medidata joins DASSAULT SYSTEMES

THE BIG BOOK OF CASE STUDIES

A look behind-the-scenes of how Medidata customers are innovating to optimize trial performance and quality

Introduction

The next generation of clinical trials will be faster, more efficient, and produce higher quality patient outcomes. To support your business goals, help you think more strategically about the impact of the right technological approach to next-generation trial execution, and to help your business deliver more in the next decade, Medidata has designed three technology strategies to help modernize your trials - Improving Patient Experience, Ensuring Effective Management, and Simplifying Data Complexity. Focused on patients, processes, and data, each strategy is designed to seamlessly work across your teams and business areas and each can be adopted one at a time or all at once.

Modernizing clinical trials is not simply about integrating technology into old ways of conducting trials. Even with regulating functions like the FDA suggesting a number of innovative approaches to run modern clinical trials, there has been a continued reluctance to adopt such approaches among sponsors and CROs. While smaller companies are nimble and hence better suited for innovating and modernizing their trials, they lack the resources and budget needed to move forward with such approaches. Meanwhile, larger companies who have the resources to innovate and modernize have not yet scaled into pivotal studies. Generally, the pharmaceutical industry has been used to taking a “wait and see” approach where they wait for larger companies or one or two early adopters to demonstrate a superior process and manage to get regulatory approval. But this is not a long-term strategy.

Modernizing clinical trials is possible with a focused effort and in this eBook, we present real-life examples of select Medidata customers who have aligned the right technology strategies with their business priorities to optimize trial performance and data quality. To learn more about strategies for modernizing clinical trials, visit www.medidata.com/modern-tech-strategy.

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TECH STRATEGY:
Improving Patient Experience

Improving the trial experience with innovative, patient-centric technology improves patient satisfaction, trial retention, and ultimately outcomes. Medidata's approach to improving the patients' clinical trial experience is to bring their perspectives and needs into our technology development. By doing so together, we optimize outcomes and accelerate trial execution.

Medidata looks to the patients to help improve their experience in clinical research

Medidata operates on three core principles as it relates to Patient Centricity.

Co-Design

To design and develop products and services with the patient perspective at the forefront

Engagement

To build consistent points of interaction with the patient

Activation

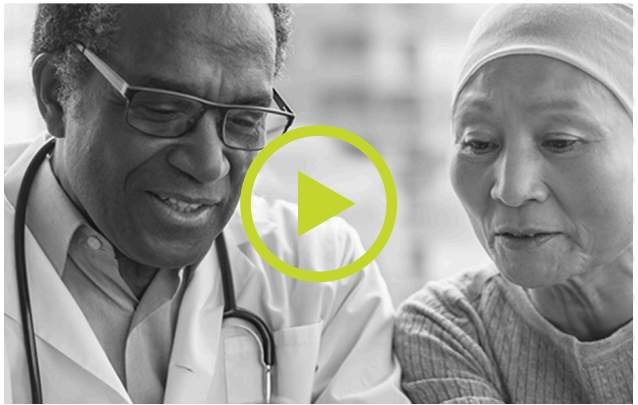
To enable patients to be active participants in the clinical research process

These pillars are reflected in our Patient Centricity by Design (PCbD) initiative. We're building long lasting relationships with industry recognized patient advocates and global advocacy organizations to ensure the infusion of the patient perspective into the software development lifecycle. With this patient perspective, we strive to create technical solutions that improve the overall patient experience in clinical research interactions. Medidata's PCbD framework utilizes design thinking principles where patient advocates regularly engage in Medidata's software design and development processes through in-person workshops called Patient Design Studios. Through multiple sessions held over the last two years, as well as our first-ever COVID-driven virtual session, we are very proud of the significant accomplishments achieved together including the launch of our first ever Patient Design Advisory Board and patient portal technology offerings.

> **"You can do better; I challenge you to think about how you can change the way in which clinical research is done and not imitate the paper world and what already exists."**
>
> T.J. Sharpe

> **"...it feels as if we've been invited not only to have a seat at the table, but to help prepare the meal."**
>
> Linnea Olsen

Watch the video below to listen to a more detailed discussion on Patient Centricity by Medidata's Senior Director of Patient Engagement, Alicia Staley, and her panel of patient advocates — T.J. Sharpe, Liza Bernstein, and Anne Marie Mercurio.



Arena Pharmaceuticals considers Rave eCOA a win-win solution for sponsors and patients

"With the eCOA technology, patients get daily reminders. Every morning when they wake up, it reminds them to enter your 'How are you feeling today? What is your daily pain score?' It helps the patients stay on track to enter data, give them reminders. It's more convenient for them. It doesn't require them to recall what they thought their pain was seven days ago. The patients presumably like it because it allows them a tool to capture their data, and it helps the sponsor capture the data as it should be captured on a daily basis in a certain time window. It's a win-win."

