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Research integrity in biomedical research

INTEGRITY AND REPRODUCIBILITY IN THERAPEUTIC RESEARCH

Florian Naudet
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Conflict of Interest Disclosure

Funded by European Union

institut universitaire de France

Fondation pour la Recherche Médicale

Région Bretagne

MINISTÈRE DES SOLIDARITÉS ET DE LA SANTÉ
Liberté
Égalité
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MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION
Liberté
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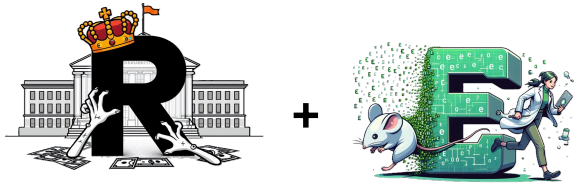
Conflict of Interest Disclosure



siris

Grant agreement
No. 101094725

SHARE · CTD
Cooperate to share and gain

Grant Agreement
HORIZON-MSCA.2022-DN 101120360

Global
Research
Initiative on
Open Science

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Credits:
Artificial limbs for a thalidomide child, 1961-1965.
Science Museum
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Journal of Chronic Diseases

THALIDOMIDE—A NEW NONBARBITURATE SLEEP-INDUCING DRUG

LOUIS LASAGNA, M.D.
BALTIMORE, MD.

From the Departments of Medicine (Division of Clinical Pharmacology), Pharmacology, and Experimental Therapeutics, Johns Hopkins University School of Medicine

(Received for publication Dec. 9, 1959)

TABLE I. MEAN SLEEP INDUCTION TIME (MINUTES)

PATIENT GROUP	PLACEBO (POOLED)	THALIDOMIDE	
		100 MG.	200 MG.
Those whose usual induction time was less than 30 minutes	26 (N = 17)	32 (N = 15)	11 (N = 10)
Those whose usual induction time was 30 minutes or more	81 (N = 24)	100 (N = 10)	30 (N = 15)
All patients	58 ± 10.3 (N = 41)	59 ± 16.8 (N = 25)	23* ± 4.9 (N = 25)

*Significantly different from placebo and 100 mg. of thalidomide at 0.05 level.

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Scientometrics

The "Free lunches" index for assessing academics: a not entirely serious proposal

Alexandre Scanff[1] · Nicolas Mauhe[2] · Marion Taburet[1] · Pierre-Etienne Savourat[3] · Thomas Clément[3] · Benjamin Bastian[3,4] · Ioana Cristea[5] · Alain Braillon[6] · Nicolas Carayol[2] · Florian Naudet[1,7]

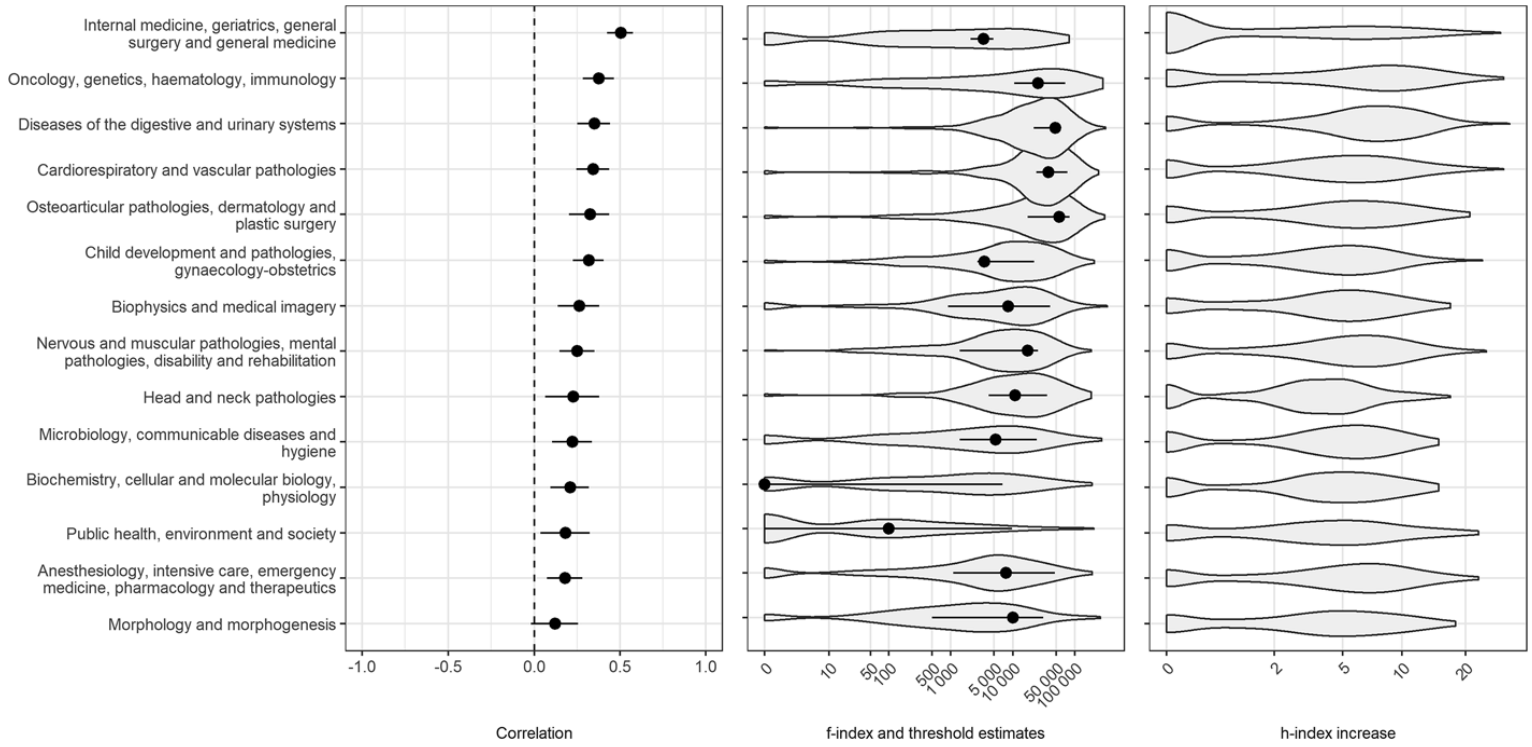

Fig. 2 Subgroup analyses per medical discipline: correlations, *fl-index* distribution (with the identified threshold and 95% IC) and *h*-index distribution

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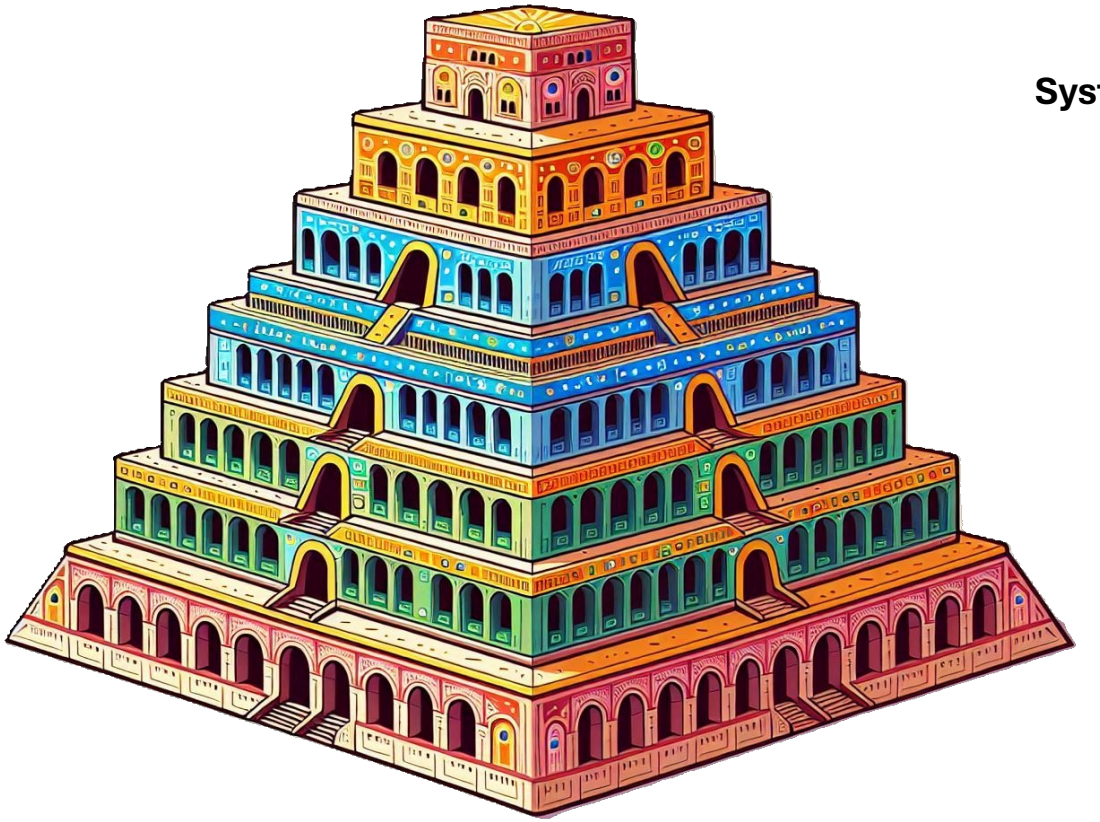


Systematic reviews and meta-analyses

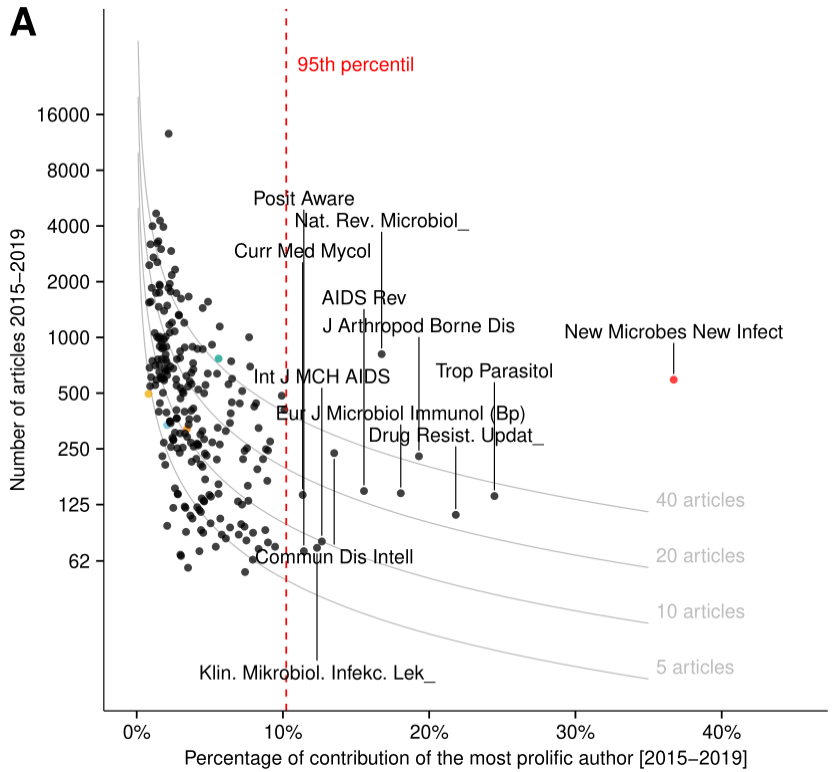
Randomised controlled trials

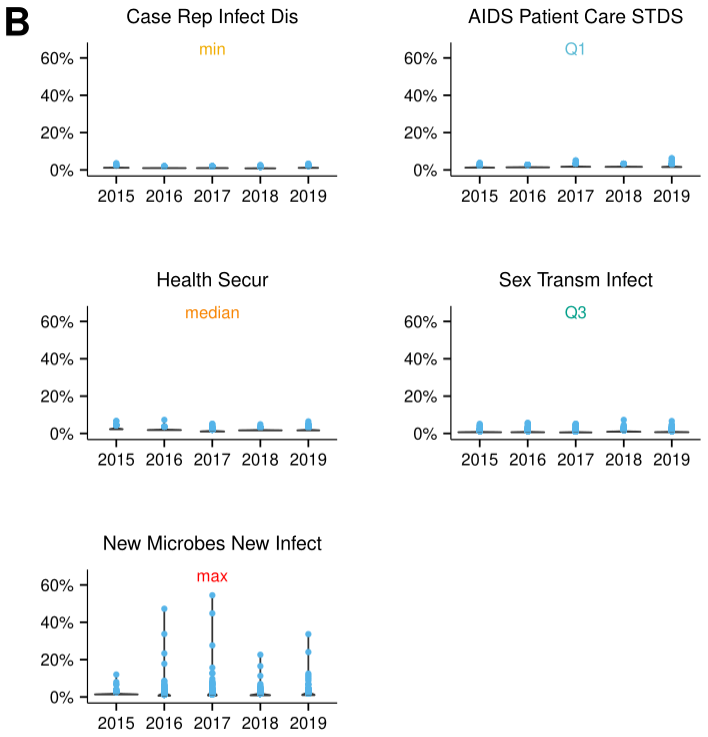
Observational studies

Case reports / Case series

Credits:
ChatGPT

BMJ EBM





EBM analysis

Publication by association: how the COVID-19 pandemic has shown relationships between authors and editorial board members in the field of infectious diseases

Clara Locher [1], David Moher [2], Ioana Alina Cristea [3], Florian Naudet [1]

PLOS BIOLOGY

META-RESEARCH ARTICLE

A survey of biomedical journals to detect editorial bias and nepotistic behavior

Alexandre Scanff[1], Florian Naudet[1], Ioana A. Cristea[2], David Moher[3,4], Dorothy V. M. Bishop[5], Clara Locher[1]*

1 Univ Rennes, CHU Rennes, Inserm, CIC 1414 (Centre d'Investigation Clinique de Rennes), Rennes, France, **2** Department of Brain and Behavioral Sciences, University of Pavia, Pavia, Italy, **3** Centre for Journalology, Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada, **4** School of Epidemiology and Public Health, University of Ottawa, Ottawa, Ontario, Canada, **5** Department of Experimental Psychology, University of Oxford, Oxford, United Kingdom

