Symposium 8

Toward responsible clinical trial data sharing practices

Speakers

Nchangwi Syntia Munung, Daniel Kulp, Maximilian Siebert, Ulrich Mansmann

Moderator

Florian Naudet

COIs

Fundings

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Symposium 8

Toward responsible clinical trial data sharing practices

Clinical trials are important!

A comparative randomized clinical trial evaluating the efficacy and safety of tacrolimus versus hydrocortisone as a topical treatment of atopic dermatitis in children

Amal A. Mohamed[1], Radwa El Borolossy[2], Eman M. Salah[3], Maha S. Hussein[4], Nashwa M. Muharram[5], Naglaa Elsalawy[6], Mona G. Khalil[7], Maha O. Mahmoud[8], Reham Y. El-Amir[9], Heba M. A. Elsanhory[10], Nourelhuda Ahmed[11], Ahmed S. Adaroas[11], Mahmoud Montaser[12] and Amal A. El Kholy [13]*

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Sometimes, you don't need to have the data…

A comparative randomized clinical trial evaluating the efficacy and safety of tacrolimus versus hydrocortisone as a topical treatment of atopic dermatitis in children

Amal A. Mohamed[1], Radwa El Borolossy[2], Eman M. Salah[3], Maha S. Hussein[4], Nashwa M. Muharram[5], Naglaa Elsalawy[6], Mona G. Khalil[7], Maha O. Mahmoud[8], Reham Y. El-Amir[9], Heba M. A. Elsanhory[10], Nourelhuda Ahmed[11], Ahmed S. Adaroas[11], Mahmoud Montaser[12] and Amal A. El Kholy [13]*

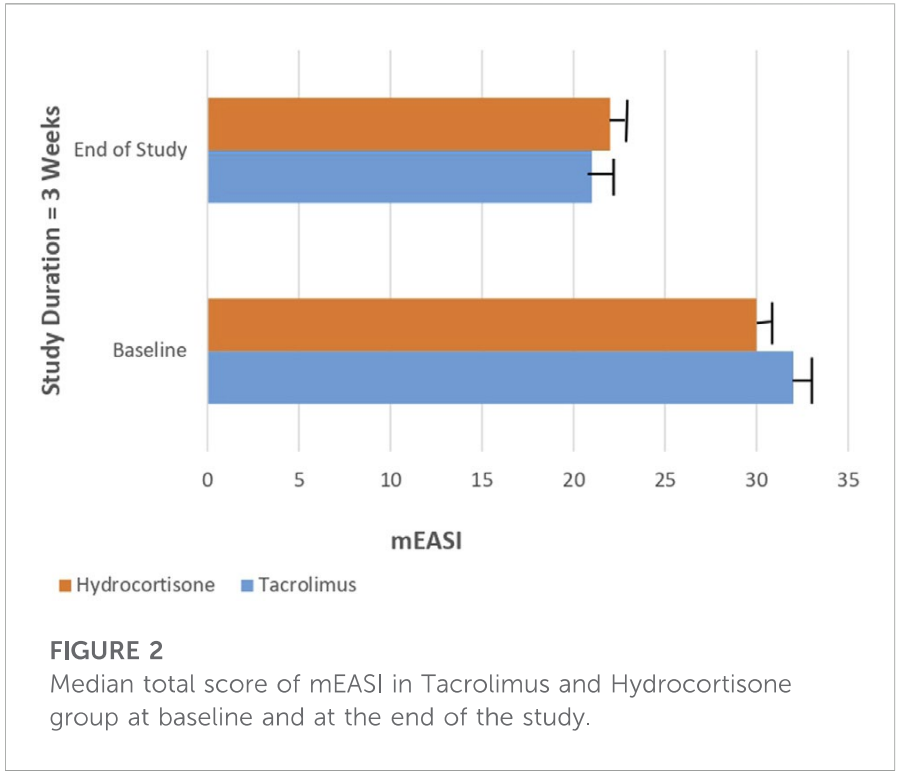

FIGURE 2
Median total score of mEASI in Tacrolimus and Hydrocortisone group at baseline and at the end of the study.

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… but having the data would be fun.

A comparative randomized clinical trial evaluating the efficacy and safety of tacrolimus versus hydrocortisone as a topical treatment of atopic dermatitis in children

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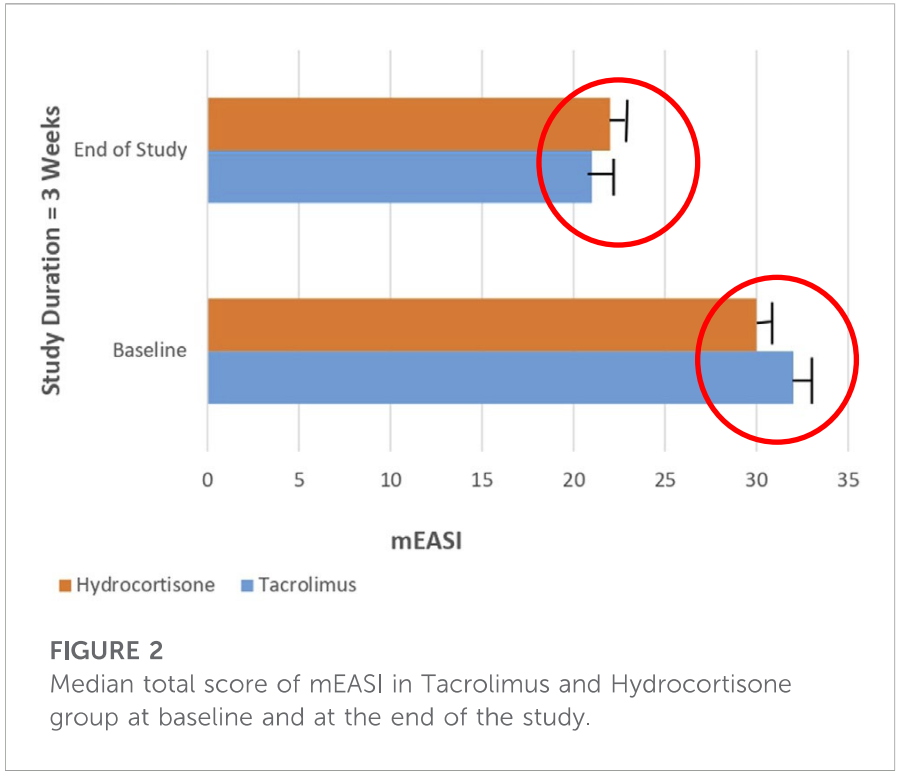

FIGURE 2
Median total score of mEASI in Tacrolimus and Hydrocortisone group at baseline and at the end of the study.

Symposium 8

Toward responsible clinical trial data sharing practices

Sometimes, it matters

RESEARCH

OPEN ACCESS

Restoring Study 329: efficacy and harms of paroxetine and imipramine in treatment of major depression in adolescence

Joanna Le Noury,[1] John M Nardo,[2] David Healy,[1] Jon Jureidini,[3] Melissa Raven,[3] Catalin Tufanaru,[4] Elia Abi-Jaoude[5]

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Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/bmj.h4320)

Cite this as: *BMJ* 2015;351:h4320
doi: 10.1136/bmj.h4320

Accepted: 03 August 2015

ABSTRACT

OBJECTIVES
To reanalyse SmithKline Beecham's Study 329 (published by Keller and colleagues in 2001), the primary objective of which was to compare the efficacy and safety of paroxetine and imipramine with placebo in the treatment of adolescents with unipolar major depression. The reanalysis under the restoring invisible and abandoned trials (RIAT) initiative was done to see whether access to and reanalysis of a full dataset from a randomised controlled trial would have clinically relevant implications for evidence based medicine.

DESIGN
Double blind randomised placebo controlled trial.

SETTING
12 North American academic psychiatry centres, from 20 April 1994 to 15 February 1998.

PARTICIPANTS
275 adolescents with major depression of at least eight weeks in duration. Exclusion criteria included a range of comorbid psychiatric and medical disorders and suicidality.

INTERVENTIONS
Participants were randomised to eight weeks double blind treatment with paroxetine (20-40 mg), imipramine (200-300 mg), or placebo.

MAIN OUTCOME MEASURES
The prespecified primary efficacy variables were change from baseline to the end of the eight week acute treatment phase in total Hamilton depression scale (HAM-D) score and the proportion of responders (HAM-D score ≤8 or ≥50% reduction in baseline HAM-D) at acute endpoint. Prespecified secondary outcomes were changes from baseline to endpoint in depression items in K-SADS-L, clinical global impression, autonomous functioning checklist, self-perception profile, and sickness impact scale; predictors of response; and number of patients who relapse during the maintenance phase. Adverse experiences were to be compared primarily by using descriptive statistics. No coding dictionary was prespecified.

RESULTS
The efficacy of paroxetine and imipramine was not statistically or clinically significantly different from placebo for any prespecified primary or secondary efficacy outcome. HAM-D scores decreased by 10.7 (least squares mean) (95% confidence interval 9.1 to 12.3), 9.0 (7.4 to 10.5), and 9.1 (7.5 to 10.7) points, respectively, for the paroxetine, imipramine and placebo groups (P=0.20). There were clinically significant increases in harms, including suicidal ideation and behaviour and other serious adverse events in the paroxetine group and cardiovascular problems in the imipramine group.

CONCLUSIONS
Neither paroxetine nor high dose imipramine showed efficacy for major depression in adolescents, and there was an increase in harms with both drugs. Access to primary data from trials has important implications for both clinical practice and research, including that published conclusions about efficacy and safety should not be read as authoritative. The reanalysis of Study 329 illustrates the necessity of making primary trial data and protocols available to increase the rigour of the evidence base.

WHAT IS ALREADY KNOWN ON THIS TOPIC
- There is a lack of access to data from most clinical randomised controlled trials, making it difficult to detect biased reporting
- In the absence of access to primary data, misleading conclusions in publications of those trials can seem definitive
- SmithKline Beecham's Study 329, an influential trial that reported that paroxetine was safe and effective for adolescents, is one such study

WHAT THIS STUDY ADDS
- On the basis of access to the original data from Study 329, we report a reanalysis that concludes that paroxetine was ineffective and unsafe in this study
- Access to primary data makes clear the many ways in which data can be analysed and represented, showing the importance of access to data and the value of reanalysis of trials
- There are important implications for clinical practice, research, regulation of trials, licensing of drugs, and the sociology and philosophy of science
- Our reanalysis required development of methods that could be adapted for future reanalyses of randomised controlled trials

Introduction
In 2013, in the face of the selective reporting of outcomes of randomised controlled trials, an international group of researchers called on funders and investigators of abandoned (unpublished) or misreported trials to publish undisclosed outcomes or correct misleading publications.[1] This initiative was called "restoring invisible and abandoned trials" (RIAT). The researchers identified many trials requiring restoration and emailed the funders, asking them to signal their intention to publish the unpublished trials or publish corrected versions of misreported trials. If funders and investigators failed to undertake to correct a trial that had been identified as unpublished or misreported, independent groups were encouraged to publish an accurate representation of the clinical trial based on the relevant regulatory information.

