



# JAPAN ACADEMIC WORKSHOP

Friday, 17 November | 1:00pm -5:15pm

**”Clinical Data Sharing”という宝箱を開けてみませんか？  
Why don't you open the treasure chest of "Clinical Data Sharing"?**

月田あづさ Senior Advisor, Vivi





## Meet the Speaker

月田あづさ

**Title:** Senior Advisor

**Organization:** Vivli

2022年、シニアアドバイザーとしてVivliチームに参加。  
日本における臨床データの共有とアウトリーチに注力。

Vivliに参加以前は、サノフィにて東京の生物統計・プログラミング部門のリーダーとして約15年の経験を持つ。グローバルファーマにて30年以上の実務経験を有し、臨床開発業務のみならず、JPMAタスクフォースにて電子データ申請関連の活動にも従事。PMDA SWGの初期メンバーであり、2020年までICH M11のJPMAトピックリーダーを務める。ICH M11のJPMAのAdditional Support Memberとして活動を継続している

# 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 and Vivli.*
- *The author(s) have no real or apparent conflicts of interest to report.*



## Agenda

1. 匿名化加工した臨床試験データの利用
2. Vivliの紹介
3. 研究者からのデータ共有
4. これから
5. Q&A



## 匿名化加工した臨床試験データの利用

臨床試験データが2次利用可能であることご存じですか？

# 臨床試験データの2次利用とは

- 自ら臨床試験を計画し、実施するのではなく、既に実施された臨床試験データを利用して研究を実施
- Clinical Questionの解を得るために必要なデータを含む臨床試験を特定  
必要に応じて試験データを統合する
- 必要な解析を実施し、公表(投稿)する



*Report of Insititute of Medicine:*

*Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Rights*  
*2015 Apr 20*

Dr. Victor Dzau, president of the Institute of Medicine

“We think that the question today is not whether you share clinical trial data, but instead, what types of data do you share, when do you share and how do you share it?” Apr 2023

[Committee on Strategies for Responsible Sharing of Clinical Trial Data](#); [Board on Health Sciences Policy](#); [Institute of Medicine](#)

Washington (DC): National Academies Press (US); 2015 Apr 20

<https://pubmed.ncbi.nlm.nih.gov/25590113/>

# なぜ企業は臨床試験データの個々の患者のデータを共有するのでしょうか？

- 試験参加者に対する倫理的義務
- 主要な学会誌の要望
- 
- BIO, EFPIA, PhRMA, IFPMA, JPMA 等各国の業界団体が個別データの共有することを宣言





# データ共有に関する臨床試験参加者の期待 調査結果(米国)より

- データ共有への支持は高いが、患者は純粋に商業的利益のためにデータが「商品化」されることには消極的<sup>1</sup>
- 適切な個人情報の保護措置が講じられていれば、臨床試験参加者は自分のデータが共有されることに対しサポーター<sup>2</sup>

<sup>1</sup> 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](#)

<sup>2</sup> 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.

# 治験登録

- データ共有計画はClinicalTrials.gov登録すべき情報の一部である。  
(日本において臨床試験の登録はjRCTにIPD Data sharingの有無を記載)

## ▼ 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


- 2019年1月1日より、ICMJEは試験登録時にデータ共有計画の登録を義務付けている

# 主要な雑誌の要求内容 (ICMJE)

- 主要な雑誌:  
NEJM, JAMA, The Lancet, BMJ, Annals of Internal Med, PLoS Medicine, and hundreds of others
- 試験原稿はデータ共有声明とともに提出されなければならない。  
Must describe how you will share your Individual participant-level data (IPD), including who, what, when, where, and why
- IPDの共有は(まだ)義務付けられていないが、"編集者は編集上の決定を下す際にデータ共有に関する記述を考慮することができる"

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 clinical trials. This requirement is explained at [www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html](http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html). If the data sharing plan

# Platform Types

Type	Key Features	Examples
<b>Broad and generalist repository</b>	Accept all data types regardless of therapeutic area or domain	NIH generalist repositories: <ul style="list-style-type: none"><li>• Dryad</li><li>• Figshare</li><li>• OSF</li><li>• <b>Vivli</b></li><li>• Zenodo</li></ul>
<b>Specific or focused repository</b>	Accepts only certain data types or has a specific disease focus	<ul style="list-style-type: none"><li>• <b>AMR Registry – Vivli</b></li><li>• Github – code</li><li>• IDDO (Malaria)</li><li>• VISTA-Stroke</li></ul>



