberculosis Depression Heart-Failure
Bipolar disorder Cannabinoids Asthma Lung cancer Lymphoma
Multiple Sclerosis Sickle Cell disease Atopic Dermatitis
Tumor burden Vitamin D Total Joint Replacement Cancer
Vedolizumab Pulmonary Arterial Hypertension Infarction
Hemophilia Sleep Apnea Edoxaban Type 1 Diabetes Mellitus
HPV Humira Colorectal Cancer Osteoarthritis
Lymphoma Stroke Ulcerative Colitis Vitiligo

How Vivli works

SEARCH

Search Vivli platform for information about available studies.



REQUEST

Request IPD Data sets.
Each Data Request will be **reviewed** according to contributors' publicly stated requirements.



ACCESS

Data from approved requests can be **accessed** in Vivli's secure research environment or **downloaded** with permission.



ANALYZE

Use robust **analytical tools** to combine and analyze multiple data sets.



DISSEMINATE

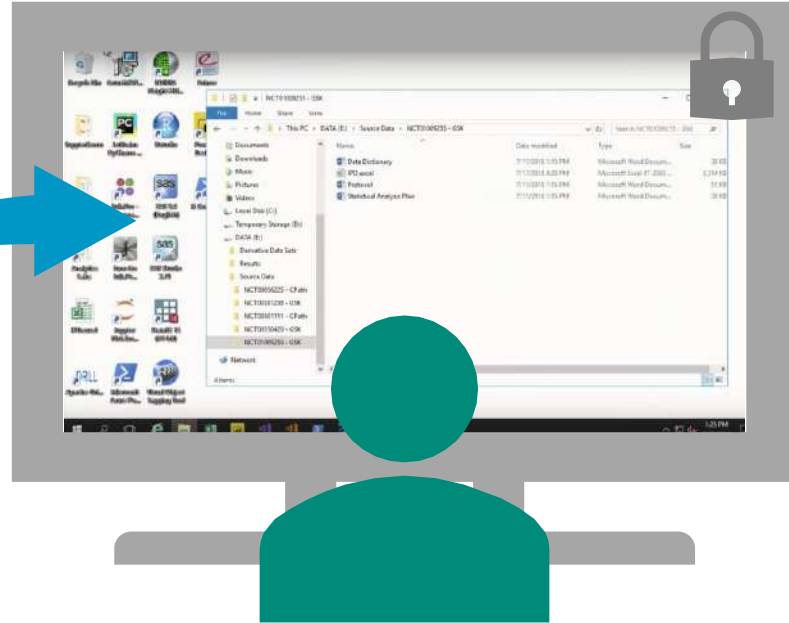
Completed **research results** will be assigned a DOI.
Researchers may use the Vivli platform to meet their **publication** requirements.



Secure Environment Bridges Multiple Platforms



Vivli Secure Environment



30+ packages

- STATA
- MS Office
- R
- Jupyter Notebook
- Python
- SAS

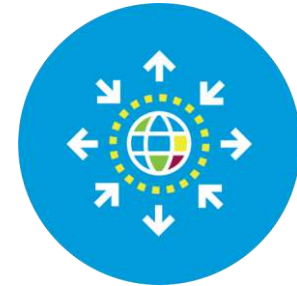
BYO data, scripts, software on request







Harmonization for Efficiency

Harmonization based on wide stakeholder consultation reduces friction for both data contributors and data users:

- Harmonized Data Request Form
- Harmonized Data Use Agreement
- Harmonized Data Contributor Agreement



Usage Metrics (as of January 1, 2020)

GLOBAL HITS TO VIVLI	57,030	
STUDIES AVAILABLE FOR SHARING	4,788	
DATA CONTRIBUTORS	22	
DATA REQUESTS SUBMITTED	91	

Vivli FAIR Data Sharing

- Findable
 - metadata model, annotated using Cochrane vocabulary (SNOMED, WHO ATC, MedDRA)
 - Dataset DOIs minted by DataCite
- Accessible
 - from fully downloadable to available only in secure MS Azure environment
- Interoperable, Reusable
 - SDTM format recommended but not required
 - No requirement for common variables

Explore Vivli

Log on to

Vivli.org

To explore the ~4,800 trials and begin the search

