

“Will They Pay?” Let’s Find Out First! Saving Time and Money in Industry-Trial Activation

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1. Background

As the number of trials offered to cancer centers is constant, vetting and selection of clinical trials by sites becomes increasingly important. The activation process can be costly from the moment solicitation begins, as compared with the sites’ operational budgets. Trial sites have limited funding as compared to sponsors and contract research organizations (CROs). Because of this, the financial consequences associated with incomplete or failed startup are likely much more impactful to sites than to sponsors. If a trial is not successful in getting through activation and achieving a signed contract, it ends in a financial loss for the effort expended. Historically, the feasibility team would do a quick review of the budget to identify any red flags. However, many trials moved forward with activation, incurring significant costs, only to be abandoned once we realized the sponsor would not cover our site fees. These trials often had over six months of budget negotiation time before failing, which negatively impacted activation timelines.

2. Goals

Our goal was to identify significant barriers to a successful budget negotiation, address them at an earlier time in the study lifecycle, and decrease loss incurred by trials that had a high likelihood of failure before activation.

3. Solutions and Methods

The clinical trials office finance team identified non-negotiable fees (i.e., items that if not agreed to “as-is” would ultimately lead to start-up abandonment) as frequent sticking points. They developed a standard listing of these fees and provided them to sponsors ahead of our internal feasibility committee approval. If the sponsor was unable to agree to them, the Feasibility and Administrative Review committee (FAR) would not schedule the study for review as it was strong indication budget negotiations would fail. At this point, the principal investigator would be engaged if a path forward with the sponsor could not be achieved the FAR committee would decline trial activation saving significant effort and resources.

4. Outcomes

- The finance team developed a standard, non-negotiable fee sheet
- Activation administrator sends site fees as early as possible for new sponsors that we have not worked with before
- Studies are not approved by FAR until the non-negotiable fees have sponsor approval
- If the sponsor cannot agree to the fees, the FAR committee deems the trial not feasible, and the trial is declined
- Saved significant start-up effort on at least five trials since implementing this process in July 2022

5. Lessons Learned and Future Directions

We are encouraged by the time and effort saved by our new process. However, further improvements are being made. Additionally, there are some points to be aware of when implementing this. Firstly, because sponsors are unfamiliar with a process like this, it is important to clearly communicate your

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site's process and expectations. For instance, we let the sponsor know that the fees are not negotiable and that our FAR committee requires approval before proceeding with any other activity. Secondly, we have found that for us the earlier we begin the fee discussion the more time we can save. We are moving towards implementing fee discussions as early as site selection.