# Vivliの紹介

# Vivliの紹介

## 企業

非営利団体 (NPO)  
メンバー

- バイオメディカル業界 (製薬、バイオ、デバイス)
- アカデミア
- 非営利の資金提供者と財団
- 政府 (資金提供者と規制当局)
- 患者 / 患者支援者

ガバナンスと政策

- 言語と協定の調和
- データ共有の文化を動かす

アドボカシー

- 障壁の低減
- インセンティブの促進

運用監督

Confidential Do Not Distribute

## プラットフォーム

- ◆ ユーザーフレンドリーで安全な
- ◆ 最先端のデータ共有および
- ◆ コンピューティング・プラットフォーム
- ◆ あらゆる疾患、国、スポンサー、資金提供者、治験責任医師による治験を含む

国際的なコミュニティへの貢献

- ◆ オープンサーチ
- ◆ 強固なセキュリティ
- ◆ 最新のツールと技術

# Vivliの紹介

## MISSION

Vivli's mission is to promote, coordinate, and facilitate clinical research data sharing through the creation and implementation of a sustainable global data-sharing enterprise.

## COMMITMENT

As a company with a commitment to transparency and data sharing, the Vivli platform will make it easy for studies to be found, requested and analyzed securely.

## BENEFITS

Join Vivli as a member to reap all the benefits of our innovative, secure and user-friendly global data-sharing and analytics platform.

Show your commitment as a leader in data sharing, and together we can drive forward scientific innovation and advance human health.

## 数字でみるVivli





# Vivli Industry Members

abbvie

Alnylam<sup>®</sup>  
PHARMACEUTICALS

AstraZeneca

BAYER

Boehringer  
Ingelheim

Biogen

Bristol Myers Squibb<sup>™</sup>

cdisc

Daiichi-Sankyo

Galápagos

gsk  
do more  
feel better  
live longer

IPSEN  
Innovation for patient care

Johnson & Johnson  
FAMILY OF COMPANIES

KYOWA KIRIN

Lilly

Lundbeck

Mallinckrodt

Mitsubishi Tanabe Pharma

Otsuka

Pfizer

PLATFORM  
LIFE  
SCIENCES

REGENERON

Roche

sanofi

SHIONOGI

Sumitomo Pharma  
sunovion

TAIHO

TEMPUS

Takeda

ucb  
Inspired by patients.  
Driven by science.

# Academic, Platform & Foundation Members



AccessClinicalData@NIAID



**NIDDK CR-R4R**

**BILL & MELINDA GATES foundation**



# Share NIH-Funded Data

## Guidance for researchers on preparing a DMSP and sharing NIH-funded data

The NIH has updated its policies on [data management and sharing](#) (DMS). Effective January 25, 2023, the NIH DMS policy applies to most research funding by the NIH, and requires all applicants planning to generate scientific data to prepare a DMS Plan (DMSP) that describes how they will manage and share data. An effective DMSP requires thoughtful planning, preparation, and execution. We've compiled information and resources here to support every step of the process.

### How to prepare a DMSP

The DMSP is a set of principles and guidelines that outline requirements for sharing data generated by NIH-funded research. It includes six major elements:

## How to submit studies to Vivli for data sharing


If you've decided that Vivli is the right repository for your study data, great! We've developed a straightforward and efficient submission process, and we've got detailed [guidance on how to submit your data](#) and a [checklist](#) when you're ready to begin the process to share your data.



Resource	Description	
<a href="#">Vivli Study Submission Guide</a>	How to submit studies for sharing via the Vivli platform	<a href="#">Download PDF</a>
<a href="#">Study Submission Checklist</a>	A checklist of all information needed for the submission of a study	<a href="#">Download</a>


研究者向け  
NIHの助成を受ける研究に特化した画面の提供

# Vivliに登録されている試験の利用状況

GLOBAL HITS TO VIVLI 600,271 


Searches for studies 114,816

Top 10 Search Topics COVID-19, Prostate cancer, Psoriasis, Alzheimer, Breast cancer, Dementia, Gastric, NSCLC, Arthritis, Diabetes


STUDIES LISTED FOR SHARING 6,893 


Number of participants 3.6 million

Number of countries 126

PUBLIC DISCLOSURES 229 

Public disclosures resulting from data sharing (Public Disclosures) 229

Citations 526 

DATA REQUESTS SUBMITTED 892 


Data Requests Approved ([Approved Requests](#)) 489

Data Requests Denied ([Reasons for Denial](#)) 99

Data Requests Withdrawn by Researcher 302

Data Requests in Progress 108

Data Requests with Revisions Requested 69

Signed Data Use Agreements 523 

Data Use Agreements in process 64

Data Use Agreements withdrawn, agreement not reached, no response 6

Studies Accessed 2,538

Study participants included in studies shared 2,096,385



# Vivliがデータリクエスターにとってどのように機能するか

## 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で共有・保存されるデータの種類

Clinical Research data shared at the participant level:

参加者レベルで共有される臨床研究データ:

- Trials  
臨床試験
- Observational studies  
観察研究
- Registries  
レジストリ
- RWD  
リアルワールドデータ

