



CENTER FOR GLOBAL CLINICAL RESEARCH DATA

An Innovative Clinical Trial Data Sharing and Re-use Platform

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SHARE



DISCOVER



INNOVATE

Vivli: The Difference Data Re-Use Can Make



Data Sharing in the News

SHARING CLINICAL RESEARCH DATA



ADNI: Understanding Alzheimer's disease through collaboration and data sharing

Posted October 1st, 2015 by Emily Fleiss on Unimagined



Of the many outstanding mysteries of neuroscience, the pathogenic origins of Alzheimer's disease (AD) remain one of the most perplexing neurological puzzles. An estimated 5.7 million Americans are presently afflicted with the disease, which gradually ravages the aging brain, resulting in progressive loss of memory followed by other cognitive abilities. Due to this accelerating pressing public health concern, funding agencies have grasped the urgency of supporting research aimed at detecting and treating this debilitating neurodegenerative disease, and continue to increase their funding allocations for AD research. Yet, despite decades of investigation, our knowledge of the basic biological underpinnings of AD remains remarkably inconclusive.

No lab should be an island

Two significant obstacles to unraveling the mystery of AD are the complexity of this heterogeneous disease, and the challenge of unifying disparate findings from independent research groups using vastly different techniques and samples. For instance, how does the research community integrate reports on structural brain changes in AD from two labs each using different brain imaging techniques, and studying small groups of demographically and clinically distinct samples of patients? This problem, of researchers working in isolated microcosms to solve enormously complex questions, is not unique to AD researchers. In many other areas of basic and clinical research, the same problem exists.

CLINICAL TRIALS

A new portal for patient data

Vivli aims to ease sharing of anonymized clinical studies

By Joseph K. Kohn

Under pressure to be more transparent about the results of drug testing studies, some companies have begun to share anonymized patient data from clinical trials with approved researchers as secure webpages. An online platform launched this week aims to expand such efforts by offering a one-stop clearinghouse for those seeking to mine these data for new insights.

The platform, created by Vivli, a non-profit based in Cambridge, Massachusetts, debates with access to more than 4000 clinical trial data sets from eight companies and researchers. It also features tools for searching and analyzing the data.

"This is the first time it's all going to be available in one place," Vivli Executive Director Katherine Li says.

Vivli, which spun out of a policy think tank at Harvard University-affiliated Brigham and Women's Hospital in Boston, is part of a push to encourage drug developers to share their data—even negative results, findings that show a treatment has no benefit.

Companies seeking U.S. regulatory approval for a drug, as well as investigators funded by the National Institutes of Health, must post limited, summary results on ClinicalTrials.gov. But many researchers and policy makers believe sharing detailed raw data on individual patients, stripped of identifying information, would be valuable. Researchers could confirm that a drug works, look for side effects, or explore new questions.

Starting this month, the International Committee of Medical Journal Editors—which includes the leaders of many major journals—will ask submitting authors to include a data sharing plan that can include patient data. Such sharing remains controversial. In 2010, Jeffrey Drazen, editor of *The New England Journal of Medicine*, wrote in an editorial that "it would exclude 'researcher'—academics who request others' data and quickly publish papers, presenting the scientists who generated the data. But Drazen ultimately endorsed the committee's plan.

Some companies have already responded. Drug giant Johnson & Johnson allows

researchers to request patient data at a 3-year-old site called VIDA, sponsored by Yale University, whereas GlaxoSmithKline and 18 other firms share data at ClinicalStudyDataRequest.com.

Vivli aims to streamline researchers' ability to find, request, and combine data from these and other sites, Li says. It will both let data deposited elsewhere and eventually host data sets. GlaxoSmithKline, for example, is allowing Vivli to list more than 3000 of its data sets. Vivli will have an independent panel review some requests, but other rules to the data that hold the data. Because of patient privacy concerns, some often won't be able to download the data to their own computers, but will use the Vivli platform.

Companies can purchase memberships to have Vivli share their data. Academic researchers will pay \$2000 to \$4000 per study for storage and sharing services. Data miners can freely use the site's basic tools for a year, but after that will pay a daily fee of \$12. Both the Bill & Melinda Gates Foundation and Harvard plan to help research cover data administration costs.

At the Gates Foundation in Seattle, Washington, officials anticipate that many groups will deposit their clinical trial results in Vivli in order to meet the foundation's data-sharing requirements. And Harvard officials will be encouraging faculty to add their clinical data sets, including hundreds from already completed studies.

Some data sharing advocates are pleased by Vivli's arrival. "We need to get everyone behind one platform instead of having a proliferation of these things," says epidemiologist Evan M. Goepfert of Johns Hopkins University in Baltimore, Maryland. There is uncertainty about demand, however. A 2014 study by researchers at Duke University in Durham, North Carolina, found that scientists had requested access to just 10% of more than 2000 patient data sets available on three platforms. One obstacle was the difficulty finding the data, says Duke cardiologist Eric Peterson, an author. Vivli could make that problem, he says, by serving as a clinical data "local catalog."

