Policies In Practice: Lessons Learned An Independent Review Panel Perspective

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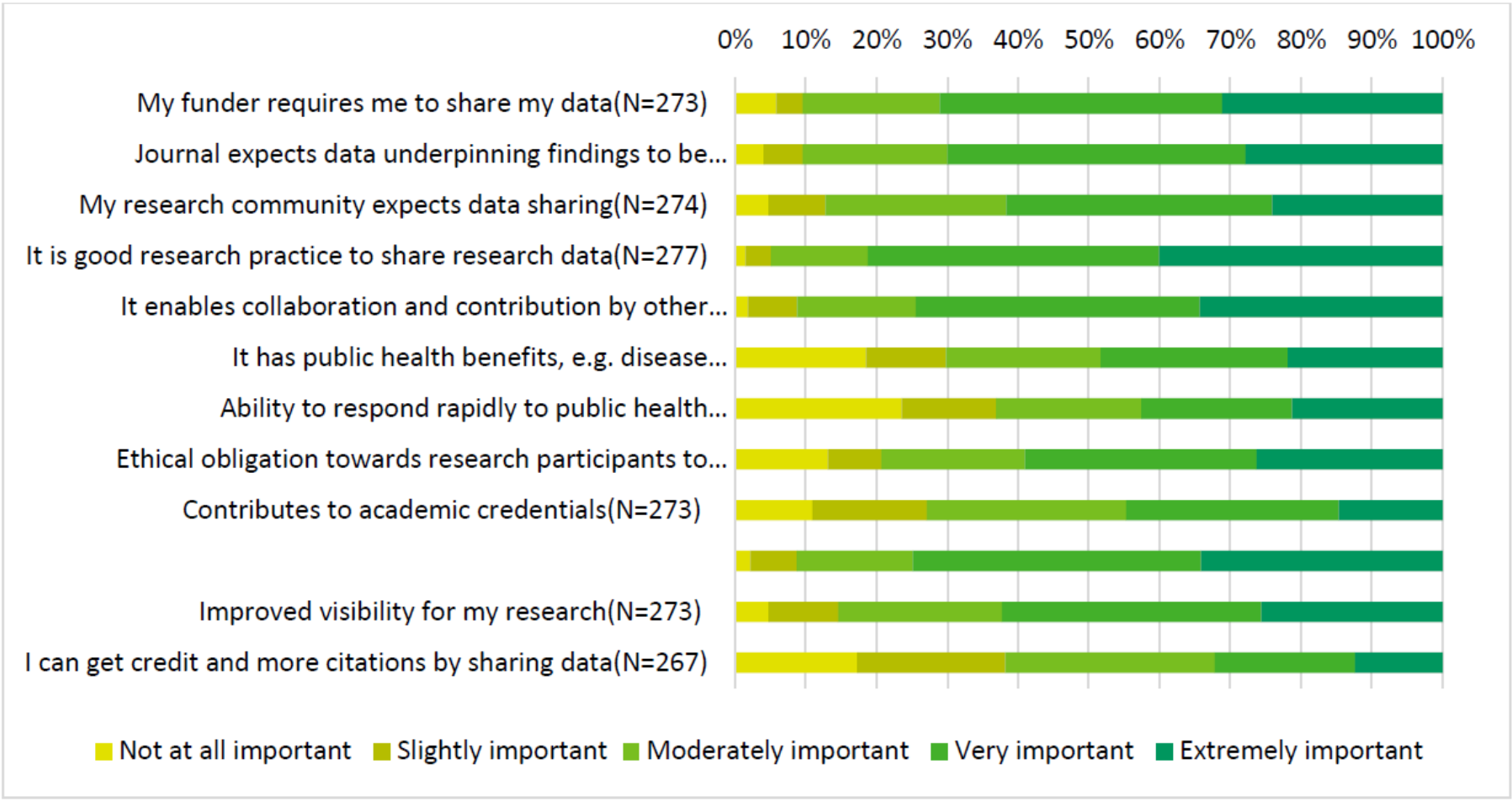
Challenges and a Way Forward in Sharing Clinical Trial Data- A Workshop

