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Aumentare il value delle risorse investite nella ricerca biomedica
La campagna Lancet-REWARD
Bologna, 9 novembre 2016

Raccomandazioni REWARD. Sessione III

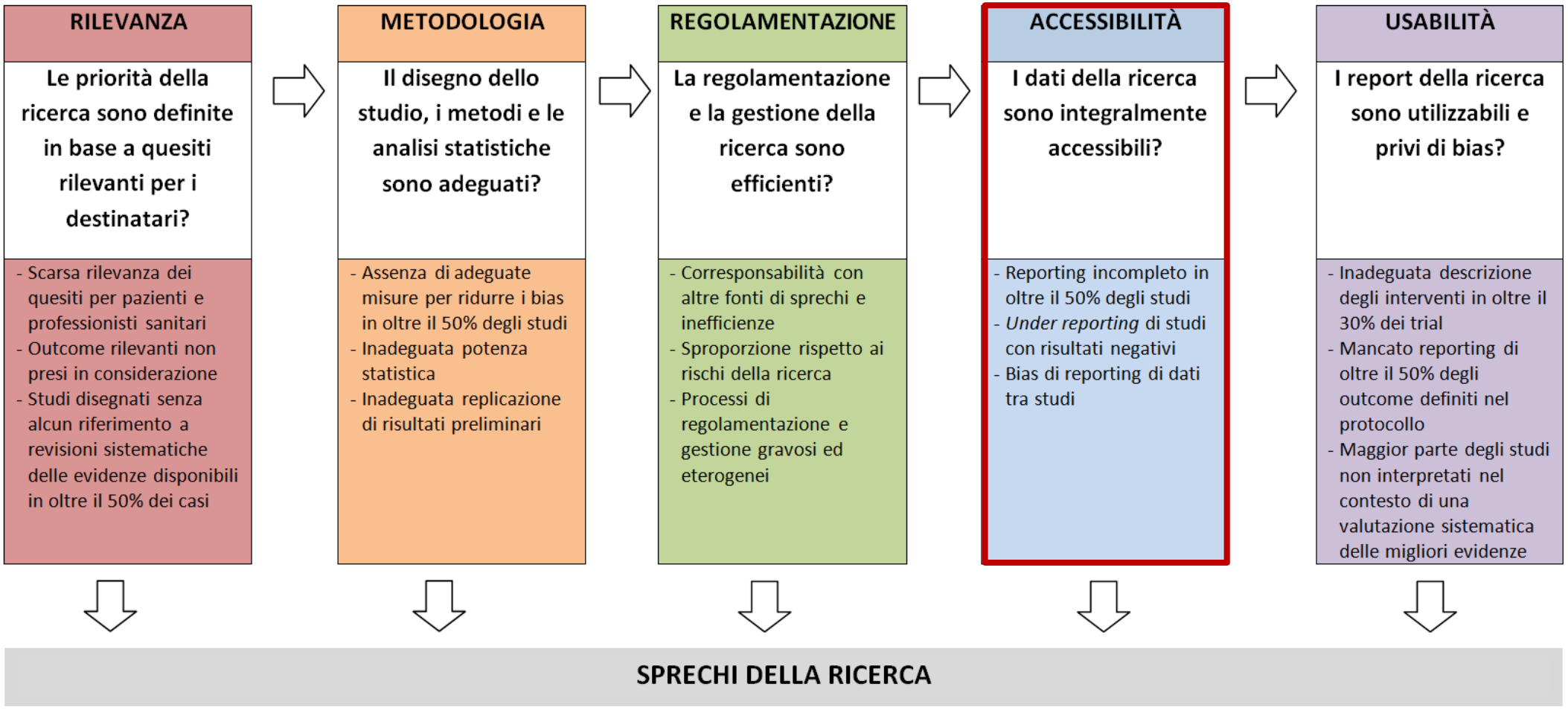
Accessibilità ai dati e usabilità dei report della ricerca

DISCUSSANT

Luca De Fiore
Direttore generale, Il Pensiero Scientifico Editore

Giuseppe Remuzzi
Direttore del Dipartimento di Medicina e U.O. di Nefrologia
Azienda Ospedaliera Papa Giovanni XXIII, Bergamo

Coordinatore della ricerca presso l'Istituto Mario Negri di Bergamo e del Centro di Ricerche Cliniche per le Malattie Rare Aldo e Cele Daccò di Ranica (BG)



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Increasing value and reducing waste: addressing inaccessible research

An-Wen Chan, Fujian Song, Andrew Vickers, Tom Jefferson, Kay Dickersin, Peter C Gøtzsche, Harlan M Krumholz, Davina Ghersi, H Bart van der Worp

Recommendations

1 Institutions and funders should adopt performance metrics that recognise full dissemination of research and reuse of original datasets by external researchers
   - Monitoring—assessment of the proportion of institutional and funding-agency policies that explicitly reward dissemination of study protocols, reports, and participant-level data

2 Investigators, funders, sponsors, regulators, research ethics committees, and journals should systematically develop and adopt standards for the content of study protocols and full study reports, and for data sharing practices
   - Monitoring—surveys of how many stakeholders adopt international standards

3 Funders, sponsors, regulators, research ethics committees, journals, and legislators should endorse and enforce study registration policies, wide availability of full study information, and sharing of participant-level data for all health research
   - Monitoring—assessment of the proportion of stakeholder policies that endorse dissemination activities, and the proportion of studies that are registered and reported with available protocols, full study reports, and participant-level data

ACCESSIBILITÀ

I dati della ricerca sono integralmente accessibili?

- Reporting incompleto in oltre il 50% degli studi
- Under reporting di studi con risultati negativi
- Bias di reporting di dati tra studi

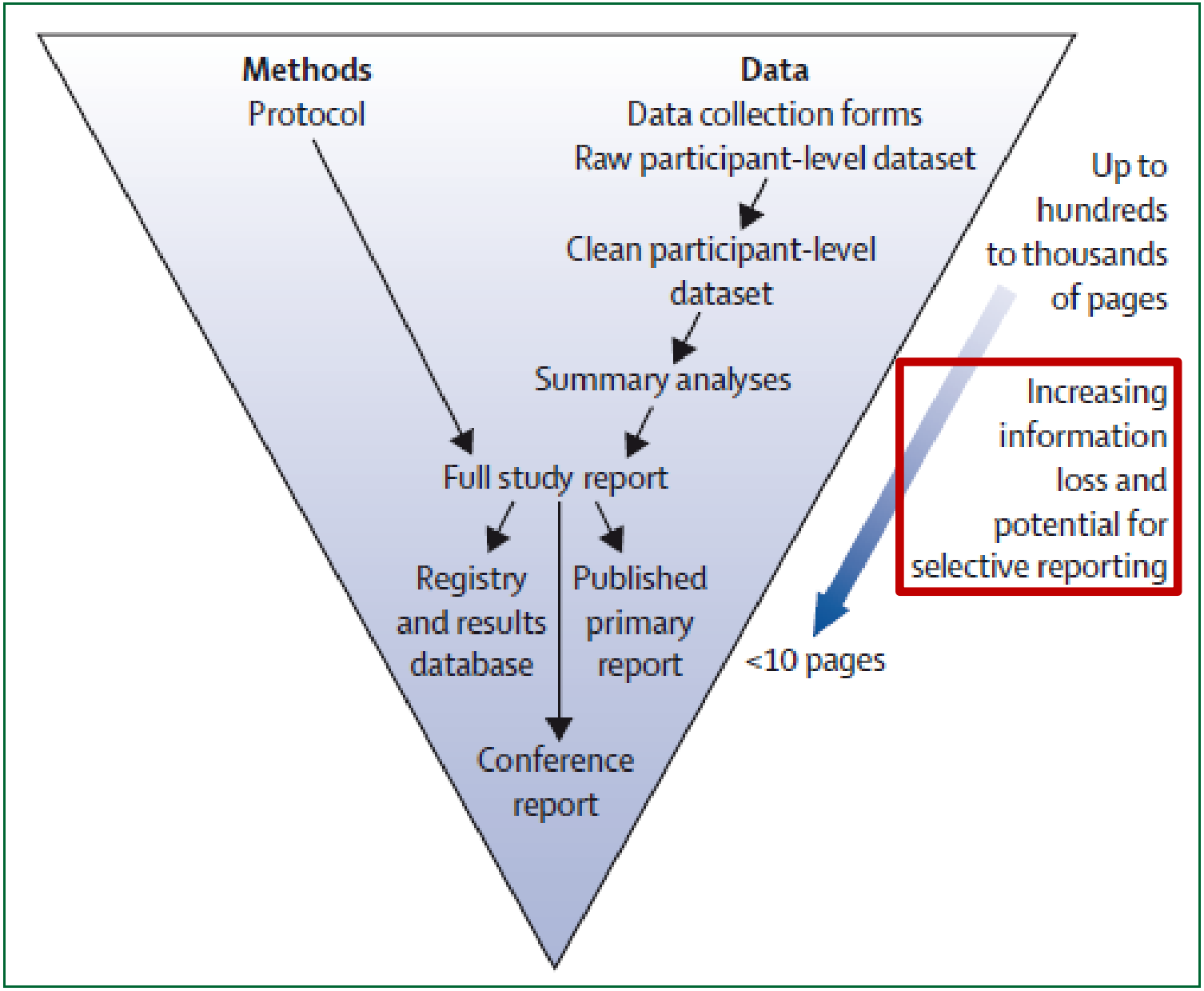


Figure 4: Key sources of information about study methods and results, with associated information loss and potential for selective reporting

Sharing clinical trial data: a proposal from the International Committee of Medical Journal Editors

Published Online
January 20, 2016

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

Data Sharing
An Ethical and Scientific Imperative

Howard Bauchner, MD; Robert M. Golub, MD; Phil B. Fontanarosa, MD, MBA

JAMA March 22/29, 2016 Volume 315, Number 12

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

AUGUST 4, 2016

Strengthening Research through Data Sharing

Elizabeth Warren, J.D.

