*Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Completed Project*

**Strategies for Expansion and Efficiency of Biospecimen Management for Multi-site Investigator Initiated Trials (IITs)**

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**1. Background**

Over the course of 10 years, the Research Biofluid Management Unit (RBMU) of the Clinical Trial Office (CTO) at NYU Langone Health (NYULH) Perlmutter Cancer Center (PCC) has supported the exponential growth of multi-site investigator-initiated trials (IITs) from three to 17 research studies, with patient enrollment growing from 85 participants in 2016 to 580 participants across trials in 2024. To support such growth, RBMU biospecimen management needed to be streamlined and standardized across sites. Creation of sustainable and efficient biospecimen management workflows is crucial to reduce the loss of valuable human specimens and maintain reliable pre-analytical conditions for downstream biospecimen analysis at NYU Langone Health research laboratories.

**2. Goals**

- Identify cost-effective and efficient solutions that would enable expansion of IIT activity across multiple sites at a national scale.
- Implement operational workflows that reduce time of supply provision to sites.
- Provide thorough processing/shipping instructions in a standardized manner to reduce deviations and errors upon sample submission to NYU Langone laboratories.
- Adapt for growing scope of processing techniques and requirements commonly found in IIT research.

**3. Solutions and Methods**

- Consultation with PIs during protocol development for specimen management
- Protocol-Specific lab manual creation
- Pre-labeled kit provision to external sites
- REDcap order form request system
- REDcap specimen submission system
- Increase specialty full-time equivalents for overnight specimen shipments and PBMC isolation

**4. Outcomes**

- Increased efficiency of specimen intake process with pre-labeled specimens and electronic manifests
- Decreased time of kit order fulfillment from 3 weeks to 1 week (on average, +/- 7 days)
- Minimized errors in specimen collection and shipment with use of lab manual, provided kit supplies, pre-printed shipping labels, and shipping supplies
- Enabled growth of IIT support, increased range of specimen processing techniques, absorbed PBMC isolation processing previously outsourced. Nurses have noted that the process has become noticeably smoother and more seamless since the implementation of the workflow.

**5. Lessons Learned and Future Directions**

Implementation of standard instruction, supplies, and specimen management for IITs is crucial for reliable research outcomes and downstream biospecimen analysis. By minimizing the risk of deviations

due to specimen processing/shipping errors at external sites, we were able to streamline support for IITs at our cancer center and enable overall expansion of multi-site activity. Going forward for continued expansion, we may look to outsource kit provision to transfer the burden of creating "homemade" specimen collection and processing kits from our staff to a third party. It will also be necessary to integrate external specimen submission with current RBMU LabVantage LIMS specimen management programs currently in the final stages of development and implementation this year.

**Figure**

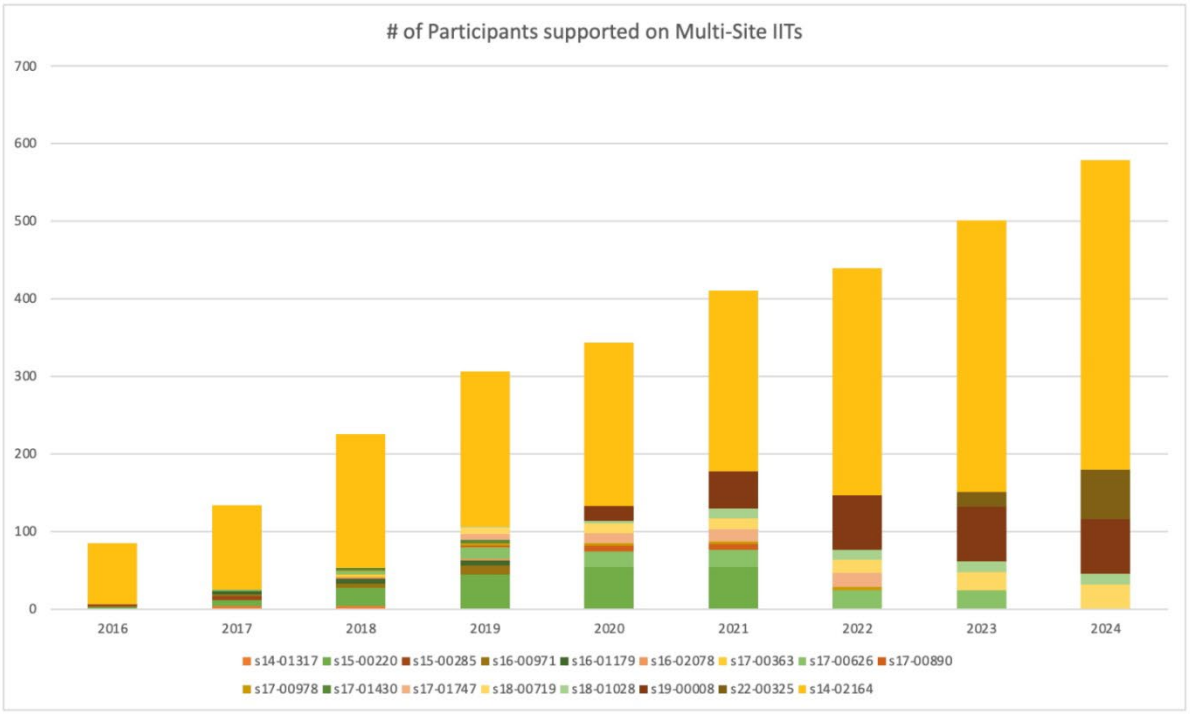


**Figure 1. Patient accrual growth on multi-site IITs from 2016 to 2024**