



Working together to help fix medicine.

AllTrials campaigns for all clinical trials - past, present and future - to be registered, and their methods and results to be fully reported.

- 1. Trial registration.** All clinical trials should be registered, with a full trial protocol, before the first participant is recruited.
- 2. Results posting.** A summary of results, including information on the primary and any secondary outcomes measured and statistical analysis, should be posted where a trial was registered within one year of completion of a trial.
- 3. Trial reports.** All trial reports (Clinical Study Reports or their equivalent in non-commercial settings) should be posted online in full, with only minimal redactions.

AllTrials does NOT actively campaign for individual patient data sharing or for publication of trial findings in peer-reviewed academic journals.

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Working together to fix medicine

The AllTrials campaign for all clinical trials to be registered and results reported involves hundreds of organisations worldwide. Many of them play an active role in running, funding and publishing clinical trials - and all of them are working towards our shared goal.

This document is an attempt to set out the campaign initiatives already in place and to suggest what organisations can do to change things in their sector. It is designed to show, clearly and simply, what campaign supporters can do to make the biggest impact.

We developed this roadmap by talking to hundreds of individuals and organisations involved in the campaign around the world. We hope this document will spark more conversations that will develop and improve the recommendations and help us to reach our campaign goal. Please get in touch to tell us how you think we could improve this working document or to let us know if there is something you or your organisation are already doing that we should include. alltrials@senseaboutscience.org

Below are the practical steps you can take if you are a...

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-commercial
trial funder

Medicines
regulator

Ethics
regulator

Health technology
assessment agency



Image credit: Hea Poh Lin

Patient groups

Recommendations

1. Actively campaign to get all clinical trials registered and reported.
2. Nominate AllTrials ambassadors to raise awareness among your members and other groups you interact with.
3. Develop a plan for monitoring ongoing registered trials in your area for missing trial results, and for following up on those cases.
4. Identify the drug companies most relevant to your disease area and write to them, asking them to confirm that they have registered all trials and reported full results for that area. Post their responses on your website and tweet them out using #AllTrials.
5. Regularly bring up the topic in your interactions with pharma companies, regulators, policy makers and the media.

Examples

- Dr Aus Alzaid, a practicing physician caring for people with diabetes, [successfully challenged the principal investigator](#) of a diabetes trial to publish the findings of his research.
- National Voices, a coalition of health and social care charities in England, and the Association of the British Pharmaceutical Industry [jointly produced a guide for charities and pharmaceutical companies on how to collaborate](#). The guide explicitly states that “charities may wish to take account of a company’s track record and position on the disclosure of clinical trial data in deciding whether or not to enter a collaboration”.



Image credit: Mungang Kim

Trial participants

Recommendations

1. Encourage any patient support groups you are a member of to [join the AllTrials campaign](#).
2. When you consider joining a clinical trial, always ask:
 - Has the trial been registered?
 - Is the study protocol publicly available?
 - Will the summary study results be posted online within one year?
 - If it is a long-term trial, what are the arrangements for publishing interim results?
 - Will you be provided with the study results?
3. If you have been a trial participant in the past, ask the trial sponsor for links to where the trial was publicly registered, and check whether the sponsor posted results within one year of trial completion. If results were not posted on time, ask the trial sponsor why not, copying in AllTrials.

Example

- Dr Aus Alzaid, doctor caring for people with diabetes, [challenged the principal investigator](#) of a diabetes trial to publish the findings of his research – with success.



