



REPUBLIC OF NAMIBIA

Ministry of Health and Social Services



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NMRC Hosts Clinical Trials Stakeholder Consultation Workshop Under SEARCH II Initiative.



- The Namibia Medicines Regulatory Council (NMRC), through its Therapeutics Information and Pharmacovigilance Centre (TIPC), recently hosted a Clinical Trials Stakeholder Consultation Workshop as part of the Southern Africa Regulatory for Clinical Research (SEARCH II) Project.

The SEARCH II Project, which is funded by the European & Developing Countries Clinical Trials Partnership (EDCTP), is a regional initiative aimed at strengthening regulatory and ethical oversight of clinical research across Southern Africa.

The project promotes collaboration among National Regulatory Authorities and National Ethics Committees in Botswana, Eswatini, Lesotho, Mozambique, Namibia, and Zambia, while also benefiting from technical support from European partners. The initiative seeks to improve the integrity, quality, safety, and effectiveness of clinical research oversight while ensuring the protection of research participants.

Currently, Namibia does not have a dedicated legislative framework governing the conduct, authorization, and oversight of clinical trials. As a result, no clinical trials are being conducted or regulated under a national clinical trials system. The development of a comprehensive legal and regulatory framework is therefore essential to enable the ethical conduct, review, monitoring, and oversight of clinical research in the country.





The stakeholder consultation workshop formed part of Namibia's contribution to the SEARCH II Project and focused on reviewing clinical trial provisions contained in the draft medicines bill. Participants examined the draft bill provisions, provided technical input, and discussed opportunities to strengthen the country's regulatory framework in line with international and regional standards. The workshop also sought to incorporate recommendations from the World Health Organization's Global Benchmarking Tool (WHO GBT) assessments to enhance clinical trial oversight systems and legislative frameworks.

By hosting the stakeholder consultation workshop, NMRC reaffirmed its commitment to building a strong, transparent, and internationally aligned regulatory environment for clinical research. The outcomes of the workshop will contribute to ongoing efforts to strengthen clinical trial legislation, improve regulatory oversight, and ensure that clinical research conducted in Namibia adheres to the highest standards of ethics, quality, and participant safety.

NMRC extends its appreciation to all stakeholders who participated in the workshop and contributed valuable insights towards strengthening Namibia's clinical research ecosystem. The Council remains committed to fostering collaboration and advancing regulatory excellence in support of public health and scientific innovation.

Through interactive discussions and collaborative group work, stakeholders shared their expertise and perspectives on key aspects of clinical trial governance, ethics review systems, participant protection, compliance, monitoring, and enforcement. The engagement provided an important platform for consensus-building and ensured that a broad range of views were considered in the development of a robust and effective clinical trials regulatory system.

