18 MAY 2017 | GENEVA – Some of the world's largest funders of medical research and international non-governmental organizations today 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.

Today, 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.

"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 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of results from clinical trials, which defines timeframes within which results should be reported, and calls for older unpublished trials to be reported.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'sÂ 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.

"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. Today's statement is in line with Wellcome's broader ambition to make all research outputs which arise from our funding more findable, accessible, and re-usable."

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."

Comments from other signatories:

Dr Micaela Serafini, Medical Director, Médecins Sans Frontières
"Timely reporting of all clinical trial results is of upmost importance to MSF allowing fully informed decisions when it comes to health strategies, treatments and diagnostics. We fully support this move towards increased transparency and accountability in clinical research."

Dr Trevor Mundel, President, Global Health, Bill & Melinda Gates Foundation
"It's a 21st-century best practice - and an essential part of the social contract that underlies medical research - that clinical trial data should be made publicly available less than one year after a clinical trial's completion. We strongly support WHO's effort to establish a global standard for reporting data within this timeframe, which is a practice we require of our grantees as well."

Dr David C. Kaslow, Vice President of Essential Medicines, PATH
"PATH remains deeply committed to the timely public disclosure of clinical trial results to accelerate development of new interventions and to ensure access to and transparency of safety and efficacy data, no matter if positive or negative. Full and consistent implementation of WHO standards on reporting clinical trial results is an important step towards better understanding the risks and benefits of vaccines, drugs and medical devices, and the optimal use of new interventions."