# Building Institutional Infrastructure for Investigator-Initiated Treatment Trials

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## Background

The Sponsor-Investigator Support (SISU) provides comprehensive investigator-initiated trial (IIT) support from concept development through closeout for NCI-Designated Cancer Center, Hollings Cancer Center, at Medical University of South Carolina. Following a major reorganization in late 2024, institutional investment expanded SISU's scope, resources, and central role in supporting investigator-initiated treatment trials.

SISU collaborates with the Hollings Advisory Rapid Translation (HART) committee, which vets concept rationale and design, and the Biostatistics Shared Resource core, which oversees statistical analysis and database management, as a collaborative group to develop and operate IITs. This centralized model improves efficiency, reduces fragmentation of stakeholders, and brings together subject matter expertise to support the investigator. SISU resources integrate early in development to provide regulatory, operational, and project management support. The core scope of SISU is focused on MUSC sponsored treatment IITs, and all these studies have mandatory support from this model.

## Goals

The overarching aim of SISU is to support the activation and maintenance of IIT treatment trials, with a current goal to increase the number of these trials open to accrual. The SISU ensures regulatory and operational consistency and compliance, and promotes standardization across the IITs. It enables the expansion of investigator-initiated research at scale. SISU aligns concept prioritization and start-up activities with cancer center strategic priorities, including accrual growth in specific patient populations critical for achieving comprehensive cancer center status. SISU also reduces the barrier to entry for new investigators developing IITs by providing a structured project management resource throughout the study lifecycle.

## Solutions & Methods

The SISU works in a centralized model with the HART committee and BSR to promote success of concept development and execution. SISU maintains standardized workflows and templates, and owns protocol writing, project team meetings and action items, U.S. Food and Drug Administration (FDA) submissions, Protocol Review Committee (PRC) submissions, Institutional Review Board (IRB) submissions, Site Initiation Visit (SIV) conduct, maintenance of site regulatory binder and sponsor file, eligibility reviews, source data verification and data queries, Data Safety Monitoring Committee (DSMC) submissions and presentations, and other sponsor-level operational and regulatory responsibilities.

The SISU structure includes two specialized teams – one focused on start-up and the other on trial maintenance – to streamline workflow and ensure appropriate depth of experience during the study lifecycle. The start-up team typically works with the same investigators but is flexible in assignments based on workload and are not specific to a disease type. Maintenance team staff focus on specific disease portfolios, but all team members perform eligibility reviews on all studies.

## Outcomes

Following restructuring and resource expansion, trial openings rebounded significantly, rising from zero in 2024 to five in 2025, all aligned with institutional priority areas. The table below details the number of MUSC sponsored investigator-initiated treatment trials opened at Hollings Cancer Center from 2022 through May 2026.

| Year | Number of Tx IITs Opened | Disease Areas |
|---|---|---|
| 2022 | 4 | Lung, Prostate, Oral |
| 2023 | 3 | Lymphoma, Prostate, Sarcoma |
| 2024 | 0 | N/A |
| 2025 | 5 | Lung, Prostate, Ovarian, Breast, Pancreas |
| 2026* | 4 | Brain, Prostate, Breast, Head & Neck |

**Data current as of May 22, 2026.*

## Lessons Learned and Future Directions

Due to the success in increasing the number of opened trials, the workload has increased for the SISU team. However, it is critical to increase the pipeline to demonstrate success in treatment accruals in our IITs. In the future, SISU will collaborate with HART committee leaders to implement a formal concept scoring tool prioritize which concepts to move into development and start-up. A consistent challenge is scaling SISU staff and resources with limited funding, as most IITs lack external support.

The relationship development and engagement with investigators is crucial in moving the concept successfully through development and start-up. The time investment of building relationships with investigators and departments has encouraged new investigators to develop IITs.

There is an ongoing challenge of broad support from SISU across all disease areas, as each study is unique in its design and patient population, and requires engagement from the investigator to ensure timely progress. Collectively, these lessons emphasize the importance of proactive resource planning, transparent prioritization criteria, and early investigator engagement to sustain continued growth in IIT activation. This model provides a scalable foundation for IIT infrastructure that may be adopted or adapted by other academic cancer centers seeking to expand Sponsor-Investigator research.

## Contact Info

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