Phase 1 clinical trials are essential to improving outcomes in cancer care. The investigational agents in these trials may be associated with adverse events that can contribute to symptom burden and declining performance status for trial participants. The emerging role for oncology nurse practitioners (ONPs) as subinvestigators offers a unique practice setting for advanced practice nurses. In this role, ONPs provide expert oncology care, are responsible for swift recognition and management of adverse events, and ensure adherence to the clinical trial protocol.

AT A GLANCE

- Phase 1 clinical trials are critical to advancing cancer treatment options.
- The demand for phase 1 clinical oncology trials is expanding, and continued growth is expected.
- ONPs are well suited to assume the role of phase 1 subinvestigator, based on their advanced practice preparation and clinical expertise.

KEYWORDS
nurse practitioners; subinvestigator; phase 1 oncology clinical trial

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Clinical Trial Subinvestigator

An emerging role for oncology nurse practitioners

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Phase 1 clinical trials are conducted to explore safety, tolerability, adverse events (AEs), and the pharmacokinetics of an investigational agent (West & Dahlberg, 2018). Although phase 1 agents have been tested in laboratory and animal studies, the side effects in humans cannot always be predicted (West & Dahlberg, 2018) and are often identified or further described in the course of conducting the trial. Traditionally, phase 1 trials were referred to as toxicity trials, with low clinical utility (Adashek et al., 2019). With the introduction of targeted therapies and immunotherapies for cancer treatment, phase 1 trials have resulted in improved overall response rates ranging from 20% to 42% (Adashek et al., 2019).

In part because of the success of clinical trials involving targeted and immunotherapy agents, the demand for phase 1 trials has accelerated (Malik & Lu, 2019). For example, 849 new cancer drugs were launched in 2018, an increase from 711 in 2017; all were targeted therapies (IQVIA Institute, 2019). Other factors contributing to the growth of clinical trials include increased knowledge regarding the molecular and immune aspects of cancer, development of highly specific molecular targeted agents, increased identification and use of biomarkers, and new technological advances such as liquid biopsies and artificial intelligence (Adashek et al., 2019; Garralda et al., 2019; IQVIA Institute, 2019; Rolfo et al., 2018).

Although the demand for phase 1 clinical trials has increased, investigator-specific barriers may affect trial availability and access. The oncologist's level of engagement may play a pivotal role in patient recruitment and retention, patient follow-up, the quality of data collected, and the overall success of a clinical trial; however, barriers to engagement exist, including time constraints, increased paperwork, complex patient education, and extended follow-up or clinic visits (Mahmud et al., 2018). In fact, the American Society of Clinical Oncology (2017) has recognized that the growing demand for phase 1 trials is expected to outpace the supply of oncologists available to serve as investigators.

Oncology nurse practitioners (ONPs) are already delivering high-quality, safe, and effective patient-centered care to patients with cancer. The population of patients enrolling in phase 1 trials includes those with complex care needs. Phase 1 study participants have usually exhausted standard-of-care therapies (Kinahan et al., 2017). Most have advanced disease, distant metastases, a prognosis of 6–24 months, and a significant symptom burden secondary to progression of disease and/or investigational agent toxicities (Ferrell et al., 2017). The increasing demand for phase 1 trials, the potential anticipated shortage of oncologists to meet that demand, and the complex nature of these patients' disease support the case for increased involvement of ONPs in clinical trials. To date, there is limited discussion in the literature about ONPs as