Accelerating SCTU's Digital Transformation, while Supporting its COVID-19 Studies

How Medidata Helped Southampton Clinical Trials Unit Accelerate its Digital Transformation Journey and Provided Support During the Global Health Pandemic

Southampton Clinical Trials Unit (SCTU) is one of eight clinical trials units core funded by Cancer Research UK and receives National Institute for Health Research (NIHR) CTU support funding. SCTU sits within the Faculty of Medicine at the University of Southampton, working in partnership with the University Hospital Southampton NHS Foundation Trust and Southampton Experimental Cancer Medicines Centre, and undertakes non-commercial academic trials. An academic clinical trials unit such as SCTU is a registered organization (within the UKCRC CTU network), usually hosted by a university or NHS Trust, which works in partnership with chief investigators across the UK to develop and run non-commercial trials and ensure the quality of the conduct of these studies.

From Static to Streamlined

Previously, the Unit was using largely manual and paper-based processes to run its studies. As the IT support provided by the University was not specialized in clinical trials software, the SCTU team decided to move to a Software as a Service (SaaS) model to help streamline their clinical trials on a unified platform.

SCTU began a competitive tender process in 2015 to replace its in-house and manual clinical trials system with a modern, responsive SaaS platform. Throughout the tender and EU procurement process, each of the potential providers were scored based on their ease of use, functionality, support model, time to implementation, and cost. Medidata scored highest out of the potential providers and had a reputation as having a reliable and leading platform, was selected by SCTU to reinvigorate its clinical trial processes. Two key factors in the decision-making journey were the fact that Medidata's solutions are uniquely integrated on one platform with advanced functionality, and they are one of the few commercial providers that have a favorable academic pricing model.

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Susannah Condie
Head of Clinical Data Management, Southampton Clinical Trials Unit

After receiving detailed training on the platform and completing the implementation in six months, the SCTU team began conducting their clinical trials on the Medidata platform. Designed as a unified data platform, Rave EDC (electronic data capture) simplifies the data entry process and ensured that data was streamlined throughout the end-to-end suite of Medidata data management and clinical operations solutions. With optimized operational execution, the data entry burden was decreased and the number of passwords and excel sheets was significantly reduced. SCTU now has 20-25 active studies on the platform, ranging in phases and therapeutic areas, utilizing Rave CTMS (clinical trial management system) for study management and Rave EDC, Rave TSDV (Targeted Source Data Verification) and Rave Coder for centralized quality data collection and management.

A Trusted Provider for a Small Team

Susannah Condie, Head of Clinical Data Management, Southampton Clinical Trials Unit, commented, "We're a small unit. In Pharma, you typically have one group doing the system configuration with user acceptance testing and implementation and another group doing the actual build of each trial – in our case, our small team has to do it all. The Medidata Professional Services team was incredibly supportive during the enablement phase and implementation process, and its e-learning and certification helped us to learn about the platform and quickly increase efficiency and optimize our clinical trial processes."

Medidata's unified platform has a strong reputation as a fully secure and regulated system and is accepted and well-known by regulators and inspectors. "If we have another inspection and I were to say we're using Medidata's software, the inspectors are familiar and happy with the platform," Condie continued. "By using a system - that both the pharmaceutical industry recognizes, and the regulators accept - to execute high quality clinical trials, our mission to bring better treatments to patients faster can, ultimately, be realized." This also means that, with the appropriate data sharing agreements in place, there are no issues sharing data when working with pharmaceutical companies.

With Medidata's unified platform, SCTU has transitioned from paper and manual processes to 100 percent electronic data capture. Rave EDC's extensive capabilities – including wide support of industry data standards, flexibility to implement any data management workflow with secure access for all study team members, and on-demand data extraction and ad hoc reporting tools – provide SCTU with a robust platform to manage all its data from EDC and make it easily and quickly available to the team. Additionally, SCTU has been able to integrate Medidata's Rave RTSM (randomization and trial supply management) to randomize patients within EDC, rather than using an external system that requires duplicate data entry and reconciliation throughout the study. The platform has allowed SCTU to concentrate on their core deliverable of fit for purpose quality data and has also removed reliance on the University IT team.

Condie added, "Adopting Medidata's platform has allowed for more people to engage with the data and for us to broaden the use of the data. We've shifted to the idea that everyone owns the data."

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Prioritizing Support in the Pandemic

More recently, as the world was gripped by the COVID-19 pandemic, Medidata also supported SCTU on its COVID-19 studies. The AGILE platform, a collaboration between the University of Liverpool, the Southampton CTU, and other external partners, is a new type of platform designed for pandemic drug testing and was launched specifically to test new COVID-19 treatments. The platform represents the first of its kind for infectious diseases, capable of testing multiple potential treatments in parallel and speeding up testing by pooling control data across patient groups. This allows new treatments to go through testing in a matter of months rather than years, while always maintaining a high level of safety.

Medidata's Rave EDC and Rave RTSM (randomization and trial supply management) were selected to support this program, and due to the recent increase in need for more hygienic processes, Medidata eConsent was also included to consent the patients electronically using an iPad as opposed to traditional paper forms. These three solutions required a rapid response and significantly reduced lead time to meet the demands of these COVID-19 studies, in the hopes of getting a treatment to market as soon as possible.

"When it came to building trials in Rave EDC for the AGILE clinical trial platform, Medidata's turnaround was brilliant and the service and support our team received was excellent. The Medidata team worked swiftly, were incredibly responsive and reliable, and the turnaround process helped us to get the clinical trial platform up and running quickly," Condie concluded.

See full protocol of the AGILE-ACCORD trial **here**, as well as the AGILE website **here**.

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