WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR EUROPE

WELTGESUNDHEITSORGANISATION
REGIONALBÜRO FÜR EUROPA

ORGANISATION MONDIALE DE LA SANTÉ
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ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ЗДРАВООХРАНЕНИЯ
ЕВРОПЕЙСКОЕ РЕГИОНАЛЬНОЕ БЮРО

Regional Consultation on Strengthening Clinical Research and Trial Ecosystem in the WHO European Region **/1**

In-person meeting
10-11 June 2025
Prague, Czechia

01 April 2025
Original: English

Scope and purpose

Background

The European Programme of Work (EPW) and the ongoing process of developing the EPW2 recognizes the crucial role of science, research and evidence in advancing health across Europe and addressing complex health challenges in a rapidly changing world. While the EPW emphasizes leveraging research and innovation to identify effective solutions, recent insights have highlighted significant challenges within the clinical research and development ecosystem. These challenges reveal underutilized potential and create barriers to timely access to effective treatments and health interventions. The 75th World Health Assembly resolution (WHA75.8)1 called for Global Guidance on Best Practices for Implementing Scientifically and Ethically Sound Clinical Trials. This guidance addresses the current paradigm where clinical trials often prioritize commercial interests over public health needs, leading to a disconnect between research efforts and societal health priorities.

The development of this guidance began in January 2023, involving a Technical Advisory Group (TAG) of global experts in clinical trials, health research methodology, regulation, and ethics. The process included extensive consultations with a WHO Steering Committee and diverse stakeholders. The WHO's first Global Clinical Trials Forum (GCTF) in November 2023 brought together over 130 stakeholders from research institutions, regulatory bodies, ethics authorities, patient organizations, funding agencies, and the healthcare industry. This forum highlighted the need for a more coordinated approach to clinical research that is aligned with public health priorities.

The resulting Global Action Plan for Clinical Trial Ecosystem Strengthening (GAP-CTS) aims to operationalize strategies for maintaining and sustaining efficient clinical research infrastructure, capabilities, and capacities, focusing on addressing unmet medical needs and ensuring equitable access to treatments. The Guidance for Best Practices for Clinical Trials was published in September 2024. It offers key scientific and ethical considerations for clinical trial design and implementation and recommendations for strengthening national and global clinical trial ecosystems.

1 Strengthening clinical trials1 to provide high-quality evidence on health interventions and to improve research quality and coordination: https://apps.who.int/gb/ebwha/pdf_files/wha75/a75_r8-en.pdf

On that backdrop WHO Regional Office for Europe will host the consultation together with the Science Division of the WHO Headquarters and WHO Country Office in Czechia to leverage the global momentum generated by WHA75.8 and to achieve the following:

- to support and strengthen countries' capacities in conducting research and clinical trials that generate high-quality evidence for health interventions and decision-making, and
- to contextualize evidence-based Guidance to improve health policy and practice, with a particular focus on addressing the challenges of the European clinical development landscape.

Consultation Objectives
The consultation is targeted towards informing Member States and stakeholders about WHA75.8 and presenting the guidance for best practices for clinical trials, emphasizing the need for a paradigm shift in clinical trial design and implementation. It also aims to identify and discuss regional challenges and priorities in clinical research and trial ecosystems, including barriers to access and the misalignment between research focus and public health needs.

Format
The in-person consultation is planned for two full working days and will take place in Prague.

Participants
The consultation will bring together all nominated focal points from the 53 Member States of our Region, actively involved in or responsible for the coordination and collaboration with various national and international stakeholders in clinical research and trials at the national level and/or organizing clinical research and trial guideline development at the national level.