
Strengthening clinical trials¹ to provide high-quality evidence on health interventions and to improve research quality and coordination

**Draft resolution proposed by Argentina, Peru,
United Kingdom of Great Britain and Northern Ireland**

The Seventy-fifth World Health Assembly,

(PP1) Recalling resolutions WHA58.34 (2005) acknowledging that high-quality, ethical research, and the generation and application of knowledge, are critical in achieving internationally agreed health-related development goals, WHA63.21 (2010) outlining the World Health Organization's role and responsibilities in health research, WHA66.22 (2013) and WHA69.23 (2016) on the follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, WHA67.20 (2014) on regulatory system strengthening for medical products, WHA67.23 (2014) on health intervention and technology assessment in support of universal health coverage, WHA74.6 (2021) on strengthening local production of medicines and other health technologies to improve access, and WHA74.7 (2021) on strengthening WHO preparedness for and response to health emergencies, which notes the importance of basic and clinical research and recognizes the critical role of international collaboration in research and development, including in multi-country clinical and vaccine trials, as well as rapid diagnostics test and assay development, while acknowledging the need for further rigorous scientific evidence;

(PP2) Noting the recommendations made by the Independent Panel for Pandemic Preparedness and Response in their review "COVID-19: Make it the Last Pandemic"² relating to health research and development, including clinical trials;

¹ "A clinical trial is defined by WHO as any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc. This definition includes Phase I to Phase IV trials." WHO joint statement on public disclosure of results from clinical trials 2017 <https://www.who.int/news/item/18-05-2017-joint-statement-on-registration>.

² The Independent Panel for Pandemic Preparedness and Response. Covid-19: Make it the Last Pandemic. 2021.

(PP3) Recognizing that well-designed¹ and well-implemented clinical trials are indispensable for assessing the safety and efficacy of health interventions;

(PP4) Noting the role of clinical trials in the development of safe and efficacious new health interventions, and in informing associated comparative cost-effectiveness evaluations vis-à-vis existing interventions with a view to promoting the affordability of health products;

(PP5) Noting that clinical trials on new health interventions are likely to produce the clearest result when carried out in diverse settings, including all major population groups the intervention is intended to benefit, with a particular focus on under-represented populations;

(PP6) Recognizing the potential benefits available from collaboration, coordination and the exchange of information between public and non-public funders of clinical trials, while actively preventing and managing conflicts of interest, and noting the potential benefits from public and non-public funders of clinical trials taking steps to ensure funding is targeted towards well-designed and well-implemented clinical trials that will produce actionable evidence regarding health interventions, which address public health priorities and in particular the health needs of developing countries, such as neglected tropical diseases, while seeking to strengthen the capability in developing countries to conduct scientifically and ethically sound clinical trials;

(PP7) Recognizing the essential contribution of clinical trial participants;

(PP8) Underscoring that clinical trials should be health-needs driven, evidence-based, well-designed, well-implemented and be guided by established ethical guidance, including principles of fairness, equity, justice, beneficence, and autonomy; and that clinical trials should be considered a shared responsibility;

(PP9) Acknowledging the importance of promoting equity in clinical trial capability, including by enhancing the core competencies of research personnel, ensuring human subject protections from the risks of clinical trials and acknowledging the shared benefits from the results generated from clinical research and development, including clinical trials, both by strengthening the clinical trial global ecosystem to evaluate health interventions and by working to strengthen country capacities to conduct clinical trials that provide the highest human subjects protections and meet relevant regulations and internationally harmonized standards by considering:

- (a) systematic assessment of country level clinical trial capabilities to promote the ability to conduct rigorous clinical trials compliant with international guidelines and the ability to safeguard human subjects;
- (b) strengthened global clinical trial capabilities, in coordination with existing organizations and structures, in order to promote well-designed and well-implemented clinical trials which produce high-quality evidence, as well as to ensure trials are designed to reflect the heterogeneity of those who will ultimately use or benefit from the intervention being evaluated, and are

¹ Throughout this document “well-designed trials” refers to trials which are scientifically and ethically appropriate. For submission to medical product regulatory authorities trials should adhere to International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines and some Member States may consider International Coalition of Medicines Regulatory Authorities (ICMRA) guidelines. In order to generate evidence which is robust enough to support decision-making, such as widespread use of therapeutics or preventives, trials should be designed, conducted, analysed and reported appropriately. A well-designed trial must also be practically feasible to conduct.

conducted in diverse settings, including all major population groups the intervention is intended to benefit, with a particular focus on under-represented populations;

(c) where possible, inclusion of all trial stakeholders, including representatives of patient groups, according to best practices in the development of clinical trials with affected communities to ensure that the health interventions address their needs, such as solutions on neglected tropical diseases;

(d) that clinical trial participants include all major population groups which the intervention is intended to benefit;

(e) promoting transparent and voluntary sharing, while ensuring information and data security, both of well-designed clinical trial methodologies and the results of clinical trials, including negative results, through open-source methods internationally to enable capability building in diverse settings;

(f) that regulatory measures and other related processes be solidly defined and implemented, including for public health emergencies of international concern;

(PP10) Recognizing that data from clinical trials play an important role in informing cost-effectiveness assessments of new health interventions and their comparison with existing interventions in order to assess their affordability within the context of national health systems,