* clara.locher@univ-rennes1.fr

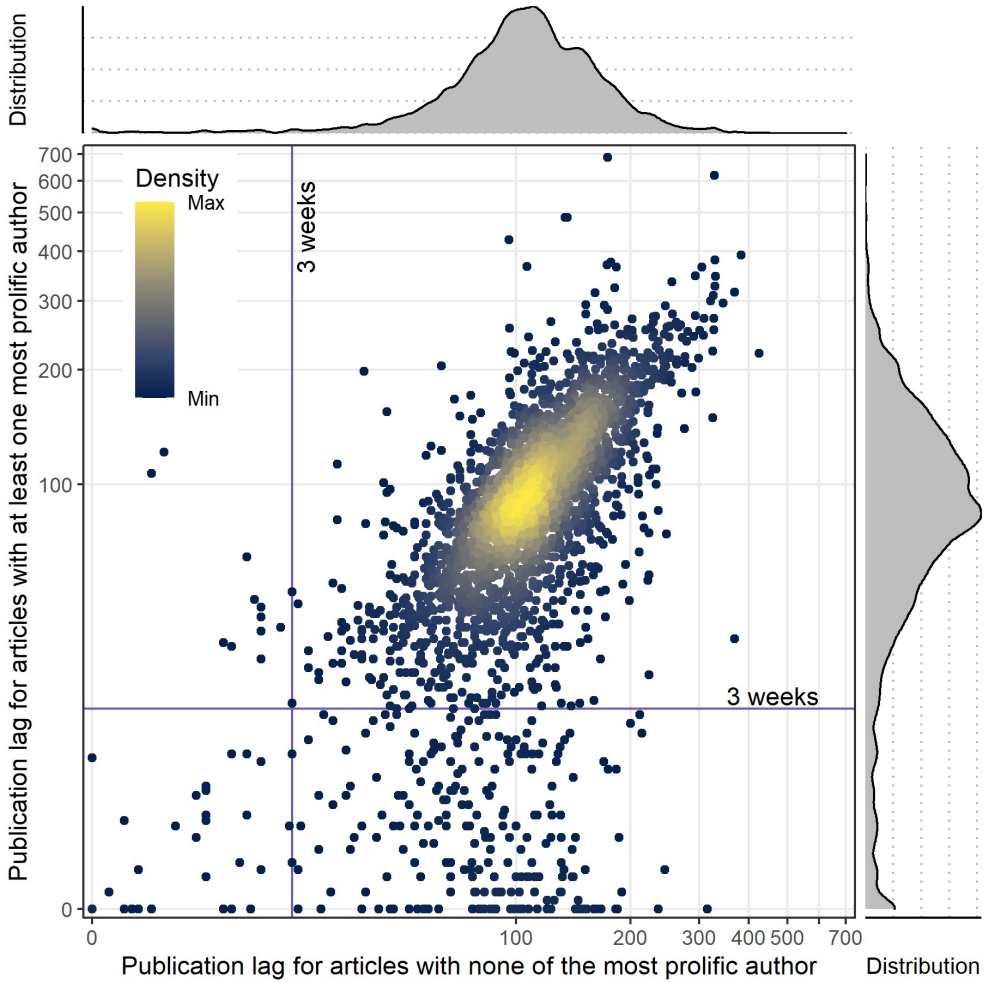


Fig 3. Publication lag. Distribution of the publication lag median for the subgroup of 2,725 (49.8%) journals reporting submission and publication dates. Publication lag median (in days) are presented for articles signed by the most prolific authors compared to the articles without any of the most prolific authors (with marginal density plot of distributions). The data underlying this figure may be found in https://osf.io/6e3uf/.

https://doi.org/10.1371/journal.pbio.3001133.g003

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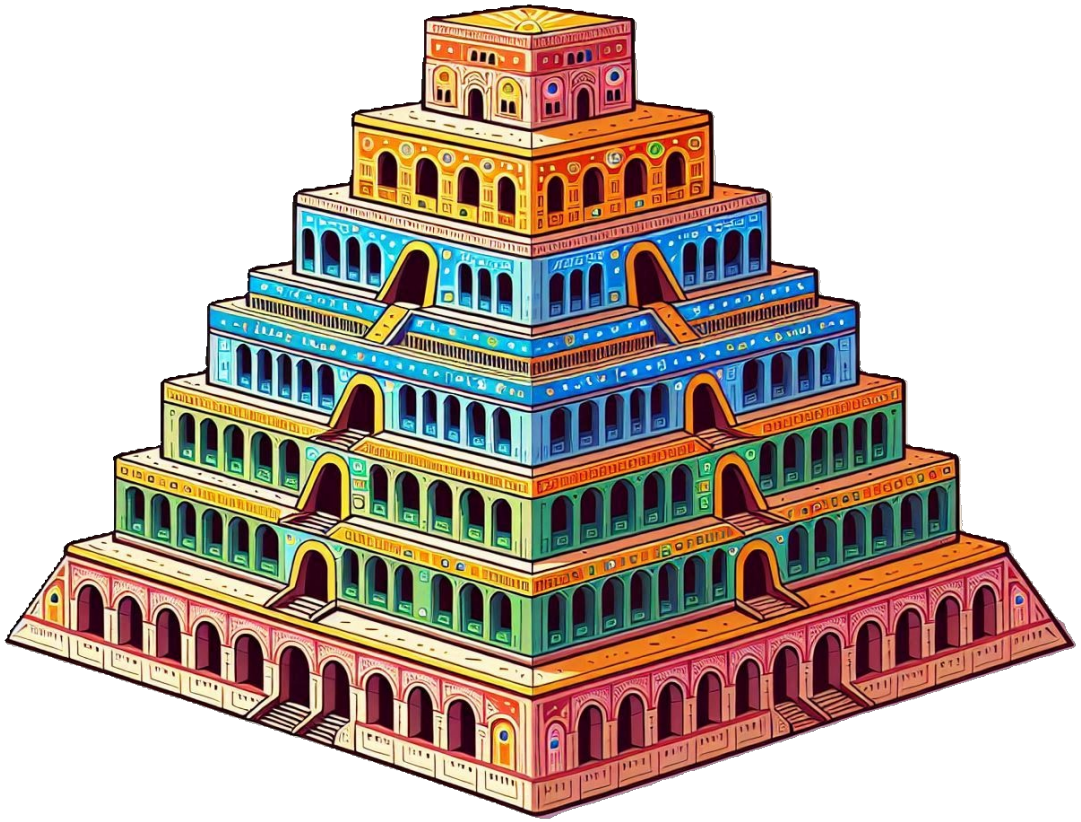

Thoughful, well-conducted studies of any design

The other shit

Credits:
Microsoft Designer

Credits:
Darren Dahly

An international consensus on core reproducibility items in research: the OSIRIS Delphi study

Rita Banzi, Monika Varga, Yuri Andrei Gelsleichter, Constant Vinatier, David Moher, Florian Naudet and the OSIRIS-Delphi study group

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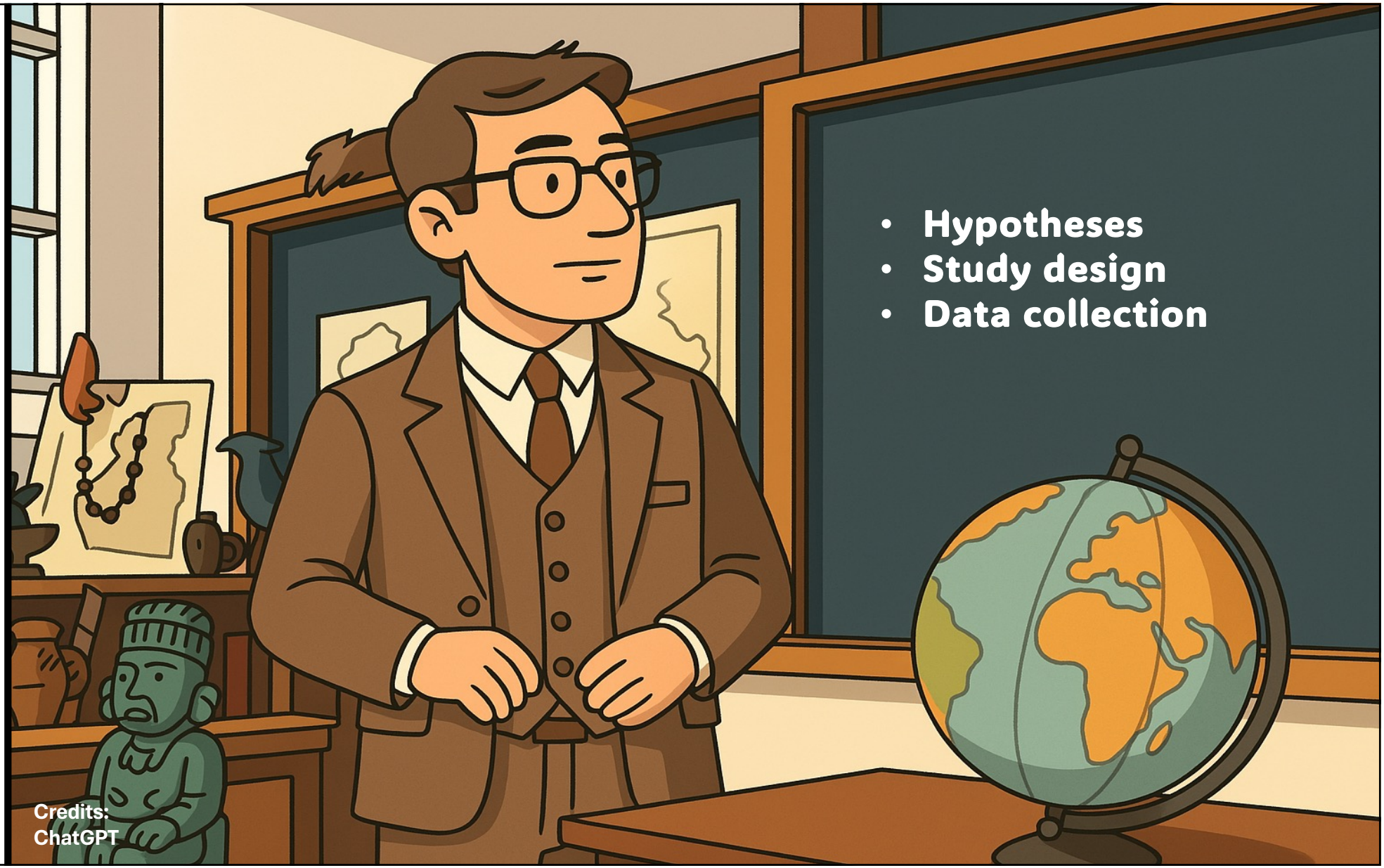

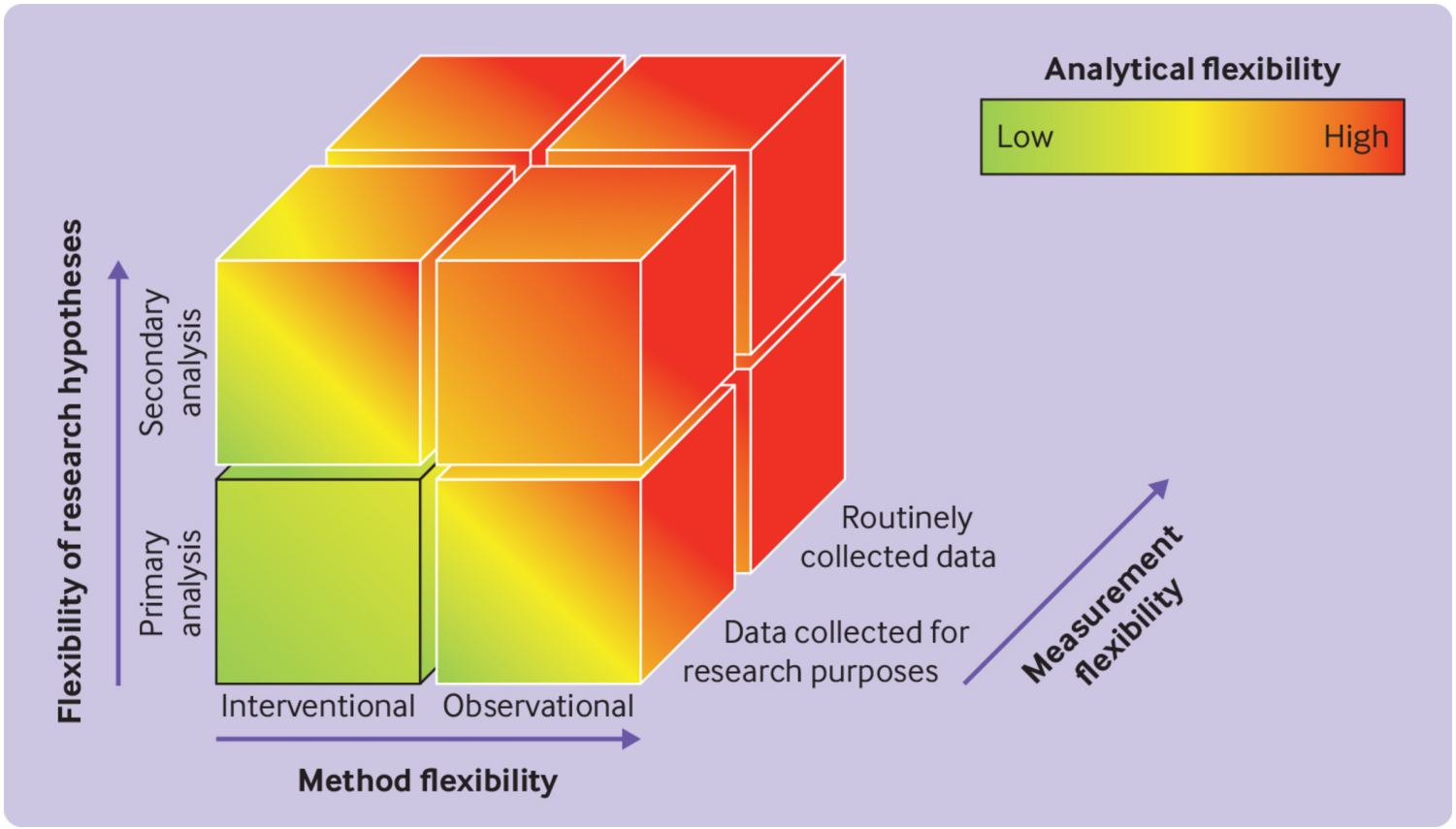

Fig 1 | Idealised version of analytical flexibility across the research landscape. Analytical flexibility is greater for observational research because the research question does not shape the design of the experiment (methods flexibility). Unlike clinical trials, which require prespecified measures, researchers analysing routinely collected data have to choose among many imperfectly measured variables that may have to be curated, combined, cleaned, and derived, with each step adding opportunities for analytical choices (measurement flexibility). Use of existing data also allows the analysis of relations between many variables, making it easy to test multiple hypotheses (flexibility in research hypotheses). The black line delimits the studies for which the International Committee of Medical Journal Editors requires registration

Improving the transparency and reliability of observational studies through registration

Florian Naudet,[1,2] Chirag J Patel,[3] Nicholas J DeVito,[4] Gérard Le Goff,[5] Ioana A Cristea,[6] Alain Braillon,[7] Sabine Hoffmann[8,9]

BMJ EBM

What is the vibration of effects?

