Faster Answers Delivered Together: Medidata Drives Richmond Pharmacology's Strategy Delivering Early- and Late-Stage Studies

Executive summary

How Medidata supports Richmond to create next-level CRO services combining their expertise and talent in advanced data visualization

In the digitized world, all CROs recognise that sponsors expect compliant protocols, accurate data at scale from diverse representative patient cohorts, and fast delivery. The growing ecosystem of software platforms can help to ensure the accuracy and speed of clinical studies. However, success also depends on selecting and deploying the right tools, the skill of the data scientists using them, and how quickly they can adapt to sponsors' changing needs to deliver results faster.

It's with this mindset that Richmond is building on its legacy clinical trial experience of over 500 studies delivering 30+ new medicines. Guided by the continuity of the founders' expertise, Richmond deploys Medidata **Rave EDC** to control and speed up the implementation of clinical trials, using agile and experienced customer-focused teams, to deliver early-phase and expand into late-phase studies, creating a new level of CRO service experience for sponsors.

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Dilshat Djumanov
Director of Data Science

Richmond history and evolution

Richmond is an experienced early-phase CRO with a disciplined and compliant approach to adapting and successfully delivering late-phase, multi-site studies. Starting from 2001 in Atkinson Morley's Hospital, Wimbledon, the Richmond vision created a new clinical research unit allowing clinicians to engage in clinical studies in a hospital setting. Moving to St George's University and Hospital Tooting in 2003, creating a 32-bed site for Phase I studies, profits were reinvested or used to fund academic research. By this time, Richmond had assembled a large 25,000 volunteer register in only 2 years. Adding a new centre at Croydon Hospital, Richmond became the UK's first CRO with a dedicated Phase I and clinical trials unit based in two acute NHS Teaching Hospitals. Three years later in 2008, Richmond became the first early-phase CRO in the UK to receive MHRA Standard and Supplementary Accreditation.

Fast-forward through 20 years, this model has expanded Richmond's capabilities into a 50-bed, purpose-built hospital-style facility in London, next to Guy's Hospital at London Bridge. Through its Trials4us recruitment brand, its volunteer registry now stands at 310,000 participants, the largest of any CRO based in the UK. In 2020, the Richmond Research Institute was established to focus on under-researched areas while the CRO passed the 500+ mark for clinical studies, helping to deliver more than 30 new treatments. Over this period, Richmond has developed long-standing relationships with Japanese pharmaceutical companies delivering Japanese bridging studies, and evolved its work from small molecules to monoclonal antibodies, RNA therapeutics, and most recently, partnering with Intellia Therapeutics on pioneering Nobel Prize-winning gene editing therapy.

Delivering a high-level CRO service experience

Medidata is an active partner across a 5-year working relationship, with **Rave EDC** and other solutions that Richmond uses to refine and drive its delivery of more accurate data in real-time for sponsors. 'Faster answers' is Richmond's mantra across all departments and its people play a key role in its delivery. Since its inception, Richmond has continuously developed and improved ways of working for adaptive clinical trials. New processes are required to enable these trials to run quickly and effectively, and the team considers all the possible opportunities and constraints when developing an adaptive study protocol. These learnings are captured as pre-approved schemes which create flexibility and can accommodate changes required in the future.

Powered by Medidata's solutions, "Richmond operates in a lean and agile style. We pride ourselves on the upskilling of our trained staff whose capabilities allow us to offer a high-level service to our customers. In practice, this means that every person can engage with customers from a position of expertise and knowledge," said Naseer Ud Din, Head of Data Management, Richmond. "This is central to our way of working and it means we take action to deliver answers faster - we are all service providers using a flexible approach that drives a quick close-out of clinical trials."

Richmond delivers data management using **Rave EDC** and statistical analysis services using this smart team approach. Being proactive and responsive to sponsors' needs means Richmond shrinks time for its trial sponsor customers to help them achieve their goals. The team can set up a study and lock it within 3 to 4 weeks and have responded successfully to deliver the start-up of a study in only 2 weeks. This is a key element of the work delivered using a global library that is streamlined through Rave EDC, which holds all the data and is at the heart of Richmond's operation.

