AACI Clinical Research Initiative Meeting
July 11-12, 2013
Abstract Submission Template

Abstract Title:	*Performance Based Web-Application Accelerates Clinical Trial Activation in Pilot Study*
Author Name(s):	Therica Miller, MBA, Sheilah Hurley, MA, Mahendra Yatawara, MBA, Rebecca Flores-Stella, BS, CIP, Keren Dunn, BA, CIP, Ryan Schroeder, BA, Haibin Wang, PhD, Shao-Chi Huang, BS, Kevin Dudley, BA, Robert Figlin, MD, Monica Mita, MD, Christine Szekely, PhD, Howard Sandler, MD, Steven Piantadosi, MD, PhD
Cancer Center Name/Organization(s):	Samuel Oschin Comprehensive Cancer Institute (SOCCI) at Cedars Sinai Medical Center, Los Angeles, CA

A. Describe the background of the problem:

In spite of shared scientific interest with sponsors, academic sites are challenged to improve timelines for collaborative trial activation. Required committee reviews, regulatory approvals, contracting, and budgeting are often conducted serially without standard processing timelines, resulting in unpredictable and usually lengthy activation times. This, coupled with the lack of reliable key milestones tracking, led us to redesign our study activation workflows, develop timetables for key tasks and design an online system to identify real-time delays through links to Forte's OnCore™ and Huron's Click™ IRB system.

B. List the problem's root causes or obstacles to overcome if applicable:

Historically we had a non-systematic approach to activating cancer clinical trials with as many 10 internal reviews and 15 approvals required to activate a protocol. Distinct silos existed and there was no well-defined shared goal to improve efficiency. This resulted in linear processes with limited flexibility for adaptation or change. Further, there had been no standards set for each stage of the process, allowing for disparate work flows and independent serial processes throughout the research enterprise, with no target completion deadlines for key milestones. The absence of aligned priorities across functional teams resulted in poor collaborations and costly delays. Additionally there was no method of monitoring deliverables and accountability, or optimizing performance.

C. Provide metrics or goals hoped to be achieved with the solutions to address the problem:

Our goal was to activate high priority cancer clinical trials within 42 days of receipt of the complete protocol package, measuring time to completion for major milestones: Regulatory preparation and submission to the Institutional Review Board (IRB) Review, IRB processing and review, Medicare Coverage Analysis (MCA), Scientific Review, Radiation Safety (MRSC) Review, Budget Negotiation and Contract Execution. Six clinical trials from the Cancer Center portfolio were used to test, measure and redesign the activation workflow without compromise to subject protections, regulatory compliance, and scientific integrity.

D. Describe the solutions implemented:

We successfully redesigned our institutional workflow to complete selected high priority clinical trial activation tasks within six weeks; historical procedures were replaced rather than scrutinized. Incremental revisions in structurally suboptimal workflows do not yield strong improvements. A high level leadership committee was required to change and integrate procedures across the medical center,

and engage sponsors to improve their turnaround times. Ad-hoc IRB and MRSC committees were established while target completion dates were set for key tasks and parallel processing was implemented. The Protocol Rapid Activation Tracking (PRAT) tool, a web-based application, was developed. This collaborative tool provides a single platform for all key stakeholders to manage, track and prevent bottlenecks, while simultaneously measuring performance.

E. Describe what happened when solutions were implemented or data showing a positive or negative outcome:

Cancer clinical trial activation times were reduced significantly from the standard of approximately six months. For the six studies used as tests of change over the course of one year, the activation times were 49, 54, 78, 58, 62, and 32 days. Times in excess of 6 weeks were largely due to sponsor delays; the outliers were contracting and budgeting. The PRAT system's "Timetable" provided a simple visual interface, in the form of a color-coded Gantt chart displaying the hold-ups, if any, during the activation process. Stakeholders were then able to rectify any issues and thus remove hindrances.

F. Show lessons learned, others to involve in the future, or ideas of other initiatives to pursue:

The next phase of our project will be to study the feasibility of expanding Rapid Activation (RA) to a larger portfolio of clinical trials. Using the PRAT collaborative tool, baseline data will be captured for all hematology/oncology trials processed in the coming twelve months, including hours expended by individual staff for each critical task. These data will be used to change processes and modify staffing to expand RA procedures and timelines to a larger number of protocols. We will also measure sponsor interactions and other dependent processing times. We expect a cascade of benefits from this improved process in our entire portfolio including savings in staff time, minimal delays in study activation, better alignment with the needs of industry partners, and improved support for investigator initiated cancer clinical trials.