Theranostic Clinical Trials: Lessons in Collaboration at an Academic Medical Center (AMC)

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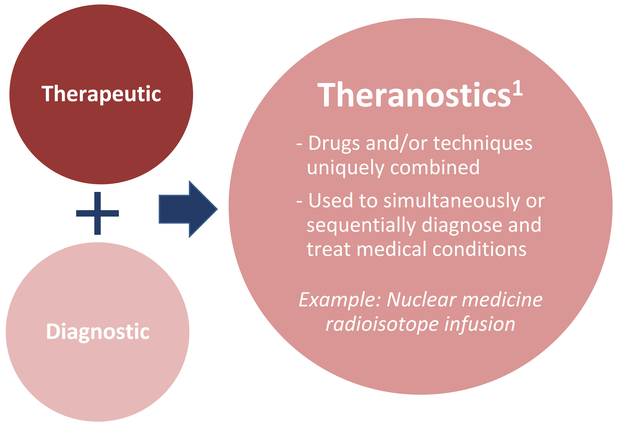
NURSING

Background



Implementation and operationalization of theranostic clinical trials requires collaboration with many departments. Confusion around the interdisciplinary team members' roles and responsibilities results in safety concerns, protocol deviations, and inefficiencies.

When treatments are carried out on the Clinical Research Unit (CRU), the clinical research nurse (CRN) is at the juncture of all disciplines, involved in all aspects of the visit. Because of the focus on participant safety and research protocol fidelity, CRNs are uniquely positioned to identify breakdowns in processes and gaps in knowledge and communication.

Objectives

To improve implementation and operationalization of theranostic clinical trials on the CRU through ongoing collaboration and cultivation of a greater understanding of interdisciplinary teams; roles and responsibilities.

[1] Damien Joanas Wilson, MD. https://www.news-medical.net/health/What-is-Theranostics.aspx

Implementation

CRNs leading this initiative used the RACI model to identify who is responsible for what activities in this process, identify processes to ensure accountability, work with leadership to support the initiative, consult with stakeholders, and inform the multidisciplinary research team about theranostic research studies and related workflows. We met to identify challenges and gaps in knowledge, and finally, determine how to best streamline communications.

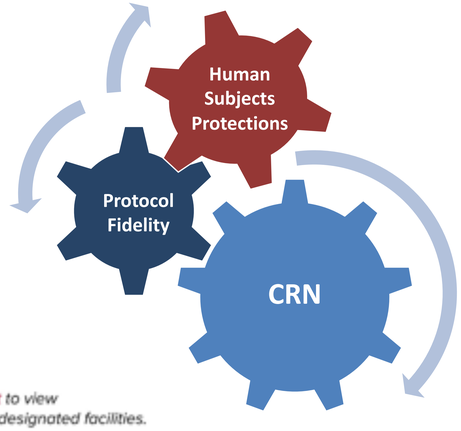
R	**Responsible –** for performing the task: ▪ PI ▪ Clinical Provider ▪ Radiation Safety Officer ▪ CRN ▪ Nuclear Pharmacist ▪ Nuclear Medicine Tech ▪ Study Coordinator ▪ Environmental Services ▪ Clinical and Research Lab Techs
A	**Accountable** –for ensuring the following tasks are completed and has the authority to make changes and decisions: ▪ Eligibility ▪ Treatment Parameters ▪ Dose Calculations and Preparations ▪ Radiation Exposure Monitoring ▪ Patient and Staff Education ▪ Patient Care ▪ Drug Administration and Documentation ▪ Participant and Staff Safety
C	**Consulted** – for their expertise and input: ▪ All Stakeholders
I	**Informed** – of decisions and process changes: ▪ All Stakeholders ▪ Impacted Departments

Quality Improvement Outcome

- Defined interdisciplinary team members roles and responsibilities.
- Educated CRU CRNs and interdisciplinary research team members on practice implications for participants on theranostic trials.
- Developed processes to streamline communications and workflows:
  - Pre-dose huddle immediately prior to every theranostic treatment.
  - Created a "smart phrase" to standardize the huddle process and documentation by the bedside CRN.
- Communicated changes to all interdisciplinary team members.

Implications for CRN Practice

CRNs are integral to human subjects' protections, fidelity to the research protocol, and they are involved in all aspects of participant treatments on the CRU. Because of this holistic view, CRNs are perfectly positioned to identify challenges and opportunities for improvements and serve as leaders in clinical research.



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