A Partnership Supporting Emerging Techniques that Drive Digital Transformation for Sponsors

About PHASTAR

PHASTAR is a specialist biometrics contract research organization (CRO) offering statistical consulting, clinical trial reporting, data management and data science services. Their expert consultants manage and deliver in-house data projects and Functional Service Provision (FSP)-style arrangements. PHASTAR's number one priority is to ensure that its projects are completed on time and to a high standard, with every project designed and managed to guarantee optimal quality.

With offices across five continents, PHASTAR works with large pharmaceutical, biotechnology, and medical companies across the globe to provide expert support on their clinical trial programs. Medidata's teams across more than 140 countries around the world are strategically placed to support PHASTAR as it continues to grow its global presence, customer base and number of studies - together, they can support sponsors regardless of where they are based.

PHASTAR has a unique approach to data - standardized internal processes are in place for all services, and all data sets and outputs are checked both internally and independently at multiple stages during development. As a result, 100% of projects undertaken by PHASTAR are delivered on time, error free and with rigorous processes to ensure delivery to the highest standard. Medidata equally believes that a meticulous focus on data elements is truly critical to the overall quality of any study. With Medidata's breadth and depth of experience across more than 25,000 clinical trials, PHASTAR has access to the industry's most powerful data sets and benefits from the largest regulatory-grade clinical trial performance data repository connected with real-world data.

PHASTAR and Medidata: Partners you can trust

PHASTAR and Medidata have been partners since 2019. PHASTAR leverages the Medidata Partner Program with accreditation in several Medidata solutions, including Rave EDC (electronic data capture), ePRO (electronic patient-reported outcomes), a component of Medidata eCOA (electronic clinical outcome assessments), and RTSM (randomization and trial supply management system).

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Using the Medidata Clinical CloudTM to store data in one place, Rave EDC allows clinical research teams to collect and integrate data from both clinical and non-clinical sources. Rave EDC enables PHASTAR to manage various unique and complex study requirements without having to use custom programming, ensuring consistent and efficient trial execution. Additionally, the Partner Program gives PHASTAR access to Medidata's resources and support to ensure growth and success through the entire sales cycle and throughout the clinical development process.

Sheelagh Aird, Senior Director of Data Operations at PHASTAR, shared, "Medidata's eCOA and ePRO solutions provide a single-system deployment model for capturing patient data and solutions like this can transform trials to make them more pragmatic, patient-centric and efficient by maximizing the potential to access data quickly through electronic health records, and help trial managers to make reliable, data-driven decisions and mitigate risks."

PHASTAR works in close collaboration with all its customers, regularly implementing their feedback to deliver best in class customer service, at the cutting edge of innovation. Medidata connects partners' business goals to the collective mission of extending greater value and improving outcomes to sponsors and patients. As such, PHASTAR is always taking the opportunity to engage more with Medidata to leverage the partnership and further support its joint customers.

The breadth of Medidata's solutions across the clinical trial lifecycle complements PHASTAR's emphasis on quality, harnessing the power of machine learning and real-time insights for prediction, remediation, and ongoing performance improvement. For instance, Medidata's Rave RTSM allows mid-study changes to be made in real time, the first capability of its kind in the industry, enabling adaptive trials that optimize operational efficiency and reduce burden.

Aird said, "Medidata is a valued and trusted partner. We use a range of their solutions which have allowed us to manage various unique and complex study requirements without having to use custom programming. This has ensured consistent and efficient trial execution. Our customers value the depth and breadth of Medidata's solutions, which complement our own emphasis on quality and focus on data. Medidata's decades of digital experience, data-driven platform, patient-centricity focus, and a culture of innovation is unmatched in the industry."

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Navigating the pandemic

Like most companies over the past 18 months, PHASTAR had to change its ways of working in response to the pandemic. They were quickly able to adapt and respond to the newfound challenges, and their systems allowed for uninterrupted, effective remote working. Together with Medidata, PHASTAR was able to support several sponsors with rapid database development, efficient clinical trial design and review, and communication with regulatory agencies.