Vice president of Data Management at
Arena Pharmaceuticals

Duke Clinical Research Institute Carries out the Largest-ever Decentralized Clinical Trial, the ADAPTABLE Study

Over 15,000 patients across 40 centers enrolled in ADAPTABLE, making it the largest 100 percent virtual pragmatic clinical trial conducted to date.

Millions of Americans living with heart disease rely on daily aspirin to help prevent a heart attack or stroke. The Duke Clinical Research Institute (DCRI), the world's largest academic clinical research organization and a part of the Duke School of Medicine, wanted to determine the dosage that most effectively maximizes results while minimizing harmful side effects.

Their five-year clinical trial, called ADAPTABLE (Aspirin Dosing: A Patient-centric Trial Assessing Benefits and Long-term Effectiveness), required a virtual interface to engage with thousands of patients throughout the trial. Rave Virtual Trials provided the platform to remotely recruit patients, manage the informed consent process, enrollment, and randomization of ADAPTABLE participants between two dosage groups.

Over 650,000 patients were identified as matching the inclusion criteria for the study, and 450,000 of these were issued a "golden ticket" with a unique access code and invited to review the ADAPTABLE materials. More than 30,000 people used their unique access codes to enter the patient-friendly Medidata portal via a browser on their desktop, laptop, smartphone, or tablet. The golden ticket ensured that the correct informed consent and site information was presented to the right patient.

Over half of the 30,000 patients who used their golden tickets enrolled in ADAPTABLE, making it the largest 100 percent virtual pragmatic clinical trial conducted to date. Patients reported health outcomes in real-time from the comfort of their homes. Instead of in-person check-ins, patients attended virtual follow-up appointments. Automatic notifications through text or email reminded them to attend follow-ups, complete electronic case report forms, and update their health information in the platform.

"When compared with traditional cardiovascular trials that engage hundreds or thousands of sites, this technology allowed us to enroll 15,000 participants from 40 centers. We think this infrastructure and approach will facilitate studies that can be direct-to-patient, easier for patients and investigators, and faster to completion"

Dr. Schuyler Jones, Associate Professor of Medicine Duke University Medical Center and co-principal investigator of the ADAPTABLE study.

"Rave Virtual Trials allows us to reach patients who wouldn't normally participate in a clinical trial because of location or convenience."

Dr. Holly Robertson, Project Leader at DCRI

Memorial Sloan Kettering Cancer Center conducts continuous mobile wearable bio-monitoring of newly diagnosed multiple myeloma patients using Rave Wearable Sensors along with Rave eCOA

Memorial Sloan Kettering Cancer Center

In a study published in Blood Journal (2018) 132 (Supplement 1): 4751, Sloan Kettering concluded that electronic mobile device monitoring may be a useful tool to assess a patient's overall wellness and health as they are receiving chemotherapy. Further, they also concluded that mobile wearable monitoring may be an even more useful strategy for tracking elderly and unfit patients that are more prone to side effects, where the balance of response versus quality of life is paramount.

Specialty division of a top 10 pharma company improves all enrolled patients' understanding of the study using Rave eConsent (Electronic Informed Consent) in a blood collection study

In preparation for an upcoming blood collection study, a specialty division of a top ten pharma looked to recruit thousands of patients across ten sites. Rather than conduct the informed consent and enrollment process with paper forms, the forward-thinking sponsor wanted to deliver information to patients through familiar technology.

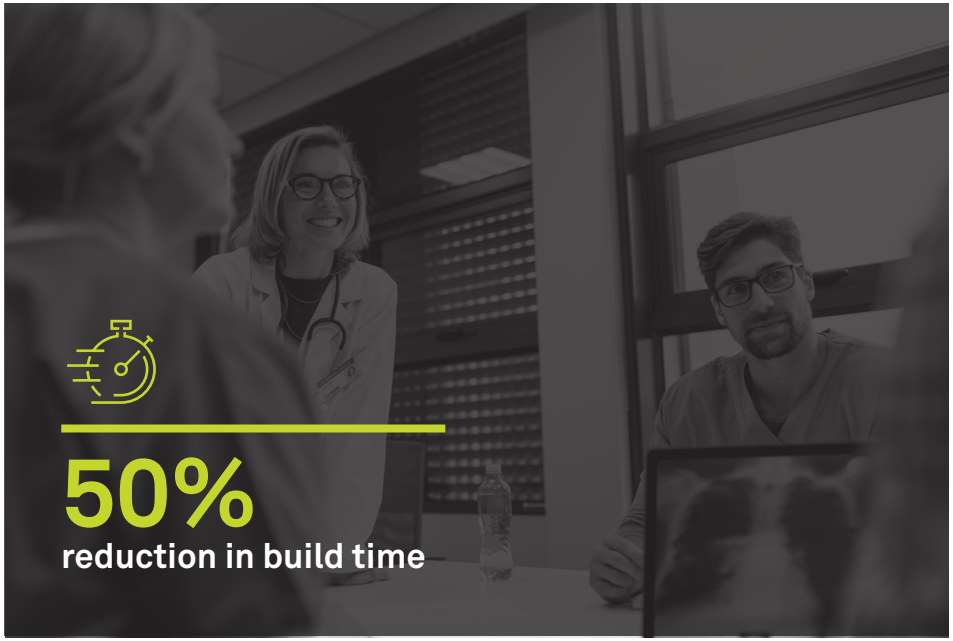
With Rave eConsent, the study's 2,726 patients completed the consent process on an iPad. Patient comprehension significantly improved with the intuitive experience—patients asked more educated questions and gained insights they may have missed while reading a 40-page paper document. 94% of site staff reported Rave eConsent improved assessing the participant's understanding of the study.

