

Frontier Science Keeps HIV/AIDS Clinical Trials Moving with Remote Source Review

Short-Term Gain Leads to Long-Term Efficiencies

Frontier Science Foundation needed a quick pivot to address a pandemic challenge: Despite shutdowns affecting onsite study monitoring, they were committed to continuing the science. Frontier Science is a not-for-profit organization collaborating with research networks and sponsors to conduct clinical trials. Frontier Science has been involved in research for the past four decades and its work has significantly advanced the development of HIV/AIDS and oncology therapies. When Frontier Science suddenly needed to implement remote study monitoring, they turned to Medidata for a technology solution.

The Challenge: Launch Remote Monitoring with 33 Studies in the Queue

Frontier Science had been working with Medidata for nearly ten years to automate their clinical trials data collection and implement their digital transformation strategy. Rave EDC has been the cornerstone of their implementation and from there they have used a variety of other Medidata solutions to build out their functionality and streamline their workflows. When pandemic travel restrictions inhibited onsite monitoring, Medidata's Remote Source Review (RSR) offering caught Frontier Science's eye as a possible solution to help their team move a full trial pipeline forward while ensuring study safety and data integrity.

Challenges included Frontier Science's unique structure, as they are not a traditional CRO. Their collaborative structure would require multiple players – sponsors, networks, sites, and the Frontier Science team – to provide input on the process.

Also, clinical monitors would require support once Frontier Science studies were live on the RSR system. Medidata would need to be an integral part of the team, addressing site questions as monitors navigated the system. With sponsors and participants eager to keep timelines moving, the need for speed was key. The Frontier Science team wanted to implement a solution for their first study within four months. Ultimately, we would address implementation for all 33 studies in the queue with 70+ sites.

What Is Remote Source Review?

Medidata Remote Source Review (RSR) is a cloud-based solution that:

- Supports flexible on-site/off-site study oversight
- Enables monitors to quickly acquire critical documents
- Automates document workflows to the right monitor for the right study and site
- Allows monitors to review documents for compliance and quality, supporting Source Data Verification (SDV) and Source Data Review (SDR)
- Helps optimize Risk-Based Quality Management (RBQM)

The Solution: Implement RSR in Just 4 Months

Frontier Science approached us with the concept of implementing RSR in May of 2020. We quickly provided an RSR demo for the client team and described how the service could meet their needs. The client’s response was enthusiastic. Marlene Cooper, Frontier Science’s Data Management Center Director of their largest HIV trials, says, “We appreciated the Medidata team’s rapid response on this time-sensitive issue; they worked quickly to provide pricing and configure the program.”

Over the summer, we implemented RSR for the client. “By August, we created a dedicated team and were building user specifications and moving through interactive verification,” Marlene notes. “This was unheard-of speed. We were in production with our first study and sponsor by mid-September.”

Additional studies were quickly added to the system – for a total of 33. Marlene reflects, “We implemented remote monitoring to address pandemic travel restrictions but quickly realized that we didn’t always need an onsite presence for monitoring. RSR became integrated into our normal workflow.” Broadscale implementation made RSR available to all 70+ sites internationally.

The Benefits: Short-Term Win Leads to Long-Term Gains

A collaborative relationship was vital to this project’s short-term success. The client notes that having a dedicated Medidata team was critical, as the team appreciated Frontier Science’s unique, nonprofit perspective. “Medidata understood our process and provided insights on ways we could take advantage of RSR capabilities. We received rapid response plus personalized support. Medidata’s team also demonstrated flexibility,” says Marlene. “They were always willing to go find the answers we needed. It was a case of close collaboration.”

Smooth implementation made the process painless. “The RSR template ensured a smooth and efficient process,” adds Marlene. “The Medidata team had the interactive verification process down to a science. Smartsheet tools and electronic document sign-offs were fast and easy, and the workflow was well defined. As a collaborative team, we shared tracking spreadsheets to identify studies in the queue with timelines and prioritization.” Integrating RSR through Frontier Science’s existing Medidata Rave EDC platform was seamless, and the team reported that inviting users to the module was painless.

“Speed and collaboration were our two project pillars. We quickly moved from idea to implementation by leveraging our strong Medidata working relationship. Their rapidity was striking; this type of speed requires a high level of dedication – where everyone on the team is committed to meeting an aggressive timeline.”

Marlene Cooper
 Frontier Science

Frontier Science also found our training robust and highly effective, and their team was able to augment the modules for Frontier Science's unique needs and study-specific context. "Medidata's quality eLearning took a considerable burden off our staff. We appreciated having that level of training support," notes Marlene.

Realizing Significant Efficiencies

The client has gained long-term benefits since its implementation. Frontier Science's measure of success was having RSR efficiencies available for a study's very first site visit – having the solution available as the study opened and keeping the module aligned. "We are always looking to maximize limited resources," Marlene shares. "Reducing the requirement for site monitors to travel provides cost savings. Long-term, we have gained significant efficiencies."

Frontier Science also gained value in terms of workflow. "Medidata and RSR addressed our urgent need and then became an integral part of study build and rollout," reflects Marlene. "Initially, our networks did not require RSR but rather encouraged the use of the tool. Today, we are seeing an uptick in sites using the tool because of the efficiency and streamlined process. We're always looking for ways to work smarter and innovate using technologies. In fact, we're looking at other Medidata solutions to further increase efficiency for Frontier Science, our project portfolio, and our sites as we move deeper into decentralized clinical trials."

Underscoring Patient-Centricity

What is the far-reaching impact of this success story? Marlene notes, "The research networks we support are committed to eliminating HIV/AIDS and finding a cure for cancer. Our trials focus on therapeutics that help study participants lead normal lives while sponsors achieve scientific goals. By leveraging innovation and efficiency, we can stay at the forefront of research and better serve our participants. They are the reason for everything we do."

The Medidata team functioned as an extension of the Frontier Science team in regard to user support.

"The professional services team made sure that we were navigating the system correctly, using online tools and resources, and determining the appropriate course of action to resolve any issues. I feel like Medidata Professional Services was an integral part of our team and always went above and beyond to assist us when sites reached out with questions."

Marlene Cooper
Frontier Science