Strengthening Clinical Trials to Improve Public Health

The Seventy-fifth World Health Assembly,

(PP1) Recalling resolutions WHA63.21 (2010) outlining the World Health Organization's role and responsibilities in health research and WHA58.34 (2005) acknowledging that high-quality research, and the generation and application of knowledge, are critical in achieving internationally agreed health-related development goals;

(PP2) Recognizing the critical role of effective randomized controlled trials in appraising the efficacy of prospective healthcare interventions prior to implementing their results in practice as a cornerstone of high-quality healthcare, and the contribution of quality clinical trials in progressing universal health coverage through equitable access to healthcare interventions;

(PP3) Noting the recommendations made by the Independent Panel for Pandemic Preparedness and Response in their review 'COVID-19: Make it the Last Pandemic'[1] relating to clinical trial research, development and infrastructure, and recognizing the importance of quality clinical trials in responding to public health threats nationally, regionally and globally, including during the COVID-19 pandemic;

(PP4) Noting the urgent need to enhance international clinical trial capability, collaboration and coordination, and to adopt robust clinical trial standards in routine practice, to expedite the development of effective healthcare interventions and acknowledging that current variation in clinical trial standards impacts the quality of evidence available to inform the development of healthcare interventions;

(PP5) Recognizing the importance of collaboration and coordination between public and non-public funders of clinical trials to help ensure funding is targeted towards quality clinical trials that will produce actionable evidence, and which aim to address issues of public health importance;

URGES Member States[2], in accordance with their national and regional legal and regulatory frameworks and contexts, to:

(OP1) prioritise the development and strengthening of national clinical trial research capabilities;

(OP2) increase clinical trial capability globally, particularly in developing and low-and-middle-income countries, including through enabling a greater number of clinical trials sites and more readily co-ordinating activity through existing and new clinical trial networks, and taking measures to enhance information sharing on innovative and efficient clinical trial design and delivery to help researchers conduct effective trials and funders to make informed decisions based on methodological rigour;

(OP3) co-ordinate research priorities in order to align and prioritise clinical trials when mutually beneficial and to avoid duplication, helping to ensure public and private resources are effectively deployed where they are needed;

(OP4) collaborate with private sector funders and academic institutions to ensure that clinical trials are targeted towards the development of interventions that tackle communicable and non-communicable diseases of global, regional and national importance;

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[1] The Independent Panel for Pandemic Preparedness and Response. *Covid-19: Make it the Last Pandemic*. 2021

[2] And, where applicable, regional economic integration organisations

(OP5) ensure national research funding agencies prioritise and fund clinical trials that are both well designed and have adequate statistical power to generate the reliable and actionable evidence needed to inform policy and practice, including through:

> **(OP5.1)** encouraging investment in effective clinical trials by ensuring new trials are not duplicative, are of sufficient size and appropriate design, are developed in collaboration with affected communities, and are funded to build long-term research capacity particularly in developing and low-and-middle-income countries;
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> **(OP5.2)** introducing grant conditions for funding clinical trials to encourage the use of standard data protocols where available and to mandate registration on a clinical trial registry within the World Health Organization's International Clinical Trials Registry Platform (ICTRP);
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> **(OP5.3)** establishing mechanisms to secure a commitment from researchers to share pre-publication results with regulatory bodies, the World Health Organization and national clinical guideline development bodies as appropriate, to enable rapid regulatory approvals, evidence reviews and changes to national and international clinical guidelines;
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> **(OP5.4)** establishing mechanisms to ensure the results of clinical trials are reported in a timely manner following primary study completion, including through registering the results on a clinical trial registry within the ICTRP, and encouraging timely publication of the trial results ideally in an open-access publication;

(OP6) support ethics and regulatory committees to streamline governance processes to focus on the fundamental scientific and ethical principles that underpin randomized controlled trials, whilst embracing flexibility and innovation, and acting proportionately to risk, to best support novel trial designs and more readily facilitate multi-country clinical trials where scientifically appropriate;

(OP7) ensure data from clinical trials, demonstrating positive, negative or no overall effect, are considered and acted upon rapidly by regulators to ensure that healthcare interventions proven to be safe and effective can be swiftly approved by regulatory bodies, incorporated within clinical practice guidelines and recommended for use in routine practice;

(OP8) encourage regulators to rapidly share their assessment reports on decision making for approvals and safety monitoring of clinical trials and approvals for effective healthcare interventions with other relevant regulators to help facilitate trial approvals in other countries;

(OP9) acknowledge the immense contributions of participants in vaccine clinical trials to the development of COVID-19 vaccines and agree to recognize participants in COVID-19 vaccine clinical trials regulated by a World Health Organization listed Stringent Regulatory Authority as fully vaccinated against COVID-19, and to introduce mechanisms to recognize their vaccination status for travel and domestic certification purposes;

URGES non-governmental international organisations and other relevant stakeholders:

(OP10) to explore opportunities to develop novel processes to improve co-ordination of research priorities in a public health emergency, and to ensure the effective deployment of resources and funding globally for clinical trials in both pandemic and non-pandemic contexts;

REQUESTS the Director General to:

(OP11) develop a global action plan, in consultation with Member States[3] and relevant stakeholders, to guide implementation of the principles of this resolution to strengthen clinical trial practice to support preparedness and response in both pandemic and non-pandemic contexts;

(OP12) present the draft action plan for consideration by the Seventy-sixth World Health Assembly through the Executive Board at its 152nd session in 2023.

[3] And, where applicable, regional economic integration organisations