> **"We involved our sites early on in the decision-making process, which helped them understand the benefits of Rave eConsent. While implementing a new technology always poses challenges, our sites ultimately loved Rave eConsent and were able to adapt and realize the benefits quickly."**
>
> Principal Clinical Research Associate

The modernized approach freed staff members at the sponsor's sites from cumbersome administrative efforts and allowed them to focus on addressing specific study participant questions and concerns. The paperless process also mitigated data and quality risks associated with manual data capture and transfer. Over 70% of sites involved with the study strongly agreed Rave eConsent reduced their paperwork and quality risks by eliminating physical paper from the consenting process.

Information collected through the digital process was hosted in a remotely accessible database which reduced monitoring and travel expenses. The sponsor understood the value of automated reporting and gained immediate, real-time ownership of the data in the cloud and increased visibility into the enrollment process. Ultimately, the added insight and increased benefits for patients and site staff reduced costs for the sponsor.

Leading Biopharma Company takes Unified Platform Approach enabled by Rave eCOA to Streamline Processes, Speed Start Up, and Improve Data Quality



One of the world's leading biopharmaceutical companies wanted to transform its clinical development process from a patchwork process involving multiple vendors and a mixture of paper and electronic data collection methods.

Frustrated by lengthy database and application build times lasting up to 16 weeks, delays in accessing data, and costly data discrepancies, the sponsor sought a technological solution that could be applied consistently across therapeutic areas. With C-suite support, a multi-disciplinary team undertook a bold, end-to-end overhaul of several work streams within clinical operations and data management, including electronic clinical outcomes assessment (eCOA).

The sponsor elected to replace its legacy vendor and paper systems with Rave eCOA for all new studies requiring collection of patient-reported outcomes. With modernized, consistent processes, the sponsor reduced build time by 50%. Now using Rave eCOA for ten studies, the company also enjoys efficiencies in data management, real-time reporting, speed to database lock, fewer inspection findings, and savings from reusable documents and hardware.

Large global pharmaceutical company transforms localization and translation process for hundreds of ongoing studies using Rave eCOA

English screen reports delivered 6 months prior to FPI compared to 3 weeks

100% reuse of screen reports and certificates of translations if they have been previously used

Significant reduction in eCOA total cost of ownership

Availability of localized languages prior to FPI

The localization and translation process is typically lengthy, cumbersome, and complex which often led to missed timelines in which the pharma company had little control over. They were seeking a way to reduce reliance on external vendors, improve operational efficiencies and accelerate the availability of all required translated instruments.

