Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Work in Progress

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

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1. 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.

2. Goals
PCC CTO leadership aimed to establish a designated Transplant and Cellular Therapy (TCT) research program to streamline operations, enhance trial management, and better support the expanding cellular therapy landscape.

3. Solutions and Methods
Key initiatives included forming the TCT Review Committee, recruiting specialized staff across clinical, data, regulatory, and leadership roles, and developing standardized processes and workflows. This collaborative effort involved close coordination between CTO leadership, PCC leadership, and TCT investigators.

We implemented a comprehensive, multi-step review process to ensure thorough evaluation and efficient management of new cellular therapy studies. Initially, new studies are reviewed by the primary DMG. Within one week, the Principal Investigator (PI) presents the trial to the TCT Review Committee, which is comprised of TCT investigators and clinical staff. Approval is determined by the TCT Committee Lead, who is a Transplant & Cell Therapy Investigator.

The TCT team manages cellular therapy 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.

4. Outcomes
In 2024, we operationalized 10 oncology cellular therapy trials. The TCT committee now meets weekly to review new studies with a cellular therapy or apheresis component, facilitating timely and thorough evaluations. We have formalized workflows, standardized processes, and 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.

Our multi-step review runs in parallel with the trial activation process, ensuring that the additional layer of evaluation does not delay timelines. The median activation time from the Protocol Review & Monitoring Committee (PRMC) for TCT trials was 67 days, slightly faster than the overall median of 75 days for all treatment trials in 2024.

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

5. Lessons Learned and 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.