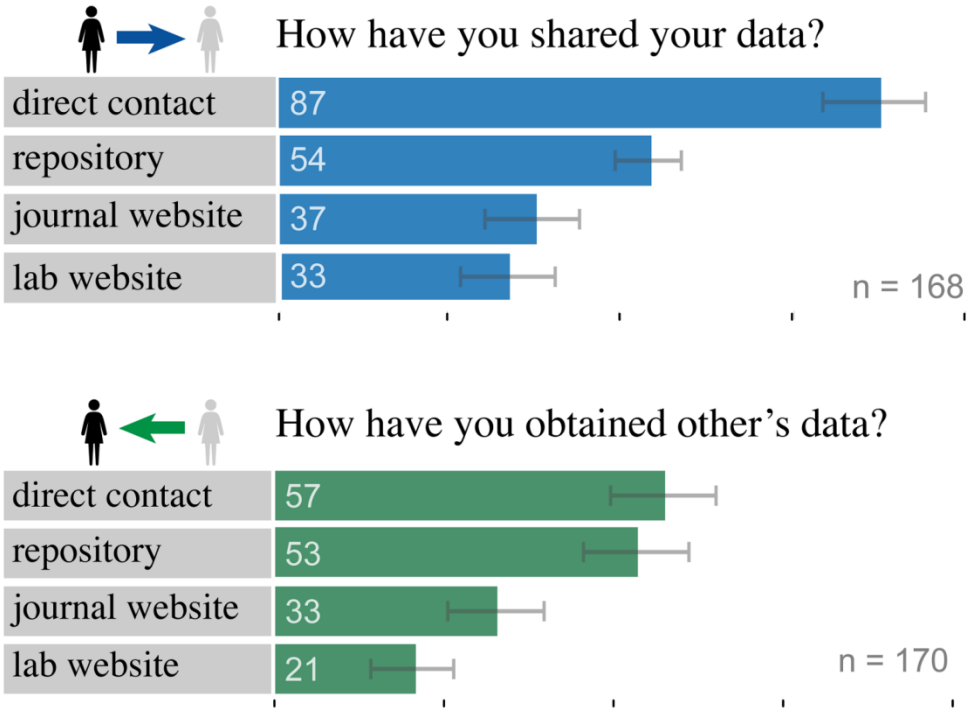
November 18, 2019

Why Researchers Share Data- Wellcome Trust



Van den Eynden, Veerle et al. (2016) https://dx.doi.org/10.6084/m9.figshare.4055448

