

Challenges and disincentives for sharing and using data: A researcher perspective

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Sharing Clinical Trial Data: Challenges and a Way Forward: A Workshop
17-Nov-2019

Data sharing at ICTMC 2019

- ICTMC 2019 = conference on clinical trials methodology
 - 730 registered
 - 500 abstracts
- Only 4 (<1%) related to clinical trials data sharing
 - Applicant experiences of CSDR
 - Systematic review of “anonymisation methods”
 - Do data silos jeopardise IPD meta-analyses
 - CTU changing approach

ICTMC2019

5th International Clinical Trials Methodology Conference



ICTMC 2019 – BRIGHTON

6th – 9th October 2019



Some Challenges

Using data in a valid way and usefulness of new knowledge generated from data sharing

Rationale for linking to trial data and linkage to routine data for sharing

Oversight processes necessary for access to shared data

Recognition of researchers involved in creating data

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Using data in valid way & utility of new knowledge

- Need: maximize highest quality science to have greatest societal benefit
 - Much from clinical trials
 - Much from associated research
- Conscious of opportunity costs
- Effort to prepare datasets
 - Development of trial with view to sharing
 - Preparation and documentation of datasets at “end”
- Effort to support released datasets
 - None if not requested
 - Much if many secondary requests that provoke engagement

Costable

Uncostable

Using data in valid way & utility of new knowledge

- Trials analyzed by **highly qualified teams** with
 - Clear stats planning in design
 - Statistical analysis plans detailing analyses
 - Primary, secondary and exploratory, & accounting for multiple testing
- Trials teams routinely criticized if (perceived to be) doing lots of testing and subgroup analyses
 - Some ICMJE journals will not put subgroups analyses into abstracts
 - Reproducibility crisis in psychological literature
- How to protect trial integrity and integrity of secondary analysis?

Using data in valid way & utility of new knowledge

- Applicants set out analyses in advance
 - Needs to know whether data would be available?
- Applicant qualifications logged?
- “Approved researcher” status – register with relevant professional body
- Agree to repeat analyses and do, and work together if differences
- Specific training courses for new researchers seeking data for secondary use?

doi:10.1001/jama.2017.18556

The screenshot shows the JAMA Network website interface. At the top, there's a search bar and navigation links. The article title is 'Guidelines for the Content of Statistical Analysis Plans in Clinical Trials', dated December 19, 2017. It's a 'Special Communication' and is marked as 'FREE'. The authors listed are Carrol Gamble, PhD¹; Ashma Krishan, BSc²; Deborah Stocken, PhD^{3,4}; and g.t.a.l. The article has 62,084 views, 31 citations, and an Altmetric score of 278. On the right, there's a 'Top of Article' sidebar with links to Abstract, Introduction, Methods, Results, Discussion, Conclusions, Article Information, and References. The 'Abstract' section is partially visible at the bottom, starting with 'Importance While guidance on statistical principles for clinical trials exists, there is an absence of guidance covering the required content of statistical analysis plans (SAPs) to support transparency and reproducibility.'

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2. Which data source and why

- Many applications require trial data
 - e.g. IPD meta-analysis, linkage to samples
- Anticipate proportion of applications do not need individual trials, just good, prospectively collected data
 - e.g. estimating events rates in some subset of patients
 - Trial = convenience sample set for researchers who can't access prospective data when needed
- What if better access to routinely-collected health data (RCHD)*?
 - Good EHR → few applications for trial data?
- Solve issues for access to RCHD at same time or separately to trials?