Constant Vinatier ,[1] Sabine Hoffmann,[2,3] Chirag Patel,[4]
Nicholas J DeVito ,[5] Ioana Alina Cristea ,[6]
Braden Tierney,[7] John P A Ioannidis ,[8] Florian Naudet [1,9]

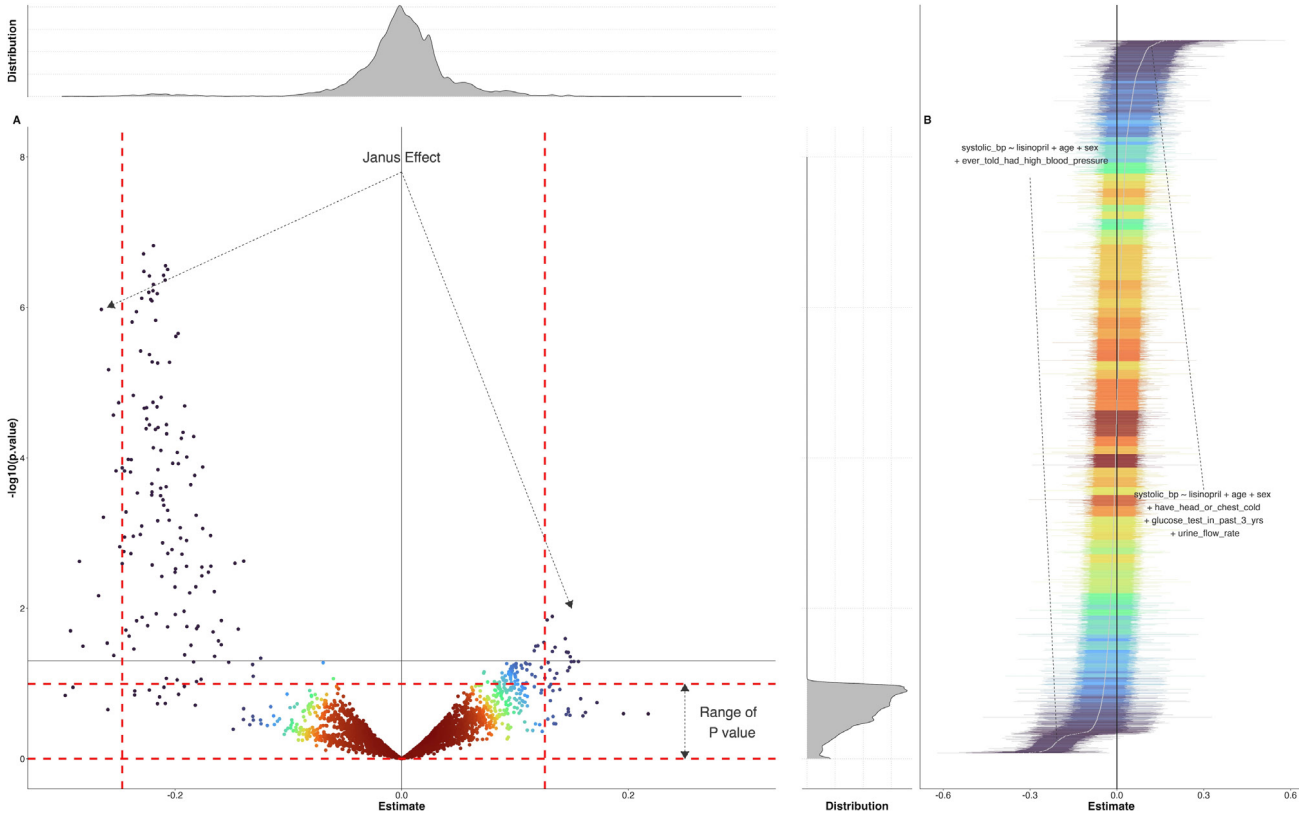

Figure 1 Vibration of effects of beta coefficient in the exploration of the association between lisinopril usage and systolic blood pressure. An estimate ‹0 suggests lower systolic blood pressure with lisinopril. This figure was produced using data from Tierney *et al*[10] by fitting 9595 random select models, among all possible models, exploring the association and using 253 covariates, with a maximum number of variables in the model set to 20. Data and code to reproduce the figure are available on the Open Science Framework at https://osf.io/xfy75/. (A) Dots represent the 6242 convergent regression models among the 9595 randomly selected models. Colours represent densities (red=high, blue=low), with marginal density plot of distributions. (B) Point estimates and 95% CIs for all models. Colours represent densities (red=high, blue=low).

BMJ EBM

Vibration of effects resulting from treatment selection in mixed-treatment comparisons: a multiverse analysis on network meta-analyses of antidepressants in major depressive disorder

Constant Vinatier [1], Clement Palpacuer [2], Alexandre Scanff [1], Florian Naudet [1,3]

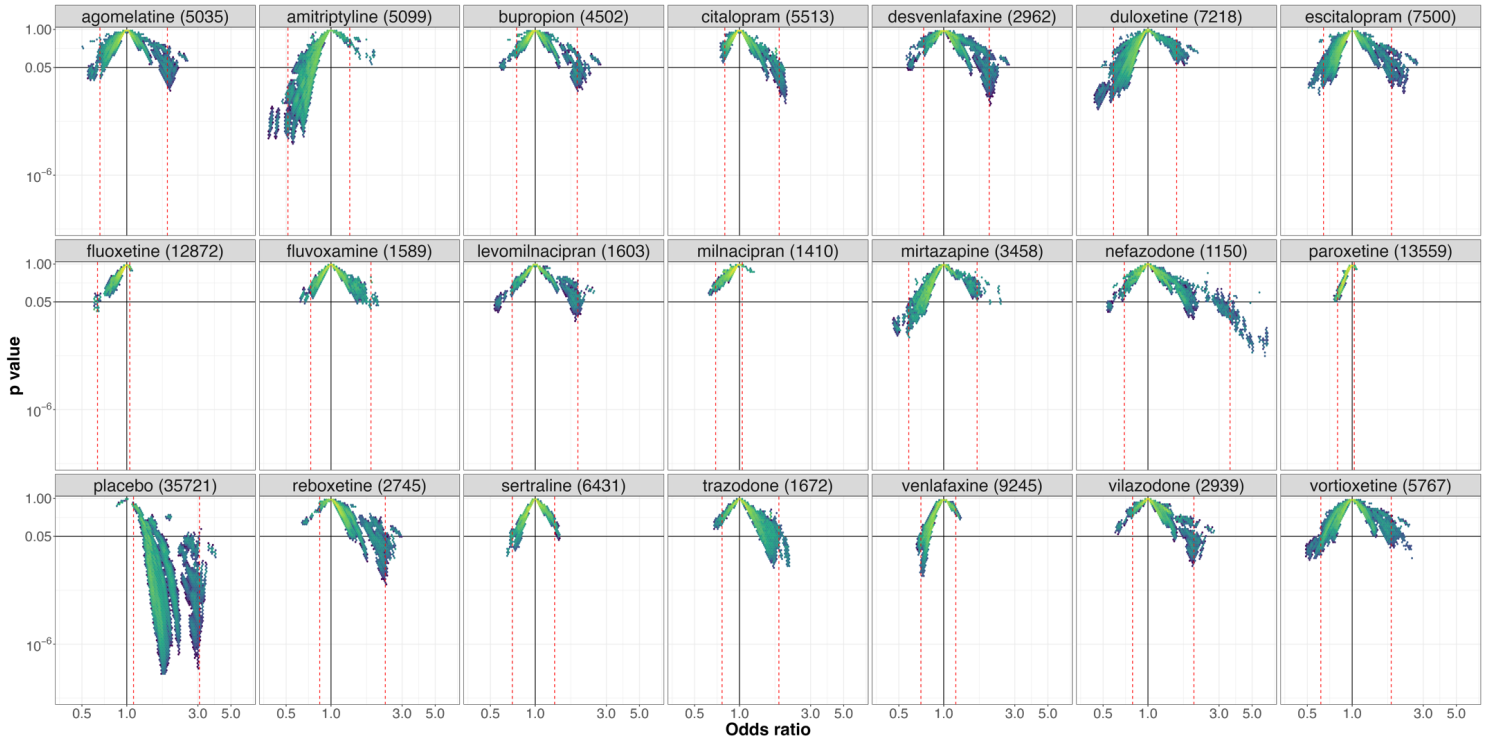

Figure 3: *Vibration of effects for treatment response for the comparisons of clomipramine with the 20 remaining antidepressants and placebo (with the number of patients included in the most complete network for this comparison). An Odd ratio >1 favors clomipramine. The colors indicate the log densities of network meta-analyses (yellow: high, green: moderate, blue: low). Dotted red lines show the 1st and 99th percentiles.*

BJD

SYSTEMATIC REVIEW

Overlapping network meta-analyses on psoriasis systemic treatments: an overview, quantity does not make quality

R. Guelimi ✉, S. Afach, J.-P. Régnaux, T. Bettuzzi, G. Chaby, E. Sbidian, F. Naudet, L. Le Cleach

NMA	Date of publication	ACI	CIC	FUM	MTX	ITO	EFA	ALE	BRIA	TYK2	APR	TOFA	BRO	CERT	ADA	ETA	UST	GUS	INF	IXE	RIS	SEC	TIL	BIM	GOL	MIRI
MROWIETZ 2021	2021												X	X	X	X	X	X	X	X	X	X	X			
TORRES 2020	2021				X				X				X	X	X	X	X	X	X	X	X	X	X		X	
BLAUVELT 2021	2020													X	X		X	X	X	X	X	X				
SONG 2020	2020											X				X										
DIAZ ACEDO 2020	2020												X				X			X		X				
XUE 2020	2020												X		X	X	X	X	X	X		X				
MAHIL 2020	2020				X								X	X	X	X	X	X	X	X	X	X	X			
XU 2020	2020								X				X	X	X	X	X	X	X	X	X	X	X	X		X
TADA 2020	2020												X		X		X	X	X	X	X	X				
DU JARDIN 2020	2020																	X					X			
JIANZHEN	2020																X	X			X		X			
ARMSTRONG 2020	2020	X	X	X	X						X		X	X	X	X	X	X	X	X	X	X	X			
SBIDIAN 2020	2020	X	X	X	X					X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
WARREN 2020a	2019												X	X	X	X	X	X	X	X	X	X	X			
WARREN 2020b	2019												X		X	X	X	X	X	X		X	X			
BAI 2019	2019												X				X	X		X	X	X	X			
XU 2019b	2019														X		X	X			X		X			
SAWYER 2019a	2019	X		X	X						X		X	X	X	X	X	X	X	X	X	X	X			
SAWYER 2018	2019	X			X						X		X		X	X	X		X	X		X				
XU 2019a	2018					X	X	X	X				X		X	X	X	X	X	X		X	X			
ARMSTRONG 2018	2018										X				X	X	X		X	X		X				
LV 2018	2018																X									
GENG 2018	2018		X		X				X						X	X	X		X							
CAMERON 2018	2018										X		X		X	X	X	X	X	X		X	X			
LOOS 2018	2018										X		X		X	X	X		X	X		X				
WARREN 2018	2017															X	X			X		X				
IMAFUKU 2018	2017														X		X		X			X				
AL SAWAH 2017	2017														X	X	X			X		X				
GOMEZ GARCIA 2017	2017														X	X	X		X			X				
JABBAR LOPEZ 2017	2017				X										X	X	X		X	X		X				
SBIDIAN 2017	2017	X	X	X	X	X		X			X	X	X	X	X	X	X	X	X	X		X	X			
FAN 2015	2015																X		X							
SIGNOROVITCH 2015	2015														X	X	X		X							
GUPTA 2014	2014				X			X							X	X	X		X							
SCHMITT 2014	2014		X	X	X			X							X	X	X		X							
IGARASHI 2013	2013						X								X	X	X		X							
GALVAN BANQUERI 2013	2013														X	X	X		X							
LIN 2012	2012							X							X	X	X		X							
REICH 2012	2012						X								X	X	X		X							
BANSBACK 2009	2009		X		X	X		X							X	X			X							
REICH 2008	2008						X	X								X			X							
WOOLACOTT 2006	2006		X	X	X		X									X			X							

Treatments cited as best in the abstract in relation to the included treatments for each NMA.

Each "X" represents the included treatments, squares filled in green represent the treatments cited as best, red squares represent the treatment of the funding pharmaceutical company

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frontiers | Frontiers in Pharmacology

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]*

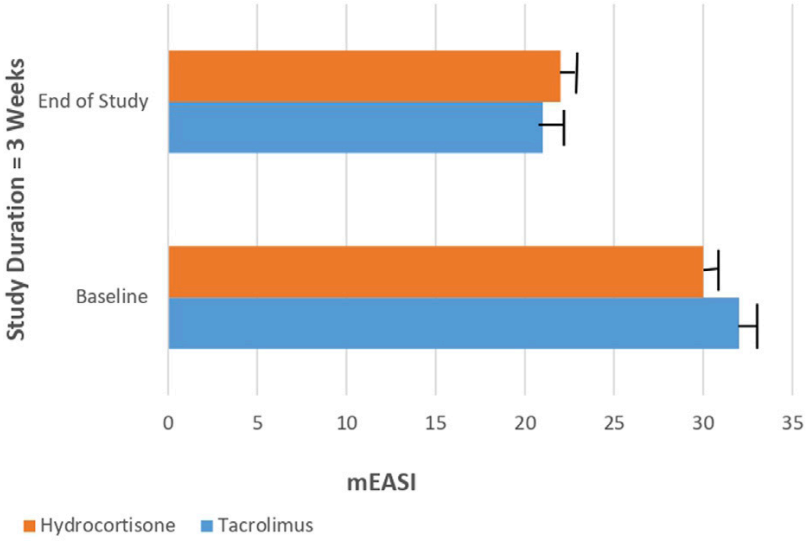

FIGURE 2
Median total score of mEASI in Tacrolimus and Hydrocortisone group at baseline and at the end of the study.

frontiers | Frontiers in Pharmacology

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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]*