The current article represents a RIAT publication of Study 329. The original study was funded by

Data Sharing and Clinical Trials
-
The role of journals & funders

Meta-Research Innovation Center at Stanford

Maximilian Siebert, PhD
Postdoctoral Fellow

World Conference on Research Integrity Athens 2024
June 5, 2024

Conflicts of Interest:
Receiving personal fees from the European Commission
for consulting activities outside these works

WAME

INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS

NATIONAL LIBRARY OF MEDICINE

ICMJE Transparency Policies for Clinical Trials

Clinical trials **need to be registered at the beginning of the trial** or before the enrolment of the first patient

Results of **Clinical Trials** submitted to ICMJE journals must contain a data sharing statement

First proposal regarding data sharing

The ICMJE *"believes that there is an ethical obligation to responsibly share data generated by interventional clinical trials because participants have put themselves at risk. "*

Data Sharing Statement

Wang M, Barrientos JC, Furman R, et al. Zilovertamab Vedotin Targeting of ROR1 as Therapy for Lymphoid Cancers. NEJM Evidence. DOI: 10.1056/EVIDoa2100001.

Question	Authors' Response
Will the data collected for your study be made available to others?	Yes
Would you like to offer context for your decision?	—
Which data?	Complete de-identified patient data set. Other (eg, partial data sets)
Additional information about data	Clinical study report
How or where can the data be obtained?	Merck & Co., Inc.'s data sharing policy, including restrictions, is available at http://engagezone.merck.com/ds_documentation.php. Requests for access to the clinical study data can be submitted through the EngageZone site or via email to dataaccess@merck.com.
When will data availability begin?	After product approval in the US and EU or after product development is discontinued
When will data availability end?	—
Will any supporting documents be available?	—
Which supporting documents?	—
Additional information about supporting documents	—
How or where can supporting documents be obtained?	—
When will supporting documents availability begin?	—
When will supporting documents availability end?	—
To whom will data be available?	Qualified scientific researchers
For what type of analysis or purpose?	Specific purpose outlined in a proposal
By what mechanism?	After researcher enters into a standard data sharing agreement and the proposal is approved

Open access Original research

BMJ Open

Data-sharing recommendations in biomedical journals and randomised controlled trials: an audit of journals following the ICMJE recommendations

Maximilian Siebert ,[1,2] Jeanne Fabiola Gaba,[1,2] Laura Caquelin,[1] Henri Gouraud,[1] Alain Dupuy,[2] David Moher ,[3] Florian Naudet[1]

BMJ Open, May 2020, https://doi.org/10.1136/bmjopen-2020-038887

Data Sharing Statements & Intention to Share

ICMJE Member Journals

- **8/14**
  explicit Data Sharing Policy on their website

- **98%** Data Sharing Statements in a sample of 100 Clinical Trials

- **77%** Intention to share data

Journals stating that they follow the ICMJE Recommendations

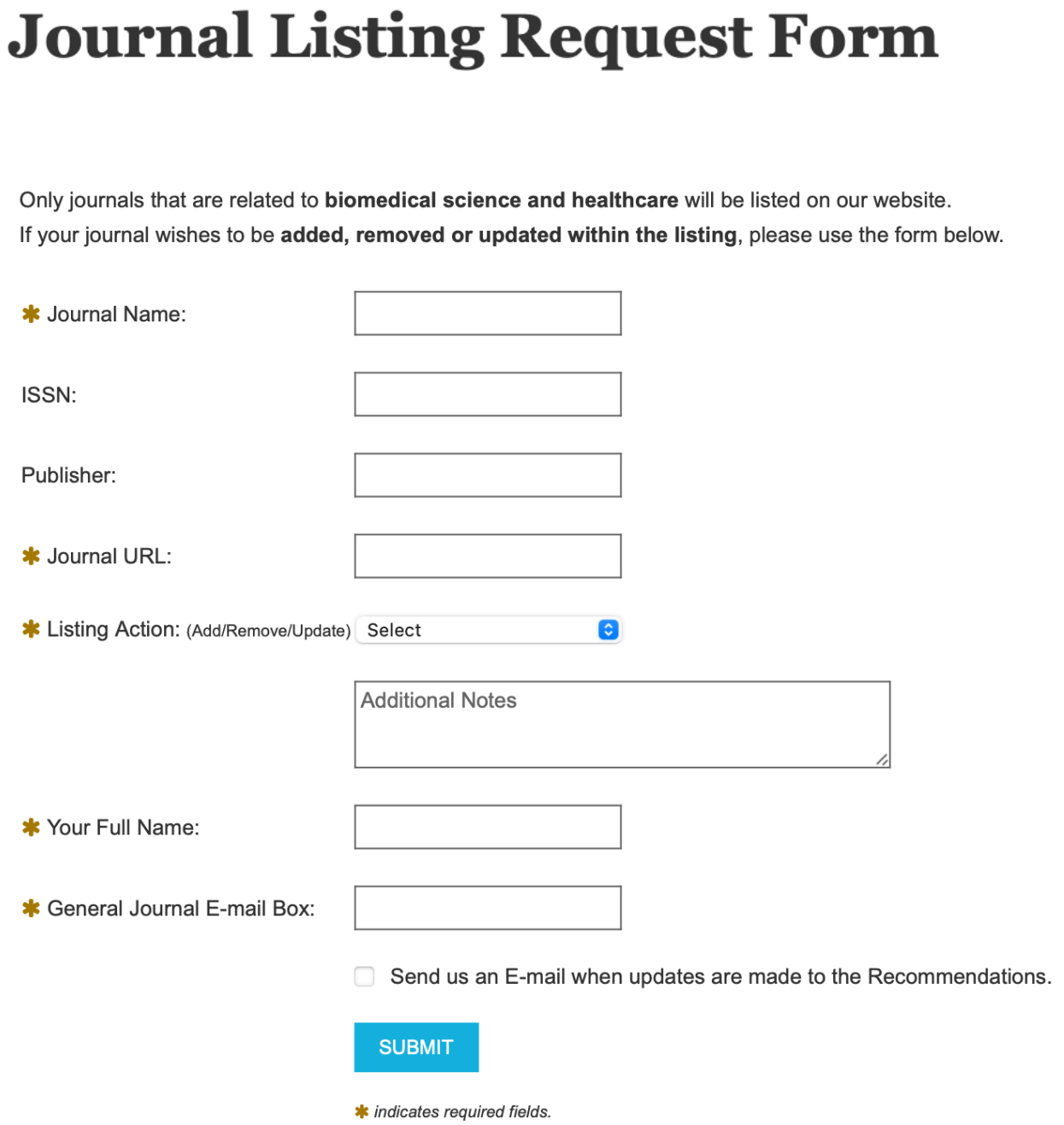
The following is a list of journals whose editors or publishers have contacted the International Committee of Medical Journal Editors (ICMJE) to request listing as a journal that says it follows the ICMJE's Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals. Although these journals are not "members" of the ICMJE itself, nor does their inclusion indicate "certification" by the ICMJE, maintenance of such a list may help to promote improvements in the quality of medical science and its reporting by indicating the standards many editors indicate they work to uphold.

The ICMJE cannot verify the completeness or accuracy of this list.

- There may be some journals that follow the ICMJE recommendations, but have never requested listing.
- There may be some listed journals that do not follow all of the many recommendations and policies in the document.

Editors whose journals have requested inclusion on this list by indicating that they follow the ICMJE Recommendations must be mindful of their responsibility to do so. Although we believe that most editors take this responsibility seriously and strive to achieve high standards, a growing number of entities advertise themselves as scholarly, peer-review medical journals yet do not function as such ("predatory" or "pseudo-journals"). Such journals may request listing here merely to gain the appearance of legitimacy. Unfortunately there remains no validated mechanism to reliably define or identify such journals and we therefore emphasize the need to evaluate each journal's practices carefully

Journals stating that they follow the ICMJE Recommendations



Journal Listing Request Form

Only journals that are related to **biomedical science and healthcare** will be listed on our website.
If your journal wishes to be **added, removed or updated within the listing**, please use the form below.

✱ Journal Name:

ISSN:

Publisher:

✱ Journal URL:

✱ Listing Action: (Add/Remove/Update) Select

Additional Notes

✱ Your Full Name:

✱ General Journal E-mail Box:

Send us an E-mail when updates are made to the Recommendations.

