

Data sharing in trials: All trials should share all their data?

The bigger picture: from open access to open scholarship

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AOASG: who we are



What we do: advocacy, collaboration (nationally and globally) raising awareness and capacity building for open & FAIR research in Australasia



PLOS Medicine 2004



“So in starting afresh, what should a new medical journal retain, and what should it ditch?

Most obviously, we should throw out the old way of disseminating information.”

<https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0010022>

Feb 2014: new statement on data availability at PLOS



“PLOS has always required that authors make their data available to other academic researchers

...for all PLOS journals: authors must make all data publicly available, without restriction, immediately upon publication of the article.

...Beginning March 3rd, 2014, all authors who submit to a PLOS journal will be asked to provide a Data Availability Statement, describing where and how others can access each dataset that underlies the findings.”

They said:

“The latest round of waccaloonery is the [new PLoS policy on Data Access](#).”

PLOS responded:

“A flurry of interest has arisen around the revised PLOS data policy...

This **does not mean that authors must submit all data collected** as part of the research, but that they must provide the data that are relevant to the specific analysis presented in the paper...

What is changing is that authors need to indicate where the data are housed, at the time of submission.”

Jan 2016: The NEJM weighs in

- “There is concern among some front-line researchers that **the system will be taken over by what some researchers have characterized as “research parasites.”**
- This issue of the *Journal* offers a product of data sharing that is exactly the opposite. The new investigators arrived on the scene with their own ideas **and worked symbiotically**, rather than parasitically, with the investigators holding the data, moving the field forward in a way that neither group could have done on its own.

<https://www.nejm.org/doi/full/10.1056/NEJMe1516564>

April 2016: New ICMJE policy

As a condition of consideration for publication of a clinical trial report in our member journals, the ICMJE proposes to require authors to share with others the deidentified individual-patient data (IPD) underlying the results presented in the article (including tables, figures, and appendices or supplementary material) no later than 6 months after publication.

<https://annals.org/aim/fullarticle/2482115/sharing-clinical-trial-data-proposal-from-international-committee-medical-journal>

August 2016: Response to ICMJE proposal

Although we believe there are potential benefits to sharing data (e.g., occasional new discoveries), **we believe there are also risks** (e.g., misleading or inaccurate analyses and analyses aimed at unfairly discrediting or undermining the original publication) and opportunity costs (e.g., the ICMJE proposal **would have enormous direct costs** and would probably **divert resources**, both financial and human, from the actual conduct of trials).

...We believe consideration needs to be given to whether it is worthwhile to undertake data sharing for all published trials or just for those whose results are under question or those that are likely to influence care.”

<https://www.nejm.org/doi/full/10.1056/NEJMp1605654>

June 2017: ICMJE revised

In response to our request for feedback we received many comments from individuals and groups

As of July 1, 2018 manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement as described below.

Clinical trials that begin enrolling participants on or after January 1, 2019 must include **a data sharing plan** in the trial's registration.

<https://doi.org/10.1371/journal.pmed.1002315>

Why share data?

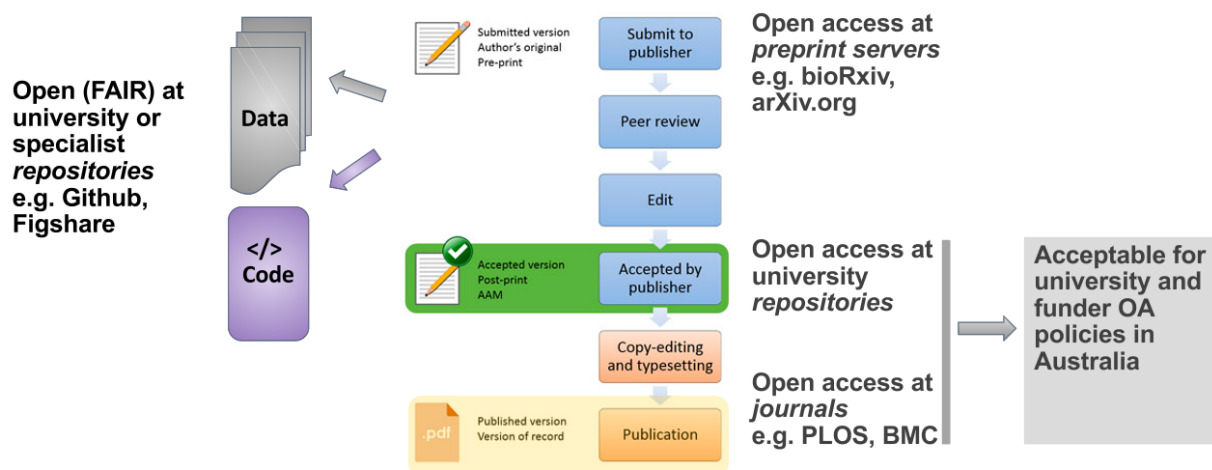
“Transparent, truthful, open science, **including open access publications, following recommendations such as the FAIR Guiding Principles for scientific data management** and stewardship and public communication are ways to optimize value to society and enhance research integrity.”