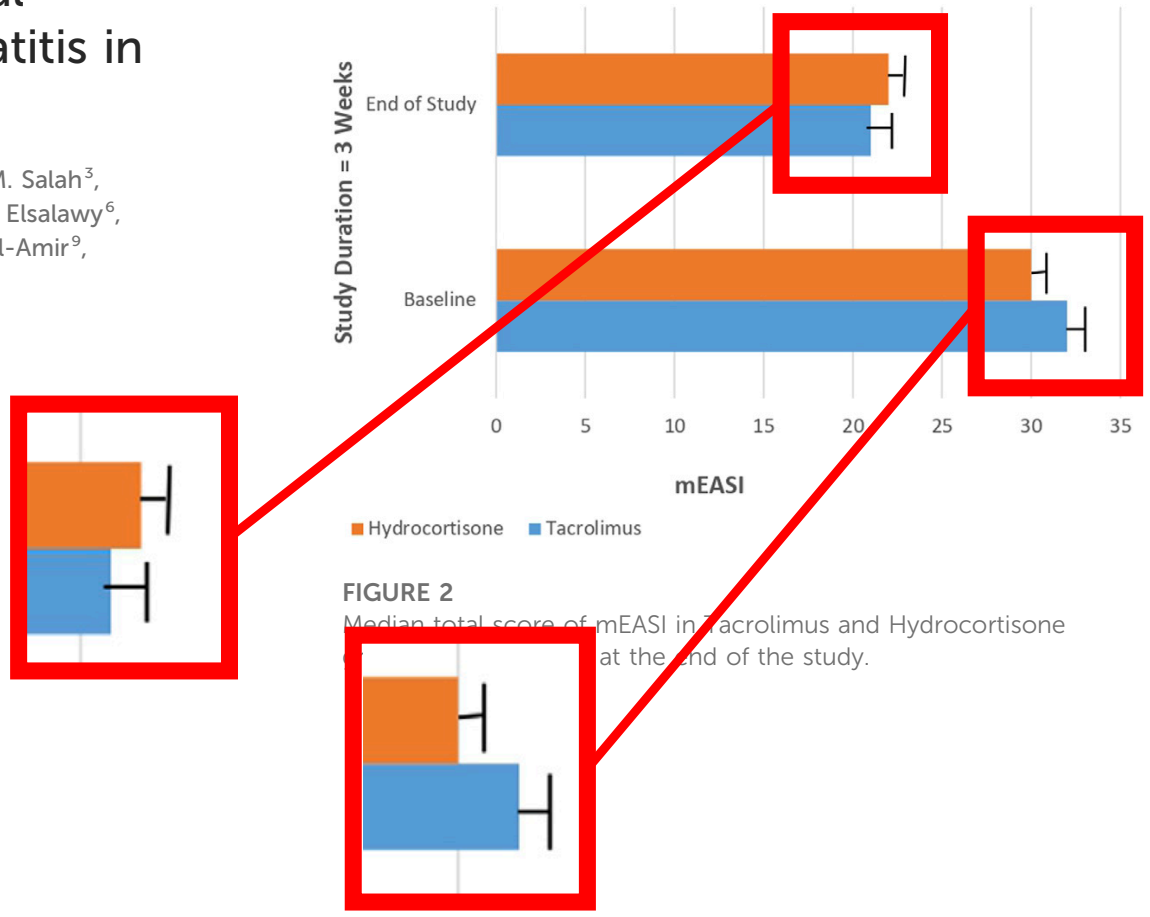

FIGURE 2
Median total score of mEASI in Tacrolimus and Hydrocortisone at the end of the study.

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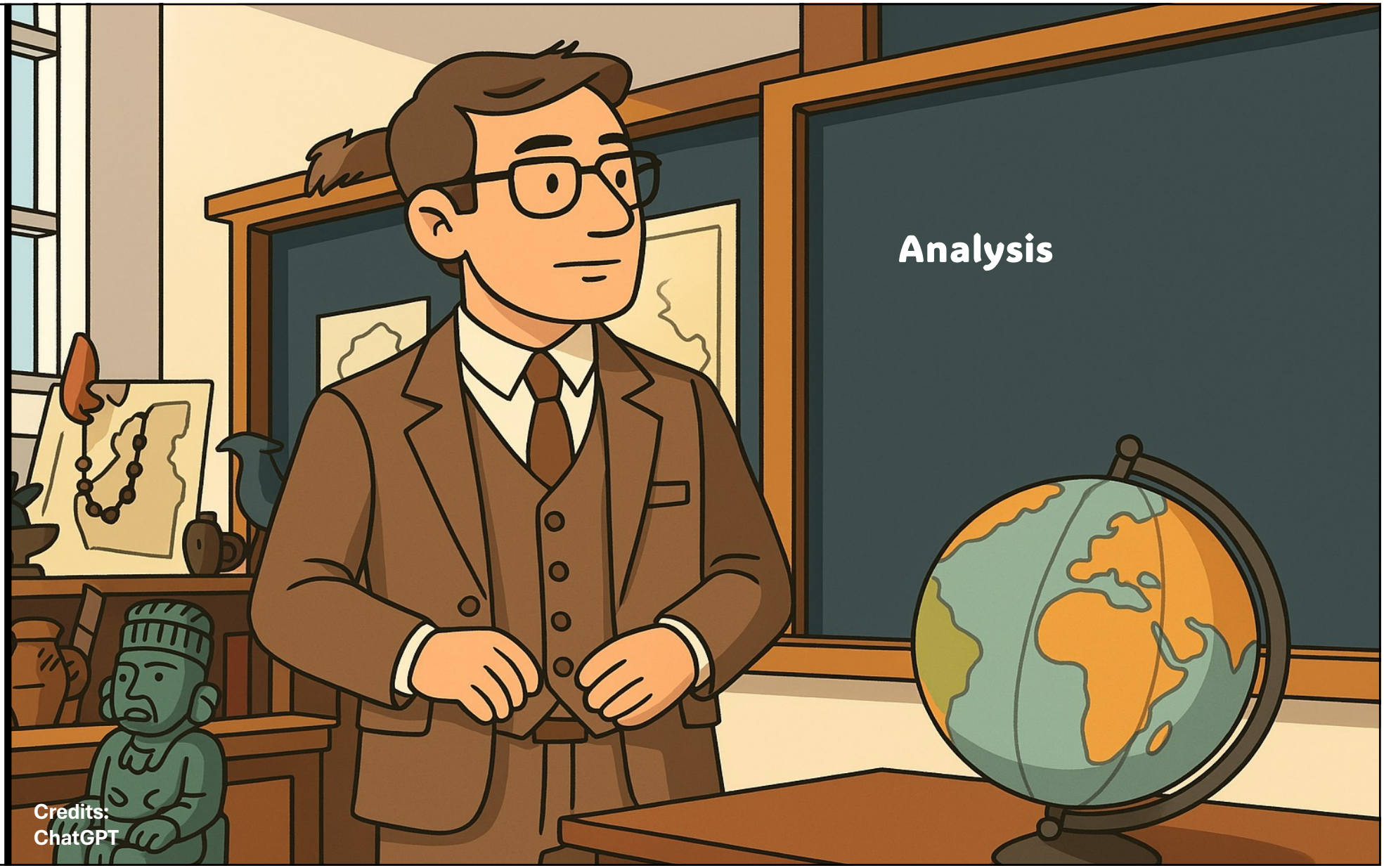

PLOS MEDICINE

Table 2. Effect of allocation to high-dose or standard-dose vitamin D3 supplementation on the primary and secondary outcomes, in intention-to-treat and per-protocol populations.

Outcome	High-dose vitamin D3 supplementation	Standard-dose vitamin D3 supplementation	Relative risk (95% CI) *P* value	Risk difference	Unadjusted hazard ratio (95% CI) *P* value	Adjusted hazard ratio (95% CI) *P* value
	No./total no. (%)			(%)		
	Intent-to-treat population					
Primary outcome: 14-day overall mortality	8/127 (6)	14/127 (11)	0.57 (0.25 to 1.32) 0.19	4.7	0.56 (0.24 to 1.35) 0.20	0.39 (0.16 to 0.99) 0.049
Secondary outcome: 28-day overall mortality	19/126 (15)	21/126 (17)	0.91 (0.51 to 1.60) 0.73	1.6	0.89 (0.48 to 1.65) 0.70	0.70 (0.36 to 1.36) 0.29
	Per-protocol population					
Primary outcome: 14-day overall mortality	7/122 (6)	14/122 (11)	0.50 (0.21 to 1.20) 0.12	5.7	0.49 (0.20 to 1.21) 0.12	0.35 (0.13 to 0.90) 0.03
Secondary outcome: 28-day overall mortality	17/121 (14)	21/121 (17)	0.81 (0.45 to 1.46) 0.48	3.3	0.78 (0.41 to 1.49) 0.45	0.62 (0.31 to 1.22) 0.17

dose vitamin D3 group and 1 participant in the standard-dose vitamin D3 group. Adjusted analyses were controlled for randomization strata (i.e., age, oxygen requirement, hospitalization, and use of antibiotics, anti-infective drugs, and/or corticosteroids) and baseline imbalances in important prognostic factors (i.e., sex, ongoing cancers, profuse diarrhea, and delirium at baseline).

https://doi.org/10.1371/journal.pmed.1003999.t002

RESEARCH ARTICLE

High-dose versus standard-dose vitamin D supplementation in older adults with COVID-19 (COVIT-TRIAL): A multicenter, open-label, randomized controlled superiority trial

Cédric Annweiler[1]*, Mélinda Beaudenon[1], Jennifer Gautier[1], Justine Gonsard[2], Sophie Boucher[3], Guillaume Chapelet[4], Astrid Darsonval[5], Bertrand Fougère[6], Olivier Guérin[7], Marjorie Houvet[8], Pierre Ménager[9], Claire Roubaud-Baudron[10], Achille Tchalla[11], Jean-Claude Souberbielle[12], Jérémie Riou[2], Elsa Parot-Schinkel[2], Thomas Célarier[13], on behalf of the COVIT-TRIAL study group¶

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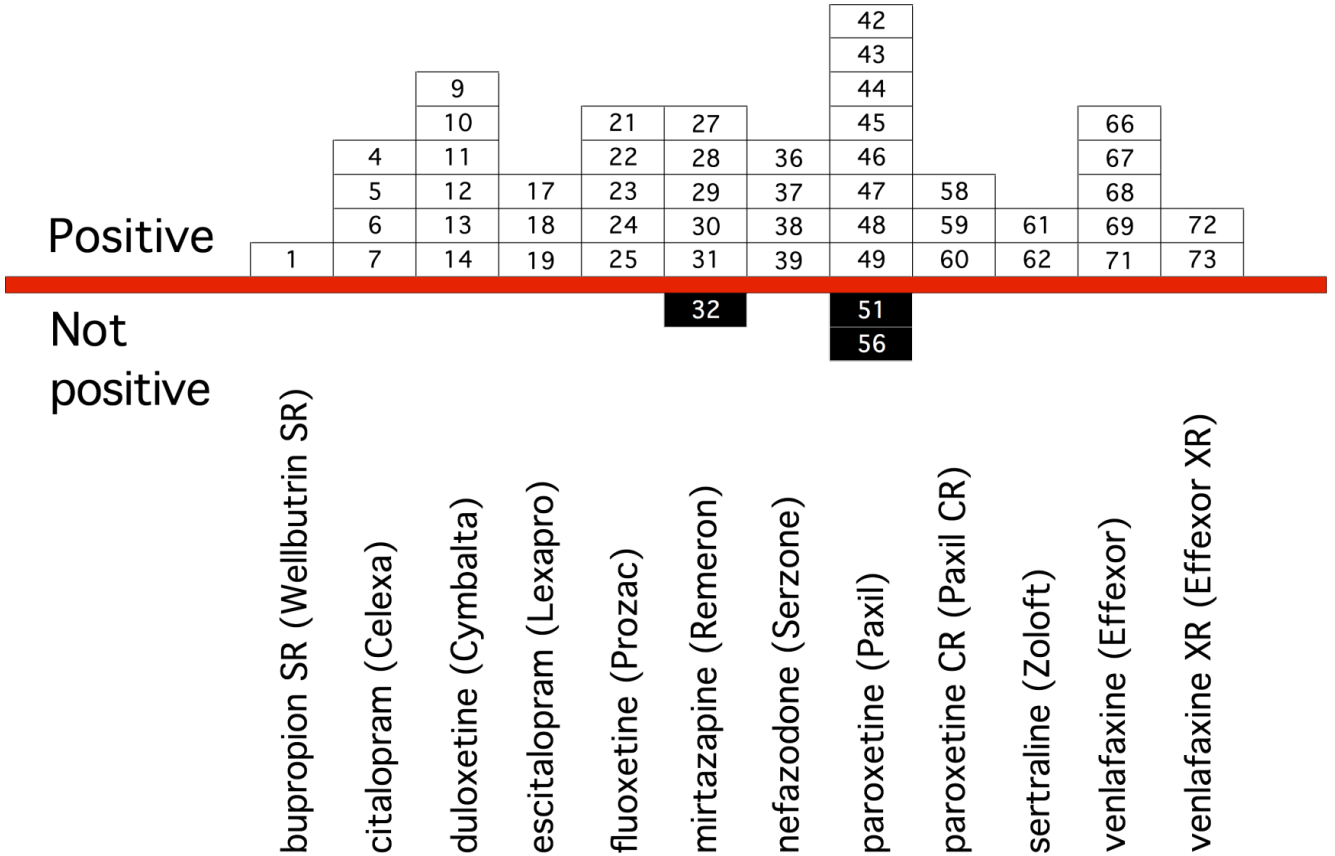
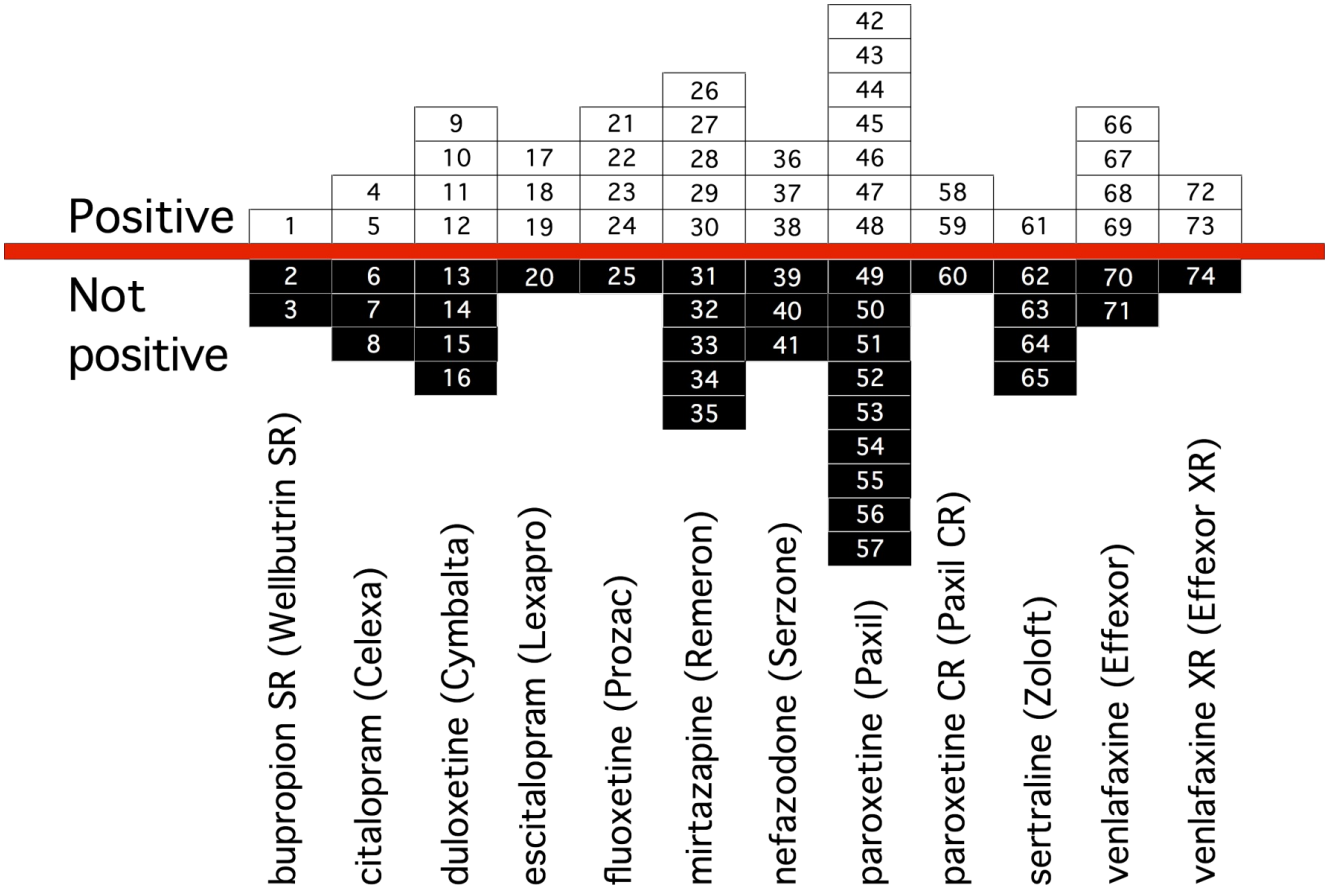
The NEW ENGLAND JOURNAL of MEDICINE



Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy

Erick H. Turner, M.D., Annette M. Matthews, M.D., Eftihia Linardatos, B.S.,
Robert A. Tell, L.C.S.W., and Robert Rosenthal, Ph.D.

