Improving Start-Up Times in Oncology Clinical Trials at an NCI Designated Comprehensive Cancer Center (NCORP site)

An ASCO Quality Improvement Project

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Abstract

Delays in opening clinical trials adversely affect patient care. New Mexico Cancer Care Alliance's (NMCCA) / University of New Mexico Comprehensive Cancer Center (UNMCCC) average time from clinical working group (CWG) review to trial opening is 33 weeks. Shortening this time will expedite patient access to novel therapies.

Goal: Identify where delays occur in the process and create strategies to shorten the time of trial activation without creating excessive burden to staff and financial resources.

Primary aims:

1. To define the average time a protocol stays within each timeline for clinical trial initiation
2. To identify the timeline where an intervention will make the most impact in shortening start-up time
3. Through an ASCO driven project, create an intervention with the goal of decreasing this time by 50% by December 31, 2018

Methods and Materials

1. Data Gathering

This study analyzed 81 clinical trials opened in 2017 which included industry, investigator initiated and NCTN trials. Data on the average time a trial spent in the following timelines were collected and a Pareto chart was generated (Figure 1):

- Clinical Working Group Review
- Protocol Review and Monitoring Committee (PRMC) Approval
- IRB Submission
- IRB Pending
- IRB Approved
- Open Active

2. Focus Group Approach

After identifying the timeline accounting for the longest delay, a focus group of staff directly involved in this process was organized. Two meetings were conducted.

First meeting: Identify barriers. A blinded approach to data collection was used.

Second meeting: Interactive discussion. The top 3 barriers were identified and strategies were formulated, in the context of staff limitations.

Results and Discussion

Data from 2017 showed that the time between IRB approval and a study becoming open active was 12.67 weeks. As outlined in Figure 1, this represents 38% of the total time (33 weeks) for trial initiation. The data allowed us to identify the timeline that would be the focus of intervention.

The focus group identified the delays encountered from IRB approval to open active as represented in Figure 2. Among these, the 3 lengthiest processes identified were:

- Scheduling and completion of site initiation visits
- Completion of site budgets
- Access to study portals, EDC, IWRS

There was agreement amongst all the group members that the time to complete these tasks could not be shortened due to staffing resources. However, strategically shifting these tasks by working in parallel with earlier timelines is estimated to decrease the time by at least 50% (6 weeks).

On closer analysis of the average length of these processes, it was also determined that the NMCCA's arbitrarily set goal of reducing this timeline to 2 weeks is likely not achievable and 6 weeks is a more realistic goal.

Figure 1

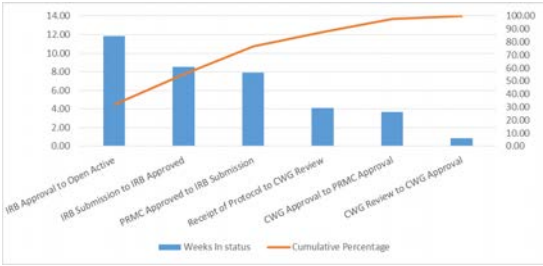
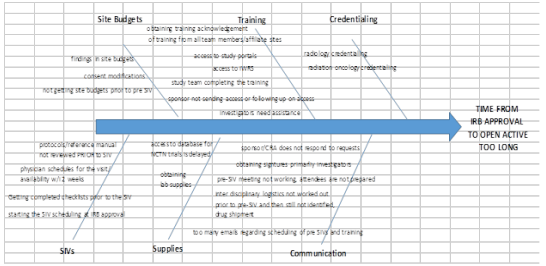
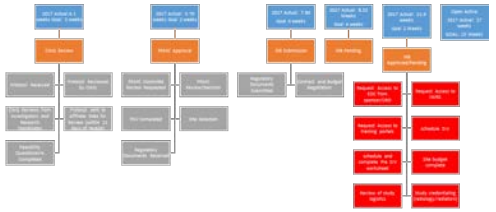


Figure 2

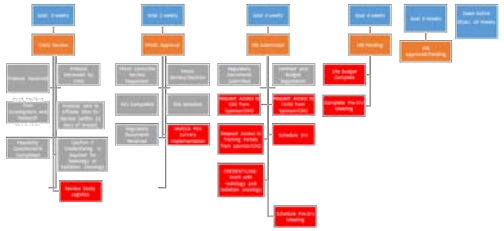


Workflow Changes

Pre-Intervention Work Flow



Post-Intervention Work Flow



Process Interventions

To effectively implement the shift in the new workflow, beginning February 2018, strict deadlines for the 3 priority processes will be established for each new trial submitted to IRB.

Process interventions include:

1. New study feasibility questionnaires will be given to sponsors to identify barriers earlier.
2. Template emails have been drafted for the regulatory coordinators to communicate more efficiently at the time of PRMC approval.
3. A template for timeline reporting to the clinical working groups has been created and mandatory deadlines will be established and tracked.

Conclusions

Detailed analysis of 2017 data of newly opened trials at NMCCA/ UNMCCC showed that protocols spent the longest amount of time from IRB approval to open active. The identification of this delay is the critical first step in developing strategies to shorten time to trial initiation at our institution.

The focus group identified the most significant causes of delay. It was determined that shifting the tasks to run in parallel with earlier timelines will allow for the same amount of time for task completion without increasing the stress on the clinical trials staff. It is anticipated that this strategy will reduce the amount of time from IRB approval to open active from 12 weeks to 6 weeks.

This process was a constructive exercise creating a positive team experience that encouraged collaborative problem solving.