Building a Dedicated Non-Therapeutic Trials Unit (NTTU) to Strengthen Clinical Research in a Comprehensive Cancer Center

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Background

Non-therapeutic oncology studies, including biospecimen, registry, patient-reported outcome, and supportive care studies, are essential to cancer discovery and survivorship research. However, they are often managed through systems built for therapeutic trials, leading to delays, inconsistent oversight, staffing gaps, and lower accrual.

Objective

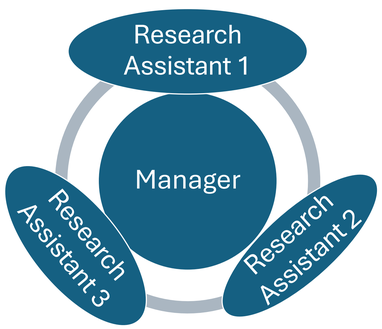
Create a dedicated Non-Therapeutic Trials Unit to:

- Accelerate activation of studies for investigators without dedicated lab staff (e.g., reducing the need to hire staff for each study individually)
- Standardize start-up and study execution
- Strengthen regulatory and operational oversight
- Increase accrual to investigator-initiated studies
- Reduce the burden on therapeutic disease-site teams

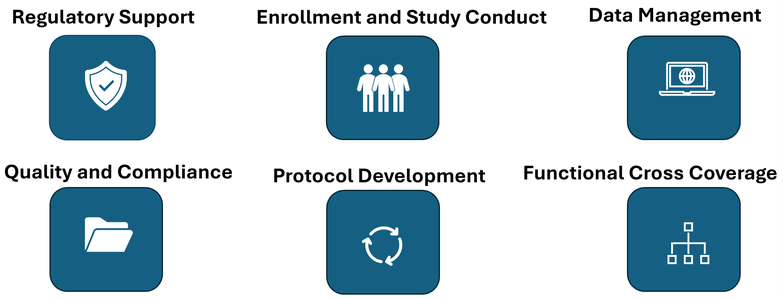
Conclusion

Since its launch, the NTTU has expanded from 0 to 10 active protocols across biospecimen, observational, supportive care, and educational studies. Accrual has increased from 8 participants in 2023 to 45 in 2024, and 74 in 2025.

Organizational Framework



NTTU Supported Activities



KEY TAKEAWAY

Operational Problem: Important studies were being supported through systems not built for their needs.

Operational Response: Create a dedicated unit with defined workflows, staffing ,and oversight.

Strategic Goal: Strengthen non-therapeutic research while maintaining therapeutic trial capacity, improve non-therapeutic trial oversight, and accelerate investigator- led science.

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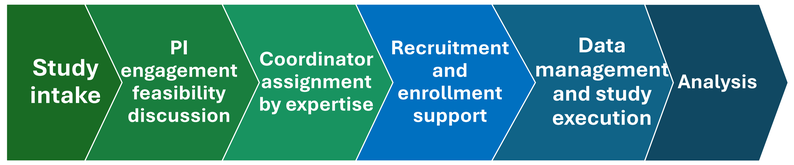
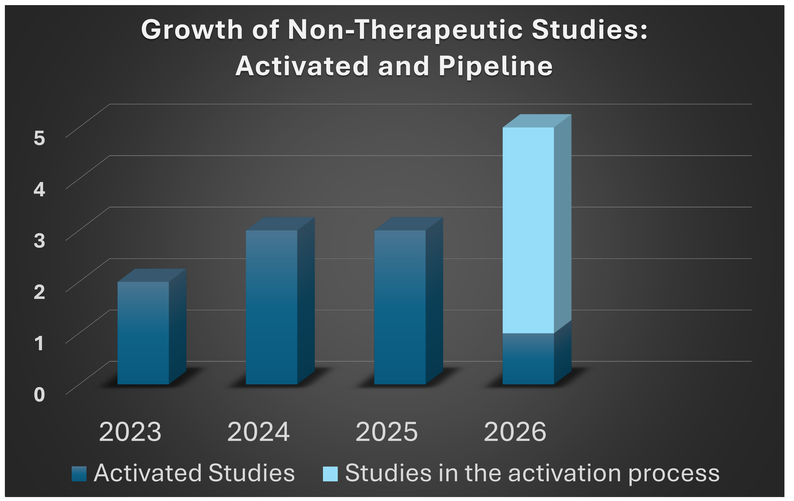
Core Operational Workflow



Study Portfolio Growth



NTTU Summary Table

Domain	Metric	Result
Portfolio Growth	Active protocols	0 -> 10 in 2years
Study Mix	Protocol types supported	Biospecimen, Observational, supportive care, educational
Funding Model	Source mix	Grants 50%, Industry 30%, institutional/ philanthropic 20%
Total NTTU Accrual	2023	8
Total NTTU Accrual	2024	45
Total NTTU Accrual	2025	74
Capacity Signal	Change in Accrual	Nine-fold growth from 2023 to 2025
Investigator Enablement	Investigator Initiated Study	Major share of growth