Vivli

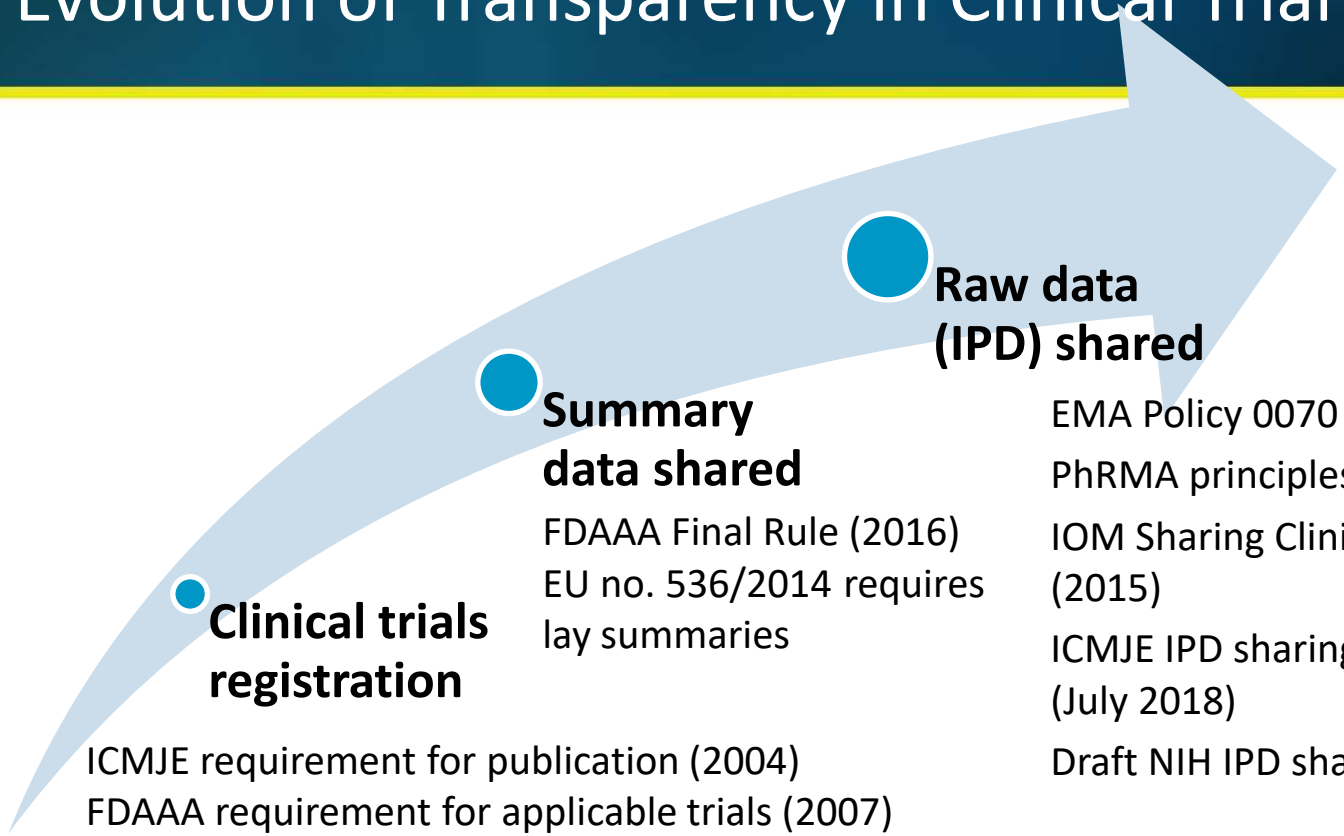
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Vivli: A Global Secure Data-Sharing Platform for Participant-Level Clinical Trial Data

Ida Sim, UCSF and Vivli

March 27, 2019

Evolution of Transparency in Clinical Trial Data



Clinical trials registration

ICMJE requirement for publication (2004)
FDAAA requirement for applicable trials (2007)

Summary data shared

FDAAA Final Rule (2016)
EU no. 536/2014 requires lay summaries

Raw data (IPD) shared

EMA Policy 0070 (2014), Policy 0043 (TBD)

