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

# **Strengthening clinical trials to provide high-quality evidence and improve research quality and coordination: outline of Secretariat activities**

## **INTRODUCTION**

1. In May 2022, the Seventy-fifth World Health Assembly adopted a resolution on strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination,<sup>1</sup> in which several activities were requested of the Director-General.
2. In the present document, the activities requested of the Director-General are outlined, along with the process planned for carrying them out. Input on this from the regional committees will inform the activities being carried out by the Secretariat.

## **ACTIVITIES REQUESTED OF THE DIRECTOR-GENERAL**

### **Organizing stakeholder consultations on roles and to identify and propose best practices and other measures to strengthen the global clinical trial ecosystem**

3. The Director-General was requested to organize, in a transparent manner, stakeholder consultations in line with the Framework of Engagement with Non-State Actors, with Member States, nongovernmental organizations including patient groups, private-sector entities including international business associations, philanthropic foundations and academic institutions, as appropriate, on the respective roles of the WHO Secretariat, Member States<sup>2</sup> and non-State actors, and to identify and propose to Member States, for consideration by the governing bodies, best practices and other measures to strengthen the global clinical trials ecosystem, taking into account relevant initiatives where appropriate.
4. The consultations are planned to be held between September and October 2022, to obtain input from all relevant stakeholders, spanning all diseases and health conditions. It is expected that the consultations will focus on what improvements in the global clinical trials ecosystem are needed in normal times as well as during public health emergencies of international concern.
5. Following the consultations, it is anticipated that a report will be produced that summarizes the input from the 2022 consultations and previous relevant consultations on the respective roles of the Secretariat, Member States and non-State actors. It is expected that actions will be proposed on how to improve the global clinical trials ecosystem, focusing on aspects such as governance, capacities

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<sup>1</sup> Resolution WHA75.8 (2022).

<sup>2</sup> And, where applicable, regional economic integration organizations.

(institutional, human and financial), oversight procedures, networks to be supported, reporting of results, sharing of data and translation of results into regulatory approval, and health policy.

### **Reviewing existing guidance and developing new guidance as needed on best practices for clinical trials**

6. The Director-General was also requested 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 and other organizations by providing, as appropriate: guidance on best practices to help to guide Member States' implementation of scientifically and ethically sound clinical trials within their national and regional contexts; and 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 Member States<sup>1</sup> and relevant non-State actors.

7. The guidance on best practices for clinical trials that will be developed should be applicable to any disease or health condition and all population groups and settings around the world, with provisions for application of the guidance during a public health emergency of international concern.

8. Building on the most applicable existing guidance, the Secretariat is developing, following the standard WHO processes, guidance for the implementation of high-quality clinical trials that can provide actionable evidence. This will focus on the regulation of medical products, research ethics committees, including expedited processes for emergencies, and the importance of the translation of results into guidelines and policy processes. The guidance will also cover the sharing of underlying datasets.

9. As specified in the resolution, it will be important to take 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 and other organizations. The new guidance must be complementary.

10. It is not yet clear how long this process will take, but it is likely to take at least two years, given the scope of the work required and the need to ensure that the guidance is relevant to all appropriate technical areas and complements existing guidance.

### **Providing to Member States, on their request, guidance on best practices for developing the legislation, infrastructure and capabilities required for clinical trials**

11. Another activity requested of the Director-General was 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. As stated, the provision of this support to Member States is on their request. No such requests have yet been received.

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<sup>1</sup> And, where applicable, regional economic integration organizations.

## **Engaging with relevant non-State actors to strengthen clinical trial capabilities**

12. The Director-General was requested to engage with, as appropriate, relevant non-State actors in line with the Framework of Engagement with Non-State Actors to strengthen clinical trial capabilities, particularly in developing countries, on innovations that meet the needs of major population groups that the intervention is intended to benefit, with a particular focus on under-represented populations. The Secretariat will engage with non-State actors through the process of stakeholder consultation outlined above.

## **Reporting on progress made**

13. In line with resolution WHA75.8, a substantive report outlining the progress made in the activities requested of the Director-General will be submitted for consideration by the Seventy-sixth World Health Assembly in 2023 through the Executive Board at its 152nd session.

## **ACTION BY THE REGIONAL COMMITTEE**

14. The Regional Committee is invited to provide input, to inform the relevant activities being carried out by the Secretariat. It is proposed that the discussions should be structured around the following questions.

- (a) Are there specific regional considerations regarding implementation of any of the activities outlined above? If so, please specify the considerations that should be taken into account.
- (b) Regarding developing guidance on best practices for strengthening clinical trials quality, coordination and capacity, are there regional initiatives in these areas that the Secretariat should be aware of and take into account?

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