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

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NYU Langone Health

NYU CTSI

Perlmutter Cancer Center

An NCI-designated Comprehensive Cancer Center

INTRODUCTION

- Cellular therapies (CT) are rapidly expanding beyond oncology into autoimmune, genetic, metabolic, and neuromuscular diseases.
- CT scalability is limited by fragmented workflows, siloed IT systems, limited provider familiarity, lack of standardized processes, and insufficient CT-dedicated infrastructure, requiring coordinated teams, standardization, integrated information systems, and deliberate implementation planning.
- While NYU Langone's Perlmutter Cancer Center (PCC) developed a centralized CT oncology program in 2024, non-oncology CT trials evolved in a decentralized fashion, despite national evidence that successful CT translation relies on centralized infrastructure, disease-specific leadership, and structured governance with role delineation.
- **In 2025, NYU Langone's Clinical and Translational Science Institute (CTSI), in collaboration with the PCC Clinical Trials Office (CTO), launched a centralized Non-Oncology Cellular Therapy Program (NOCTP) to align non-oncology CT studies with existing CT infrastructure, standardize workflows, and embed continuous quality improvement.**

METHODS

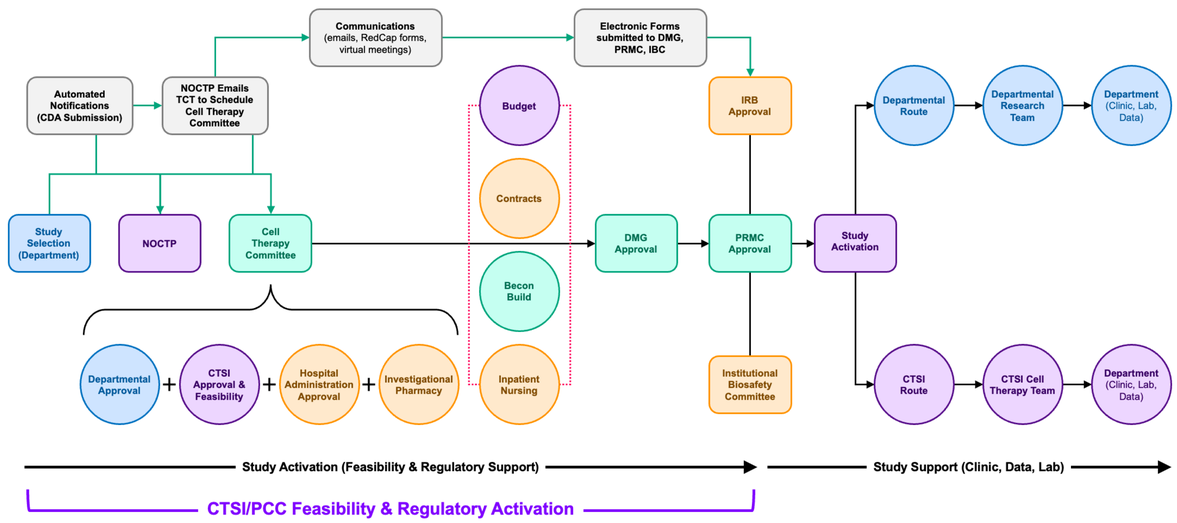
- Conducted structured key informant listening sessions with investigators and departmental/research leadership, and engaged PCC stakeholders to leverage existing oncology CT SOPs, guides, and training materials for NOCTP design and scale-up.
- Obtained external input via the NIH Clinical Translational Science Award (CTSA) Research Unit Network (RUN).
- Mapped end-to-end workflows, including feasibility through infusion and follow-up to identify bottlenecks, redundancies, and handoffs.
- Created process maps, RACI charts, and communication models to define roles, governance, and communication, and the use of standardized tools and procedures.

RESULTS

- The NOCTP has grown into a team of 3 from CTSI, 9 from PCC, and 2 from collaborating departments.
- NOCTP now serves as a centralized platform for CT trials across Medicine, Neurology, Rheumatology, and Surgery.
- NOCTP closely aligned its activation processes with the PCC CTO, enabling **4 non-oncology CT studies to be activated within nearly 60 days** of CT group approval, significantly reducing historically delayed start-up timelines.
- Developed system-level role delineation and early process mapping to reduce duplication of effort, prevent redundancies, and mitigate operational bottlenecks.
- Delivered educational sessions and implemented standardized tools (SOPs, guides, workflows, EPIC smartphrases) to increase awareness of centralized resources, promote NOCTP adoption, and streamline study activation.

OPERATIONAL MODEL & ROLE DELINEATION

CTSI & PCC Non-Oncology Cellular Therapy Workflow



5 Collaborating Departments

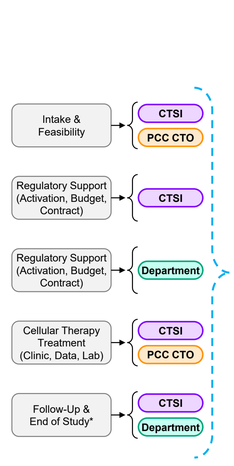
4 Open Trials

14 Research Staff

8 Patients Enrolled

NYU Langone Health Non-Oncology Cellular Therapy Program

Operational Framework for Non-Oncology Clinical Trials
(Triage, Feasiblity, Activation, Recruitment, Treatment, and Follow-Up)



Assignments & Roles		CTSI	PCC CTO	Department
Intake	Project Manager	R/A	C	I
Regulatory (Activation)	Sr. Reg Specialist	R/A	I/C	I/C
Recruitment/ Prescreening	Sr. CRC	I	I	R/A
Consent	CRN/ Sr. CRC	I	I	R/A
Eligibility & Screening*	CRC/ Sr. CRC	R/A	I/C	I/C
PMH*	CRC/ Sr. CRC	R/A	I	I
Baseline AE's & Conmeds*	CRC/ Sr. CRC	R/A	I	I
Treatment → EOT	CT PI/ Sub-I	I	R/A	I/C
Data (Treatment)*	CRC/ Sr. CRC	R/A	I	I
LTF*	CRC/ Sr. CRC	R/A	I	I/C
Data (LTF)*	CRC/ Sr. CRC	I	I	R/A
Reg-Enrollment Closed	CRC/ Sr. CRC	I	I	R/A
End of Study	CRC/ Sr. CRC	I	I	R/A

RACI Legend

R: Responsible / A: Accountable / C: Consulted / I: Informed

* These assignments are adjusted on a departmental/divisional basis. Adjustment factors include department research team staff capacity, interest in managing these activities, and experience with CT workflows.

CONCLUSIONS & FUTURE DIRECTIONS

- Structured process mapping and centralized governance clarify roles, inform development of guides, IT tools, and communication processes, and support the conduct of high-quality trials.
- Ongoing education for investigators and staff drives culture change, promoting early NOCTP engagement and consistent use of standardized processes.
- Developing master agreements, cell therapy-specific fee schedules, and pre-agreed contract and IRB language is expected to further reduce activation timelines.
- Future work at NYULH will extend NOCTP to additional specialties and campuses (e.g., Brooklyn, Long Island) and harmonize operations across sites and departments.
- **Frameworks created at NYULH can serve as models in establishing non-oncology cell therapy programs nationally across sites.**

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