*Electronic health records

Some Challenges

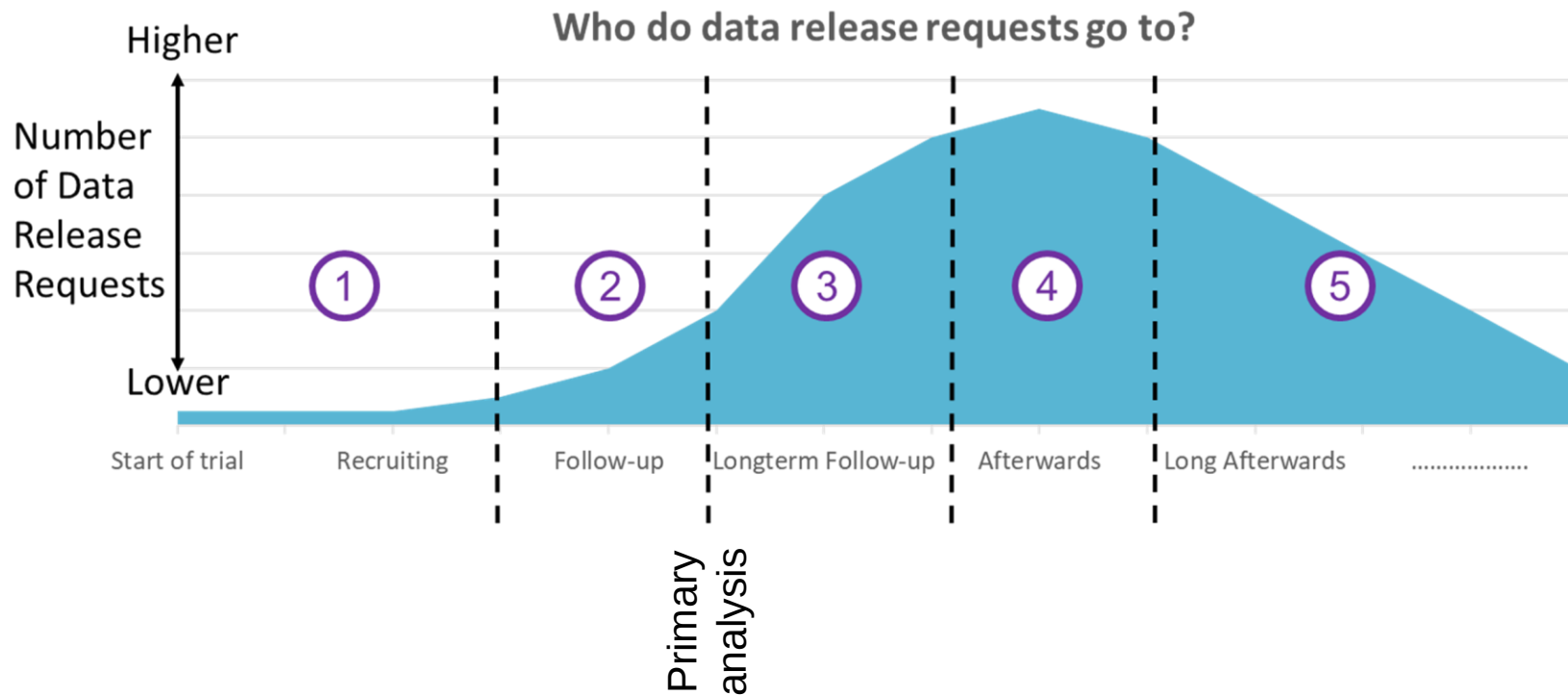
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Rationale for linking to trial data and linkage to routine data for sharing