OP1 CALLS ON Member States,¹ in accordance with their national and regional legal and regulatory frameworks and contexts and as appropriate:

(1) to prioritise the development and strengthening of national clinical trial capabilities able to comply with international standards of trial design and conduct and human subject protections as well as strengthening and developing national regulatory and quality control frameworks and authorities;

(2) to increase clinical trials capability, and strengthen clinical trials policy frameworks, particularly in developing countries, to enable a greater number of clinical trial sites that can conduct well-designed and well-implemented clinical trials, and to ensure readiness for coordination of trials through existing, new or expanded clinical trial networks, that meet relevant regulations and internationally harmonized standards, promoting sharing of information and best practices on efficient and ethical clinical trial design and delivery, and in designing, preparing and conducting clinical trials;

(3) to coordinate clinical trials research priorities based on public health needs of Member States including collaborative, and as appropriate, multi-country and multi-regional clinical trials when mutually beneficial, while avoiding unnecessary duplication of work, taking into account that aligning clinical trials across countries will require preparatory work, including the coordination, as appropriate, in national regulatory practices and funding frameworks;

(4) to collaborate with private sector funders and academic institutions, while actively preventing and managing conflicts of interest, to encourage the targeting of clinical trials towards the development of health interventions that address public health priorities and concerns of

¹ And, where applicable, regional economic integration organizations.

global, regional and national importance including communicable and noncommunicable diseases, with a focus on the health needs of developing countries, and that evaluate the safety and efficacy of health interventions, including having special regard to common diseases in LMICs, unmet medical needs, rare diseases and neglected tropical diseases;

(5) to note and, as appropriate, benefit from the potential role of regional organizations in coordinating clinical trials and recruiting participants;

(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, have adequate statistical power, and relevant control groups and interventions in order to generate the scientifically robust and 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;

(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 trials¹ and the WHO joint statement on transparency and data integrity,² 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;

(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

¹ World Health Organization. Joint statement on public disclosure of results from clinical trials. 2017.

² International Coalition of Medicines Regulatory Authorities (ICMRA) and World Health Organization. Joint Statement on transparency and data integrity. 2021.

(EUL), to support rapid regulatory decision-making and emergency adaptation of clinical and public health guidelines as appropriate, including through pre-print publication;

(7) to support ethics committees and regulatory authorities to enable efficient governance processes to focus on the fundamental scientific and ethical principles that underpin randomized controlled trials, maintaining patient and other trial participant protections, including personal data protection and acting proportionately to risk, to best support well-designed and well-implemented clinical trials and facilitate the development of preparedness for clinical trials including, when appropriate multi-country trials during PHEICs, where scientifically appropriate, while embracing flexibility and innovation;

(8) to support new and existing mechanisms to facilitate rapid regulatory decision-making during public health emergencies of international concern, so that:

(a) safe, ethical, well-designed clinical trials can be approved and progress quickly; and

(b) data from clinical trials can be assessed rapidly, including through WHO EUL, and health interventions deemed safe and effective swiftly authorized;

(9) to facilitate while protecting confidentiality of information when appropriate, in normal times as well as in public health emergencies of international concern, sharing among regulatory authorities of:

(a) their assessments of clinical trial protocols to enable the implementation of rigorous protocols in practice; and

(b) assessment reports on health interventions with potential significance and public health importance to inform, when possible, decision-making processes in other countries including for potential regulatory assessments and decisions related to the inclusion of health interventions in their national health system, as well as for safety monitoring;

(10) to support new and existing mechanisms to facilitate the rapid interpretation of data from clinical trials to develop or amend, as necessary, relevant guidelines during public health emergencies of international concern;

(11) to facilitate collaboration and synergies among actors, institutions and networks in the clinical evidence ecosystem throughout the continuum from clinical research to utilization of data from clinical trials in clinical practice through comparative evidence evaluations, evidence synthesis, health technology assessments, regulatory decisions, comparative cost-effectiveness analysis, vis-à-vis existing health interventions and, as appropriate, development of evidenced based guidelines and monitoring of implementation in clinical practice;

OP2. INVITES nongovernmental international organizations and other relevant stakeholders: to explore opportunities to coordinate research priorities, and promote investments in clinical trial research and the effective, equitable and timely deployment of resources and funding, while actively preventing and managing conflicts of interest, to support robust, quality clinical trials as well as to strengthen clinical trial research capacities globally, particularly in developing countries and for diseases disproportionately affecting developing countries;

OP3. REQUESTS the Director-General:

- (1) to organize, in a transparent manner, stakeholder consultations in line with FENSA, 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 States¹ 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;
- (2) to review existing guidance and develop, following the standard WHO processes, 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 International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and other organizations by providing, as appropriate:
 - (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 States¹ and relevant non-State actors s;
- (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;
- (4) to engage with as appropriate relevant non-State actors in line with FENSA to strengthen clinical trial capabilities, particularly in developing countries, on innovations which meet the needs of major population groups that the intervention is intended to benefit, with a particular focus on under-represented populations;
- (5) to present a report outlining progress in the activities requested of the Director-General in this resolution for consideration by the Seventy-sixth World Health Assembly through the Executive Board at its 152nd session in 2023.

= = =

¹ And, where applicable, regional economic integration organizations.