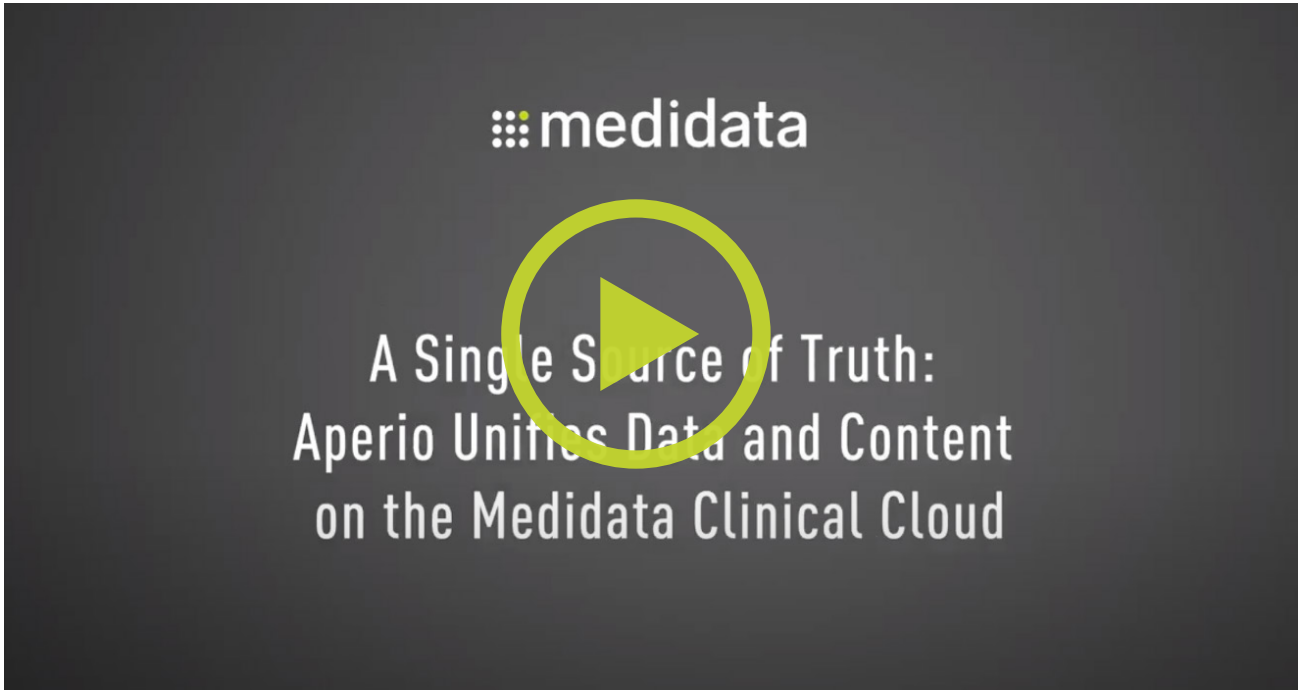
The company's approach was to separate the system delivery from the screen report delivery and chose Rave eCOA as the eCOA solution. They were able to take advantage of the unified platform eliminating the need for data integration, custom data transfers and the data would be made available immediately in EDC. Since they were already a user of Rave EDC, they were able to control more of the processes by bringing some of the build work in-house and creating a centralized team composed of sponsor resources and vendors. They were also able to take advantage of the Global Instrument Library, which enables the reuse of instruments, minimizes efforts for translations and licensing, while shortening the timelines for eCOA instrument builds.

2

TECH STRATEGY:
Ensuring Effective Management

Delivering end-to-end efficiency, our suite of Rave trial management tools provides machine learning, and advanced analytics capabilities to reduce time-intensive manual review, streamline oversight, and accelerate study execution. Free your study teams from the time-and effort-intensive activities of multiple system integrations with a unified tech solution that protects data integrity and accelerates timelines.

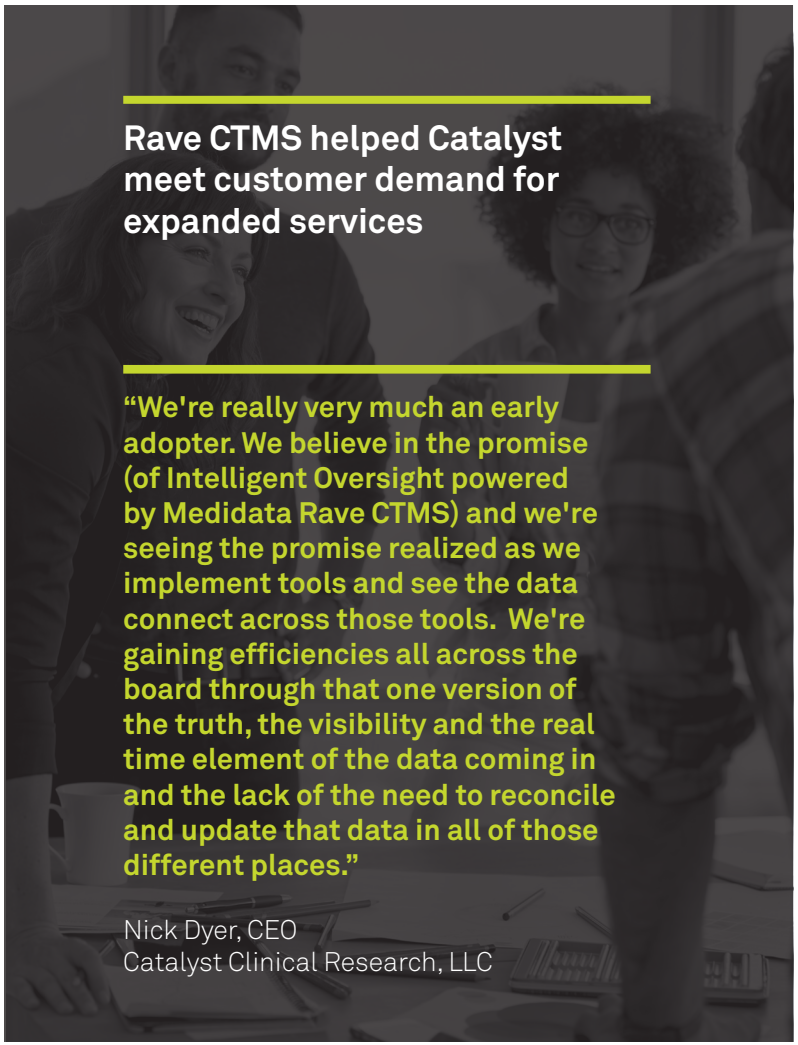
Aperio Unifies Data and Content using Rave CTMS and Rave eTMF on the Medidata Rave Clinical Cloud



aperio

"Being a Medidata partner allows for the clients to know that we're serious. We're a small CRO with a lot of knowledge and some really awesome people, but without the technology, the sponsor had to trust the people. With all of the Medidata products and the Rave Clinical Cloud, we have the ability to share that information directly to the end user, a single source of truth."