Data are part of open scholarship

An interconnected, equitable, global scholarly ecosystem of well-curated, interoperable, trusted research articles, data and software supported by a diversity of open publishing models.

Sharing data is part of the research lifecycle



Why now?

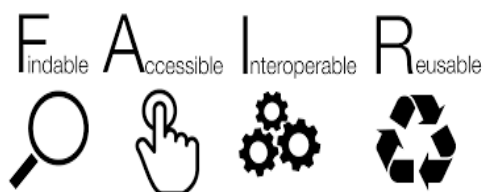
As OA2020 says:

“Our vision is to finally and rapidly achieve the benefits of the open information environment conceived 15 years ago: the advancement of science powered by the full potential of our digital environment and barrier-free access to knowledge.”

and - we are developing the frameworks to do this.

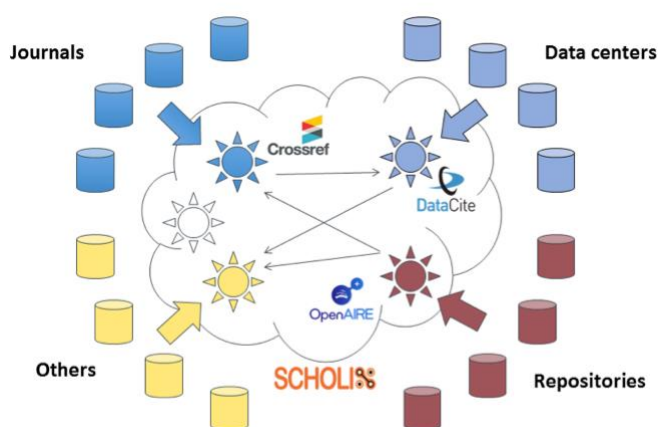
<https://oa2020.org/>

A pragmatic framework





Rich metadata,
infrastructure
and good
linkages are key
to meaningful
data sharing



Data linking needs
infrastructure

<http://www.dlib.org/dlib/january17/burton/01burton.html>

Research Projects

Efficacy and Mechanism Evaluation

Health Services and Delivery Research

Health Technology Assessment

Public Health Research

Systematic Reviews programme

Programme Grants for Applied Research

NIHR Clinical Trials Unit Support Funding

HTA - 09/22/165

Development and validation of a risk score for trauma patients with haemorrhage The CRASH-2 score

Project title: Development and validation of a risk score for trauma patients with haemorrhage The CRASH-2 score

Call to action: 09/22 09/22 Diagnostic tests and test technologies

Research type: Primary Research

Chief investigator: Associate Professor Pablo Perel

Lead Author: Associate Professor Pablo Perel

Contractor: London School of Hygiene & Tropical Medicine

Cost: £140,022.00

Co-investigators: Dr Ewout Steyerberg, Mr Tim Clayton, Ms Haleema Shakur, Professor Fiona Lecky, Professor Ian Roberts.

Started: October 2010 | Status: Published June 2013

Toolkit

Print

Alerts & updates

PROJECT PUBLISHED ✓

VIEW REPORT

Latest project information

Protocol (05 Aug 2010)

Protocol (05 Aug 2010)

Share

Twitter Facebook LinkedIn Email

Project overview

Application Plain English Summary

Application Abstract

Journals Library Report

Links to project documents

The links and documents below are provided by the research team and when they are produced over the life of the project. The information is provided by the research team using editorial, production and publication models, which differ to NIHR Journals Library reports. Links are to both internal (NIHR) and external websites – the NIHR is not responsible for the content of external websites.