Earning a global CRO reputation

"The effect that we have seen is the achievement of end of study and 'on to market times' reducing rapidly from 10 years to an average of 6 years; shrinking end-of-study times by 4 years is a major benefit to sponsors translating to faster delivery of new treatments to patients in need," said Dilshat Djumanov, Director of Data Science. Richmond understands that sponsors value a responsive team, driven by a direct 'specialist to specialist' working relationship. The organization prides itself on its motivated team, all customer counterparts that speak the language, and draws on solid experience and skills to deliver sponsors' studies. It means fewer calls, shorter set-up times, and fewer meetings to get started, and being available for sponsors through a continuous and flexible close-support program of scheduled calls. Reflecting on their achievements and outcomes from the studies they manage, realising the impact on patients waiting for new life-saving treatments is a critical part of acknowledging their purpose that helps to motivate the team.

"When you think that in May 2014 we collaborated with Hisamitsu Pharmaceutical to study a transdermal antipsychotic treatment for adult schizophrenia and dosed the first patient with schizophrenia in a 45+ day residential stay study at our pharmacology unit," said Dilshat Djumanov, Director of Data Science, "...then you see Hisamitsu Pharmaceutical's transdermal antipsychotic patch approved for use in Japan in Oct 2019, we feel the impact and understand the purpose of what we do well together."

A key partnership with Intellia Therapeutics and Richmond Pharmacology, in collaboration with the Royal Free Hospital, marked a milestone in gene editing with the treatment of the first patient in a landmark CRISPR/Cas9 clinical trial. Intellia Therapeutics announced the Phase 3 study, MAGNITUDE, the first large-scale in-human trial of a genetic cure for ATTR Amyloidosis. Their dedication and efficacy in working on this, and other novel and critical treatments, has helped to develop Richmond's 'word-of-mouth' global CRO reputation. Today, they actively seek to partner with sponsors by offering a full CRO service, and a new flexible data visualisation solution.

5-year partnership delivers for sponsors

Richmond's decision to switch from its desktop system to the most widely used and market-leading electronic data capture solution, **Rave EDC**, has proven to be a wise choice.

Rave EDC is the cornerstone of the Medidata Platform, offering fast implementation and maximum control to support Phase I to IV studies of any size, length, or complexity. A single source of truth that eliminates silos end-to-end, it is a key tool for Richmond, ensuring efficient trial execution from small patient populations in rare disease studies to large scale 'mega-trials'.

Commenting on Richmond's experience, Dilshat Djumanov continued, "It is important to utilize tools like Rave EDC between the dose escalations because you have a maximum of two weeks to prepare the data, and reporter tools and data visualizations allow the interim safety reports to be created quickly. The Safety Review Committee (SRC) meeting typically happens two to three days before the next cohort is dosed with an escalated dose level, where the decision is taken whether to add or remove additional assessments. So the table of the assessments will be changed as part of the protocol amendment. As data managers, my team would have only one or two working days to update and release the database by performing the UAT. And this was possible with Rave EDC."

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The combination of Medidata software solutions and support services has created tangible value for Richmond's sponsors.

"The level of professional services allied with Medidata's platform and robust and user-friendly tools, meant that we achieved study-lock faster, and that's critically important for our sponsors," said Naseer Ud Din - Head of Data Management. "It's not just the consistent support and weekly calls to help keep us on track, it's also the small user-interface features that make a big difference for our teams. Take query management, for example, they appear next to the field, clearly visible and easy for users to access, saving effort. We can automatically generate seventy built-in reports and extract them all in one action, saving us time and accelerating our work – exactly what our sponsors expect."

These positive user experiences are reflected in surveys citing **Rave EDC** as the industry leader for reasons including ease of use, scalability, real-time data access, flexibility for mid-study changes, and excellent technical support and training[1]. Richmond has an enterprise agreement with Medidata and the potential to add a comprehensive data quality and risk surveillance solution that serves multiple operational end users in clinical trials at the patient, study, site, and country levels.