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 three-fold. 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.

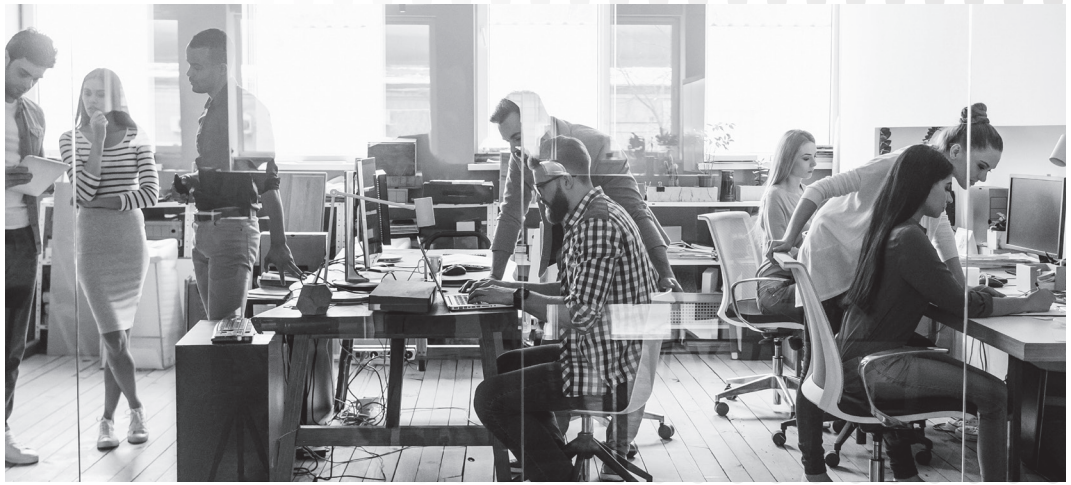
To achieve this, Catalyst selected Rave CTMS to manage their clinical trial services. Now Catalyst offers broad-based functional services along with full-service CRO solutions. They help plan, execute, and manage studies with cross-functional dependencies using a single source of truth with real-time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

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

Syneos Health, a Global Full-Service CRO, considers Medidata Detect a truly a 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 realize 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 organization including Clinical Operations, Data Management, Biostatistics and Medical Monitors. We have to recognize that there are things that we have to do within our organization 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



UroGen empowered to consistently pay sites in a timely and accurate manner with Rave Site Payments

Below is an excerpt from a panel held at Medidata NEXT NYC 2019 on the topic of Establishing Study and Site Financial Success where Demitry Zolotaryov, Clinical Budgets and Logistics Manager, UroGen Pharma, Inc, provided an insight into the biggest organizational changes that were made to help make site payments in less than 30 days.

Volger (Medidata):
What is the biggest change you have made in your organizations, or with other partners, to achieve less than 30 days? Demirty, maybe you can kick us off?

Zolotaryov (UroGen):
Yeah, sure. So, I'll give an example of this trial we ran. It's an oncology trial [UroGen 101]. And we started the trial, it's 75 patients, about 45 sites. It's a rare disease. So, we thought, "Okay, there's not a lot of patients, maybe we can just handle it inhouse without any kind of assistance." So, I have some experience in procurement as well, so I know the ERP that the company was using at the time, and we decided to maybe just try it and do it ourselves.

So, quickly after nine patients, it was very cumbersome to just aggregate all the payments into one invoice, and then wait for the sites to actually — you first generate a request for invoice, send it over to them, they prepare the invoice, send it back to you, which is not a straightforward process whatsoever. And once, I had to open the purchase orders in the ERP system, get my finance to transfer the money, which is also not straightforward.

And then I had to provide the site with the payment confirmation, and get the receipt from them back to finance. So, this whole process took about a month and a half, two, in the best case. And then I felt that I was not keeping up with everything, so when I had a backlog of about three months, I'm like, "That's it. We just need something else."

So, we went with Medidata, and right now, we're running basically — I'm the only person handling the payments for two studies right now at the same time. And we always pay on time on the first of every month. We have a cutoff at 17th of every month, so in the timeframe of a week and a half, every payment is calculated, done and transferred.

To listen to the full panel, please click here.

A Biopharmaceutical Company reduces clinical trial costs by 34% with Rave Grants Manager, a Trial Planning and Budgeting Application

A biopharmaceutical company expected to pay $34,644 per patient for a Phase IIb investigation based on costs it had previously paid in similar trials. With 30 patients across six sites, the total grant payments were expected to be $1,039,320. The budgeting team wanted to verify these payments against industry benchmarks, so they turned to Medidata Rave Grants Manager, a trial budgeting application.

