Strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination

World Health Organization

Resolution proposed by Argentina, Peru,
United Kingdom of Great Britain and Northern Ireland

Also co-sponsored by Norway, Switzerland and Singapore

Problem statement
Research waste
Problems with current ecosystem in efficiently providing high quality trials that produce actionable evidence

Scope all clinical trials capabilities for priority use cases in "normal times", rapidly deployable in times of PHEIC
All diseases and conditions
Not "all research". Not access.
Includes comparative effectiveness, cost-effectiveness
From trial design through to licensure and guidelines

Actions for research funders in resolution

World Health Organization

(6) to encourage research funding agencies to prioritise and fund clinical trials that are well-designed and well-implemented, conducted in diverse settings and include all major population groups the intervention is intended to benefit, … in order to generate … actionable evidence needed to inform public health policy, regulatory decisions, and medical practice while preventing underpowered, poorly-designed clinical trials and avoiding the exposure of clinical trials participants to unjustified and unnecessary risk, in normal times as well as in public health emergencies of international concern, including through:

(a) encouraging investment in well-designed clinical trials, including through clinical trials networks, that are developed in collaboration with affected communities, with a view to addressing their public health needs and with the potential for trials to contribute to clinical trial capabilities, including strengthening the core competencies of research personnel, particularly in developing countries;

Actions for research funders in resolution

World Health Organization

(b) introducing grant conditions for funding clinical trials to encourage the use of standardized data protocols where available and appropriate and to mandate registration in a publicly available clinical trial registry within the World Health Organization's International Clinical Trials Registry Platform (ICTRP) or any other registry that meets its standards;

(c) promoting, as appropriate, measures to facilitate the timely reporting of both positive and negative interpretable clinical trial results in alignment with the WHO joint statement on public disclosure of results from clinical trials and the WHO joint statement on transparency and data integrity, including through registering the results on a publicly available clinical trial registry within the ICTRP, and encouraging timely publication of the trial results preferably in an open-access publication;

Actions for research funders in resolution

World Health Organization

(d) promoting transparent translation of results, including comparison to existing treatments and data on effectiveness, based on thorough assessment, into clinical guidelines where appropriate;

(e) exploring measures during public health emergencies of international concern to encourage researchers to rapidly and responsibly share interpretable results of clinical trials, including negative results, with national regulatory bodies or other appropriate authorities, including WHO for clinical guideline development and emergency use listing (EUL), to support rapid regulatory decision-making and emergency adaptation of clinical and public health guidelines as appropriate, including through pre-print publication

Actions for WHO secretariat

World Health Organization

(1) to organize … stakeholder consultations, with Member States, NGOs including patient groups, private sector entities including international business associations, philanthropic foundations and academic institutions, as appropriate, on the respective roles of the WHO, Member States and non-State actors, and to identify and propose to Member States, for consideration in governing bodies, best practices and other measures to strengthen the global clinical trials ecosystem, taking into account relevant initiatives where appropriate

Actions for WHO secretariat in resolution

World Health Organization

2) to review existing guidance and develop ***new guidance as needed on best practices for clinical trials***, including on strengthening the infrastructure needed for clinical trials, to be applied in normal times and with provisions for application during a public health emergency of international concern, taking into account relevant initiatives and guidelines as appropriate such as those led by the ICH and other organizations by providing, as appropriate:

(2

(a) guidance on best practices to help guide Member States implementation of scientifically and ethically sound clinical trials within their national and regional contexts;

(b) guidance on best practices for non-State actors in the design and conduct of clinical trials and in strengthening the global clinical trials ecosystem to meet the needs of major population groups that the intervention is intended to benefit, with a particular focus on under-represented populations, developed in consultation with WHO Member States and relevant non-State actors

Actions for WHO secretariat in resolution

World Health Organization

(3) to provide to Member States, on their request, guidance, taking into account relevant initiatives and guidelines, as appropriate, on best practices for developing the legislation, infrastructure and capabilities required for clinical trials taking into account national and regional contexts