Offline: Data sharing—why editors may have got it wrong

Richard Horton
richard.horton@lancet.com

www.thelancet.com Vol 388 September 17, 2016

The NEW ENGLAND JOURNAL of MEDICINE

EDITORIALS

The Importance — and the Complexities — of Data Sharing

Jeffrey M. Drazen, M.D., Stephen Morrissey, Ph.D., Debra Malina, Ph.D., Mary Beth Hamel, M.D., and Edward W. Campion, M.D.

N ENGL J MED 375;12 NEJM.ORG SEPTEMBER 22, 2016

ANALYSIS

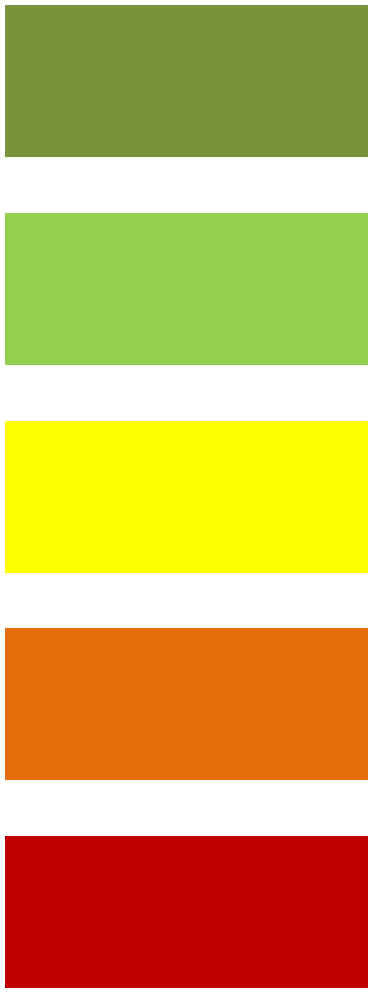
Beyond open data: realising the health benefits of sharing data

Accessible data are not enough. We need to invest in systems that make the information useful, say **Elizabeth Pisani and colleagues**

Key messages

- Simple accessibility of data is enough to promote research transparency, but public health gains require more complex models
- Meaningful and equitable collaboration with local researchers and policy makers in low and middle income countries is needed to ensure the right research questions get asked and research results are used
- Useful data sharing requires long term investment in infrastructure, networks, and scientific careers, including in the data sciences
- It is not enough to share data: we need to share governance structures, scientific questions and ideas, and interpretation

Priorità raccomandazioni REWARD



5= Indispensabile

4= Priorità elevata

3= Priorità intermedia

2= Priorità bassa

1= Non è una priorità

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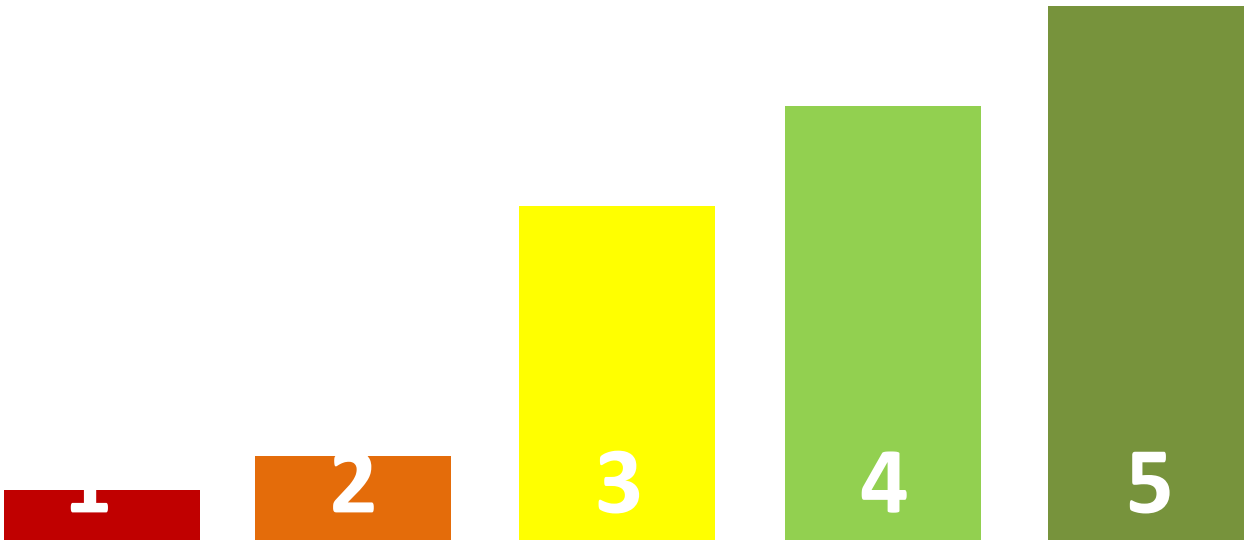
ACCESSIBILITA'

12. Istituzioni e finanziatori dovrebbero adottare indicatori di performance per valutare un’adeguata disseminazione della ricerca e il riutilizzo dei dataset originali da parte di ricercatori esterni

ACCESSIBILITÀ

Raccomandazione 12

Media	DS
3.92	± 1.07



ACCESSIBILITA'

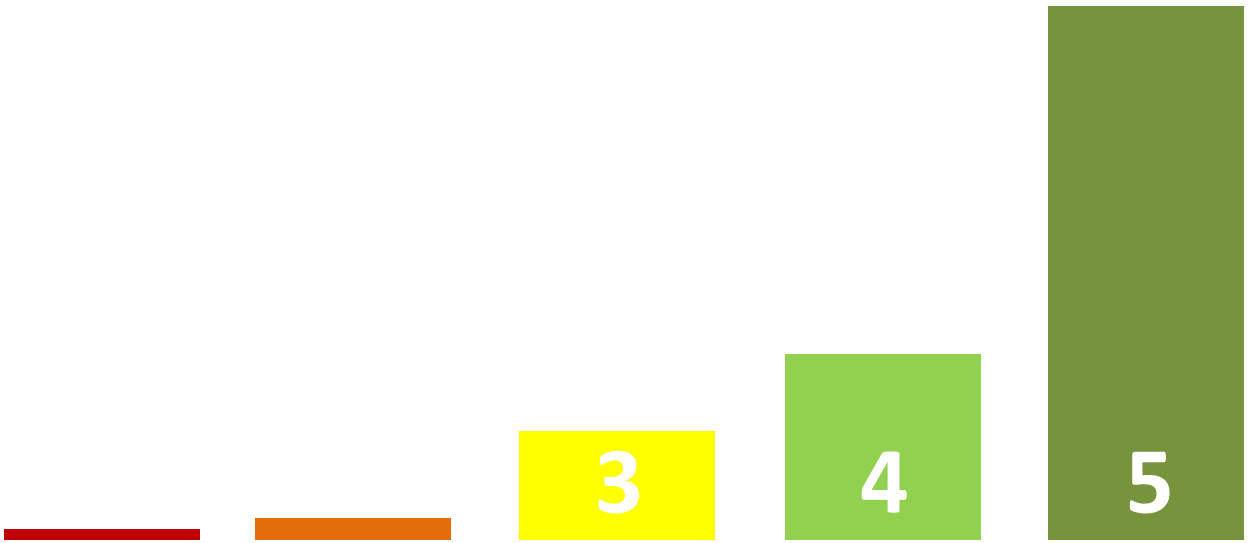
13. Ricercatori, finanziatori, sponsor, enti regolatori, comitati etici e riviste biomediche dovrebbero sviluppare e adottare in maniera sistematica standard internazionali relativi a:

- contenuto di protocolli e report completi degli studi
- procedure di condivisione dei dati

ACCESSIBILITÀ

Raccomandazione 13

Media	DS
4.41	± 0.89



EDITORIALS

Big strides in Europe towards clinical trial transparency

The EMA, EU, and UK HRA usher in an age of evidence enlightenment

Trish Groves *deputy editor*

The BMJ, London WC1H 9JR, UK

The European Medicines Agency (EMA) decided on 2 October that, for all new centralised drug marketing authorisations submitted after 1 January 2015, it will provide public access to the core content of clinical study reports and will allow researchers to download and use the reports for further analyses.[3]

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2 October 2014
EMA/240810/2013

European Medicines Agency policy on publication of clinical data for medicinal products for human use

POLICY/0070
Status: Adopted
Effective date: 1 January 2015
Review date: No later than June 2016
Supersedes: Not applicable

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 October 2016
EMA/650519/2016
Media and Public Relations

Press release

Opening up clinical data on new medicines

EMA provides public access to clinical reports

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EUROPEAN MEDICINES AGENCY

Clinical data

Home | Find Clinical Data | About

Online access to clinical data for medicinal products for human use

Easterbrook PJ, Berlin JA, Gopalan R, Matthews DR.

