Creating Value by Working Together

2021 Vivli Annual Meeting

Wednesday, November 3rd
9:30 am - 12:30 pm ET

We will begin shortly.
Disclaimer

This event will be recorded and these images may be used in conjunction with this event without your name or affiliation.

In the event that the images are used with your name/affiliation we will notify you in advance for your consent to publish.

The recording and slides will be shared after the meeting.

Please post your questions in the Q&A section. We will respond to your question during the Q&A sections. All participants will be muted.

Annual Meeting
3 November 2021

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<th>Time</th>
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Vivli Update

• Vivli Overview
• Current Projects
• Outlook and Vision
Vivli is a Global Data Platform
Snapshot of Frequently Searched Terms

Bimekizumab  Acute Myeloid Leukemia  Bapineuzumab  Immunotherapy
Atrial Fibrillation  Atezolizumab  Baricitinib  Multiple Myeloma  PACE
Rheumatoid Arthritis  Psoriasis  Lung Cancer  GALLIUM
Coronavirus  Diabetes  LY450139
Cancer  Alzheimer’s Disease  Leukemia
Asthma  Breast Cancer  Lupus  Colchicine
Breast Cancer  Atopic Dermatitis  Depression  Palbociclib
Hidradenitis  Nivolumab  Parkinson’s Disease  BNT162b2
Surpass  Migraine  Lymphoma  CAR-T  Idiopathic Pulmonary Fibrosis
Vivli by the numbers ...from launch to today...

- **6,300+ Trials**
- **3.6M Participants from 101 countries**
- **38 Members**

- **1.3M Participants from 98 countries**
- **~2,500 Trials**
- **15 Members**
Academic, Platform & Foundation Members
Steady Increase in Submitted Proposals
Types of Secondary Analysis conducted on the Vivli platform (> 1 may be selected by researcher)

- Other: 4%
- Training / Testing: 4%
- Support of Clinical Trial Design: 5%
- Preliminary Research: 4%
- Summary Level Meta Analysis: 8%
- Confirmatory Research: 27%
- Participant level data Metaanalysis: 27%
- New Research: 37%
### 2021 Annual meeting

<table>
<thead>
<tr>
<th>Area</th>
<th>Number of Proposals</th>
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<tbody>
<tr>
<td>AI technology</td>
<td>4</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>37</td>
</tr>
<tr>
<td>Clinical Trial design</td>
<td>2</td>
</tr>
<tr>
<td>Dermatology</td>
<td>14</td>
</tr>
<tr>
<td>Endocrinology</td>
<td>12</td>
</tr>
<tr>
<td>Gastroenterology</td>
<td>24</td>
</tr>
<tr>
<td>Immunology</td>
<td>8</td>
</tr>
<tr>
<td>Infectious Diseases</td>
<td>22</td>
</tr>
<tr>
<td>Methods</td>
<td>19</td>
</tr>
<tr>
<td>Nephrology</td>
<td>4</td>
</tr>
<tr>
<td>Neurology</td>
<td>52</td>
</tr>
<tr>
<td>Oncology</td>
<td>119</td>
</tr>
<tr>
<td>Ophthalmology</td>
<td>4</td>
</tr>
<tr>
<td>Orthopedics</td>
<td>7</td>
</tr>
<tr>
<td>Pharmacokinetic (PK)</td>
<td>3</td>
</tr>
<tr>
<td>Psychiatry</td>
<td>33</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>13</td>
</tr>
<tr>
<td>Rheumatology</td>
<td>31</td>
</tr>
<tr>
<td>Vaccines</td>
<td>3</td>
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<tr>
<td>Other</td>
<td>11</td>
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# Top 40 Requested Studies

<table>
<thead>
<tr>
<th>Category</th>
<th>Condition</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Oncology (16)</strong></td>
<td>Bladder</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Breast</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>NSCLC</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>RCC</td>
<td>1</td>
</tr>
<tr>
<td><strong>Rheumatology (16)</strong></td>
<td>Crohn's Disease</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>RA</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>UC</td>
<td>3</td>
</tr>
<tr>
<td><strong>Cardiology (4)</strong></td>
<td>ACS</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>AFIB</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Stroke</td>
<td>1</td>
</tr>
<tr>
<td><strong>Other (4)</strong></td>
<td>Covid 19</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Duchenne</td>
<td>1</td>
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<tr>
<td></td>
<td>Hidradinitis</td>
<td>2</td>
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### Current Externally Funded Projects

