



Vivli

Clinical Research Data Sharing:  
Share. Discover. Innovate.

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

# Creation of Vivli

Vivli was created through a project of the Multi-Regional Clinical Trials Center (MRCT Center) of Brigham and Women's Hospital and Harvard.

Supporters and funders of this project (in alphabetical order):

- *Deloitte Consulting*
  - *GlaxoSmithKline*
  - *Doris Duke Charitable Foundation*
  - *Helmsley Charitable Trust*
  - *Institute of Medicine (now National Academies of Medicine)*
  - *Johnson & Johnson*
  - *Laura and John Arnold Foundation*
  - *Lyda Hill Foundation*
  - *Pfizer Foundation*
  - *Wellcome Trust*
- *And the volunteer efforts of over 150 individuals*

# Main Pain Points Addressed by Vivli

- 1) Hosting and anonymizing data for data contributors as needed;
- 2) Coordinating and harmonizing existing data-sharing initiatives, policies, and processes;
- 3) Enabling aggregation of data from multiple contributors;
- 4) Access to secure full-featured analytic environment and tools;
- 5) Sustainability for both data contributors and researchers



# Introducing Vivli

## THE ENTITY

- Vivli is a Massachusetts-based non-profit 501(c)(3) 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 VIVLI PLATFORM

- A user-friendly, secure, state-of-the-art data sharing and analytics platform
- Serving the international community, including trials from any disease, country, sponsor, funder or investigator
  - Open search
  - Robust security
  - Modern tools and technologies

# Critical Three-Part Solution

- **Sustainability:** Independent non-profit bringing together multiple stakeholders in a trusted, neutral broker under transparent shared governance
- **Policy:** Harmonized policies and streamlined processes for data submission, data request, data access, and sharing of academic credit
- **Technology:** Powerful comprehensive global data-sharing and analytics platform



SEARCH

Data available through the Vivli platform



CONNECT

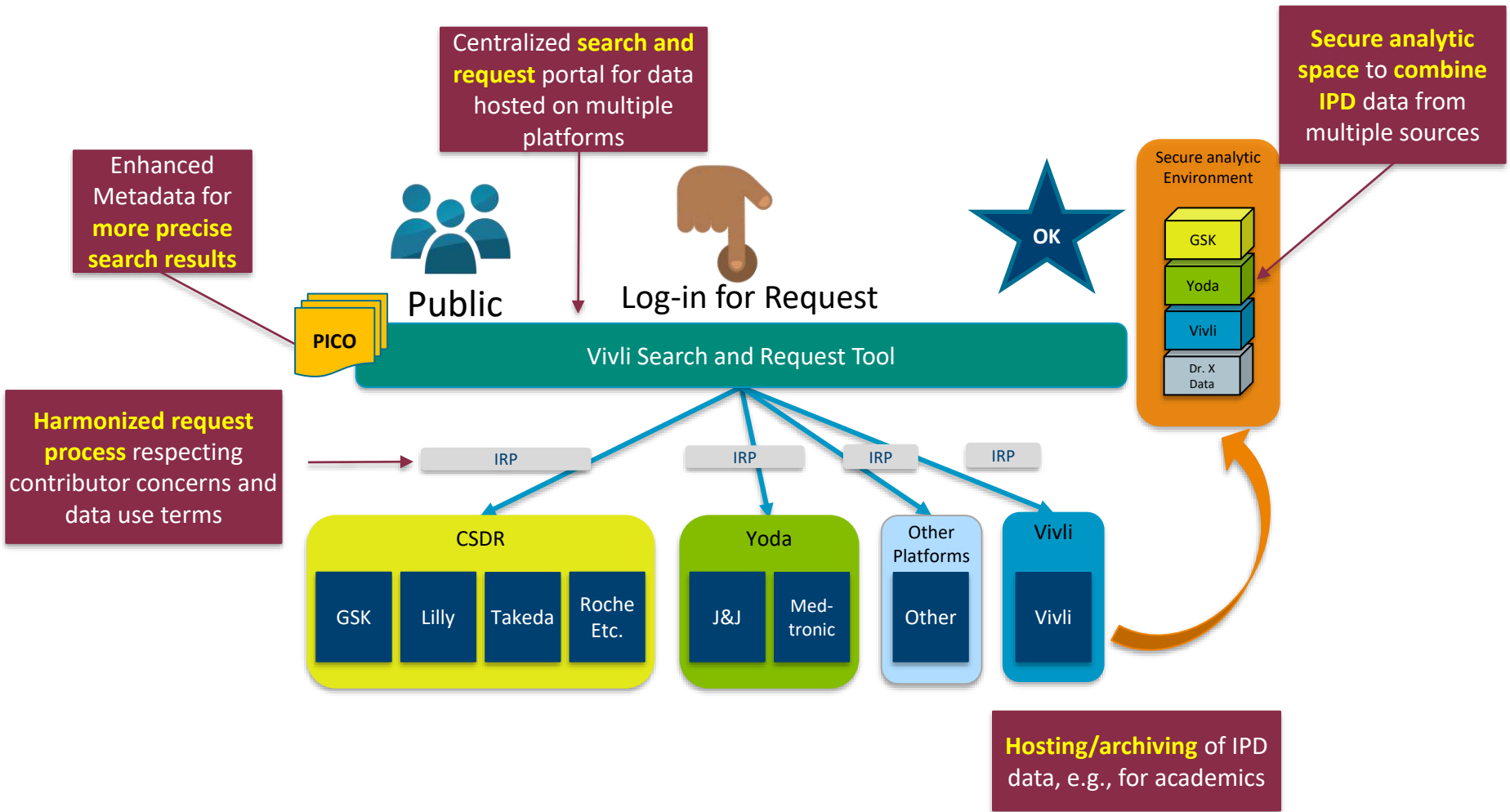
Make your data discoverable through Vivli



