Timeline reforms increase initiation speed of NCI sponsored clinical trials

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The National Cancer Institute (NCI) and investigators have reduced the deadlines for initiation of trials with the goal of reaching more patients in need of new treatments, according to a study published June 17 in the *Journal of the National Cancer Institute*.

In the year 2008, the NCI created the Operational Efficiency Working Group (OWEG) to develop recommendations for increasing the speed at which NCI-sponsored trials are initiated. An approach to mobilize and improve business processes among the research community was devised that included new staff positions, protocols, and planned conference calls between the NCI staff and the investigator teams. These measures were implemented to ultimately meet new target timelines and deadlines for initiation of phase 1-2 and 3 studies by eliminating redundant efforts and rapidly resolving critical issues quickly. For phase 1-2 studies, the target timeline was set as 7 months and the absolute deadline was18 months. For phase 3 studies, the target timeline was 10 months and the absolute deadline was 24 months. If a trial was not initiated by the absolute deadline, it was automatically disapproved.

Jeffrey S. Abrams, M.D., from the Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis at the NCI in Bethesda, Maryland, and colleagues compared trial initiation times before and after implementation of the OEGW recommendations. A total of 525 pre-OEWG trials and 152 post-OEWG phase 1-2 trials were included in the analysis, whereas 112 pre-OEWG trials and 24 post-OEWG phase 3 trials were included.

The researchers found that the median time to activation of phase 1-2 trials decreased from 541 to 442 days. Similarly, the median time to activation of phase 3 trials decreased from 727 to 395 days, and none of the 25 trials included in the analysis reached or went beyond the predetermined absolute deadline of 730 days. These results provide evidence that the implementation of the OEWG recommendations have led to more rapid initiation of NCI-sponsored trials, ultimately benefiting patients in need of new treatments for cancer. The authors conclude, "improvements in trial initiation should encourage potential partners in the pharmaceutical and biotechnology industries to view the NCI's publicly funded clinical trials system as a place where their new agent or device can be rapidly moved into the clinic."

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