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INTERCHANGE
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Lessons learned from sharing clinical trial data using Vivli

Azusa Tsukida, Senior advisor Vivli

Meet the Speaker

Azusa Tsukida

Title: Senior Advisor

Organization: Vivli

Joining Vivli team in 2022 as a Senior Advisor. Focusing on clinical data sharing and outreach in Japan. Before joining Vivli, she has nearly 15 years' experience as leader for the Biostatistics & Programming Department at Sanofi in Tokyo.

Over three decades of working experience in Global Pharma, not only the clinical development activities, but also engaged in JPMA task force activities related to e-data submission. Initial member of PMDA SWG for e-data submission and also ICH M11 JPMA topic leader until 2020.

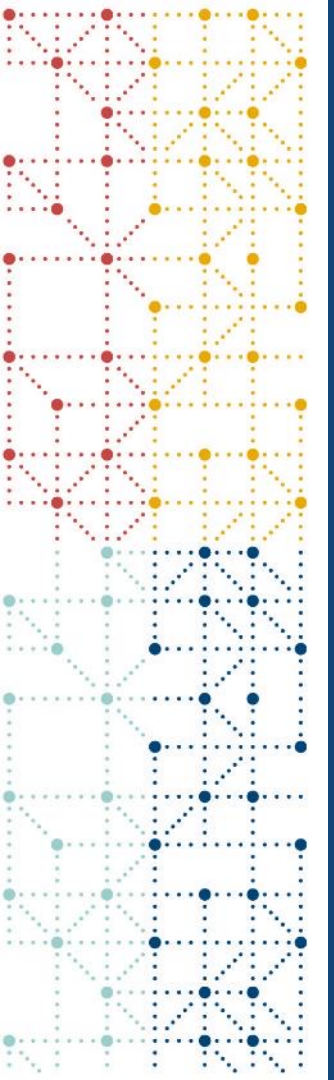
Christian University.

Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*
- *The presenter have no real or apparent conflicts of interest to report.*

Agenda

1. Why sharing patient level data
2. What is Vivli
3. Vivli’s collaboration with CDISC
4. What is the challenges for data sharing in future



Why sharing patient level data

Why Should My Organization Share Its Data?

- Ethical obligations to trial participants
- Journal requirements
- BIO, EFPIA, PhRMA, IFPMA,JPMA publicly stated commitments for members

What Do Surveys Show Regarding Patient and Participant Preference Regarding Data Sharing?

- High levels of support for data sharing; however, patients are reluctant to have their data “commodified” purely for commercial gain [1]
- If adequate safeguards were in place, trial participants are willing to share their data[2]

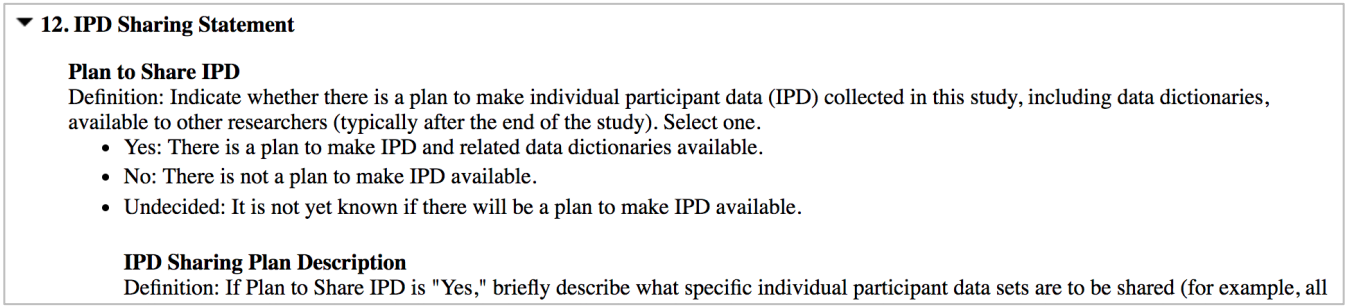
[1] Davidson S, McLean C, Treanor S, Aitken M, Cunningham-Burley S, Laurie G, et al. Public acceptability of data sharing between the public, private and third sectors for research purposes. Edinburgh: Scottish Government Social Research; 2013. Google Scholar

[2] Mello, Michelle M., Van Lieou, and Steven N. Goodman. “Clinical trial participants’ views of the risks and benefits of data sharing.

