Expert consultation on strengthening national capacity for the conduct of randomized controlled trials and large-scale studies in countries of the Eastern Mediterranean Region*

Citation: World Health Organization. Expert consultation on strengthening national capacity for the conduct of randomized controlled trials and large-scale studies in countries of the Eastern Mediterranean Region. East Mediterr Health J. 2024;30(6):461–462. https://doi.org/10.26719/2024.30.6.461.

Introduction

The World Medical Association Declaration of Helsinki on the Ethical Principles for Medical Research Involving Human Subjects recommends that all clinical trials must be registered in a publicly accessible database before recruiting the first subject (*1*). The WHO International Clinical Trials Registry Platform (ICTRP) (*2*) emphasizes that all interventional clinical trials should be registered and publicly disclosed to ensure transparency, and the 24 items in the ICTRP trial registration data set are based on the items proposed by the International Committee of Medical Journal Editors (ICMJE) (*3*). WHO has been making efforts to establish clinical trial registries in the Eastern Mediterranean Region with little success.

In 2022, the Seventy-fifth World Health Assembly endorsed Resolution WHA75.8 on strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination (*4*). Among other things, the resolution recommends that to strengthen clinical trials globally, WHO should prepare a global guidance document on implementation of scientifically and ethically sound clinical trials by Member States and non-State actors. Following endorsement of the Resolution, WHO began consultations and development of the guidance document with the support of leading experts in clinical trials, health research methodology, regulation, and research ethics.

In November 2023, the WHO Regional Office for the Eastern Mediterranean (WHO/EMRO) held an expert consultation to discuss the importance of the Resolution and the guidance document and how to implement them in the region.

Summary of discussions

The national bioethics committees on randomized controlled trials (RCTs), clinical trials and large-scale studies have a crucial role to play in the establishment of a clinical trials registry in the region, particularly in ensuring that research has scientific merit and is conducted ethically. To do this effectively, they require adequate guidelines, legislation, regulation, logistic support, and coordination.

Many factors are necessary to improve clinical trials in the region. These include strong leadership at country and regional levels, community engagement, policy advocacy, networking, partnerships, collaborations, awareness-raising about and adherence to quality standards, building trust in clinical trials, as well as the provision of training and capacity-building, grants, and feedback mechanisms. It is important to address the deep-rooted cultural beliefs that could hamper the conduct of the trials. In recent years, digital technology has gained traction globally in the conduct of RCTs and this should be used with adequate provision for data security, hence, there is a need to improve the regulatory environment (*5*). Research should aim to build local capacity and health outcomes by aligning local health research to local health needs and priorities.

Although there are challenges to the conduct of large-scale cohort studies in the region, such studies can provide valuable insights into trends and disease patterns specific to the region and provide high-quality region-specific data to support long-term monitoring of health outcomes and improvement of the impact of public health programmes.

Some challenges affecting clinical trials in the region include poor medical record keeping, limited RCT and clinical trial expertise, multiple institutional review boards and approvals, use of ad-hoc committees, too much focus on pharmaceutical or industry-led trials, delays in seeking ethical clearance, poor quality research with poor designs and dissemination, interference due to armed conflicts, and poor research funding. To address these challenges Member States need to develop strong digital health records systems, conduct training in RCT research using existing capacity, improve ethics review systems, include patient care component in clinical trials, base clinical trials on country needs, develop separate ethics guidance for new drugs or interventions, establish networks of bioethics researchers, improve communication among RCT stakeholders, and develop frameworks for data-sharing and research funding.

* Summary report on the expert consultation on strengthening national capacity for the conduct of randomized controlled trials and large-scale studies in countries of the Eastern Mediterranean Region, Cairo, Egypt 14–15 November 2023. https://applications.emro.who.int/docs/WHOEMRPC054E-eng.pdf?ua=1.

Recommendations

Participants recommended the following actions for Member States and WHO to strengthen clinical trials in the region:

For Member States

1. Establish a clinical trials unit, including specialized units, at country and sub-country levels.
2. Invest in capacity-building, infrastructure development, and governance for RCTs and clinical trials.

For WHO

1. Facilitate engagements with national authorities to increase understanding of clinical trials in the region.
2. Support the mapping of clinical research centres in the region to inform capacity-building, infrastructure development, and research governance improvement efforts.
3. Support the development of a regional framework, strategy, and tools for strengthening RCTs and clinical trials, including regulation and certification systems.
4. Facilitate resource mobilization for clinical trials and RCT research.

References

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