sense about science

+AllTrials

All trials registered, all results reported **the publisher's role**

Síle Lane
slane@senseaboutscience.org

No entry

AllTrials campaign

All trials past and present should be registered, and the full methods and the results reported.

All Trials Registered | All Results Reported

www.AllTrials.net

Make clinical trials count

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Link to video:
https://youtu.be/1bnN0KebX-s

87,000 people and 625 organisations

@senseaboutsci www.senseaboutscience.org #AllTrials

Keeping results hidden is a betrayal of patients' trust

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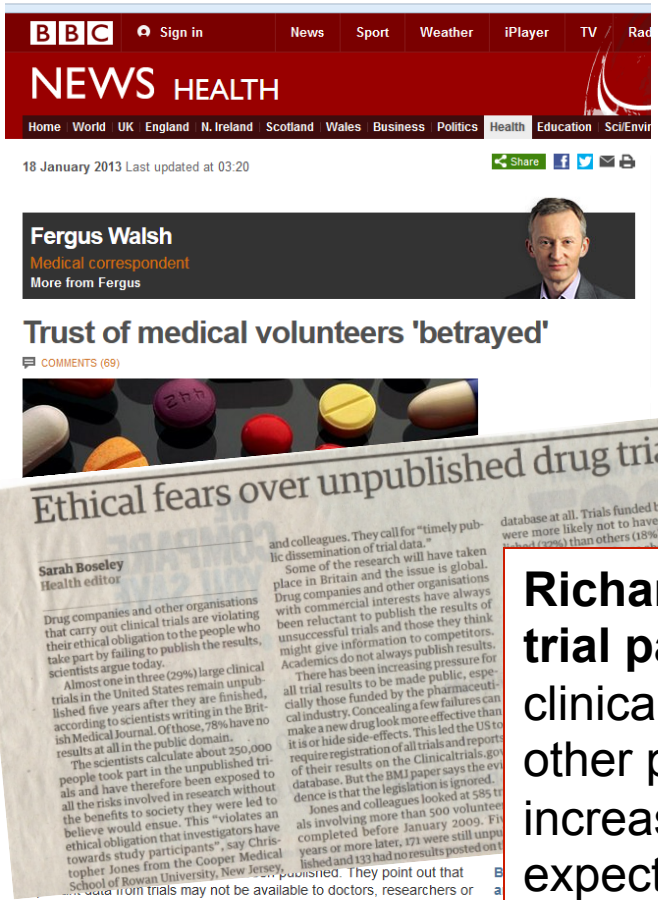

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18 January 2013 Last updated at 03:20

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Fergus Walsh
Medical correspondent
More from Fergus

Trust of medical volunteers 'betrayed'

COMMENTS (69)

Ethical fears over unpublished drug trials

Sarah Boseley
Health editor

Drug companies and other organisations that carry out clinical trials are violating their ethical obligation to the people who take part by failing to publish the results, scientists argue today.

Almost one in three (29%) large clinical trials in the United States remain unpublished five years after they are finished, according to scientists writing in the British Medical Journal. Of those, 78% have no results at all in the public domain.

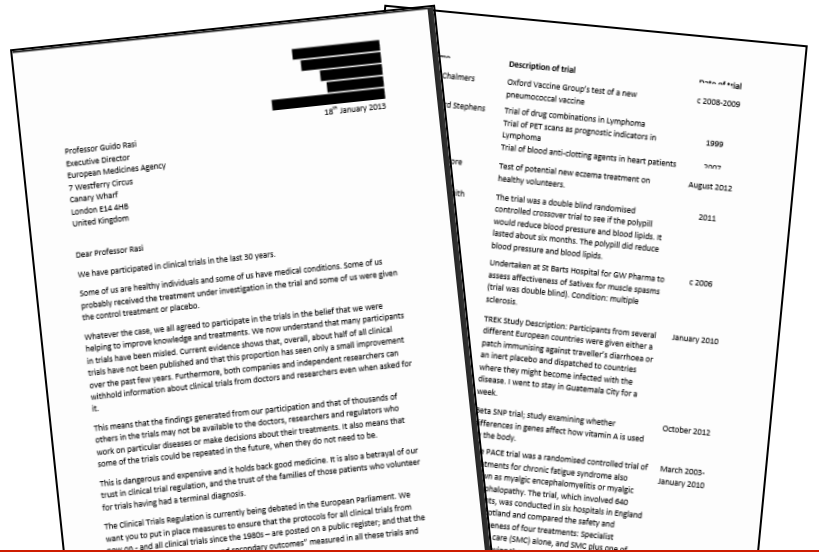
The scientists calculate about 250,000 people took part in the unpublished trials and have therefore been exposed to all the risks involved in research without the benefits to society they were led to believe would ensue. This "violates an ethical obligation that investigators have towards study participants", say Christopher Jones from the Cooper Medical School of Rowan University, New Jersey, and colleagues. They call for "timely public dissemination of trial data."

