Enhancing Efficiency and Expertise in Cellular Therapy Research: Establishing a Dedicated Transplant and Cellular Therapy Program

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BACKGROUND

Historically, the Perlmutter Cancer Center Clinical Trials Office (PCC CTO) participated in a limited number of cellular therapy trials, each managed by different disease management groups (DMGs) based on tumor type. This fragmented approach led to a lack of concentrated expertise, as teams did not handle enough patient volume to develop the in-depth knowledge required for these complex trials. Consequently, this decentralized model resulted in inconsistencies in trial management and operational inefficiencies.

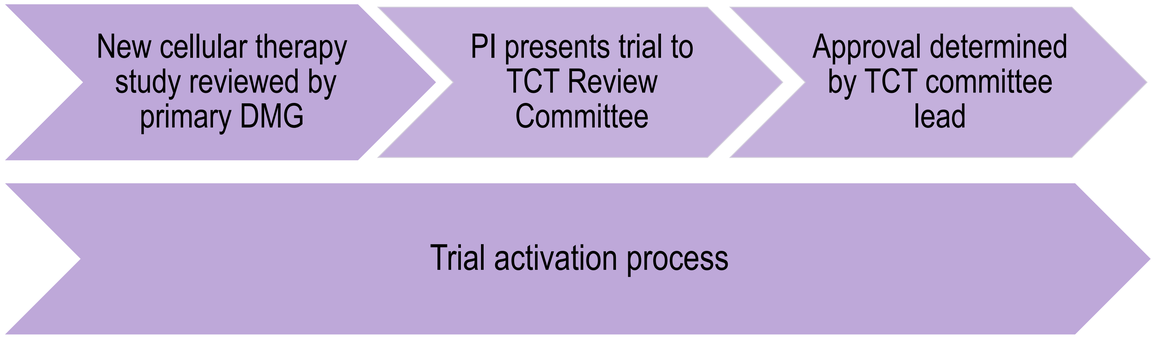
GOALS

Establish a designated Transplant and Cellular Therapy (TCT) research program to:

- Streamline operations
- Enhance trial management
- Better support the expanding cellular therapy landscape

SOLUTIONS & METHODS

- The TCT Review Committee was formed, comprised of TCT investigators and clinical staff.
- Specialized staff were recruited to fill clinical, data, regulatory, and leadership roles.
- Standardized processes and workflows were developed.
- A multi-step review process was established to ensure thorough evaluation and efficient management of new cellular therapy studies. Initially, new studies are reviewed by primary DMG. Within one week, the Principal Investigator (PI) presents trial to TCT review committee and approval is determined by the TCT committee lead, who is a TCT investigator. This runs in parallel with the trial activation process.



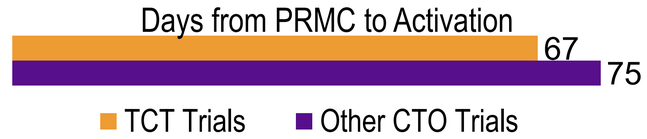
- The TCT team manages cellular therapy research patients beginning at the time of consent through an average of 30 days post-cell infusion, after which patients are transitioned back to the primary team for ongoing care.

OUTCOMES

The TCT Review Committee meets weekly to review new studies with a cellular therapy or apheresis component, facilitating timely and thorough evaluations.

We have successfully hired and onboarded specialized staff, including a TCT Program Manager, Research Nurse Practitioner, Clinical Research Nurse, Clinical Research Coordinators, Data Coordinators, and a Regulatory Pre-Activation Specialist.

In 2024, we operationalized 10 oncology cellular therapy trials. Since our multi-step review runs in parallel with the trial activation process, there has been no delay in timelines.



These efforts have collectively enhanced our operational efficiency and expertise in managing cellular therapy trials.

LESSONS LEARNED & FUTURE DIRECTIONS

The establishment of the TCT Review Committee has significantly improved communication and ensured a thorough review of cellular therapy trials. Streamlined processes and specialized staff have led to greater uniformity in trial management and enhanced operational efficiency. Additionally, the CTO is now supporting four non-oncology clinical trials in areas such as solid organ transplant and rheumatology. We are evaluating the level of support the CTO will provide for these non-oncology trials moving forward and how best to integrate them into our existing workflows. Our TCT team currently operates out of our Manhattan location, but we aim to eventually expand operations to our Long Island site to broaden our reach and impact.

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