すべてのデータは、Vivliにアップロードされる際に匿名化されなければならない。  
前向きに計画されたプロトコール主導の研究であること

# What is included in a data package? データパッケージには何が含まれますか？

Item	Description
<i>Recommended Data Package Set</i>	
Study Protocol 試験実施計画書	Final protocol with all amendments
Data dictionary データ辞書	Detailed descriptions of each variable in the dataset, including the definition, source, coding, etc. of the variable
Statistical Analysis Plan 統計解析計画書	Description of the principal features of the analysis described in the protocol
IPD dataset 個別患者データ	Final cleaned individual participant-level data, de-identified/anonymized
Anonymization Guidance 匿名化ガイダンス	Outlines the method used to anonymize the data
<i>Optional</i>	
Analytic code 統計解析用ソースコード	Software code used to carry out prespecified and additional analyses
Analysis ready IPD data set 解析用個別患者データ	Dataset in a format used to carry out a sponsor's analyses
Case report forms 症例報告書	Forms used to collect the data that is described in the protocol for each trial participant

# Vivliは安全かつ柔軟な解析環境を提供

## Software and Tools Available in the 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)

柔軟性: 研究者は、独自のデータセット、統計ソフト、スクリプトを持ち込み、安全な研究環境を構築することができる。

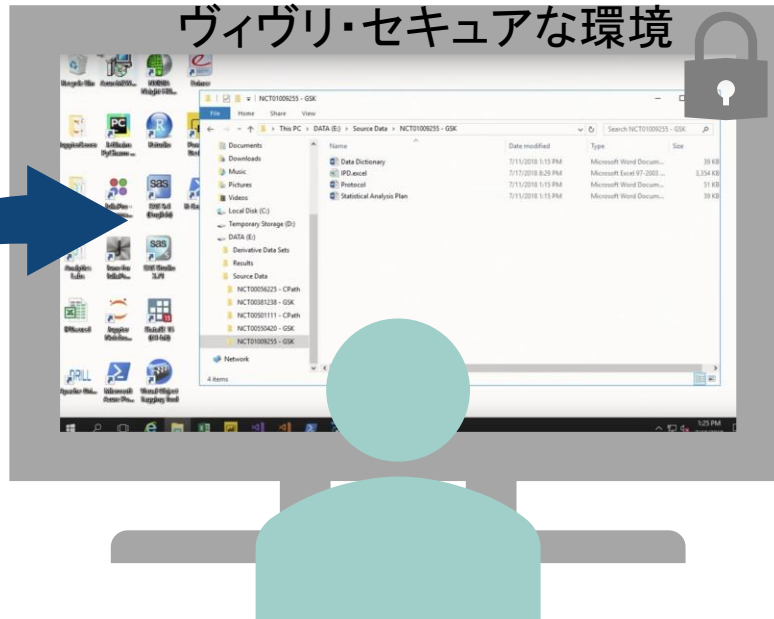


# Vivli's Secure Environment Bridges Multiple Platforms

## Vivliのセキュアな環境は複数のプラットフォームをつなぐことも可能



Vivli Secure Environment  
ヴィヴリ・セキュアな環境



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

## 20 Areas Covered by Vivli's Proposals

From AI to Vaccines...

9/25/23

	Number of Proposals
AI technology	4
Cardiovascular	37
Clinical Trial design	2
Dermatology	14
Endocrinology	12
Gastroenterology	24
Immunology	8
Infectious Diseases	22
Methods	19
Nephrology	4
Neurology	52
Oncology	119
Ophthalmology	4
Orthopedics	7
Pharmacokinetic (PK)	3
Psychiatry	33
Pulmonary	13
Rheumatology	31
Vaccines	3
Other	11

# Request Data from Vivli



Vivli provides a global data-sharing and analytics platform to serve all elements of the international research community.

Users may search for studies, request data packages, and analyze data sets within the Vivli platform.

[Data Request Process Overview](#)



[Data request review process](#)



[Data Use Agreement](#)



[Secure Research Environment](#)



<https://vivli.org/resources/requestdata/>

# Public Disclosures

These tables provide details of approved research proposals that have published or presented their results.