Some of the research will have taken place in Britain and the issue is global. Drug companies and other organisations with commercial interests have always been reluctant to publish the results of unsuccessful trials and those they think might give information to competitors. Academics do not always publish results.

There has been increasing pressure for all trial results to be made public, especially those funded by the pharmaceutical industry. Concealing a few failures can make a new drug look more effective than it is or hide side-effects. This led the US to require registration of all trials and reporting of their results on the Clinicaltrials.gov database. But the BMJ paper says the evidence is that the legislation is ignored.

Jones and colleagues looked at 585 trials involving more than 500 volunteers completed before January 2009. Five years or more later, 171 were still unpublished and 133 had no results posted on the database at all. Trials funded by industry were more likely not to have been published (29%) than others (18%).

Data from trials may not be available to doctors, researchers or regulators who work on particular diseases.



18th January 2013

Professor Guido Rasi
Executive Director
European Medicines Agency
7 Westferry Circus
Canary Wharf
London E14 4HB
United Kingdom

Dear Professor Rasi

We have participated in clinical trials in the last 30 years.

Some of us are healthy individuals and some of us have medical conditions. Some of us probably received the treatment under investigation in the trial and some of us were given the control treatment or placebo.

Whatever the case, we all agreed to participate in the trials in the belief that we were helping to improve knowledge and treatments. We now understand that many participants in trials have been misled. Current evidence shows that, overall, about half of all clinical trials have not been published and that this proportion has seen only a small improvement over the past few years. Furthermore, both companies and independent researchers can withhold information about clinical trials from doctors and researchers even when asked for it.

This means that the findings generated from our participation and that of thousands of others in the trials may not be available to the doctors, researchers and regulators who work on particular diseases or make decisions about their treatments. It also means that some of the trials could be repeated in the future, when they do not need to be.

This is dangerous and expensive and it holds back good medicine. It is also a betrayal of our trust in clinical trial regulation, and the trust of the families of those patients who volunteer for trials having had a terminal diagnosis.

The Clinical Trials Regulation is currently being debated in the European Parliament. We want you to put in place measures to ensure that the protocols for all clinical trials from [illegible] and all clinical trials since the 1980s – are posted on a public register; and that the [illegible] secondary outcomes" measured in all these trials and

Description of trial

Oxford Vaccine Group's test of a new pneumococcal vaccine	c 2008-2009
Trial of drug combinations in Lymphoma	
Trial of PET scans as prognostic indicators in Lymphoma	1999
Trial of blood anti-clotting agents in heart patients	
Test of potential new eczema treatment on healthy volunteers.	August 2012
The trial was a double blind randomised controlled crossover trial to see if the polypill would reduce blood pressure and blood lipids. It lasted about six months. The polypill did reduce blood pressure and blood lipids.	2011
Undertaken at St Barts Hospital for GW Pharma to assess affectiveness of Sativex for muscle spasms (trial was double blind). Condition: multiple sclerosis.	c 2006
TREK Study Description: Participants from several different European countries were given either a patch immunising against traveller's diarrhoea or an inert placebo and dispatched to countries where they might become infected with the disease. I went to stay in Guatemala City for a week.	January 2010
SNP trial; study examining whether differences in genes affect how vitamin A is used the body.	October 2012
PACE trial was a randomised controlled trial of atments for chronic fatigue syndrome also wn as myalgic encephalomyelitis or myalgic phalopathy. The trial, which involved 640 ts, was conducted in six hospitals in England ntland and compared the safety and eness of four treatments: Specialist care (SMC) alone, and SMC plus one of	March 2003-January 2010