How Researchers Share



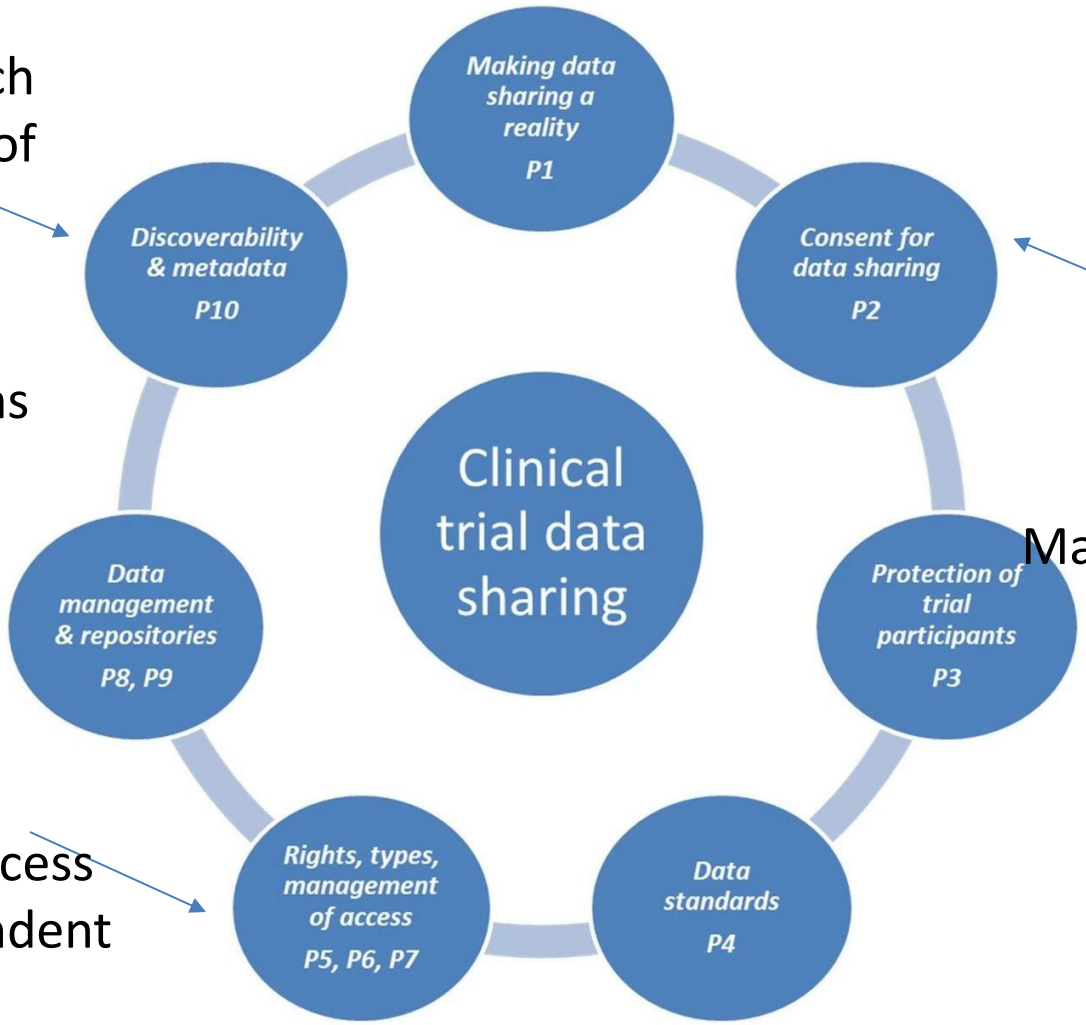
Kratz JE, Strasser C (2015) PLoS ONE 10(2) https://doi.org/10.1371/journal.pone.0117619

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

BMJ Open

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

ClinicalStudy DataRequest.com

Many years since establishment (2013)	✓
>3,000 studies available to request	✓
Supports applications for studies from multiple sponsors	✓
SAS secure analysis environment which includes; SAS, STATA, NONMEM, and lots of open source software	✓
No charge to secondary data users	✓
All applications for re-use are assessed by an **Independent Review Panel**	✓
Secondary user responsible for approvals e.g. EC, IRBs	✓

