The Big Book of CRO Case Studies

A look behind the scenes at how Medidata partners of all sizes are innovating to optimise trial performance and quality

INTRODUCTION

Attract and win more sponsor bids and execute them successfully.

CROs need to respond to their clients' requirements with the latest in trial performance, data science and analytics, and clinical intelligence. Your choice in technology partner directly impacts your ability to successfully deliver to these requirements. And a successful partnership goes beyond transactional business solutions, to enable CROs to be the first to adapt, respond, and perform in any trial environment.

What differentiates a great partner from an average one?
What should CROs expect from a technology vendor?
How can a technology partnership provide you a competitive edge to win more business?
Does your technology partner help you scale your growing business while ensuring quality and compliance?

With over 20 years of proven success partnering with CROs, Medidata delivers not only the gold standard in technology that sponsors and CROs count on to run their trials, but a superior focus on partnership, enablement, and thought leadership to help our CRO partners shine. Each Medidata partner is supported by our strong leadership and has a cross-functional team committed to their success, including partner teams, professional services, sales support, marketing, legal, and more.

In this eBook we present real-life examples of select Medidata CROs who have aligned the right technology strategies with their business priorities enabling them to attract and win more sponsor bids and execute them successfully to deliver improved outcomes.

Together, we can connect your business goals to our collective mission of extending greater value and improving outcomes for your customers and for patients. Become a Medidata Partner today.

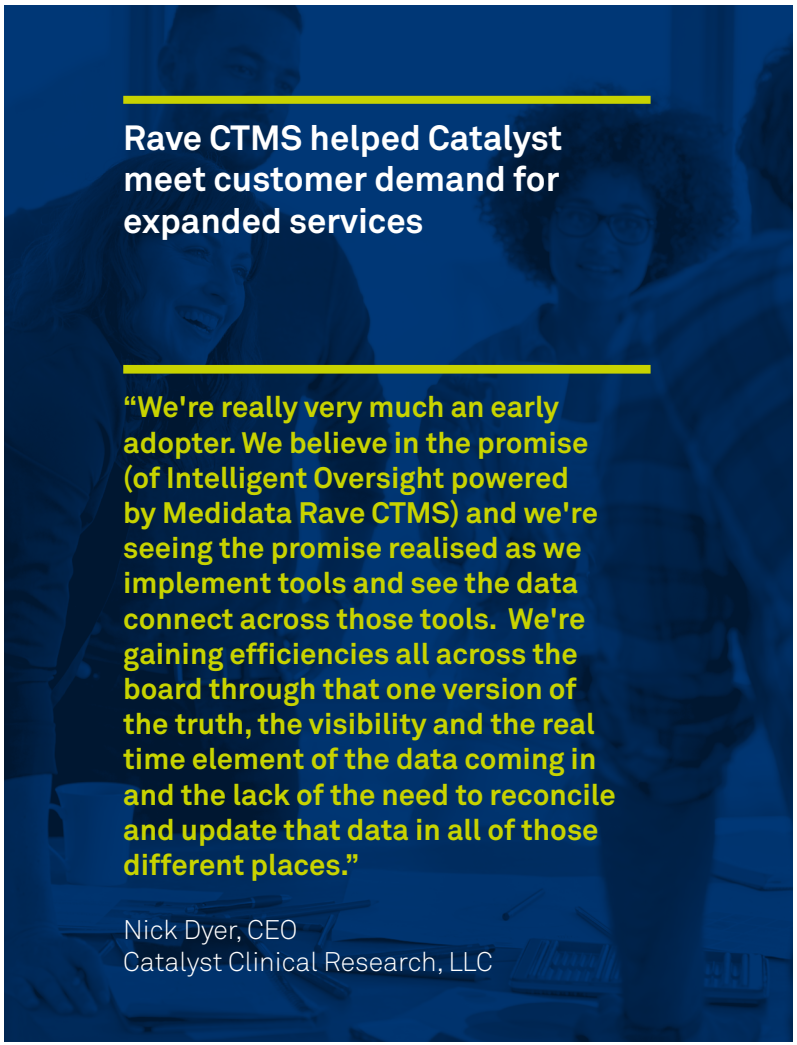
Katrina Weigold
VP Global Partners,
Medidata

TABLE OF CONTENTS

INNOVATE WITH PROVEN TECHNOLOGY

Medidata's technology platform accelerates the business of clinical research, integrates processes, and improves collaboration with your sponsors. The Medidata Clinical Cloud, used in over 25,000 trials, has the depth and breadth of solutions no other vendor can offer. CROs can be assured that they will be the first to adapt and meet the demands of any trial environment.

