

# Protocol Rapid Activation Tracking: A Web-based Collaborative Workflow Tracking Tool for Accelerating the Clinical Trial Start-Up Process for Early Phase Cancer Studies

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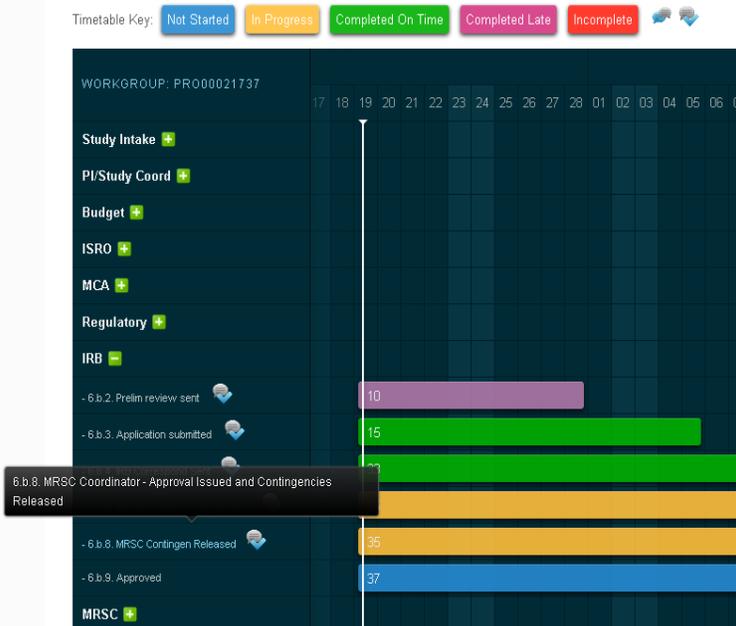
## Background

Activating trials within a few weeks of sponsor agreement is known to be difficult for academic medical centers, partly due to engaging the necessary committee reviews, regulatory approvals, contracting, and budgeting in serial fashion. Since incremental advances in such workflows do not result in strong improvements, the Samuel Oschin Comprehensive Cancer Institute (SOCCI) created a novel process for rapid activation of trials, whilst not diminishing the emphasis on the scientific review process. The Rapid Activation Process, developed by SOCCI, defined the key milestones in the life of a protocol and identified players critical in achieving these milestones [1]. In creating this Rapid Activation Process, SOCCI is able to meet an institutional mandate requiring that early phase oncology studies be activated within a six-week timeline (42 days) from the execution of the Confidential Disclosure Agreement to the activation of the trial.

## Methods

We developed a Web-based intranet application – Protocol Rapid Activation Tracking (PRAT), a collaborative platform to help coordinate the necessary tasks and identify bottlenecks in the Rapid Activation Process. Specific workgroups are assigned to specific tasks with a specific target date, and all stakeholders involved in the process are able to identify and correct potential delays within the 42 days activation timeline. The PRAT is developed on the free, open-source, Yii framework utilizing PHP, jQuery, and CSS. The backend database is MySQL. The PRAT's authentication is LDAP-based and utilizes components of the Zend Framework. It has role-based access control. The PRAT obtains protocol information directly via import from Forte's OnCore™ and near real-time data feed from Huron's Click™ IRB system.

## Screen Snapshot of Timetable for Workgroup Workflow Task



## Results

The PRAT system's user-friendly Web interface is based on the requirements of "ease of viewing for Leadership." Varied "views" are provided for the four user roles in the system: SysAdmin, Admin, Workgroup and Leadership. Key features of the system include two dynamically generated Gantt charts based on fifty five workflow tasks, displayed in both workgroup workflow timetable view and process workflow timetable view. The Gantt chart timetable views display nine workgroup workflows and eight process workflows respectively. All workgroup and process workflow tasks are associated with specific task comments and are color coded based on timeline for completion of the task. Color codes for tasks specify the status as follows: Not Started, In Progress, Completed On Time, Completed Late, Incomplete. Effort spent on each task by the end user is also captured in the system.

## Discussion

The PRAT system helps Workgroup members stay on track with defined targets for completion of processes, increases visibility among Leadership to identify and address delays in real time, and facilitates the improvement of efficiencies in activating clinical trials within six weeks.

## References

1. Stella R., Dunn K., Pucci A. and Li E., MEETING THE CHALLENGE: Development of an Ad-Hoc IRB to address fast-track protocols, AAHRPP conference, April 2013, Florida, USA.

## High Level System Architecture of PRAT