Publication bias in clinical research

Lancet 1991;337:867-72

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OPEN ACCESS Freely available online

PLoS MEDICINE

Trial Publication after Registration in ClinicalTrials.Gov: A Cross-Sectional Analysis

Joseph S. Ross[1,2]*, Gregory K. Mulvey[3], Elizabeth M. Hines[4], Steven E. Nissen[5], Harlan M. Krumholz[3,6,7]

1 Department of Geriatrics and Adult Development, Mount Sinai School of Medicine, New York, New York, United States of America, **2** HSR&D Research Enhancement Award Program and Geriatrics Research, Education, and Clinical Center, James J. Peters VA Medical Center, Bronx, New York, United States of America, **3** Center for Outcomes Research and Evaluation, Yale-New Haven Hospital, New Haven, Connecticut, United States of America, **4** Amherst College, Amherst, Massachusetts, United States of America, **5** Department of Cardiovascular Medicine, Cleveland Clinic, Cleveland, Ohio, United States of America, **6** Robert Wood Johnson Clinical Scholars Program and Section of Cardiolovascular Medicine, Department of Medicine, Yale University School of Medicine, New Haven, Connecticut, United States of America, **7** Section of Health Policy and Administration, Yale University School of Epidemiology and Public Health, New Haven, Connecticut, United States of America

Published September 8, 2009

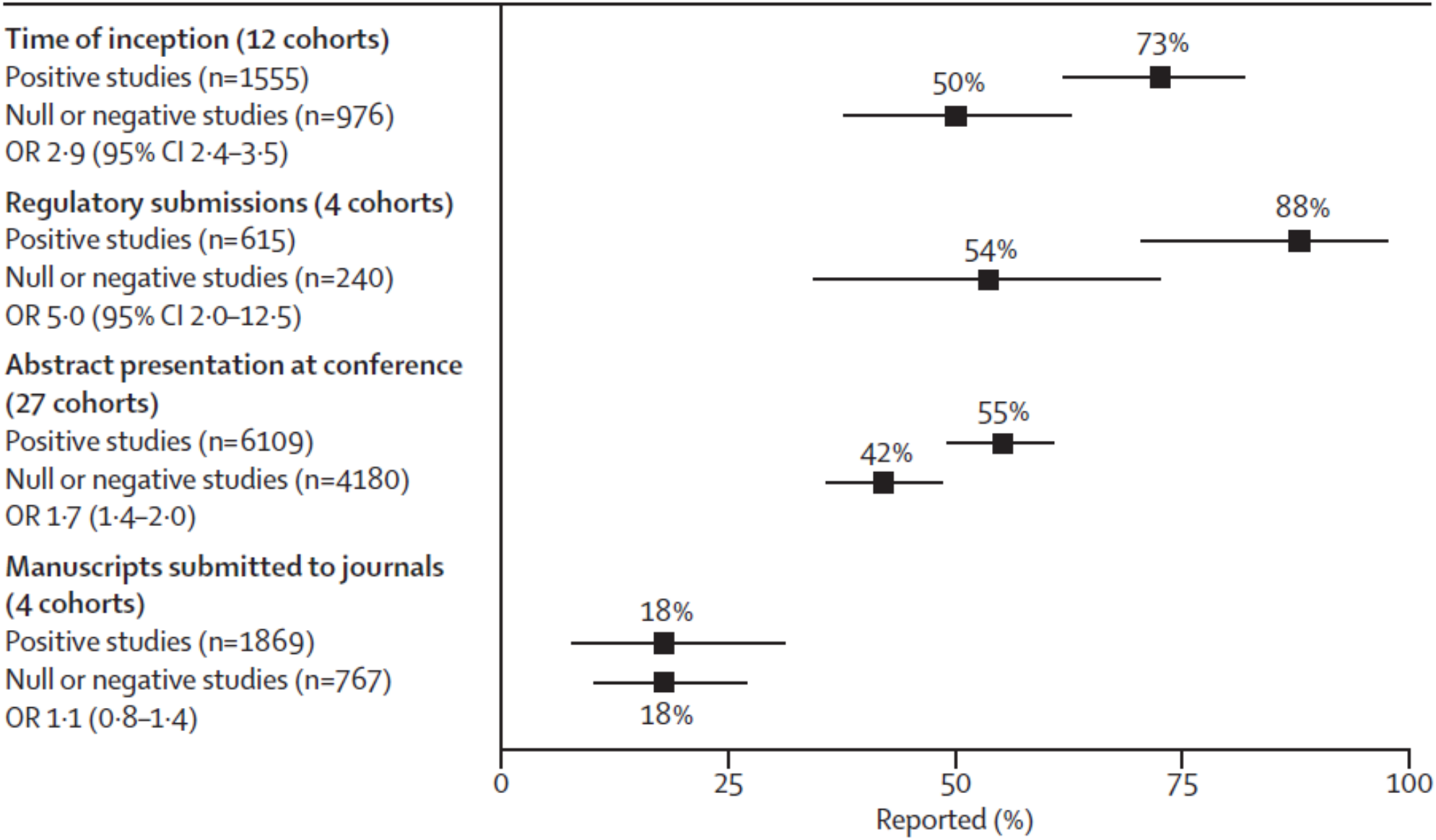


Figure 1: **Reporting of studies with positive results versus those with null or negative results tracked in cohorts from time of inception, regulatory submission, or abstract presentation, and for manuscripts submitted to journals**[3,8]

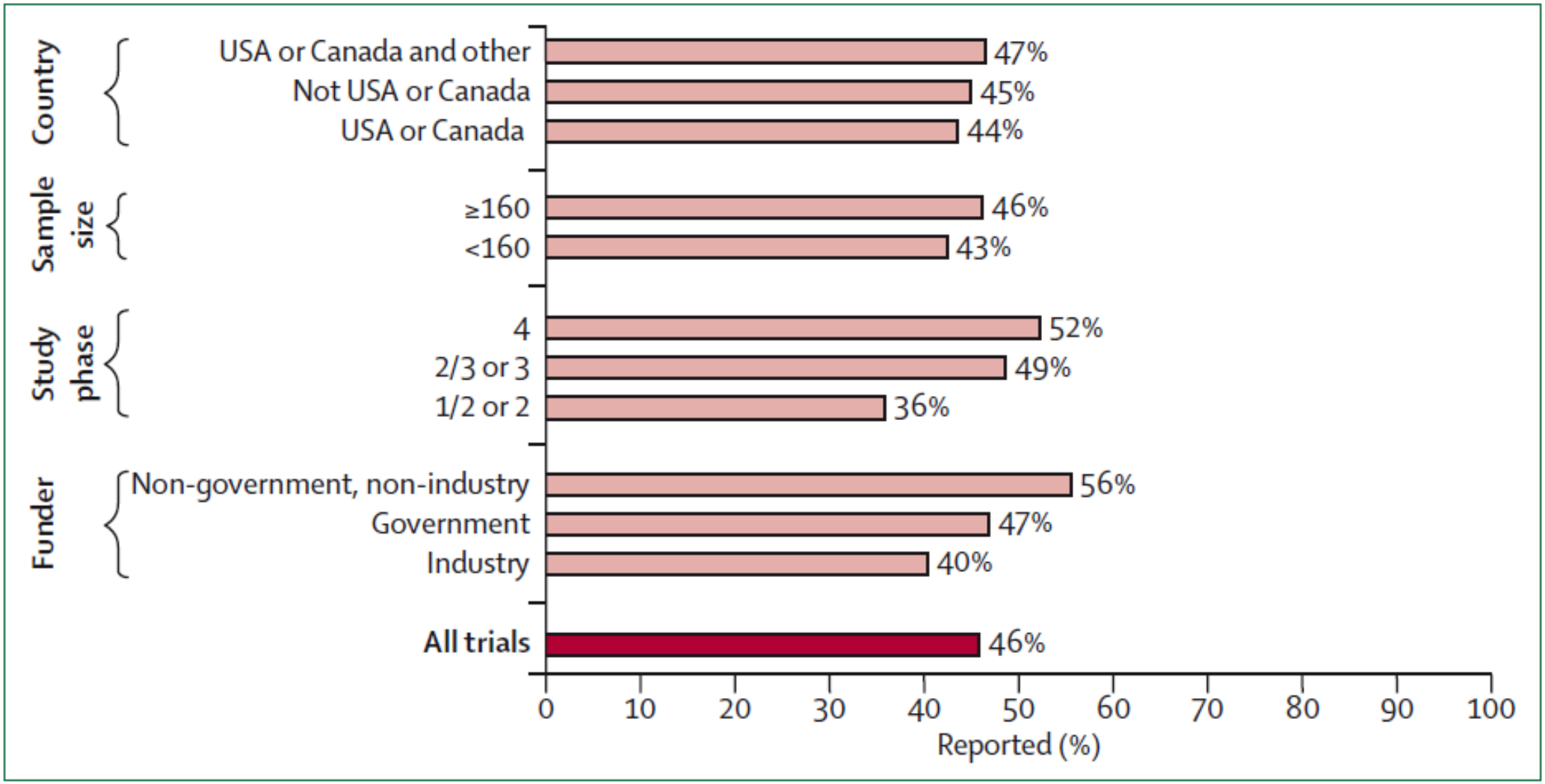


Figure 2: **Reporting of completed trials, by study characteristic**

Data taken from Ross and colleagues' analysis[11] of a random sample of 677 completed trials registered with ClinicalTrials.gov between 2000 and 2007.

10 esempi clamorosi

- Oseltamivir
- Rosiglitazon
- Gabapentin
- TGN1412
- Paroxetine
- Lorcainide
- Rofecoxib
- Celecoxib
- Ezetimibe–simvastatin
- Vitamin A and albendazole

Quali sprechi?

EU-funded health research from 1998-2006

- 6 billion of euros → 50% unpublished

Galsworthy MJ et al. Lancet 2012

Quali effetti su morbilità e mortalità?

