

EXECUTIVE SUMMARY





Quanticate is one of the world's largest global biometric Clinical Research Organizations (CRO). With a 25-year heritage, it is trusted by organisations - from top tier pharmaceutical giants to niche biotechnology and medical device companies - for statistical and data expertise in clinical trials.

"We have a strong partnership that goes way beyond a service provider relationship and enables us to drive highquality analysis that would otherwise not be possible."

Claude Price, Director, Clinical Data Management, Quanticate With offices across three continents, Quanticate employs over 280 staff globally and is primarily focused on the management, analysis and reporting of data from clinical trials and postmarketing surveillance. As experts in clinical data, Quanticate provides high-quality teams that offer efficient outsourcing solutions for clinical data management, biostatistics, statistical programming, medical writing, pharmacovigilance and regulatory submission review.

Its mission is clear - to help bring new life-improving and medicinal products and medical devices to the market as quickly and safely as possible.





Quanticate in the CRO Ecosystem

CROs support drug manufacturers on their road to discovery and approval of drugs by absorbing some of the burdens at the clinical trial stages. Data research, project management, testing, and pre-clinical, clinical and post-approval trials, are just some of the activities covered. CROs that offer the entire spectrum of support are often considered 'full-service' compared to those that specialise in specific tasks. As a data specialist, Quanticate falls into the latter category.

Indeed, it is the focus on biometrics that sets Quanticate apart from the crowd. Being 100% geared to this specialisation means that training, processes and the company-wide expertise is focused on delivering high-quality data to impact the success of a trial.

"Data quality is critical during the entire lifecycle of a clinical trial. From regulatory submissions to efficacy and testing, it is our job to put data first and make sure it doesn't let our customers down."

Claude Price, Director, Clinical Data Management, Quanticate

The Quanticate team consists of best-in-class statistical consulting groups that regularly work with academics on new, adaptive ways of analysis to ensure they are at the leading edge of research and development. It actively embraces new technologies while insisting on in-house validation teams for every trial. The combination of these factors means Quanticate is able to scale with its clients' needs on-demand with the speed required to hit critical milestones. Traits that means it frequently works alongside full-service CROs as key partners.



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Why Medidata

As an expert in its chosen discipline, finding a partner that reflected Quanticate's values, quality and commitment to excellence was essential. That's why they chose Medidata.

Addressing the holistic clinical research process from start to finish, the Medidata Clinical Cloud[™] is the industry's only unified data platform for clinical research. The unique cloud-based platform helps CROs make more precise data-driven decisions to help reduce protocol amendments, accelerate enrollment, reduce cost, ensure data quality, reduce patient burden and bring drugs to market faster. CROs using Medidata's proven innovative technology have seen a 64% reduction in study build times, 80% reduction in data correction rates and database lock in as little as 5 days. The unified data platform creates a single source of truth for all study-related data, and Quanticate uses a variety of complementary solutions from Medidata ranging from electronic Clinical Outcome Assessment (eCOA), electronic Patient Reported Outcome (ePRO), Rave EDC (Electronic Data Capture) and Randomization and Trial Supply Management (RTSM).

But the decision to use Medidata goes way beyond the Medidata Clinical Cloud platform. For Quanticate, communication, trust, transparency and the ability to quickly contact the Medidata team are the driving forces behind the successful relationship. As well as offering reassurance, the combination of a seamless transition between people, technology and data offers unrivalled synergy. Medidata includes its CRO partners' business goals into its collective mission of extending greater value and improving outcomes for sponsors, customers and patients alike, with an unmatched partner ecosystem and partnership experience.

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The Value of Working with Medidata

Such a successful relationship is not forged overnight. Indeed, Quanticate has partnered with Medidata since 2012. During this

Medidata Rave Clinical Cloud™

- Cloud-based clinical research solutions
- Innovative technology
- Data-driven analytics
- Reduced costs
- Improved time to market
- Faster decisions
- Minimized risk

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period, there have been 21 won studies together (with RTSM, electronic Consent (eConsent), Targeted Source Data Verification (TSDV), and Safety Gateway) in dermatology, gastrointestinal, neurology/CNS, oncology, pain/anesthesia, respiratory and rheumatology/inflammation, across all phases, including medical devices. It's a long-term successful relationship adapting together to the evolving clinical research environment. By using a technology platform that has the depth and breadth of solutions that no other vendor can offer, CROs like Quanticate can be assured that they will be the first to adapt and meet the demands of any trial environment and gain a competitive edge.

"There is no doubt that virtual trials are going to become more prevalent. At the same time, clients will be looking to reduce costs. This means working with Medidata - where the scope of the platform can be adapted - will be critical to future project success."

Claude Price, Director, Clinical Data Management, Quanticate

As a data and quality-focused CRO, the partnership with Medidata enables an innovative approach to the complete clinical trial lifecycle from planning through to monitoring, data capture, reporting and regulatory submission. Medidata's technology allows Quanticate to focus exclusively on data while simultaneously providing flexibility and scalability as needed to support sponsors around all aspects of the data. This drives better, faster and higher-quality results. The relationship is such that Quanticate has won projects based on Medidata's involvement, and vice versa.

The platform of choice for clinical research

The Medidata Rave Clinical Cloud[™] is the cutting-edge platform that transforms the clinical trial experience for patients, sponsors, CROs, and research sites. Designed with a unified data platform, the Rave Clinical Cloud creates a single source of truth for all study-related data. Simply put, enter data once and let the platform master and populate it throughout the end-to-end suite of Rave applications. Optimize operational execution, decrease the data entry and maintenance burden, and reduce the number of clinical systems across your study teams. Throw away your list of passwords, you are now on a truly unified platform.





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Case Studies

For a customer whose focus is to reduce individual risk and population harm associated with tobacco use, the relationship between Quanticate and Medidata has been critical in establishing clinical trials. In fact, the synchronicity between all parties has already seen one trial go live involving eight ePRO questionnaires - with the translations done by Medidata - as well as EDC and TSDV. With speedy project sign-off due to reliable cross-team communications and the ability to get the EDC up and running quickly, it promises to be the first of many, with more trials in the pipeline into 2021 and beyond.

A Quanticate customer that focuses on offering care solutions to patients in more than 100 countries globally had initially chosen to go with an alternative clinical trial software provider in the market. But given the unique offering and expertise of Medidata's platform, the decision was made to switch to the Medidata system for the remainder of the portfolio, as well as all future studies. This change has proven to be much more effective for the customer and their ongoing trials. Medidata products currently being used are EDC, RTSM and TSDV. Comprising nine studies in one portfolio, the project is currently at its midway point and progressing well. So much so that Quanticate has been invited to add additional studies into the programme to ensure the patients are offered the best possible drugs available as the data passes through approvals country by country.

"This trial is a best-in-class example of the positive impact working with Medidata can have. We were able to win a project from a competitor, add value to the trial process to deliver better results and improve the lives of the patients involved in the trial. It's a situation that benefits all parties." Claude Price, Director, Clinical Data Management, Quanticate





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 <u>www.medidata.com/en/become-a-</u>partner/ to learn more. If you are already a Medidata CRO Partner, visit <u>www.medidata.com/en/cro-partners/</u> to learn about how you can do more with us.

About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,500 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

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