Richard Stephens, a cancer patient and clinical trial participant: "Patients who choose to take part in clinical trials believe that by doing so, we are helping other patients in the future. We participate in order to increase knowledge and to help others. We do not expect the knowledge to be kept secret or the help for others to be denied."

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Department of Health
PARLIAMENT of CANADA
FEDERAL REGISTER
Vol. 79 Friday,
No. 225 November 21, 2014
Part II
Department of Health and Human Services
42 CFR Part 11
Clinical Trials Registration and Results Submission; Proposed Rule
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH
NHS
Health Research Authority
FEDERAL REGISTER
The Daily Journal of the United States Government
Notice
Announcement of a Draft NIH Policy on Dissemination of NIH-Funded Clinical Trial Information
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Sharing Clinical Trial Data
MAXIMIZING BENEFITS, MINIMIZING RISK
INSTITUTE OF MEDICINE

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Deborah Zarin, Director of ClinicalTrials.gov: "This is a statement that the expectations have changed: if you're a researcher or a research sponsor, there's going to be an expectation that you're going to make data available at the end of your study"

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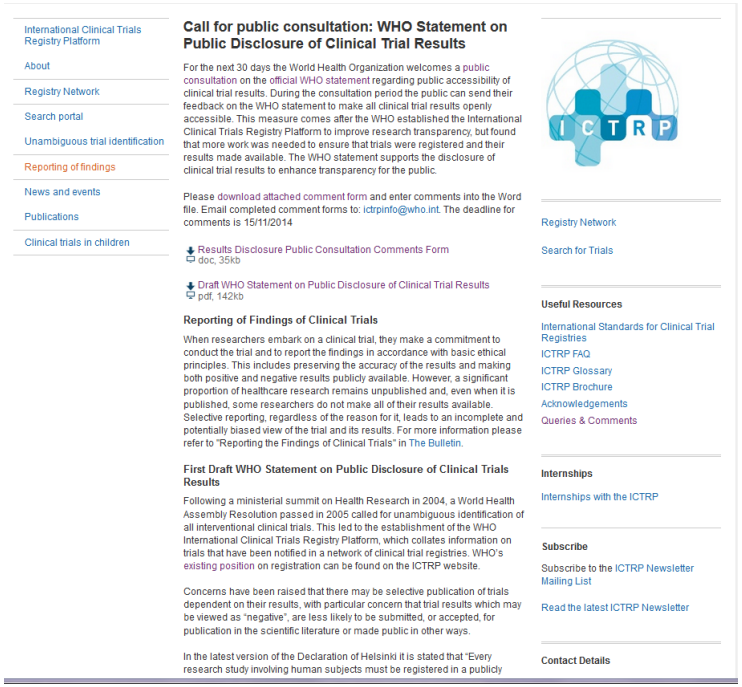
World Health Organization



International Clinical Trials Registry Platform

About

Registry Network

Search portal

Unambiguous trial identification

Reporting of findings

News and events

Publications

Clinical trials in children

Call for public consultation: WHO Statement on Public Disclosure of Clinical Trial Results

For the next 30 days the World Health Organization welcomes a public consultation on the official WHO statement regarding public accessibility of clinical trial results. During the consultation period the public can send their feedback on the WHO statement to make all clinical trial results openly accessible. This measure comes after the WHO established the International Clinical Trials Registry Platform to improve research transparency, but found that more work was needed to ensure that trials were registered and their results made available. The WHO statement supports the disclosure of clinical trial results to enhance transparency for the public.