PhRMA principles for data sharing (2014)

IOM Sharing Clinical Trial Data report (2015)

ICMJE IPD sharing statement requirement (July 2018)

Draft NIH IPD sharing requirements (2019)

Vivli

Barriers to IPD Sharing for Academics

- For most academic trialists (Data Contributors)
  - secure data hosting and sharing platforms not available or limited to within the institution
  - no standard data use and data sharing agreements
  - no independent review process available to adjudicate data requests
  - cost and difficulty of de-identifying IPD and making it available
  - **All this makes it difficult to meet data sharing requirements**
- For Data Users
  - difficult to discover what IPD is available for sharing
  - combining datasets from different platforms is resource- and time-intensive
  - different data standards, data requirements, security standards, policies
  - disease-specific data sharing platforms limit cross-disciplinary data discovery
  - limited range of analytic tools available

Vivli Addresses Pain Points for Contributors and Requesters

	IPD Sharing Requirements	Figshare & Dryad	University Repository	CT.gov	Vivli
Data Contributors	IPD can be stored and securely hosted	✔	✔		✔
	Harmonized data contributor and data use agreements	✔			✔
	IPD can be shared securely to anyone in the world				✔
	Independent review available				✔

Vivli By the Numbers

3200+
Trials

1.5M
Participants from
100
countries

16
Members

Vivli Members

abbvie

Aegerion Pharmaceuticals
A NOVELION THERAPEUTICS COMPANY

Biogen

BioLINCC
Biologic Specimen and Data Repository Information Coordinating Center

CRITICAL PATH INSTITUTE

Daiichi-Sankyo

Duke UNIVERSITY

gsk do more feel better live longer

HARVARD UNIVERSITY

THE LEONA M. AND HARRY B. HELMSLEY CHARITABLE TRUST

IMMPORT
BIOINFORMATICS FOR THE FUTURE OF IMMUNOLOGY

JOHNS HOPKINS UNIVERSITY

Pfizer

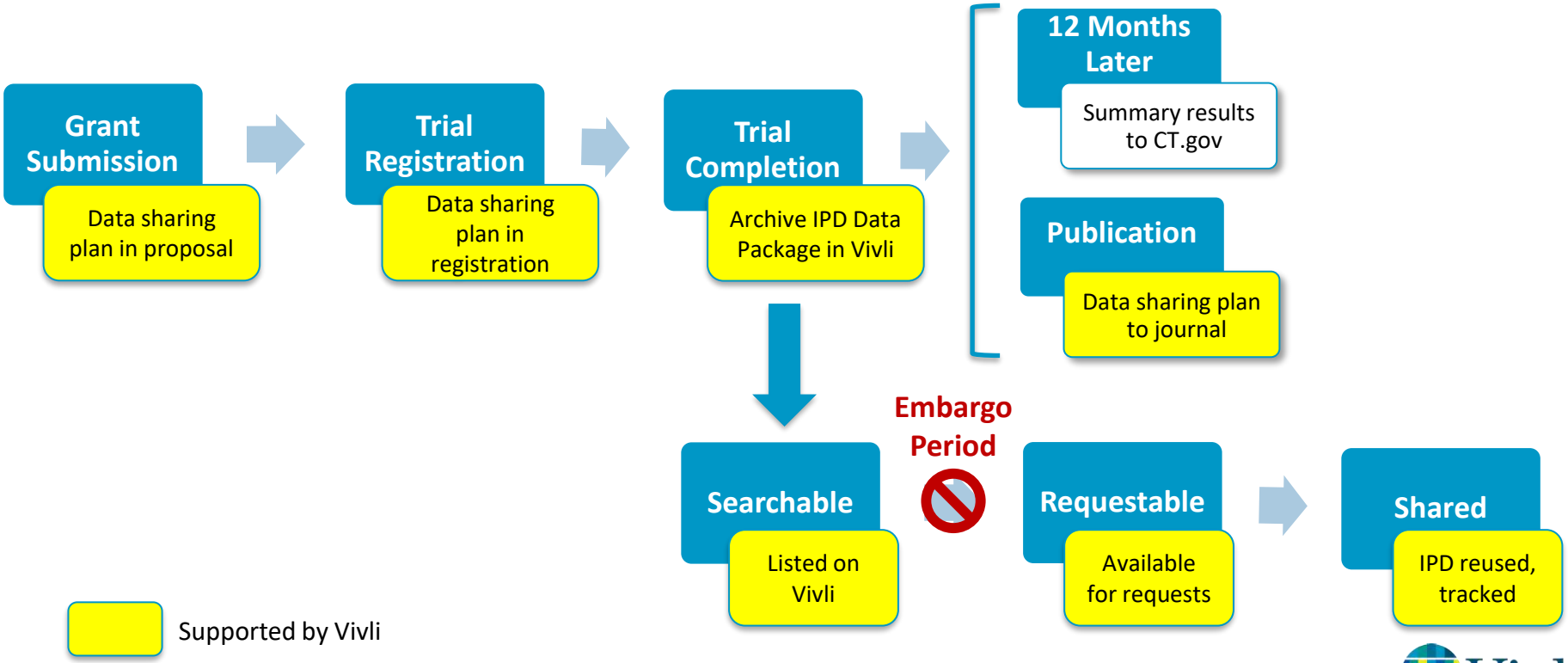
Project Data Sphere

Takeda

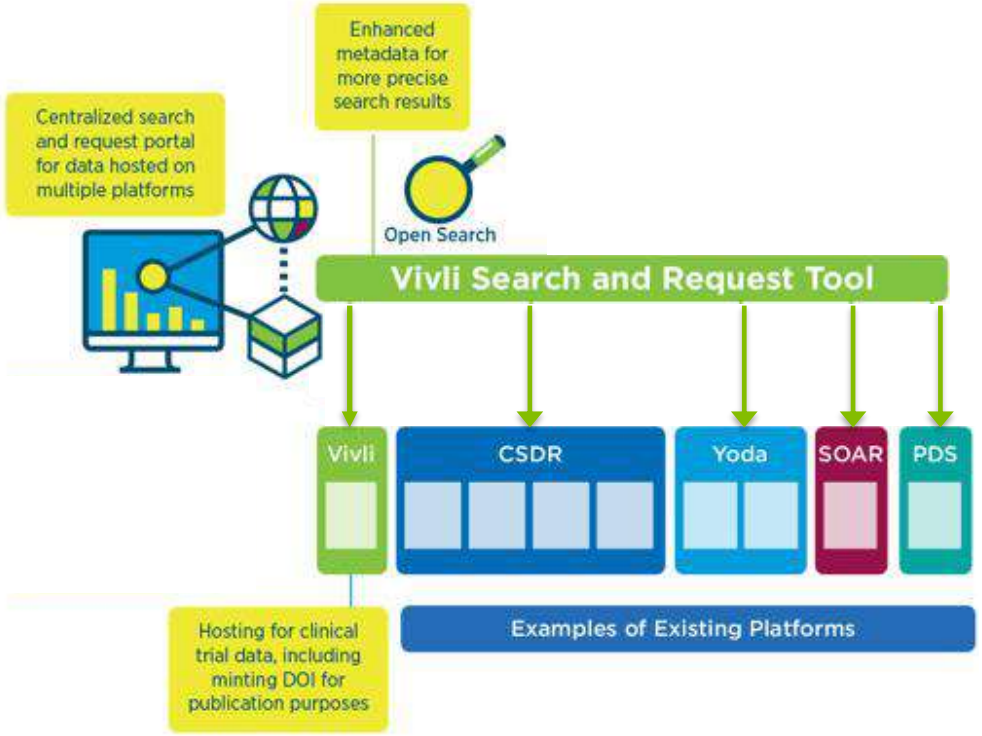
UCSF
University of California San Francisco

