ADVARRA

The State of Clinical Trial Activation at Sites

When conducting the study activation survey, we categorized five areas of protocol feasibility and identified items in each area indicating successful activation practices. These included:

- Financial viability
- Accrual assessments
- Resource optimization
- Protocol feasibility assessments
- Activation timeline length

Determine Financial Viability

When asked, 11% of respondents reported financial feasibility was not part of their study activation process. A study's financial feasibility is informed by:

1. The budget negotiation process	2. Medicare Coverage Analysis (MCA)
• *Takes a long time* 63% of respondents indicating negotiating fees were a reason for activation hold up • *Is held up on the sponsor end too* half of respondents stating their sponsor's response time is slow This can be improved through partnerships with experienced negotiators who are well informed about budgeting and focused on this task alone	• *The MCA process:* Determines what might be covered by a participant's health insurance plan Mitigates or eliminates billing compliance risks Is required to understand the true cost of a study, but 46% of respondents indicated they do not complete MCA at their site

However, study activation costs can be negotiated. Sites use a variety of strategies to negotiate startup costs, including:

15% A single bundled startup fee

48% Itemized startup costs

38% A hybrid method with itemized and bundled costs

Optimize Resourcing

A protocol feasibility analysis needs to include staff and infrastructure resource evaluation, including what is necessary to activate the trial. Additionally, staff expertise needs to be accounted for.

However, the largest pain point indicated across all organization types was research team staff turnover:

20-25%

of academic medical centers (AMCs) and health system-based sites reporting this as their top staff-related issue related to IRB

47%

of AMCs and universities indicated number of staff is a sticking point relating to staffing and budget negotiation

What can we do to improve staffing challenges?

Augment and outsource to reduce research staff workload. Working with an external partner to complete specialized tasks allows staff to focus on the tasks requiring an onsite presence.

Beyond staff resourcing, sites should consider:

Facilities and infrastructure required to conduct clinical trials

Infrastructure shared by multiple investigators and studies

The cost to license and maintain systems

Survey findings concluded if sites ask for these costs, they are more likely to receive them.

75%

of respondents who included CTMS costs in the budget received payment.

97%

of respondents including eReg costs in the budget received payment.

Shorten Activation Timelines

Sites conducting clinical trials naturally compete for accruals. Research sites that do not open studies promptly miss out on enrollment opportunities.

While 99% of respondents provided a turnaround time for overall study activation, 35% reported activation timelines of 91 days or more. Only 19% achieved efficient timelines of 30 days or less.

Activation timelines varied by organization type and research portfolio

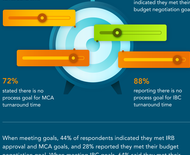
80% of investigative sites were more likely to report shorter activation times (60 days or fewer)

34% of hospital/health system-based sites reported activation within 60 days

21% of AMCs and universities completing activation within 60 days

Regardless of organization type, smaller portfolios of less than 100 industry-sponsored trials more likely reported turnaround times under 30 days. Organizations with larger portfolios of more than 300 industry-sponsored trials reported turnaround times of at least 121 days.

In regard to sub-processes within the study activation process:



What can be done in tandem with IRB review?

81% survey respondents indicated ancillary reviews such as conflict of interest or radiation safety review are done at the same time as IRB review, but 35% of organizations do not allow simultaneous IBC and IRB review. Additionally, 13% of respondents require a finalized budget and contract before IRB submission occurs.

54% indicated their institution had no specific goal for IRB turnaround time

28% indicated they met their budget negotiation goal

72% stated there is no process goal for MCA turnaround time

88% reporting there is no process goal for IBC turnaround time

When meeting goals, 44% of respondents indicated they met IRB approval and MCA goals, and 28% reported they met their budget negotiation goal. When meeting IBC goals, 64% said they met their turnaround time.

Accurate Accrual Assessments

At the site level, 20-50% of clinical trials accrue zero participants, therefore wasting time and effort put forth by study staff.

While 92% of respondents evaluate the pool of participants during study activation, 32% of these respondents don't evaluate past study successes or failures. Evaluating past performance can enable sites to:

- Adopt successful recruitment strategies
- Illuminate screen failure rates
- Estimate staff and investigator effort

Conduct Early Feasibility Assessments

What is protocol feasibility?

Protocol feasibility is the process of reviewing the logistical aspects of a clinical trial and determining if the site's available resources are sufficient for conducting the trial. Conducting a feasibility assessment includes assessing:

- Financial viability
- Available resources
- Past performance and ability to accrue
- Potential pitfalls

Sites should maximize their chances of trial success by answering the following during the trial evaluation period:

- Is it financially viable to run the study at your site?
- Do you have sufficient available staff to conduct the study?
- Do you have the infrastructure required to conduct the study?
- Can you activate the study in a timely manner?
- Can you meet the required accrual goal?

In late 2020, Advarra conducted the Study Activation Survey, asking clinical research site professionals to examine the current state of study activation in the industry and identify the processes and resource components impacted. For more information on report findings, please visit Advarra.com.