Feedback form for the public consultation for WHO guidance for global practices for clinical trials

Please note we are providing this word file of the full list of questions to help you plan your online submission – DO NOT make a submission using the word file, the submission should be through the online form. Wherever possible, please coordinate one submission per organization or per institution using the word file to collate input into consolidated submissions through the online form.

Personal information:

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General comments:

Please provide general comments on addressing context-specific issues, considerations, and implications for adapting and implementing the guidance, as well as identifying gaps in the evidence that should be addressed through future research. Please also provide any comments about the strengths of the draft guidance. Feedback to specific content to enhance clarity, address technical errors, and provide any missing information will be in the **suggested amendments**.

The proposed draft guidance includes positive aspects, which deserve to be highlighted, in particular:

- the focus on a major problem: paucity of reliable clinical trial evidence (point 1.3 of the document) and research waste (also recently well documented during the COVID 19 pandemic) (points 1.3.2 and 1.4);
- the positive and affirmative wording of the titles in section A on key scientific and ethical considerations for good controlled trials pointing out key principles of "good clinical trials".

Missing information

The draft guideline points out the problem of research waste but does not clarify who exactly should be responsible for stopping badly designed or underpowered trials from being launched. The guideline should provide indications to national authorities to designate a gatekeeper (ethics committees, regulators) to avoid research waste.

We encourage WHO to point out the necessity to conduct comparative clinical trials versus established treatment of proven therapeutic value whenever it does exist. It is in patients' interests that new drugs be compared in trials with the standard-of-care treatment(s), pharmacological or non-pharmacological, based on relevant clinical outcomes. This would be crucial for the generation of scientifically robust and actionable evidence needed to inform public health policy, regulatory decisions and medical practice while avoiding research waste.

Furthermore, a section should be added to highlight the weaknesses linked to the increased use of surrogate endpoints and/or uncontrolled clinical trials: this kind of data is insufficient

to provide relevant clinical trial evidence. The guideline shall point out the exceptional situations where these might be acceptable.

For accelerated and/or conditional marketing authorisations to be complemented by post-marketing authorisation clinical trials, the guideline should call on competent authorities to lay down strict criteria for the submission of comprehensive and reliable evidence on the efficacy and safety of the medicinal product, based on relevant clinical endpoints with a pre-specified deadline.

Sometimes Medical Devices (MD) and food supplements look like medicinal products but whose status doesn't protect consumers to the extent required by medical products regulations. The guideline should point out that trials on MD and food supplements should be subject to the obligation to demonstrate that the action of these products is NON-pharmacological, NON-immunological and NON-metabolic.

Please provide general comments for Section A: Key scientific and ethical considerations for good clinical trials.

Please provide general comments for Section B: Guidance on strengthening the clinical trial ecosystem.

Please provide general comments for Section C: Addressing under-represented subpopulations.

Please provide general comments for ANNEX 1: Provisions for rapid funding and approval of good randomized evidence generation in emergencies.

Please provide general comments for ANNEX 2: Recommendations for Member States, research funders and researchers.

Suggested amendments (maximum 30 amendments):

Please indicate the line number the suggested amendment starts	
Amendments	
Please provide the rationale for the suggested amendments	

Please copy the above form if you wish to suggest more amendments.

Thank you for your participation in the public consultation.