The analysis generated by Rave Grants Manager revealed that the industry benchmark costs were significantly lower than the sponsor had expected to pay for this study. In fact, the sponsor's cost saving across all sites averaged nearly $12,000 per patient.

After negotiations were concluded with all sites, the total savings for site payment were $356,075—34% below the original budget. This represented a considerable savings for a company with a relatively limited budget and significant goals across an expanding research portfolio.

This case study illustrates a typical use of Rave Grants Manager to generate an accurate and rapid view of the actual site costs paid by the industry for a clinical trial. With the use of this data, sponsors are assured of paying an appropriate amount for site work activity, not too much and not too little, based on cost benchmark information specific to the characteristics of the actual trial being conducted. With the use of Rave Grants Manager research sponsors are armed with the facts of trial costs and can render confident and informed decisions about appropriate budgets for site work activity.

Sites	Estimated Initial Site Budget Per Patient	Final Negotiated Site Budget Per Patient	Variance per patient	Number of Patients	Savings at Each Site
Site 1	$34,644	$20,758	$13,886	5	$69,430
Site 2	$34,644	$24,512	$10,132	5	$50,660
Site 3	$34,644	$20,512	$14,132	5	$70,660
Site 4	$34,644	$21,533	$13,111	5	$65,555
Site 5	$34,644	$24,336	$10,308	5	$51,540
Site 6	$34,644	$24,998	$9,646	5	$48,230
			$11,869 Avg.	**30 Total**	**$356,075 Total**

Top 25 Global Pharma De-Risks Trials using Rave Trial Assurance

Nearly 50 percent of new molecular entities (NME) submissions fail their first FDA approval, and 32 percent of these failures are attributed to data quality, data integrity and data inconsistency issues. A top 25 global pharma company avoided these issues with Rave Trial Assurance.

Medidata's team of data analysts, led by former FDA statistical reviewers, worked with the company to focus on five areas commonly examined by regulators: site inconsistency for unknown risks, site inconsistency for known risk, differences in adverse event reporting, potential misconduct, and data inconsistency.

Rave Trial Assurance helped the global pharma company resolve 453 data quality issues across ten studies. 26% of the data quality issues had potential to delay drug approval—NMEs with first-cycle approvals beat others to regulatory approval by a median 17.9 months while delays incur massive revenue losses and leave patients waiting. With Rave Trial Assurance, the top 25 pharma avoided those pitfalls.

453 data quality issues avoided across ten studies;
26% had potential to delay drug approval

Anomaly Categories Detected in 10 Studies

Percent of **studies** at least one category anomaly

100%
Differences in Adverse Event Reporting

90%
Site Inconsistencies due to known risks

90%
Site Inconsistencies due to unknown risks

90%
Data Inconsistencies

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 outsourced 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.

Leading biotech company reduces time, cost, and risk with Medidata's Site Cloud: End of Study (EOS)

The biotech company invests heavily in research and development, conducting dozens of studies and clinical trials over the past decade. The company relied on Medidata Rave EDC as its electronic data capture solution of choice. However, the company had struggled to find a better way of sharing data once each clinical trial was completed.and followed the traditional method of sharing End of Study (EOS) documents with each site. It burned secure DVDs filled with PDF documents and then mailed copies of the DVD to each site. Processing all of these DVDs took a lot of time and money, and the company didn't always receive the regulatory required confirmation from the sites that DVDs were received.

Medidata invited the company to be one of the first users of Site Cloud: End of Study (EOS), Medidata's end-to-end solution to streamline and simplify the EOS media process. Rather than burning data onto physical DVDs, EOS allows the company to seamlessly generate, distribute, and manage EOS data through a more secure digital platform. It is simple to use, both for the company and its sites. EOS operates as a stand-alone application but also works like an add-on to the Rave EDC solution.

The biotech reduced regulatory compliance risks with the ability to track 100% of sites receiving data. This is compared to the previous workflow where approximately 30% to 40% of sites that would neglect to notify the company that they had received the media. The company now receives updates from all sites through automated audit trails that indicate when sites receive data.

"We want to be the sponsor of choice for our sites, so we focus a great deal on the site experience. Sites were frequently asking for another method of sharing data, but thumb drives and cloud services didn't have the level of security that we wanted or was required. We needed to find a new solution. We always had great success with Rave EDC, so the introduction of Site Cloud:End of Study has been ideal for us. We've had overwhelmingly positive feedback from sites, who praise how easy it's been to get data through the familiar Medidata platform. Medidata has been a fruitful partnership for us in driving greatly enhanced engagement with our sites and patients"

Director of eClinical Operation

3

TECH STRATEGY:
Simplifying Data Complexity

By delivering the data they need, when and where they need it, study teams are freed from manual input or review processes, able to devote more time and effort to higher output initiatives, and able to execute trials faster and with more confidence knowing their working from the same single source of high-quality data. Our approach to simplifying data complexity hinges on unity: deliver fit-for-purpose patient, clinical, and operational data for the entire ecosystem with a single, unified platform.