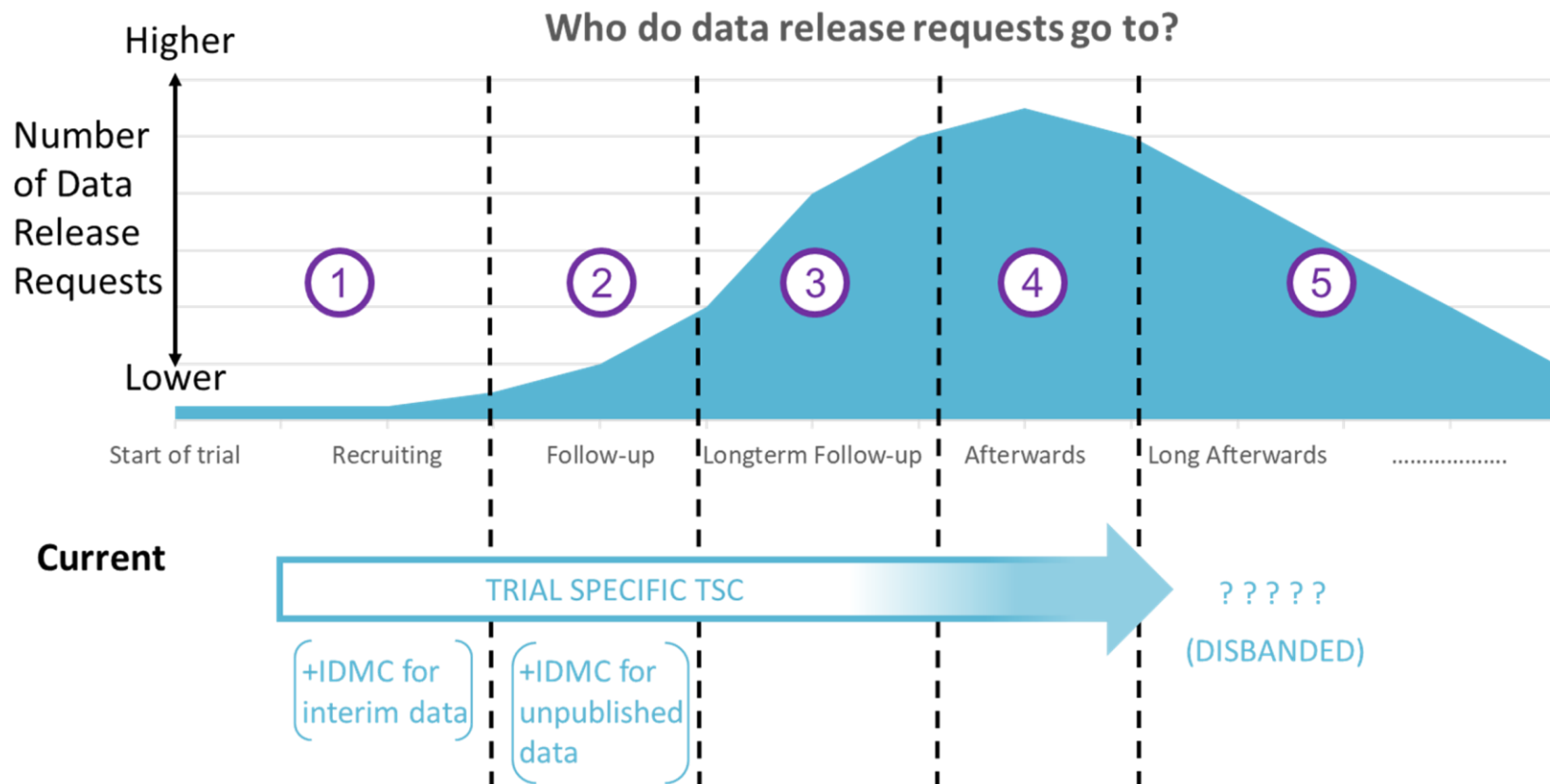
Oversight processes necessary for access to shared data

