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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 uni□ed data platform, Rave EDC simpli□es the data entry process and ensures data is streamlined throughout the end-to-end suite of Rave applications. With optimized operational execution, the data entry burden is decreased and the number of passwords and excel sheets is signi□cantly 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 (electronic data capture), Rave TSDV (Targeted Source Data Veri□cation) and Rave Coder for centralized quality data collection.

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 con□guration 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 certi□cation helped us to learn about the platform and quickly increase ef□ciency and optimize our clinical trial processes."

Medidata's 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 uni□ed 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, □exibility to implement any data management work□ow 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 □t 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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Susannah Condie
Head of Clinical Data Management, Southampton Clinical Trials Unit

PRIORITIZING SUPPORT IN THE PANDEMIC

More recently, as the world has been gripped by the COVID-19 pandemic, Medidata also supports 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 speci□cally to test new COVID-19 treatments. The platform represents the □rst 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 were selected to support the study, and due to the recent increase in need for more hygienic processes, Medidata's

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