“ *New England Journal of Medicine* 378.23 (2018): 2202-2211.

Trial Registration

- Data sharing plan is part of the ClinicalTrials.gov registration record



12. IPD Sharing Statement

Plan to Share IPD
Definition: Indicate whether there is a plan to make individual participant data (IPD) collected in this study, including data dictionaries, available to other researchers (typically after the end of the study). Select one.

- Yes: There is a plan to make IPD and related data dictionaries available.
- No: There is not a plan to make IPD available.
- Undecided: It is not yet known if there will be a plan to make IPD available.

IPD Sharing Plan Description
Definition: If Plan to Share IPD is "Yes," briefly describe what specific individual participant data sets are to be shared (for example, all

- As of 1 January 2019, ICMJE requires registration of your data sharing plan at time of trial registration

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What are Journals Requiring?

The NEW ENGLAND JOURNAL of MEDICINE

EDITORIALS

Data Sharing Statements for Clinical Trials — A Requirement of the International Committee of Medical Journal Editors

The International Committee of Medical Journal Editors (ICMJE) believes there is an ethical obligation to responsibly share data generated by

explained at www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html. If the data sharing plan

Taichman DB, et al. N Engl J Med 2017; 376:2277-2279

- Major journals including NEJM, JAMA, The Lancet, BMJ, Annals of Internal Med, PLoS Medicine, and hundreds of others
- Trial manuscripts must be submitted with a data sharing statement
  - ✓ Must describe how you will share your Individual participant-level data (IPD), including who, what, when, where, and why
- IPD sharing is not (yet) required but "editors may take into consideration data sharing statements when making editorial decisions"

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What is Vivli

What is 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

Vivli by the numbers …TODAY

Industry Members

Japanese Industry members

Academic, Platform & Foundation Members

AccessClinicalData@NIAID

NIDDK CR-R4R

How Vivli works for a data requester

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

Type of Data Shared and Archived on Vivli

Clinical Research data shared at the participant level:

- Trials
- Observational studies
- Registries
- RWD

All data must be anonymized when uploaded to Vivli

Studies are prospectively planned and protocol-driven

What is included in a data package?

Item	Description
Recommended Data Package Set	
Study Protocol	**Final protocol with all amendments**
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 analysis described in the protocol**
IPD dataset	**Final cleaned individual participant-level data, de-identified/anonymized**
Anonymization Guidance	**Outlines the method used to anonymize the data**
Optional	
Analytic code	**Software code used to carry out prespecified and additional analyses**
Analysis ready IPD data set	**Dataset in a format used to carry out a sponsor's analyses**
Case report forms	**Forms used to collect the data that is described in the protocol for each trial participant**

Vivli's Secure Environment Bridges Multiple Platforms

BioLINCC
Biologic Specimen and Data Repository Information Coordinating Center

Johnson & Johnson

IMMPORT
BIOINFORMATICS FOR THE FUTURE OF IMMUNOLOGY

Project Data Sphere®

gsk
do more
feel better
live longer

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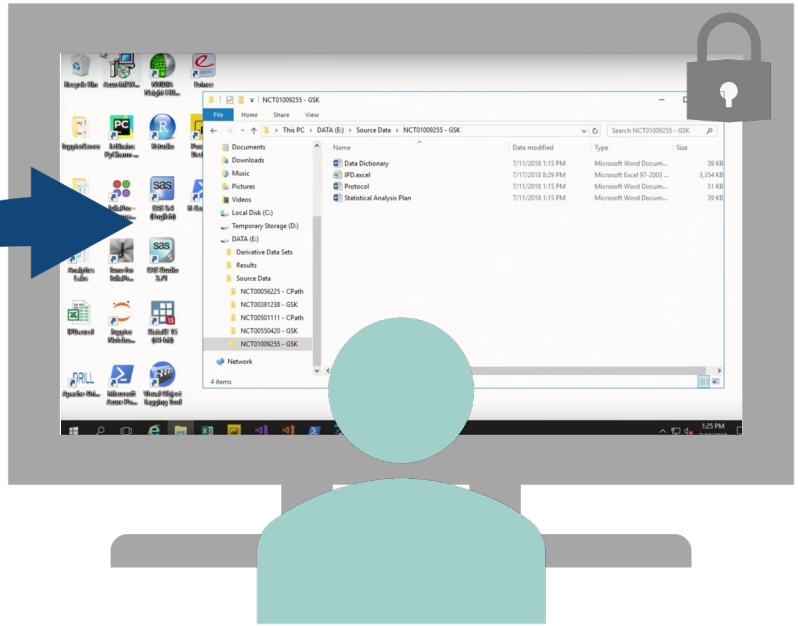
Vivli Secure Environment