Background & Research Questions

Methods

Results

Impact

Why the research is being done and what is being asked

How the research is being done

What the research found

What impact the research has had

Protocol (05 Aug 2010)

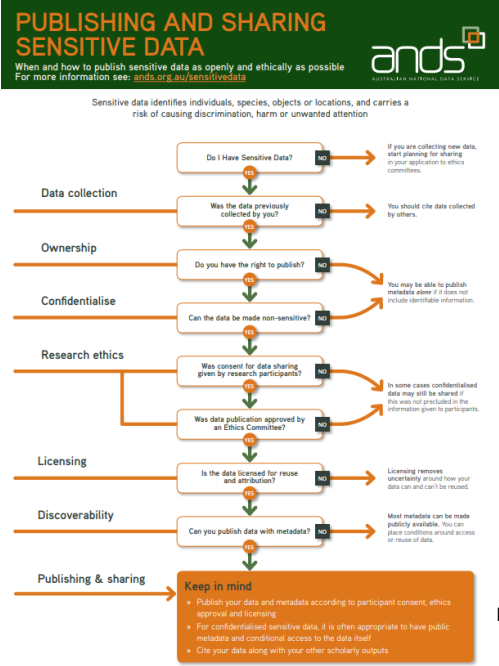
Protocol (05 Aug 2010)

Related Articles

NHS
National Institute for
Health Research

We can
then link
everything

Paper and
data
Protocol
Impact



It's not trivial

<https://www.andsonline.org.au/working-with-data/sensitive-data/sharing-sensitive-dat>



CARE Principles for Indigenous Data Governance



<https://www.gida-global.org/care>

Policies have their place...

Australian Code for the Responsible Conduct of Research

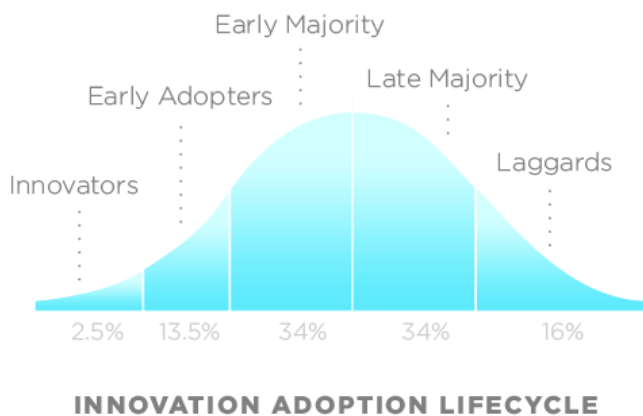
Principle 3

‘Transparency in declaring interests and reporting research methodology, data and findings’, which requires researchers to share and communicate research methodology, data and findings openly, responsibly and accurately.