Catalyst Clinical Research increases capabilities and operational efficiency with Rave CTMS



CATALYST CLINICAL RESEARCH

Catalyst Clinical Research was formed in 2013 and is focused on clinical operations including site start-up, monitoring, and site management. As demand grew, Catalyst increased its offerings to include regulatory, medical, and safety services in 2018, and in early 2019 merged with Triangle Biostatistics.

Catalyst's technology strategy was threefold. They wanted a way to address the complexity of oncology trials and surpass their previous capabilities, avoid the change management challenges that come with legacy system conversion, and manage the technology merger between the two companies in the most effective way possible.

To achieve this, Catalyst selected Rave CTMS to manage their clinical trial services. Now Catalyst offers broad-based functional services along with full-service CRO solutions. They help plan, execute, and manage studies with cross-functional dependencies using a single source of truth with real-time visibility into their data.

Watch this webinar to learn more about how Catalyst realised the power of Medidata CTMS.

Syneos Health, a global full-service CRO, considers **Medidata Detect** a truly disruptive technology with game-changing potential

"[Medidata Detect (formerly Rave CSA)] is truly a disruptive technology and has the potential to be a game changer. To realise the true power of it, you have to consider that it is going to have a much broader impact. This is a tool that is going to have an impact on a number of roles/ functions within your organisation including Clinical Operations, Data Management, Biostatistics, and Medical Monitors. We have to recognise that there are things that we have to do within our organisation to improve and change our operations in a way that actually moves the needle on our productivity, our efficiency, and our delivery."

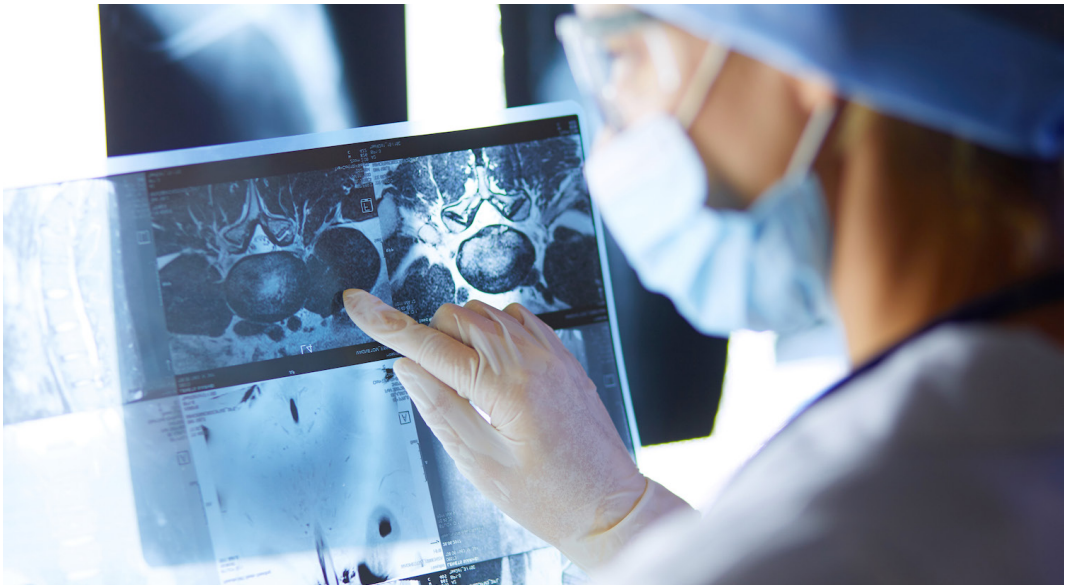
Executive Director, Data Operations, Syneos Health

Medpace announces the Rave Imaging and Rave EDC combination as the most powerful imaging trial management environment in the marketplace

MEDPACE

"Through our partnership with Medidata, Medpace is now able to provide seamless integration of our quantitative image analysis pipelines with Medidata's Rave Imaging system and database. The combination of these tools produces the most powerful imaging trial management environment currently available to the clinical trial market."