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

Vivli enables a secure yet flexible research environment

- R version 4.0.2, + over 446 R packages
- Python 3.8.5, + over 392 Python packages
- Anaconda 3
- Apache Spark 2.2.0
- STATA 16.1
- Microsoft Word, Excel, Powerpoint, Photo Viewer
- Plink whole genome association analysis toolset
- WinBUGS
- OpenBUGS
- stan and rstan
- Adobe Acrobat Reader

Premium Research Environments:
- SAS 9.4, m4 (academic)

- **Flexibility:** Researchers will have the ability to bring in their own data sets, statistical software and scripts to their own secure research environment

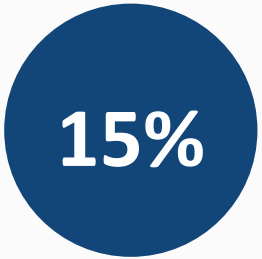
Data requests via Vivli

Metrics	Jan. 2019	Jan. 2020	Jan. 2021	Jan. 2022	Jan. 2023
Cumulative Submitted Requests	9	91	258	451	659
Cumulative Submitted Requests from Japanese researchers	0	1	5	13	19

Publications via Vivli

Metrics	Jan. 2019	Jan. 2020	Jan. 2021	Jan. 2022	Jan. 2023
Cumulative Publications	0	1	13	55	136
Cumulative Publications from Japanese researchers	0	1	2	2	5