NHMRC Open Access Policy

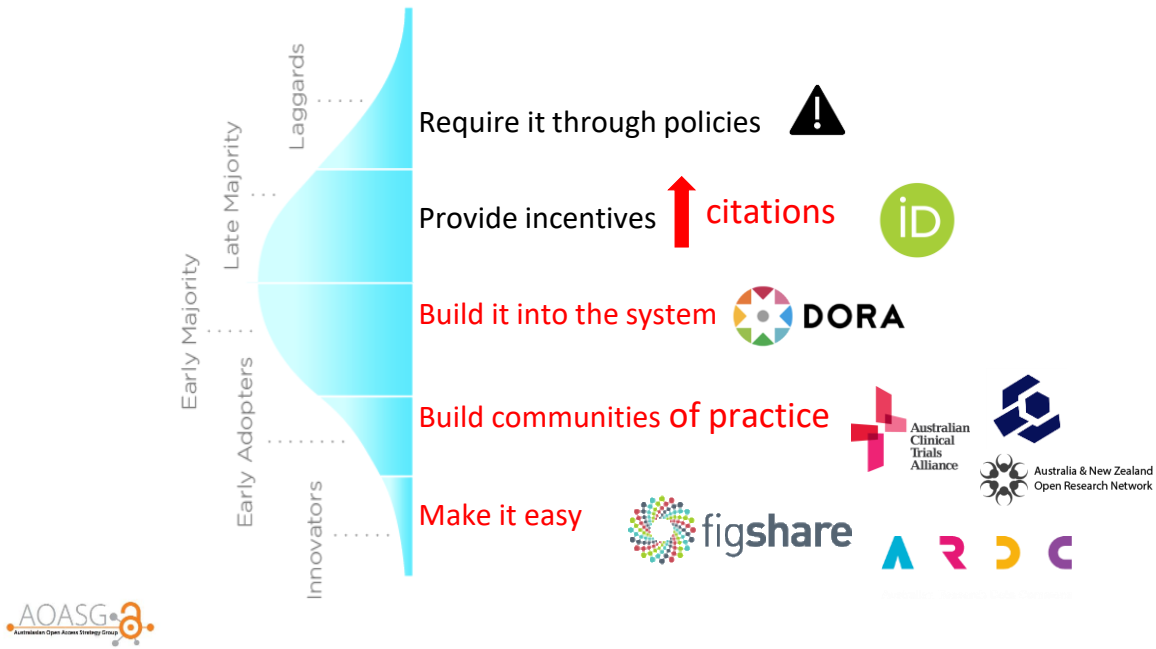
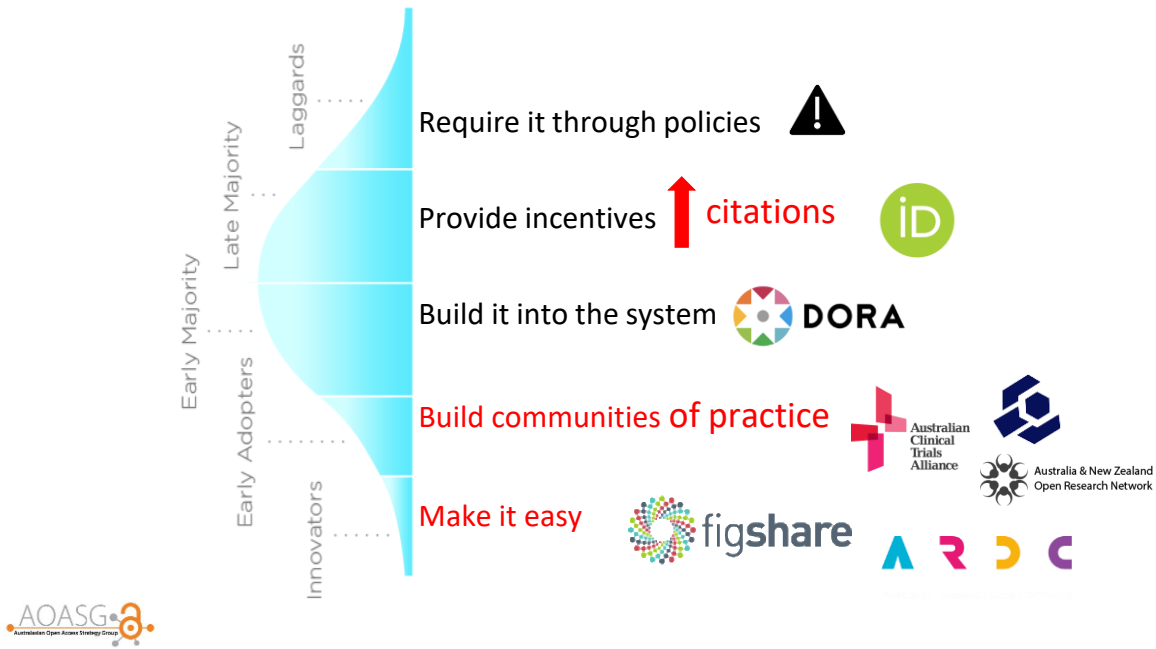
NHMRC supports the sharing of outputs from NHMRC funded research including publications and data. The aims of the NHMRC Open Access Policy are to mandate the open access sharing of publications and encourage innovative open access to research data.

