Category: Trial Start-up and Activation – Work in Progress

Collaboration to Develop Recommendations to Improve Trial Activation Timelines

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1. Background

In July 2020, during the first months of the COVID-19 pandemic, the CRI steering committee met with the AACI Corporate Roundtable industry leaders to discuss mutual clinical research challenges. One topic of interest was trial activation timelines. In a 2018 survey developed by AACI for its members to use for benchmarking purposes, 61 AACI cancer centers reported the median trial activation time was 167 days, above the National Cancer Institute (NCI) benchmark of 90 days[1]. Many delays result from stalled negotiations and a lack of communication responsiveness from both sides. The starting point for trial activation varies between sponsors and trial sites, and resources dedicated to industry-sponsored trials may vary based on cancer center priorities. However, both sites and sponsors agree that transparency in communication is key to trial activation; for example, when protocol amendments are available, the site should be aware of these to avoid delays in trial activation. AACI created the Trial Activation Task Force from this meeting's discussion.

2. Goals

During the pandemic, collaborations between industry and trial sites became a priority for sponsors and cancer centers to activate trials faster and minimize costly delays. Both agreed contract and budget negotiations were areas to target and develop expectations for both sides to avoid delays and improve communications to resolve any issues.

3. Solutions and Methods

In November 2020, the task force had its first meeting. The task force identified key areas in the activation process for improvement. After the initial meeting, we divided the task force into small groups to discuss:

a) Developing communications pathways and workflow maps
b) Determining the benefits of implementing a National Coverage Analysis (NCA) for industry-sponsored trials
c) Utilizing master trial agreements (MTA) to shorten contract negotiations
d) Educating industry on the requirements for academic cancer centers who have or are seeking NCI designation and the cancer center's protocol review and monitoring systems (PRMS) used to develop a trial prioritization

To develop recommendations, the task force was subdivided into three working groups (WG):

1) Streamline Contract Negotiations
2) Streamline Trial Site Activation Committee Reviews and Communications – "The Clock"
3) National Coverage Analysis

4. Outcomes

Each WG developed a charter to guide them in developing recommendations. Discussions, surveys, and polls were used to create the following suggestions:

1) Develop a process map outlining start-up workflows and staff contact information
2) Utilize study "kick-off" meetings to create expectations for trial activation
3) Encourage transparent communications and have an escalation process when negotiations are stalled
4) Make available all study information to truncate review timelines
5) Encourage MTAs to speed up negotiations and use the last budget negotiated as a starting point; provide CPT codes to assist in developing an accurate MCA
6) Develop master CDAs to eliminate unnecessary negotiation of a CDA for unwanted trials

5. Lessons Learned and Future Directions

Sites and industry share the frustrations with working together to activate trials, and transparency in communication and expectations builds relationships and collaboration.