Category: Clinical Trial Operations (Trial Start-up, Regulatory, Finance, Data Management, IITs) – Completed Project

Integration of Clinical Trials With Nuclear Medicine for Radiopharmaceutical Treatments

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1. Background

Radiopharmaceutical therapies are increasingly used in oncology clinical trials and require tight coordination between clinical trial units and Nuclear Medicine. Lack of standardized workflows can cause scheduling delays, communication gaps, and treatment inefficiencies. We developed a streamlined, role-based workflow integrating Nuclear Medicine into clinical trial operations from prescreening through follow-up and subsequent cycles.

2. Goals

- Expand the standardized Nuclear Medicine clinical trials workflow to additional disease groups.
- Support activation and execution of radiopharmaceutical clinical trials across programs.
- Maintain efficient scheduling, protocol compliance, and patient safety as trial volume increases.

3. Solutions and Methods

A multidisciplinary workflow was established involving the Clinical Trials Office (CTO) treating physicians, Nuclear Medicine (NM) physician, advanced practice provider (APP), technologists and scheduler, the research team, and Interventional Radiology for APP coverage when needed. NM physicians perform consultation visits, review trial protocols for feasibility, verify radiopharmaceutical doses, and provide treatment-day oversight. NM APPs coordinate radiopharmaceutical supply with sponsors or investigational drug services, administer radiopharmaceutical therapy, and collect protocol-required research procedures while patients are in NM. Technologists prepare the NM suite, perform identity and pre-treatment checks, coordinate ordering of standard-of-care radiopharmaceuticals and document administrations in the electronic health record. The scheduler books research-designated NM appointments in Epic and links required follow-up NM visits. The CCU research team identifies and prescreens candidates, obtains informed consent, completes protocol-required screening, ensures pre-treatment labs and imaging are done, and sends treatment clearance and infusion sheets to NM prior to each treatment.

Key standardized steps include: (1) Prescreening, where the treating MD and CCU team identify potential participants and, if preliminarily eligible, contact the NM APP to review potential treatment dates and tentatively hold initial therapy slots. (2) Consenting and NM consultation, with patients consented in clinic and referred to NM to confirm suitability; NM then initiates insurance authorization and ordering for standard-of-care agents or coordinates investigational product shipment for sponsor-provided drugs. (3) Scheduling initial treatment, with research teams proposing dates within protocol windows and NM confirming provider, room, technologist, and radiopharmaceutical availability before scheduling. (4) Screening and enrollment, with completion of protocol-required assessments, eligibility confirmation, and written treatment clearance sent to NM. (5) Treatment day, with same-day clinic evaluation for labs and eligibility, followed by NM therapy administration, trial-specific safety assessments, and documentation of dose, timing, route, and immediate adverse events, plus radiation safety and follow-up instructions. (6) Follow-up and subsequent cycles- CCU ensures pre-treatment visits and NM APPs complete sponsor order forms and adhere to institutional and sponsor ordering timelines.

4. Outcomes

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Implementation of this workflow improved coordination and supported timely radiopharmaceutical delivery. Within the GU disease group, five Nuclear Medicine–incorporating clinical trials were activated using this model, with 33 patients successfully enrolled and treated and no workflow-related treatment delays. The workflow has also been used in the Breast Disease Group, enabling successful enrollment and treatment of their first Nuclear Medicine trial participant. Clear role delineation and structured communication supported protocol compliance, documentation, and radiation safety.

5. Lessons Learned and Future Directions

This standardized workflow highlights the importance of early multidisciplinary engagement, explicit role definition, and centralized communication between CCU and Nuclear Medicine. Based on its success in the Genitourinary Disease Group, additional disease groups are adopting this integrated model. Future work will focus on expanding capacity, further refining scheduling processes, and supporting broader implementation of radiopharmaceutical trials across disease programs.