Image credit: Mungang Kim

Doctors and medical students

Recommendations

1. Table a formal motion for the annual meetings of professional societies you are a member of, asking them to [join the AllTrials campaign](#).
2. Put up an AllTrials poster in your faculty, office or waiting room.
3. Advocate for medical curricula and education events to include information on why clinical trials registration and reporting matter, and to spread the word about what medical professionals can do to improve the situation.
4. When you are participating in a trial or encouraging patients to enrol in a trial, inform patients of trial sponsors' obligation to post results publicly and make them available to participants, and explain why it matters.
5. Always ask pharma reps whether the company they represent has joined AllTrials.
6. If you see a trial that was registered but whose results have still not been reported one year later, contact trial sponsors and/or principal investigators and ask them to post the missing results. Tweet out their responses using #AllTrials, or write a guest blog for us about your experiences.
7. For medicines you frequently prescribe, ask companies to provide a list of all the clinical trials conducted, highlighting those that have not (yet?) reported results publicly. Tweet out their responses using #AllTrials, or write a guest blog for us about your experiences.

Examples

- Medical student members of the American Medical Association (AMA) [drafted a detailed proposal](#) on why clinical trial transparency will be pivotal for future physicians, resulting in the AMA joining the campaign.
- Dr Aus Alzaid, a practicing physician caring for people with diabetes, [successfully challenged the principal investigator](#) of a diabetes trial to publish the findings of his research.
- A Spanish medical student contacted AllTrials, rallied medical professionals around the cause, and is currently starting up a national campaign for trial registration and reporting.

This is an evolving document and we would appreciate any [feedback](#)

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Image credit: Delwar Hossain

Academics and researchers

Recommendations

1. Register all clinical trials on a publicly accessible register before recruitment begins, with the full protocol.
2. After trial completion, publish summary results within a year, and post the full Clinical study report or equivalent document online.
3. Become an AllTrials ambassador to raise awareness within your institution and specialist field.
4. Table a formal proposal asking your university, department or research institution to [join the AllTrials campaign](#).
5. Table a formal proposal asking your university, department or research institution to publish, implement and annually audit a formal policy on trial registration and reporting.

Examples

- As a condition of publication, The BMJ [requires prospective registration of trials](#) commencing after June 2005.
- In a world first, a [clinical trial transparency audit](#) of two major UK research institutions has been made publicly available in 2016. The study, published in BMJ Open, looked at the clinical trial registration and reporting performance of the Oxford Biomedical Research Centre (BRC), and the Oxford Musculoskeletal Biomedical Research Unit (BRU), who together received over £160m of public funds from the National Institute of Health Research since 2007.

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Universities and research institutions

Image credit: Nicolas Ramello

Recommendations

1. Publish and implement a formal policy on prospective clinical trial registration, committing to registration and full reporting of all current and future trials.
2. Conduct regular public audit of compliance with your own policies, setting out proportion of registered trials, proportion of trials with reported results, and proportion of trials with Clinical study reports or equivalent reports posted online.
3. Ensure that Institutional Review Boards only approve consent forms that include a statement of trial sponsors' commitment to register trials and report their results.
4. Nominate internal AllTrials ambassadors to raise awareness among researchers and students.

Example

- In a world first, a [clinical trial transparency audit](#) of two major UK research institutions was made publicly available in 2016. The study, published in BMJ Open, looked at the clinical trial registration and reporting performance of two Oxford research centres, who together had received over £160m of public funds from the National Institute of Health Research since 2007.

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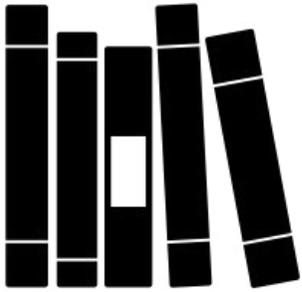


Image credit: videntnova

Learned and professional societies

Recommendations

1. Nominate internal AllTrials ambassadors to raise awareness among your members.
2. Use educational support and continuing professional development activities to disseminate best practices in clinical trials registration and reporting.
3. If you have a code of conduct, clearly define trial registration and results reporting as part of members' professional responsibilities, and/or define non-registration of trials or incomplete reporting as professional malpractice.
4. If applicable, make trial registration and full results reporting a precondition before members can present their research to a society meeting or publish in a society journal.
5. Develop a plan for monitoring ongoing registered trials in your area for missing trial results, and for following up on those cases.
6. Collaborate with other professional societies to produce field-wide expectations and standards.