- Rofecoxib 100.000 heart attacks in 1999-2004 (US)
- Lorcainide 50.000 deaths per year in 1980s (US)

Occultare i risultati dei trial clinici costa vite umane, spreca denaro e espone i pazienti a sofferenze e rischi evitabili: il caso della Lorcainide

2 ottobre 1999

Time to register randomised trials

The case is now unanswerable

Richard Horton *editor, Lancet*
Richard Smith *editor, BMJ*

A version of this editorial also appears in the *Lancet* this week.[12]

BMJ THE LANCET

EDITORIALS

All trials must be registered and the results published

Academics and non-commercial funders are just as guilty as industry

Iain Chalmers *coordinator*[1], Paul Glasziou *professor*[2], Fiona Godlee *editor in chief*[3]

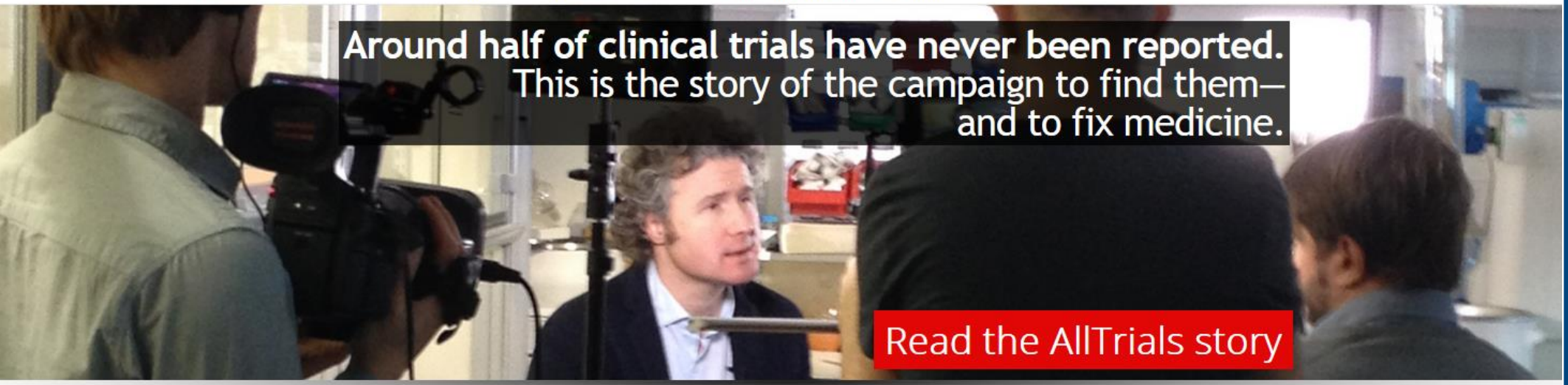
[1]James Lind Initiative, Oxford OX2 7LG, UK ; [2]Centre for Research in Evidence-Based Practice, Faculty of Health Sciences, Bond University, Gold Coast, QLD, Australia; [3]BMJ, London, UK

Español

+AllTrials

All Trials Registered | All Results Reported

Home | Find out more | Get involved | Supporters | News | **Sign the petition** | **Donate**



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Editoriale

OPEN ACCESS

Tutti i trial devono essere registrati e tutti i risultati pubblicati

Ricercatori e sponsor non commerciali hanno le stesse responsabilità dell'industria

Iain Chalmers[1*], Paul Glasziou[2], Fiona Godlee[3]

[1] James Lind Initiative, Oxford, UK, [2] Centre for Research in Evidence-Based Practice, Faculty of Health Sciences, Bond University, Australia, [3] BMJ, London, UK

Pubblicato 28 gennaio 2013

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Formazione
Ricerca
Consulenza
Sostegno iniziative
- AllTrials
- Dichiarazione di trasparenza
- International Clinical Trials' Day
- Selling Sickness

Premio Evidence
Premio Salviamo il Nostro SSN
GIMBE Awards
Report attività

Home › Cosa facciamo › Sostegno iniziative › AllTrials

AllTrials

+AllTrials

Registrare tutti i trial clinici

Riportare tutti i risultati

E' arrivato il momento di registrare tutti i trial clinici e riportarne tutti i risultati, perché la loro pubblicazione produce indubbi benefici per i pazienti, i ricercatori, i professionisti sanitari e le agenzie regolatorie di tutto il mondo.

I risultati di migliaia di trial non sono mai stati pubblicati e numerosi trial non sono mai stati registrati: di conseguenza le evidenze scientifiche emerse da questi studi - perdute per sempre - non raggiungeranno mai professionisti sanitari e ricercatori, determinando errate decisioni cliniche, mancate opportunità per migliorare la pratica professionale e inutili ripetizioni di sperimentazioni su persone e animali.

Seguici

Sostieni la Fondazione GIMBE

In primo piano

+AllTrials

Registrare tutti i trial
Riportare tutti i risultati

Migliaia di sperimentazioni cliniche non sono mai state pubblicate

Le evidenze scientifiche emerse da questi studi sono perdute per sempre e non potranno essere utilizzate da professionisti sanitari e ricercatori, determinando errate decisioni cliniche, mancate opportunità per migliorare la pratica professionale e inutili ripetizioni di trial clinici.

Oltre 500 organizzazioni (associazioni di pazienti, autorità regolatorie, società scientifiche, istituzioni accademiche) e più di 80.000 persone hanno aderito alla campagna AllTrials perché tutti i trial vengano registrati e tutti i risultati riportati.

Aderisci alla campagna AllTrials

- Scopri di più e firma la petizione: **www.alltrials.net**
- Invita la tua organizzazione ad aderire alla campagna
- Scrivi un articolo, un post, un editoriale o un comunicato per la newsletter della tua organizzazione
- Invita amici, familiari e colleghi a firmare la petizione
- Condividi la campagna su Facebook e twitta su **#AllTrials**
- Sostieni AllTrials

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sostiene AllTrials
www.gimbe.org/alltrials

www.alltrials.net

AllTrials è un'iniziativa lanciata da:

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Hot Topics

OPEN ACCESS

Occultare i risultati dei trial clinici rappresenta la violazione di un obbligo scientifico, etico e morale

Antonino Cartabellotta[1*]

[1] Presidente Fondazione GIMBE

Pubblicato 29 aprile 2013

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Box. Consigli ai pazienti invitati a partecipare a un trial clinico[17]

Accettate di partecipare ad un trial clinico solo se:

1. Il protocollo dello studio è stato registrato ed è pubblicamente accessibile.
2. Il protocollo fa riferimento a revisioni sistematiche delle evidenze disponibili che giustificano la necessità del trial.
3. Ricevete una garanzia scritta che i risultati completi dello studio saranno pubblicati e inviati a tutti i partecipanti che lo desiderano.

EDITORIALS

How medicine is broken, and how we can fix it

The chief medical officer's review on statins and oseltamivir may look for answers in the wrong places

Ben Goldacre *senior clinical research fellow*, Carl Heneghan *professor of evidence based medicine*

Centre for Evidence Based Medicine, Nuffield Department of Primary Health Care, University of Oxford, Oxford, UK

What can I do to help to fix medicine?

If I am a....

Patient group

Trial participant

Doctor or medical student

Academic or researcher

University or research institution

Learned or professional society

Scholarly publisher or journal

Shareholder or investor

Pharmaceutical company

Non-comercial trial funder

Medicines regulator

Ethics regulator

Health technology assessment agency

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Standards & Guidelines OPEN ACCESS

Rendere pubblici i risultati dei trial clinici: lo statement dell'Organizzazione Mondiale della Sanità

Organizzazione Mondiale della Sanità*

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open access journal published by the GIMBE Foundation

Editoriale OPEN ACCESS

Razionale dello statement dell'OMS sul reporting tempestivo e la pubblicazione dei risultati dei trial clinici

Vasee S. Moorthy[1*], Ghassan Karam[1], Kirsten S. Vannice[1], Marie-Paule Kieny[1]

[1]World Health Organization, Geneva, Switzerland

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

EDITORIAL

Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

Update on Trials Registration

(October 2004)

Update on Trials Registration: Is This Clinical Trial Fully Registered?: A Statement from the International Committee of Medical Journal Editors

(May 2005)

Update on Trials Registration: Clinical Trial Registration: Looking Back and Moving Ahead

(June 2007)

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ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

Le riviste affiliate richiedono agli autori di registrare i propri trial in un registro:

- accessibile gratuitamente e consultabile elettronicamente
- gestito da un'associazione no-profit
- dotato di un meccanismo che garantisca la validità dei dati di registrazione

ICMJE raccomanda di pubblicare il numero di registrazione del trial alla fine dell'abstract

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

ICMJE accetta la registrazione nei seguenti registri

- www.anzctr.org.au
- www.clinicaltrials.gov
- www.ISRCTN.org
- http://www.umin.ac.jp/ctr/index.htm
- www.trialregister.nl
- Uno dei registri primari che partecipano al progetto dell'OMS "International Clinical Trials Portal"

International Clinical Trials Registry Platform (ICTRP)

Welcome to the WHO ICTRP

The mission of the WHO International Clinical Trials Registry Platform is to ensure that a complete view of research is accessible to all those involved in health care decision making. This will improve research transparency and will ultimately strengthen the validity and value of the scientific evidence base.

WHO/P. Virot

The registration of all interventional trials is a scientific, ethical and moral responsibility.

SOFTWARE TOOL ARTICLE

The TrialsTracker: Automated ongoing monitoring of failure to share clinical trial results by all major companies and research institutions [version 1; referees: awaiting peer review]

Anna Powell-Smith, Ben Goldacre

Evidence-Based Medicine Data Lab, Centre for Evidence-Based Medicine, Nuffield Department of Primary Health Care Sciences, University of Oxford, Oxford, UK

v1 **First published:** 03 Nov 2016, **5**:2629 (doi: 10.12688/f1000research.10010.1)
Latest published: 03 Nov 2016, **5**:2629 (doi: 10.12688/f1000research.10010.1)

Who's not sharing their trial results?

