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

Advancing Clinical Research in Cell Therapy Trials: The Role of Centralized Operations at Princess Margaret Cancer Centre

K. Tung, P. Merante, M. Flynn-Post, S. Chan, H. Cole, S. Sellman

Princess Margaret Cancer Centre, University Health Network

1. Background

The Princess Margaret Cancer Centre (PM), as Canada's largest cancer treatment facility, is a leader in advancing cancer treatment and research. The Cancer Clinical Research Unit (CCRU) plays a pivotal role in supporting clinical research through leadership, oversight, and infrastructure. As PM continues to push the boundaries of cancer care, one of the key challenges is managing the complexities of cell therapy trials, particularly as the focus shifts toward non-oncology applications.

To address unmet medical needs in various disease areas, PM and the CCRU are expanding their cell therapy research beyond oncology. However, this expansion brings with it several challenges, including regulatory hurdles, logistical issues, and the need to maintain high standards of patient safety and research integrity. The CCRU's centralized operational framework, developed through years of oncology research, is uniquely positioned to address these challenges. By leveraging their expertise, PM aims to streamline clinical trial operations, enhance regulatory compliance, and optimize healthcare infrastructure to successfully launch non-oncology cell therapy trials.

This initiative represents a strategic effort to broaden the scope of cell therapy, bringing innovative treatments to areas that have long been underserved. Through these efforts, PM and the CCRU are paving the way for a more efficient and impactful clinical research environment.

2. Goals

The expansion of cell therapy research beyond oncology at the PM and its CCRU is driving significant advancements in clinical trial operations and infrastructure. A notable milestone was the successful identification and consent of the first non-oncology patient, a Myasthenia Gravis case. Due to PM's expertise and accreditation by the Foundation for the Accreditation of Cellular Therapy (FACT), this patient was safely treated at PM, highlighting the feasibility of applying oncology-based cell therapy expertise to non-oncology research.

To support this expansion, PM and CCRU developed a centralized and streamlined operational framework, designed to enhance the efficiency of non-oncology cell therapy trials. Key initiatives included refining clinical workflows, accelerating trial development and approval processes, and conducting structured debriefs and gap analyses to proactively identify and address operational challenges. These measures have not only improved trial execution but also set new standards for coordinating complex cell therapy studies in a highly regulated environment.

By maintaining rigorous patient safety standards and ensuring research integrity, PM and CCRU have successfully navigated the complexities of expanding cell therapy trials beyond oncology. This effort has established best practices for conducting such trials within a cancer-focused institution, creating a model for other organizations aiming to extend their research into new therapeutic areas.'

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

3. Solutions and Methods

To expand non-oncology cell therapy trials, PM and CCRU developed a centralized operational framework, improving trial efficiency by refining workflows and coordination. A structured debrief process, involving interviews with research coordinators, nurses, and staff, identified operational challenges. These insights were analyzed through a gap analysis, guiding improvements.

PM utilized its FACT accreditation to ensure compliance and patient safety in non-oncology treatments. A collaborative debrief process included research leadership, physicians, nurse practitioners, and quality assurance teams to align operations with regulatory standards.

To accelerate trial execution, PM integrated oncology expertise into non-oncology trials and introduced training initiatives to equip staff with necessary skills. This culture of continuous improvement fostered collaboration across research, regulatory, and clinical teams, building a strong foundation for conducting complex trials.

Collaboration between hospitals was key, patients consented at Toronto General Hospital (TGH) were treated at PM, leveraging PM's expertise in cell therapy. This cross-hospital teamwork ensured high-quality patient care and advanced clinical research in new therapeutic areas.

4. Outcomes

The outcomes of implementing a centralized operational framework and fostering cross-hospital collaboration have been notable. For instance, the first non-oncology patient with Myasthenia Gravis was successfully treated with cell therapy at PM, establishing a proof-of-concept for future trials beyond oncology. Streamlined workflows and centralized operations enabled faster trial setup and execution, while structured debriefs and gap analyses helped identify and address operational challenges. By adhering to FACT-accredited protocols, the initiative maintained high standards for regulatory compliance and patient safety. Moreover, the collaboration between PM and TGH enhanced communication among research coordinators, nursing teams, and regulatory staff, facilitating effective knowledge transfer and improving overall operational efficiency. Additionally, the initiative contributed to workforce development by equipping staff with the skills needed to manage non-oncology cell therapy trials, ultimately strengthening the institution's research capacity and setting the stage for continued innovation in clinical research.

5. Lessons Learned and Future Directions

Expanding non-oncology cell therapy trials at PM and its CCRU highlighted the value of centralized operations in improving trial efficiency. Streamlined workflows, structured debriefs, and cross-hospital collaboration, as seen between PM and TGH which were essential for smooth execution. Ensuring regulatory compliance with FACT-accredited protocols and engaging a multidisciplinary team helped maintain research integrity and patient safety.

Moving forward, efforts will focus on scaling these processes to support more non-oncology cell therapy trials. This includes developing standardized protocols, enhancing cross-institutional collaboration, and expanding training programs. Strengthening institutional capacity will ensure greater access to novel cell therapies, reinforcing PM's leadership in advancing clinical research beyond oncology.