Example

- The British Pharmacological Society and the American Society for Pharmacology and Experimental Therapeutics [support the publication of negative findings](#) from early clinical trials through their jointly published journal.



Image credit: Oliviu Stoian

Scholarly publishers and journals

Recommendations

1. Adopt and implement the [ICMJE's policy](#) on trial registration and [CONSORT guidelines](#) for trial reporting.
2. Develop guidelines and checklists (or similar tools) for editors and peer reviewers to ensure that papers considered for publication comply with [ICMJE's policy](#) and [CONSORT guidelines](#).
3. Ensure that published papers can be linked to the clinical trial register entry and any other papers derived from the trial, and vice versa.
4. Consider papers for publication prior to results submission based on the rigour and quality of trial protocol in order to overcome publication bias.
5. Annually audit a random sample of published papers to ensure that these guidelines and checklists are effective at ensuring compliance, and publish the results.

Examples

- As a condition of publication, The BMJ [requires prospective registration](#) of trials commencing after June 2005.
- PLOS [supports prospective trial registration](#), but will consider publishing trials registered retrospectively if accompanied by an explanatory note from authors about their failure to register before starting the trial.
- The [COMParE project](#) at Oxford University is [tracking switched outcomes](#) in academic papers reporting clinical trials.



Image credit: Mint Shirt

Shareholders and investors

Recommendations

1. Use the AllTrials campaign's benchmarking of pharmaceutical company policies on clinical trial transparency to start a discussion with companies you have holdings in.
2. Table a shareholder motion at the AGMs of companies you invest in, demanding that they follow the lead of [GlaxoSmith-Kline](#) and [join the AllTrials campaign](#).
3. [Contact the AllTrials team](#) to discuss how to measure and monitor pharmaceutical companies' clinical trial reporting policies and performance.
4. Join the other investors worth €3.5 trillion in assets under management and [join the AllTrials campaign](#) to increase the pressure on pharmaceutical companies to register and report the results of all clinical trials.

Example

- 85 pension funds and asset managers worth €3.5 trillion in assets under management have [called on companies](#) conducting clinical trials to register and report the results of all trials, past and present. [Read the investor statement](#).

Note: [BNP Paribas Investment Partners have argued that:](#)

“Alongside doctors and their patients, investors also risk being misled, given that an average of around 30% of pharmaceutical company valuations directly relates to the results of Phase III clinical trials. With company valuations and expected revenue streams a key component of the stock selection process, it is essential that companies publish complete and accurate information on trial results so that investment decisions can be fully informed.”

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Pharmaceutical companies

Image credit: Seb Cornelius

Recommendations

1. Register all clinical trials on a publicly accessible register before recruitment begins.
2. Publish summary results within a year after trial completion, and post the full Clinical study report or equivalent document online.
3. Publish and implement a formal policy on prospective clinical trial registration committing to registration and full reporting of all current and future trials.
4. Publish and implement a formal policy on retrospective clinical trial registration and reporting.
5. Conduct regular public audit of compliance with own policies, including compliance by contractors, setting out proportion of registered trials, proportion of trials with reported results, and the proportion of trials with Clinical study reports posted online.

Examples

- GlaxoSmithKline joined AllTrials and [put mechanisms and a budget](#) in place to report results and publish Clinical study reports of all multi-country clinical trials dating back to the formation of the company in 2000, and of all trials moving forwards.
- LEO Pharma [committed to making summary results from clinical trials](#) as far back as 1990 available.

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Image credit: Richard Wearn

Non-commercial trial funders

Recommendations

1. Publish and implement a formal policy on prospective clinical trial registration, committing to registration and full reporting of all current and future trials.
2. Make prospective trial registration and subsequent results reporting a condition of funding, and ensure that grants cover the related costs.
3. Consider withholding a percentage of research grants until trials have been registered and results have been fully reported.
4. Publish annual audits of funded institutions' trial registration and reporting performance, either by auditing centrally and/or by requiring institutions to conduct their own audits.
5. Publish and implement a roadmap for the retrospective registration and reporting of past trials with clear prioritisation and sequencing, and publish annual progress reports.

