Navigating clinical trials in resource-limited settings: The EASE trial experience of overcoming obstacles

Mohammed Noor Syahireen[1], Mohd Suan Mohd Azri[1], Ismail Ibtisam[1], Ahmad Faizah[1], Soelar Shahrul Aiman[1], Md Ali Siti Maisarah[1], Chan Huan Keat[2], Abu Hassan Muhammad Radzi[2]

[1]Clinical Research Centre, Hospital Sultanah Bahiyah, Alor Setar, Kedah, [2]Office of Director General, Ministry of Health Malaysia, Putrajaya

ABSTRACT

Introduction: Conducting clinical trials in resource-limited settings poses challenges such as limited infrastructure, inadequate funding, and a scarcity of qualified personnel. Understanding and addressing these obstacles is crucial to improving healthcare outcomes for underserved populations. In view of this, the EASE Trial, a Ministry of Health-owned study, was initiated to specifically focus on finding a cost-effective solution for hepatitis C treatment, with a particular emphasis on vulnerable populations. Additionally, the trial aims to build capacity in healthcare sites that have not previously conducted clinical trials, including Klinik Kesihatan. **Methods:** A comprehensive case study explored challenges faced in the EASE Trial, which aimed to address the specific needs and constraints of a resource-limited setting. Data collection included focused group discussions, document analysis, and on-site observations, providing insights into contextual factors and specific challenges encountered. **Results:** The case study uncovered challenges in the EASE Trial, including limited financial resources, patient selection and recruitment difficulties, inadequate training and capacity in primary healthcare, and insufficient laboratory facilities and logistics. Innovative solutions, such as community engagement, were implemented. Opportunities identified included motivated research teams, the potential for population health impact, and the importance of research leadership in driving successful trials. **Conclusion:** Findings highlighted the importance of addressing limited resources, infrastructure, and trained personnel while adapting to the local context. Strategies to overcome these challenges and leverage opportunities, with a strong emphasis on research leadership, can enhance clinical trial conduct in resource-limited settings, ultimately improving healthcare delivery for underserved populations.