



Bolstering the Study Startup Process and Technology for Oncology Trials



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Introduction

The study startup process for clinical trial drugs is a long process that involves many different teams. Each team has their own study checklist which verifies that the necessary tasks are done before a study can move on to the next team. This regulation process provides quality assurance and is vital for ensuring patient safety. However, without having the process centralized, study approval can take a very long time as a study passes through many different hands. To facilitate this process the regulatory management, site development, cancer center administration, and the bioinformatics teams came together to build a platform aimed at streamlining the startup process and providing a transparent view of where a study is in the startup process.

GOALS

Develop a Centralized Study Startup System that:

- Incorporates Every Stage of Study Startup
- Has a Scoring Mechanism to allow prioritization
- Generates Automatic Outcome Letters
- Provides Notifications when deadlines are close
- Allows data to be easily exported and analyzed

Methods

In August 2020, the University of Kansas Cancer Center implemented a system that allows review boards to seamlessly review and approve therapeutic trials, thereby ensuring appropriate studies are opened in a timely fashion. This system is referred to as Trial Review and Approval for Execution (TRAX) and was developed through a partnership between the clinical trials office and the Biostatistics and Informatics shared resources. The software base of the TRAX system was built in partnership with WCG Velos.

Results

Tracking all the information within a single system allowed our cancer center to track metrics that allows our operational and regulatory teams to assess the year-by-year trend and plan for the upcoming year. In case of an audit, it makes it easy for the PRMS administrator to review and gather information from the system as all the information through each review is documented electronically. Additionally, the reports allow the cancer center to obtain metrics on the fly.