Daniel O'Leary, MD, Chief Medical Officer for Medpace's imaging core lab



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UNMATCHED PARTNERSHIP EXPERIENCE

Amplify your impact and accelerate your business. Medidata can help you scale, create new revenue streams, and increase margins with efficient operations while offering more ways than anyone to amplify your brand and thought leadership through our time-tested, trusted, world-class Partner Program.

Mid-sized pharma and its CRO partner accelerate study startup by implementing a new electronic trial master file, Rave eTMF, in just 8 weeks

“The Medidata Professional Services team has been really straightforward about helping and offering their resources and knowledge about the system to ensure the workflow we’ve laid out will be an efficient way of storing documents securely and in a compliant, auditable fashion.”

Document Specialist at the CRO

A mid-sized pharma company focused on inflammatory, metabolic, and affective disorders had a number of upcoming clinical studies. They had been using a legacy eTMF solution and outsourcing electronic trial master file (eTMF) management to their CRO. Difficult navigation, manual data entry, and disparate file management systems frustrated the sponsor—they wanted a new eTMF solution to remedy these inefficiencies.

The sponsor worked closely with Medidata Professional Services to identify requirements, determine functionality, and configure a new system. They leveraged fully-delivered, out-of-the-box standard operating procedures to quickly understand the processes for Rave eTMF and clearly define the best path forward using the system.

Replacing legacy technology is rarely easy, but within eight weeks the sponsor was seamlessly managing their eTMF content and maintaining inspection readiness with Rave eTMF. The new system improved efficiency, security, and customer service.

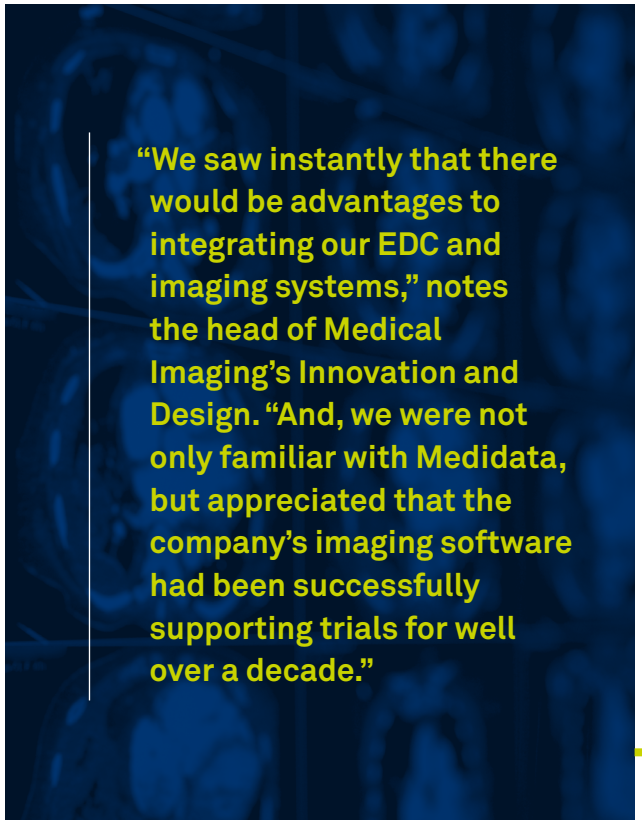
Global CRO adopts Rave Imaging with Rave EDC and achieves study setup in just four to six weeks

Sponsors increasingly rely on image-based biomarkers to assess the effectiveness of therapies—particularly in oncology and immunotherapy. To meet this demand, the medical imaging division of a global CRO was looking for a new platform that could scale with its business. "We have experienced, passionate, and capable people who work hard to deliver results to our sponsor clients," explains the Vice President of Medical Imaging, "but needed a new solution to scale the way we capture, manage, analyse, and deliver imaging data."

