Policies In Practice: Lessons Learned
An Independent Review Panel Perspective

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On behalf of the Wellcome Trust IRP for CSDR and Vivli

Challenges and a Way Forward in Sharing Clinical Trial Data- A Workshop
November 18, 2019
Why Researchers Share Data - Wellcome Trust

How Researchers Share

How have you shared your data?

<table>
<thead>
<tr>
<th>Method</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct contact</td>
<td>87</td>
</tr>
<tr>
<td>Repository</td>
<td>54</td>
</tr>
<tr>
<td>Journal website</td>
<td>37</td>
</tr>
<tr>
<td>Lab website</td>
<td>33</td>
</tr>
</tbody>
</table>

n = 168

How have you obtained other’s data?

<table>
<thead>
<tr>
<th>Method</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct contact</td>
<td>57</td>
</tr>
<tr>
<td>Repository</td>
<td>53</td>
</tr>
<tr>
<td>Journal website</td>
<td>33</td>
</tr>
<tr>
<td>Lab website</td>
<td>21</td>
</tr>
</tbody>
</table>

n = 170

How Do Data Sharing Platforms Help?

- Standard search for meta data of studies
- Some platforms offer storage
- Standard, transparent access route, independent of the data generator
- May assist with data anonymization.
- May restrict access to align with original consent and protect anonymity

Adapted from Christian Ohmann et al. BMJ Open 2017;7:e018647
Challenges for Data Sharing Platforms

• Costs recovery model – Data contributor, data requestor or central core grant needs to cover costs for platforms
• Costs of secure analysis environments
• Lack of internationally agreed minimum standards for meta data
• Lack of sufficient information to assess whether a study is worth requesting for research analysis
• Lack of interoperability between platforms (so researchers have to go to multiple places)
• Lack of internationally agreed standard for Data Sharing Agreement (DSA) – particularly institutional legal offices
• Different governance structures of platforms
<table>
<thead>
<tr>
<th>Feature</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Many years since establishment (2013)</td>
<td>✓</td>
</tr>
<tr>
<td>&gt;3,000 studies available to request</td>
<td>✓</td>
</tr>
<tr>
<td>Supports applications for studies from multiple sponsors</td>
<td>✓</td>
</tr>
<tr>
<td>SAS secure analysis environment which includes; SAS, STATA, NONMEM, and lots of open source software</td>
<td>✓</td>
</tr>
<tr>
<td>No charge to secondary data users</td>
<td>✓</td>
</tr>
<tr>
<td>All applications for re-use are assessed by an <strong>Independent Review Panel</strong></td>
<td>✓</td>
</tr>
<tr>
<td>Secondary user responsible for approvals e.g. EC, IRBs</td>
<td>✓</td>
</tr>
</tbody>
</table>
Independent Review Panel (IRP)

- Wellcome secretariat provides the IRP for CSDR and Vivli
- Ensures a trusted, consistent, and transparent controlled access option (Charter available online)
- Multi-disciplinary panel with years of experience considering proposals
- Provides constructive feedback to researchers

Applications through CSDR (to August 2019)

60% rejected proposals are revised, re-submitted

- Total submitted: 531
- Met initial check: 409
- Approved by IRP: 338
- Agreed DSA: 269
- Access provided: 260
- Access closed: 115
- Published or expected: 80

83% approval rate
CSDR Time Metrics From Website

Primary factors that affect the timelines:
- Response to questions from IRP Secretariat
- Institution DSA review process
- Sponsor Publication Steering Committee review
- Sponsor review meeting schedules

Note that DSA negotiation period can be greatly reduced if a standard DSA is accepted

WT = Wellcome Trust Secretariat
DSA = Data Sharing Agreement
IRP = Independent Review Panel
<table>
<thead>
<tr>
<th>Questions IRP Considers</th>
<th>Common Reasons for IRP Rejection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plain English summary clear with sufficient detail</td>
<td>Plain English summary too technical, no clear patient benefit cited</td>
</tr>
<tr>
<td>- Scientific rationale for research</td>
<td>Insufficient information, plan and aims unclear</td>
</tr>
<tr>
<td>- Research question relevant for medical science and/or patient care</td>
<td></td>
</tr>
<tr>
<td>Does the study design, methodology or analysis plan have significant limitations</td>
<td>Statistical methods issues; insufficient detail, incorrect methodology</td>
</tr>
<tr>
<td>Research team’s relevant qualifications and experience</td>
<td>Skills/qualifications of the team not clear or insufficient</td>
</tr>
<tr>
<td>Plan to publish findings</td>
<td>No publication/dissemination plan</td>
</tr>
<tr>
<td>Real or potential conflicts of interest (COI), appropriately managed</td>
<td></td>
</tr>
</tbody>
</table>
Vivli Metrics

• 4000 + Studies
• Data from approved requests analyzed in secure research environment
• IRP joined Vivli in 2018
• Use same criteria as CSDR, 16 proposals considered (Jan-Sept 2019)
  – 11 approved
  – 4 approved with minor edits
  – 1 declined with advice to re-submit (which was then approved at second submission)
IRP Suggestions For The Future

• Research agendas informed by whole community to drive sharing, re-use of data
• Data access process should be easily discoverable with transparent metrics for potential users
• Funders could support capacity building efforts in LMIC
• Consent for clinical research from participants could include provision for re-use of their anonymized data beyond original study
• In the absence of specific guidance, institutional ethics committees should also adopt consistent policies for the need (or not) for ethics review for secondary use of anonymized data
• Common data sharing agreement should be available for data providers
• Common data standards will reduce resources needed for secondary analysis
• Common metrics across different data sharing platforms e.g. numbers and types of requests, approval data, reasons for not providing access, summary data (including links) for published papers
• Academic funders to encourage grant holders to share clinical research data
Conclusions

- There are lots of data now available to request for analysis
- Challenges remain to speed up access process
- Researchers need incentives to share and re-use data
- Costs of sharing and re-use need to decrease
- Guidance from professional bodies (e.g. for consent issues, common DSA) would help promote data sharing
Extra slides
## CSDR Metrics (Aug 2019)

<table>
<thead>
<tr>
<th>Status</th>
<th>Feasibility checks</th>
<th>IRP approval</th>
<th>Data sharing agreement</th>
<th>Data preparation</th>
<th>Data access provided</th>
<th>Publication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did not meet requirements</td>
<td>23</td>
<td>57</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Withdrawn by requestor/No response</td>
<td>73</td>
<td>6</td>
<td>27</td>
<td>5</td>
<td>2</td>
<td>39</td>
</tr>
<tr>
<td>In process</td>
<td>26</td>
<td>8</td>
<td>42</td>
<td>4</td>
<td>145</td>
<td>30</td>
</tr>
<tr>
<td>Complete</td>
<td>409</td>
<td>338</td>
<td>269</td>
<td>260</td>
<td>115</td>
<td>50</td>
</tr>
</tbody>
</table>

- Feasibility checks: 550 proposals
- IRP approval: 500 proposals
- Data sharing agreement: 350 proposals
- Data preparation: 250 proposals
- Data access provided: 150 proposals
- Publication: 100 proposals

The chart above shows the number of research proposals in each status category as of August 2019.