



Impact of the CIRP Workflow Scheduling Tool on the Operational Efficiency of Complex Psychiatry Trials

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Objective

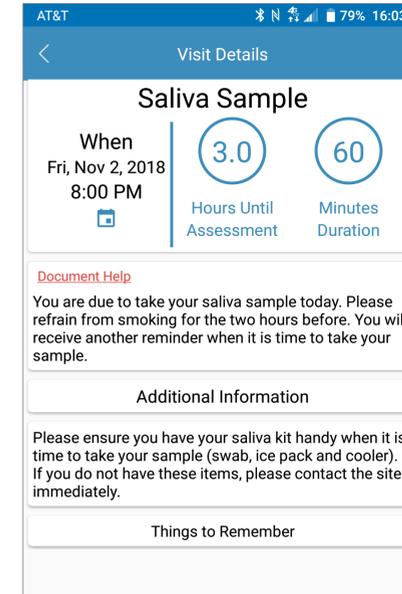
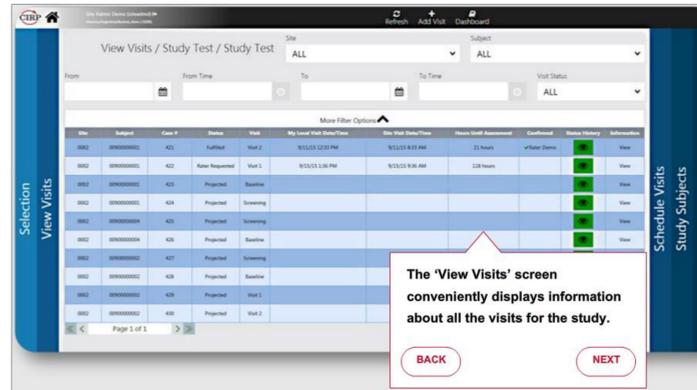
CNS trials fail for a variety of reasons unrelated to the efficacy of the drug, such as incorrect patient selection, high placebo response, or functional unblinding. The industry has responded with innovative approaches such as independent eligibility determination, re-randomization of placebo non-responders, and remote independent ratings. Although these may address the scientific issues, increasing the complexity of trials generates operational challenges which themselves pose a risk to study success. We examined the impact of a role-based and criteria-based workflow scheduling tool designed to improve the operational efficiency of complex trials.

Design

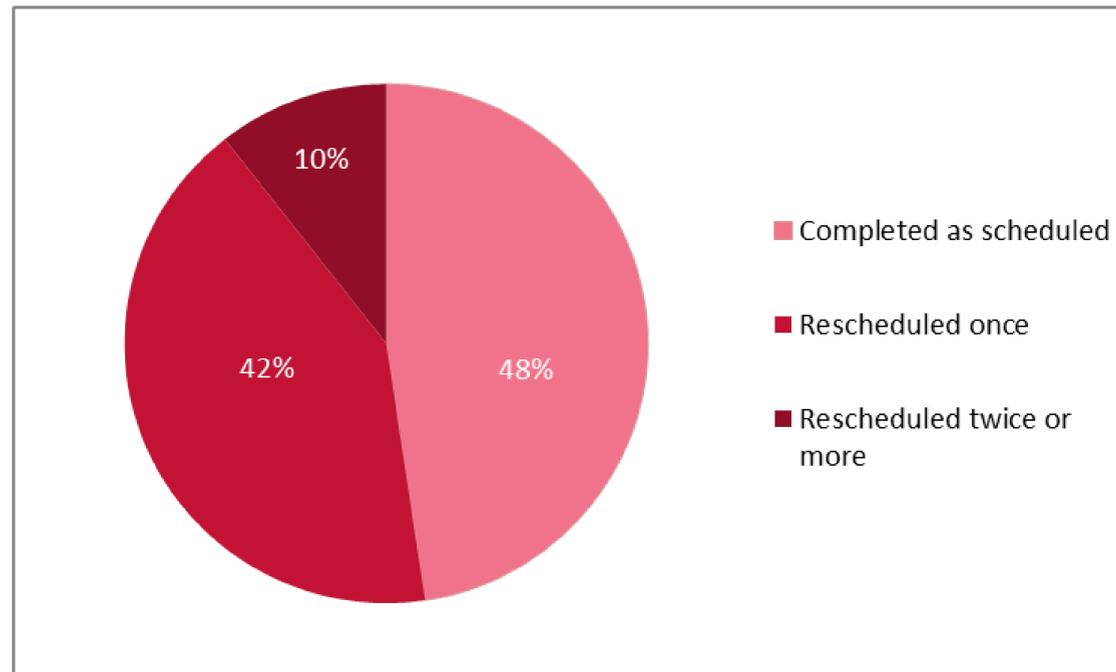
We aggregated metrics from 5 global psychiatry studies where sites used the cloud-based Cronos Integrated Research Platform (CIRP) to coordinate study-related events across multiple vendors and patients. Activities included online scheduling of blinded, remote raters for conducting clinical assessments, and automated reminders to patients to perform at-home biometric sampling.

Disclosures: BKS, CM, KM, CY are fulltime employees, and GDC is the Founder & President of Cronos Clinical Consulting Services, Inc., developer and commercial provider of the Cronos Integrated Research Platform (CIRP) for use in clinical trials.

CIRP User Interface and Engage app notification



Scheduling Effort Required for Completed Study Events



Results

Data were collected over 30 months, from 5 studies conducted in 21 countries, including North America, South America, Western Europe, Eastern Europe, and South Africa. Studies involved n=1962 patients, 142 independent raters, and 590 registered CIRP users.

The CIRP user interface and notifications were translated into 20 non-English languages, and incorporated scheduling over 16 time zones.

Event scheduling actions (including attempts/cancellations) totaled 124,513, with 500,000+ active and passive notifications sent to users.

Of the 24,201 completed events, 10,115 were cancelled/rescheduled at least once, and 2,561 twice or more i.e. >50% of the completed activities encountered operational disruption that could have led to missing data.

Conclusion

The operational impact of increased complexity is not simply a workload issue, but can have a direct effect on study data. Tools should be considered that can centrally coordinate activities, but more importantly, include the capability to monitor protocol compliance in the same system. By examining operational burden in realtime, preventative actions can be taken to minimize the risk to data completeness and quality.