



Case Study



Through Integration of Medrio and Veracity Logic, Atlantic Research Group Expands Capabilities

Finding themselves under a strict timeline and in need of drug supply management, Atlantic Research Group was searching for a way to bolster their software repertoire. Using a free API from Medrio, they were able to access the comprehensive drug supply management capabilities of Veracity Logic without forfeiting Medrio's top-shelf electronic data capture.

Challenges

- Strict 6-week study timeline
- Unmet need for drug supply management
- Reluctance to sacrifice strong EDC

Solutions

- Integrated with the Veracity Logic IRT, using Medrio's Import API
- Maximized convenience by delegating subject randomization to Veracity Logic
- Minimally involved in programming process

Results

- Achieved necessary randomization and supply management capabilities
- Comfortably met strict timeline needs
- Enjoyed security, control, and fast conflict-response of Medrio's API

Background

As the rapid development of new technologies continues to impact clinical research, a multitude of technological systems useful to the industry - eCOA, CTMS, and others - have emerged. In response, many electronic data capture (EDC) companies have taken a jack-of-all-trades approach to their business, investing significant time and energy into expanding their capabilities into these other fields. Medrio has chosen a more optimal track, offering robust application programming interfaces (API) that allow customers to integrate Medrio's EDC with other systems outside the software. Through these integrations, Medrio is able to direct its efforts toward becoming a top-tier EDC while still allowing customers to access the capabilities provided by these external systems.

Atlantic Research Group (ARG), a CRO and Medrio customer, first harnessed one of Medrio's APIs to integrate with Veracity Logic, an interactive response technology (IRT) provider. The integration allowed ARG to meet the challenges of a high-stakes study head-on, gaining access to necessary special functionalities and averting a potentially serious timeline crisis.

Challenges

“ What would have been a three-month project needed to be figured out in about six weeks.”

- Hunter Walker, CTO, ARG

The circumstances of the study required that ARG work under particularly strict time constraints. The study took place in an emergency room setting; recruitment drew from a pool of patients who were seriously ill, creating a mandate to recruit as quickly as possible. The screening period was therefore unusually short, and patients had limited time to decide whether to participate.

A need for something more

As the study protocol developed amid this urgency, a conflict began to come to light. The sponsor required drug supply management, a specialized functionality currently outside Medrio's native offerings, for the study at hand; ARG would either need to switch to a potentially weaker EDC with in-house drug supply management, or turn to an IRT solution that could provide this functionality. This created a challenge that, depending on how the researchers handled it, had the potential to double the start-up timeline that the sponsor demanded.

The researchers valued the user-friendly flexibility of Medrio's data capture and management, and had no desire to swap it out for another EDC. In order to stay on track, they would need to find a way to satisfy both the subject and drug supply management requirements without making time-consuming, fundamental changes to the tools in their arsenal. Their best prospect would be to integrate with an IRT.



Solutions

“ Given our previous experience with the Medrio import API and the flexibility of our system, we were able to seamlessly integrate the two systems on time and on budget.

- Steve Zimmerman, Founder and Director of Operations, Veracity Logic

ARG knew that Medrio had worked with Veracity Logic in the past, and was impressed with its subject and drug supply management capabilities and readiness for integration. They also knew that Medrio offered APIs at no charge to customers looking to integrate, and that these APIs could serve as a bridge between Veracity Logic and Medrio so that ARG could take advantage of both. Though Medrio's subject randomization had served them well in the past, ARG opted to simplify matters by delegating the full scope of the study's randomization-related tasks – both subject and drug supply management – to Veracity Logic.

To conduct the integration, ARG used Medrio's ODM Import API, one of three web-based APIs Medrio offers, which allows external systems to send their data into Medrio. Veracity Logic helped make the process smooth and easy for ARG, handling almost all of the programming that was required for the integration. “We used Medrio's API to pass information from Veracity Logic's IRT to the Medrio EDC system,” says Steve Zimmerman, Founder and Director of Operations at Veracity Logic. Soon, ARG had the deft EDC of Medrio and the additional subject and drug supply management capabilities of Veracity Logic's IRT system at their fingertips.

Medrio's ODM Import API: An overview

- **Allows external systems to submit transactional CDISC ODM files and their data into Medrio**
- **Exposed as a web service**
- **Must conform to CDISC ODM 1.3.1**
- **Directly available via Medrio's documentation**
- **Supports clinical data, subject data, study event data, form data, item group data, and item data**

Results

“ Our sophisticated customers often require the functionalities of third-party vendors. Our APIs allow them to fulfill that requirement.”