SUBMIT

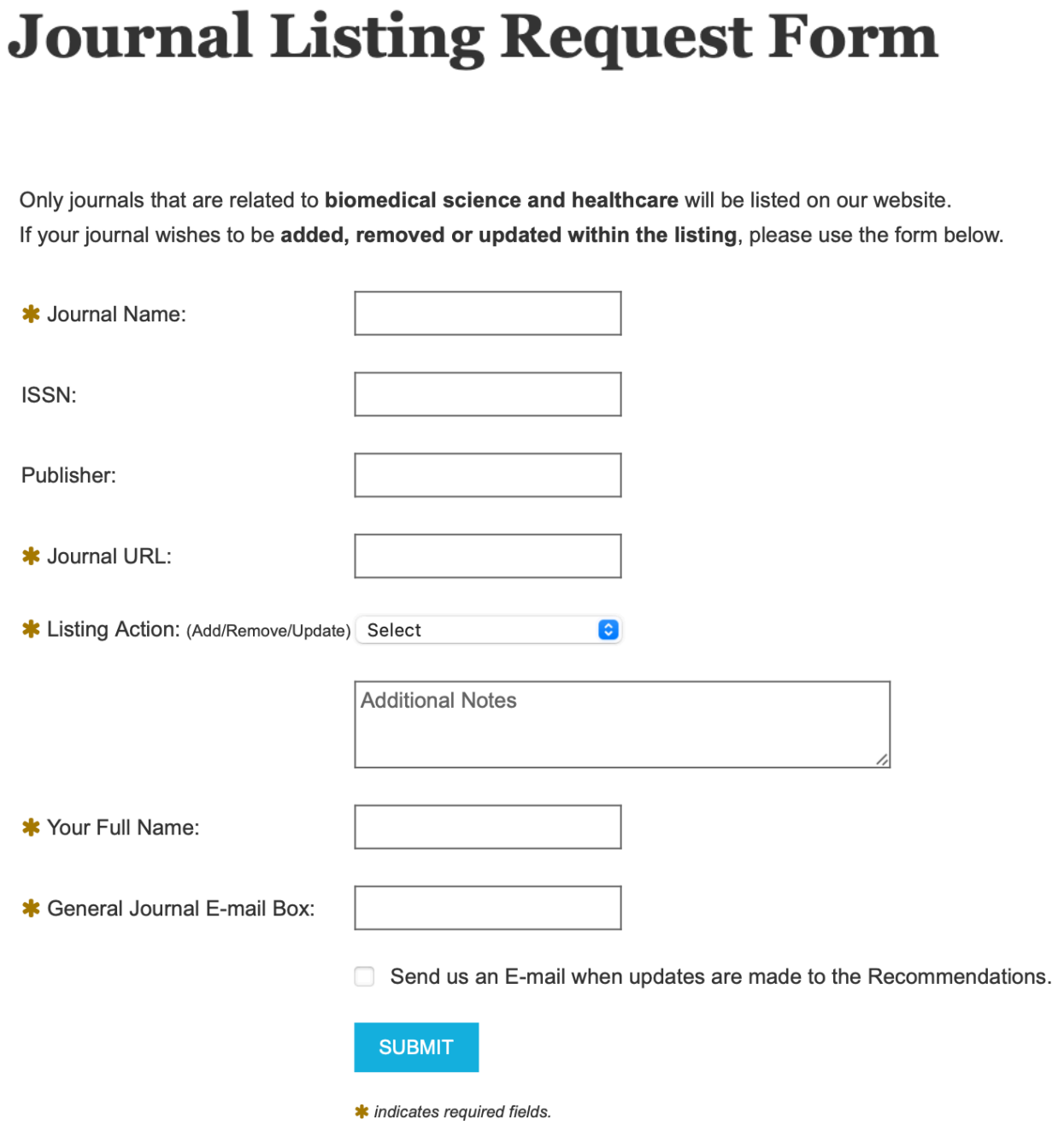
✱ *indicates required fields.*

Journals stating that they follow the ICMJE Recommendations

February 2019 : ~ 5000

February 2022 : ~ 7000

June 2024: ~ 9000



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Additional Notes

✱ Your Full Name:

✱ General Journal E-mail Box:

Send us an E-mail when updates are made to the Recommendations.

SUBMIT

✱ *indicates required fields.*

Data Sharing Statements & Intention to Share

ICMJE Member Journals

- **8/14** explicit Data Sharing Policy on their website
- **98%** Data Sharing Statements in a sample of 100 Clinical Trials
- **77%** Intention to share data

Journals stating to follow ICMJE guidelines

- **30%** explicit Data Sharing Policy on their website
- **25%** Data Sharing Statements in a sample of 100 Clinical Trials
- **22%** Intentions to share data

What about the funders?

PLOS ONE

RESEARCH ARTICLE

Funders' data-sharing policies in therapeutic research: A survey of commercial and non-commercial funders

Jeanne Fabiola Gaba[1,2]*, Maximilian Siebert[1,2], Alain Dupuy[2], David Moher[3,4], Florian Naudet[1]

PLOS ONE, August 2020, https://doi.org/10.1371/journal.pone.0237464

Sherpa Services
Under Active Development

Funders

Non-commercial Funders (78 funders on Sherpa/Juliet)	Commercial Funders (100 top pharmaceutical companies)
• **38%** explicit Data Sharing Policy on their website	• **41%** explicit Data Sharing Policy on their website
• **77%** Data Sharing Statements in a sample of 100 Clinical Trials	• **81%** Data Sharing Statements in a sample of 100 Clinical Trials
• **12%** Intention to share data	• **59%** Intentions to share data

Is it possible that ICMJE recommendations and data sharing statements are only a checkbox?

And what would this mean for other guidelines?

Way forward

New BMJ data sharing policy

EDITORIALS

Check for updates

The BMJ, London, UK

Correspondence to: E Loder
eloder@bmj.com

Cite this as: *BMJ* 2024;384:q324
http://dx.doi.org/10.1136/bmj.q324
Published: 5 March 2024

Mandatory data and code sharing for research published by *The BMJ*

New policy requires authors to share analytic codes from all studies and data from all trials

Elizabeth Loder, Helen Macdonald, Theodora Bloom, Kamran Abbasi

"From 1 May 2024, The BMJ will require authors of all submitted trials to post relevant trial data in an enduring, publicly accessible repository such as Vivli before publication."

Research Letter

December 28, 2023

Lifting of Embargoes to Data Sharing in Clinical Trials Published in Top Medical Journals

Maximilian Siebert, PhD[1]; John P. A. Ioannidis, MD, DSc[1]

» Author Affiliations

JAMA. 2024;331(4):354-355. doi:10.1001/jama.2023.25394

Data Sharing Statement

Wang M, Barrientos JC, Furman R, et al. Zilovertamab Vedotin Targeting of ROR1 as Therapy for Lymphoid Cancers. NEJM Evidence. DOI: 10.1056/EVIDoa2100001.

Question	Authors' Response
Will the data collected for your study be made available to others?	Yes
Would you like to offer context for your decision?	—
Which data?	Complete de-identified patient data set. Other (eg, partial data sets)
Additional information about data	Clinical study report
How or where can the data be obtained?	Merck & Co., Inc.'s data sharing policy, including restrictions, is available at http://engagezone.merck.com/ds_documentation.php. Requests for access to the clinical study data can be submitted through the EngageZone site or via email to [illegible].
When will data availability begin?	After product approval in the US and EU or after product development is discontinued
[illegible]	[illegible]
Will any supporting documents be available?	—
Which supporting documents?	—
Additional information about supporting documents	—
How or where can supporting documents be obtained?	—
When will supporting documents availability begin?	—
When will supporting documents availability end?	—
To whom will data be available?	Qualified scientific researchers
For what type of analysis or purpose?	Specific purpose outlined in a proposal
By what mechanism?	After researcher enters into a standard data sharing agreement and the proposal is approved

Methods

- 158 Clinical Trials published between July 1, 2018, and April 4, 2020
  - JAMA
  - The Lancet
  - The New England Journal of Medicine

which included embargoes on data sharing in their data sharing statements

Results

- 2/3 of Clinical Trials in our sample had lifted (65.8%) their embargo
- Half of them were deposited on data sharing platforms
- Only 3 of them were accessible without any restriction

NIH's new data sharing policy

National Institutes of Health

- When submitting a funding application from 2023, the NIH will ask for a DMS plan at the time of submission
- The two main requirements of the final policy are

  (1) the submission of a Data Management and Sharing (DMS) plan

  (2) compliance with the approved Plan

- The DMS plan should contain details about the software or tools needed to analyze the research data, when and where the scientific data will be published and any special considerations for accessing or distributing that research data

Conclusion

Issues have been detected in the past

Many incentives over the last 5 years

Tilting at windmills

Thank You

maxsiebert@stanford.edu

Symposium 8

QUESTIONS

WORLD CONFERENCES ON RESEARCH INTEGRITY

WCRI 2024

ATHENS GREECE

8th World Conference on Research Integrity

2–5 June 2024

www.wcri2024.org

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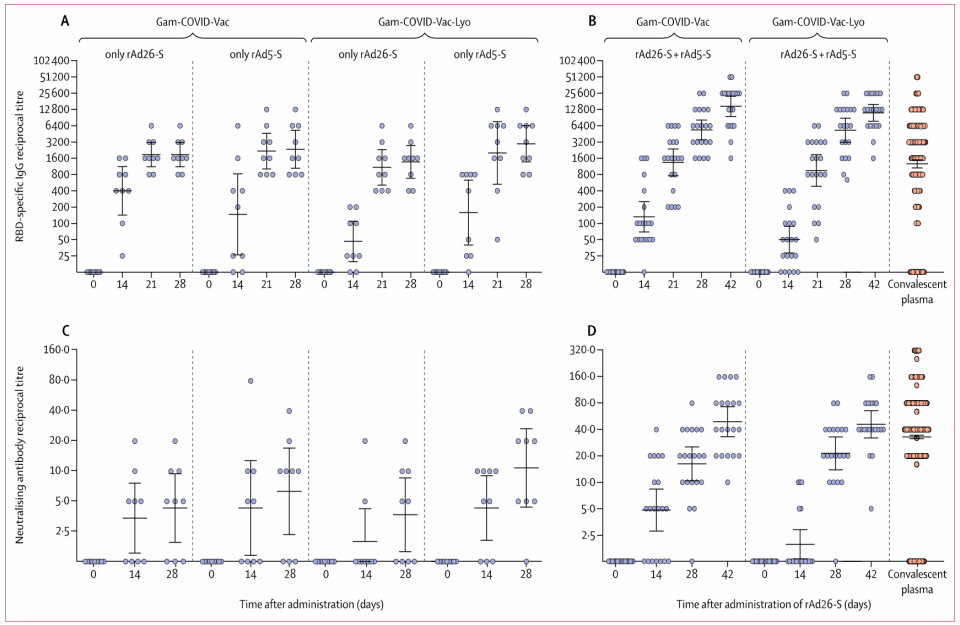

Safety and immunogenicity of an rAd26 and rAd5 vector-based heterologous prime-boost COVID-19 vaccine in two formulations: two open, non-randomised phase 1/2 studies from Russia

Denis Y Logunov, Inna V Dolzhikova*, Olga V Zubkova, Amir I Tukhvatulin, Dmitry V Shcheblyakov, Alina S Dzharullaeva, Daria M Grousova, Alina S Erokhova, Anna V Kovyrshina, Andrei G Botikov, Fatima M Izhaeva, Olga Popova, Tatiana A Ozharovskaya, Ilias B Esmagambetov, Irina A Favorskaya, Denis I Zrelkin, Daria V Voronina, Dmitry N Shcherbinin, Alexander S Semikhin, Yana V Simakova, Elizaveta A Tokarskaya, Nadezhda L Lubenets, Daria A Egorova, Maksim M Shmarov, Natalia A Nikitenka, Lola F Morozova, Elena A Smolyarchuk, Evgeny V Kryukov, Vladimir F Babira, Sergei V Borisevich, Boris S Naroditsky, Alexander L Gintsburg*

Figure 2: **Humoral immune response**
Data are geometric mean titres and 95% CIs. (A) RBD-specific antibodies on days 0, 14, 21, and 28, as measured by ELISA, in participants vaccinated with rAd26-S or rAd5-S only. (B) RBD-specific antibodies on days 0, 14, 21, 28, and 42, as measured by ELISA, in participants vaccinated with rAd26-S on day 0 and rAd5-S on day 21. (C) Neutralising antibodies on days 0, 14, and 28, as measured by neutralisation assay with 100 TCID50, in participants vaccinated with rAd26-S or rAd5-S only. (D) Neutralising antibodies on days 0, 14, 28, and 42, as measured by microneutralisation assay with 100 TCID50, in participants vaccinated with rAd26-S on day 0 and rAd5-S on day 21. RBD-specific IgGs and neutralising antibodies of in convalescent plasma are also shown in (B) and (D). Gam-COVID-Vac=frozen vaccine formulation. Gam-COVID-Vac-Lyo=lyophilised vaccine formulation. rAd26-S=recombinant adenovirus type 26 carrying the gene for SARS-CoV-2 full-length glycoprotein S. rAd5-S=recombinant adenovirus type 5 carrying the gene for SARS-CoV-2 full-length glycoprotein S. SARS-CoV-2=severe acute respiratory syndrome coronavirus 2. RBD=receptor-binding domain. TCID50=50% tissue culture infective dose.