Recognition of researchers involved in creating data

3. Oversight and timing



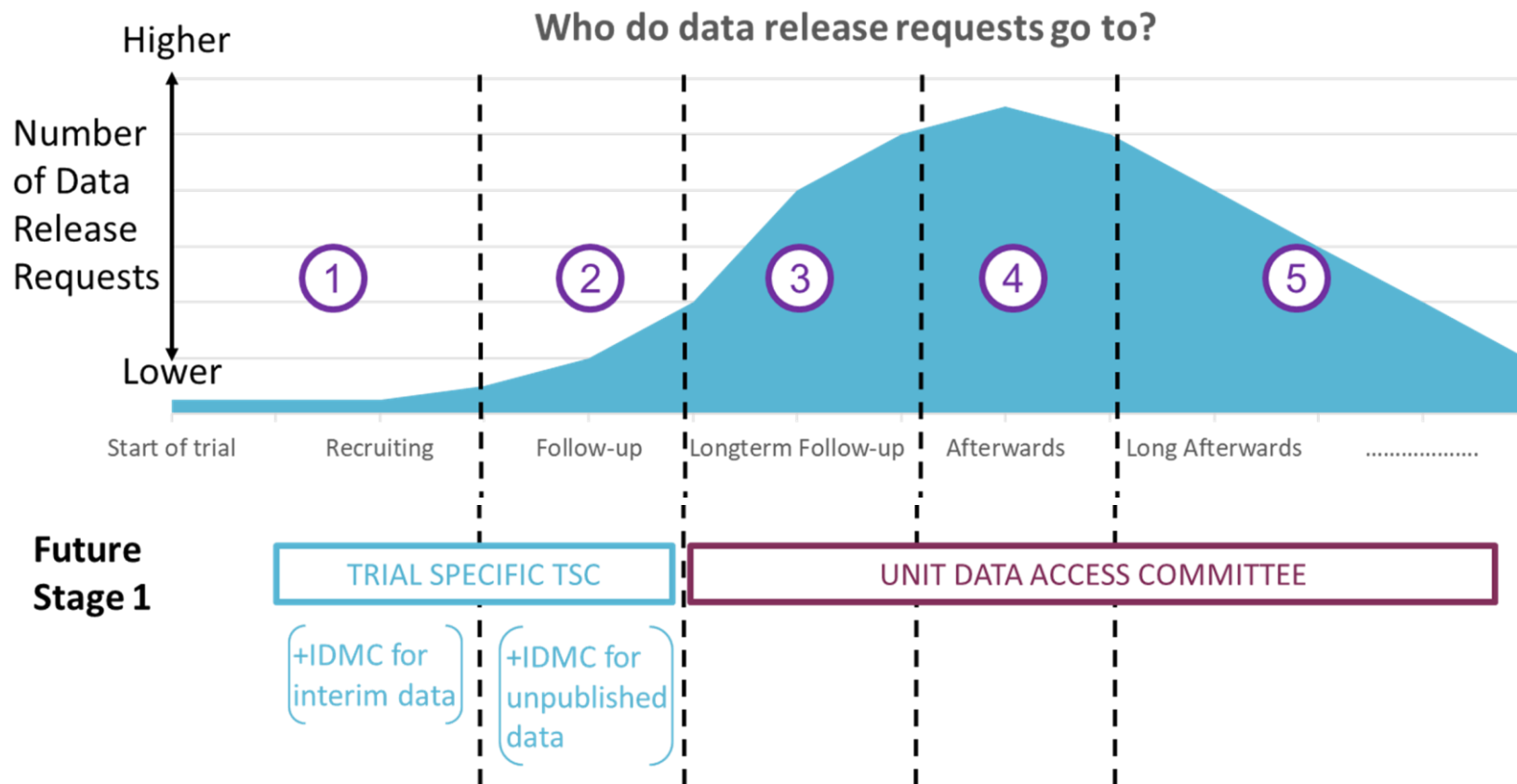
3. Oversight and timing



TSC = Trial Steering Committee

MRC CTU at UCL

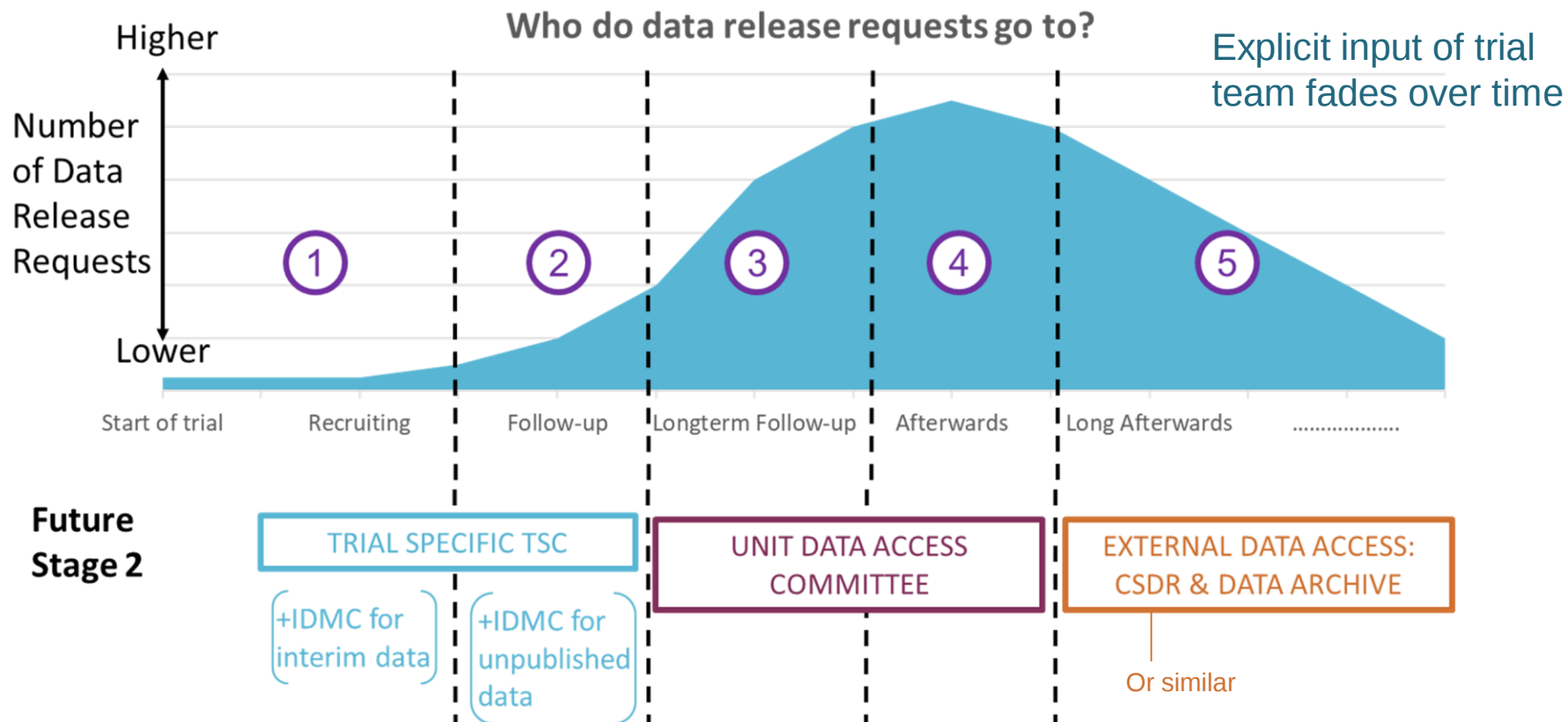
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A question of recognition



A question of recognition

IMDb



Rashida Jones

[imdb.com/name/nm0429069](https://www.imdb.com/name/nm0429069)



Toby Jones

[imdb.com/name/nm0429363](https://www.imdb.com/name/nm0429363)



Chawana Jones

[imdb.com/name/nm6398989/](https://www.imdb.com/name/nm6398989/)

A question of recognition



Rashida Jones

[imdb.com/name/nm0429069](https://www.imdb.com/name/nm0429069)

Filmography

| | [Edit](#)

Jump to: [Actress](#) | [Producer](#) | [Soundtrack](#) | [Writer](#) | [Director](#) | [Thanks](#) | [Self](#) | [Archive footage](#)

Actress (77 credits)

[Show](#)

Producer (15 credits)

[Show](#)

Soundtrack (11 credits)

[Show](#)

Writer (6 credits)

[Show](#)

Director (4 credits)