2023

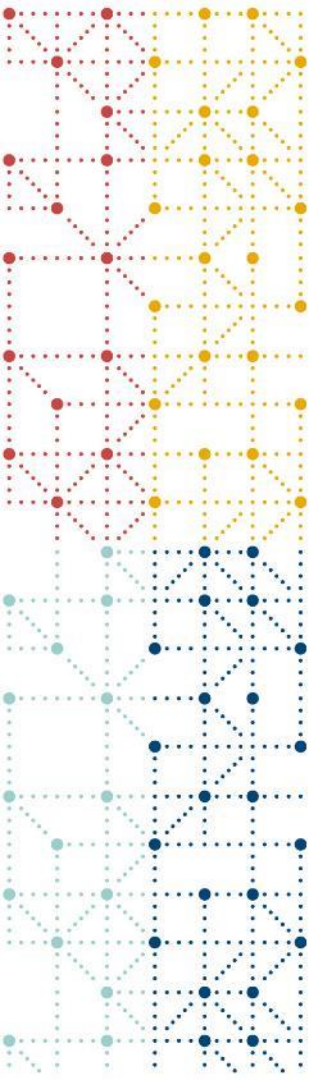


Search:

Data Request ID	Lead Investigator	Institution	Research Proposal Title	Public Disclosure	Data Contributor(s)	Altmetrics Score
3876	Changyu Shen	Beth Israel Deaconess Medical Center	Risk and Benefit Stratification of Treatment Effects in Patients with Atrial Fibrillation	Aggarwal R, Ruff C T, Virdone S, Perreault S, Kakkar A K, Palazzolo M G, Dorais M, Kayani G, Singer D E, Secemsky E, Piccini J, Tahir U A, Shen C, 7 Yeh R W. (2023). Development and Validation of the DOAC Score: A Novel Bleeding Risk Prediction Tool for Patients With Atrial Fibrillation on Direct-Acting Oral Anticoagulants. Circulation.  Doi: 10.1161/CIRCULATIONAHA.123.064556	Boehringer Ingelheim, Daiichi Sankyo	115
4113	Lesley Inker	Tufts Medical Center	Chronic Kidney Disease Epidemiology – Clinical Trials Consortium (CKD-EPI CT)	Collier W, Inker LA, Haaland B, Appel GB, Badve SV, Caravaca-Fontan F, Chalmers J, Floege J, Goicoechea M, Imai E, Jafar TH, Lewis JB, Li PKT, Locatelli F, Maes BD, Neuen BL, Perrone RD, Remuzzi G, Schena FP, Wanner C, Heerspink HJL, Greene T. Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI). Evaluation of Variation in the Performance of GFR Slope as a Surrogate End Point for Kidney Failure	GSK, Takeda	13

# 研究目的での利用の費用

Environment Type	Computer Charge (for 2023)	Size of Compute Space and Tools
Standard Research Environment	No charge, 365 days \$12/day after 365 days	2CPUx&7GB size Office 365, Jupyter Notebook, Python, STATA and R tools available
Premium Research Environment	No charge, 90 days \$25/day after 90 days	4CPUx14GB size Office 365, Jupyter Notebook, Python, STATA, R, and SAS* tools are available  *Alternative pricing applies for industry users of SAS, email <a href="mailto:support@vivli.org">support@vivli.org</a> for details.



# 研究者からのデータ共有

Slides Using Images



## NIH POLICY FOR DATA MANAGEMENT & SHARING データ管理と共有に関するNIH(米国国立衛生研究所) Policy

### 基本的な2つの要件

- すべてのNIH助成研究に対するデータ管理・共有「計画」の提出
- ICOが承認した計画の遵守

2023年1月25日発効 (2003年のデータ共有ポリシーに代わるもの)

*Susan Gregurick, Office of Data Science  
and Strategy*

*NIH, Vivli Annual meeting 2022*

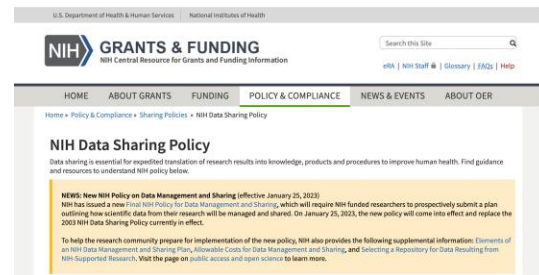
# New NIH data sharing policy went into effect Jan. 2023

すべての研究提案には、誰が、何を、いつ、どこで、どのようにデータを共有するかを詳細に記した2ページのデータ共有計画を含めなければならない。

- 「可能な限り、確立されたリポジトリ(保管場所)を使用することを強く推奨する  
汎用のリポジトリ: Dryad、Figshare、Dataverse、Vivliなど