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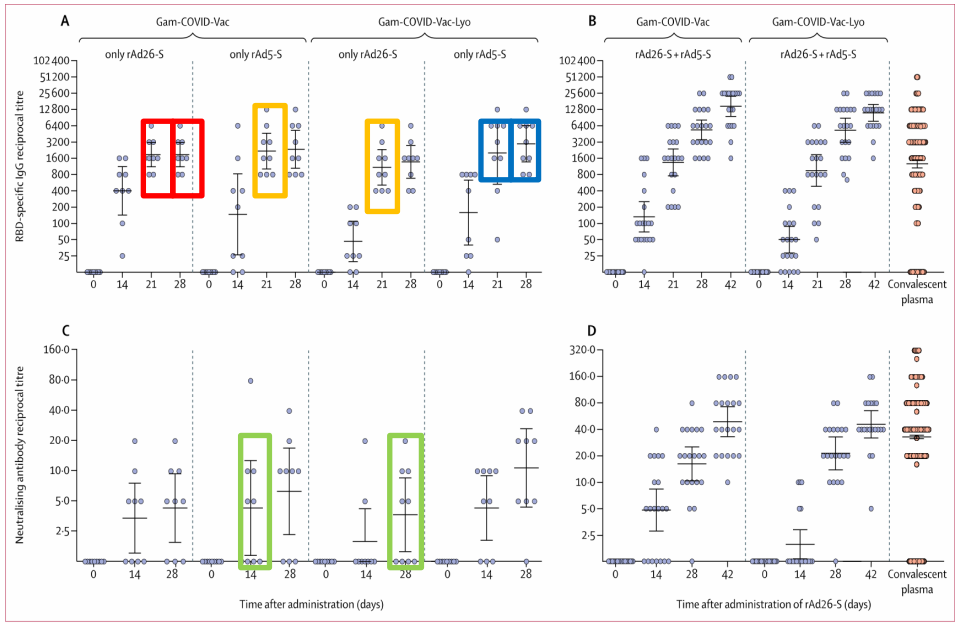

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disproportionately higher numbers than have other groups in the United States. The panel determined that these groups are vulnerable chiefly for socio-economic reasons tied to systemic racism — for example, they have high-risk jobs and live in high-risk areas — and therefore addressed the request through this lens, without singling out the groups because of their identities.

"We really are trying to make sure that people of colour, who have been disproportionately impacted, will also have priority — but for the factors that put them at risk, not highlighting just their racial and ethnic make-up," says Helene Gayle, president and chief executive of the Chicago Community Trust in Illinois and a co-chair of the NASEM committee that drafted the proposal.

Faden says the recommendations acknowledge the current focus on racial injustice in the United States. "I was reading to see: does this report speak to the cultural moment in the United States, does it speak to racism and other forms of structural inequality? And it does," she says.

The WHO's strategic advisory group will continue to update its guidance, first to assign rankings to its priority groups, and then to include real data from vaccine trials, such as how effective a given vaccine is in older people. In the United States, the NASEM committee is due to issue a final plan in October. Ultimately, the CDC will consider these recommendations, among others, while developing its own vaccine-allocation plan for the country, expected later this year.

That will be the guidance that public-health departments, doctors and pharmacies throughout the United States should follow when handing out vaccines — assuming that one has been proved safe and people are willing to take it.

"We really are trying to make sure that people of colour will have priority."

Trump has been rooting ready by November, in tim dential election — but a pe vaccine has been rushed c it, says Sandra Crouse Qui scientist at the Center fo the University of Marylan This could make vaccine-al effective.

RESEARCHERS QUESTION RUSSIAN COVID VACCINE TRIAL RESULTS

Scientists flag trial findings that seem to be duplicated and call for access to the underlying da

By Alison Abbott

A group of researchers have expressed concern about repetitive patterns of data in a paper describing early-phase clinical trials of Russia's coronavirus vaccine — the first jab worldwide to be approved for widespread use.

In an open letter to the study authors, who published the trial results[1] this month, the researchers highlight values that seem to be duplicated, and warn that the paper presents its results only as box plots, without providing a detailed breakdown of the data on which they are based. "While the research described in this study is potentially significant, the presentation of the data raises several concerns which require access to the original data to fully investigate", the letter says. It has been signed by almost 40 scientists (see go.nature.com/3kqvsqv).

The trials tested two slightly different viral-vector vaccines — wh engineered adenoviruses t virus proteins in the body – The results indicated tha duced a strong immune r side effects were limited to mild, short-term effects, such as irritation at injection sites or headaches, in a few people. In August, the Russian authorities approved the vaccine, called Sputnik V, for widespread use, and have said that it could be available to the general public within months. This fast-track approval caused consternation among researchers, who argued that the decision to roll out the vaccine before larger safety and efficacy tria had been completed was dangerously rushed.

Possible duplications

The open letter was posted on a blog run b molecular biologist Enrico Bucci, who head a science-integrity company called Res in Samone, Italy. Bucci says that he noticed irregularities in the paper soon after it was published (D. Y. Logunov *et al. Lancet* https://doi.org/gg96hq; 2020). For example, in one figure, in which the authors report their measurements of markers of a type of immune cell in the blood, many members of two groups of nine volunteers tested with different formulations of the vaccine seem to have the same levels. "The odds of this arising by coincidence are extremely small," Bucci says.

"To see such similar data patterns between unrelated measurements is really not likely," says Konstantin Andreev, who studies viral respiratory infections at Northwestern University at Evanston, Illinois. "These discrepancies are not minor." Andreev had been independently concerned about aspects of the clinical trial, and signed the open letter shortly after it was made public.

in Moscow, did not respond to requests for comment from *Nature*'s news team. But he told the Russian news outlet Meduza that he did not intend to respond to the open letter. He denied that there were errors in the publication, and stated that measured antibody levels were "exactly as they were presented" in the figures. He added that he was in contact with *The Lancet* and "was ready to clarify any issues".

The Lancet declined to comment on its policy for providing data in support of clinical trials that it publishes, but said that it "has invited the authors of the Russian vaccine study to respond to the questions raised in the open letter by Enrico Bucci", and that it would continue to follow the situation closely.

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Symposium 8

Toward responsible clinical trial data sharing practices

	Total cases	Vaccine group	Placebo group	Vaccine efficacy (95% CI)	p value
First COVID-19 occurrence from 21 days after dose 1 (day of dose 2)*					
Overall	78	16/14 964 (0·1%)	62/4902 (1·3%)	91·6% (85·6–95·2)	<0·0001
Age group (years)					
18–30	5	1/1596 (0·1%)	4/521 (0·8%)	91·9% (51·2–99·3)	0·0146
31–40	17	4/3848 (0·1%)	13/1259 (1·0%)	90·0% (71·1–96·5)	<0·0001
41–50	19	4/4399 (0·1%)	15/1443 (1·0%)	91·3% (73·7–96·9)	<0·0001
51–60	27	5/3510 (0·1%)	22/1146 (1·9%)	92·7% (81·1–97·0)	<0·0001
>60	10	2/1611 (0·1%)	8/533 (1·5%)	91·8% (67·1–98·3)	0·0004
Sex					
Female	32	9/5821 (0·2%)	23/1887 (1·2%)	87·5% (73·4–94·2)	<0·0001
Male	46	7/9143 (0·1%)	39/3015 (1·3%)	94·2% (87·2–97·4)	<0·0001
Moderate or severe cases	20	0/14 964	20/4902 (0·4%)	100% (94·4–100·0)	<0·0001
First COVID-19 occurrence after dose 1†					
Any time after dose 1	175	79/16 427 (0·5%)	96/5435 (1·8%)	73·1% (63·7–80·1)	<0·0001
From 14 days after dose 1	109	30/14 999 (0·2%)	79/4950 (1·6%)	87·6% (81·1–91·8)	<0·0001
First COVID-19 occurrence after dose 2 (28 days after dose 1)*					
All	60	13/14 094 (0·1%)	47/4601 (1·0%)	91·1% (83·8–95·1)	<0·0001

Data are n/N (%), unless otherwise stated. *Includes those who received both doses. †Includes participants who received at least one dose.

Table 2: Interim results on vaccine efficacy

Safety and efficacy of an rAd26 and rAd5 vector-based heterologous prime-boost COVID-19 vaccine: an interim analysis of a randomised controlled phase 3 trial in Russia

Denis Y Logunov, Inna V Dolzhikova*, Dmitry V Shcheblyakov, Amir I Tukhvatulin, Olga V Zubkova, Alina S Dzharullaeva, Anna V Kovyrshina, Nadezhda L Lubenets, Daria M Grousova, Alina S Erokhova, Andrei G Botikov, Fatima M Izhaeva, Olga Popova, Tatiana A Ozharovskaya, Ilias B Esmagambetov, Irina A Favorskaya, Denis I Zrelkin, Daria V Voronina, Dmitry N Shcherbinin, Alexander S Semikhin, Yana V Simakova, Elizaveta A Tokarskaya, Daria A Egorova, Maksim M Shmarov, Natalia A Nikitenko, Vladimir A Gushchin, Elena A Smolyarchuk, Sergey K Zyryanov, Sergei V Borisevich, Boris S Naroditsky, Alexander L Gintsburg, and the Gam-COVID-Vac Vaccine Trial Group†*

COPE position on Data and Reproducibility

Daniel Kulp, COPE Chair and
Founder, PIE Consulting

publicationethics.org

PROMOTING INTEGRITY IN SCHOLARLY RESEARCH AND ITS PUBLICATION

DANIEL KULP

Publishing History

- With American Chemical Society from January 2020 – June 2023
- Prior 24 years with the American Physical Society

Chair, COPE (Committee on Publication Ethics)

- Term: May 2021 – April 2025

Founder, Publication Integrity & Ethics Consulting

- January 2024

PIE CONSULTING
PUBLICATION INTEGRITY & ETHICS

Daniel Kulp
COPE Chair

PROMOTING INTEGRITY IN SCHOLARLY RESEARCH AND ITS PUBLICATION

Conflicts of Interest

I have no conflicts of interest.