Examples

- The Wellcome Trust has a [10 per cent grant retention policy](#), withholding funds when researchers do not meet the conditions of their open access policy.
- The Medical Research Council, a UK government agency responsible for co-ordinating and funding medical research, joined the AllTrials campaign in 2013. The MRC [requires its grantees](#) to register all clinical trials and report their results, and covers trial registration fees.
- [Researchfish](#), an MRC-initiated platform now used by over 110 research organisations worldwide to track research grants and their impacts, includes a dedicated field for the clinical trial number, which serves as a reminder to grantees to register trials, and facilitates tracking of related outputs and the auditing of compliance by funders.



Image credit: Parkjisun

Medicines regulators

Recommendations

1. When a company is applying for a license for a treatment, only initiate the licensing process when you have verified that all trials on that treatment have been registered and reported their results.
2. After initiation of the licensing process, post the Clinical study reports and all other data for trials cited in licensing application documentation online, with minimal redactions. [Why this matters.](#)
3. If past trials were initiated before trial registration became a legal requirement and/or before the regulator adopted a policy mandating prospective registration of trials, make retroactive registration and reporting of all trials listed in the licensing application a precondition for initiating the licensing process
4. Post all Clinical study reports received in past licensing applications online, with only minimal redactions.

Examples

- The European Medicines Agency has [committed to proactively publishing](#) all Clinical study reports that it receives from January 2015 onwards as part of new marketing authorisation applications, 60 days after a decision has been made.
Note: The EMA [expects to release](#) the first Clinical study reports in September 2016.
- Since 2007, [the Food and Drug Administration in the United States legally requires registration](#) and results reporting for many types of clinical trials.
Note: In practice, this U.S. law is [not being effectively enforced](#).

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Image credit: Edward Boatman

Ethics regulators

Recommendations

1. Explicitly define non-compliance with best practices in clinical trial registration and reporting as a breach of ethical guidelines.
2. Only grant ethics approval to a clinical trial if the trial protocol contains detailed, time-bound and verifiable commitments to trial registration and reporting.
3. Audit compliance with commitments to trial registration and reporting contained in trial protocols
4. Only grant ethics approval if all parties involved in conducting the trial explicitly declare that they are currently fully compliant with registration and reporting requirements for all past trials they have been involved with.

Examples

- Since 2013, the UK's Health Research Authority has made clinical trial registration [a condition of ethics approval](#) to run clinical trials, leading to an increase in registration rates.
- In 2015, the UK's Health Research Authority [conducted a partial audit](#) of trials it had approved to determine publication rates and check the consistency of outcome reporting.



Image credit: Delwar Hossain

Health technology assessment agencies

Recommendations

1. Only initiate the assessment process when you have verified that all trials on that treatment have been registered and reported their results.
2. After initiation of the assessment process, [post the Clinical study reports](#) and all other data for trials cited in licensing application documentation online, with minimal redactions.
3. If past trials were initiated before trial registration became a legal requirement and/or before the assessor adopted a policy mandating prospective registration of trials, make retroactive registration and reporting of all trials listed in the licensing application a precondition for initiating the assessment process.
4. Post all Clinical study reports reviewed in past assessments online, with only minimal redactions.

Examples

- The German agency IQWiG [requires that pharmaceutical companies share](#) the results of all trials the companies have funded involving that drug or medical device. If a company fails to submit these materials in time and there is evidence that relevant data is missing, IQWiG does not attribute any benefit to the drug or medical device under consideration. Read more in Section 3.2.1.
- The [Protecting Canadians from Unsafe Drugs Act](#) allows some stakeholders to [request clinical trial](#) information submitted to Health Canada.