Please download attached comment form and enter comments into the Word file. Email completed comment forms to: ictrpinfo@who.int. The deadline for comments is 15/11/2014

Results Disclosure Public Consultation Comments Form
doc, 35kb

Draft WHO Statement on Public Disclosure of Clinical Trial Results
pdf, 142kb

Reporting of Findings of Clinical Trials

When researchers embark on a clinical trial, they make a commitment to conduct the trial and to report the findings in accordance with basic ethical principles. This includes preserving the accuracy of the results and making both positive and negative results publicly available. However, a significant proportion of healthcare research remains unpublished and, even when it is published, some researchers do not make all of their results available. Selective reporting, regardless of the reason for it, leads to an incomplete and potentially biased view of the trial and its results. For more information please refer to "Reporting the Findings of Clinical Trials" in The Bulletin.

First Draft WHO Statement on Public Disclosure of Clinical Trials Results

Following a ministerial summit on Health Research in 2004, a World Health Assembly Resolution passed in 2005 called for unambiguous identification of all interventional clinical trials. This led to the establishment of the WHO International Clinical Trials Registry Platform, which collates information on trials that have been notified in a network of clinical trial registries. WHO's existing position on registration can be found on the ICTRP website.

Concerns have been raised that there may be selective publication of trials dependent on their results, with particular concern that trial results which may be viewed as "negative", are less likely to be submitted, or accepted, for publication in the scientific literature or made public in other ways.

In the latest version of the Declaration of Helsinki it is stated that "Every research study involving human subjects must be registered in a publicly

ICTRP

Registry Network

Search for Trials

Useful Resources

International Standards for Clinical Trial Registries
ICTRP FAQ
ICTRP Glossary
ICTRP Brochure
Acknowledgements
Queries & Comments

Internships

Internships with the ICTRP

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"Researchers have an ethical imperative to make results from all clinical trials – including past trials – publicly available"

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GlaxoSmithKline

GlaxoSmithKline to publish clinical trial data

GSK becomes first major pharmaceutical company to commit to publishing the results of all its drug trials

ClinicalStudy DataRequest.com

Johnson & Johnson

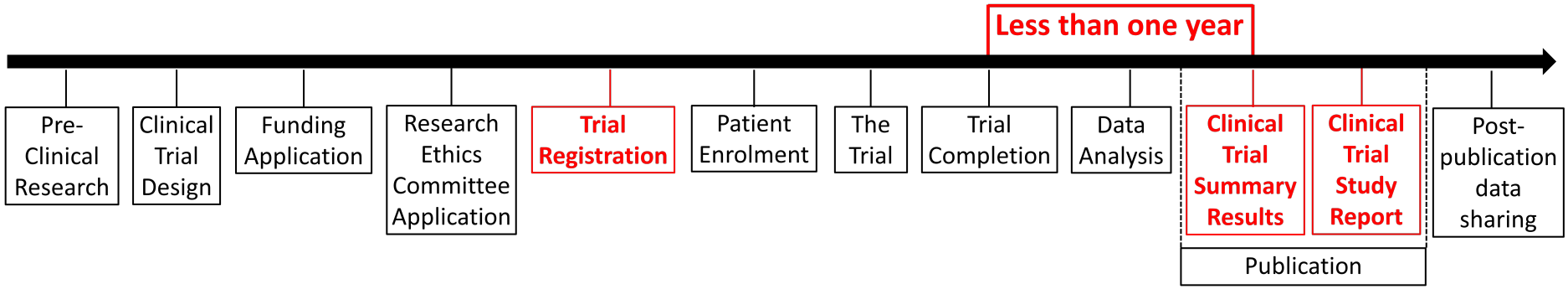
In Stunning Win For Open Science, Johnson & Johnson Decides To Release Its Clinical Trial Data To Researchers

Bristol-Myers Squibb

Bristol-Myers Squibb Expands Access to Clinical Trial Data Through Collaboration with Academic Research Institute