Daniel Kulp
COPE Chair

ABOUT COPE

13500+
COPE MEMBERS

Members from
97 COUNTRIES

GLOBAL COMMUNITY
on publication ethics

- Non-profit established in 1997; operated, managed, and governed by small group of paid employees, with volunteers on **Trustee Board and Council**
- **>13,500 members** from 97 countries:
  - primarily editors of scholarly journals; also:
  - universities and research institutes
  - associated individuals and companies (including editorial and publishing support services)
- COPE brings together all those involved in scholarly research and its publication to strengthen the network of support, education, and debate in publication ethics:
  Creating a culture of publication integrity together

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PROMOTING INTEGRITY IN SCHOLARLY RESEARCH AND ITS PUBLICATION

COPE Core Practices

Policies and core practices required to reach the highest standards in publication ethics:

Allegations of misconduct

Authorship and contributorship

Complaints and appeals

Conflicts of interest/ Competing interests

Data and reproducibility

Ethical oversight

Intellectual property

Journal management

Peer review processes

Post-publication discussions and corrections

PROMOTING INTEGRITY IN SCHOLARLY RESEARCH AND ITS PUBLICATION

COPE Core Practices

Policies and core practices required to reach the highest standards in publication ethics:

Data and Reproducibility

Journals should include **policies on data availability** and encourage the use of reporting guidelines and registration of clinical trials and other study designs according to standard practice in their discipline.

To achieve **greater transparency, replicability, and trust in scientific findings**, research authors are increasingly expected to enhance reporting by registering clinical trials, using standardised guidelines, and **sharing associated data, code, and materials**.

Pros

- Accessibility to data
- Increased transparency
- Interpretation of data

Cons

- Incorrect use of data
- Privacy and consent
    - Mosaic effect
- Costs and sustainability of open data projects

https://merlcenter.org/guides/pros-and-cons-of-open-data/

Biomedical Research Data

- Healthy and well-being of patients
- Trust in science
- Availability of data should be the rule with few exceptions

Biomedical Research Data

- Pre-registration
- Registered reports
- Ethical approvals

AI as Author

- https://world.hey.com/ian.mulvany/data-to-paper-and-some-reflections-on-llms-5ffe9350

"In February I had the great pleasure to participate in a small workshop at EMBO in Heidelberg to discuss the role LLMs may play in the future of single cell biological science. It was Chatham house rules, and in the two days we covered an extensive set of themes. We should be having a paper coming out soon with a structured write up.

One of the things that blew me away is one of the people at the workshop demoed data-to-paper - a system they built to get two instances of LLMs to work together in an agent based framework to write an academic paper, from coming up with the hypothesis, writing the analysis code, doing to analysis, writing the paper. I see that the code is now available and you can check out the code here - https://github.com/Technion-Kishony-lab/data-to-paper. It really works, though the papers are not top flight science, the fact that you can even do this is frankly astonishing."

Daniele Fanelli

Policies should have a light touch and be adaptable.

THANK YOU

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Symposium 8

QUESTIONS

Symposium 8

Toward responsible clinical trial data sharing practices

Sometimes, data are FAIR…

NIH SCIENTIFIC DATA SHARING

Are you Ready for NIH's Data Management and Sharing (DMS) Policy?

NIH has issued the DMS Policy **(effective for due dates on/after January 25, 2023)** to promote the sharing of scientific data. See sharing.nih.gov for details and instructions.

Planning & Budgeting for Data Management and Sharing

Prospectively planning for how scientific data will be managed and ultimately shared is a crucial first step in optimizing the reach of data generated from NIH-funded research.

- **Determine** if proposed research is subject to the DMS policy.
- **Identify** appropriate methods/approaches and repositories for managing and sharing scientific data.
- **Develop a Plan** for managing and sharing scientific data and include in application or proposal. If subject to Genomic Data Sharing Policy, submit a single Plan that addresses genomic data considerations.
- **Estimate and request funds** for data management and sharing activities (if not already covered by institution or other sources.)

Submission & Review of DMS Plans

Applicants planning to generate scientific data will submit DMS Plans to NIH as part of the funding application or proposal.

- **Submit** DMS Plans and budget requests as part of the funding application or proposal.

Note: Plans are reviewed by NIH program staff for completeness and acceptability. If Plan is not acceptable and complete, work with NIH staff to modify as appropriate.

Implementing DMS Plans

Awardees are expected to carry out data management and sharing as outlined in approved plans and as a term and condition of award.

- **Manage and share** data as described in the approved DMS Plan.
- **Provide updates** on data management and sharing activities in annual progress reports.
- **Work with NIH staff** to obtain review and approval of modifications if plans change.

Symposium 8

Toward responsible clinical trial data sharing practices

… and data sharing must be « fair »

Among NIH funded trials started between 1-January-2018 and 31-December-2023, 918 (**8.6%**) did not involve US sites.

Dal Ré et al. In preparation

Data Sharing for Clinical Trials and Health Research in Africa

Nchangwi Syntia Munung

University of Cape Town, South Africa

PUBGEM-Africa
Public Understanding of Big data in Genomics Medicine in Africa

GeneMAP
Genetic Medicine of African Populations

SADaCC
Sickle Africa Data Coordinating Centre

Conflict of Interest

None to declare in relation to this presentation

Outline of Presentation

- Clinical trial support systems in Africa
- Incentives and disincentives for data sharing in Africa (qualitative study)
- Interface of data sharing and research Integrity
- Personal reflections on the way forward

The State of Clinical Trials in Africa

- Compared to other regions Africa significantly fewer clinical trials
- Clinical trials started and completed December -March 2023
- less than 3% of global clinical trials take place on the African continent (about 5K)
- Majority of trials;
  - Egypt
  - South Africa
  - Nigeria
  - Kenya
  - Uganda

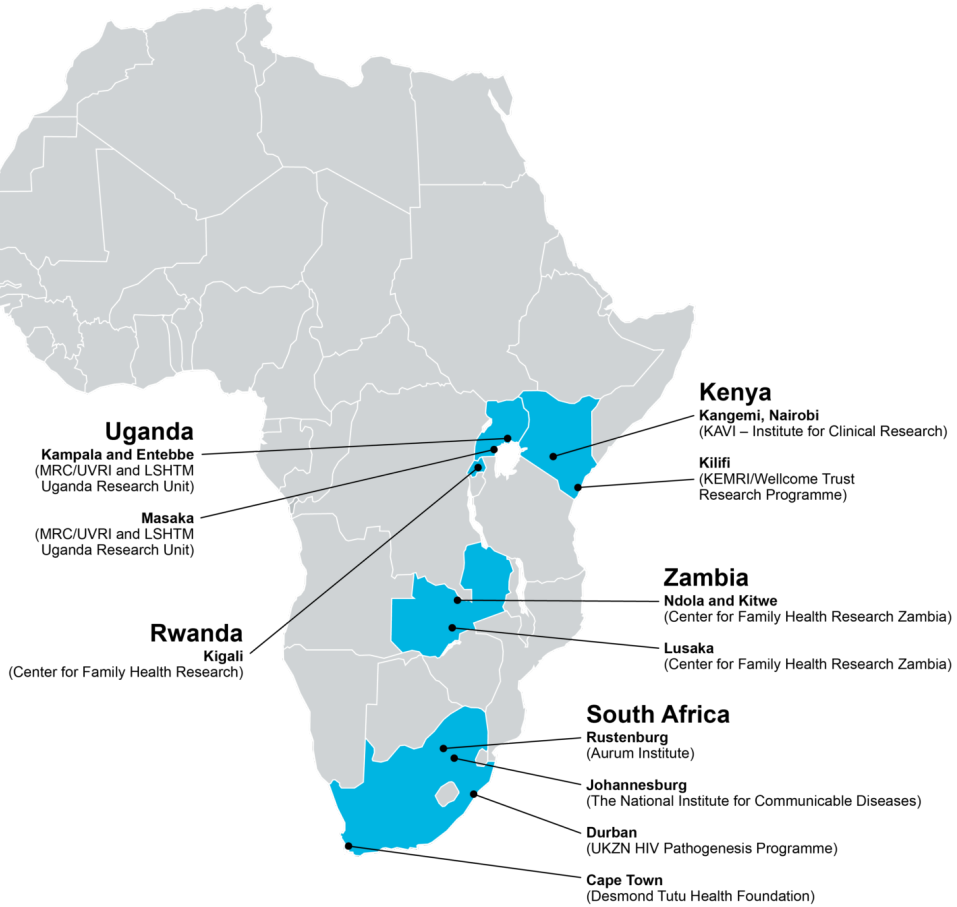
https://www.pharmaceutical-technology.com/sponsored/africa-unleashing-the-potential-of-the-new-superpower-in-clinical-trials/

Supporting Clinical Trial Implementation in Africa

PACTR
Pan African Clinical Trials Registry

Clinical Trials Community Africa Network

Africa CRC locations



https://www.iavi.org/africa/africa-clinical-research-centers/

PUBGEM-Africa
Public Understanding of Big data in Genomics Medicine in Africa

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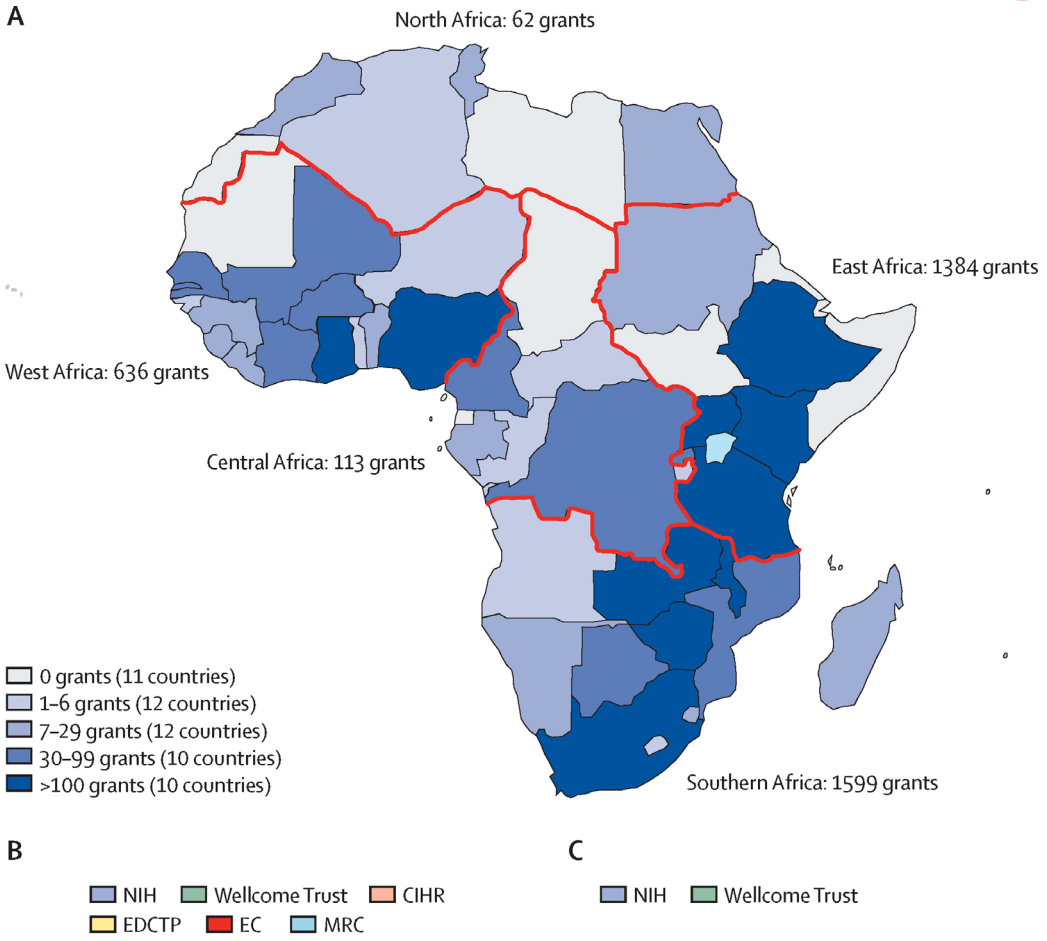
Big Funders of Health Research in Africa and Position on Data Sharing



EDCTP2 policy on clinical trials registration, publication and data sharing

Type: Guidance for applicants and grantees
Date: 06 Jul 2018

Download (EN)

EDCTP became a signatory to the Joint statement on public disclosure of results from clinical trials on 5 July 2017. This policy document sets out the expectations of EDCTP and the requirements that EDCTP grant holders conducting clinical trials and clinical studies must comply with. Amended on 28-10-2021.

