Category: Clinical Research Operations – Work in Progress

Institutional Perspectives on Cancer Community Activation Timelines

S. Stewart[1], W. Tate[2], L. Hilty[2];

[1]University of Wisconsin Carbone Cancer Center; [2]Forte Research Systems

1. Background

Cancer centers have multiple competing deadlines coming from their institutions as well as from clinical trial sponsors, including pressure to decrease the time it takes to activate a study. However, there is a lack of information available to institutions on whether timelines requested by internal and external stakeholders are comparable to peer organizations. Without knowing whether shorter timelines are being achieved by peer organizations, institutions have a greater difficulty knowing if they are competitive in the activation space and whether shortening study activation timelines to a value set by sponsors (whether industry or NCI) are achievable.

2. Goals

Median turnaround times from the aggregated Forte Benchmarks cancer community will be generated. These include times to complete the PRMC, IRB, budgeting, contracting, and overall activation processes. Collaborating institutions will review these timelines and provide commentary and assessment of the community timelines, current requirements of the center by internal and external stakeholders, and what these metrics mean in the current landscape of activating clinical trials.

3. Solutions and Methods

The Benchmarks database will be queried by Forte to look at turnaround times for protocols that were activated in calendar year 2018. These timelines will be shared with the institutional partners for their analysis. Responses will be aggregated and presented for broader community discussion at the AACI CRI conference.

4. Outcomes and Future Directions

Analysis to be completed in Spring 2019. A similar analysis was performed by Forte in Fall 2018 for the AACI-CCAF conference and showed that the overall activation timelines for institutional protocols took approximately 20-30 days longer than industry, while national group protocols took about 60 days fewer than industry. The fastest of national group protocols met the NCI cutoff for activation of 60-90 days while; however, the majority of these protocols were above this requirement. Time to finalize study budgets has decreased over the last five years, while PRMC review times have remained steady.

Many organizations are in a vacuum when it comes to understanding where they stand in comparison to their peers in activation timelines. This puts them at a disadvantage when it comes to negotiating with sponsors or setting achievable process improvement goals. Analyses and discussions such as this remove the “black box” and allows institutions to come together to better the clinical research enterprise through the sharing of realistic and streamlined processes and timelines.