Abstract

The Pivotal Role of the Clinical Research Nurse in Phase I Oncology Clinical Trials: Managing Complexity, Safety and Coordination

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Introduction. Phase I oncology clinical trials primarily aim to define the safety profile, tolerability and optimal dosing of investigational therapies. The introduction of targeted agents and immunotherapies has markedly increased trial complexity, introducing novel challenges in toxicity assessment, clinical surveillance, and protocol execution. Accumulating evidence demonstrates significant discordance between clinician-reported adverse events and patient-reported outcomes (PROs), thereby exposing inherent limitations of conventional safety evaluation frameworks and emphasizing the need for more sensitive, multidimensional, and patient-centered assessment methodologies. This review aims to critically appraise and systematically synthesize contemporary evidence on the increasing complexity of Phase I oncology trials, with particular emphasis on the role of the Clinical Research Nurse (CRN) in ensuring patient safety, data integrity, and protocol adherence. Additionally, this review aims to examine the CRN's contribution to multidisciplinary coordination, the early detection and management of adverse events, and the identification of priority areas for nursing research to support the implementation and advancement of early-phase clinical practice.

Methods. A scoping review was conducted in accordance with the Arksey and O'Malley methodological framework and reported following PRISMA-ScR guidelines. A comprehensive search of international databases was performed for studies published between 2015 and April 2026, using keywords related to oncology, Phase I clinical trials, and clinical research nursing. Twelve English-language studies, including observational, qualitative, and review designs, were selected based on predefined inclusion and exclusion criteria. Studies lacking full-text availability were excluded.

Results. Phase I oncology trials are characterized by substantial operational complexity, evolving

endpoints, and stringent regulatory requirements. The evidence consistently demonstrates a marked underestimation of symptomatic adverse events by clinicians when compared with patient-reported outcomes (PROs), with some studies reporting discrepancies of up to an order of magnitude. Patient participation appears to be influenced by a range of psychosocial determinants, including expectations of therapeutic benefit, individual coping mechanisms, and trust in the healthcare team. Within this context, the CRN emerges as a pivotal figure in safety surveillance, early identification and management of adverse events, protocol compliance, and the maintenance of data quality. Moreover, CRNs play a pivotal role in patient education, the informed consent process, and interdisciplinary coordination, operating within a highly demanding and multidimensional workload environment.

Discussion. Clinical Research Nurses are integral to ensuring patient safety, methodological rigor, and protocol adherence in Phase I oncology trials. Systematic integration of PROs and the formal recognition of advanced CRN competencies have the potential to enhance the accuracy of toxicity assessment, strengthen patient-centered care, and improve overall research quality in early-phase oncology. Future research should focus on standardizing the CRN role across clinical research networks and on structured incorporation of PRO-based monitoring into early-phase trial design.

Keywords: Phase I Clinical Trials, Research Nurse, Patient Safety, Adverse Events, Clinical Trial Complexity, Care Coordination

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