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

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 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 were selected to support this program, and due to the recent increase in need for more hygienic processes, Medidata's Rave 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 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 as well as the AGILE website

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