Accelerating the clinical trial start-up process for early-phase cancer studies: A test of process change to support rapid activation in an academic medical center.

Meeting:
2013 ASCO Annual Meeting

Category:
Health Services Research

Subcategory:
Outcomes and Quality of Care

Session Type and Session Title:
This abstract will not be presented at the 2013 ASCO Annual Meeting but has been published in conjunction with the meeting.

Abstract Number:
e17507

Citation:
J Clin Oncol 31, 2013 (suppl; abstr e17507)

Author(s):
Sheilah K Hurley, Therica M Miller, Rebecca Flores Stella, Keren Dunn, Ryan Schroeder, Mahendra Yatawara, Robert A. Figlin, Monica M. Mita, Howard Mark Sandler, Steven Piantadosi; Samuel Oschin Comprehensive Cancer Institute, Cedars-Sinai Medical Center, Los Angeles, CA; Office of Research Compliance, Cedars Sinai Medical Center, Los Angeles, CA; Office of Sponsored Research Funds, Cedars Sinai Medical Center, Los Angeles, CA

Background: Clinical trial sponsors have strong scientific, financial, and regulatory interests in rapidly activating studies at participating sites. Academic medical centers have difficulty activating trials within a few weeks of sponsor agreement because, among other inefficiencies, they engage the necessary committee reviews, regulatory approvals, contracting, and budgeting in serial fashion. Incremental revisions in such workflows do not result in strong improvements. **Methods:** We redesigned our institutional workflow to complete clinical trial activation tasks within six weeks. Historical procedures were replaced rather than scrutinized. A high level leadership committee was required to change and integrate procedures across the medical center, and engage sponsors to improve their turnaround times. A web-based collaborative workflow tracking tool was created to help coordinate the necessary tasks and measure performance. Six clinical trials from the Cancer Center portfolio were used to test and improve the new workflow. **Results:** Clinical trial activation redesign took one year. For the six studies used as tests of change, the activation times were 49, 54, 78, 58, 62, and 32 days. Times in excess of 6 weeks were largely due to sponsor delays. **Conclusions:**

Considerable effort is required to significantly alter a complex workflow like clinical trial activation. Appropriate priorities, leadership, staffing, and tools are required. Markedly shortened study activation for a small series of cancer trials taught our academic medical center lessons that will be useful for improving the process for all clinical trials, and will make us a better partner for pharmaceutical and academic sponsors as well as for investigator initiated research.

Rapid activation of early-phase trials.

	Days to completion					
Key activities	**Trial 1**	**Trial 2**	**Trial 3**	**Trial 4**	**Trial 5**	**Trial 6**
CRO regulatory: IRB preparation	37	29	20	14	15	10
IRB processing	43	42	9	18	46	25
MCA processing	16	16	20	19	13	4
PRMC review	30	35	30	22	22	5
MRSC review	21	72	48	36	60	25
Budget negotiated	21	43	37	36	50	12
Contract executed	43	54	78	53	59	31
Trial activation complete	49	54	78	58	62	32