The CONTROL

(COgNitive Therapy for depRessiOn in tubercuLosis treatment)

to improve outcomes for depression and TB in Pakistan and Afghanistan

Funded by: RIGHT3, NIHR

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“Good Clinical Practice GCP Training ”

30-31 October 2024

EXECUTIVE SUMMARY

Capacity development is an integral component of CONTROL study as the research team comprises of: early careers researchers as Research Assistants, qualitative and quantitative researchers, data input administrators, DOTs facilitators, master's students, Ph.D. scholars, Post Doc Fellows. Developing their knowledge, skills and attitude will in turn contribute to the quality of project deliverables.

The Good Clinical Practice (GCP) training workshop was arranged for new members of the CONTROL Program, including research assistants and psychologists involved in the trial. It was conducted on October 30th and 31st, 2024, from 9:00 am to 1:00 pm at Khyber Medical University. The training, led by experts Prof. Akhtar Sherin and Mr. Muhammad Saleem, focused on important topics like clinical trial procedures, ethical research practices, informed consent, accurate data collection, and following regulations. The goal was to give participants the knowledge and skills they need to conduct clinical trials responsibly and effectively. This training was essential to ensure high-quality research and protect the well-being of trial participants. By the end of the training, participants successfully completed and passed their GCP training test. This report will narrate the proceeding of a two-day GCP training.

INTRODUCTION

Good Clinical Practice (GCP) is a set of ethical and scientific quality standards that guide the design, conduct, recording, and reporting of clinical trials involving human participants. Adhering to these standards is essential for maintaining the reliability of research data and ensuring the safety and welfare of participants. This workshop was intended for members who have yet to complete their GCP training. By participating, attendees learnt about clinical trial protocols, informed consent, data integrity, and regulatory compliance, skills essential for maintaining participant safety and the reliability of research data.

Activity Background

The need for this workshop was identified after reviewing the status of GCP training among members. It was found that newly recruited CONTROL staff members have not yet completed this training, which is a requirement for participating in clinical research and ensuring compliance with ethical guidelines.

Objectives

The main objectives of the workshop were to provide a thorough understanding of GCP guidelines, strengthen participants' ability to conduct clinical research ethically, and ensure that they were well-prepared to adhere to high clinical research standards.

Facilitators

- Prof. Akhtar Sherin — Director, Clinical Trial Unit, KMU
- Mr. Muhammad Saleem — Coordinator, Clinical Trial Unit, KMU

Participants

The workshop was attended by 15 participants including research assistants and psychologists who would be working in CONTROL trials in the field.

Workshop proceeding

Day 1- 30th October 2024

The GCP training workshop was successfully conducted

over two days, on the 30th and 31st of October 2024, from 9:00 am to 1:00 pm each day. The sessions were led by Prof. Akhtar Sherin and Mr. Muhammad Saleem, who guided participants through a comprehensive and engaging program. The first part of the workshop focused on introducing the participants to the key principles of Good Clinical Practice (GCP). Facilitators presented an overview of GCP guidelines and emphasized the importance of maintaining ethical and scientific quality standards in clinical trials. This was followed by discussions on clinical trial protocols, the informed consent process, data integrity, and regulatory compliance. Real-world examples were shared to highlight how these principles are applied in clinical research.

Participants actively engaged in group discussions, sharing experiences and asking questions to deepen their understanding of GCP. Interactive exercises were conducted to reinforce key concepts, such as accurate record-keeping and maintaining patient confidentiality. The participants were divided into smaller groups to work on case studies that explored potential challenges in clinical research and proposed solutions in line with GCP standards.

Day 2- 31st October 2024

The second day continued with more in-depth activities that focused on practical scenarios, prompting participants to identify and address challenges commonly encountered in clinical trials. Facilitators provided guidance and feedback throughout these activities, ensuring that each participant grasped the necessary skills and knowledge. Short quizzes were used as a tool for participants to assess their understanding, and facilitators provided personalized feedback to address any gaps in comprehension.

The workshop concluded with a reflection session where participants

shared their key takeaways and discussed how they would apply the learned principles in their professional practices. This final session emphasized the importance of integrating GCP into daily work and maintaining the highest ethical standards in clinical research.

Overall, the workshop was well-received and achieved its goal of enhancing participants' knowledge and understanding of Good Clinical Practice.

Reflection

The workshop achieved its goal of providing participants with a deeper understanding of GCP and its application in clinical research. The participants left with a stronger commitment to conducting clinical trials ethically and with high standards. The workshop not only met the training needs of the attendees but also emphasized the importance of continuous adherence to GCP guidelines for the well-being of participants and the integrity of clinical research.