The global CRO selected Rave Imaging and became Medidata's first accredited partner authorised to sell, build, and set up Medidata's Rave Imaging software —a service that saves time in meeting sponsors' study needs. Across dozens of studies, Rave Imaging has helped the global CRO slash "go-live" times by 86%, reduced image queries by an additional 24%, cut image prep time by 66%, shaved two minutes off every baseline read, and provided sponsors with unprecedented visibility.

But the digital transformation for the CRO's Medical Imaging division was not only about the end result—the process also mattered. "Medidata involved us as partners in designing the solution," offers senior management. "We collaborated as subject matter experts, and enjoyed transparency, knowledge-sharing in both directions, and executive support. This has made the final product so much more valuable in meeting everyone's needs."

"Go-live" times slashed by 86% with an additional 24% fewer image queries and 66% cut in image prep time



PHASTAR, a global CRO, completes sponsor's live study data migration during active recruitment in 13 days leveraging Rave EDC.

A specialist biometrics CRO with offices across five continents offering statistical consulting, clinical trial reporting, data management, and data science services, PHASTAR leverages the Medidata Partner Program with accreditation in several Medidata solutions including Rave EDC, Rave eCOA/ePRO, and Rave RTSM.

When a 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 Sponsors' long-standing relationship with PHASTAR and their accreditation in Medidata's solutions made the value proposition unmatched.

A seamless migration and validation strategy was built with the combined knowledge of PHASTAR and Medidata and, thanks to the multiple tests conducted in the previous stages of the process, the final migration and process was completed in 13 days — earlier than scheduled.

Based on their success, the Sponsor has continued to engage PHASTAR on other studies, reusing Medidata Rave forms and code which has led to additional efficiencies in study execution and workflows.

phastar

"Medidata's eCOA and ePRO solutions provide a single-system deployment model for capturing patient data and solutions that can transform trials to make them more pragmatic, patient-centric, and efficient."

Sheelagh Aird,
Senior Director of Data Operations at PHASTAR

Palleos healthcare, a full-service CRO, partners with Medidata to deliver cutting edge sponsor research to patients

As a full-service CRO providing access to clinical trial planning and execution strategies from phase I to phase IV studies, palleos healthcare partnered with Medidata to provide innovative clinical trial solutions after finding that its own in-house data platform required a broader range of features.

Palleos, acting as a strategic partner, identified from an operational perspective that its client, Phaon Scientific, was juggling increasingly complex trials rife with randomisation algorithms, interim analyses, and complex databases. In addition to these challenges, timelines lengthened by non-core procedures and operational hurdles needed to be mediated.

Supported by data gathered and unified through Medidata’s Rave EDC solution, palleos and Medidata were able to work with Phaon to streamline their processes and pave the way for the investigation of new therapies and development of a greater understanding of treatment.

Palleos was also able to leverage the Medidata Clinical Cloud to monitor patients and conduct trials remotely, resulting in Phaon’s trial progressing on time despite challenges brought by the pandemic and supporting what was the largest and fastest recruiting Phase II trial in immuno-oncology worldwide.

Bioforum partners with Medidata to guarantee data accuracy and integrity for sponsor

> **"The fact that Medidata's products are on one unified platform saves time and the effort-intensive activities of multiple system integrations, and also protects data integrity and helps accelerate study timelines."**
>
> Amir Malka,
> CEO and co-founder of Bioforum

