Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Work in Progress

So You Want to Build A Radiopharmaceutical Program? Lessons Learned

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1. Background

In spring of 2024, the University of Kansas Cancer Center (KUCC) experienced a surge in radiopharmaceutical clinical trial opportunities presented to our Site Development team. Recognizing the need for a structured approach to support these trials, key physicians and staff initiated the development of a comprehensive radiopharmaceutical program.

2. Goals

- Establish regular meetings of key physicians and staff to determine the feasibility of each protocol and begin developing a comprehensive portfolio.
- Assess KUCC's sites for space and capability to accommodate these unique trials.
- Collaborate with health system departments to establish necessary partnerships within the program.
- Work toward making KUCC a premier location in our region for radiopharmaceutical treatment and clinical trials.

3. Solutions and Methods

A Radiopharmaceutical Trial Review Committee was established that contained representatives from Project Management, Nuclear Medicine, Radiation Oncology, Radiation Safety, and Clinical Operations, that meets at least every two months to discuss trial feasibility, and the development of the program. Project Management worked with the key representatives of this group to begin establishing firm feasibility outlines for the available space at each of our sites, and the needed workflows for new processes involving radiopharmaceuticals, radioactive biospecimens, and collaboration between hospital and cancer center staff.

4. Outcomes

The Radiopharmaceutical Trial Review Committee expanded to include leadership and additional members from other departments so that all stakeholders could be aware of the trials and the program's progression. Additional meetings are held as needed to discuss specific issues a trial, or workflow, is facing and work towards solutions. KUCC was ultimately able to open its first radiopharmaceutical trial under the new program in Fall of 2024 and is in the process of opening its second.

5. Learned and Future Directions

As more trials were assessed for the KUCC site and the early stages of the radiopharmaceutical program were implemented, it became easier to identify the gaps within the workflows. Space and staffing for a new program were two of the largest challenges KUCC faced, as radiopharmaceutical trials require specific staff with knowledge of nuclear medicine and dedicated space for patients, drugs, and biospecimens to avoid radiation contamination of non-radioactive spaces and equipment. It was crucial to onboard Nuclear Medicine staff to the research infrastructure, as the Nuclear Medicine department takes the place of the Investigational Pharmacy on these trials and ultimately needs to be included in Site Initiation Visits and Delegation of Authority logs. Additionally, establishing a strong working

relationship with the Radiation Safety team was essential, as they have oversight over much of the equipment, spaces, biospecimens, and the workflows needed for these trials to function.

Workflow and feasibility gaps were also identified during the start-up these initial radiopharmaceutical trials. In 2025, KUCC will focus on addressing these gaps, securing the required equipment, and strengthening the inter-departmental relationships needed for the program to grow and succeed.