Vivli

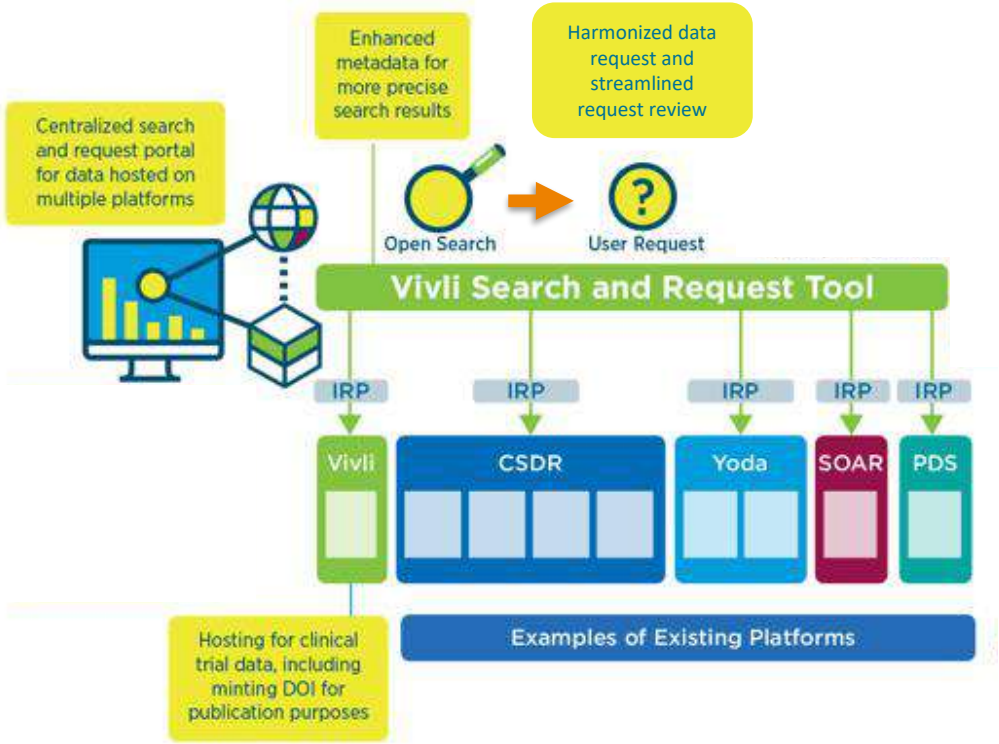
Data Sharing Timeline



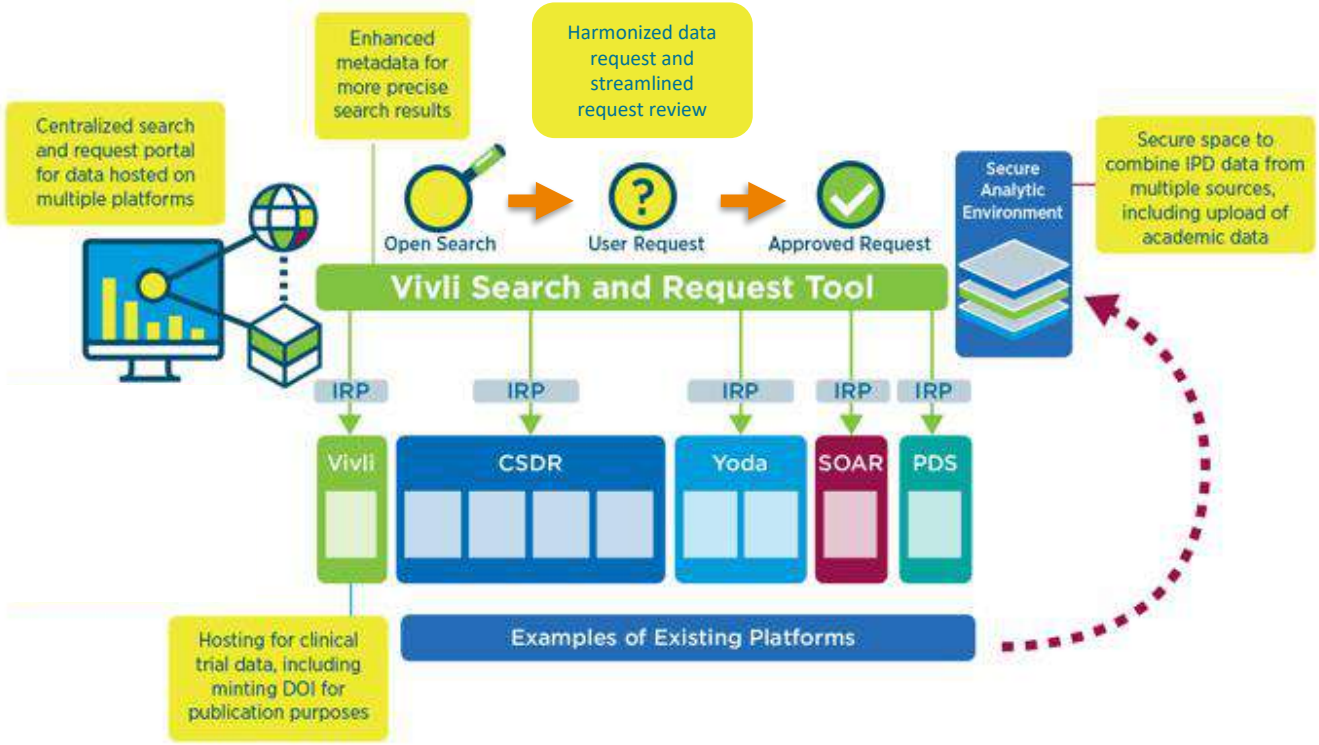
The Vivli Platform

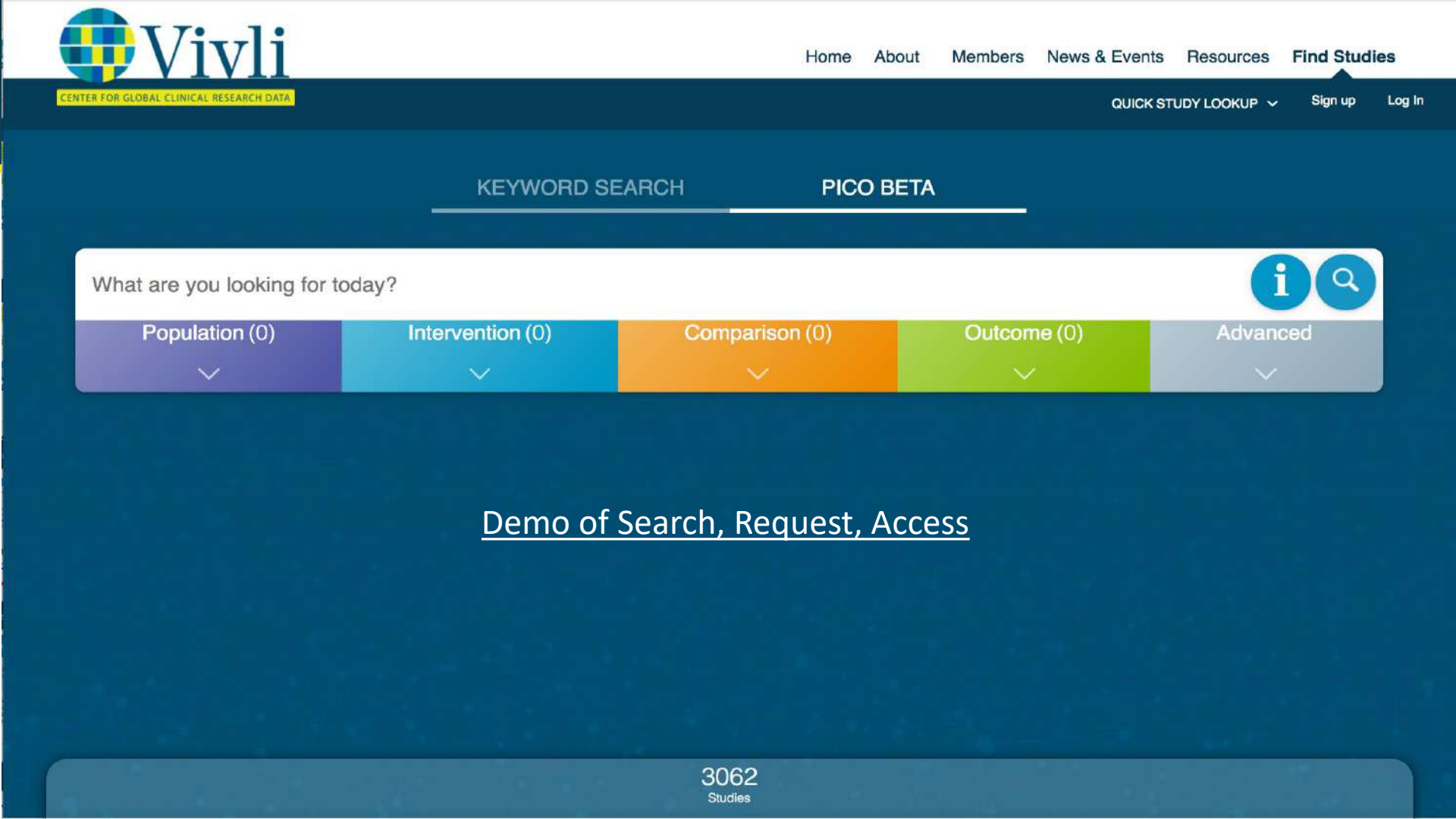


The Vivli Platform



The Vivli Platform




Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA
Home
About
Members
News & Events
Resources
Find Studies
QUICK STUDY LOOKUP
Sign up
Log In
KEYWORD SEARCH
PICO BETA
What are you looking for today?
Population (0)
Intervention (0)
Comparison (0)
Outcome (0)
Advanced
Demo of Search, Request, Access
3062
Studies

Summary: Benefits of Requesting Data through Vivli

- **One-stop search** – find individual-level participant data from more than 3,200 completed clinical trials
- **Harmonized request form** – use a single data request form for all studies
- **Bridges platforms** – can bring together data sets from Vivli and multiple other platforms
- **Secure yet customizable** – bring in your own data, tools and scripts to a secure research environment

Vivli

Summary: Benefits of Sharing through Vivli

- **Citation** – DOIs allow for citation and credit of your research data
- **Metrics** – Yearly metrics on number of data requests, resulting publications, etc.
