

How Visby Achieved De Novo Marketing Authorization with Medrio CDMS/EDC

Supporting a nimble study helped achieve first-to-market status.

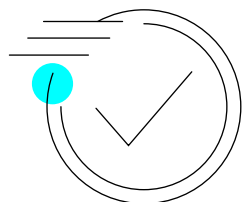
CHALLENGE

Visby Medical developed a first-of-its-kind, at-home STI test. To successfully bring the test to the at-home market, they needed to trust the data management software used in their study.

SOLUTION

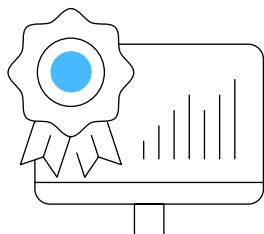
In 2025, Visby made history when their at-home Women's Sexual Health Test received FDA De Novo authorization, becoming the first and only PCR test authorized for at-home use.

Visby selected Medrio CDMS/EDC to support their pivotal clinical study. Medrio enabled rapid timelines, informed decision-making, and high-quality data.



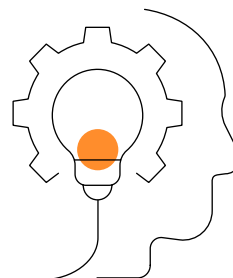
Rapid Timelines

Enabling a quick build and troubleshooting via responsive tech support



Quality Data

Supporting quick approval via interim database locks and cohort segmentation



Informed Decisions

Allowing for early issue identification and action via reporting capabilities

STUDY SPECIFICS

METRICS:

“For a small company like Visby, this study was a critical undertaking, so we needed a partner we could trust with our data. Thanks to Medrio, the FDA submission was done soon after the last subject was enrolled. Medrio was instrumental in our success.”

Shradha Prabhulkar
Manager, Clinical Affairs
Visby Medical

RESULTS

Fast-paced studies demand responsive tools and expert support. With Medrio’s intuitive interface and hands-on guidance, Visby Medical kept their STI trial moving smoothly—resolving issues quickly while maintaining momentum.

Functionality



Intuitive interface that required minimal training



Responsive, hands-on, and knowledgeable support



Reliable and efficient partnership

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RESULTS

Collecting comprehensive study data was streamlined through flexible data capture and management. Beyond efficacy data, observational data, including a photograph, was needed. Medrio was able to efficiently support all of these data collection needs.

Functionality



Real-time image uploads



Cohort segmentation



No-code form and workflow updates

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RESULTS

The study team configured daily customized reports in Medrio. Near real-time snapshots of study performance allowed them to identify any issues quickly. Medrio's reports also helped the team identify a necessary data collection change.

Features & Support



Flexible reporting configuration by user role



Automated custom reporting options



Real-time data access



User-friendly data export tools

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