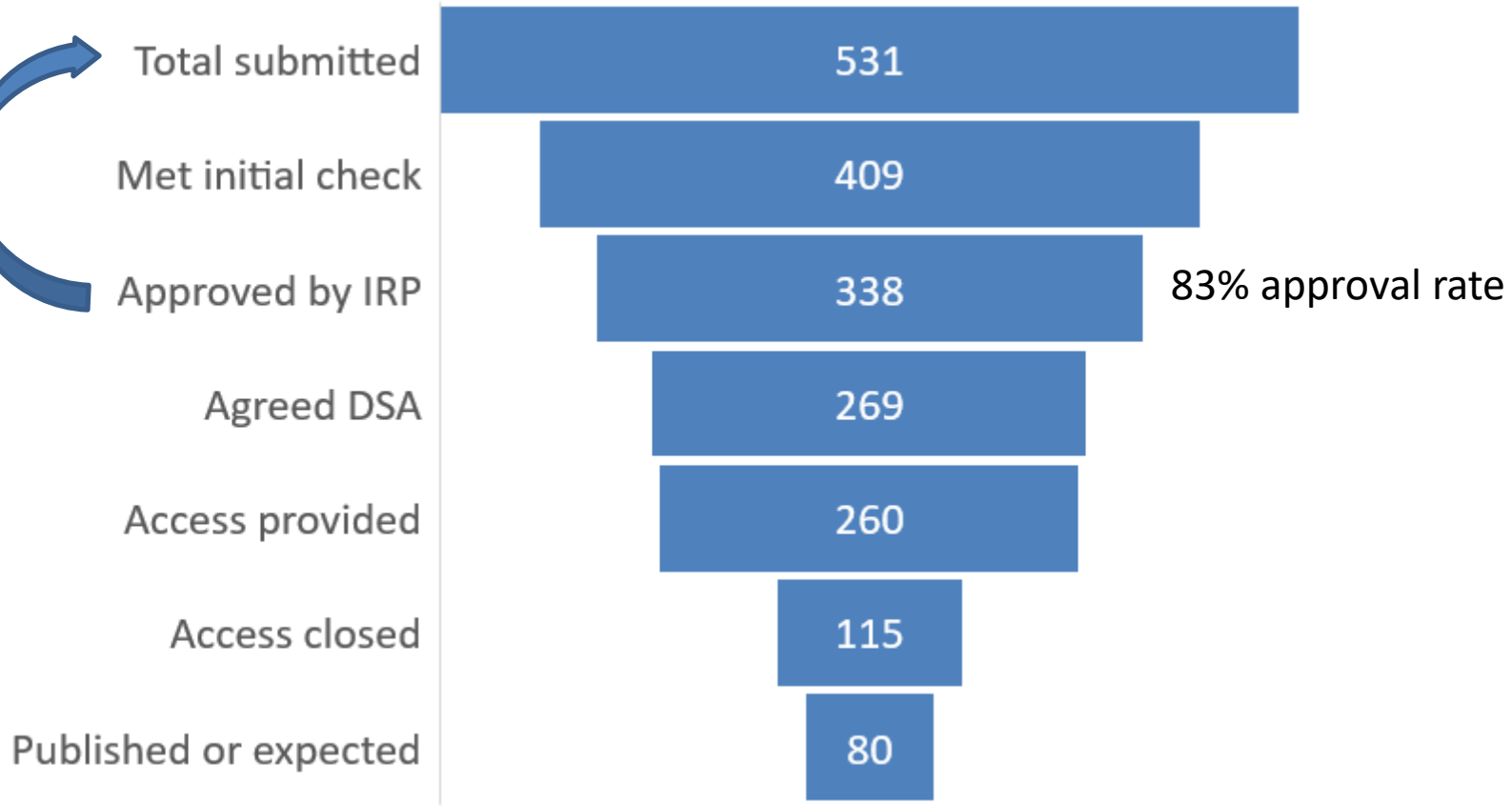
Independent Review Panel (IRP)

- 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

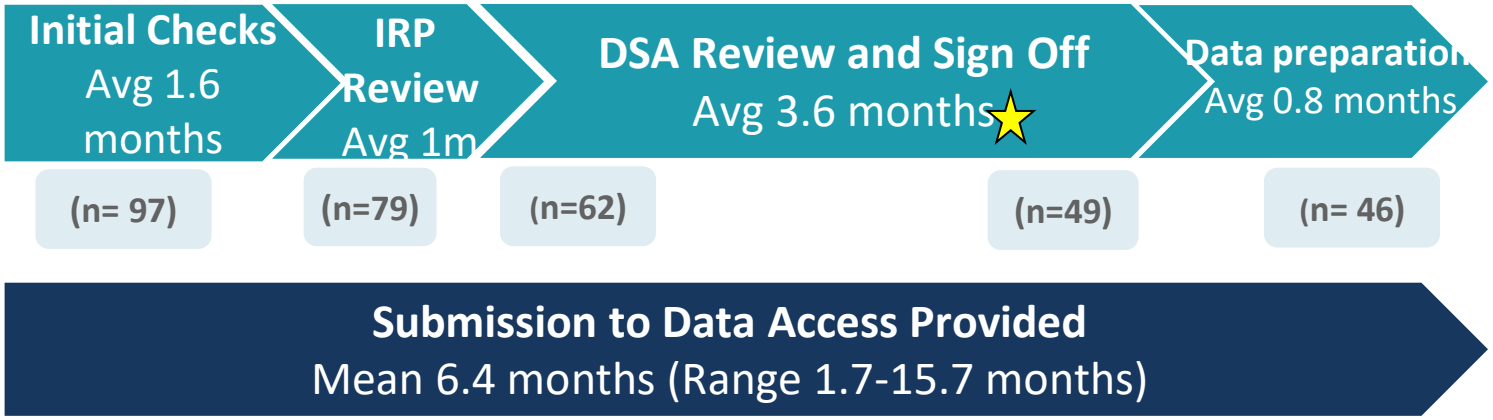
https://clinicalstudydatarequest.com/Help/Help-Independent-Review-Panel.aspx