[Show](#)

Thanks (7 credits)

[Show](#)

Self (76 credits)

[Show](#)

Archive footage (5 credits)

[Show](#)

A question of recognition



Toby Jones

[imdb.com/name/nm0429363](https://www.imdb.com/name/nm0429363)

Filmography

▼ Show all | Show by... ▼ | Edit

Jump to: [Actor](#) | [Soundtrack](#) | [Writer](#) | [Thanks](#) | [Self](#) | [Archive footage](#)

Actor (121 credits) [Show](#) ▼

Soundtrack (2 credits) [Show](#) ▼

Writer (1 credit) [Show](#) ▼

Thanks (1 credit) [Show](#) ▼

Self (26 credits) [Show](#) ▼

Archive footage (8 credits) [Show](#) ▼

A question of recognition



Chawana Jones

Filmography

Show all | Show by... | Ed

To always display TV and movie credits separately, [edit your site preferences](#).

Makeup Department (29 credits)

Hide ▲

True You (makeup department head)

Wild 'N Out (TV Series) (key makeup artist - 24 episodes) 2019

- Love and Hip Hop Hollywood: MissNikkiiBaby, Brooke Valentine, Paris Phillips and Shawty Shawty (2019) ... (key makeup artist)

- Shiggy (2019) ... (key makeup artist)

- Swizz Beatz/Kash Doll (2019) ... (key makeup artist)

- Perez Hilton/Lay Lay (2019) ... (key makeup artist)

- Tory Lanez (2019) ... (key makeup artist)

Show all 24 episodes

Stranger Things (TV Series) (makeup artist - 2 episodes) 2019

- Chapter Two: The Mall Rats (2019) ... (makeup artist)

- Chapter One: Suzie, Do You Copy? (2019) ... (makeup artist)

The Mule (makeup artist - uncredited) 2018

Goosebumps 2: Haunted Halloween (makeup artist) 2018

The Bobby Brown Story (TV Series) (makeup artist - 1 episode) 2018

- Episode #2.2 (2018) ... (makeup artist)

Authorship alone does not recognise input

Part 1

Part 2

Columns = 10+ editorials and 30+ papers for one clinical trial protocol

Rows = authors (names removed)

Cells = green if named author, red if not

Proposal for recognition



- Would “film credits” for trials improve recognition of effort?
- Would “IMDb for trial engagement” allow recognition and ameliorate some anxieties about data sharing?
 - How might this differ between commercial and non-commercial settings?
- Recognition of researchers involved in creating data
 - Differences between academia and industry?
- DOI for shared datasets
 - Each version uploaded or one per trial?
- New models need buy in from:
 - Journals
 - Promotion committees

doi: 10.1056/NEJMc1707245

The NEW ENGLAND JOURNAL of MEDICINE

Data Authorship as an Incentive to Data Sharing

TO THE EDITOR: Eierer et al. (April 27 issue)¹ conceptualize “data authorship” as an incentive for data sharing by clinical trialists. We support secondary use to advance scientific aims, and the authors’ proposal may start to ameliorate one commonly expressed concern: how the effort of the

THE AUTHORS REPLY: We had hoped to stimulate public discussion about how best to align the varying extant systems to result in one normative system to credit persons who contribute and share scientific data for secondary use. The proposal from Sydes and Ashby to establish an IMDb-like

Two other challenges to mention quickly...

- How / when to properly anonymise / pseudonymise / de-link datasets
 - Dedicated training courses for statisticians and data scientists
 - Could be a specialist (and credited!) role at (larger?) organisations?
- Feedback of results to participants?
 - Getting better at this for main trial results
 - Whose responsibility after data sharing?

<http://www.stampedetrial.org/media-section/news/news-stories/2019/june-2019/m1rt-results-videos/>

Full version:



Short version:



Summary

- Number of challenges
- Addressing them requires buy in secondary data users as well as primary trial researchers and broader trial community
- Society needs us to find ways to ensure answering the questions that matter in the best way

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