データは、「可能な限り速やかに、本研究に関する投稿が行われる時点、または表彰／支援期間の終了時点のいずれか早い時点までにアクセスできるようにすべきである」

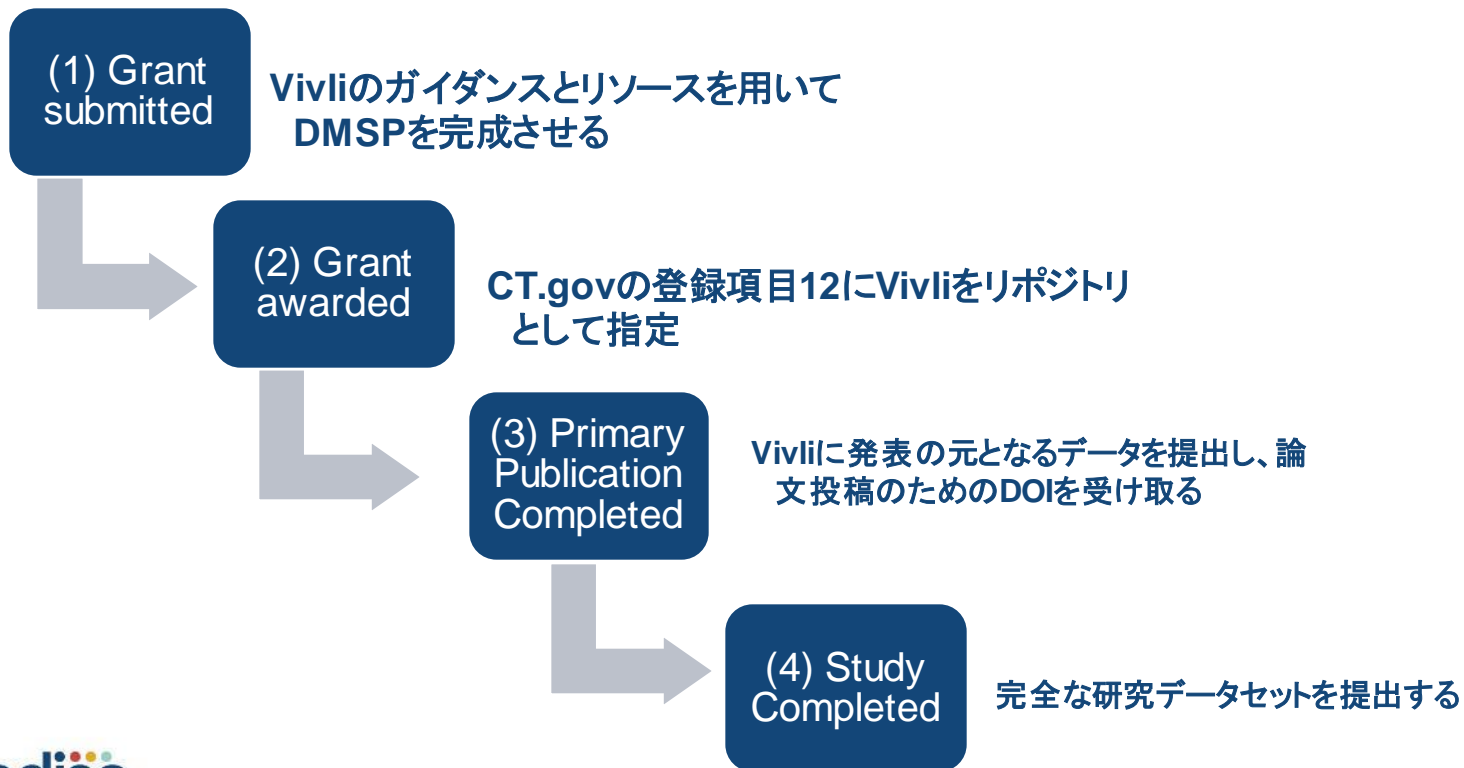
- 研究費にはデータ共有費用が含まれる場合がある

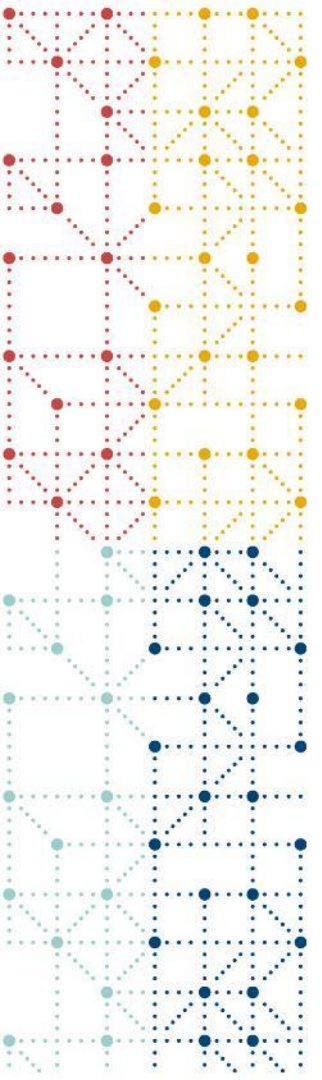


The screenshot shows the NIH website's 'GRANTS & FUNDING' section. The main heading is 'NIH Data Sharing Policy'. Below the heading, there is a sub-heading 'Data sharing is essential for expedient translation of research results into knowledge, products and procedures to improve human health. Find guidance and resources to understand NIH policy below.' A news alert box states: 'NEWS: New NIH Policy on Data Management and Sharing (effective January 25, 2023). NIH has issued a new Final NIH Policy for Data Management and Sharing, which will require NIH funded researchers to prospectively submit a plan outlining how scientific data from their research will be managed and shared. On January 25, 2023, the new policy will come into effect and replace the 2003 NIH Data Sharing Policy currently in effect.' Below the news alert, there is a link to 'To help the research community prepare for implementation of the new policy, NIH also provides the following supplemental information: Elements of an NIH Data Management and Sharing Plan, Allowable Costs for Data Management and Sharing, and Selecting a Repository for Data Resulting from NIH-Supported Research. Visit the page on public access and open science to learn more.'