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

Pharm-Olam
Helping Create A Healthier World

Cancer Research UK Accelerates Study Progress using Medidata's Unified Platform Supported by Rave EDC and Rave RTSM

Rave RTSM led to site satisfaction and faster study-start up.

Cancer Research UK (CRUK), the world's largest cancer charity dedicated to saving lives through research, was conducting a study for patients with head and neck cancer. CRUK needed a solution to manage the drug supply and randomize their trial subjects into placebo and active arms.

With Rave RTSM, the CRUK team was able to get trained quickly on the intuitive user interface. The integration between Rave EDC and Rave RTSM enabled the monitors to see multiple tasks in one place, including detailed tracking and reporting capabilities. Even when they were traveling or offsite, the trial monitors could download data for quick access in places like a pharmacy. Rave RTSM led to site satisfaction and faster study-start up.

CANCER RESEARCH UK

"We're investing in technology to help us unlock cancer's secrets, and Medidata's cloud-based platform provides us with the flexibility and scalability we need to accelerate progress, "Everything is there in one place. We can filter by site, we can filter by what's been dispensed, and it's really easy for us to track"

Nigel Blackburn, Director,
CRUK Centre for Drug Development

Syneos Health, a Global Full-Service CRO, accomplishes ambitious build times using Rave EDC and Rave RTSM

Syneos, a global full-service contract research organization (CRO), wanted randomization 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 benefited 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.