Wired reporting by Elizabeth Gershon



Science

Blockchain Key to Enhancing Clinical Research, Patient Data Sharing

Blockchain could potentially improve clinical research by facilitating patient data sharing and improving interoperability.

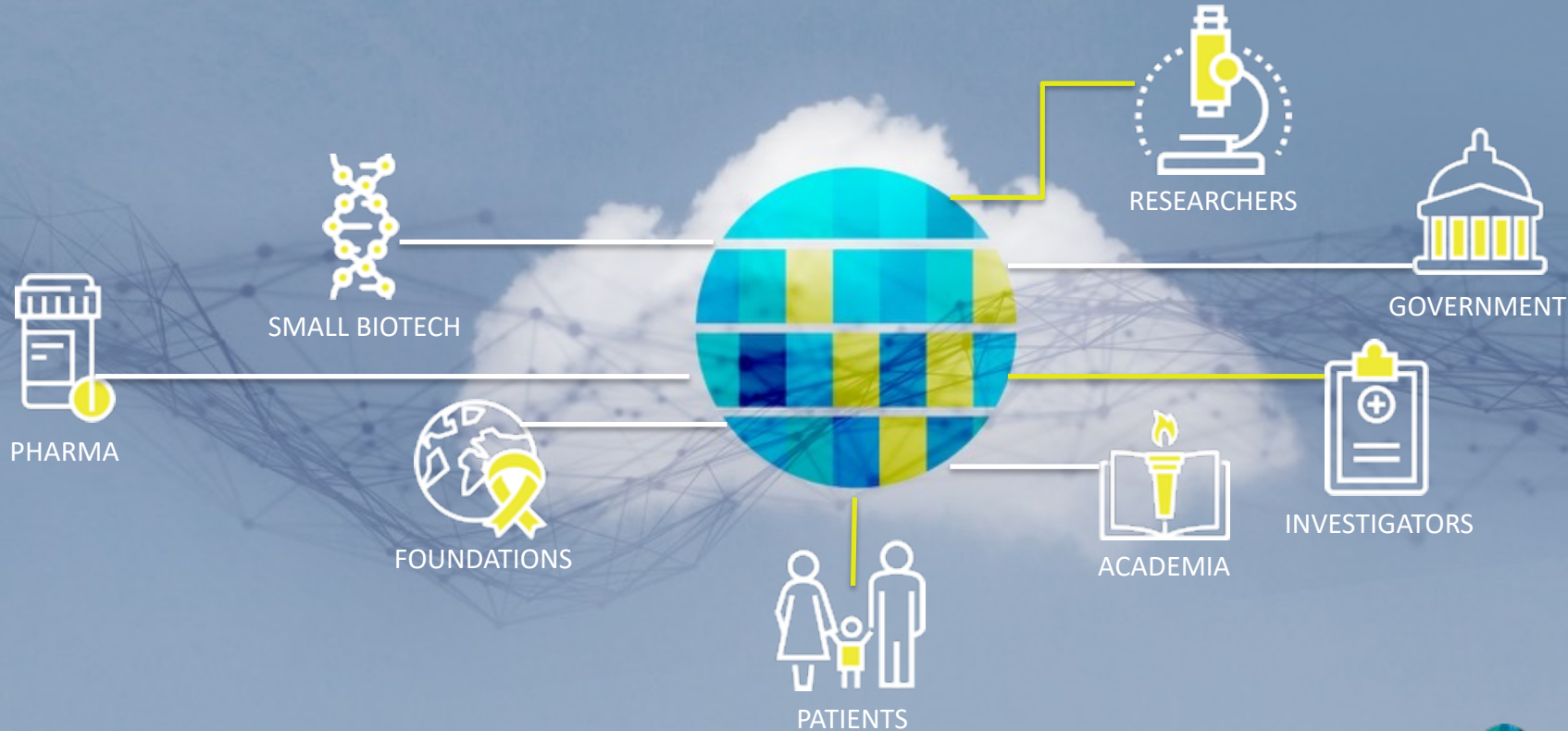


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Vivli – Big Data in Action with Clinical Trials



