Good or bad, medical research funders promise to publish clinical trial results

About 50% of clinical trials go unreported, according to several studies, often because the results are negative. These unreported trial results leave an incomplete and potentially misleading picture of the risks and benefits of vaccines, drugs and medical devices, and can lead to use of suboptimal or even harmful products.

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Therefore some of the world's largest funders of medical research and international non-governmental organisations have agreed on new standards that will require all clinical trials they fund or support to be registered and the results disclosed publicly.

In a joint statement, the Indian Council of Medical Research, the Norwegian Research Council, the UK Medical Research Council, Médecins Sans Frontières and Epicentre (its research arm), PATH, the Coalition for Epidemic Preparedness Innovations (CEPI), Institut Pasteur, the Bill & Melinda Gates Foundation, and the Wellcome Trust agreed to develop and implement policies within the next 12 months that require all trials they fund, co-fund, sponsor or support to be registered in a publicly-available registry. They also agreed that all results would be disclosed within specified timeframes on the registry and/or by publication in a scientific journal.

Timely clinical trial results

"Research funders are making a strong statement that there will be no more excuses on why some clinical trials remain unreported long after they have completed," said Dr Marie-Paule Kieny, assistant director-general for health systems and Innovation at the World Health Organisation (WHO).

The signatories to the statement also agreed to monitor compliance with registration requirements and to endorse the development of systems to monitor results reporting.

"We need timely clinical trial results to inform clinical care practices as well as make decisions about allocation of resources for future research," said Dr Soumya Swaminathan, director-general of the Indian Council of Medical Research. "We welcome the agreement of international standards for reporting timeframes that everyone can work towards."

In 2015, WHO published its position on public disclosure of results from clinical trials, which defines timeframes within which results should be reported, and calls for older unpublished trials to be reported. That position builds on the World Medical Association's Declaration of Helsinki in 2013. Today's agreement by some of the world's major research funders and international NGOs will mean the ethical principles described in both statements will now be enforced in thousands of trials every year.

Open-access registries

"Requiring summary results of clinical trials to be made freely available through open-access registries within 12 months of study completion is good for both science and society," said Dr Jeremy Farrar, director of the Wellcome Trust. "Not only will this help ensure that these research findings are more discoverable, but it will also reduce reporting biases, which currently favour publication of trials which have a positive outcome."

Most of these trials and their results will be accessible via WHO's International Clinical Trials Registry Platform, a unique global database of clinical trials that compiles data from 17 registries around the world, including the United States of America's clinicaltrials.gov, the European Union's Clinical Trials Register, the Chinese and Indian clinical trial registries and many others.

"We fully support this statement and look forward to working towards increasing the availability of results from clinical trials," said Dr John-Arne Røttingen, chief executive of the Research Council of Norway. "The public disclosure of results from clinical trials will improve resource allocation to research in a broad sense, and is also in line with our policies on transparency, and on open access."