

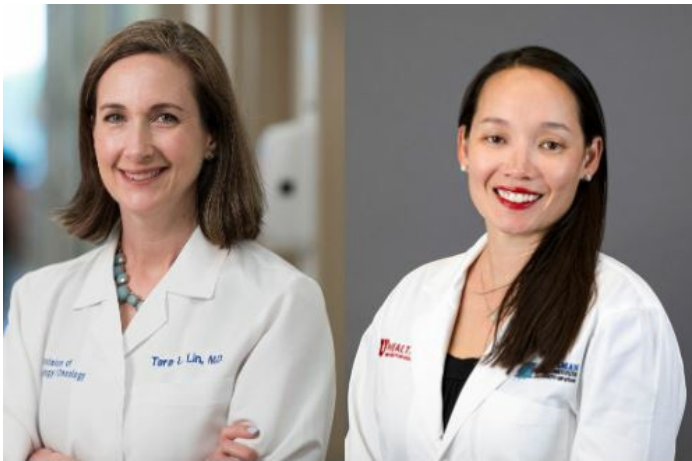
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# Commentary

## Collaborating to Improve Clinical Trial Activation Timelines

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### Commentary Overview

- Cancer centers and pharmaceutical company partners share an interest in opening clinical trials expeditiously.
- To improve cancer clinical trial operations, the AACI Corporate Roundtable Trial Activation Task Force examined the trial activation process and developed best practices to address common barriers to clinical trial activation.
- The task force chose three areas to provide recommendations for improving timelines: contract negotiation; budget development; and trial start-up committee reviews.
- The task force's deliberative process and recommendations reflect the rich discussions and collaborations between colleagues who work at trial sites and industry representatives who share in the challenges of activating trials.

**Cancer centers and pharmaceutical company partners share an interest in opening clinical trials expeditiously. Steps in the process are numerous and variable between sponsors and cancer centers. To improve cancer clinical trial operations, the AACI Corporate Roundtable Trial Activation Task Force convened to critically examine the trial activation process and develop best practices to address common barriers to clinical trial activation.**

The task force achieved several goals, including defining the study start-up timeline and required documents and steps in the study start-up process; outlining best practices and necessary information from sponsors to streamline budget and contract negotiation; and determining

information from both sponsors and sites to understand a site's start up process, required documents, and contacts. Both trial sponsors and sites agreed that clear and frequent communication is essential to expedite study start-up.

## Survey Shows Prolonged Trial Activation Times

In a [2018 AACI benchmarking survey](#) on clinical trials operations, 61 cancer center members reported a median trial activation time of 167 days. [Guidance from the National Cancer Institute](#) (NCI) suggests a target activation timeline of 90 days. Prolonged budget and contract negotiations, the submission of multiple trial amendments during the trial activation process, staff turnover, and the lack of responsiveness in communications from the trial site and sponsor were the main reasons for delayed trial activation. The starting point for study activation ('when the clock starts') for research sites and industry sponsors is different. NCI-Designated Cancer Centers have additional reviews mandated by the NCI, including Protocol Review and Monitoring Systems (PRMS) requirements, which can add complexity to the activation process and impact study activation timelines. In addition, fewer cancer centers are free-standing entities, with the majority having additional layers of review from a distinct university and/or health system review process. Trial sites and sponsors agree that transparency in communications and expectations are key to improving trial activation timelines, which led to the development of the AACI Corporate Roundtable Trial Activation Task Force to discuss process improvements in trial activation and recommend best practices.

## Partnering with Pharmaceutical Industry Sponsors

To advance cancer center clinical research programs, AACI launched a forum in 2012 for cancer centers to address topics of mutual interest with pharmaceutical industry colleagues, known as the AACI Corporate Roundtable. There currently are 10 roundtable members who meet at least twice a year with AACI leadership to foster relationships and collaborations that ultimately benefit patients with cancer and their families.

In early 2020 AACI leadership and industry leaders from the corporate roundtable met to discuss cancer research operational challenges that emerged during the pandemic, including effects on trial activation, lessons learned during the COVID pandemic with remote staff and remote practices, such as remote site monitoring, and utilizing telehealth for trial patients.

It was apparent to sponsors and cancer centers during this meeting that the time to trial activation needed to be addressed more purposefully, as the lengthy delays to start a trial increased costs for all involved, including patients, trial sites, and sponsors. Participants agreed that transparency in communications and understanding of expectations and processes by both the sponsors and cancer centers are key to improving trial activation timelines, and it was suggested that this group would be ideally suited to create recommendations to address trial activation pitfalls and identify process improvements.