The NEW ENGLAND JOURNAL of MEDICINE



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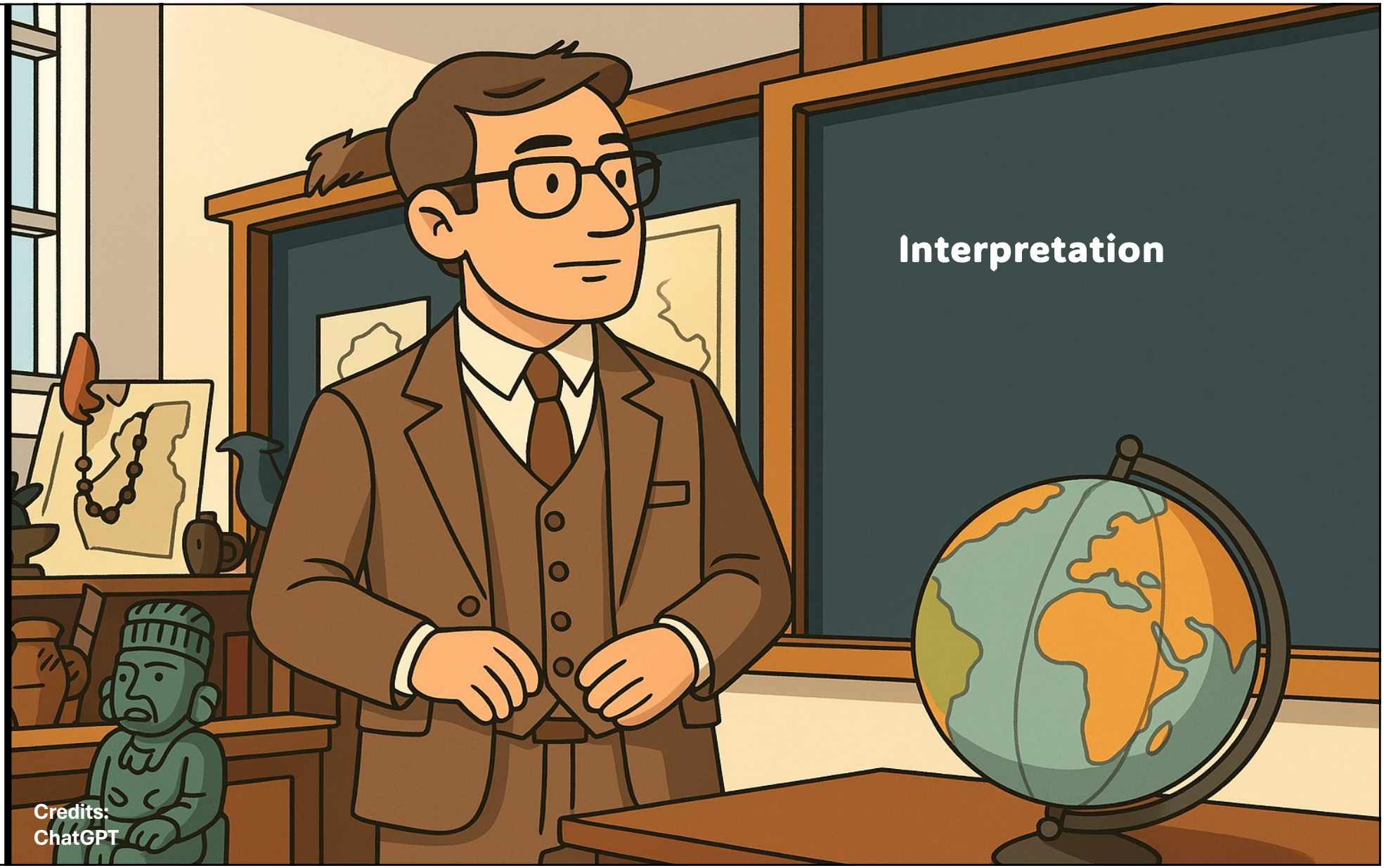
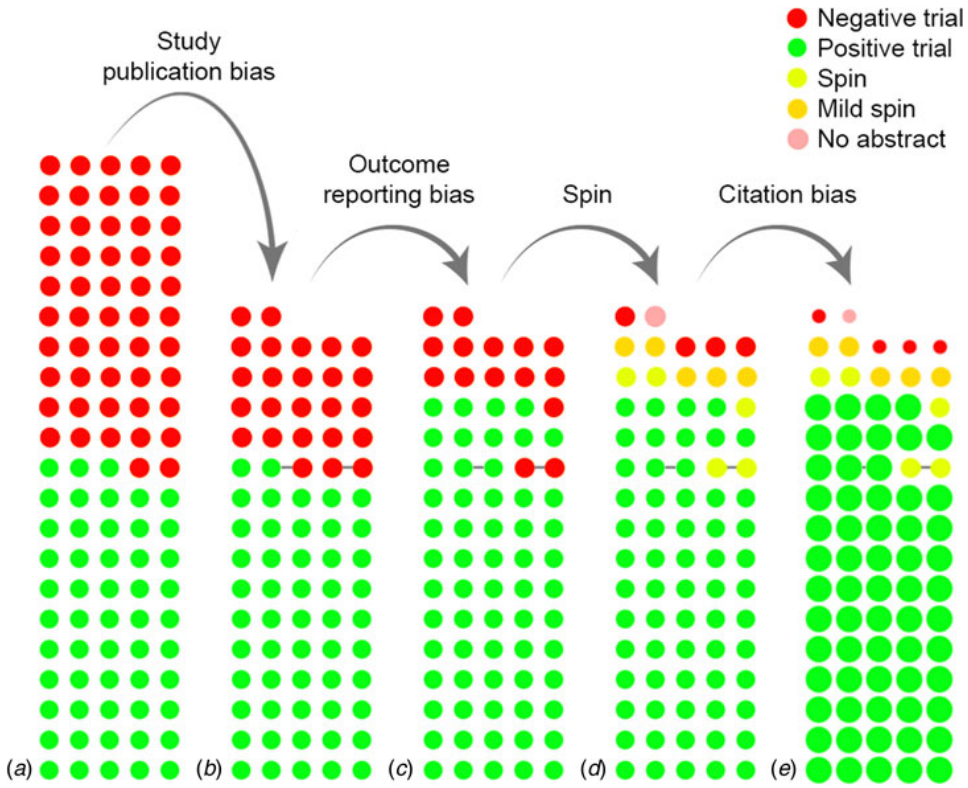


Psychological Medicine



The cumulative effect of reporting and citation biases on the apparent efficacy of treatments: the case of depression

Y. A. de Vries[1,2], A. M. Roest[1,2], P. de Jonge[1,2], P. Cuijpers[3], M. R. Munafò[4,5] and J. A. Bastiaansen[1,6]

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.

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]

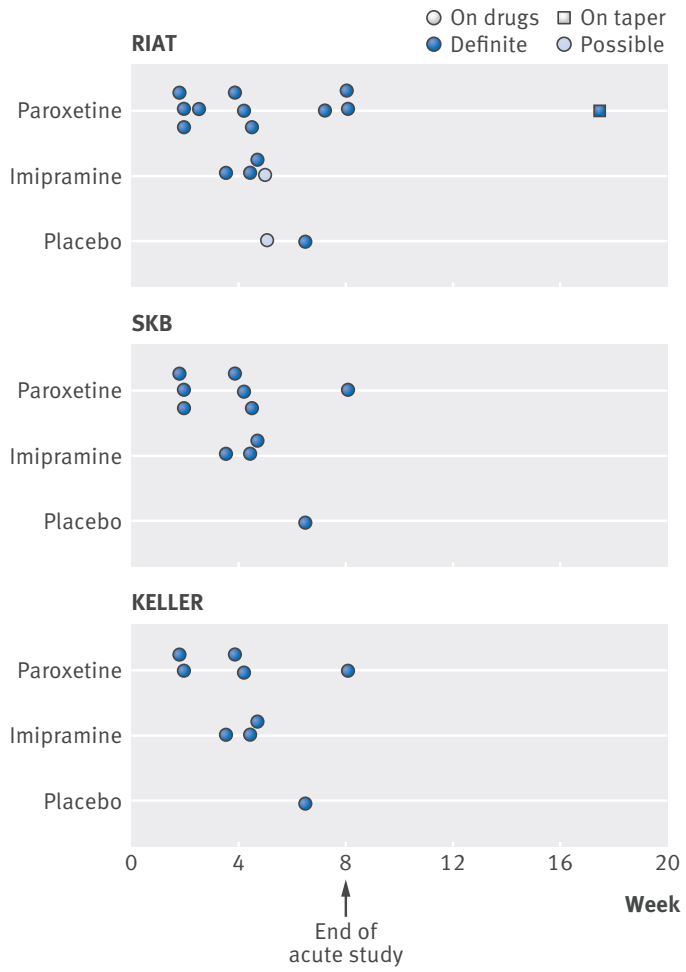


Fig 4 | Timing of suicidal and self injurious events in Study 329, Keller and colleagues, and RIAT analysis

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Spoiler alert:

LOL

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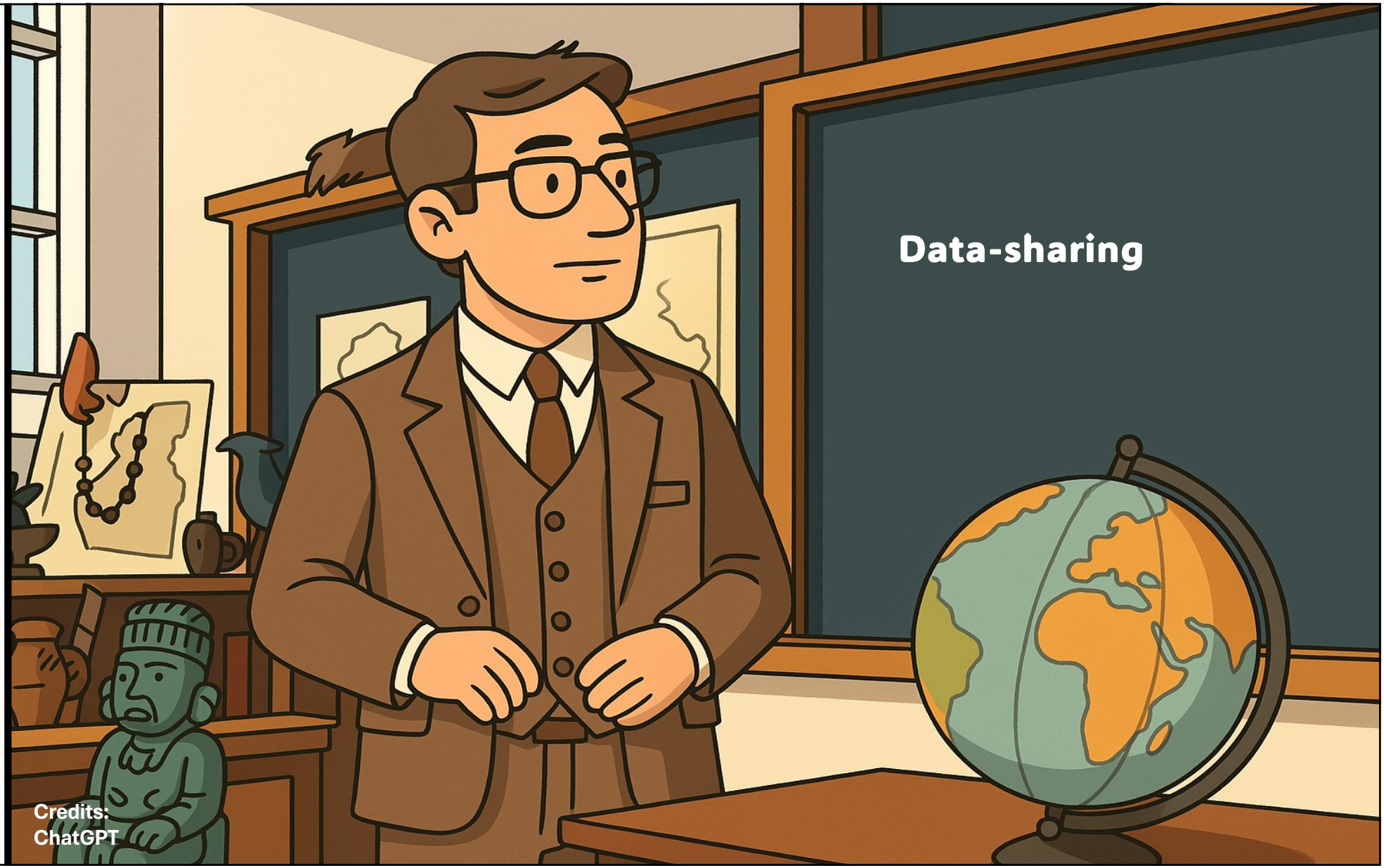


PLOS MEDICINE

ESSAY

Sharing Individual Participant Data (IPD) within the Context of the Trial Reporting System (TRS)

