HOPA
Hematology/Oncology Pharmacy Association

Pharmacists Optimizing Cancer Care®

Clinical Trials Issue Brief

Background:

Clinical trials are essential to advancing cancer care and improving outcomes for patients with cancer. Through clinical research, patients gain access to innovative therapies, precision medicine approaches, and supportive care strategies that have transformed oncology treatment over recent decades. In addition to expanding treatment options, clinical trials contribute to improved survival, quality of life, and deepening our understanding of cancer biology. As oncology treatment continues to evolve with increasingly complex therapies and precision medicine approaches, the operational and clinical demands required to safely conduct clinical trials have expanded significantly. Successful trial programs rely on a multidisciplinary infrastructure, including hematology/oncology pharmacists, who play a critical role in investigational drug management, protocol implementation, medication safety, patient education, and supportive care.

Despite the importance of clinical research, barriers including financial constraints, limited geographic access, workforce and operational challenges, regulatory complexity, and patient misconceptions continue to limit trial access and participation. Underrepresentation of diverse patient groups limits generalizability by those that are already disproportionately affected by higher cancer morbidity and mortality rates. Addressing these challenges is critical to ensure equitable access to clinical trials, support sustainable research infrastructure, and continue progress in cancer treatment innovation.[1,2]

Role of Hematology/Oncology Pharmacists and Investigational Drug Service Pharmacist in Clinical Trials:

Investigational Drug Services

Pharmacists play a critical role in investigational drug services (IDS) by ensuring the safe, compliant, and efficient management of investigational agents used in clinical trials. Their responsibilities include protocol review, facilitation of study protocol adoption into site-specific pharmacy workflows and operational procedures, creation of electronic treatment plans, investigational product procurement, storage, preparation, dispensing, accountability, and destruction in accordance with sponsor requirements, institutional policies, and federal regulations. Oncology pharmacists also collaborate with principal investigators, study coordinators, and institutional review boards to evaluate protocol feasibility, identify medication-related safety concerns, and ensure appropriate handling of hazardous investigational therapies.[3] Pharmacists maintain accurate drug accountability records and participate in regulatory audits and monitoring visits to ensure compliance with Good Clinical Practice standards. These activities support patient safety, protocol integrity, and the overall success of oncology clinical research.[4]

Patient Clinical Activities

Pharmacists are directly involved in patient-centered clinical activities throughout the clinical trial process. They provide medication education to medical staff and counseling to patients regarding investigational therapies, including administration, potential adverse effects, drug interactions, and adherence expectations.[5] Pharmacists monitor patients for treatment-related toxicities, assess laboratory values, and recommend supportive care interventions to optimize safety and therapeutic outcomes. Their expertise in pharmacokinetics, pharmacodynamics, and oncology therapeutics allows them to identify and manage adverse drug reactions early, contributing to improved patient care during trials. Pharmacists also assist with treatment plan verification, dose modifications, and medication reconciliation to ensure protocol compliance and continuity of care.[6] Furthermore, they collaborate with multidisciplinary teams to evaluate patient eligibility, support enrollment efforts, and provide clinical insight during protocol implementation. By integrating direct patient care with research activities, pharmacists enhance both the quality of clinical trial conduct and the patient experience.

Barriers Facing Cancer Clinical Trials:

Despite the critical role clinical trials play in advancing cancer care, significant barriers continue to limit the ability of healthcare institutions, pharmacists, and patients to fully participate. Only about 7% of patients with cancer take part in clinical trials, and 20 – 40% of cancer trials do not meet enrollment targets, often leading to premature study termination. These barriers span funding and reimbursement, regulatory and policy challenges, workforce capacity, and patient-level misconceptions.[7,8,9]

Funding

- Justifying the cost of pharmacy services in clinical trials is difficult, especially at smaller and community-based sites. Supporting pharmacist involvement in clinical trials requires staff, infrastructure, and ongoing operational resources. Larger academic medical centers may absorb these costs more readily, but smaller sites and satellite locations often cannot. There is little to no dedicated funding source for pharmacy research activities at many institutions.
- Billing and reimbursement for pharmacy services during clinical trials are still unclear and insufficient. Medicare covers the "routine costs" of qualifying clinical trials, services that would normally be provided even outside a trial but does not cover the investigational item or service itself, nor does it cover services provided solely for data collection purposes. There is currently no clear billing mechanism for pharmacist counseling or clinical pharmacy services provided to clinical trial patients, meaning pharmacists deliver significant value without a corresponding reimbursement pathway.[10]
- Grant funding often does not cover the full cost of supporting clinical trial patients**.** Per-patient reimbursement through grants frequently falls short of actual costs, particularly when accounting for pharmacy personnel time, drug procurement, inventory management, and patient education. Recent disruptions in federal research funding, including the attempted 15% cap on NIH indirect costs in 2025[11], created significant uncertainty for institutions that rely on these funds to support research infrastructure such as laboratory space, compliance systems, and administrative support for clinical trials.