[1] EDC Benchmarking and Market Dynamics (5th Ed.), Industry Standard Research, June 2023.

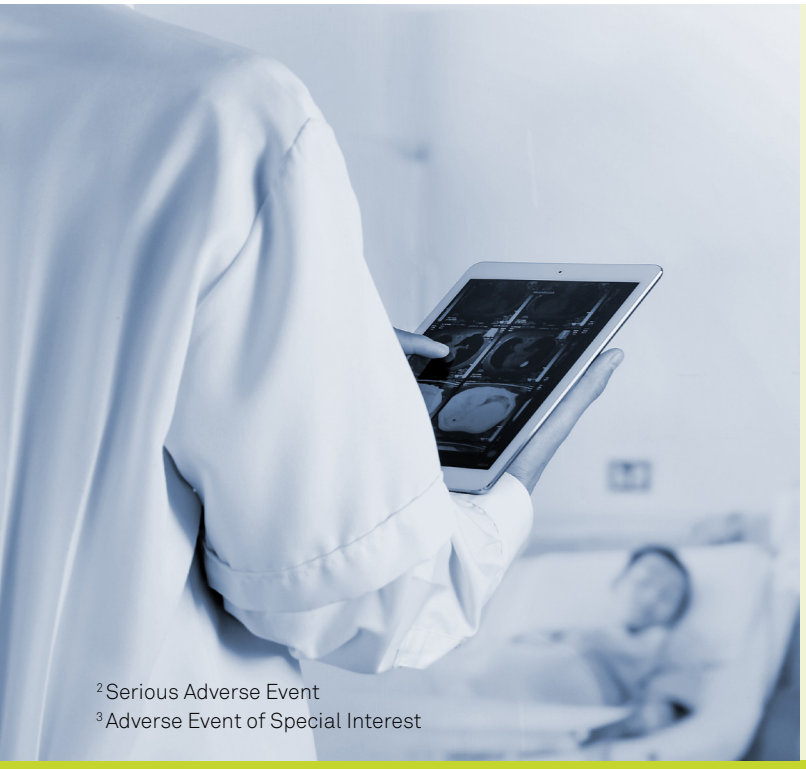
The symbiotic future with Richmond

"Our collaboration with Medidata is essential – you could say it's symbiosis. We each bring unique strengths and capabilities, sharing resources to achieve a common goal: faster answers and high-quality data answers for our sponsors," said Naseer Ud Din, Head of Data Management. "Our partnership with Medidata makes sense because we have the same focus and target, delivering accurate clinical trial data to accelerate studies and deliver life-changing medicines faster to patients who need them," added Dilshat Djumanov, Director of Data Science.

Richmond is now creating a separate division focused on data science and data visualization using a specific Medidata solution that can harmonize data from different sources into one location, helping to negate operational and data source silos. While the massive increase in ways to collect and monitor remote and on-site patient data helps to deliver critical insights during the study, it also creates complexity for the teams tasked with identifying and correcting quality issues that need to be addressed to keep trials on budget and on time. This solution gives members of the Richmond team role-based capabilities powered by advanced analytics that improve patient safety, data quality oversight, and risk management.

Richmond will use this tool as a new element of their complete offer or as a standalone custom service designed for midmarket biotech sponsors of early-phase clinical trials. For sponsors, this service visualizes data from every study, including completed studies that can be accessed in real time. This facilitates clinical oversight and utilizes time course graphs for the patient's journey. It will also include SAEs[2] and AESIs[3] in the coming iterations in development.

Launching and growing with input from the same dedicated professionals that created the organisation in 2001, partnering with Medidata has helped it to increase its capabilities. At the same time, Richmond is continually developing its people and their expertise, adapting to find better ways to serve sponsors, and ultimately delivering faster answers to improve patients' lives.



[2] Serious Adverse Event
[3] Adverse Event of Special Interest

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/cro-partners/become-a-cro-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.