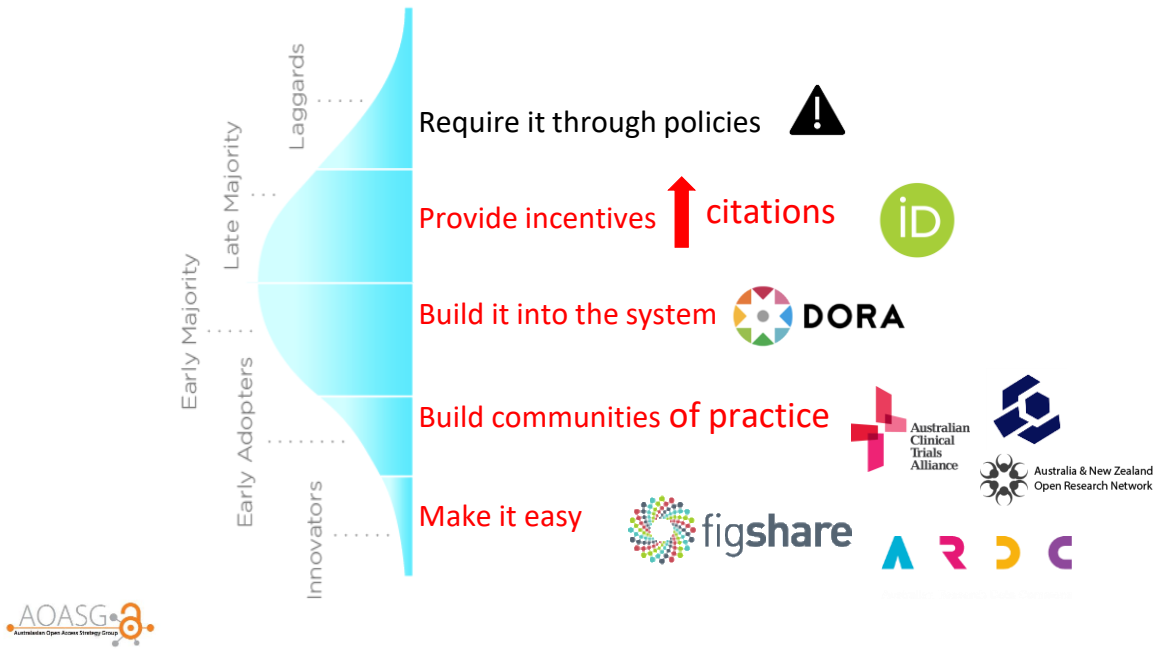
... but are not enough



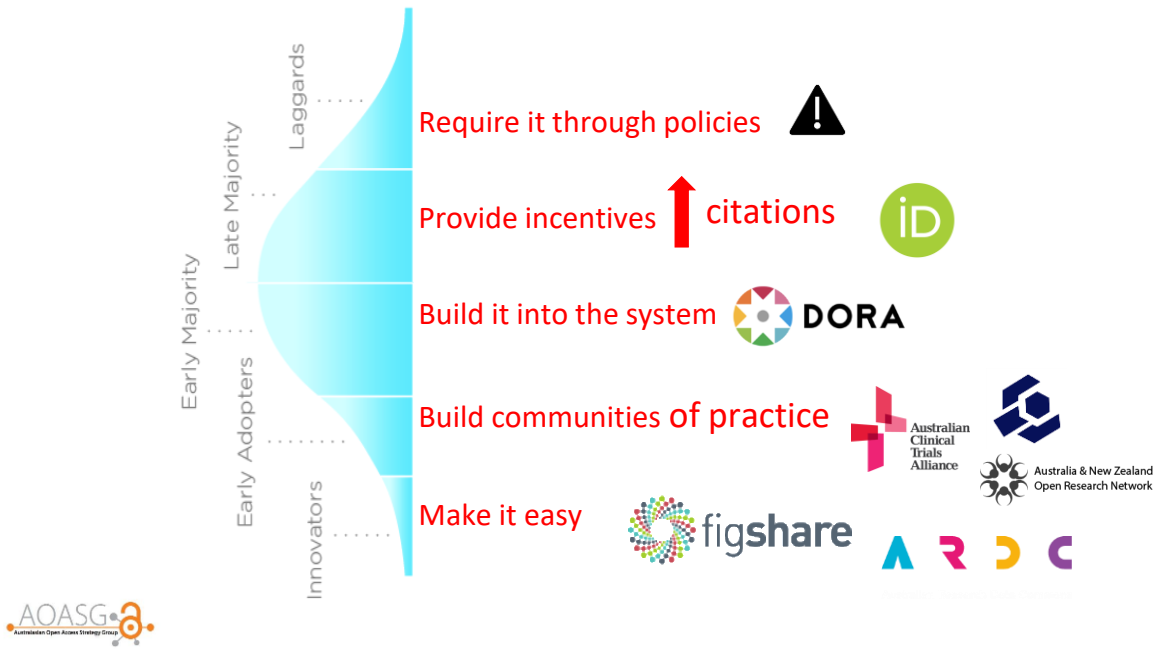
<https://en.wikipedia.org/wiki/File:DiffusionOfInnovation.png>







Adapted from Brian Nosek : Shifting Incentives from Getting It Published to Getting it Right <https://osf.io/bxjta/>



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Comments
and follow
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