Syneos Health Looks "Outside the Box" and Works with Medidata Rave EDC and Rave RTSM to Support Adaptive Trial Design Changes Using Custom Functions

Syneos Health (Syneos), a global, full-service contract research organization (CRO), has been using Medidata's Rave EDC (electronic data capture) and Rave RTSM (randomization and trial supply management) solutions to support their Phase I-IV clinical trials for several years. Syneos was contracted by a global pharmaceutical company to provide EDC and RTSM capabilities to support a complex adaptive trial protocol design on the AZ201801 (Azura) trial, which allowed modifications to the trial and/or statistical procedures of the trial after its initiation without undermining its validity and integrity. The goal was to make the clinical trial more flexible, efficient and expedient. Due to the level of flexibility required, these trial designs are also called "flexible designs." The term flexibility did not mean the trial could be modified at any time, rather, the modification and adaptations had to be pre-planned and based on data collected from the study itself.

The Challenges

Syneos decided to use Rave RTSM together with Rave EDC for this study; however, protocol complexities associated with adaptive trial design required the team to creatively think of ways to manage changes to the protocol outside of the traditional RTSM work flows.

The Solution

The study team was already using Rave EDC with Rave RTSM for a unified approach to randomization and trial supply management. After evaluating the benefits of "out of the box" solutions to support adaptive trial design, Syneos and Medidata determined that it would be most efficient to implement custom functions from Rave EDC to support changes in RTSM. Programmers and/or study builders used programmatic codes within Rave EDC to execute changes in Rave RTSM.

Five custom functions were implemented in the Azura study to meet the challenging dosing frequency changes required at Day 1 and Month 15. Additionally, custom functions were developed to carry over frequency changes from one time period to the next. Derivations were programmed into the custom functions to allow the system to address dosing changes as needed in accordance with study specifications.

The Results

By looking at the capabilities of Rave EDC to drive updates within RTSM, Syneos was able to manage unpredicted changes as a result of adaptive trial design and reduce cycle time and resource allocation associated with the reduction in software development and validation efforts. The unified interface between Rave EDC and RTSM allowed creativity for programmers to apply updates without disrupting system validation or causing unnecessary downtime for entry into Rave EDC.

As stated by one of Syneos' key stakeholders on this study, "When the current RTSM functionality cannot support the study design, you need to look outside of [Rave] RTSM, but still within the [Medidata system]. [In] our case, we leverage[d] the ability of Rave EDC to let build [and] add custom functions to provide some of the randomization functionality, which [was] supported only in RTSM."

Rave EDC and Rave RTSM Integrated Platform

The study relied on both Rave EDC and Rave RTSM with customization, and the integrated platform delivered benefits for all stakeholders involved in managing the study. The site staff had only one point of data entry, benefited from a streamlined workflow, and was spared duplicative data entry. The sponsor was able to eliminate data reconciliation across separate systems and to report data from across platforms.

Having a prevalidated and a unified EDC and RTSM eliminated the setup delays associated with a custom system, allowing Syneos to meet the ambitious build timelines for FPI and manage adaptive trial design introduced with a complex protocol.