

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

Novel Study Start-up Agreement - Guarantee Compensation for Start-up Work Performed Prior to Clinical Trial Agreement While Reducing Study Start-up Timelines

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1. Background

Considerable amounts of study start-up work to prepare clinical trials for opening happens prior to execution of the Clinical Trial Agreement (CTA) by Cancer Center staff including clinical, regulatory, finance, and contract team members. These start-up services are performed by sites without the guarantee of compensation. If sponsors no longer pursue the study, the site can be left with hours of work performed without reimbursement. Sites may then devote months to recuperating the costs from sponsors for start-up activities, ending with partial or no payment for services rendered due to the absence of a fully-executed CTA.

2. Goals

Create and implement a Study Start-Up Agreement (SSUA) to:

- Protect the site's financial interest by executing a separate contract—after site selection and before CTA negotiation—to ensure that start-up services performed are paid in full should the CTA fail to be fully-executed
- Reduce Time to Activation (TTA) by agreeing to the start-up fees before negotiations and creating study award accounts (AWD) earlier to reduce post-award processing time

3. Solutions and Methods

Lombardi Comprehensive Cancer Center (LCCC) created a separate SSUA contract to be executed prior to CTA negotiations, to ensure start-up activities performed will be reimbursed by the sponsor should the CTA not be fully-executed or the study fail to open. Ultimately, the fully-executed CTA supersedes the SSUA, and start-up fees are invoiced upon execution of the CTA. Should the sponsor not move forward with the trial, the site will have a fully-executed SSUA, allowing for proper compensation for all study start-up services performed.

SSUAs are proposed to sponsors after site selection, including only applicable standard start-up fees to enable swift execution with little-to-no discussion with recurrent sponsors. These fees do not require renegotiation when CTA negotiations begin.

Clinical trial award (AWD) accounts, used to invoice for clinical trial services, are created earlier in the process, providing more time and decreasing the chances for delays in the opening of the clinical trial.

4. Outcomes

SSUA was ultimately well received by nearly all our clinical trial partners to date, with only one industry sponsor out-right refusing to sign

- Informational meetings were leveraged to explain concepts to sponsors and subsequent SSUAs with those sponsors were quickly executed, with some agreed upon within one week
- Removing the need to negotiate the start-up fees in the CTA decreased the number of items requiring negotiation, leading to quicker activation

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5. Lessons Learned and Future Directions

The first SSUA between LCCC and a sponsor required additional correspondence and meetings to educate the sponsors and convey the need. LCCC pivoted from a rigid template to a more flexible, sponsor-customized approach, ensuring the core functionality remained intact while incorporating sponsor-specific language to allow for quicker agreement and execution of the document.

SSUAs additionally served as a gauge of financial feasibility for first-time sponsors – if sponsors were not comfortable with LCCC's start-up rates, the hesitation was realized earlier in the process in advance of hours of cross-departmental work.

With the demonstrated successes with the SSUA in oncology clinical trials, Georgetown plans to mirror this process in non-oncology clinical trials.