

Decreasing Time to Activation for National Cooperative Group Trials and Industry-Sponsored Trials at the University of Arizona Cancer Center

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1. Background

In 2021, the median time to activate interventional treatment trials at the University of Arizona Cancer Center (UACC) was 176 days. To decrease trial activation timelines, a trial activation manager was hired.

2. Goals

The goal of the trial activation manager is to develop strategies to reduce timelines, navigate trials through activation, and ensure all barriers and roadblocks are addressed to reduce overall time to activation.

3. Solutions and Methods

The UACC Time-To-Activation (TTA) Committee was critical in identifying issues affecting timelines and the need for dedicated staff to focus efforts on these issues.

The UACC trial activation manager had extensive regulatory and startup experience prior to starting this new role. The approach taken to reduce start-up timelines was assigning startup tasks and processes into distinct categories:

Category 1 – “We have absolute control.”

These are tasks that are in the control of the researchers and mainly include internal processes such as Scientific Review Committee, investigator signatures, scheduling the site initiation visit (SIV), etc. The trial activation manager leverages these types of tasks to reduce as much time as possible.

Category 2 – “We know that we don’t control this.”

These are tasks others are responsible for but can be navigated and followed for optimal efficiency. This includes ensuring contracts and budget staff are working with responsive sponsors, establishing master contractual agreements with key pharmaceutical companies, requesting activation approval immediately after a SIV, etc. The trial activation manager utilizes relationships and regular follow-up with our institutional partners and sponsors to navigate these processes effectively and efficiently.

Category 3 – “We didn’t know just how much we don’t control this.”

This includes processes that are required but not streamlined nor efficient, for which the trial activation manager has little control of the outcome. For example, ‘Conflict of Interest’ review processes at UACC can take several weeks to complete and impacts the IRB review and other aspects of the trial activation process. The trial activation manager addresses these types of issues by working with department leaders, educating them, keeping them engaged in the issues, to help them better understand how minor alterations or adoption of concurrent processes could have positive impacts on TTA.

4. Outcomes

With the creation of the trial activation manager role, the median time to activation was reduced from 176 days in 2021 to 154 days in 2023. The largest reduction in TTA was for national trials, due to having

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the greatest internal control over the timeline given the lack of contract and budget negotiations. Contract and budget negotiations remain the largest obstacle to lowering TTA at UACC.

National Time to Activation:

2021 – 95 Days

2022 – 62 Days

2023 – 30 Days

Overall Time to Activation:

2021 – 176 Days

2022 – 162 Days

2023 – 154 Days

5. Lessons Learned and Future Directions

The trial activation manager at UACC plays a key role in reducing the time to activate trials. While entrenched institutional interests may resist change, gaining control over the key aspects of the startup process and constantly refining those processes is key to success.