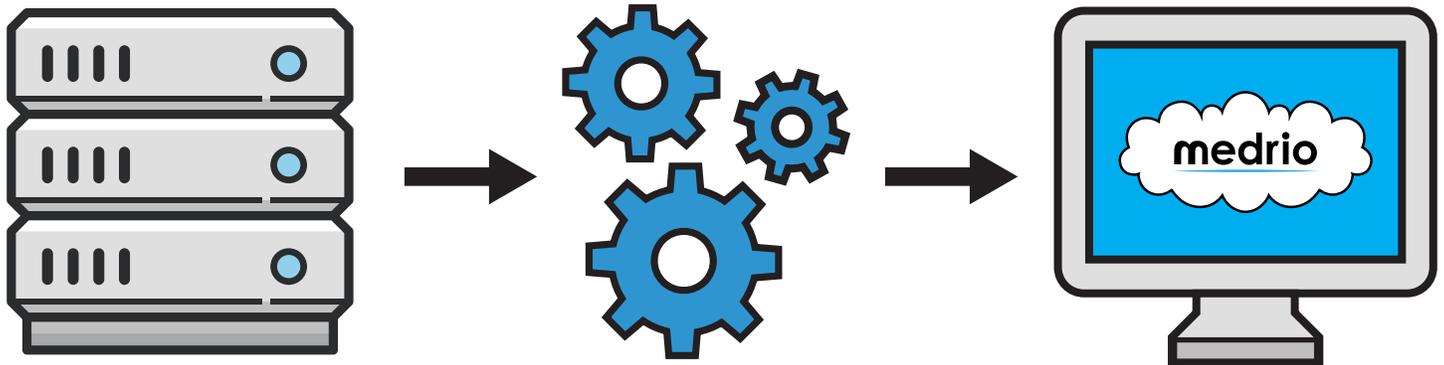
- Mike Novotny, Founder and CEO, Medrio

With the two systems linked by the Import API, ARG was able to resolve a conflict that had posed a major threat to the study. They achieved sufficient drug supply management; the ability of Veracity Logic to send data directly into Medrio allowed ARG to remain within the strict six-week timeline imposed by the sponsor; and they did it all without having to surrender one of their preferred EDCs.

Additional benefits

In these ways, the integration helped ARG solve a number of specific yet significant challenges. But in a more general sense, ARG also found the experience of working with the API to be smooth, intuitive, and convenient. The API offered more control over access than others that ARG had used: while other APIs remained on by default, with no authentication required between client and server, Medrio's API keys are secured by email- and phone-based two-factor authentication. The API was also easy to use, and any minor problems that did arise were resolved within an hour.

The integration was the largest that ARG had conducted, and the role of Medrio's Import API in making it a smooth process was of tremendous value to both ARG and the study sponsor.



Veracity IRT

**Medrio ODM
Import API**

Medrio EDC

Conclusion

// The integration was very important to us and to the client. The solution worked. //

- Hunter Walker, CTO, ARG

It took a savvy research team with a solid awareness of the resources available to them to circumnavigate the challenges of this study. The team at ARG possesses this savvy. Their strong competence with APIs, out-of-the-box thinking, and coolness under pressure allowed them to bridge the gaps in their resources and get their study done on time.

Many companies have to choose between fortifying their expertise in a niche and providing adequate but unremarkable service in a variety of areas. Software integrations have allowed Medrio and Veracity Logic to sidestep this dilemma. Medrio's Import, Export, and Events-Based APIs allow the company to diversify its offerings through external avenues, providing access to capabilities like those of Veracity Logic's IRT system while still devoting all of its in-house efforts to becoming an elite EDC.

The result is a solution that can both contend with the EDC capabilities of any industry leader and provide the tangential functionalities that sophisticated studies, like the one undertaken by ARG, often require.

About Medrio

Medrio offers an integrated eClinical software platform with a fully hosted EDC system. Our cloud-hosted technology features an easy drag-and-drop interface, allowing study managers to build their studies in days instead of months without requiring any programming. Medrio's new mobile suite of eSource products supports both event-based and subject-based workflows, offline data entry, and Patient Reported Outcomes. Though Medrio has extensive experience in all study phases, our software leads the way in early-phase and Phase I trials, with over 500 Phase I trials to date. For more information, please visit our website. To schedule a demo, please submit your information here and a member of our team will be in touch shortly.

About Veracity Logic

Veracity Logic, a North Carolina based LLC, was founded in 2005 and has focused entirely on deploying powerful and user-friendly IRT systems for global and domestic clinical trials. Since its inception, the company – which prides itself on being “fast, adaptable, responsive, and affordable” – has provided IRT services in more than 50 countries and more than 45 languages. “The Veracity Logic-Medrio partnership has proven to be a robust solution for Sponsors, CROs and Clinical Suppliers.,” says Veracity Logic Managing Director David Goldston. “Our proprietary IRT system – which we call VLIRT® – provides a simple, user-friendly interface with sophisticated power under the hood for managing subjects and drug supply for clinical trials. We enjoy working with our clients to find creative solutions to the endless challenges of conducting a successful clinical trial. To learn more about us, visit our website at www.veracitylogic.com.”

About Atlantic Research Group

Atlantic Research Group (ARG) is a full-service CRO and preferred provider for biotechnology organizations developing everything from orphan status immunology and oncology compounds to pivotal Phase III trials and beyond. ARG knows how difficult it is to develop a therapy, but also knows that great things happen when passionate people combine their strengths. They create smart, feasible studies with protocols that reflect everyday life, and connect individuals—even if there are only 50 in the entire world with a rare disease—to organizations that have the drive and know-how to develop potential treatments. ARG uncovers far-reaching insights in research, no matter how limited data may be. They began using Medrio in May of 2014 to utilize various capabilities, including Skip Logic functionality, which allows them to effectively keep study timelines and budgets in check. Medrio's API also allows ARG to integrate with other systems, like IVR/IWR, enabling ARG to offer a best-in-class solution for eClinical.