Deborah A. Zarin*, Tony Tse*

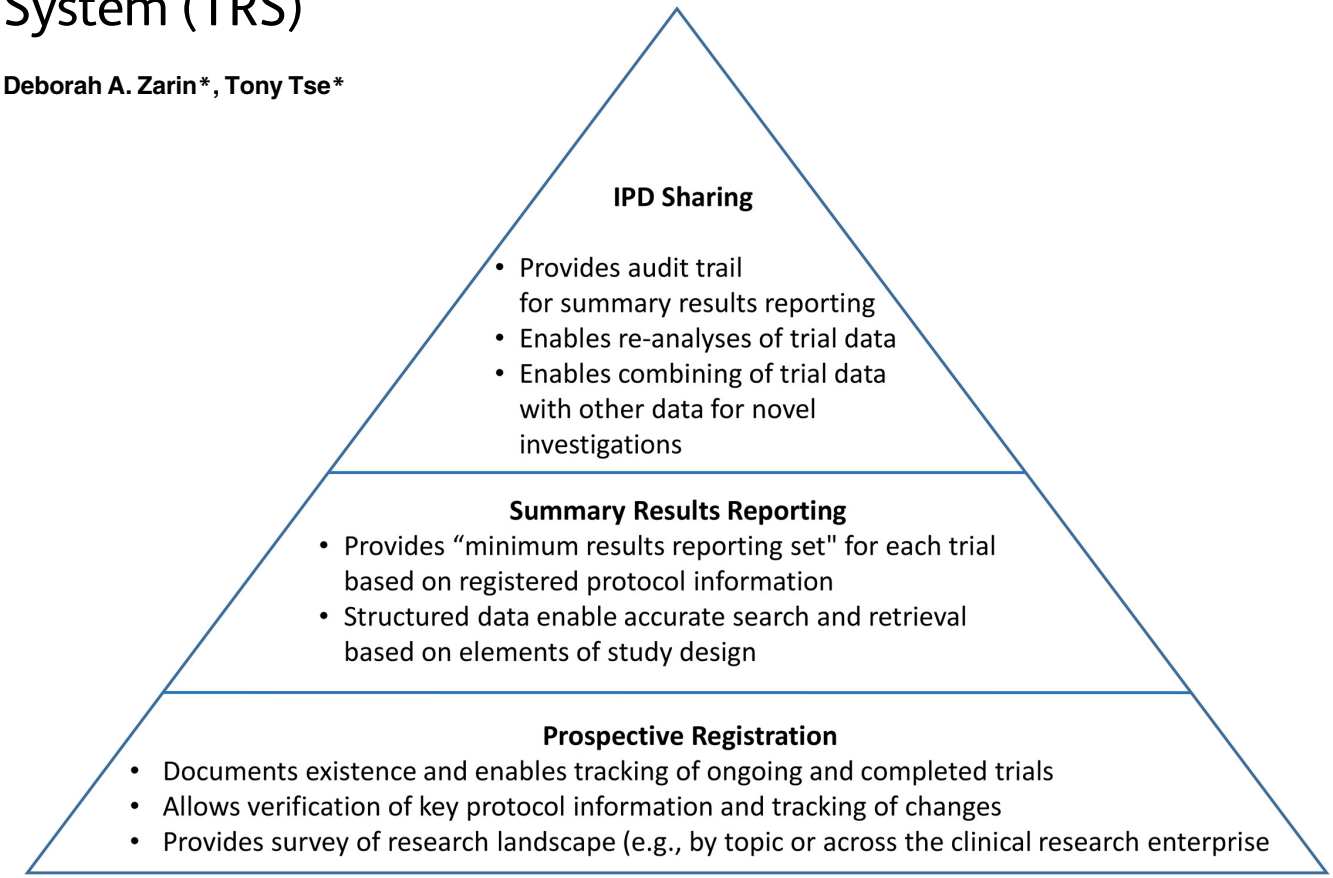


Fig 2. Schematic depicting the functions of the three key components of the TRS.

doi:10.1371/journal.pmed.1001946.g002

JCE
JOURNAL OF CLINICAL EPIDEMIOLOGY

Intent to share Annals of Internal Medicine's trial data was not associated with data re-use

Claude Pellen[a,*], Laura Caquelin[a], Alexia Jouvance-Le Bail[a], Jeanne Gaba[a], Mathilde Vérin[a], David Moher[b], John P.A. Ioannidis[c,d,e], Florian Naudet[a]

Data sharing and reanalysis of randomized controlled trials in leading biomedical journals with a full data sharing policy: survey of studies published in *The BMJ* and *PLOS Medicine*

Florian Naudet,[1] Charlotte Sakarovitch,[2] Perrine Janiaud,[1] Ioana Cristea,[1,3] Daniele Fanelli,[1,4] David Moher,[1,5] John P A Ioannidis[1,6]

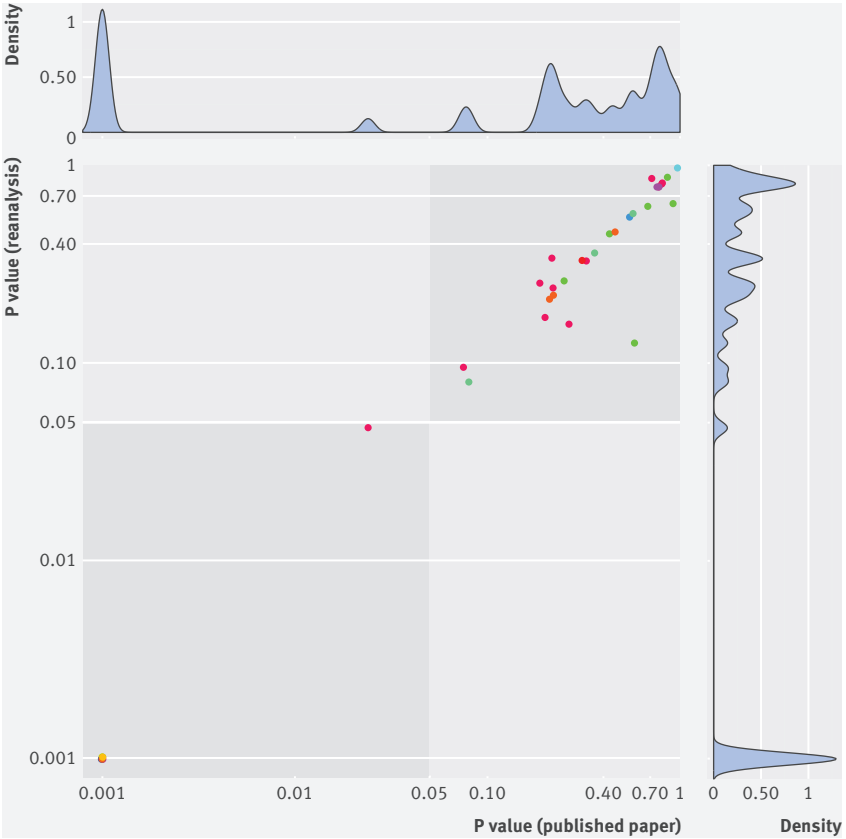
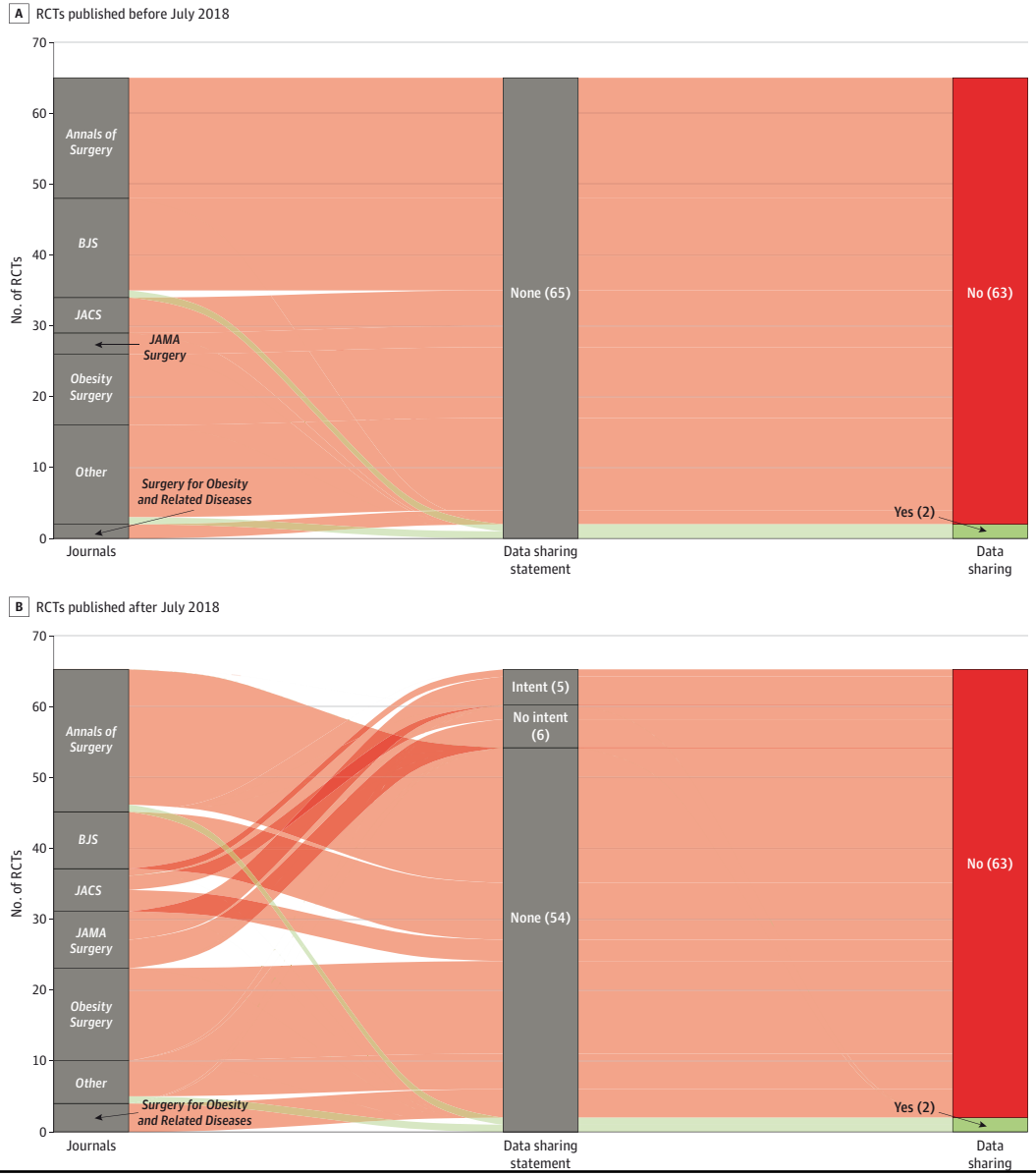


Fig 2 | P values in initial analyses and in reanalyses. Axes are on a log scale. Blue indicates identical conclusion between initial analysis and reanalysis. Dots of same colors indicate analyses from same study

JAMA Network Open™



Original Investigation | Medical Journals and Publishing

Data Sharing and Reanalyses Among Randomized Clinical Trials Published in Surgical Journals Before and After Adoption of a Data Availability and Reproducibility Policy

Damien Bergeat, MD, PhD; Nicolas Lombard, MD; Anis Gasmi, MD; Bastien Le Floch, MD; Florian Naudet, MD, PhD

Key Points

Question What is the association of the implementaton of the International Committee of Medical Journal Editors (ICMJE) data sharing policy with data sharing practices and data availability in the 10 leading surgical journals publishing randomized clinical trials?

Findings This cross-sectional study of 65 RCTs published before and 65 RCTs published after the ICMJE data sharing policy found no association between the policy and data sharing in the journals studied.

Meaning This study suggests that most randomized clinical trials published in the 10 leading surgical journals lack transparency and that their results may not be reproducible by external researchers.

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]

COMMERCIAL FUNDERS

Forty-one (of 100; 41%) had a data-sharing policy.

Among funders with a data-sharing policy, in a survey of 100 RCTs registered on clinicaltrials.gov:
. Data-sharing statements were present for eighty-one **(81% [72% - 88%])** registered RCTs.
. Intention to share data was expressed in **59% [49% – 69%]** of registered RCTs.

NON COMMERCIAL FUNDERS

Thirty (of 78; **38%**) had a data-sharing policy with eighteen (of 30, **60%**) **making data-sharing mandatory** and twelve (**40%**) **encouraging data-sharing**.

Among funders with a data-sharing policy, in a survey of 100 RCTs registered on clinicaltrials.gov:
. Data-sharing statements were present for seventy-seven (**77%, 95% IC [67%-84%]**) registered RCTs.
. Intention to share data was expressed in **12% [7%-20%]** of registered RCTs.

BMC Medicine

REGISTERED REPORT Open Access

Data-sharing and re-analysis for main studies assessed by the European Medicines Agency—a cross-sectional study on European Public Assessment Reports

Maximilian Siebert[1,2], Jeanne Gaba[1,2], Alain Renault[1,2], Bruno Laviolle[1,2], Clara Locher[1,2], David Moher[3] and Florian Naudet[1,2,4*]

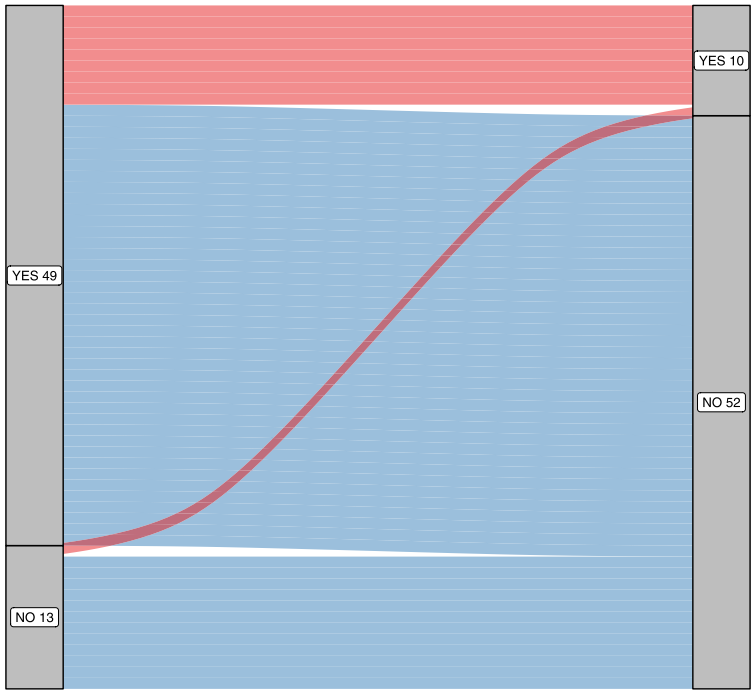


Fig. 2 Outcome of data-sharing demands in relation to data-sharing policies

PLOS MEDICINE

Table 2. Proposed actions for various stakeholders to ensure that the ICMJE policy meets the mark.