~ 7,000 Vivli Trials Inventory
28 Therapeutic



Pulmonary/
Respiratory

Infectious
disease

Oncology

Neurology

Immunology

Psychiatry

Rheumatology

Cardiology

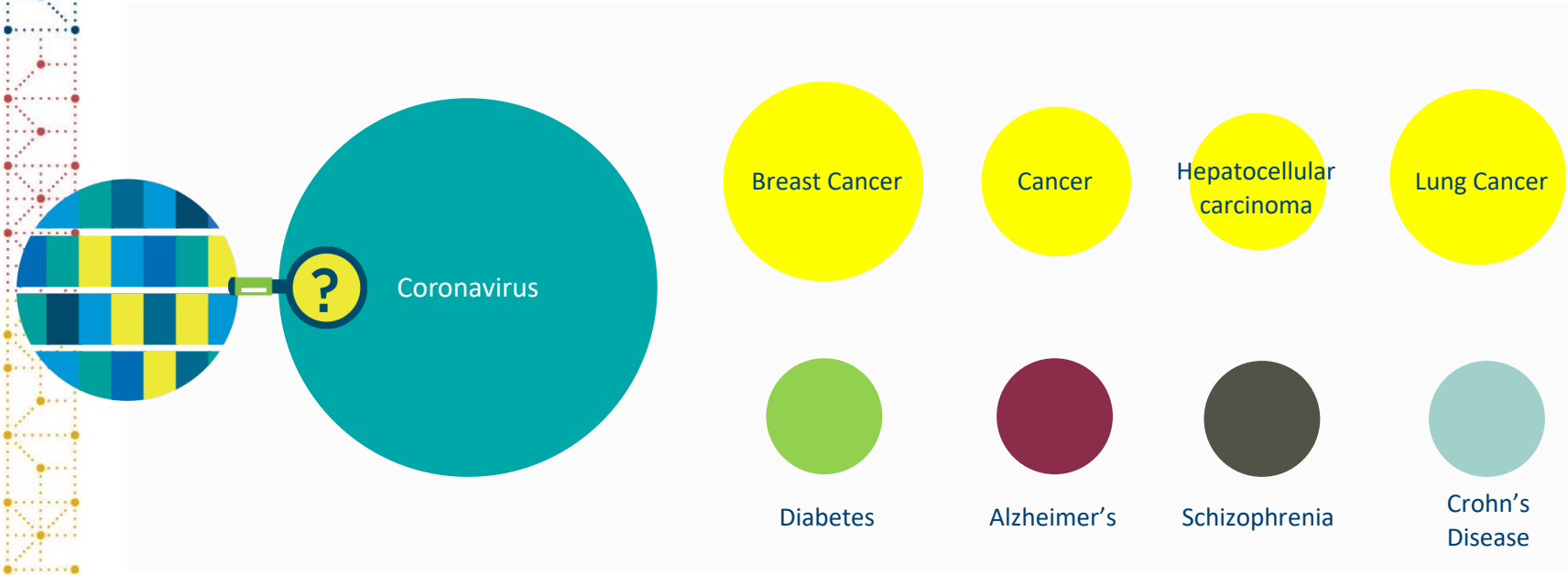
Metabolism
& Nutrition

Endocrinology

Gastro-
enterology

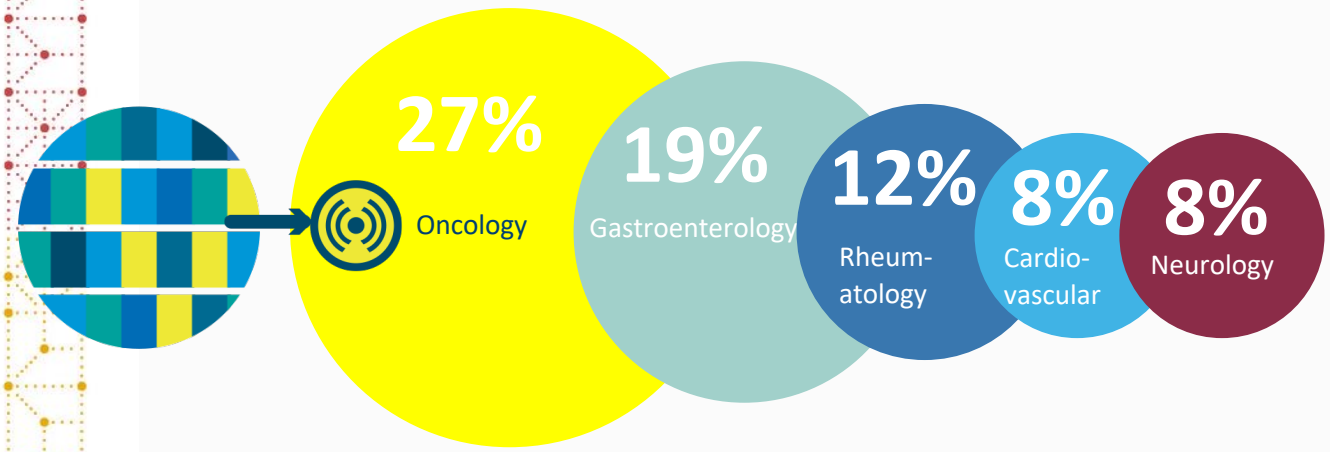
Additional 17 Therapeutic areas comprise 1-3% each