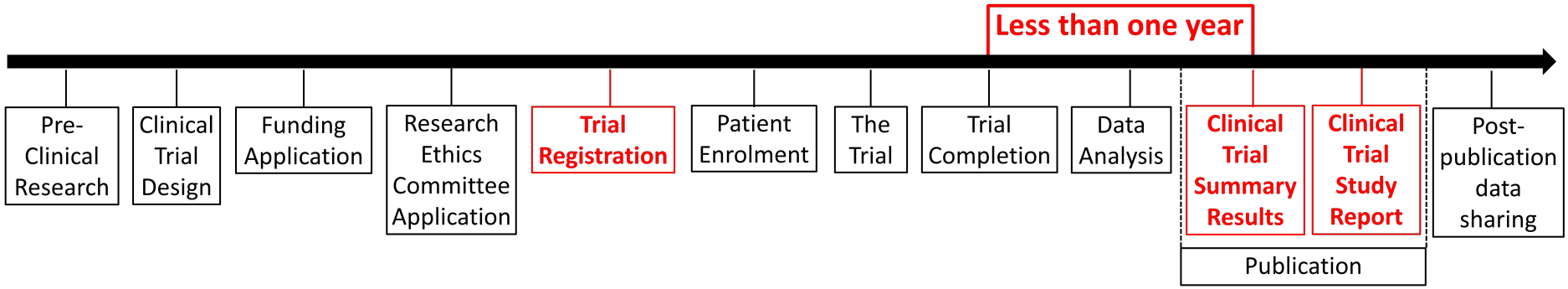
Join AllTrials

- Write editorials
- Internal communications for employees
- Watch, share and post the AllTrials videos
- Host AllTrials button on websites
- Join the campaign as individuals