Applications through CSDR (to August 2019)

60% rejected proposals are revised, re-submitted



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

WT = Wellcome Trust Secretariat
DSA = Data Sharing Agreement
IRP = Independent Review Panel

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

Common Reasons for IRP Rejection

Questions IRP Considers	Common Reasons for IRP Rejection
Plain English summary clear with sufficient detail	Plain English summary too technical, no clear patient benefit cited
- Scientific rationale for research - Research question relevant for medical science and/or patient care	Insufficient information, plan and aims unclear
Does the study design, methodology or analysis plan have significant limitations	Statistical methods issues; insufficient detail, incorrect methodology
Research team's relevant qualifications and experience	Skills/qualifications of the team not clear or insufficient
Plan to publish findings	No publication/dissemination plan
Real or potential conflicts of interest (COI), appropriately managed	

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

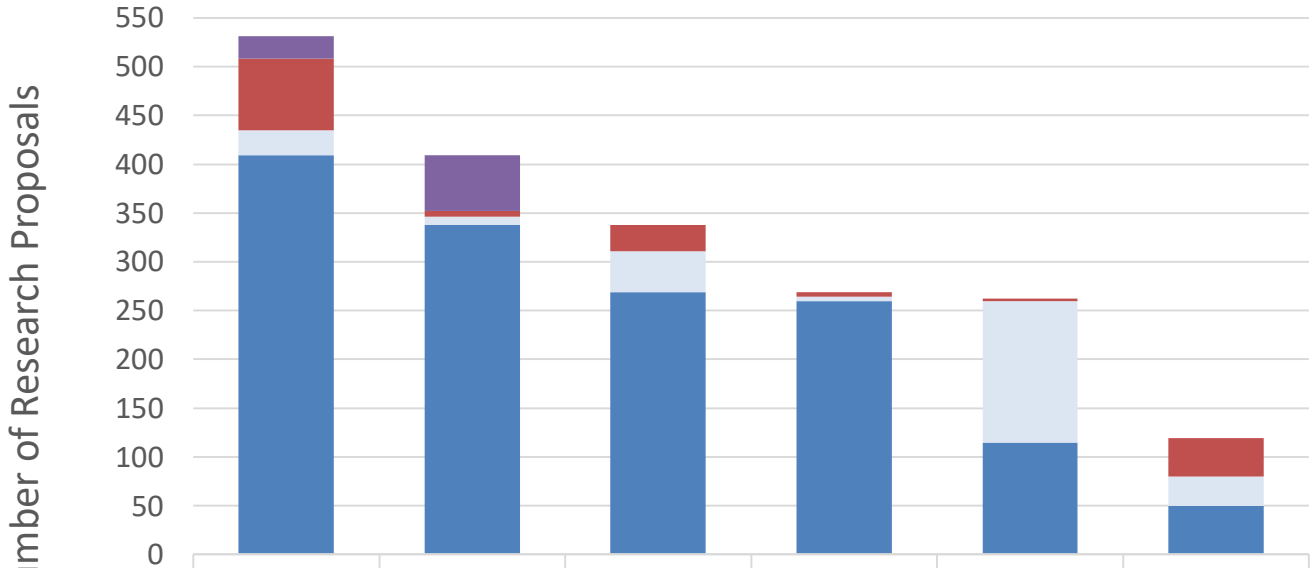
- Research agendas informed by whole community to drive sharing, re-use of data
- Data access process should be easily discoverable with transparent metrics for potential users
- Funders could support capacity building efforts in LMIC
- Consent for clinical research from participants could include provision 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)



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