

# Syneos: A Global Full-Service CRO Shares RTSM Success

Syneos, a global, full-service contract research organization (CRO), started using Medidata Rave electronic data capture (EDC) and randomization and trial supply management (RTSM) services to support its Phase I-IV clinical trials. Syneos was introduced to Rave EDC over a decade ago, and through interest from Sponsors and internal interest in technology, Syneos looked further at RTSM to evaluate its capabilities and services.

## The Challenge

There are many companies across the industry offering EDC and randomization and trial supply management (RTSM) services. Many of these technology providers promise seamless integration and drastically reduced or eliminated reconciliation, decreased turnaround time, and shorter time from last patient last visit (LPLV) to database lock (DBL). In reality, many of these EDC/RTSM providers still require reconciliation of the imported data to the EDC source. The time associated with batch and QC upload, validation that data has been properly uploaded and the programming to match like variables to those collected in EDC can be considerable and burdensome.

Syneos recognized these challenges when they wanted to select a preferred EDC and RTSM service provider and therefore needed to decipher which companies were best suited to their business needs as well as providing the best long-term organizational fit.

## The Solution

Medidata's Rave EDC and Rave RTSM provide a unified platform that delivers benefits for all stakeholders involved in managing aspects of the study. Having a prevalidated and inbuilt integration between Rave EDC and Rave RTSM eliminates the setup delays associated with disparate, custom systems, allowing Syneos to meet, as needed, the ambitious build time lines for FPI and manage trial design complexities. There is no need to perform those timely and costly uploads associated with traditional RTSM solutions.

Clinical data is entered into a single source of truth, Rave EDC. From here, Rave EDC uses edit checks to “speak” to RTSM, driving functions as set-up during both EDC and RTSM design. As data is entered in EDC, RTSM returns information directly to Rave EDC; hence creating a seamless interface and eliminating duplicate data entry and reconciliation while reducing resource needs and increasing efficiency.

## The Results

Syneos provided EDC and RTSM services using Rave EDC and Rave RTSM, respectively. As Syneos became more comfortable using these Medidata products and saw their value, they proposed it to more prospective clients. As Voitek Gradziuk, Principal Solutions Consultant at Syneos Health stated, **“Over the last 6 years, we have implemented over 130 studies in Rave RTSM and this number is growing every week. We use the Rave RTSM for all aspects of the clinical study related to a randomization drug distribution and assignment, and also, of course, unmasking. For most of the studies, we use the existing built-in and validated functionality of RTSM. So this is our standard approach that we configured.”**

## Rave EDC and Rave RTSM Integrated Platform

Syneos relied on both Rave EDC and Rave RTSM, and the unified 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. Sponsors were able to eliminate data reconciliation across separate systems and to report data from across platforms.

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### About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,400 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

Medidata, a Dassault Systèmes company (Euronext Paris: #13065, DSY.PA), is headquartered in New York City and has offices around the world to meet the needs of its customers.

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