Trials registered on ClinicalTrials.gov should share results on the site shortly after completing, or publish in a journal. But many organisations fail to report the results of clinical trials. We think this should change. Explore our data (last updated October 2016) to see the universities, government bodies and pharmaceutical companies that aren't sharing their clinical trial results.

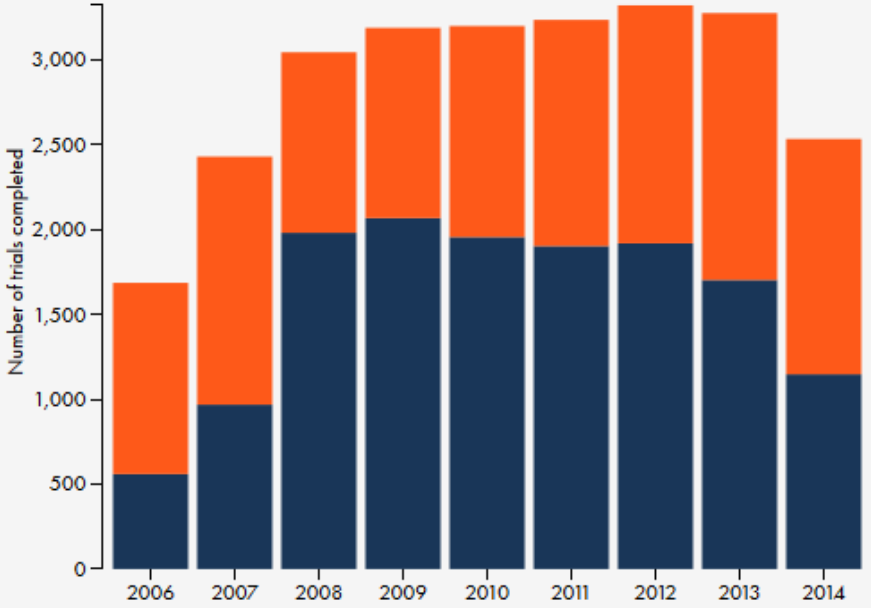
Trial sponsors

We've ranked the major trial sponsors with the most unreported trials registered on ClinicalTrials.gov. Click on a sponsor's name to find out whether it's getting better at reporting completed trials - or worse.

	Name of sponsor	Trials missing results	Total eligible trials	Percent missing
1	Sanofi	285	435	65.5%
2	Novartis Pharmaceuticals	201	534	37.6%
3	National Cancer Institute (NCI)	194	558	34.8%
4	Assistance Publique - Hôpitaux de Paris	186	292	63.7%
5	GlaxoSmithKline	183	809	22.6%
6	Mayo Clinic	157	312	50.3%
7	Yonsei University	139	194	71.6%
8	Seoul National University	131	207	63.3%

Trials by year

Since Jan 2006, **all major trial sponsors** completed 25,927 eligible trials and **haven't published results for 11,714 trials**. That means 45.2% of their trials are missing results.



Who's not sharing their trial results?

Why it matters: Clinical trials are the best way we have of testing whether a medicine is safe and effective. They can involve thousands of people, patients and healthy volunteers, and take years to complete. But trials with negative results are twice as likely to remain unreported as those with positive results. This means that patients and doctors don't have the full information about the benefits and risks of treatments. We believe all clinical trials, past and present, should be reported in full. Read more on AllTrials.net and sign the petition.

Our methodology: We regularly download details of all trials registered on ClinicalTrials.gov. We include all interventional trials completed between Jan 2006 and two years ago, except for Phase 0/1 trials and those that have made a formal request to delay results. Next, we look for summary results on ClinicalTrials.gov, or linked results on PubMed. Our table includes only sponsors with more than 30 trials: to see all sponsors, download the full dataset. We understand this method isn't perfect. However, we feel that researchers have a clear obligation to ensure that their results are published, and discoverable. If they have failed to post summary results, or to ensure the trial ID is in their PubMed entry, then their results will be listed here as missing. See our paper for full details.

How to improve your score: Hello trial sponsors! Want to improve your score? Simply post summary results on ClinicalTrials.gov, or ask your journal to add the trial's NCT ID to the PubMed entry for published results. You should see the data update shortly.

Get in touch: We welcome feedback. See our full data and code and please get in touch by email or on Twitter with feedback.

Half of medical trial results kept secret

Tom Whipple, Science Editor

November 4 2016, 12:01am,
The Times

By not publishing the results of clinical trials, researchers can skew the assessment of new treatments, campaigners say
GETTY IMAGES

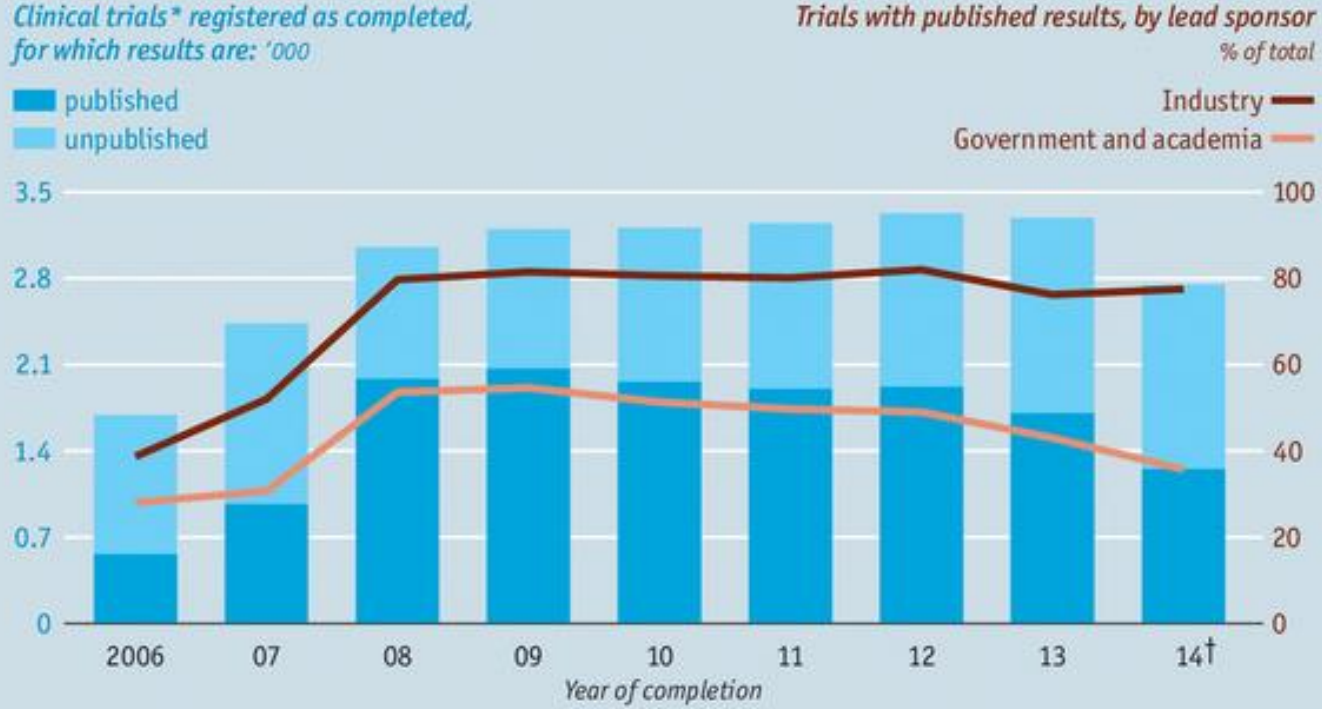
Almost half of all clinical trials worldwide still go unpublished despite repeated warnings that pharmaceutical companies and universities are endangering the public by not revealing the results of their research.

Tracking down missing clinical trials

Tested, and found wanting

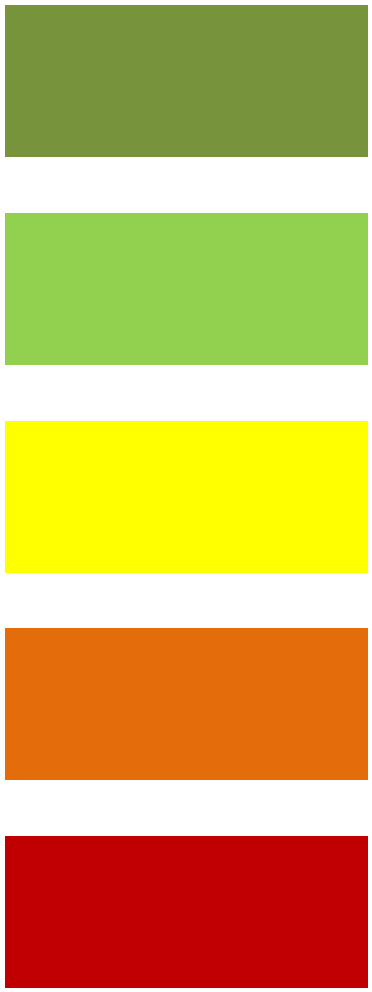
Nov 5th 2016 | From the print edition

Clinical suppression



Economist.com

Priorità raccomandazioni REWARD



5= Indispensabile

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3= Priorità intermedia

2= Priorità bassa

1= Non è una priorità

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ACCESSIBILITA'