New!

NIH Data Management & Sharing Policy

Effective January 25, 2023 -
All research applications generating scientific data will be subject to providing a data management & sharing plan.

Adam et al. 2020 **World RePORT: a database for mapping biomedical research funding** The Lancet Global Health 8: 1, e27 - e29

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Attitudes and Perceptions Towards-Data Sharing

- Personal reflections as part of consortia with a data sharing mandate
- Qualitative study (African Researchers involved in health data sharing)

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Sickle Africa Data
Coordinating Centre

H3Africa
Human Heredity & Health in Africa

PUBGEM-Africa
Public Understanding of Big data
in Genomics Medicine in Africa

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in Genomics Medicine in Africa

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Data Sharing and Reuse: How Is Africa Doing?

- Willingness to share data
- Institutional data repositories on the rise
- Research Consortia developing data policies
- Noticeable investment in data management and infrastructure

It is not enough that we require data to be shared

Attitudes and Perceptions Towards-Data Sharing

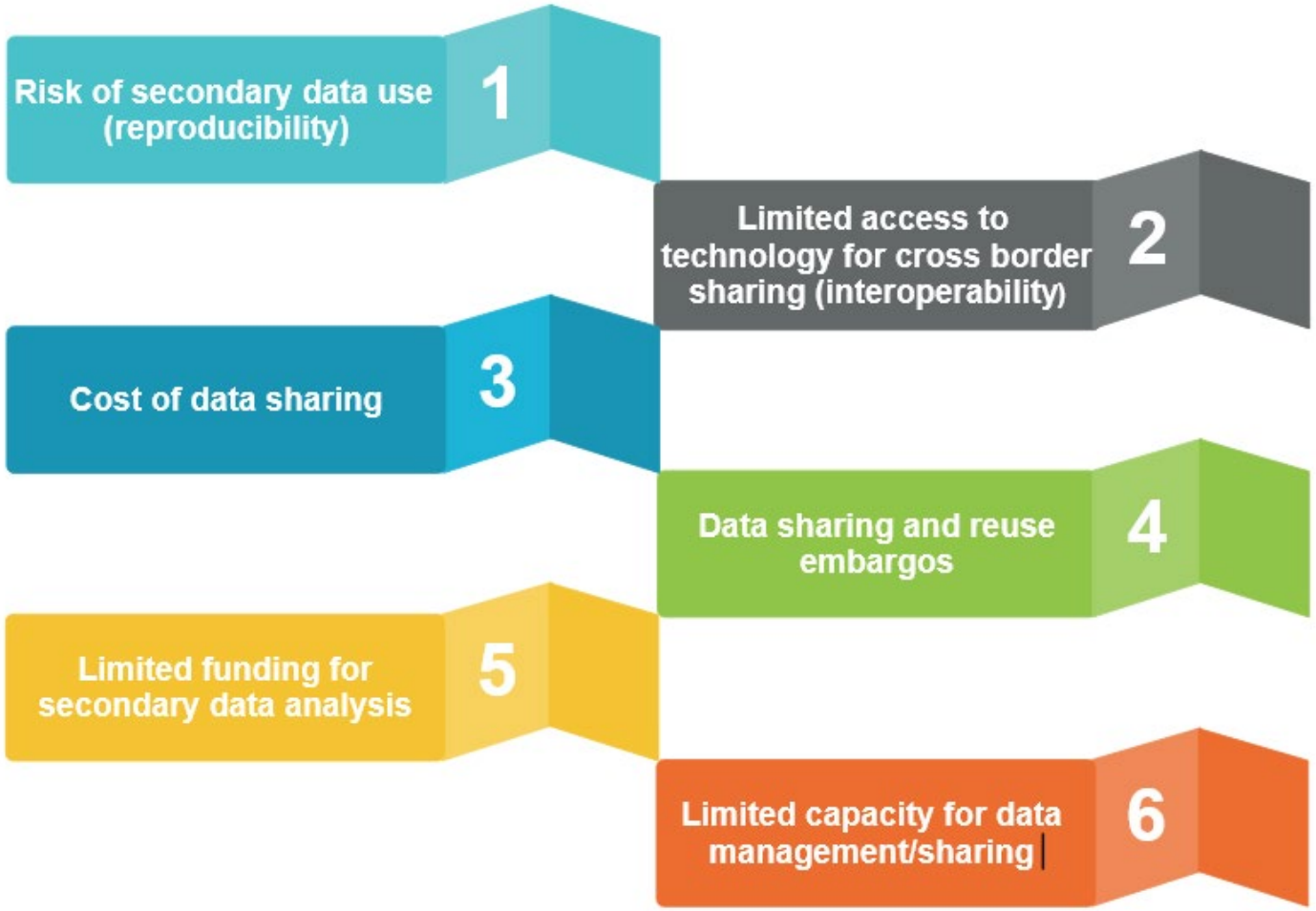
- Complete and quality data is not often shared even if a requirement of funders
- *ISRCTN* registry (primary clinical trial registry recognized by WHO and ICMJE)
  - Raw data for studies in Africa not readily available (results available)
- Tend to provide information on data availability-**requested by journal**
- **Promise**: Request for data by contacting authors-No response
- **Data privacy and protection laws-** more confusion or reason not to share?

Data Culture: HOW WOULD YOU LIKE TO SHARE DATA?

- Federated approach (most preferred approach)
- Centralised System (if really required)
- Open Data Sharing (common with those wo do secondary analysis)

Are we developing a culture of data hoarding or other factors at play?

Barriers and Disincentives to Data Sharing and Reuse

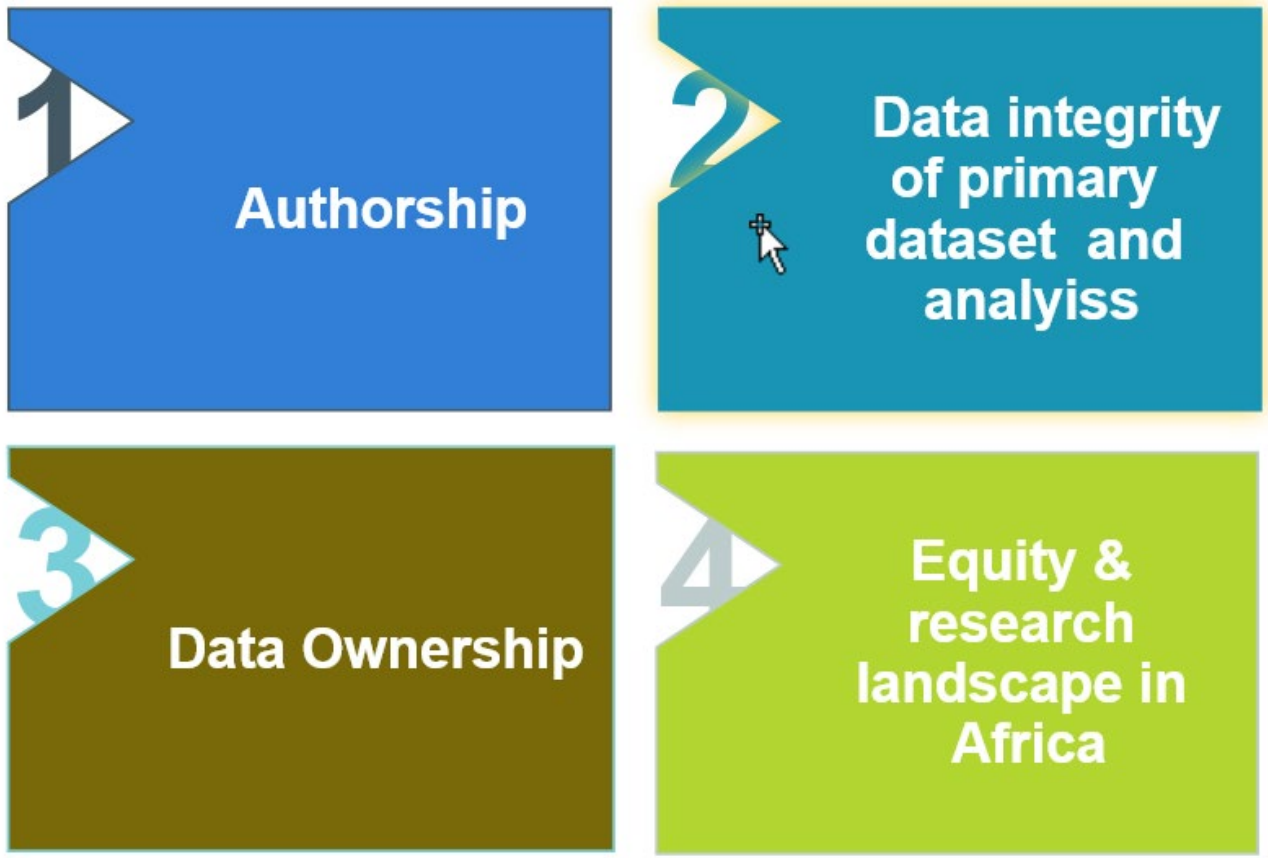


Both Incentives and Disincentives

- Data Sharing embargoes
- Data Sovereignty (DPAs)

Incentives for Data Sharing

Research Integrity Considerations for Data Sharing in Africa



Research Integrity Considerations

- In appropriate authorship
- Concerns around data integrity and reproducibility
- Whose data is it anyway?
- Reward system in academia

Reflections of Improving Data Sharing and Reuse

- Develop and promote a culture of responsible data sharing and reuse
- Set up and sustain data access committees post trial/study
- Invest in data management and sharing infrastructure (including policies)
- Develop mechanisms for appropriate and transparent use of data
- Training (FAIRification of data and ethical reuse of data sets)
- Address issues at the interface of ethics and science integrity (funders, librarians research consortia, ethicists, research integrity professions etc)
- Codes of conduct for responsible data sharing and reuse in Africa (Ethics and integrity offices?????)