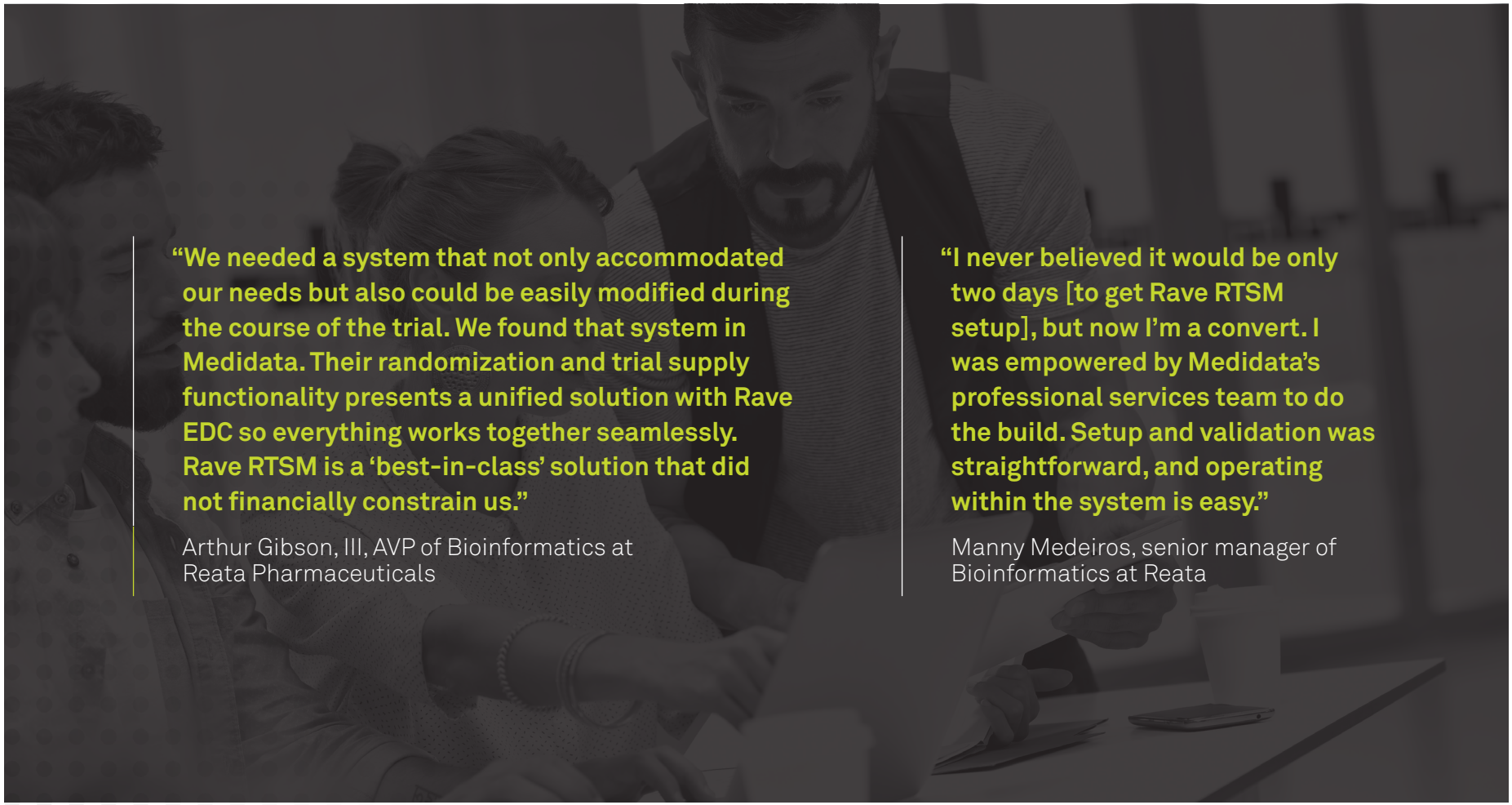
Syneos Health

"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 randomization 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

Reata finds Rave RTSM to be a best-in-class, financially unconstraining solution

REATA PHARMACEUTICALS



"We needed a system that not only accommodated our needs but also could be easily modified during the course of the trial. We found that system in Medidata. Their randomization and trial supply functionality presents a unified solution with Rave EDC so everything works together seamlessly. Rave RTSM is a 'best-in-class' solution that did not financially constrain us."

Arthur Gibson, III, AVP of Bioinformatics at Reata Pharmaceuticals

"I never believed it would be only two days [to get Rave RTSM setup], but now I'm a convert. I was empowered by Medidata's professional services team to do the build. Setup and validation was straightforward, and operating within the system is easy."

Manny Medeiros, senior manager of Bioinformatics at Reata

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

A leading academic medical center streamlines data capture and achieves randomization efficiency via Rave EDC and Rave RTSM

Faster database builds and deployments among unified clinical and statistical teams

A leading academic medical center noticed a disconnect between clinical and statistical teams—they wanted to remedy randomization list disconnects by positioning the statisticians as primary stakeholders. Using Rave RTSM, they electronically created randomized lists that were also synced with Rave EDC. With unified platform capabilities, their clinical and statistical teams linked and communicated more effectively.

> **"Medidata Rave EDC eliminated the burden of data entry for our users. By removing duplicate work and streamlining the process for managing standards reusing eCRFs and edit checks functions, we are able to adapt to protocol amendment changes more quickly and efficiently."**
>
> Project manager for the academic medical center

Experienced nurses became the primary study builders within a few short weeks of training on the Rave EDC platform, and multiple user groups established consistent standards with Rave's global library. The combination of users with an extensive clinical trial background and an understanding of how the data should look served as an important catalyst for a more efficient study build process.

The clinical team also realized the benefits of Rave RTSM when trials called for randomization when blinding was in place. The tool eased the complex process of having an unblinded party handling drug supply with configuration options for view permissions; the unblinded party was also able to take necessary actions while maintaining the blind of the study across the multiple stakeholders, which was especially valuable for the investigators when conducting vaccine trials.

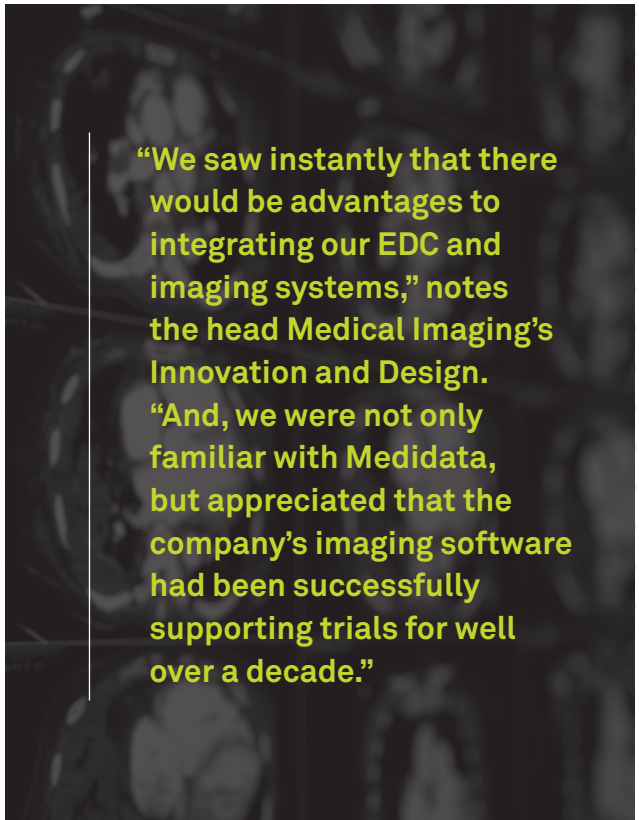
Global CRO Adopts Rave Imaging with Rave EDC and Achieves Study Set Up in Just Four-Six Weeks

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, analyze, and deliver imaging data."

The global CRO selected Rave Imaging and became Medidata's first accredited partner authorized 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



THE BIG BOOK OF 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, 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. 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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