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.
Current Gaps

> 60 existing sites, different standards, policies, security, access

Insufficient capacity to host data
Duplication of effort
Limited analytic tools and environments

Global neutral data sharing and analytics platform
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
## 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
The Vivli Platform

Centralized search and request portal for data hosted on multiple platforms

Enhanced Metadata for more precise search results

Harmonized request process respecting contributor concerns and data use terms

Secure analytic space to combine IPD data from multiple sources

Hosting/archiving of IPD data, e.g., for academics

Vivli Search and Request Tool

Public

Log-in for Request

CSDR
GSK  Lilly  Takeda  Roche Etc.

Yoda
J&J  Medtronic

Other Platforms

Vivli

GSK  Yoda  Vivli

Dr. X Data

PICO

IRP

IRP

IRP

IRP
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 anticholinesterases treat Dementia in Parkinson's Disease

218 studies found matching your criteria

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
Vivi ID: #123456789-02
Principal Investigator: Jack Frost, PhD
Sponsor: Newcastle-upon-Tyne Hospitals NHS Trust

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
Vivi ID: #123456789-02
Principal Investigator: Jack Frost, PhD
Sponsor: Novartis

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
Vivi ID: #123456789-02
Principal Investigator: Jack Frost, PhD
Sponsor: University of Pennsylvania

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
Vivi ID: #123456789-02
Principal Investigator: Jack Frost, PhD
Sponsor: Eisai Limited; Eisai Inc.

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
Vivi ID: #123456789-02
Principal Investigator: Jack Frost, PhD
Sponsor: Inje University
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/