Reflections of Improving Data Sharing and Reuse

- Training (FAIRification of data and ethical reuse of data sets)
- Address issues at the interface of ethics and science integrity (funders, librarians, researchers, ethicists, research integrity professionals etc)
- Codes of conduct for responsible data sharing and reuse in Africa (ethics and integrity offices)

Thank you/ Merci/ Asante Sana

Global Forum on Bioethics in Research

DS-I Africa
Data Science for Health Discovery and Innovation in Africa

NIH
National Institutes of Health

PUBGEM-Africa
Public Understanding of Big data in Genomics Medicine in Africa

SADaCC
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institut universitaire de France

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Symposium 8

QUESTIONS

Symposium 8

Toward responsible clinical trial data sharing practices

Sometimes, data sharing is not so easy

"[…] However, I am just wanting to confirm School policy and our ethical obligations regarding the sharing of data before we proceed"

"Please can you let me know how you have been receiving data from other centers securely?"

"As the study was launched we did not plan the cost for this preparation"

" Please find attached the data-spreadsheet from our trial "XXX" . The variables are all labelled in a way that should be self-explanatory, if you require further explanation, I am very happy to answer you questions and support your work."

Symposium 8

Toward responsible clinical trial data sharing practices

Sometimes, it is easy

"thank you for your request. […]

In the "XXX" trial, there is one single primary efficacy outcome (number of vertigo attacks). Therefore, you will need the corresponding dataset only for these data, right?
=> I could provide an R workspace (or an export .csv-file, or the original SAS dataset). If an R file is OK with you, I would prepare a separate document explaining labels for each variable.
The efficacy analyses were performed in R. Hence, I could provide relevant R code to reproduce the results of the principal model (maybe I should include some comments in English...).
Additionally, we used WinBUGs to get estimates of primary interest reported in Table 4.
We could send all these files in the next couple of weeks..."

LMU LUDWIG-MAXIMILIANS-UNIVERSITÄT MÜNCHEN
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CHAIR OF BIOMETRY AND BIOINFORMATICS
PETTENKOFER SCHOOL OF PUBLIC HEALTH
PSPH

How and why to teach young medical scientists about clinical trials data sharing?

The SHARE-CTD project

Ulrich Mansmann
ulrich.mansmann@lmu.de

Conflicts of interest

I receive funds from the EU (MSCA-DN), the German Research Agency (DFG), the Federal Institute for Nutrition and Agriculture (Max-Rubner Institute, MRI), and the German Ministry of Education and Science (BMBF).

Funded by the European Union
HORIZON-MSCA-2022-DN-01
Project: 101120360

- **Nine medical schools** from six European countries
- **Twelve partners** covering a wide range of data sharing activities.

SHARE AND RE-USE CLINICAL TRIAL DATA TO MAXIMISE IMPACT – SHARE-CTD

SHARE-CTD is a doctoral network involving nine principal investigators and twelve academic and non-academic partners.

SHARE-CTD's research projects look at best practices as well as measuring impact of preparing data for sharing and using shared data.

SHARE-CTD aims to train a new generation of biomedical researchers with a deep understanding of processes, values, and merits of clinical trial data sharing. To gain a comprehensive understanding, biomedical researchers need to be trained in fields like data science, trial regulation, meta-research, as well as ethical, legal and social issues.

WWW.SHARE-CTD.EU

Contact and information
ulrich.mansmann@lmu.de

MARIE CURIE ACTIONS

SHARE-CTD
Cooperate to share and gain

Role of CTDS for validation of prognostic and predictive models for MS patients
Dr. Ulrich Mansmann, LMU München, Germany

Impact of clinical trial data sharing
Dr. Florian Naudet, University Rennes, France

Innovative approaches to trial data anonymisation and its role for CTDS
Dr. Fabian Prasser, Charité, BIH, Germany

Automated screening tools for identifying data sharing, data-re-use and common reporting problems in clinical trials
Dr. Tracey Weisberger, Charité, BIH, Germany

Methodology for FAIRification, Data Enrichment and Data Sharing
Dr. Ulrich Sax, University Medical Center Göttingen, Germany

Added value of meta-analyses of shared individual patient data (IPD) in mental health
Dr. Ioana Alina Cristea, University of Padova, Italy

Towards understanding and accepting data sharing within patients
Dr. Evelyne Decullier, Hospices Civils de Lyon, France

Methodology for cross-design synthesis
Dr. Valentijn de Jong, University Medical Center Utrecht, The Netherlands

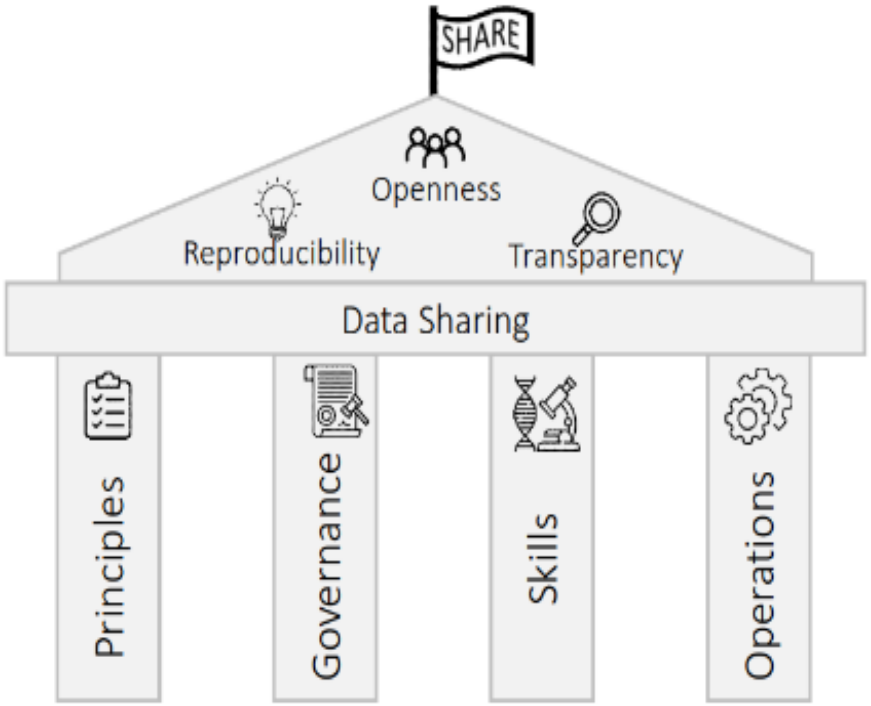
Using shared historic data to augment prospective clinical trials
Dr. Martin Posch, Medical University of Vienna, Austria

Evaluating outcome reporting bias in clinical trials
Dr. Leonhard Held, University of Zurich, Switzerland

Impact of clinical trial data sharing for pivotal trials in oncology
Dr. Clara Locher, University of Rennes, France

- **Eleven** individual scientific projects and
- **Six** joint projects (group papers)

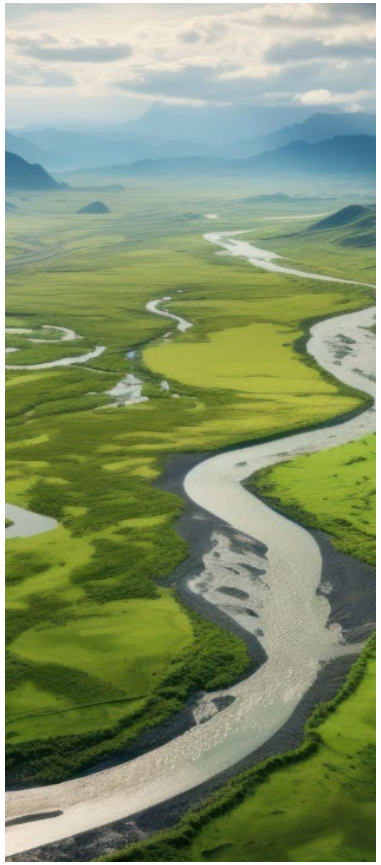
Four pillars of data sharing and three specific foci



- Impact
- Practices
- Competences

https://pubmed.ncbi.nlm.nih.gov/36732626/

The State of Open Data November 2023 (Springer Nature Report)



- Support is not making the way to those who need it;
- One size does not fit all;
- Challenging stereotypes;
- Credit is an ongoing issue;
- AI awareness hasn’t translated to action.

Support is not reaching those who need it: Role models and roadmaps in different areas

- **Roadmaps for industry**: Infrastructure, big data agenda
- **Academic prospects**: Data Champions, Centers for Data Competencies, Biostatistic Units, Clinical Study Centers
- **Funders**: Promoting, reviewing, crediting
- **Journals**: Promoting, crediting, business models
- **Agencies**: Initiating and using clinical trial data sharing (CTDS)

take the stage as architect of a brighter scientific future

Six European academic medical research systems
Example Germany – stakeholder for academic CTDS

- NFDI
- DZ..(..HK, ..L, ..I, ..NE, ..KJ, ..PG)
- MII
- Specific medical societies
- AWMF: Working Group of the Scientific Medical Societies (Umbrella organization)

What SHARE-CTD can do: Collect ideas, set impulses, participate on opinion building, get in touch with stakeholders in different systems, provide synopses.

One size does not fit all: Why clinical trial data sharing (CTDS) ?

- **Data of high quality**;
- Well defined by a **PICO**;
- **Data with a rich set of metadata**: Protocol, DMP, DVP, SAP, Data dictionary, annotated CRFs, ….
- **Sharing platforms** are established and developing;
- Using the **multiversity of clinical trial data** for further research.