Science has no borders



Why it matters



Reduce duplication of trials



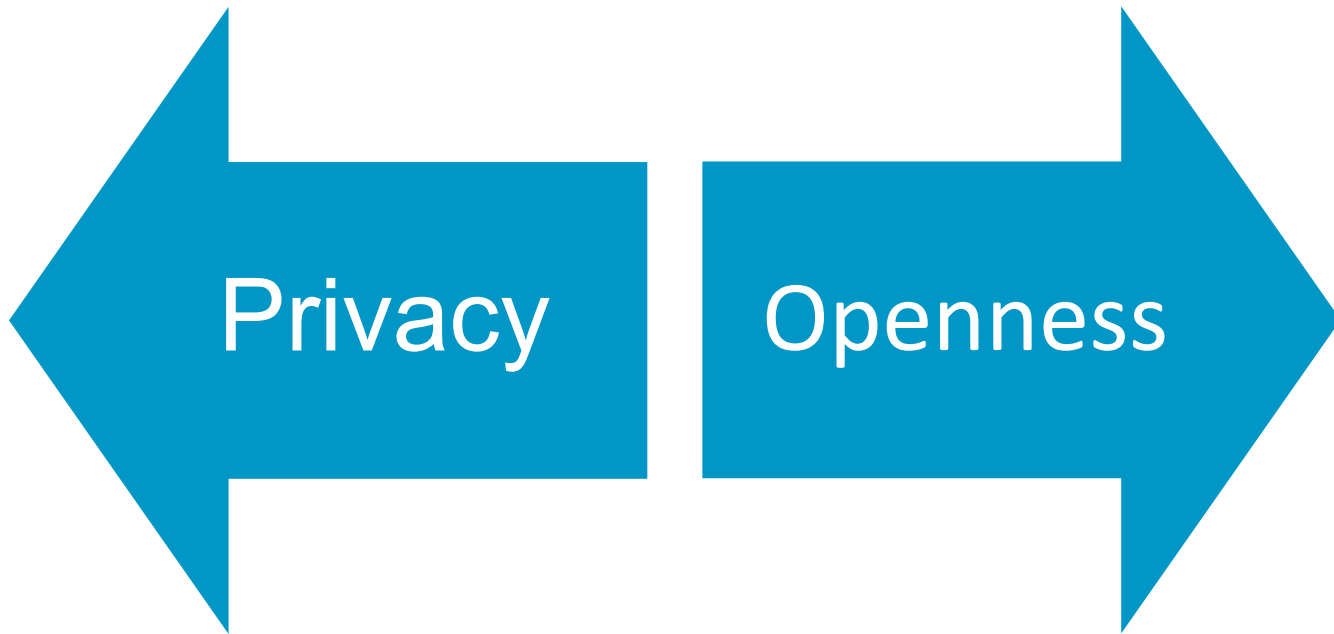
Shape clinical trial design



Leverage patient contribution



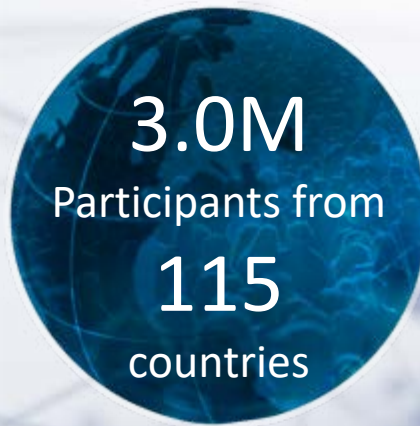
Balancing Risks and Benefits



Protecting participant privacy

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

Vivli by the numbers ...TODAY



Vivli Members

abbvie



Duke UNIVERSITY



HARVARD
UNIVERSITY



THE LEONA M. AND HARRY B.
HELMSLEY
CHARITABLE TRUST



Johnson+Johnson
FAMILY OF COMPANIES

Lilly

Lundbeck



Mitsubishi Tanabe Pharma



REGENERON



TEMPUS



Inspired by patients.
Driven by science.

UCSF

University of California
San Francisco



Vivli COVID Portal



PORTAL FOR GLOBAL CLINICAL RESEARCH DATA

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We are committed to advancing the knowledge around the COVID-19 pandemic

All fees are waived for sharing and accessing clinical trials

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KEYWORD SEARCH

PICO BETA

COVID or SARS-CoV-2 or 2019-nCoV



STUDY DESIGN

INTERVENTIONAL STUDIES

Select Multiple

OBSERVATIONAL STUDIES

Select Multiple

STUDY PHASE

Select Multiple

SPONSOR INFORMATION

SPONSOR TYPE

Select Multiple

SPONSOR

Select Multiple

LOCATION

Select Multiple

START DATE

FROM

TO

mm/yyyy

mm/yyyy

END DATE

FROM

TO

mm/yyyy

mm/yyyy

SAMPLE SIZE

(Disabled) ☐

Vivli's COVID-19 Portal Objectives

- Provides a dedicated search function
- Potential for fast-tracked review and sharing
- Vivli has waived fees to share, archive and access COVID-19 trials
- Vivli key partners have offered to waive anonymize fees (often a major barrier to sharing)

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.



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 Depression Interleukin-6 Zoloft
Tysabri Tuberculosis 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

Platform Pillars of Security

