

Clinical Research Strategic Partnerships (CRSP) Program Initiatives and Future Goals

S. Salvati, S. Yoon

Memorial Sloan Kettering Cancer Center

1. Background

The Clinical Research Strategic Partnership Program mission is to expand access to clinical trials and cutting-edge cancer research raising standards of care at community-based hospitals and academic centers. To address programmatic needs and ensure protocol compliance, two initiatives were implemented in May 2019.

The first initiative restructured the team. The initial structure could not maintain increased numbers of sites and protocols. Furthermore, as the number and complexity of protocols increased, roles focused on protocol start up, operations, and quality assurance were created.

The second initiative ensures compliance by confirming site protocol capabilities. We ensure sites have the target population and resources needed to conduct protocols. Previously, the protocol review was not standardized, leading to gaps in resources and capabilities.

2. Goals

The initiatives goals were to provide dedicated protocol support by restructuring the team and to increase protocol compliance by conducting feasibility reviews.

3. Solutions and Methods

Until May 2019, the team consisted of two Program Managers, a Protocol Activation Manager, Research Project Manager and two Research Project Associates. The Program Managers divided the portfolio and oversaw protocol and patient management and provided monitoring. The Activation Manager oversaw start up; the Research Project Manager conducted source verifications for site participants; and the Research Project Associates managed protocol identification and finances.

Since implementation, there are teams for each protocol phase. The Activation team manages startup by identifying protocols of interest, gaining stakeholder approval, executing subcontracts, receiving IRB approvals and opening protocols. The Operations team oversees regulatory items and manages protocol and patient activity. The Quality Assurance team ensures program quality via source verification for participant eligibility, quarterly onsite visits, regulatory document oversight.

Prior to May 2019, there was no formal feasibility review. Now, MSK and site leadership calls into a monthly meeting to review protocols opening in the MSK pipeline. A formal feasibility process is then conducted before sending a protocol of interest into the activation process.

4. Outcomes

The team reorganization enables our team to provide specialized guidance to the sites. Because we have staff for each space, the sites know who to reach out to with their questions. The reorganization

Category: Clinical Trial Operations – Completed Project

strengthened our collaboration with the sites, decreasing the number of issues related to protocol management.

The feasibility workflow has increased the site's protocol review from the inception of protocol startup, and we have been able to address feasibility questions prior to activating a protocol. This has led to decreased roadblocks and an increased ability to seamlessly open protocols.

5. Lessons Learned

With the reorganization, there was a learning curve. We provided information sessions and distribute resources to sites. The sites also restructured their programs to support their infrastructures. The benefits of these restructures increased program success. We maintain open lines of communication to address changes.

We learned MSK Investigator Initiated Protocols oftentimes do not include instructions for external site specimen collection. This can cause a significant bottleneck in feasibility and site activation. In the future, we anticipate the development of a lab manual repository will alleviate such issues.