<table>
<thead>
<tr>
<th>PROJECT</th>
<th>Impact</th>
<th>Project/Funder</th>
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<td><strong>Platform Scale-up</strong></td>
<td>Ability to deploy larger platform versions to enable larger scale data handling (imaging, genomics)</td>
<td>📏</td>
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<td><strong>COVID Therapeutics Accelerator</strong></td>
<td>Consortium of funders (Gates, Wellcome, Chan Zuckerberg) to speed COVID Therapeutics, Vivli’s objectives are to make COVID data more discoverable through this initiative</td>
<td>⚡</td>
</tr>
<tr>
<td><strong>AMR Register – (Antimicrobial resistance)</strong></td>
<td>Platform to share industry AMR surveillance data – launching 2022</td>
<td>🍃</td>
</tr>
<tr>
<td><strong>ADDI /Gates Ventures</strong></td>
<td>Project funded to enable federated access to Alzheimer’s data, across platforms for broader sharing</td>
<td>🧠</td>
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<tr>
<td><strong>Bill and Melinda Gates Foundation data sharing</strong></td>
<td>Grant to work with BMGF grantees to share trial data</td>
<td>📚</td>
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Anti Microbial Resistance: the next global pandemic

- Currently AMR causes 700,000 deaths per year
- Could be up to 10 million deaths globally by 2050
- Opportunity to address proactively during current COVID
There is no current single platform for high quality industry surveillance data

- Detect trends in multi-drug resistance over time
- Inform national and international policy and antibiotic stewardship
- Allow modeling of future resistance trends
Vivli leveraging success in clinical trial data sharing to expand to surveillance data

Vivli

• 6,200 clinical trials
• 3.6 million participants
• 120 countries

VIVLI-AMR Platform

Selected by Wellcome Trust to manage this effort for an industry surveillance data

• Share AMR surveillance data in a single platform
• Bridge the silos between academic, private and public information.
Phase 1 (Years 0-3)
Launch to Sustainability 2018-2021

• Build the inventory of data
• Reach sustainability
• Build the user base
• Seek and Develop opportunities (external projects and partnerships) to leverage platform technology outside of our core clinical trial data sharing
Future Directions for Vivli 2022

Phase 1 (Years 0-3) – Launch to Sustainability 2018-2021

• Build the inventory of data
• Reach sustainability
• Build the user base
• Seek and Develop opportunities (external projects and partnerships) to leverage platform technology outside of our core clinical trial data sharing

Phase 2 (Years 4-6) – Focus and Vision looking forward 2022-2024

• Demonstrate a measurable impact of the scientific value of the data and core technology
• Successfully deliver innovative implementable externally funded projects and partnerships leveraging platform technology
• Expand core capabilities
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Panelists

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- **Ricardo J.O. Ferreira**, University of Coimbra
- **Katherine Tucker**, Roche
- **J.R. Meloro**, Pfizer
Individual data meta-analysis
n=5,792 patients from 11 RCTs

4V-Remission

23%
(SJC28, TJC28, CRP, PGA, all ≤1)

Non-Remission

58%

PGA-Near-Remission

19%
(only PGA is >1)

45% of all in 3V remission
Individual data meta-analysis
n=5,792 patients from 11 RCTs

Proportion of Good and Bad Radiographic outcome

- **4V-Remission**:
  - Good: 81
  - Bad: 19

- **PGA-Near-Remission**:
  - Good: 78
  - Bad: 22
Individual data meta-analysis
n=5,792 patients from 11 RCTs

Predictive Accuracy (TP+TN) of Xr outcome

4V-Remission: 41%

3V-Remission: 51%
(3V = Excluding PGA)
Panelists

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- **Katherine Tucker**, Roche
- **J.R. Meloro**, Pfizer
Roche data sharing journey – Katherine Tucker, Roche

• Roche’s journey
  – 2013 Roche data sharing policy
  – 2014 CSDR
  – 2020 Vivli

• Why share data?