Stakeholders	Proposed action
ICMJE	Should certify compliance, adopt more binding policies, and clarify when clinical trial data sharing is required and ethically possible.
Journals	Should provide oversight with editorial screening (e.g., by a reproducible research editor) and software screening (e.g., by implementing an IT infrastructure to verify data sharing processes described in submitted data sharing plans). Should embargo future publications from authors if they have not shared their data from previous manuscripts in their journal despite a promise to do so.
Funders/ institutions	Should monitor and reward data sharing. Should provide technical/regulatory guidance for clinical trial data sharing. Should implement DUACs. Should withhold support from investigators not sharing data. Should support meta-research efforts that evaluate the impact of clinical trial data sharing.
Researchers	Should commit to sharing data. Should engage in evaluating the impact of clinical trial data sharing and provide the necessary feedback to improve the policy.

DUAC, Data Use and Access Committee; ICMJE, International Committee of Medical Journal Editors.

https://doi.org/10.1371/journal.pmed.1003844.t002

POLICY FORUM

Medical journal requirements for clinical trial data sharing: Ripe for improvement

Florian Naudet[1]*, Maximilian Siebert[1☯], Claude Pellen[1☯], Jeanne Gaba[1☯], Cathrine Axfors[2,3], Ioana Cristea[4], Valentin Danchev[2,5], Ulrich Mansmann[6,7], Christian Ohmann[8], Joshua D. Wallach[9], David Moher[10,11], John P. A. Ioannidis[2,12]

PLOS COMPUTATIONAL BIOLOGY

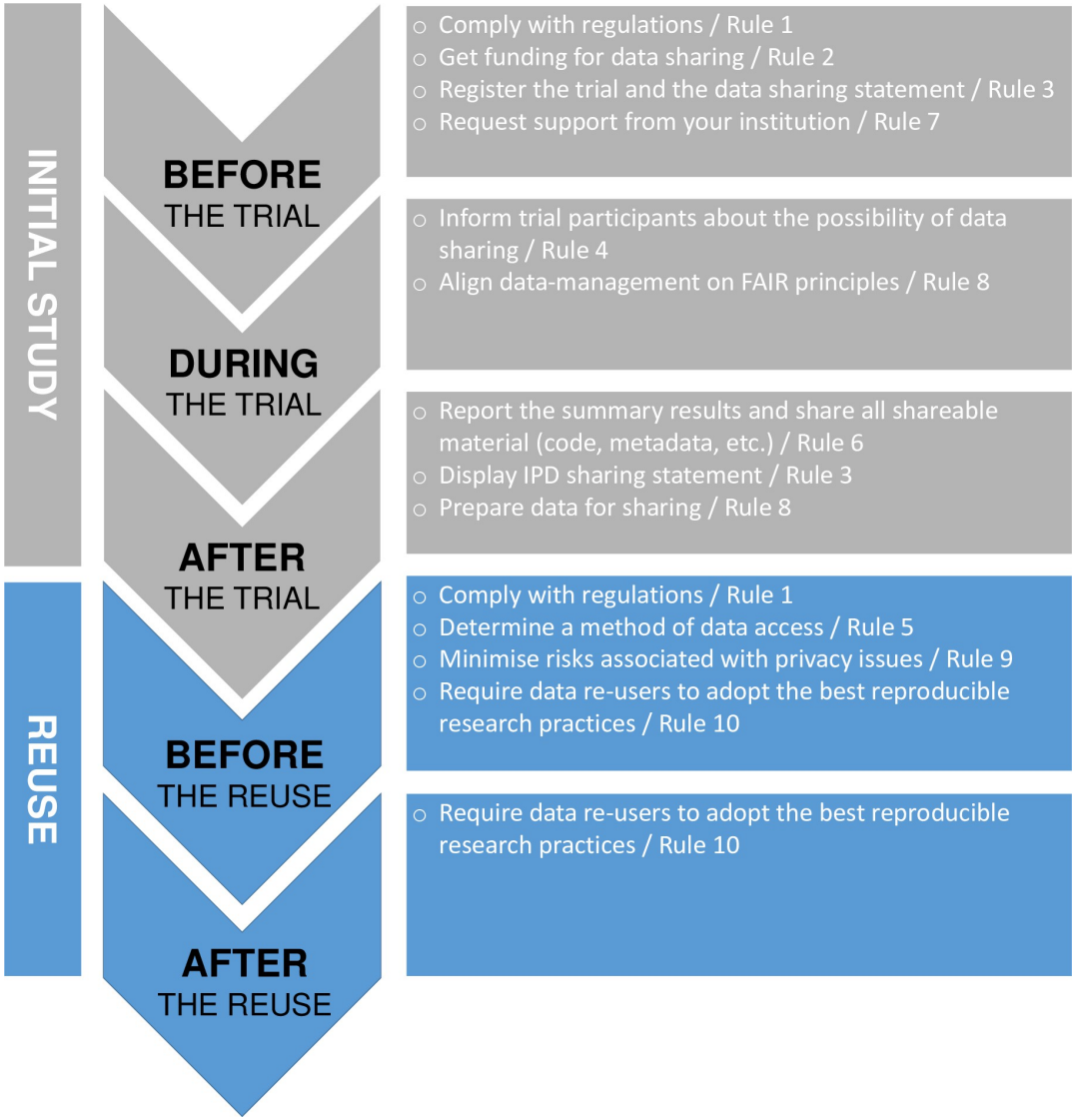


Fig 1. When researchers wishing to share data should implement the 10 rules.

REVIEW

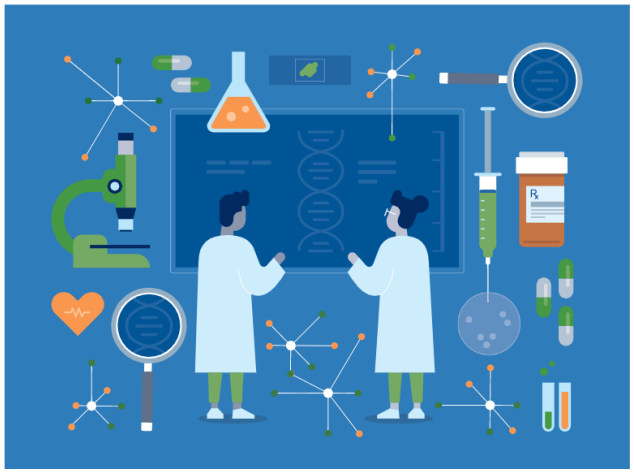
Ten (not so) simple rules for clinical trial data sharing

Claude Pellen[1]*, Anne Le Louarn[2], Gilliosa Spurrier-Bernard[3,4], Evelyne Decullier[5,6], Jean-Marie Chrétien[7], Eric Rosenthal[8], Gérard Le Goff[9], David Moher[10], John P. A. Ioannidis[11], Florian Naudet[1,12]

nature medicine

Implementing clinical trial data sharing requires training a new generation of biomedical researchers

Ulrich Mansmann, Clara Locher, Fabian Prasser, Tracey Weissgerber, Ulrich Sax, Martin Posch, Evelyne Decullier, Ioana A. Cristea, Thomas P. A. Debray, Leonhard Held, David Moher, John P. A. Ioannidis, Joseph S. Ross, Christian Ohmann & Florian Naudet



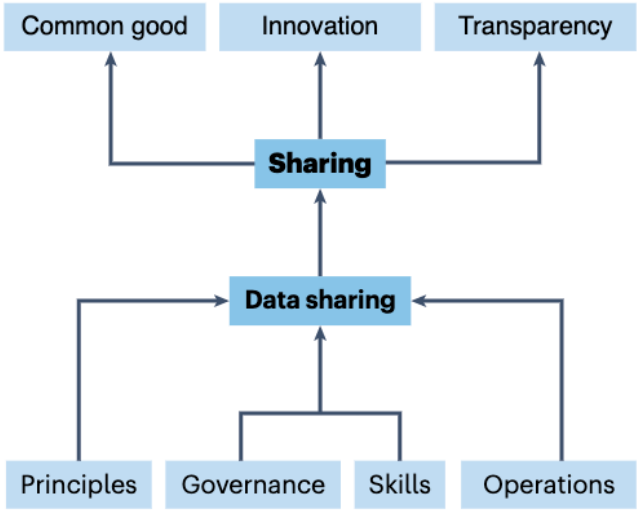


Fig. 1 | Elements of data sharing. Data sharing is built on principles, governance structures, skills and operation infrastructure. It shapes scientific openness, transparency and reproducibility as virtues of a scientific community that demonstrates good practice and supports change.

Data sharing enhances the value of medical research and builds trust in clinical trials, but more biomedical researchers need to be trained in these approaches, which include meta-research, data science and ethical, legal and social issues.

BMJ EBM

Rapid access to innovative medicinal products while ensuring relevant health technology assessment. Position of the French National Authority for Health

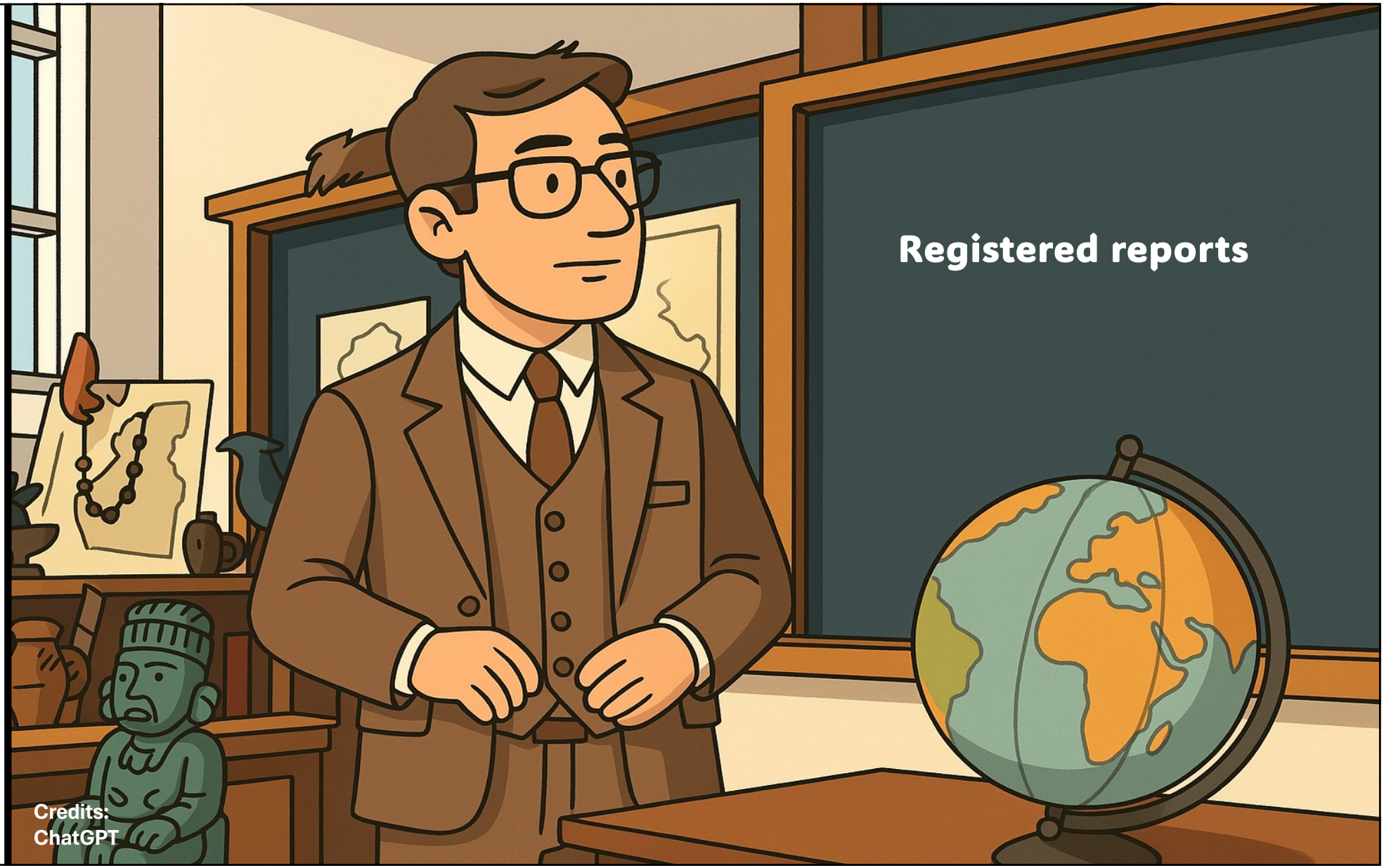
Antoine Vanier,[1,2] Judith Fernandez ,[1] Sophie Kelley,[1] Lise Alter,[1] Patrick Semenzato,[1] Corinne Alberti,[3,4] Sylvie Chevret,[5] Dominique Costagliola,[6] Michel Cucherat,[7] Bruno Falissard,[8] François Gueyffier,[9] Jérôme Lambert,[5] Etienne Lengliné,[10] Clara Locher ,[11] Florian Naudet ,[12,13] Raphael Porcher,[14] Rodolphe Thiébaut,[15] Muriel Vray,[16] Sarah Zohar,[17,18] Pierre Cochat,[19] Dominique Le Guludec[19]

HAUTE AUTORITÉ DE SANTÉ

In addition, HAS calls for greater transparency in the whole process of generating evidence through initiatives such as registered report publications, data and clinical study reports sharing.[20]