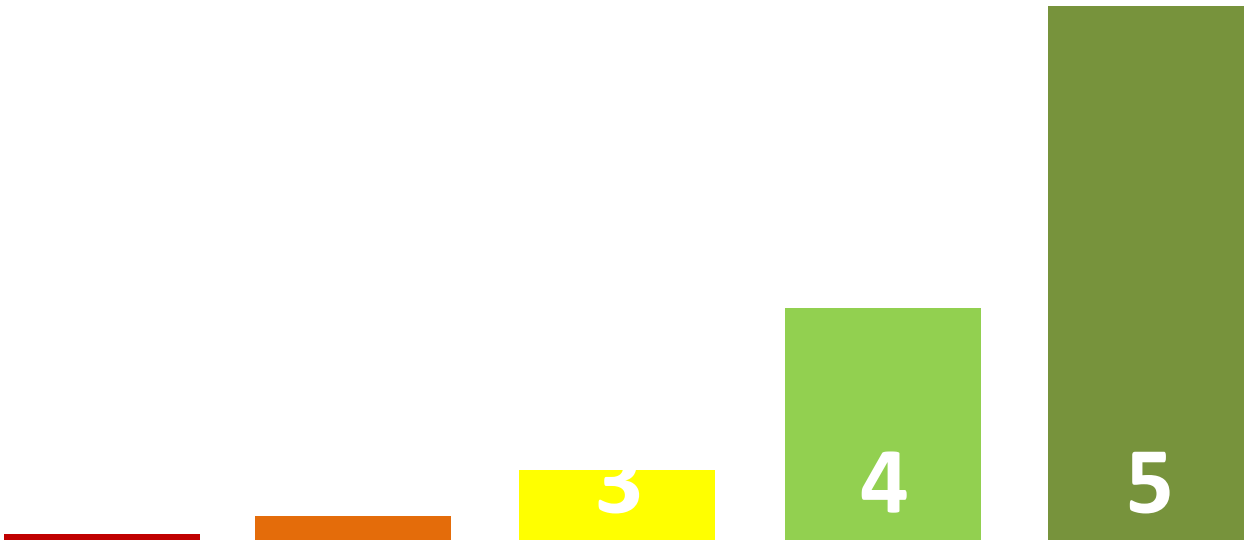
14. Finanziatori, sponsor, enti regolatori, comitati etici, riviste biomediche e legislatori dovrebbero sostenere e rafforzare per tutte le tipologie di ricerca sanitaria le policy relative a:

- registrazione degli studi
- ampia accessibilità a tutte le informazioni
- condivisione dei dati a livello di partecipante individuale

ACCESSIBILITÀ

Raccomandazione 14

Media	DS
4.49	± 0.76



RILEVANZA	METODOLOGIA	REGOLAMENTAZIONE	ACCESSIBILITÀ	USABILITÀ
Le priorità della ricerca sono definite in base a quesiti rilevanti per i destinatari?	**Il disegno dello studio, i metodi e le analisi statistiche sono adeguati?**	**La regolamentazione e la gestione della ricerca sono efficienti?**	**I dati della ricerca sono integralmente accessibili?**	**I report della ricerca sono utilizzabili e privi di bias?**
- Scarsa rilevanza dei quesiti per pazienti e professionisti sanitari - Outcome rilevanti non presi in considerazione - Studi disegnati senza alcun riferimento a revisioni sistematiche delle evidenze disponibili in oltre il 50% dei casi	- Assenza di adeguate misure per ridurre i bias in oltre il 50% degli studi - Inadeguata potenza statistica - Inadeguata replicazione di risultati preliminari	- Corresponsabilità con altre fonti di sprechi e inefficienze - Sproporzione rispetto ai rischi della ricerca - Processi di regolamentazione e gestione gravosi ed eterogenei	- Reporting incompleto in oltre il 50% degli studi - *Under reporting* di studi con risultati negativi - Bias di reporting di dati tra studi	- Inadeguata descrizione degli interventi in oltre il 30% dei trial - Mancato reporting di oltre il 50% degli outcome definiti nel protocollo - Maggior parte degli studi non interpretati nel contesto di una valutazione sistematica delle migliori evidenze

SPRECHI DELLA RICERCA

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Research: increasing value, reducing waste 5

Reducing waste from incomplete or unusable reports of biomedical research

Paul Glasziou, Douglas G Altman, Patrick Bossuyt, Isabelle Boutron, Mike Clarke, Steven Julious, Susan Michie, David Moher, Elizabeth Wager

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USABILITÀ

I report della ricerca sono utilizzabili e privi di bias?

- Inadeguata descrizione degli interventi in oltre il 30% dei trial
- Mancato reporting di oltre il 50% degli outcome definiti nel protocollo
- Maggior parte degli studi non interpretati nel contesto di una valutazione sistematica delle migliori evidenze

What is missing from descriptions of treatment in trials and reviews?

Replicating non-pharmacological treatments in practice depends on how well they have been described in research studies, say **Paul Glasziou** and **colleagues**

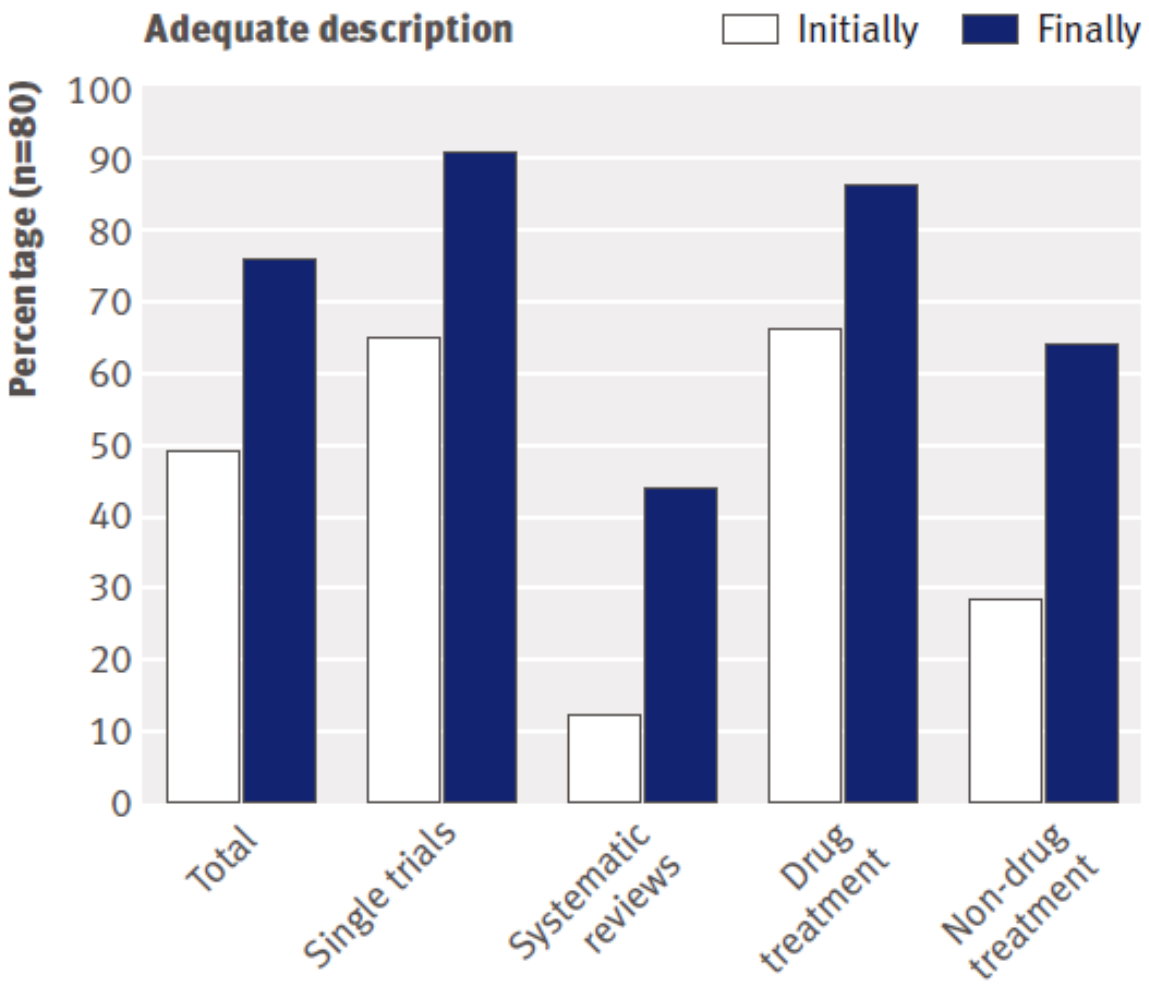

Fig 2 | Percentage of studies with sufficient description of treatment initially (based only on the published paper) and after supplementary information was obtained

RESEARCH

Poor description of non-pharmacological interventions: analysis of consecutive sample of randomised trials


OPEN ACCESS

Tammy C Hoffmann *associate professor of clinical epidemiology*, Chrissy Erueti *assistant professor*, Paul P Glasziou *professor of evidence-based medicine*

Centre for Research in Evidence-Based Practice, Faculty of Health Sciences and Medicine, Bond University, Qld, Australia, 4229