What are researchers looking for? Top 2022 searches

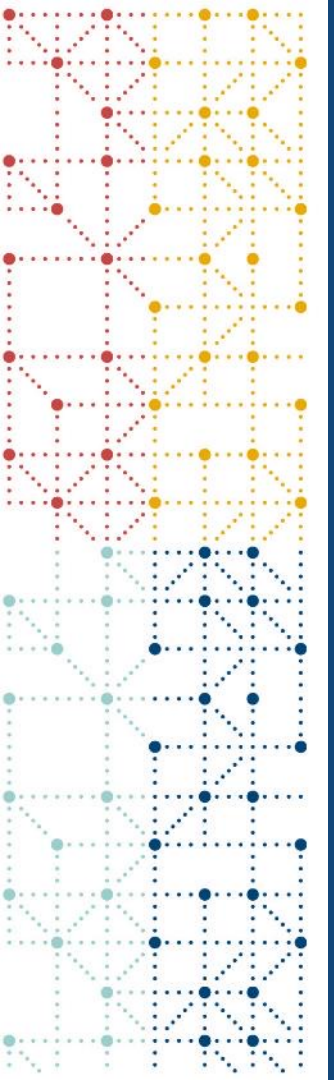


SEARCH REQUEST ACCESS ANALYZE DISSEMINATE

2022 publications



Dermatology	4%
Methods	4%
Pulmonary	4%
Orthopaedics	2%
Pain	2%
Other TAs	<2 %



Vivli’s collaboration with CDISC

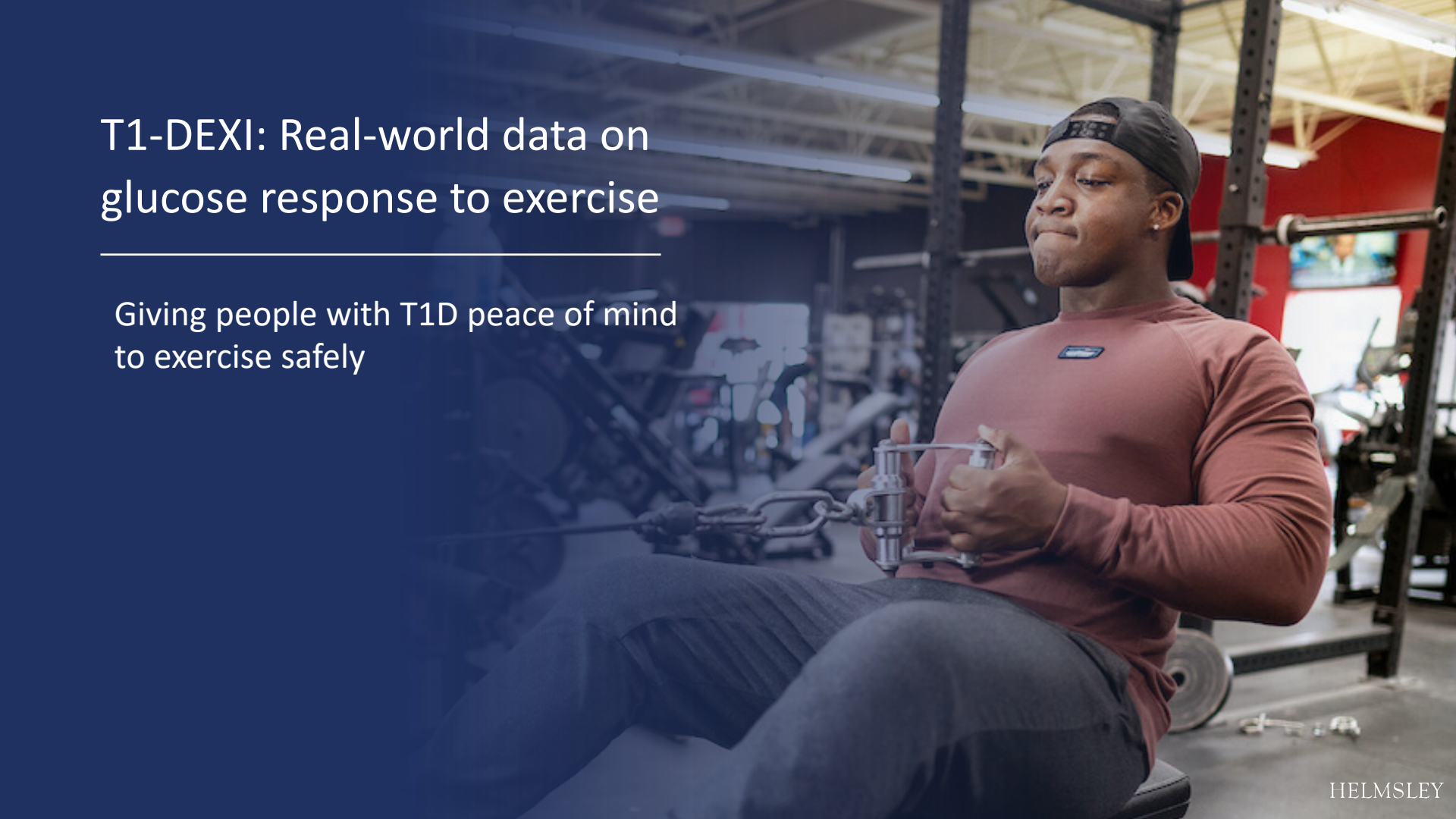
CDISC and Vivli—long time collaborators

- CDISC and Vivli have been collaborators and partners since Vivli's inception. CDISC is the preferred data format for data shared via Vivli.
- Vivli and CDISC conducted a webinar on "Why Data Sharing and Data Standardization Matters"
- More recently, Vivli and CDISC have worked to create a data standard for Type 1 Diabetes and then subsequently share a data set for Type 1 Diabetes and exercise. This is being used as part of a data challenge supported by the Helmsley Trust.