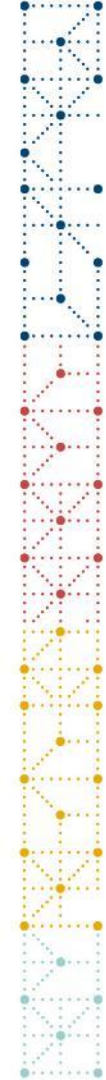
# データ共有の4つのマイルストーン






これから

# Data sharingの未来 ~ これからの10年に期待すること




**Shaping the next 10 years in Data Sharing:**  
Building on the gains made and looking ahead  
to the next 10 years in advancing human health



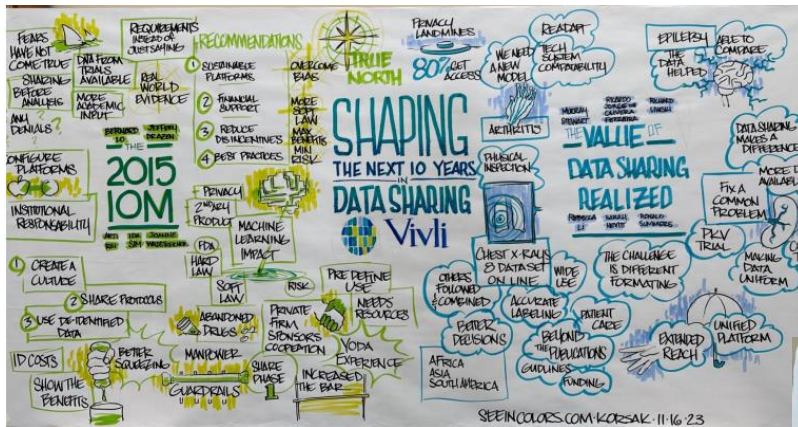
**Thursday, November 16th**  
**8:30am - 4:00pm EST**

**National Academy of Sciences**  
2101 Constitution Avenue Northwest  
Washington D.C., 20418



<https://vivli.org/event-shaping-the-next-10-years-in-data-sharing-building-on-the-gains-made-and-looking-ahead-to-the-next-10-years-in-advancing-human-health/>

# カンファレンスの成果



## ここまで

- 2015年のIOMのレポートから長い道のりを進んできた
- NIHの方針がDSの背中を押している

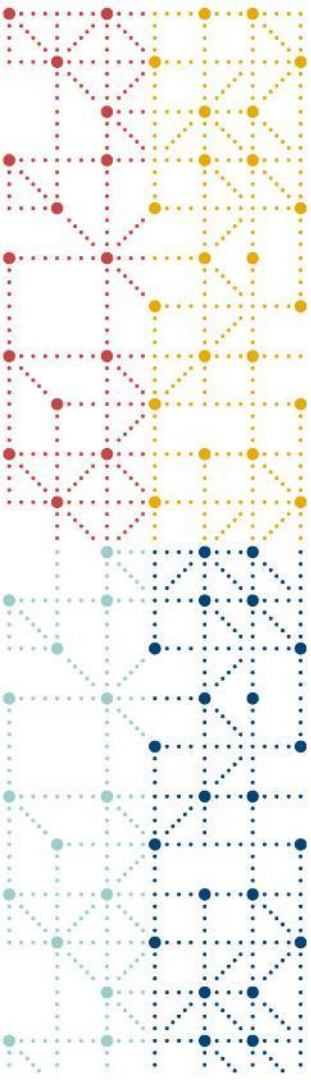
## これから

- AIの活用が鍵となる
- DSの活用方法のさらなる検討と、リスクの軽減は継続的な検討が必要





# Q & A



**Thank You!**

**Contact : [Atsukida@vivli.org](mailto:Atsukida@vivli.org)**

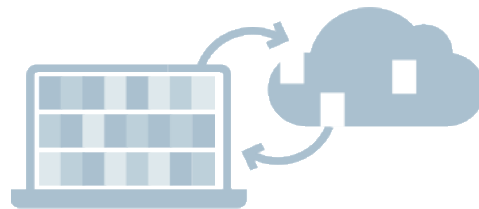
**cdisc**

# YOUR NEED

POLICY



MECHANISM



RESOURCES





# What is FAIR?








Sci. Data 3:160018 doi: 10.1038/sdata.2016.18 (2016)