Sponsors were massively impacted by the pandemic, with local restrictions and national lockdown measures leading to disruptions in study activities due to limited, or in some cases, no access to trial sites for staff and patients. Furthermore, several sponsors had to respond to varying levels of restrictions in different countries, experiencing delayed visits, which has a negative impact on the quality of a trial. This is where Medidata's digital solutions were invaluable – tools like Rave EDC and RTMS were able to support accelerated study start-up, direct-to-patient supply management and any necessary site transfers, while Medidata eCOA (ePRO) allowed patients to self-report data remotely.

Aird said, "Over the past years, our collaboration with Medidata has enabled us to deliver outstanding service and quality on a number of studies. This was unchanged during the pandemic. The seamless integration of their solutions, along with the combined technical knowledge of the PHASTAR and Medidata teams and our close collaboration, continues to ensure high-quality and efficient outcomes for sponsors."

The pandemic also highlighted the importance of flexibility and the use of new technologies. Going forward, pharma and biotech will continue to operate trials in a more decentralized fashion – leading to improved visibility and oversight of data collection, faster trial implementation, ability to share real-time data, and better patient experiences and engagement. PHASTAR will continue to deliver quality results based on these changes, leveraging Medidata's suite of solutions to support this shift.

Case study: Seamless data migration

Situation

The Sponsor was looking for a partner to take over the data management portion of an ongoing trial from its current supplier. The combination of the Sponsor's long-standing relationship with PHASTAR and recognition of PHASTAR's accreditation in Medidata's Rave EDC and eCOA (ePRO) solutions made the value proposition unmatched.

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Leveraging combined experience and expertise

The Sponsor's study was actively recruiting, with subjects having already been treated and passed their first-year visit. One of the first challenges was to migrate its study data from the previous supplier to the PHASTAR Medidata hosted URL, including all documentation, audit trials and queries, within a short timeframe. Technical experts from both PHASTAR and Medidata worked together efficiently, harnessing their expertise and knowledge of the Medidata platform and the batch uploading process, to effectively troubleshoot any known issues. The combined knowledge of PHASTAR and Medidata drove the process definition and built a seamless strategy for both the physical migration of the data and the validation of the migration process.

Collaborating to deliver best-in-class results

The final data migration was executed in the live study environment. Data entry at the site was stopped and access removed to allow the final data migration to take place. Thanks to the multiple tests conducted by PHASTAR and Medidata in the previous stages of the process, the final migration ran exactly to plan. The process was completed earlier than scheduled (delivered in 13 days rather than the scheduled 14.5 days) due to the collaboration and established communication channels between PHASTAR, Medidata and the Sponsor. There were 10,603 data points across 76 unique electronic case report forms (eCRF) for six subjects. The study is now continuing on track, conducting subject visits and soon to add another site.

The Sponsor has also engaged PHASTAR for a number of other studies in their portfolio, with the ability to re-use Medidata Rave forms and code across studies, leading to efficiencies in study execution and workflows.

Aird shared, "Our combined knowledge, integrated technologies and close collaboration have enabled us to complete a number of projects earlier than scheduled, further showcasing PHASTAR and Medidata as partners that sponsors can trust and rely on."

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About Medidata's Partner Program

Attract and win more sponsor bids and execute them successfully with Medidata's proven innovative technology complemented by an unmatched partnership experience to help you gain a competitive edge in the industry. Together, we can connect your business goals to our collective mission of extending greater value and improving outcomes for your customers and their patients. Join the Partner Program and become part of the life science industry's largest global ecosystem. Visit **www.medidata.com/en/become-a-partner/** to learn more. If you are already a Medidata CRO Partner, visit **www.medidata.com/en/cro-partners/** to learn about how you can do more with us.