• Challenges
Roche data sharing journey – Katherine Tucker, Roche

• Publications & insights from re-use of Roche data

Vivli: Long-term predictive value of patient global assessment regarding radiographic damage and physical function in patients with Rheumatoid Arthritis individual patient data meta-analysis

Vivli: Predictors of exposure, therapeutic and adverse effects of atezolizumab used in the treatment of advanced cancers

CSDR: Model based analysis of the heterogeneity in the tumour size dynamics differentiates vemurafenib, dabrafenib and trametinib in metastatic melanoma

CSDR: Racial difference in bioavailability of oral ibandronate between Caucasian and Taiwanese postmenopausal women

CSDR: Effect of early adverse events on response and survival outcomes of advanced melanoma patients treated with vemurafenib or vemurafenib plus cobimetinib: A pooled analysis of clinical trial data
Panelists

• Moderator, **Murray Stewart**, Vivli board member
• **Ricardo J.O. Ferreira**, University of Coimbra
• **Katherine Tucker**, Roche
• **J.R. Meloro**, Pfizer
Panelists—Questions and Answers

- Moderator, **Murray Stewart**, Vivli board member
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Please post your questions in the Q&A section.
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- **Thea Norman**, Gates Foundation
- **Yo Yehudi**, Wellcome Trust
- **Ishwar Chandramouliswaran**, NIH
DATA MANAGEMENT AND SHARING AT NIH

Vivli Annual Meeting – Funder’s Panel

Ishwar Chandramouli, Program Director
NOV 3, 2021
NIH requires researchers to **prospectively plan for how scientific data will be preserved and shared** through submission of a Data Management and Sharing Plan.

Submission of a Data Management and Sharing Plan outlining how scientific data and any accompanying metadata will be managed and shared, taking into account any potential restrictions or limitations.

Plan is part of the budget Justification section of the application for extramural awards and as part of the technical evaluation for contracts.

The DMS Policy applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of **scientific data**. This includes research funded or conducted by extramural grants, contracts, Intramural Research Projects, or other funding agreements regardless of NIH funding level or funding mechanism. **The DMS Policy does not apply to research and other activities that do not generate scientific data, including training, infrastructure development, and non-research activities.**
Modernizing the NIH Data Ecosystem

Goal 2 of the NIH Strategic Plan for Data Science

Preparing the NIH Data Ecosystem for more effective sharing and the new NIH Data Management and Sharing Policy (NOT-OD-21-013)

1. Active FOAs for NIH Data Resources (U24)
   - Biomedical Data Repository FOA (PAR20-089)
   - Knowledgebase FOA (PAR20-097)

2. FY21 NOSIs to provide one-year supplements to:
   - Strengthen Existing NIH Data Repositories and improve their alignment to the Desirable Characteristics for Data Repositories
   - Improve the AI/ML-Readiness of NIH-Supported Data
   - Support Enhancement of Software Tools for Open Science

3. Incorporating Generalist Repositories into the NIH Data Ecosystem

https://datascience.nih.gov/
NOT-OD-21-187

Questions that may or may not be suitable for search engines or require additional ‘reach-in’ to datasets

- Dataset Discovery
- Cohort Building
- Knowledge Search
Putting the FAIR data principles into practice

Finding appropriate data repositories

Thinking ahead about data as future research materials and not just the outcomes of an experiment
Office of Data Science Strategy

www.datascience.nih.gov

A modernized, integrated, FAIR biomedical data ecosystem
Panel: Creating Value—Building a Data Sharing Ecosystem

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- Rebecca Li, Vivli
- Tetsuyuki Maruyama, ADDI
- Andrew Morris, HDRUK
Closing Remarks

Rebecca Li, Vivli
Julie Wood, Vivli
Vivli Industry Members
Academic, Platform & Foundation Members

ADDI
Alzheimer's Disease Data Initiative

BIll & MElINDA GAteS founDation

DORIS DUKe CHARITABLE founDATION

IMMPoRT

INFECTIONous DISEASEs DATA OBSERVATORY

AccessClinicalData@NIAID

BioLINCC

CRITICAL PATH INSTITUTE

Cure Duchenne

Duke University

HARVARD UNIVERSITY

HELMSLEY CHARITABLE TRUST

UCSF

University of California
San Francisco

Vivli
Our new members in 2020-2021

ADDI
Alzheimer’s Disease Data Initiative

Bristol Myers Squibb

AccessClinicalData@NIAID

Alnylam

IDDO
Infectious Diseases Data Observatory

Otsuka

BILL & MELINDA GATES foundation

KYOWA KIRIN

SHIONOGI
Vivli Board of Directors

Michael Stebbins
Board chair

Barbara Bierer

Fiona Godlee

Eric Perakslis

Rebecca Li

Justin McCarthy

Ida Sim

Murray Stewart
Thank you
Please stay on and join us for virtual networking and informal discussion

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