**“Data and services that are  
findable,  
accessible,  
interoperable,  
re-usable**

**both for machines and for people.”**



# Vivli Current Externally Funded Projects

PROJECT	Impact	Project Funding
Platform Scale-up	Ability to enhance the Vivli platform to enable larger scale data handling (imaging, genomics)	
COVID Therapeutics Accelerator	Consortium of funders (Gates, Wellcome, others) to speed COVID Therapeutics, Vivli's objectives are to make COVID data more discoverable.	
AMR Register – (Anti-microbial resistance)	Platform to share industry AMR surveillance data	
ADDI/Gates Ventures	Project funded to enable federated access to Alzheimer's data, images across platforms for broader sharing	
T1 Diabetes Program	Project funded to enable access to T1D Exercise data collected under Helmsley's T1-DEXI's large observational studies	
Bill & Melinda Gates Foundation data sharing	Grant to work with BMGF grantees to share trial data (primarily focused on COVID)	
	CONFIDENTIAL - Not for distribution	

# 4段階のVivli Repositoryデータ提出プロセス

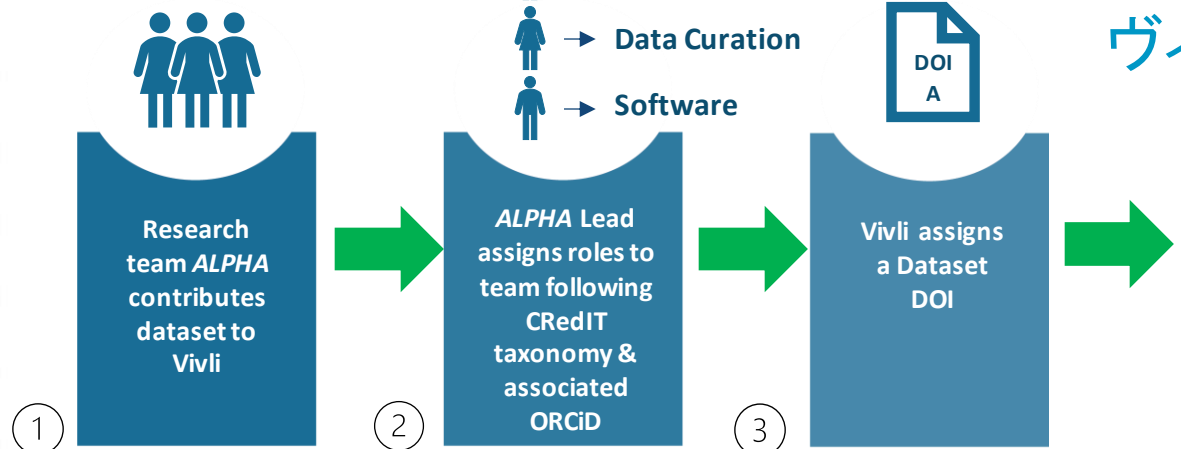


- Data Contribution Agreement can be signed in advance between Vivli and institution. データ提供契約は、Vivliと研究機関間で事前に締結することができる。
- The Vivli team will support researchers through this process. Vivliチームは、このプロセスを通じて研究者をサポートします。
- A DOI will be provided for use in subsequent publications for each dataset. 各データセットのDOIは、その後の出版物で使用するために提供される。
- A report on research proposals for secondary analysis of the data can be provided upon request  
ご要望に応じて、データの二次分析に関する調査提案の報告書をご提供いたします。