Our approach: Research, theory, practice, and communication

Understand challenges, leverages, and barriers to CTDS

Four pillars of data sharing: Principles, Governance, Skills, Operations

Best practices: Sharing and using CTD

Meta-reserach to demonstrate relevance of CTDS

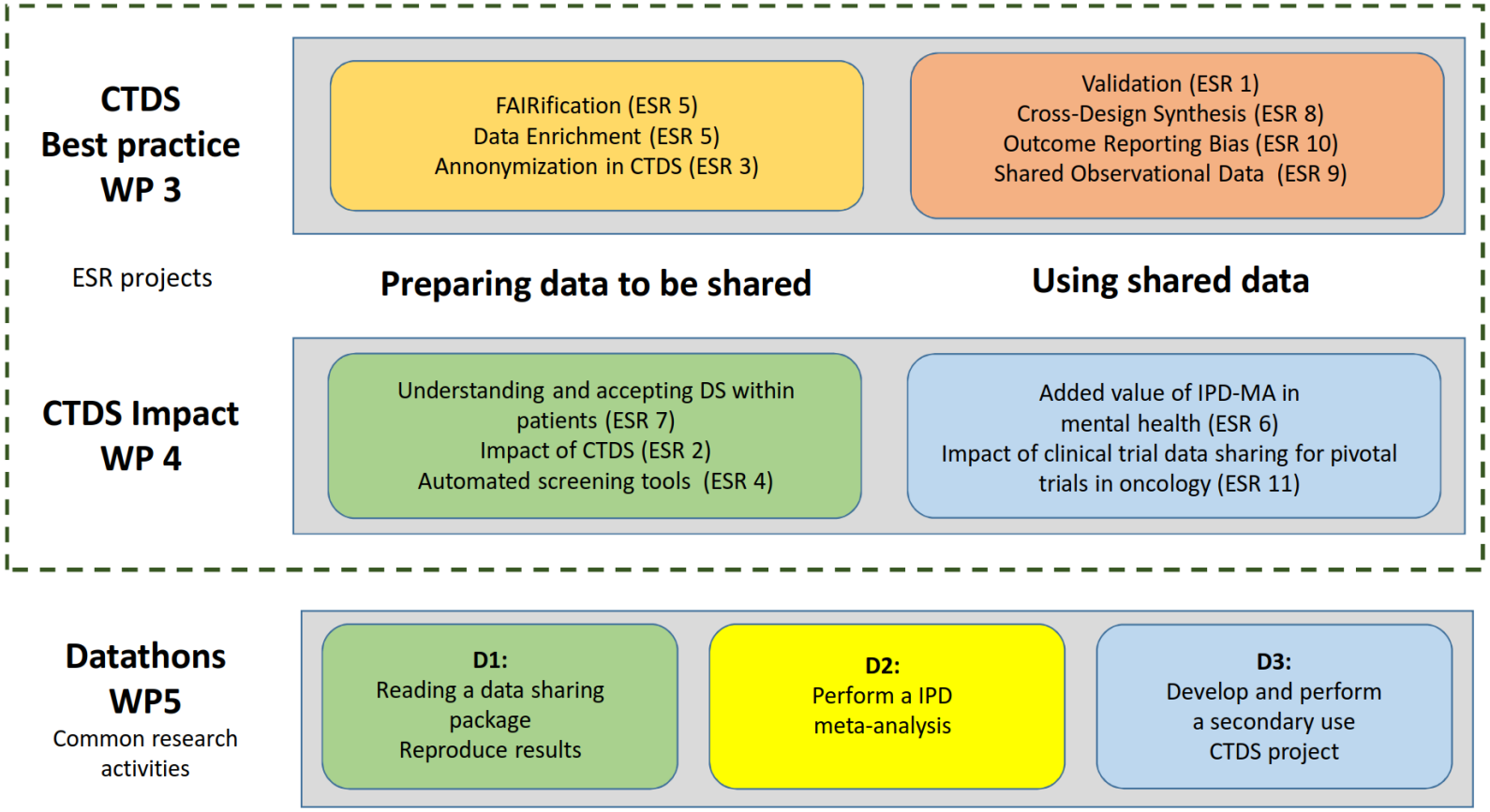
Strengthen sklills for collaborative and reproducible research

Use advanced methodology on CTDS

We are not frontrunners and thus can pair up with many consortia and projects that focus comparable intentions

CTDS: Clinical trial data sharing

Our approach: Research, theory, practice, and communication



Joint projects

- **Datathons**: Participants utilise the data provided to develop and answer topic-driven questions or to develop innovative approaches to analyse the data
- **Policies**: High grade convincing evidence on the value of CTDS for all stakeholders involved in therapeutic research
- **Communication**: Project webpage (share-ctd.eu), blog and social media, audio podcast, webinar series

We do not want to see all our DCs ending up in well functioning industrial data sharing infrastructures

- **Horrifying prospects** in the German academic system: Underfinanced and reluctant development
- **Challenging stereotypes**: we hope to meet an academic environments in which all members develop increasing enthusiasm and engagement into open science issues.

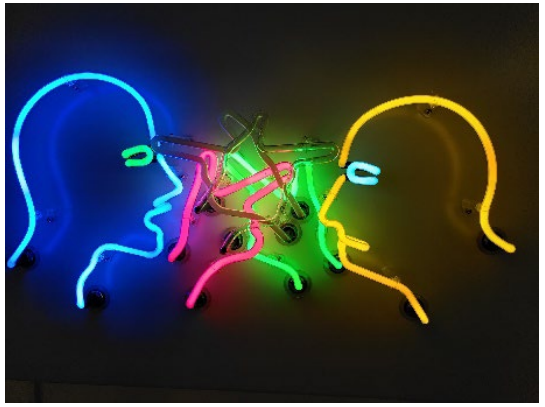
Using AI instruments

- Improve metadata
- Improve Data quality
- Improve proposals
- Help searching for papers and data

Leaving the closed circle of academia

- Enabling affordable citizen science

Research Integrity: Micro and macro level effects



- Improve your own working methods through intensive engagement with the fundamentals of research findings that are extremely relevant to your own work

- Establishing re- and sensitivity analyses as a counter-model to the current process of evidence production in medicine.

Many thanks for your attention

A landscape as seen from above

Additional slides

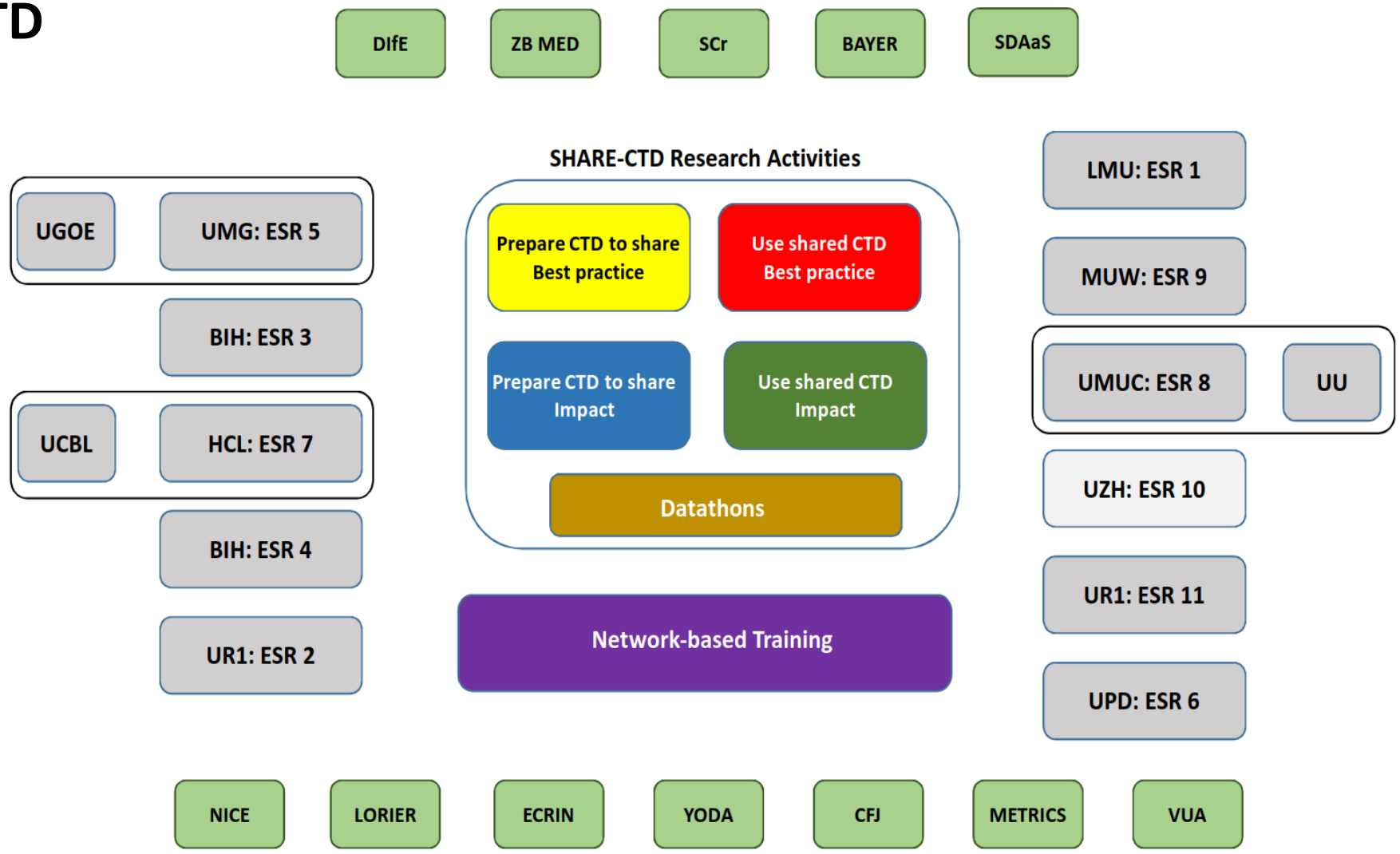
Responsible Data Sharing and Scientific integrity

- To understand what was done:
  Independent Sensitivity and re-analyses
- Exploring untapped information:
  Secondary analyses and IPD Meta-Analyses
- Leaving the closed circles of academia:
  Enabling affordable citizen science
- Scientific obligations:
  Maximize value and reduce waste

Best practices need specific infrastructures and a well trained research community

- Preparing data to be shared
- Establishing and using infrastructures to share data
- Reusing data to be shared: Designs and methodologies
- How to implement the new vision - Role models and road maps

The SHARE-CTD network



Why to train young medical scientists on data sharing?

- Lack of data related skills;
- Not knowing what opportunities communication with data experts offers them for their research;
- Searching for and finding good data promotes your own research as well as the search for relevant literature;
- Making your own research data and methods accessible increases the thoroughness, transparency, and credibility of someone's work.

The ubiquity of data and the related epistemic gap

- Data Science overtakes medicine: The self learning health care system

Symposium 8

Toward responsible clinical trial data sharing practices **QUESTIONS**

Speakers

Nchangwi Syntia Munung, Daniel Kulp, Maximilian Siebert, Ulrich Mansmann

Moderator

Florian Naudet

Symposium 8

Toward responsible clinical trial data sharing practices **THANKS**

Sometimes, one needs a break…

… and sometimes, one can take OSIRIS SURVEY ON COMPUATIONAL REPRODUCIBILTY.