Category: Cross-cutting Innovation and Collaboration – Work in Progress

Charting a New Course: Operationalizing Non-Oncology Cellular Therapy Trials

N. Muhammad, L. Reardon, S. Marsh, J. Morrison, L. Wilkerson, R. Brown,

Sidney Kimmel Comprehensive Cancer Center at Jefferson

1. Background

Cellular Therapy (CT)—whether it is CAR-T, T-cell receptor, Tumor-infiltrating lymphocyte therapy or stem cell transplant—has been used for decades to treat hematological malignancies. In more recent years, research studies have attempted to treat solid tumors with the same success. Using similar approaches to cancer treatment, non-oncology CT is being used increasingly to treat autoimmune, inflammatory and neurological disorders with the potential to outpace oncology in its applications. In spring 2024, Thomas Jefferson's Sidney Kimmel Comprehensive Cancer Center Immune Effector Cellular Therapy research team began consulting and collaborating with non-oncology stakeholders to develop a framework to operationalize non-oncology CT research.

2. Goals

- Increase buy-in for investigators
- Create awareness of CT infrastructure
- Align standard operating procedures (SOPs) and systems
- Mirror documentation requirements
- Project and adjust effort
- Ensure all appropriate regulatory and research-related costs are covered by Sponsor
- Delineate roles and responsibilities

3. Solutions and Methods

We developed a CT framework through collaborations with upper management, Oncology and Non-Oncology physicians, Budgets and Finance, Regulatory and Research personnel. Our framework is a living document which is updated to reflect lessons learned. Since its creation, it defines principal investigator (PI) roles, risks and responsibilities; it outlines study team start-up and protocol-mandated activities; it attempts to align electronic medical records and regulatory systems; it provides financial management and budget development recommendations.

4. Outcomes

Our two disparate groups met through study start-up and patient enrollment. According to our expertise, we delineated responsibilities and found that while we used some of the same systems, the manner in which we functioned within them differed greatly, including study documentation requirements. Thomas Jefferson has a very conservative view on documentation of study procedures within the EMR. The burden of documentation is greater for the CT group, requiring electronic medical record (EMR) documentation of vitals, performance statuses, concomitant drugs, etc. However, the Primary Disease Study Team's (PDST) practice does not require this level of documentation; every patient who was being seen was a research participant, so prior examinations were all the result of a clinical trial and was, therefore, not captured in the EMR. This discovery made it necessary to develop a workflow that would share patient documentation via different means between the PDST and CT teams.

Category: Cross-cutting Innovation and Collaboration – Work in Progress

We further realized that workflows that we felt would serve our patients well, had a profound impact on the day-to-day ancillary operations, despite best intentions. Several workflows have been developed. Each one was examined to determine which had the least negative impacts. For example, consenting the patient with the PDST did not provide the CT physicians an early opportunity to screen for drugs which were contraindicated for apheresis. In addition, collection of central and local labs disturbed the workflow of clinic phlebotomists. During screening, there were over 40 tubes which needed to be collected. This was disruptive to the workflow in the clinic as it tied up the phlebotomist for an extended time, creating a bottle neck for other clinic patients.

5. Learned and Future Directions

Operationalizing non-oncology CT is complex and requires coordination between offices across the institution. In order to build on this prestigious endeavor that has the potential to impact so many patients, it is essential that we expand the infrastructure that was initiated in the oncology space. This would include expanding workflows which impact ancillary groups, aligning SOPs across offices within the enterprise and centralizing research documentation systems. This expanded operational foundation would serve the program well through its growth.

Figure