RestoRes

Research integrity in biomedical research



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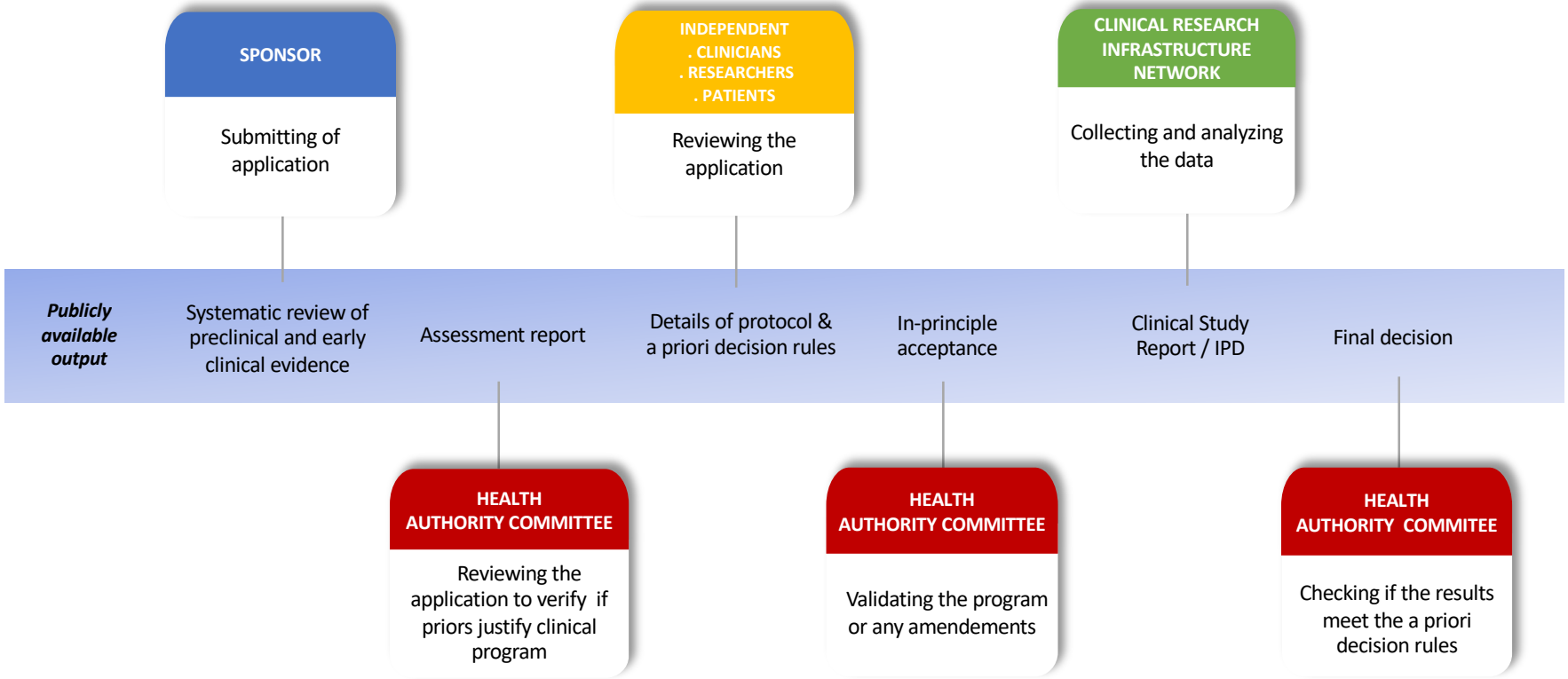

An open science pathway for drug marketing authorization—Registered drug approval

Florian Naudet[1]*, Maximilian Siebert[1], Rémy Boussageon[2], Ioana A. Cristea[3,4], Erick H. Turner[5,6]

Our original goals for protocol review of understanding the needs of researchers better, innovating faster ways to publish, and being sensitive to potential bias in decision making, remain important and continue to guide our evolution across *The Lancet* family of journals. These goals rightly find expression in new developments, such as 10+10 for rapid publication of trials[4] and the REWARD campaign (REduce research WAste and Reward Diligence).[5] As they do, it is important to re-evaluate existing projects, such as protocol review. Having done so, and noted greater appreciation for the importance of protocols, study registration, and the widespread availability of publication for protocols, our conclusion is that *The Lancet's* protocol review service has served its purpose. Therefore, we will cease to accept submissions for protocol review after Dec 31, 2015. All protocols received on or before that date will be considered and our commitments to the authors of protocols that we accept will be honoured. The editors continue to welcome the inclusion of a protocol for all research submissions and to require them for randomised trials. Furthermore, we encourage authors of accepted research papers of any design to post a copy of the full protocol on their institutional website so that *The Lancet* can publish a link to it.[6] In this way, protocol review can be open to all readers.

Protocol review at *The Lancet*: 1997–2015

The Editors of The Lancet
The Lancet, London EC2Y 5AS, UK

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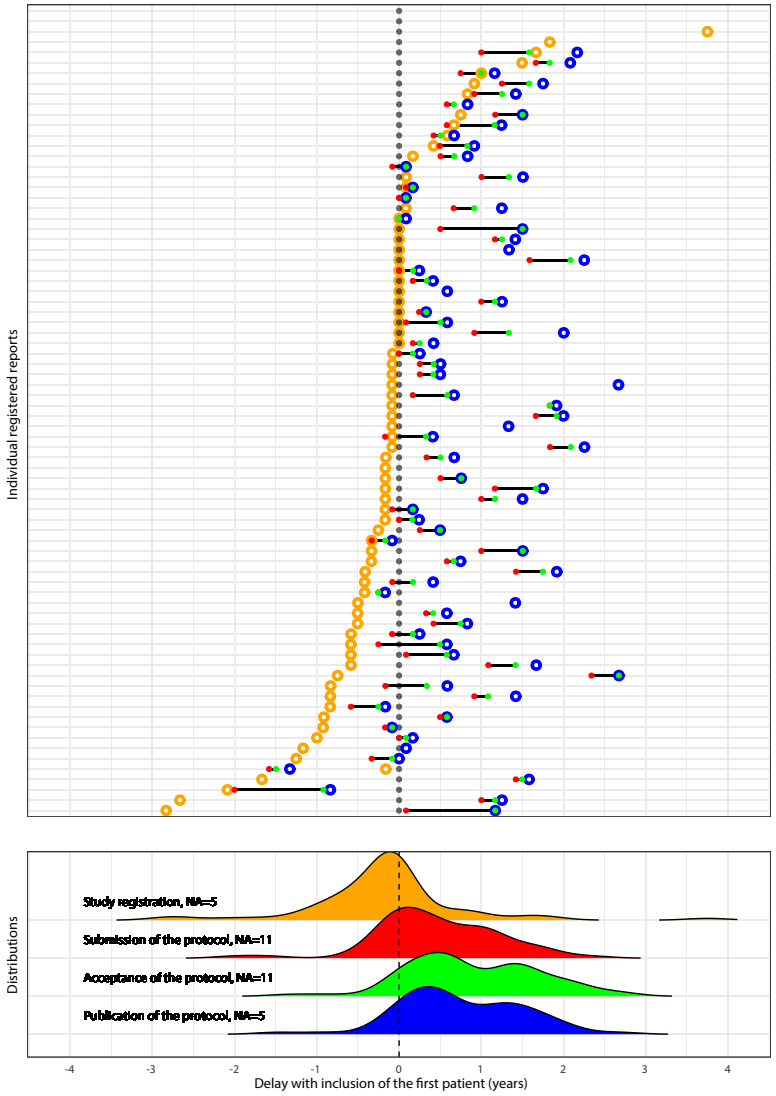
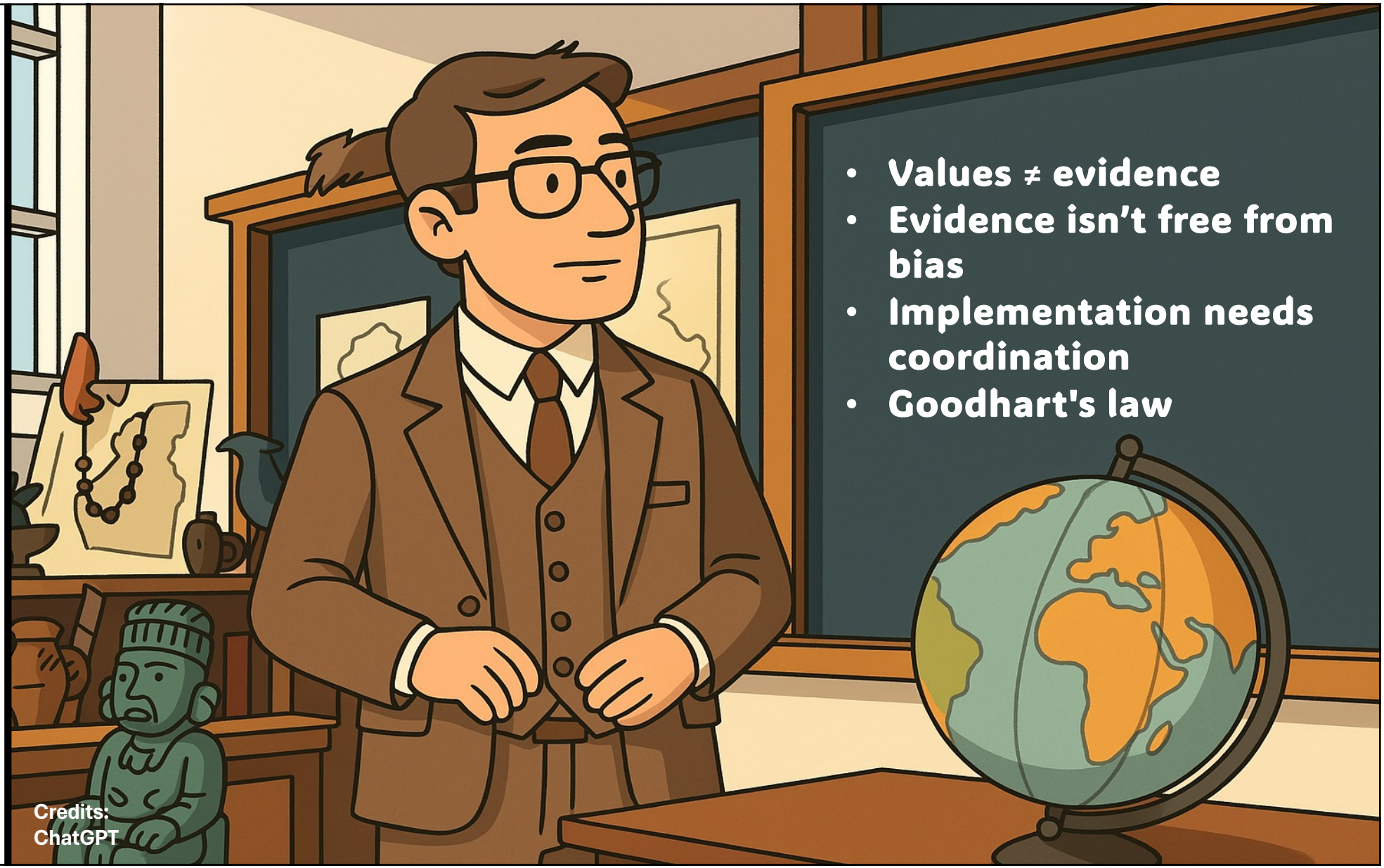


Published registered reports are rare, limited to one journal group, and inadequate for randomized controlled trials in the clinical field

Norah Anthony[a,*], Antoine Tisseaux[a], Florian Naudet[b,c]

RestoRes

Research integrity in biomedical research



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The European Code of Conduct for Research Integrity

REVISED EDITION 2023

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ET DE LA RECHERCHE
Liberté
Égalité
Fraternité

GLOBAL
RESEARCH
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OPEN SCIENCE

April 2024

BUILDING A GLOBAL RESEARCH INITIATIVE ON OPEN SCIENCE

Towards Evidence based Open Science policies

PREPARED BY
Florian Naudet
Henriikka Mustajoki
Marin Dacos

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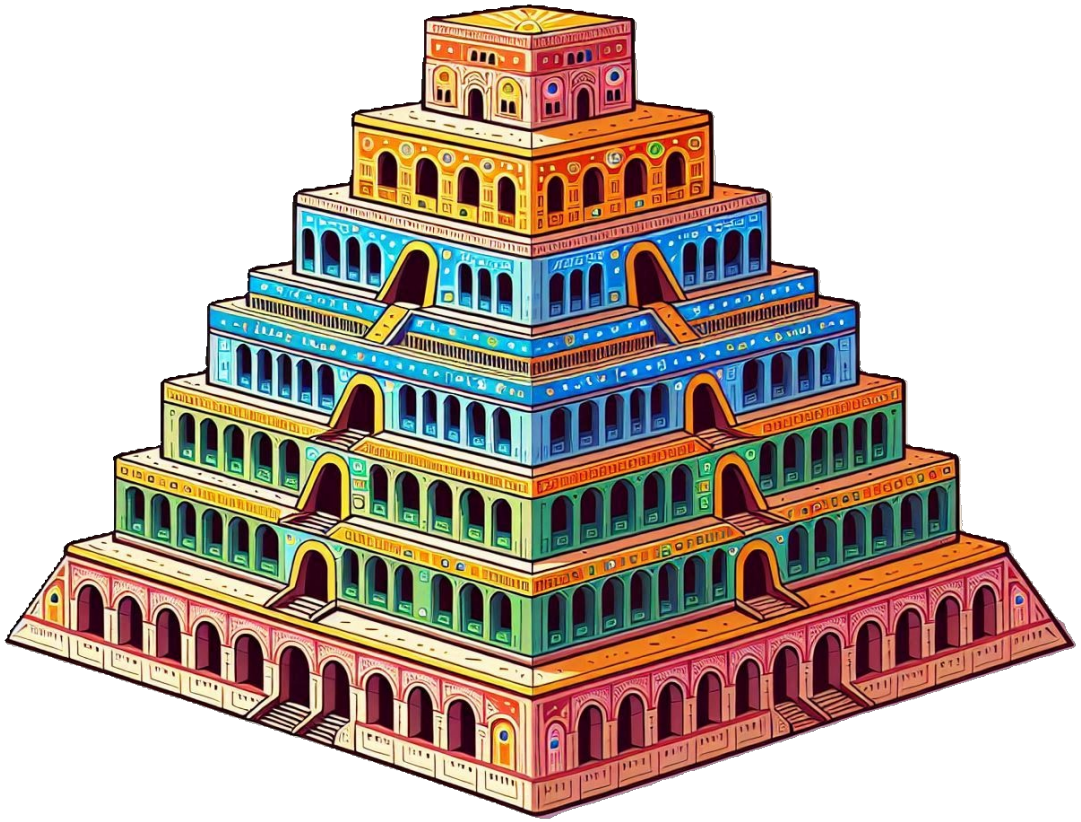


Thoughful, well-conducted studies of any design

The other shit

Credits:
Microsoft Designer

Credits:
Darren Dahly

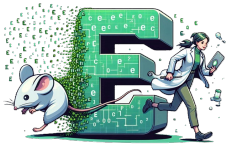
RestoRes

Research integrity in biomedical research

Agenda

Identify Problems
- Zombie trials
- Financial Conflicts of Interest (FCOIs)
- Editorial Conflicts of Interest (COIs)

Develop Solutions
- Data-sharing and management plans



Ouvrir la science !

INSPECT SR

Evaluate Solutions
- Reproducibility checks

siris

Train the Next Generation
- Educating researchers

SHARE · CTD
Cooperate to share and gain

FRRR

RRO FR Reproducible Research network

lorier
L'organisation pour une recherche Inserm éthique et responsable

Synthesize Findings
- Integration of primary evidence

Global Research Initiative on Open Science

RestoRes

Research integrity in biomedical research

Credits: ChatGPT

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INTEGRITY AND REPRODUCIBILITY IN THERAPEUTIC RESEARCH

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