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

Scaling Cellular Therapy Research: Implementing a Dedicated Transplant and Cellular Therapy Program for Non-Oncology Studies

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1. Background

Cellular therapies (CT) are rapidly expanding beyond oncology into autoimmune, genetic, metabolic, neurological, and infectious diseases. However, CT implementation remains operationally complex. Published studies cite barriers including fragmented workflows, siloed IT systems, poor communication across clinical, research, laboratory, and administrative teams, limited clinician familiarity, and insufficient staffing. At NYU Langone Health, the Perlmutter Cancer Center (PCC) began oncology CT trials in 2018 and formalized its cellular therapy Oncology Program in 2024. In contrast, non-oncology CT trials were initiated across departments without a centralized infrastructure, resulting in inconsistent processes and lost operational efficiencies. This decentralized approach limited scalability and the ability to apply established CT expertise consistently across non-oncological indications.

2. Goals

In 2025, the Clinical Translational Science Institute (CTSI), in collaboration with the PCC Clinical Trials Office (CTO), launched a centralized non-oncology cellular therapy program (NOCTP). The program supports medicine (rheumatology, endocrinology), neurology, and surgery (transplantation). The objective was to create a coordinated operating model to streamline study start-up, standardize workflows, improve quality oversight, and enhance cross-departmental collaboration.

3. Solutions & Methods

1. Listening sessions were conducted with investigators, clinical and research leadership, PCC stakeholders, and external experts through the National Institute of Health (NIH) clinical and translational science award research unit network to identify barriers and facilitators. A structured process-mapping exercise followed to document workflows, identify bottlenecks, and delineate stakeholder roles. To operationalize this model, we instituted the following implementation plan: A dedicated CTSI non-oncology CT team was established to oversee study start-up, regulatory management, clinical operations, data coordination, and laboratory oversight in partnership with the PCC CTO.
2. Individual departments retained responsibility for patient recruitment, disease-specific consultation, and longitudinal follow-up.

3. The PCC oversees CT-specific activities, including feasibility assessments, cell harvesting and chain of custody, preparation and infusion, quality assurance, inpatient admissions, treatment planning, and safety monitoring.

Targeted operational tools were developed, including centralized email distribution lists, clinical trial management system flags, standardized committee reviews, and harmonized electronic medical record documentation.

4. Outcomes

Since its launch in 2025, the NOCTP has expanded to a three-person team from the CTSI, nine from PCC, and one to two from the departments supporting six trials. CTSI closely aligned its activation processes with PCC, enabling non-oncology CT studies to be opened within 60 days of CT group approval. System-level role delineation reduced duplication and clarified accountability. Educational sessions with investigators improved awareness of centralized resources and facilitated program adoption. Implementation of standardized tools improved communication, streamlined workflows, and accelerated study activation timelines. Early process mapping prevented redundancies and mitigated operational bottlenecks.

5. Lessons Learned and Future Directions

Centralizing non-oncology CT infrastructure through CTSI, while leveraging PCC's established cellular therapy expertise and departmental clinical strengths, created a scalable and coordinated model. Routine cross-team forums and clearly defined governance structures were critical to maintaining alignment. Future directions include expansion to additional specialties and campuses in Brooklyn and Long Island, as well as embedding study start-up metrics and continuous quality improvement measures. This collaborative framework demonstrates how academic medical centers can reduce operational fragmentation, improve scalability, and accelerate non-oncology cellular therapy research.

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Figure 1