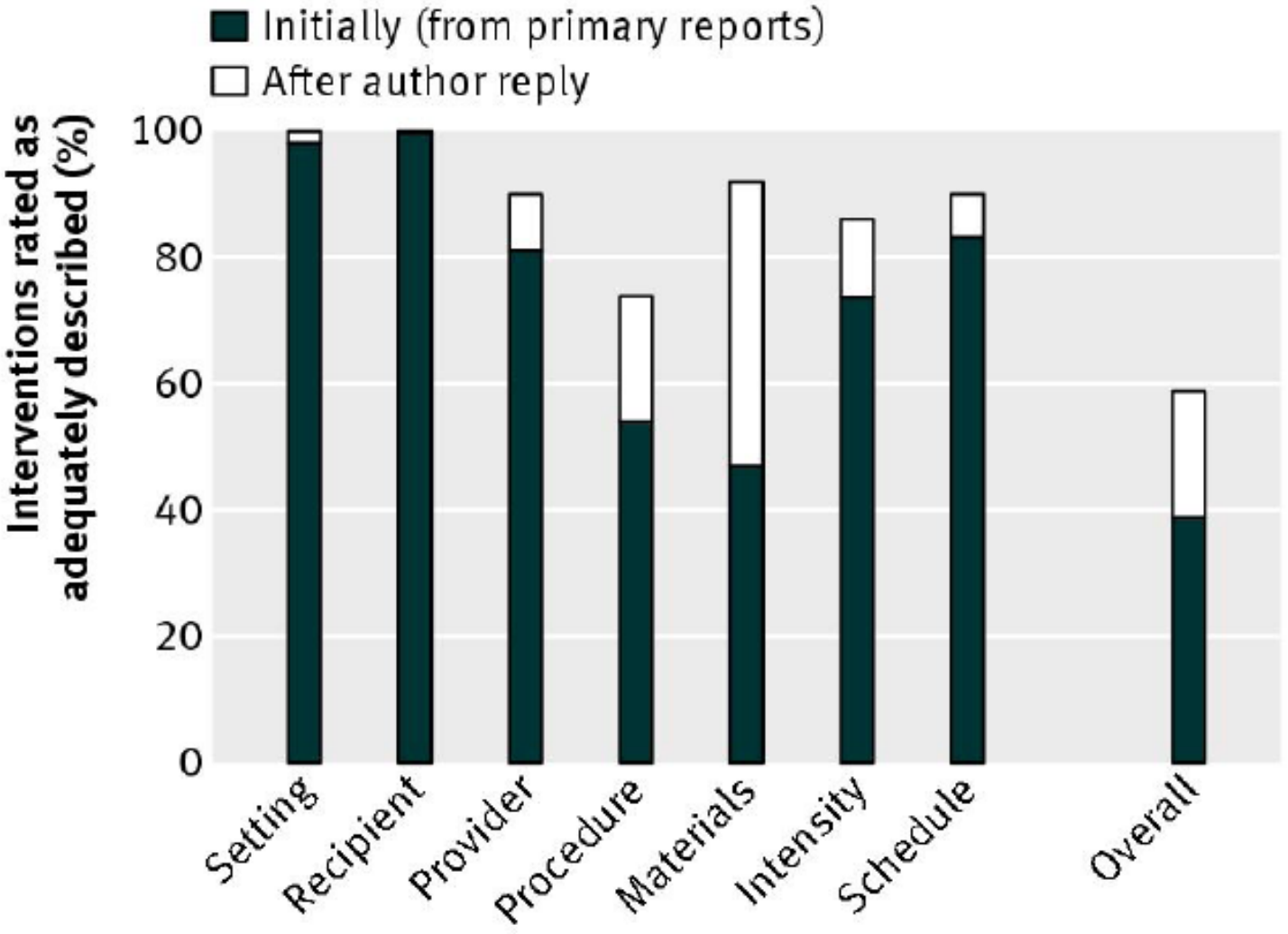

Fig 1 Percentage of interventions rated as adequately described, in primary report and after author reply, for each checklist item

Abstract
38%, 49%

Methods
40-89%, 33%
65%, 31%

Results
50%, 65%,
54%, 92%,
24%, 40%

Discussion
50%

Data
Almost all

Abstract
Trials: missing effect size and confidence interval (38%); no mention of adverse effects (49%)[72]
Methods
Trials: 40–89% inadequate treatment descriptions[11, 13] **fMRI studies:** 33% missing number of trials and durations[3] **Survey questions:** 65% missing survey or core questions[25] **Figures:** 31% graphs ambiguous[45]
Results
Clinical trials: outcomes missing: 50% efficacy and 65% harm outcomes per trial incompletely reported[6] **Animal studies:** number of animals and raw data missing[17] (54%, 92%); age and weight missing (24%) **Diagnostic studies:** missing age and sex (40%)[15]
Discussion
Trials: no systematic attempt to set new results in context of previous trials (50%)[69]
Data
Trials: most data never made available; author-held data lost at about 7% per year

***Figure* 3: Estimates of the prevalence of some reporting problems (see publication column, figure 1).**
fMRI=functional MRI.

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Frequency and reasons for outcome reporting bias in clinical trials: interviews with trialists

BMJ 2010;341:c7153

R M D Smyth, research associate,[1,2] J J Kirkham, research associate,[1] A Jacoby, professor of medical sociology,[2] D G Altman, professor of statistics in medicine,[3] C Gamble, senior lecturer,[1] P R Williamson, professor of medical statistics[1]

WHAT IS ALREADY KNOWN ON THIS TOPIC

Outcome reporting bias is the selection for publication of a subset of the original recorded outcomes on the basis of the results

Outcome reporting bias has been identified as a threat to evidence based medicine because clinical trial outcomes with statistically significant results are more likely to be published

WHAT THIS STUDY ADDS

The prevalence of incomplete outcome reporting is high

This study has, for the first time, provided a detailed understanding of why trialists do not report previously specified outcomes

Trialists seem to be generally unaware of the implications for the evidence base of not reporting all outcomes and protocol changes

Tracking switched outcomes in clinical trials

COMPare (CEBM Outcome Monitoring Project) takes a new approach. We are monitoring all trials published in the top five medical journals (NEJM, JAMA, The Lancet, Annals of Internal Medicine, BMJ).

We are analysing each trial for outcome switching, by comparing the protocol (or registry entry if a pre-trial protocol is unavailable) with the trial report. For any trial where we find that outcomes have been switched, we are writing letters to the journal to correct the record.

67
TRIALS CHECKED

9
TRIALS WERE PERFECT

354
OUTCOMES NOT REPORTED

357
NEW OUTCOMES SILENTLY ADDED

On average, each trial reported just 58.2% of its specified outcomes. And on average, each trial silently added 5.3 new outcomes.

58
LETTERS SENT

18
LETTERS PUBLISHED

8
LETTERS UNPUBLISHED AFTER 4 WEEKS

32
LETTERS REJECTED BY EDITOR

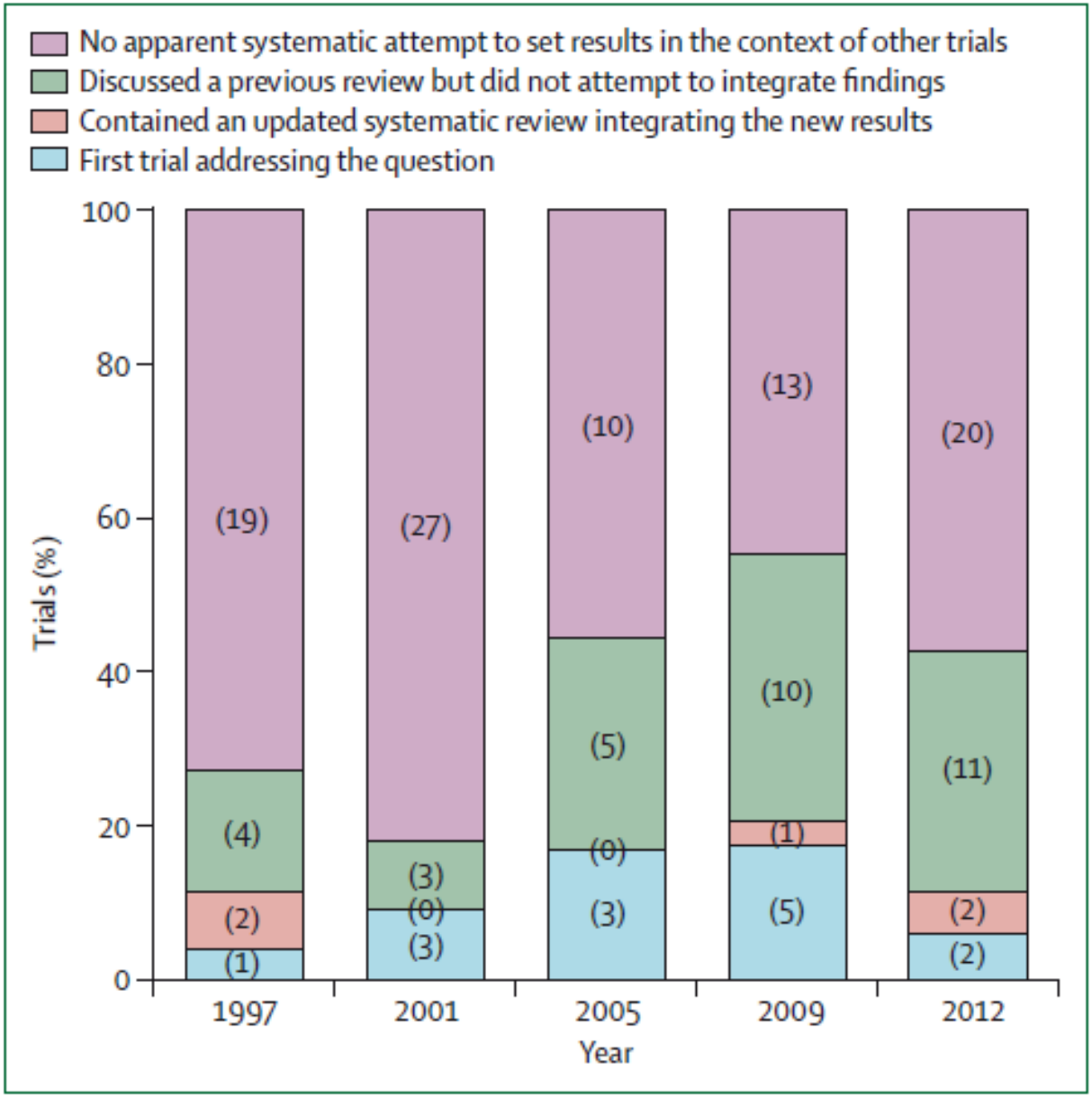

***Figure* 2: Percentage (and number) of trials that set their results in the context of a systematic review by 4 year intervals**
Data from references 69 and 70.