SHARE

Your data on the Vivli platform

# The Vivli Platform





Supporting free-text natural language search



Does Rivastigmine

**Rivastigmine**

Rivastigmine Oral Capsule

Rivastigmine Oral Solution

Rivastigmine Transdermal Patch



0 Results

Automated  
classification of terms  
into a "PICO" query



Does Rivastigmine

**Rivastigmine**

Rivastigmine Oral Capsule

Rivastigmine Oral Solution

Rivastigmine Transdermal Patch

0 Results



User can easily reclassify a term into a different PICO category



Does Rivastigmine treat Dementia in Parkinson's Disease

**Parkinson's Disease**

Parkinson's Disease Aggravated

Parkinson's Disease And Parkinsonism

Parkinson's Disease Clinic

Parkinson's Disease Nos

50 Results



does anticholinesterases treat Dementia in Parkinson's Disease



✕ Clear Refiners

218 studies found matching your criteria

STUDY DESIGN

INTERVENTIONAL STUDIES

Select Multiple ▾

OBSERVATIONAL

Select Multiple ▾

SAMPLE SIZE



LOCATION

Multiple Selected ▾

UNITED STATES ✕

POLAND ✕

DATES

+ NEW

DATE TYPE

Dates of Enrollment ▾

FROM

TO

DD/MM/YY

DD/MM/YY

SPONSOR TYPE

Pharma ▾

### Multi-centre UK Study of the Acetylcholinesterase Inhibitor Donepezil in Early Dementia Associated With Parkinson's Disease

Query Terms Matching this Trial: Parkinson's Disease, Drug: Donepezil  
 Vivli ID: #123456789-02  
 Principal Investigator: Jack Frost, PhD  
 Sponsor: Newcastle-upon-Tyne Hospitals NHS Trust

Request Study ▾

View Details

### Long-term Safety of Rivastigmine Capsule and Patch in Patients With Mild to Moderately-severe Dementia Associated With Parkinson's Disease (PDD)

Query Terms Matching this Trial: Parkinson's Disease Dementia, Drug: Rivastigmine capsule; Drug: Rivastigmine transdermal patch  
 Vivli ID: #123456789-02  
 Principal Investigator: Jack Frost, PhD  
 Sponsor: Novartis

Request Study ▾

View Details

### Mild Cognitive Impairment in Parkinson's Disease

Query Terms Matching this Trial: Parkinson's Disease; Mild Cognitive Impairment, Drug: Exelon Patch (rivastigmine transdermal system); Drug: Placebo Patches  
 Vivli ID: #123456789-02  
 Principal Investigator: Jack Frost, PhD  
 Sponsor: University of Pennsylvania

Request Study ▾

View Details

### The Efficacy, Tolerability and Safety of Donepezil (Aricept) in Parkinson's Disease Patients With Dementia

Query Terms Matching this Trial: Dementia With Parkinson's Disease, Drug: ARICEPT  
 Vivli ID: #123456789-02  
 Principal Investigator: Jack Frost, PhD  
 Sponsor: Eisai Limited; Eisai Inc.