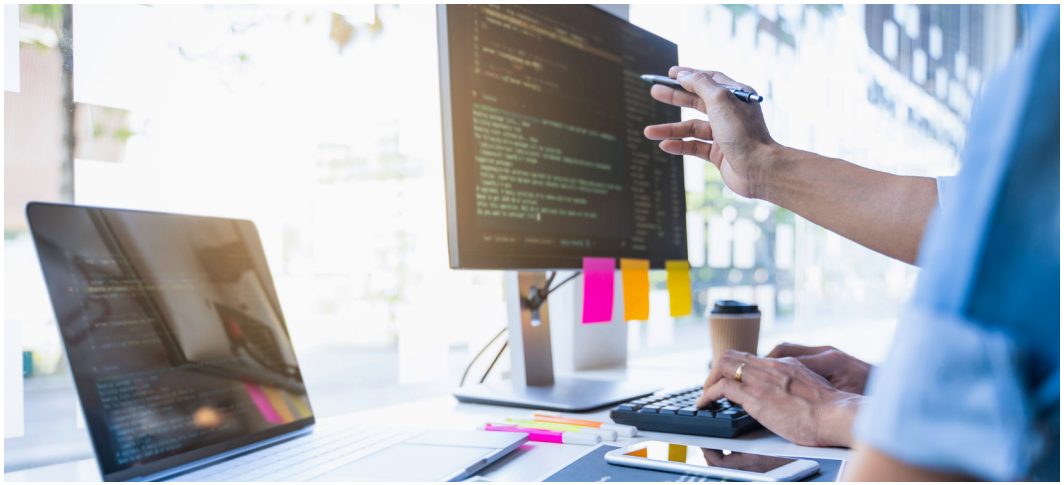
BioForum THE DATA MASTERS

Key to the success of the partnership between Bioforum, a data- focused CRO, and Medidata is their shared mission to power innovative transformations to provide a toolkit and easy accessibility to clients' data, processing, and analytics.

Bioforum is currently accredited in several Medidata solutions – Rave EDC, Coder, Custom Functions, RTSM, and Imaging. The robustness and flexibility of Medidata's solutions has been instrumental in helping Bioforum transform the conduct of clinical trials to improve access to better therapies and provide clients with an innovative, high-quality service.

PolyPid, a global clinical-stage biopharmaceutical company, was in need of trusted partners, that the pharmaceutical industry recognised and regulators accepted, to support complex study designs. They were also looking for the most advanced Good Clinical Practice-approved technology to ensure efficient design and execution of data strategies, and guaranteed data accuracy and integrity.

The clear choice was to work with BioForum and Medidata. The ease of collection and integration of data using Rave EDC on the Medidata Clinical Cloud ensured that PolyPid saved time and effort to support efficiency, and maintained and protected data integrity to meet regulatory and compliance requirements.



GAIN A COMPETITIVE EDGE

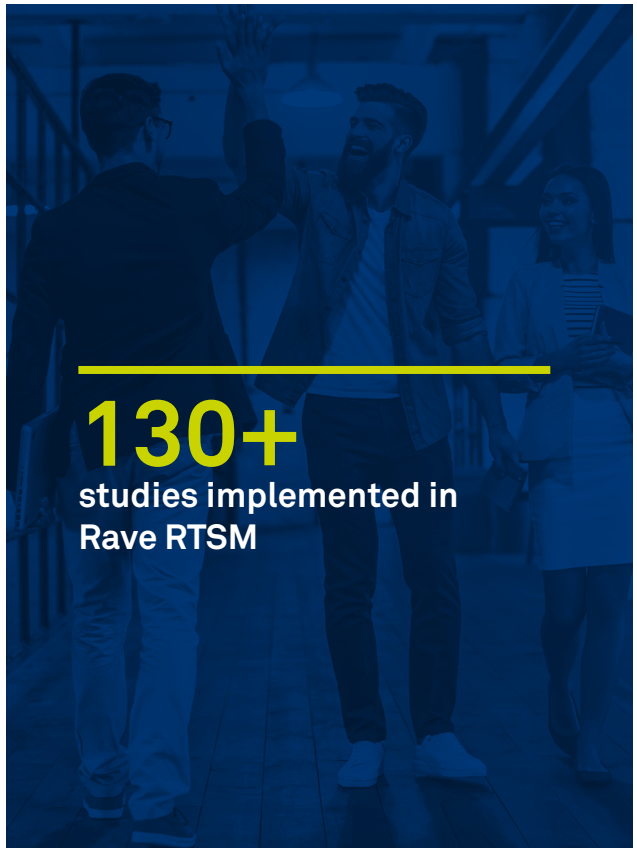
Attract and win more sponsor bids and execute them successfully in any trial environment. Make more precise, data-driven decisions by accessing the industry's most powerful data sets and benefit from the largest regulatory-grade clinical trial performance data repository connected with RWD.

