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

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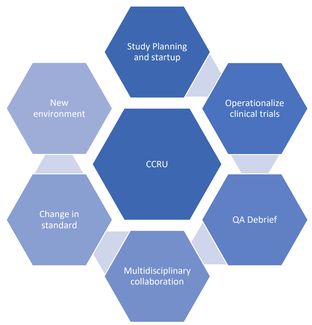
Background

The Princess Margaret Cancer Centre (PM) is Canada's largest and most comprehensive cancer treatment facility. The Cancer Clinical Research Unit (CCRU) within PM is one of the foremost clinical research centers, dedicated to advancing cancer therapies. CCRU provides essential leadership, oversight, and infrastructure for PM's research community, serving as a central hub for all clinical research inquiries. Our team of internationally recognized experts is committed to guiding investigators and operationalizing clinical studies to ensure the highest standards of research excellence.

Advancing clinical research in cell therapy trials demands a sophisticated and well-coordinated approach, particularly within leading institutions like PM, which is at the cutting edge of cancer treatment and research. Centralized operations are crucial in managing the complexities of cell therapy trials, ensuring these groundbreaking treatments are tested and delivered to patients with maximum efficiency and safety.

Role of CCRU



Objective

The initiative to broaden cell therapy clinical research beyond cancer at PM and CCRU stems from the recognition of significant unmet needs in other critical disease areas. This poster examines the strategies employed to advance non-oncology cell therapy trials within Canada's largest cancer institution.

Methods

- A non-oncology patient was identified and consented to participate in a Myasthenia Gravis trial at Toronto General Hospital, a sister hospital to PM. The cell therapy treatment was administered at PM due to the staff's expertise and the institution's capability as a Foundation for the Accreditation of Cellular Therapy (FACT) organization to safely treat the patient.
- Following the initial treatment, the research team initiated an internal debrief to address these issues.
- Interviews with research coordinators, nurses, and other frontline staff were conducted in a positive manner, promoting open communication and using a structured approach to ensure all perspectives were considered.
- The interview notes were compiled into a timeline of events, including a thorough analysis that compared the actions taken against standard practices, resulting in a gap analysis. The identified gaps were categorized to facilitate targeted improvements, ensuring that each concern could be systematically and efficiently addressed.
- A comprehensive debrief was conducted, led by research leadership and involving a clinical team of nurse practitioners, physicians, and a Quality Assurance lead trained in Immuno Effector Cell requirements.

Results

PDSA Cycle for Centralized Clinical Trials Operations Debrief

Plan

Objective: Improve efficiency and effectiveness in centralized operations for non-oncology cell therapy trials

Key Areas of Opportunity
- Streamlined process to operationalize non-oncology cell therapy trials
- Increased adherence to institutional guidelines
- Improve communication and coordination across teams
- Updated SOP and increased accessibility of SOPs

Plan:
- Improvement to internal electronic application system review process to ensure essential features are easily accessible
- Staff training on new guidelines
- Develop standardized procedures for inter-departmental coordination

Do

Execution:
- Launch updates to the internal electronic application system
- Implement training sessions to ensure understanding
- Introduce new communication protocols and conduct trial runs to identify gaps

Data collection:
- Track Patient safety and deviations
- Gather staff feedback on training and communication effectiveness

Study

Review of Outcomes
- Compare safety reporting for non- oncology trials to oncology trials
- Assess improvements in adherence to guidelines and SOPs
- Analyze feedback from team debriefs on communication

Key Findings
- Identify successful strategies and areas needing further refinement
- Determine impact of updated internal electronic impact assessment review system

Act

Refinement
- Adjust institutional SOPs and guidelines based on debrief feedback
- Enhance training by addressing any gaps identified during the operations of the study
- Formalize Best practices by documenting successful strategies as SOPs for future trials

Next Steps
- Integrate continuous monitoring and review with advisory committee for ongoing process improvements

Process Improvement Approach

Initial State
- Centralized Operations and Infrastructure for oncology trials
- Workflows and knowledge applicable and accessible to oncology study teams
- Frontline oncology trials nurses operationalize trial activities
- Debriefing occurs as required

Identified Gaps
- Knowledge and Process Gaps for external users
- Employees outside of PM was not familiar with a centralized trials operation
- Differences in documentation standards and practices
- Gaps in communication between teams external to PM
- Gaps in communication between PM team and patient
- Gaps in current SOP

Future State
- Comprehensive training and clearer guidelines is necessary
- Process gaps necessitated the development of more streamlined and standardized processes
- Development of an IEC advisory group to strategically plan for and support future non-oncology cell therapy trials
- Development of new SOPs to support non-oncology trials at PM
- Processes, guidelines, and contacts will be made available through a regularly maintained platform such as the hospital internet and intranet pages
- Foster a culture of Quality Assurance thorough debrief process routinely involving both research and multidisciplinary teams to ensure compliance and identify gaps

Summary of Current Activities at PM

	Present 2023/2024	Future Planning 2024/2025
Standard of Care	58 patients	Anticipated ~70 Patients
Number of Oncology Cell Therapy Trials0	18 Trials open 11 CAR T + 16 other cell types	9 Trials confirmed + Upcoming trials
Number of Non Oncology Cell Therapy Trials	1 trial	3 (Lupus, Myasthenia Gravis, Multiple Sclerosis)
Capacity	At capacity	Analysis underway

Lessons Learned and Future Direction

The transformative efforts of the Princess Margaret Cancer Centre (PM) and its Cancer Clinical Research Unit (CCRU) have significantly influenced the expansion of cell therapy clinical trials beyond oncology, paving the way for advancements across multiple medical fields:

Expanding Clinical Research Horizons
- PM and CCRU have effectively leveraged their deep expertise in oncology research to broaden their comprehensive workflows into non-oncology areas.

Establishing New Benchmarks in Trial Operations
- **Centralized and Streamlined Frameworks:** By centralizing operations and streamlining processes, PM and CCRU have developed a more efficient structure for conducting trials. This has accelerated the development and approval of new therapies, setting a higher standard for trials in various therapeutic domains.
- **Enhanced Regulatory Compliance:** A strong emphasis on strict regulatory adherence has ensured that all trials meet the highest standards, crucial for safeguarding patient safety and maintaining the integrity of research outcomes.

Catalyzing Innovation and Knowledge Advancement
- **Accelerated Discovery and Innovation:** PM and CCRU's progress has expedited medical discoveries, contributing to the development of new therapeutic options across a wide spectrum of diseases.
- **Global Influence:** The successful application of these practices in non-oncology trials is establishing new benchmarks worldwide, shaping how clinical research is conducted by other institutions and countries.

Reinforcing Healthcare Infrastructure
- **Building Research Capacity:** The initiatives at PM and CCRU have not only improved trial efficiency but also bolstered the overall healthcare infrastructure, fostering a more skilled workforce and nurturing a culture of continuous improvement in clinical research.

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