Request Study ▾

View Details

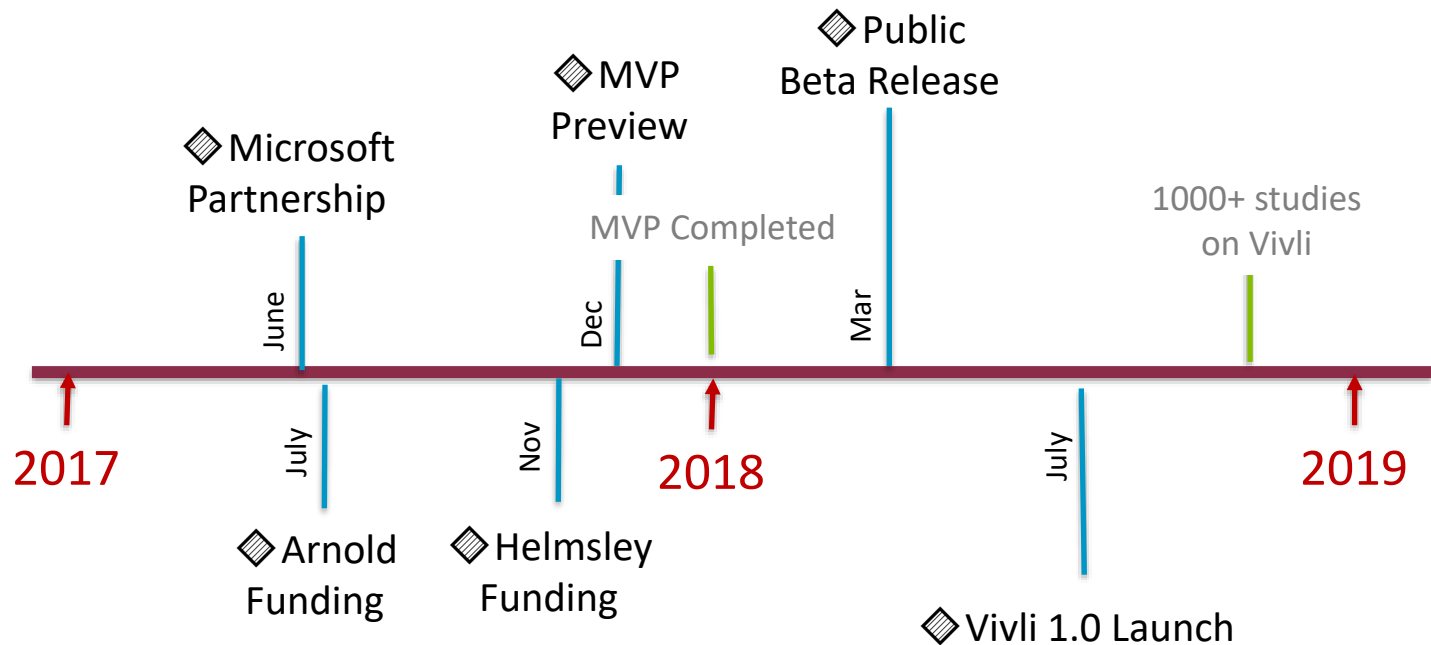
### The Efficacy and Safety Study of High Dose Donepezil in Parkinson's Disease With Dementia

Query Terms Matching this Trial: Parkinson's Disease, Drug: Donepezil  
 Vivli ID: #123456789-02  
 Principal Investigator: Jack Frost, PhD  
 Sponsor: Inje University

Request Study ▾

View Details

# Launch Activities



- Preview MVP at MRCT Annual Meeting, December 6, 2017
- Public beta release and additional features (post-MVP) in Q2
- Formal Launch planned July 2018

# Summary

- Time has come for IPD data sharing at a global scale
- Vivli operationalizes objectives, principles, and recommendations from previous groupings and events from around the world
- Provides standards-enabled data-sharing capacity to catalyze evolution of clinical research towards effective culture of data sharing and reuse

<http://vivli.org/>