- **Long-term archiving** – Archive your trials on Vivli (at least 25 years)
- **Post-grant data sharing** – Management of IPD sharing that continues even after grant funds end
- **Funder and journal mandates** – Easily fulfill requirements for data sharing plans

Vivli

Questions?

Vivli.org

- Explore the ~7,000 trials available via the Vivli platform
- Begin your search
- Contact support@vivli.org with questions

Vivli

Data Sharing Cost Per Study for Academics

	Study Metadata Curated and Listed on Vivli	De-Identified/ anonymized IPD Storage	Independent Review Panel	One-Time Cost
Study ready for sharing and needs Storage	✓	✓		Free for UCSF (otherwise $2,000*)
Study ready for sharing and needs Storage and Independent Review Panel	✓	✓	✓	$4,500
De-identification/ anonymization	✓	✓		Provided by Privacy Analytics (additional $2,000-$5000 / dataset)

*De-identified data and documentation must be shared at the time of curating and listing the study
Contributors must sign Data Contributor Agreement

Vivli

Secure Research Environment Options

Environment Type	Size	Tools Available	Platform Access	Compute Charge
Standard Research Environment	2CPUx7GB	Office 365, STATA, Jupyter Notebook, Python, R	Unlimited user accounts, 2 concurrent logins	No charge for 365 days, $12/day after 365 days
Premium Research Environment	4CPUx14GB	Office 365, STATA, Jupyter Notebook, Python, R, SAS (academic license)	Unlimited user accounts, 2 concurrent logins	No charge for 90 days, $25/day after first 90 days

* Custom environments available upon request

Vivli

Contents of the IPD Package

Item	Description
Required	
Study protocol	**Final protocol with all amendments**
Informed consent form	**Final approved informed consent form**
Data dictionary	**Detailed descriptions of each variable in the dataset, including the definition, source, coding, etc. of the variable**
Statistical Analysis Plan	**Description of the principal features of the analyses described in the protocol**
IPD dataset	**Final cleaned individual participant-level data, de-identified**
Optional	
Analytic code	Software code used to carry out prespecified and additional analyses
Case report forms	Forms used to collect the data that is described in the protocol for each trial participant
Clinical Study Report (CSR)	Report that summarizes the efficacy and safety data from the study (after regulatory decision)