Reporting of Participant Dropouts in Diabetic Clinical Trials: A PubMed-Based Analysis

Vignesh Perumal
Faculty of Clinical Research, Sri Ramachandra Institute of Higher Education and Research (SRIHER) Deemed University, Porur, Chennai, India

Lokesh R
L Statistix, Ambattur Industrial Estate, Chennai, India

Dr. Ramya S
Department of Pharmacology, Sri Ramachandra Institute of Higher Education and Research (SRIHER) Deemed University, Porur, Chennai, India

Kannan N
Faculty of Clinical Research, Sri Ramachandra Institute of Higher Education and Research (SRIHER) Deemed University, Porur, Chennai, India

Dr. Manickam P
ICMR-National Institute of Epidemiology (ICMR-NIE), Ayappakkam, Chennai, India

Dr. Mahalakshmi R*
Faculty of Clinical Research, Sri Ramachandra Institute of Higher Education and Research (SRIHER) Deemed University, Porur, Chennai, India

Abstract

Clinical trials are widely regarded as the gold standard for developing advanced medicines and therapeutic interventions. Despite their importance, they face significant operational challenges, particularly in participant recruitment and retention. High dropout rates not only increase financial burden and extend study timelines but also compromise the generalizability and reliability of trial outcomes. Even with extensive efforts by sponsors and site teams, participant retention remains a persistent challenge. This study aims to analyse how and where the dropouts and the associated reasons are documented, with a specific focus on examining inconsistencies in the terminology used to describe these reasons. A structured review of publications of diabetic drug trials indexed in PubMed was conducted over the past 1 year, including studies that explicitly reported patient withdrawal in diabetes-related clinical trials. The dropout data for the selected studies from clinical trial registries were also compared. The findings highlighted that nearly one-third of the reviewed studies did not provide any documented reasons for participant dropout. Additionally, there was considerable variability and a lack of standardisation in the terminology used to report withdrawal reasons, leading to ambiguity and challenges in interpreting and comparing results across studies. These observations highlight a critical gap in the reporting practices related to participant dropouts from clinical trials that severely undermines transparency and data quality. Establishing standardised terminologies for reporting dropouts would enhance the overall quality, interpretability, and credibility of clinical research outcomes.