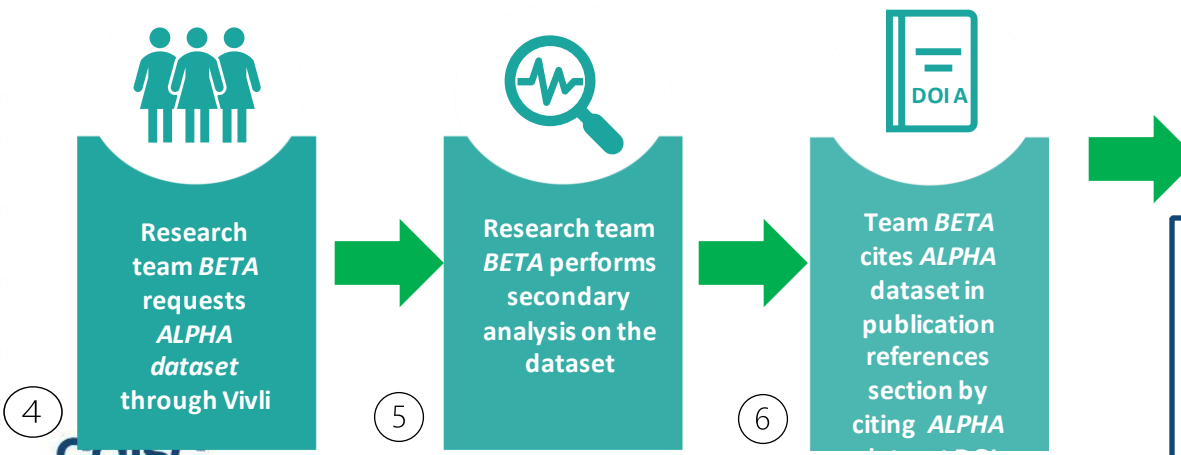
# Vivli Academic Credit Model

## ヴィヴリ・アカデミック・クレジット・モデル

-  → Funding Acquisition
-  → Data Curation
-  → Software



Research team ALPHA accesses their list of secondary dataset citations through DataCite or Vivli via DOI search. (In future, citation information will be available in researcher's ORCID profile.)  
 研究チームALPHAは、DataCiteまたはVivliのDOI検索を通じて、二次データセットの引用リストにアクセスしている。(将来的には、引用情報は研究者のORCIDプロフィールで利用できるようになる。)



Research team ALPHA receives CREDIT for their contribution to the data  
 研究チームALPHAがデータへの貢献でCREDITを受賞

**Why this matters:** Original study team can track how their study data has been used and cited in subsequent publications. Can be used on grant applications, promotion reviews, and other similar processes.  
 なぜこれが重要なのか: オリジナルの研究チームは、自分たちの研究データがその後の出版物でどのように使用され、引用されたかを追跡することができる。助成金申請、昇進審査、その他同様のプロセスで利用できる。

# Vivli offers our platform one system under one contract

One integrated system, under one contract

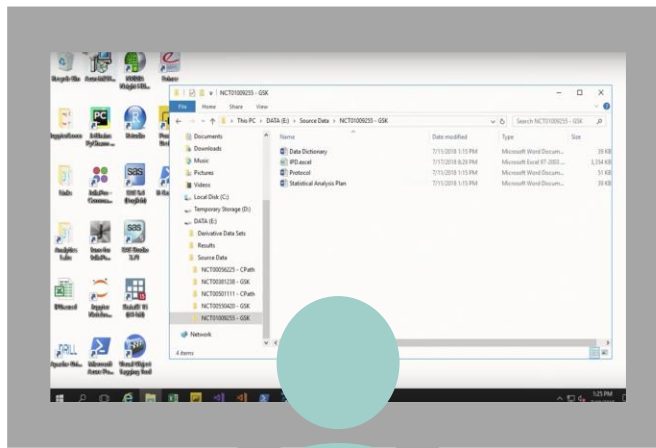
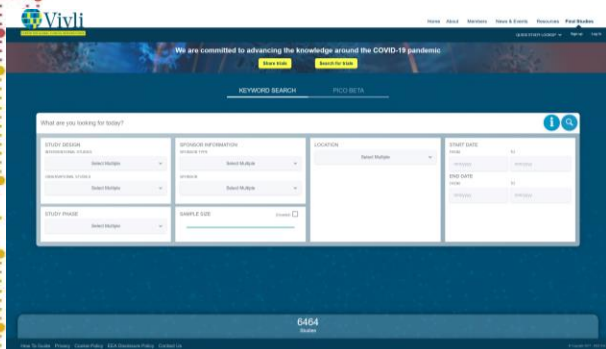
Vivli request process



Vivli Secure Environment



Independent review panel



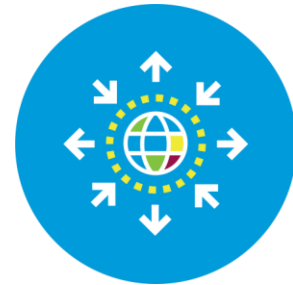
CONFIDENTIAL - Not for distribution

# Governance processes flexible and efficient

**Adaptable:** Vivli respects the review process of each data contributor and has built flexibility to accommodate various review processes into the current system.

*In areas where harmonization is critical for the user experience, we will do so:*

- Harmonized Request Form
- Harmonized Data Use Agreement
- Harmonized Data Contributor Agreement



# Approaches to Sharing Human Data

Type	Key Features
<b>Open access</b>	Anyone can access, simple account creation, simple on-line Data Use Agreement (DUA)
<b>Managed access (Gate keeping)</b>	<ul style="list-style-type: none"><li>• for scientific purposes only (standard request form)</li><li>• (independent) review process</li><li>• secure environment for data access</li><li>• clear legal framework</li></ul>
<b>Restricted access</b>	Invitation only, access only to those who provide data