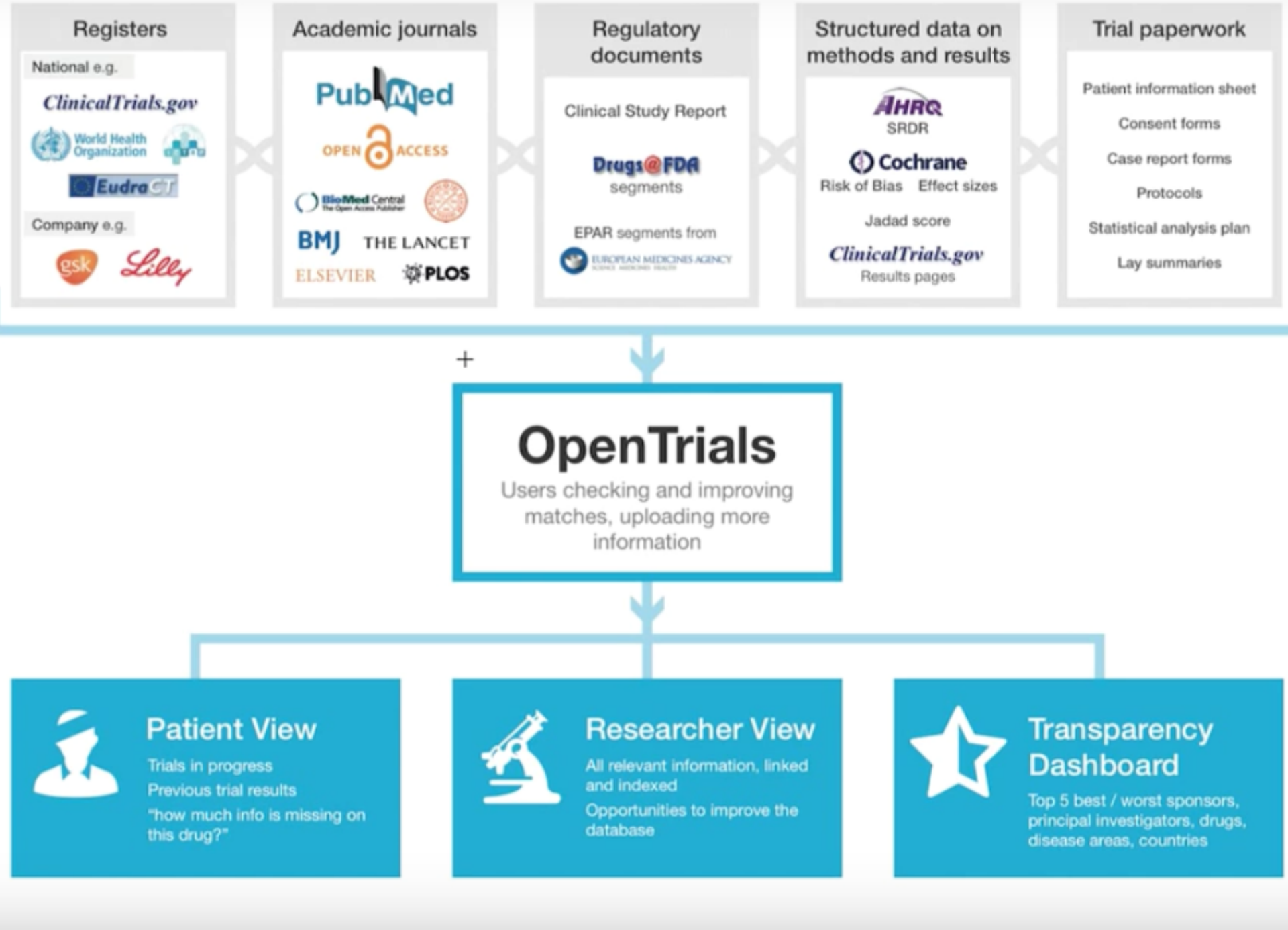
Journal Policy

- Adhere to ICMJE policy on registration
  - 20 data fields in public trial register
  - Prior to patient enrolment
  - Condition of publication
- Add to published papers
  - Registration ID
  - Date of registration, trial commencement, trial completion, summary results posted to clinicaltrials.gov, article submission
  - "Red flag" unregistered/late trials
- Ensure authors commit to releasing data set
- Audit compliance with own policies, share results publicly



"We envision this as both a strategic advisory role on how publishers can contribute, and a technical and operational one exploring how we can embed clinical trial registration in our peer review processes, in new rules for authors, and in collaborating with fellow publishers to develop new industry standards."

"The AllTrials campaign comes at a time when there is much needed attention on the problems of reliability in medical research and we are looking forward to working with the campaign and like-minded organizations to leverage this momentum for the benefit of science and, ultimately, patient care."


Registers
National e.g.
ClinicalTrials.gov
World Health Organization
EudraCT
Company e.g.
gsk
Lilly
Academic journals
PubMed
OPEN ACCESS
BioMed Central
BMJ
THE LANCET
ELSEVIER
PLOS
Regulatory documents
Clinical Study Report
Drugs@FDA
segments
EPAR segments from
EUROPEAN MEDICINES AGENCY
Structured data on methods and results
AHRQ
SRDR
Cochrane
Risk of Bias
Effect sizes
Jadad score
ClinicalTrials.gov
Results pages
Trial paperwork
Patient information sheet
Consent forms
Case report forms
Protocols
Statistical analysis plan
Lay summaries
+
OpenTrials
Users checking and improving matches, uploading more information
Patient View
Trials in progress
Previous trial results
"how much info is missing on this drug?"
Researcher View
All relevant information, linked and indexed
Opportunities to improve the database
Transparency Dashboard
Top 5 best / worst sponsors, principal investigators, drugs, disease areas, countries

langland

PLOS

ecancer

SAGE

BioMed Central
The Open Access Publisher

MedSci

BMJ

WILEY

PJ Publications

WAME
world association of medical editors

ELSEVIER

eLIFE

F1000Trials

HEALTH PRESS

Sage
BIONETWORKS

dtb
Drug and Therapeutics Bulletin
THE INDEPENDENT REVIEW OF MEDICAL TREATMENT

Journal of Kathmandu Medical College
2012
JKMC

European Journal of
Hospital Pharmacy:
Science & Practice
Helping hospital pharmacists to provide better patient care

MJA
The Medical Journal of Australia

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Síle Lane
slane@senseaboutscience.org