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

**Building a Dedicated Non-Therapeutic Trials Unit to Strengthen Non-Therapeutic Research in a Comprehensive Cancer Center**

G. Nkogbu, L. Fortin, A. Wagh, B. Kemp

*Fox Chase Cancer Center, Temple Health*

**1. Background**
Non-therapeutic research, including bio-specimen protocols, registries, patient-reported outcomes, and educational or supportive care interventions, is essential to discovery, prevention, and survivorship science. However, across academic cancer centers these studies often compete with therapeutic trials for shared infrastructure, contributing to slow activation, variable oversight, and lagging accrual. To address these barriers, Fox Chase Cancer Center launched a dedicated Non-Therapeutic Trials Unit (NTTU) in 2023.

**2. Goals**
The NTTU was created to (1) standardize non-therapeutic study start-up and execution, (2) ensure consistent regulatory compliance and operational oversight, (3) increase accrual to investigator-initiated non-therapeutic studies, (4) build a sustainable workforce model with structured training and cross-coverage, (5) reduce workload burden on therapeutic clinical disease site teams, and (6) support financial sustainability through a scalable operational structure.

**3. Solutions and Methods**
The NTTU operates as an independent program under Cancer Center leadership and supports multiple faculty principal investigators. A unit manager provides oversight, and a trained team of research assistants coordinates studies from initiation through closeout. Core processes include review of a Study Attributes and Investigator Responsibilities (SAIR) document, structured principal investigator engagement, assignment of studies by coordinator expertise, and end-to-end support for regulatory submissions, recruitment, data management, and dissemination. A steering committee meets quarterly to guide strategic growth and model refinement.

**4. Outcomes**
In the first two years, the NTTU expanded from zero to 10 active protocols spanning bio-specimen collection, observational studies, and supportive care or educational interventions. Funding sources included extramural grants (50 percent), industry (30 percent), and institutional or philanthropic support (20 percent). Accrual increased from eight participants in 2023 to 45 in 2024, surpassing 70 in 2025, representing a five-fold growth in research capacity. Investigator-initiated studies represented a major share of the growth, supporting the unit's goal of accelerating investigator-driven science.

**5. Lessons Learned and Future Directions**
A dedicated Non-Therapeutic Trials Unit can strengthen non-therapeutic research by standardizing operations, improving oversight, increasing accrual, and supporting investigator-initiated science while protecting capacity for therapeutic trials. This model addresses a common infrastructure gap and provides a replicable blueprint for National Cancer Institute-designated centers seeking financially sustainable approaches to efficient clinical research operations and broader portfolios in prevention, survivorship, and quality-of-life research.

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

**Table 1. NTTU growth and operating profile (2023 to 2025)**

| **Domain** | **Metric** | **Result** |
|---|---|---|
| Portfolio growth | Active protocols | 0 to 10 (first two years) |
| Study mix | Protocol types supported | Bio-specimen, observational, supportive care, educational interventions |
| Funding model | Source mix | Grants 50% |
| Accrual | 2023 | 8 participants |
| Accrual | 2024 | 45 participants |
| Accrual | 2025 | 74 participants |
| Capacity signal | Change in accrual | Five-fold growth from 2023 to 2025 |
| Investigator enablement | Investigator-initiated studies | Major share of growth |