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WHO demands transparency in clinical trial results

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Singapore: In a study that analysed reports from large clinical trials (more than 500 participants), registered on ClinicalTrials.gov and completed by 2009, 23 percent had no results reported. These unreported trials included nearly 300,000 participants. Among clinical trials of vaccines against 5 diseases registered in a variety of databases between 2006-2012, only 29 percent had been published in a peer-reviewed journal by the WHO recommended deadline of 24 months following study completion.

In order to bring transparency in clinical trials, WHO has issued a public statement calling for the disclosure of results from clinical trials for medical products, whatever the result, to ensure that decisions related to the safety and efficacy of vaccines, drugs and medical devices for use by populations are supported by the best available evidence.

"Our intention is to promote the sharing of scientific knowledge in order to advance public health," said Dr Marie-Paule Kieny, assistant director-general for health systems and innovation, WHO. "It underpins the principal goal of medical research, to serve the betterment of humanity."

"Failure to publicly disclose trial results engenders misinformation, leading to skewed priorities for both R&D and public health interventions," said Dr Kieny. "It creates indirect costs for public and private entities, including patients themselves, who pay for suboptimal or harmful treatments."

"We need the collaboration of all these actors to enforce transparency in their jurisdictions in order to increase the benefits and decrease the risks for patients, clinical trial volunteers and the general public," concluded Dr Kieny.

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WHO's call for disclosure includes older unreported clinical trials, the results of which may still have an important bearing on scientific research today. WHO also reaffirms the need for all clinical trials to be registered on a WHO primary clinical trial registry so that they can be accessible through the International Clinical Trials Registry platform. This will ensure transparency as to which clinical trials have occurred, and allow verification of compliance with public disclosure requirements.

The recent WHO move expands on a 2005 call for all clinical trials to be registered, and the subsequent establishment of the International Clinical Trials Registry Platform. This registry platform regularly imports trial records from ClinicalTrials.gov, ISRCTN registry, EU Clinical Trials Register, Australia-New Zealand Clinical Trial Registry, Pan African Clinical Trial Registry and Clinical Trial Registries from China, India, Brazil, Republic of Korea, Cuba, Germany, Iran, Japan, Sri Lanka, the Netherlands, and Thailand.