

A new partnership rooted in shared values of integrity and commitment to patients

A Case Study with Phaon Scientific

About Palleos Healthcare

Palleos healthcare is a German full-service organization, offering tailored services in drug and medical device development to biotech and pharmaceutical companies across the drug development process. The company's Clinical Innovation Platform creates and conducts clinical trials in the realm of investigator-initiated research with a focus in oncology. Its Full-Service Organization gives customers access to clinical trial planning and execution strategies from phase I to phase IV, including non-interventional studies. Due to its Consulting Services, palleos healthcare supports customers in product development through both the pre-clinical and drug development cycles. Palleos' holistic approach and broad experience means that it is well-placed to offer unique support and strategic advice to clients across a range of geographies, especially in central Europe.

Building the foundation for a trusted partnership

Palleos first partnered with Medidata two years ago to provide innovative clinical trial solutions after finding that its own in-house data platform required a broader range of features. They valued Medidata's culture and expertise, as well as its partnership program, which provides the support needed to partner across marketing, technology, and innovation. At the start of the partnership, both Medidata and palleos spent time learning about each other's culture and mission, creating a strong relationship built on collaboration, communication, and trust. By partnering with Medidata, it provides a best-in-class technology platform for supporting full-service clinical studies and enables palleos to design and conduct complex clinical trials, providing a unified single platform without the need for separate systems. This partnership supports emerging techniques that drive digital transformation for our mutual customers.

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and to putting the client at the center of its work aligns perfectly with palleos' values. The combination of Medidata, a large and leading provider with deep expertise and a proven track record, and palleos, a smaller niche focused provider, enables unique capabilities in the market and a wider range of use cases for customers."

Palleos and Medidata: Innovative partners with a shared goal

Medidata's broad expertise in the clinical trials space coupled with palleos' specialist oncology knowledge provides sponsors with a unique set of capabilities and access to premium technology. Palleos places emphasis on understanding a client's specific goals for each project, ensuring that it can align trial execution as closely as possible to these objectives. In the same way, Medidata weaves its customers' business goals into its collective mission of improving outcomes for clients, sponsors and patients alike, and thus is able to work alongside palleos to provide sponsors with the best possible solutions. Medidata's established ecosystem for partners, combined with its leading innovative technology, supports palleos through the entire sales cycle and clinical development process.

Palleos currently engages with two parts of Medidata's platform: Rave EDC (Electronic Data Capture) and Rave RTSM (Randomization and Trial Supply Management). Rave EDC is Medidata's unique data management system, allowing data to be captured, managed, and reported in a single data source throughout the entire clinical trial conduct. This provides palleos with a more efficient trial execution system, allowing complex study designs to be conducted with ease. RTSM, Medidata's innovative randomization and trial supply management system, is designed to support simple, adaptive, direct-to-patient, virtual and medical device trials. Rave RTSM is seamlessly integrated with EDC to eliminate duplicate data entry and decrease the administrative burden associated with traditional data collection methods which significantly reduced palleos' risk and costs. Additionally, RTSM offers unrivalled flexibility, with clients able to make mid-study changes on demand and in real time. This complements palleos' bespoke offering, allowing trial designs to be adapted as necessary to fit a client's unique goals and requirements.

Dr. Philip R ath, Vice President of palleos healthcare, shared, "Medidata offers unique solutions to help us address even the most complex of clinical trial requirements and accelerate study execution with seamless implementation in EDC technology. As a specialized company, we really benefit from the broad, industry-wide insights that Medidata's platform offers us."

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Case study

SITUATION: A NEED FOR EFFICIENCY

Palleos also acts as a strategic partner to Phaon Scientific, a study development group specializing in oncology and breast cancer research specifically. They provide insights by optimizing therapies and translational research with innovative drug therapies. With around 70% of investigator-initiated trials being amended at least once and experiencing various delays due to funding and other issues, Phaon aims to develop innovative and robust trials using modern statistical tools meeting recruitment expectations and publishing results in time thus bringing real benefits of optimized therapies to patients in due time. Palleos healthcare, as strategic partner of Phaon, from an operational perspective, recognizes that non-core procedures can account for up to 20% of a clinical trial's budget, causing unnecessary work for site personnel and increased patient burden. Palleos healthcare headed out to tackle the increasingly complex regulatory and operational hurdles.

SOLUTION: COMBINING SPECIALIST KNOWLEDGE TO DEVELOP INNOVATIVE SOLUTIONS

Phaon Scientific's trials, as many in the modern oncology space are increasingly complex, exhibiting complex randomization algorithms, interim analyses, and complex database designs. Supported by data gathered through Medidata's Rave EDC solution, palleos healthcare and Medidata are able to work with Phaon to investigate new therapies and develop a greater understanding of breast cancer treatment. Longer term, palleos will also be able to generate higher-level observations using Medidata's Acorn AI solutions, which is built upon Medidata's core platform comprising 25,000 trials and data from more than 7 million patients. Featuring the industry's largest and most complete historical clinical trial data repository, Acorn AI can help to develop insights that enable success at all stages of the commercial drug lifecycle.

OUTCOME: SUCCESS DESPITE CHALLENGES BROUGHT BY PANDEMIC

Palleos healthcare is currently supporting Phaon on a complex clinical trial involving 458 patients (see clinical trial here: neoMono), which takes place across 40 sites in Germany. Although the COVID-19 pandemic has caused major recruitment issues for clinical trials, resulting in some trials being delayed, palleos healthcare was able to use Medidata's technology to monitor patients and conduct trials remotely. As a result, the trial is currently progressing on time, operating at over 25 sites, with more than 150 patients enrolled thus far. The NeoMono trial currently is the largest and fastest recruiting Phase II in immuno-oncology worldwide. Phaon has valued the innovative solutions offered by both palleos and Medidata during the process, and they remain their partner of choice for clinical trials.

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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.

About Phaon Scientific

Phaon Scientific is an academic research group that develops innovative investigator-initiated trial (IIT) concepts, specifically patients with breast cancer. Phaon’s IITs are financed by either pharmaceutical companies or public third-party funding and commonly include stratified and personalized treatment concepts as well as comprehensive translational (i.e. biomarker) analyses. Visit <https://www.phaon.de/studies/> to learn more about Phaon’s trials and concept.