Regulatory and Policy Challenges

- Drug shortages directly disrupt clinical trials. According to a 2024 survey by the National Comprehensive Cancer Network (NCCN), drug shortages affected clinical trials at 43% of surveyed centers. Among those centers, the reported impacts included greater administrative burden (83%), reduced enrollment (58%), and reduced numbers of open trials (17%). The root causes of oncology drug shortages include supply chain vulnerabilities, insufficient manufacturing redundancy, and poor economic incentives in the generic drug market.[12,13]
- Medicare billing requirements add administrative complexity. Medicare requires that institutions bill patients for all services provided during a clinical trial, even when reimbursement may not be collected. Navigating the distinction between what is billable as routine care versus what is research-driven requires specialized knowledge and creates compliance risk, particularly at sites with limited research billing infrastructure.[10]

Workforce Capacity

- Within oncology, the demand for specialized IDS pharmacists is growing as trial complexity increases—driven by novel trial designs, gene and cellular therapies, and master protocol studies—yet few formal training programs (fellowships or residencies) exist specifically for IDS practice.[14] Additionally, the combination of high complexity, specialized knowledge requirements, and lack of clear career advancement pathways or financial incentives makes it difficult to recruit and keep pharmacists in IDS roles.
- At many institutions that conduct clinical trials, pharmacist job descriptions may not include dedicated time for research-related activities. Without protected time or clear institutional support, pharmacists who wish to participate in trial-related work—whether IDS operations, protocol development, or patient-facing clinical activities—must do so on top of existing clinical responsibilities. Research by Schmidt et al. found that key IDS pharmacy services are consistently performed less than 50% of the time, with barriers including limited time, competing workload demands, and insufficient funding and dedicated resources.[15]

Patient Misinformation and Misconceptions

- Nearly 70% of patients never or rarely consider a clinical trial when discussing treatment options with their physician. Lack of awareness, persistent myths—such as the fear of being a "guinea pig," concerns about receiving only a placebo, or the belief that outcomes are not guaranteed—deter patients from enrolling. For underserved communities, historical injustices such as the Tuskegee Syphilis Study have created deep-seated, generational mistrust of medical research.[7,16]
- Additionally, one study found that 64% of cancer clinical trial participants incurred unexpected non-medical, trial-related expenses, with 48% spending over $1,000 per month out of pocket. Lower-income patients are less likely to participate in clinical trials because of excess financial expenditures on the clinical trials.[17,18,19]

Recommendations:

HOPA makes the following recommendations to ensure that clinical trials remain operationally sustainable and accessible to all patients, regardless of their background or socioeconomic status:

- Adequately fund the National Institutes of Health (NIH) and National Cancer Institutes' (NCI) biomedical research programs through the annual federal appropriations and budget process;
- Provide incremental funding for multi-year NIH grants instead of implementing a forward funding model;
- Maintain the negotiated indirect cost rates for NIH grants instead of implementing a standardized flat cap on indirect costs;
- Expand the FDA's decentralized clinical trials model so patients can receive care closer to home;
- Create a grant program to support outreach, education, and recruitment efforts for clinical trials targeted at underrepresented populations or communities in need;
- Pass legislation that allows clinical trial sponsors to provide financial support to patients for costs associated with their trial participation, including co-pays, travel, parking, meals, and lodging;
- Exempt the following types of financial support for clinical trial participation from anti-kickback laws for federal health programs:
    - Renumeration that is offered to cover participants' expenses to participate in clinical trials;
    - The provision of free digital health technologies to support participation of underrepresented populations in clinical trials;
    - Payment for participants' cost-sharing obligations in relation to clinical trials;
- Exclude all remuneration for participation in clinical trials from taxable income;
- Require insurance providers to cover services related to clinical trial participation;
- Permanently extend the Medicare telehealth flexibilities to allow Medicare beneficiaries to receive telehealth services related to clinical trial participation from any location with no geographic restrictions;
- Support programs that educate the general public on clinical trials to improve public confidence;
- Provide a reimbursement mechanism that allows pharmacists to bill for services they provide related to clinical trials.

Conclusion:

The United States continues to lead the world in the fight against cancer, due in large part to innovations from our biomedical research and clinical trial programs. In order to ensure that this progress is maintained, clinical trials need to remain operationally and financially sustainable and continue to modernize with the rest of society. In the coming years, trial sites may begin leveraging advancing technologies, such as artificial intelligence, to reduce the administrative burden on practitioners. Pharmacists will continue to play a crucial role in ensuring that these new, innovative and life-saving treatments can be safely delivered to patients. HOPA remains committed to ensuring that all eligible patients have access to a clinical trial, regardless of where they live or their socio-economic circumstances.

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