Case 1：Real-world data on glucose response to exercise

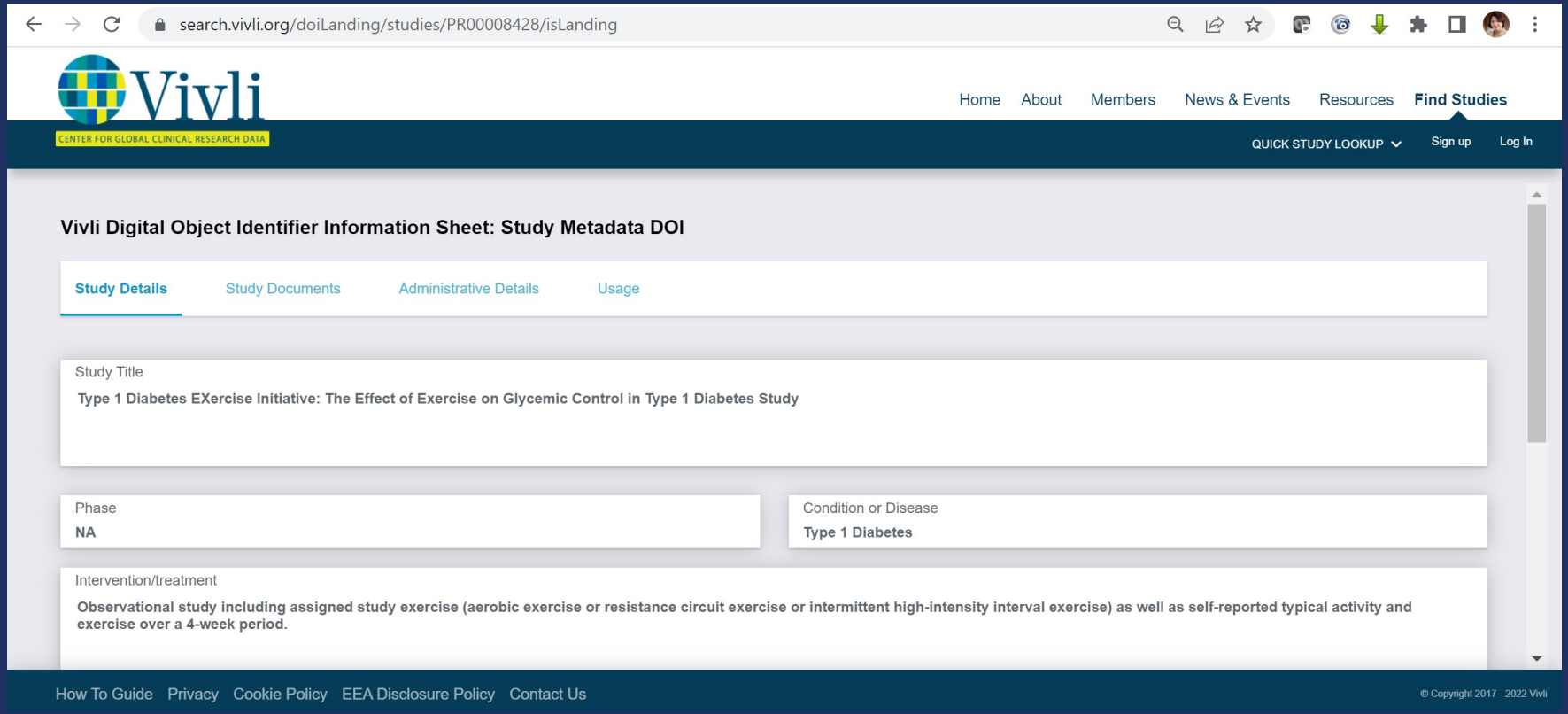
T1-DEXI: Real-world data on glucose response to exercise

