International Clinical Trials Registry Platform (ICTRP)

Joint statement on public disclosure of results from clinical trials

Introduction

Signatories on 18 May 2017

1. Indian Council of Medical Research
2. Research Council of Norway
3. UK Medical Research Council
4. Médecins Sans Frontières
5. Epicentre
6. CEPI
7. PATH
8. Institut Pasteur
9. Drugs for Neglected Diseases Initiative (DNDi)
10. Bill and Melinda Gates Foundation
11. Wellcome Trust

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The current 2013 Declaration of Helsinki states that “Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.” and that “Researchers have a duty to make publicly available the results of their research .... Negative and inconclusive as well as positive results must be published or otherwise made publicly available”. In addition to the ethical imperative, poor allocation of resources for product development and financing of available interventions, and suboptimal regulatory and public health recommendations may occur where decisions are based on only a subset of all completed clinical trials.

The signatories of this joint statement affirm that the prospective registration and timely public disclosure of results from all clinical trials is of critical scientific and ethical importance. Furthermore timely results disclosure reduces waste in research, increases value and efficiency in use of funds and reduces reporting bias, which should lead to better decision-making in health.

Within 12 months of becoming a signatory of this statement, we each

pledge to develop and implement a policy with mandated timeframes for prospective registration and public disclosure of the results of clinical trials that we fund, co-fund, sponsor or support. We each agree to monitor registration and endorse the development of systems to monitor results reporting on an ongoing basis. We agree to share challenges and progress in the monitoring of these policies. We agree that transparency is important and therefore the outputs from the monitoring process will be publicly available.

Benefits and costs of requiring public disclosure of results

The benefits of implementing and monitoring policies on public disclosure of results relate to access to more complete information about the results of clinical trials. The benefits are summarised below.

- The current bias in the reporting of results will be reduced allowing for more informed decisions in the following areas:
  o Licensure/marketing authorization (including risk-benefit assessments),
  o Public health policy recommendation on use (including cost-effectiveness), and
  o Financing decisions by public procurement bodies, and multilateral agencies
  o Optimal implementation and delivery
  o Individual treatment choices by doctors and patients
- Research funding allocation will be more efficient (avoiding the current situation, whereby funds may be allocated to answer scientific questions that have already been answered in unreported clinical trials, and waste occurs because learning from previous trials cannot be taken into account in design of current trials)
- The development of interventions will be more efficient
- Ethical requirements for dissemination of information will be met, potentially increasing trust of trial participants in the utility of clinical research
- The scientific state-of-the-art will be based on a more complete cross-section of clinical trial data; in particular the many negative clinical trials will be more available for assessments.

A further benefit is that doctors, professional bodies and the general public will be able to access the results from a larger proportion of clinical trials.

Finally patients seeking enrollment in clinical trials will be able to access results from previously completed clinical trials in their area, as they make decisions on which clinical trials they may wish to seek enrollment into.

There will be modest costs associated with public disclosure of clinical trial results. The costs of disseminating the results of research are a minor component of the overall costs of conducting such research, and results reporting is an essential component of the research enterprise. The resource allocation, public health and scientific benefits - together with the need to meet ethical imperatives - far outweigh the costs.

results reporting