Bring drugs to market faster with reduced protocol amendments, accelerated enrollment, lowered costs, and reduced patient burden.

Pharm-Olam considers the Medidata Enterprise Data Store (MEDS) a true differentiator for Medidata

Pharm-Olam
Helping Create A Healthier World

Syneos Health, a global full-service CRO, accomplishes ambitious build times using Rave EDC and Rave RTSM



Syneos, a global full-service contract research organisation (CRO), wanted randomisation and trial supply management (RTSM) services to support its Phase I–IV clinical trials.

While technology providers make big promises about seamless integrations between electronic data capture (EDC) and RTSM, Syneos understands custom integrations can involve significant amounts of time and cause delays. The company had been introduced to Rave EDC over a decade ago; combined with sponsor interest, Syneos evaluated Rave RTSM's capabilities and services.

Syneos found that Rave EDC and Rave RTSM's unified platform and prevalidated integration eliminated setup delays associated with disparate custom systems. Rave EDC and RTSM allowed Syneos to accomplish ambitious build times and manage trial complexity. With the unified platform, site staff benefitted from only one point of data entry and avoided redundant processes.

Syneos provided EDC and RTSM services using Rave EDC and Rave RTSM, respectively. As Syneos became more comfortable using these Medidata products and saw their value, they proposed it to more prospective clients.

Syneos Health

"Over the last 6 years, we have implemented over 130 studies in Rave RTSM and this number is growing every week. We use the Rave RTSM for all aspects of the clinical study related to a randomisation drug distribution and assignment, and also, of course, unmasking. For most of the studies, we use the existing built-in and validated functionality of RTSM. So this is our standard approach that we configured."

Voitek Gradziuk, Principal Solutions Consultant at Syneos Health

Quanticate, a global CRO, accelerates go-live dates and adds more trials to pipeline using complementary solutions including Rave EDC and Rave TSDV

Quanticate, one of the world's largest biometric CROs, continued its long-term partnership with Medidata to achieve successful go-live of a clinical trial involving eight Medidata-translated ePRO questionnaires as well as Rave EDC and TSDV. Accelerated by the ability to get the EDC up and running quickly, the study's success has led to the inclusion of additional trials in the pipeline.

Another Quanticate customer, offering care solutions to patients across 100 countries globally, switched to the Medidata platform mid-study and leveraged Rave EDC, RTSM, and TSDV to ensure patients were offered the best possible drugs available as the data passed through global approvals. The project's portfolio, comprising nine studies, was successful enough for the customer to retain Medidata systems for all future studies. Medidata's technology has helped increase the new projects pipeline but more importantly has allowed Quanticate to drive better, faster, and higher-quality results.

Quanticate
The Clinical Data Experts

Medidata enabled Quanticate to deliver:

64%
reduction in study build times

80%
reduction in data correction rates

5
days to database lock

"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

LET'S DO MORE TOGETHER

When it comes to proven innovative technology and best in class partnership experience, no other vendor is better suited to help you win more sponsor bids and deliver improved outcomes than Medidata.

No matter your size, your business goals are woven into our collective mission of helping you deliver more for your customers and their patients.

WHY CRO PARTNERS CHOOSE MEDIDATA

150+ CRO Partners

900K Site/ Sponsor Relationships

25K+ Trials

7M+ Patients

90 Medidata Accredited Partners with 280 Accreditations

Become a Medidata partner today. Visit medidata.com/en/cro-partners to learn more.

THE BIG BOOK OF CRO CASE STUDIES

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, minimise risk, and optimise outcomes. More than one million registered users across 1,700 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data. Medidata, a Dassault Systèmes company (Euronext Paris: #13065, DSY.PA), is headquartered in New York City and has offices around the world to meet the needs of its customers. Discover more at **www.medidata.com** and follow us **@medidata**, The Operating System for Life Sciences™.

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