Giving people with T1D peace of mind to exercise safely

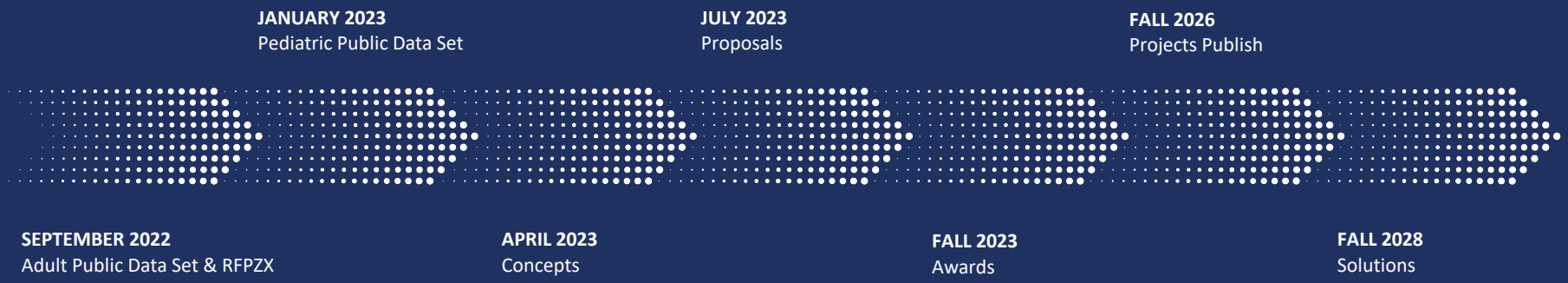


HELMSLEY

T1-DEXI DATA LIVES IN VIVLI



A Unique RFP to move data towards solutions



More than 70 requests for the data have been received to date.

Case 2 : NIH Data management and sharing plan

Recommendation to NIH Data Managememnt and Sharing plan

Element 3: Common Data Standards and Metadata (Vivli repository considerations)

What standards will be applied to the data and metadata?	The plan may indicate if consensus standards exist for scientific data and metadata	Metadata
• Vivli does not currently mandate any data standards • Data is provided in a format that can readily be used for analysis - R, SAS, STATA, Excel, CSV	• CDISC SDTM Standard Data Tabulation Model format is recommended to support for the most efficient data aggregation, re-use, and sharing • CDISC-SDTM is now the standard for those therapeutic areas that have a CDISC standard for data collection https://www.cdisc.org/standards/therapeutic-areas	Metadata is professionally curated by providing the NCT-ID (CT.gov identifier)

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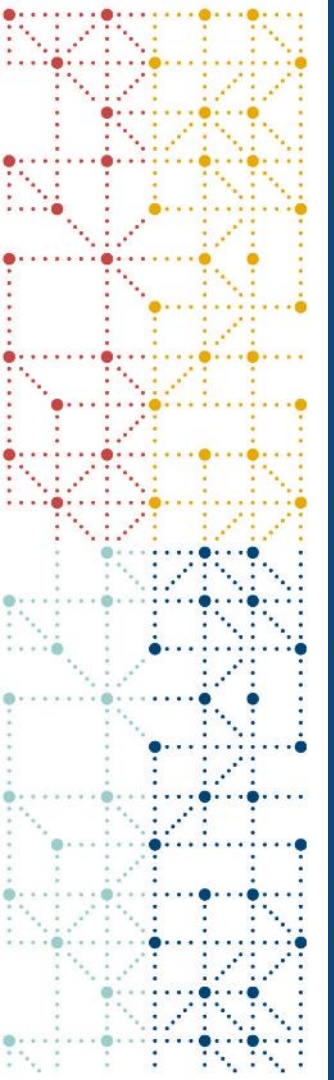

What is the challenges for data sharing in future

What is the challenges for data sharing in future

- Ensuring that all stakeholders share and analyze data from completed clinical research.
- Ensuring that the balance between data utility and patient privacy is preserved
- Ensuring that data being shared it utilized to its fullest advantage to move forward scientific discovery—having a data standard used by all can help achieve that aim

Thank You!

Providing Access to IPD Generates Value
IPDへのアクセス提供は価値の創生

- **Honors** the commitments of participants

  参加者のコミットメントを尊重する
- **Strengthens trust** in the clinical research enterprise

  臨床研究事業への信頼強化
- **Prevents repetitive trials** and putting additional patients at risk

  治験を繰り返し、さらに患者を危険にさらすことを防ぐ
- **Enables new discovery** and scientific insights through by combining data from disparate sources

  異なるソースからのデータを組み合わせることにより、新たな発見と科学的洞察を可能にする。

Perhaps most importantly for participants if the data is not shared…
参加者にとって最も重要なのは、データが共有されなければ...ということだろう。

It is used only one time to answer one question (the primary endpoint) rather than leveraging participants' contributions to answer multiple scientific lines of inquiry thereby advancing science

参加者の貢献を活用して複数の科学的探究に答え、それによって科学を発展させるのではなく、

1つの疑問（主要評価項目）に答えるために1回だけ使用される。

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