# Leading Medical Device Company Adopts Remote Source Review as New Standard

## Pilot Leads to Broader Automation in Remote Monitoring and Data Collection

*For more than 40 years, a global leader in medical device technology has advanced science and improved health through less-invasive technologies for diagnosing and treating a wide range of medical conditions. When the pandemic struck, the global medical device company – like so many other clinical trial Sponsors – urgently needed a way to conduct remote monitoring with clinical trial sites. Given the company's long-time relationship with Medidata and its familiarity with Rave EDC, the decision to adopt Medidata's Remote Source Review solution is not surprising. But, what the two company teams accomplished through a close collaboration is a true testament to trust and partnership.*

## The Challenge: Enable Remote Monitoring Across 45 Studies in 90 Days

Prior to the pandemic, the medical device company had been moving toward a risk-based approach to monitoring clinical data, including using site-based tools where practical. However, the company did not have a dedicated tool to support large-scale remote monitoring across all of its studies.

When in-person interactions with sites became limited with the shut downs and travel bans caused by the COVID-19 pandemic, remote monitoring turned from an aspiration to an imperative. The medical device company's clinical leadership from across six divisions met to identify their highest risk studies and to adopt a standardized remote monitoring tool. They identified 45 critical studies and set an aggressive goal of having a solution in place within three months. That meant selecting this solution, then building, testing, verifying, and rolling it out in record time.

To complicate the already massive undertaking, the solution would need to be embraced by sites, even though it would require them to change their practices and learn a new application. The solution had to be appealing enough that sites wouldn't want to revert to the "old ways" of doing things as pandemic restrictions eased since risk-based remote monitoring was a strategic path forward for the company. The medical device company's approach also needed to address the fact that many sites were finding their own solutions. Thus, the goal of implementing a single, standard solution couldn't be achieved with one sweeping technology implementation.

## The Solution: Implement Remote Source Review with Medidata as a Full Partner

The global medical device company selected Medidata's Remote Source Review technology as its standard, automated solution for enabling sites to upload redacted source documents for Source Data Verification (SDV) and Source Document Review (SDR). The company worked closely with the Medidata team in what quickly became a model of collaboration. "From the beginning, Medidata was a full partner with us on this implementation," said Global Clinical Project Manager at the medical device company. "We saw Medidata as an equal and invested partner to address any issue that came up."

A rollout of this magnitude required exceptional project management to deliver a compliant solution within the timeline. The dedicated Medidata team worked alongside key decision makers within the medical device company to:

- Reach a consensus on goals and methods
- Implement a milestone-based project plan
- Create a single-source of critical, trackable project information
- Hold regular status calls and meetings to answer system design/function questions
- Adopt standardized user requirements and a specification template for each functional divisional team
- Set expectations with clinical sites and engage sites proactively and continuously

Ultimately, the medical device company did not force Remote Source Review onto sites that had a compliant solution in place for existing studies. Rather, they carefully set expectations around new studies and with new sites to leverage Remote Source Review where and when it made sense.

### Efficient Monitoring with Remote Source Review

- Faster document review
- Reduced risk of effort
- Lowered site burden
- Cloud-based solution
- Secure, browser-based uploads
- Automated document workflows
- Automatic distribution of documents
- Real-time assessment of subject safety and data quality

## The Benefits: A Positive Experience for Sites and the Sponsor

Remote Source Review was successfully adopted by sites across the 45 identified critical studies, and the experience was positive for sites, ensuring their receptivity to other automation initiatives in the future.

The implementation ran smoothly, and the medical device team was quick to credit Medidata's Professional Services dedication and expertise. Global Clinical Project Manager at the medical device company said, "The Medidata Professional Services team turned our constraints into non-factors. Their goal was the same as ours: to have a successful launch of Remote Source Review."

Director of Global Clinical Infrastructure for the medical device company, added, "This experience feeds right into our long-term relationship with Medidata." The Sponsor is expanding site participation in Remote Source Review beyond the initial pilot of 45 studies and is piloting other monitoring and data collection tools from Medidata. These include electronic clinical outcomes assessment (eCOA), electronic patient reported outcomes (ePRO), and eConsent as well as central monitoring and direct access to electronic medical records (EMRs).

> "The overall experience for us from configuration and implementation to 'Go Live' has been positive. It's been a true partnership and the best solution for us at a critical time of need."
> **- Global Clinical Project Manager**