The task force is composed of 33 members, including AACI cancer center members involved with trial activation, a member from the NCI, and industry sponsor leaders in the trial activation arena. During the task force's initial meeting, in the fall of 2020, five key areas for improving trial activation timelines were identified:

- Develop communication expectations for trial activation at the site and sponsor level
- Explore the feasibility of industry creating a national coverage analysis (NCA) for industry-sponsored trials
- Utilize master trial agreements to shorten contract negotiations
- Use commercial online portals at trial sites to speed up trial activation
- Better inform industry of the complexity of trial activation at academic cancer centers with NCI designation including requirements of their PRMS used for establishing the scientific prioritization of cancer trials

From these, the task force chose three areas to provide recommendations for improving timelines: **contract negotiation**; **budget development**; and **trial start-up committee reviews**. The task force formed three working groups to allow members with relevant interests and experience to work more closely together. Each working group developed a charter to guide future discussions.

## Barriers to Trial Activation

Each of the working groups held preliminary discussions to identify roadblocks to timely trial activation. The consensus of challenges noted by the task force are listed in this chart.

### Top Trial Activation Challenges Identified by Academic Sites and Industry Partners

Budget and Contract Negotiations

Frequent Protocol Amendments Received During CTA negotiations

Misalignment of Timelines and Prioritizations

Lack of Responsiveness with Communications

Lack of a Start-up Process Roadmap

Staff Turnover

Difficulties with Technology and Systems

Coverage Analysis Inconsistencies

The task force developed a trial activation process roadmap to better define the requirements common across sites to be shared with industry sponsors to improve understanding about standard procedures during trial activation. Providing a process map outlining site-specific start-up workflows and realistic timelines to sponsors is a best practice recommendation.

Clear and frequent communication between sites and sponsors is another best practice recommendation. For example, sponsors should ensure that relevant study materials, such as laboratory manuals and imaging manuals, are included in the site's regulatory packets. Sponsors and sites should also consider developing agreed-upon master consent form templates/sections to truncate review timelines. Sites should implement staff retention strategies and contingency plans for staff turnover throughout the study and site activation process.

## Contract Negotiations

Contract negotiations were identified as another key barrier to timely trial activation. The working group developed a 19-question survey, including 10 questions to be completed by the cancer center task force members and nine questions for industry task force members to determine barriers specific to contract negotiations and to help inform best practices for the contract negotiation process.

Proposed best practices include the use of standard confidentiality disclosure agreement (CDA) processes to provide as much information to sites as possible upfront to help them determine if the trial would be of interest to open. This will save time and resources if the protocol is not a good fit for the site, and standard points would not need to be renegotiated over and over with each new trial. The task force felt it was imperative to monitor ongoing communication between the legal teams of sites and sponsors and escalate questions that arise (especially as legal teams are typically external to the sites' clinical trials offices).

## Budget Development

The third sub-group focused on the challenges of establishing a financial analysis of the trial costs included in the clinical trial agreement (CTA) and obtaining necessary approvals from sponsors and sites. Within the clinical research community, trial costs are identified as standard vs. research care based on the procedures or services and frequency identified in the research

protocol.

Other trial costs noted in the CTA include labor wage rates, startup fees, trial-related annual maintenance fees, and data collection costs. The process of securing an agreement on the budget can range from a couple of weeks up to several months. Prolonged timelines for budget is unacceptable to the trial sites, sponsors, and most importantly the patients waiting for access to novel therapies which may be the only treatment available.

This overview of the task force's deliberative process and selected recommendations, along with a companion [AACI White Paper](#), reflect the rich discussions and collaborations between colleagues who work at trial sites and industry representatives who share in the frustrations of activating trials. Through transparency and communication, we can continue to build relationships and define clear expectations from each other, resulting in a shorter process and eliminating delays in the trial activation process.

## Our Mission

The Association of American Cancer Institutes (AACI) represents 108 premier academic and freestanding cancer centers in the United States and Canada. AACI is accelerating progress against cancer by empowering North America's leading cancer centers in their shared mission to alleviate suffering.

## About AACI Commentary

To promote the work of its members, AACI publishes *Commentary*, a monthly editorial series focusing on major issues of common interest to North American cancer centers, authored by cancer center leaders and subject matter experts.



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