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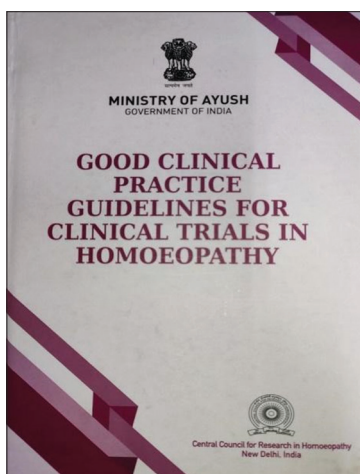
Abstract

Good Clinical Practice Guidelines for Clinical trials in Homoeopathy: Book Review

Good clinical practice guidelines for clinical trials in homoeopathy

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Good clinical practice guidelines for clinical trials in homoeopathy

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India has the highest number^[1] of practicing homoeopathic physicians compared to other countries and is unique in its institutional mechanism and research framework. Central Council for Research In Homoeopathy (CCRH), an apex body of the Ministry of AYUSH, has developed Good Clinical Practice guidelines for clinical trials in Homoeopathy (GCP-H) for researchers, practitioners, academicians and students interested in conducting ethical and credible homoeopathic research. Research in homoeopathy is vital to validate existing

drugs and practices and develop new drugs, as detailed in this book. These generic guidelines delineate minimum standards for undertaking clinical research in public health and in social and behavioural areas with homoeopathic medicines.

This GCP-H would also serve as a guiding tool for researchers and policymakers for homoeopathic research. The guidelines consider all aspects of research, including protocol development, study design, implementation, responsibilities of stakeholders, monitoring, auditing, data recording and reporting of research studies. It identifies and describes different forms of clinical studies, including novel designs to generate scientific data, which can be translated into clinical practice, education and further research.

Further, these guidelines ensure that during research, the participant's rights, safety and well-being are protected, providing at the same time that the study is authentic and the results are credible and accurate.

The text in this book is divided into ten sections, each including a list of authoritative source books in Homoeopathy, a format for the Investigator's brochure, and a checklist for practical execution. A Glossary at the beginning defines many terms used in homoeopathy and research, making this an introductory document for scientists not familiar with homoeopathy but willing to undertake research in collaboration with homoeopathic scientists. The clinical trial phases, as applicable to homoeopathy, are delineated. The documents also detail the process for validating pharmacopeial drugs and their repurposing in emergencies like epidemics/pandemics, an outbreak of a new disease or new clinical syndromes.

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The studies' prerequisites are homoeopathic drug (or the investigational homoeopathic product), supporting data, protocol and analysis registration in an appropriate registry. In addition, for conducting any research, the protocol is a vital prerequisite, the components of which are elaborated further.

The mechanism to be put in place and the regulatory requirements to ensure participant safety are also highlighted. The constitution and responsibilities of the ethical committee are detailed, considering that the studies in homoeopathy are undertaken by the involvement of practitioners/scientists with knowledge and experience working with homoeopathic medicines.

The responsibilities of the sponsor, investigators, monitors, and auditors are given in detail, and this chapter needs to be referred to frequently while conducting research.

Another critical step in the research is record-keeping, which includes all the source documents and documents developed in compliance with the protocols, Standard Operating Procedures and data handling have been explained elaborately. The chapter also elaborates on the role of digitisation in record keeping and ensures data safety and reliability. The chapter on quality assurance reiterates the steps to ensure quality in study conduct, data and reporting.

These guidelines collate CCRH's experience of more than 40 years, with the experiences of researchers from India and abroad, of developing aims and patterns of homoeopathic research researching all aspects of homoeopathy. The guidelines examine the existing provisions in the Ministry of AYUSH Document of Guidelines GCP for clinical trials on Ayurveda, Siddha and Unani medicine (2013);^[2] Central Drugs Standard Control Organisation Document on GCP Guidelines for Clinical Trials on Pharmaceutical Products (2001),^[3] International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Integrated Addendum to ICH e6 (R1): Guideline for GCP E6(R2)^[4] and World Health Organization Guidelines

for GCP for trials on pharmaceutical products (1995)^[5] and Indian Council for Medical Research Guidelines for bioethics National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017).^[6] Although these guidelines are comprehensive, there are areas where these documents may need to be referred to by the readers to gather more details and a better understanding of the processes. Some issues on research policies, conflict of interest, reporting and publishing research, including research misconduct and collaboration with national and international organisations, are given very briefly here.

Not only for established researchers; this book will significantly benefit post-graduation students and doctorate scholars as well, who are undertaking research studies for the 1st time. The book will become a vital source for researchers to comprehensively understand their responsibility for conducting high-quality research.

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