Further emphasis on research in context

Sabine Kleinert, Laura Benham, David Collingridge, William Summerskill, Richard Horton

www.thelancet.com **Vol 384 December 20/27, 2014**

Panel: Research in context

Evidence before this study

This section should include a description of all the evidence that the authors considered before undertaking this study. Authors should state: the sources (databases, journal or book reference lists, etc) searched; the criteria used to include or exclude studies (including the exact start and end dates of the search), which should not be limited to English language publications; the search terms used; the quality (risk of bias) of that evidence; and the pooled estimate derived from meta-analysis of the evidence, if appropriate.

Added value of this study

Authors should describe here how their findings add value to the existing evidence (including an updated meta-analysis, if appropriate).

Implications of all the available evidence

Authors should state the implications for practice or policy and future research of their study combined with existing evidence.

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Library for health research reporting

The Library contains a comprehensive searchable database of reporting guidelines and also links to other resources relevant to research reporting.

- Search for reporting guidelines
- Not sure which reporting guideline to use?
- Reporting guidelines under development
- Visit the library for more resources

Reporting guidelines for main study types

Randomised trials	CONSORT	Extensions	Other
Observational studies	STROBE	Extensions	Other
Systematic reviews	PRISMA	Extensions	Other
Case reports	CARE	Extensions	Other
Qualitative research	SRQR	COREQ	Other
Diagnostic / prognostic studies	STARD	TRIPOD	Other
Quality improvement studies	SQUIRE		Other
Economic evaluations	CHEERS		Other
Animal pre-clinical studies	ARRIVE		Other
Study protocols	SPIRIT	PRISMA-P	Other

See all 343 reporting guidelines

Funders: reporting guidelines key for research reproducibility and reliability

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AGREE Reporting Checklist

Checklist per il reporting delle linee guida

www.evidence.it/AGREE-checklist

CARE – Linee guida CAse REport

Linee guida per il reporting dei casi clinici

www.evidence.it/CARE

CONSORT Statement 2010

Linee guida per il reporting dei trial controllati randomizzati

www.evidence.it/CONSORT

PRISMA Statement

Linee guida per il reporting di revisioni sistematiche e meta-analisi di trial controllati randomizzati

www.evidence.it/PRISMA

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SQUIRE

SQUIRE Guidelines
Linee guida per il reporting degli studi sul miglioramento della qualità dell'assistenza sanitaria
www.evidence.it/SQUIRE

SPIRIT ☑

SPIRIT Statement
Linee guida per la stesura dei protocolli dei trial clinici
www.evidence.it/SPIRIT

STARD

STARD 2015
Linee guida per il reporting degli studi di accuratezza diagnostica
www.evidence.it/STARD

Turner *et al. Systematic Reviews* 2012, **1**:60
http://www.systematicreviewsjournal.com/content/1/1/60

SYSTEMATIC REVIEWS

RESEARCH Open Access

Does use of the CONSORT Statement impact the completeness of reporting of randomised controlled trials published in medical journals? A Cochrane review[a]

Lucy Turner[1], Larissa Shamseer[1], Douglas G Altman[2], Kenneth F Schulz[3] and David Moher[1,4*]

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Consolidated standards of reporting trials (CONSORT) and the completeness of reporting of randomised controlled trials (RCTs) published in medical journals (Review)

Turner L, Shamseer L, Altman DG, Weeks L, Peters J, Kober T, Dias S, Schulz KF, Plint AC, Moher D

THE COCHRANE COLLABORATION®

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CONSORT Checklist Item	# of Evaluations	# of RCTs	RR	99% CI
Title and Abstract	7	1,233	1.13	(0.96, 1.33)
Introduction	5	513	1.07	(1.01, 1.14)
Participants	6	683	0.95	(0.56, 1.62)
Interventions	6	638	1.00	(0.95, 1.05)
Objectives	5	540	1.01	(0.96, 1.06)
Outcomes	8	1,302	1.17	(0.95, 1.44)
Sample Size	11	1,843	1.61	(1.13, 2.29)
Sequence Generation	14	2,231	1.59	(1.38, 1.84)
Allocation Concealment	16	2,396	1.81	(1.25, 2.62)
Implementation	5	498	1.47	(0.65, 3.32)
Blinding of Paticipants	5	711	1.39	(0.87, 2.22)
Blinding of Intervention	5	710	1.25	(0.74, 2.12)
Blinding of Outcome Assessor	5	719	1.72	(0.69, 4.30)
Blinding of Data Analyst	3	497	3.56	(0.40, 31.8)
Blinding Any description	8	1,851	1.23	(0.93, 1.62)
Statistical Methods	9	894	1.03	(0.90, 1.18)
Participant Flow	16	2,461	1.16	(0.94, 1.44)
Recruitment	6	959	1.03	(0.75, 1.41)
Baseline Data	5	529	1.07	(0.94, 1.22)
Numbers Analysed	13	2,145	1.23	(0.98, 1.55)
Outcomes and Estimation	6	617	1.00	(0.95, 1.05
Ancillary Analyses	4	378	1.31	(0.48, 3.58)
Adverse Events	8	911	1.14	(0.86, 1.52)
Interpretation	5	540	1.01	(0.96, 1.06)
Generalisability	5	540	1.22	(0.88, 1.70)
Overall Evidence	4	317	1.03	(0.91, 1.17)

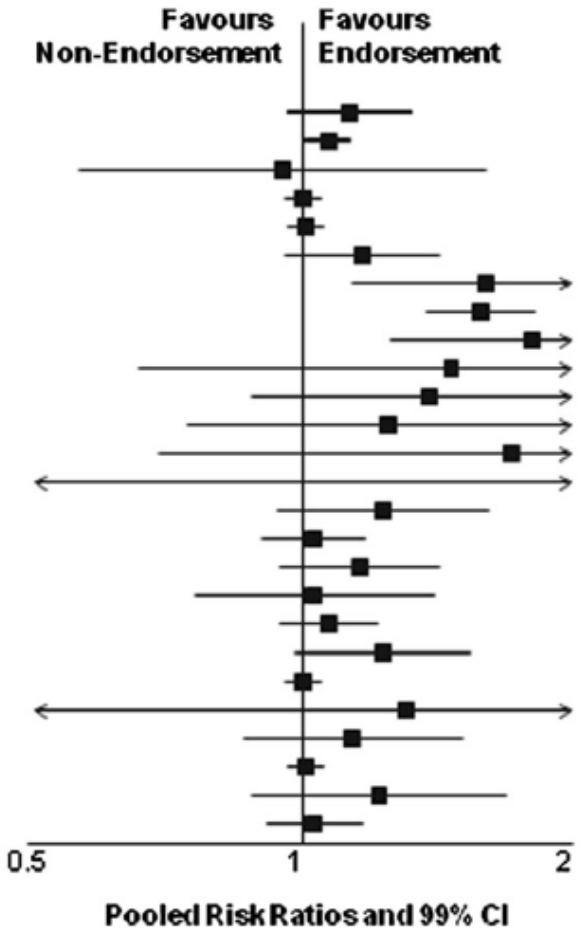
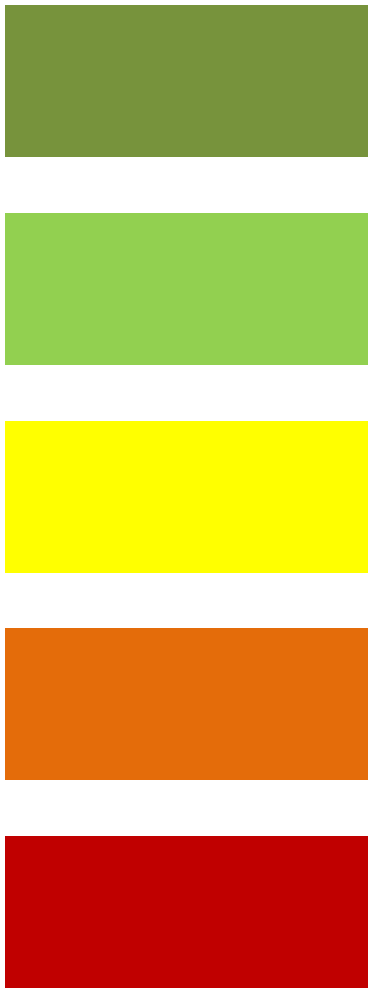


Figure 2 Pooled relative risks across assessed 2001 CONSORT checklist items with 99% confidence intervals for primary comparison, adherence of RCTs published in CONSORT-endorsing journals compared to RCTs published in CONSORT non-endorsing journals.

Priorità raccomandazioni REWARD



5= Indispensabile

4= Priorità elevata

3= Priorità intermedia

2= Priorità bassa

1= Non è una priorità

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USABILITA'

15. Finanziatori ed enti di ricerca devono allineare i criteri di regolamentazione e incentivazione della ricerca al miglioramento della qualità e completezza del reporting

USABILITÀ

Raccomandazione 15

Media	DS
4.52	± 0.74

USABILITA'

16. Finanziatori e enti di ricerca dovrebbero assumersi la responsabilità di realizzare infrastrutture di reporting, al fine di supportare buone pratiche di reporting e archiviazione

Raccomandazione 16

Media	DS
4.49	± 0.82

USABILITA'

17. Finanziatori, enti di ricerca ed editori dovrebbero migliorare le potenzialità e le capacità di autori e revisori al fine di garantire un reporting completo e di elevata qualità

Raccomandazione 17

Media	DS
4.44	± 0.87