

CUSTOMER STORY

Onera Health Chooses Jama Connect® to Provide Flexibility and Consistency for Sleep Diagnostic System Development

ABOUT ONERA

Onera Health develops clinical-grade remote diagnostics and monitoring solutions, making home polysomnography broadly accessible and user-friendly for anyone who needs it, wherever they are.

CUSTOMER STORY OVERVIEW

Onera Health has developed a sleep diagnostic system utilizing four patch-based sensors that patients could apply at home. Initially, the Onera STS 1 product development team conducted pilot studies and relied on Microsoft Excel and Word to manage requirements and create the necessary documentation for successful Medical Device Directive (MDD) and Food and Drug Administration (FDA) submissions.

With the development of the company's second-generation commercial product, the Onera STS 2, and its integration into Onera's enhanced end-to-end solution, Onera Health took an active approach in recognizing and acknowledging the increased complexity of its second product. The company began seeking a more structured procedure for managing requirements, tests, and risks.

The new solution needed to provide better access, efficiency, and collaboration for teams working in different disciplines so they could accelerate development with confidence.

Onera Health chose Jama Connect because it enabled faster iterations, greater consistency of requirements after changes are made, and visibility into risks and related mitigations.

WITH JAMA CONNECT, USERS EXPERIENCE:

- Faster iterations on requirements due to less time spent in alignment, review, and audit meetings
- Consistency of requirements, terminology, configurations, and documents for all teams affected by design changes
- Visibility into risk identifications and mitigations for internal and regulators' teams

“We needed a more structured approach due to the complexity involved in maintaining consistency across our entire documentation set. With our first generation, tracking the impact of a design change or updates impacting multiple disciplines was time-consuming and came with its own challenges.”

- PIETER ERMERS, FOUNDER AND VP QUALITY & REGULATORY, ONERA HEALTH

“We chose Jama Connect because of its intuitive user experience, cloud-based availability, and flexible output that our global team needed. Jama Software Consultants were very supportive in helping us understand how to set up Jama Connect to achieve our goals.”

**- PIETER ERMERS, FOUNDER AND VP
QUALITY AND REGULATORY,
ONERA HEALTH**

“When making changes in a requirement used in multiple sensors, we must maintain consistency of requirements, tests, and documents across teams and disciplines. Jama Connect's structured approach for automatically checking that everything is covered is very beneficial for us.”

**- PIETER ERMERS, FOUNDER AND VP
QUALITY AND REGULATORY,
ONERA HEALTH**

CHALLENGES

Complexity of product design, regulations, and document strategy lacking efficiency, scalability, consistency, and accessibility.

Managing requirements and tests, while maintaining document consistency, was generally challenging due to product and regulatory complexity, as well as the limitations of an on-premises document database. Additionally, accessing the database required a VPN which can slow work or interrupt progress when the connection was down.

EVALUATION

One cloud-based system, accessible and user-friendly, with integrated collaboration and reviews, automated test input, and flexible reporting.

The evaluation demonstrated that Jama Connect could easily be accessed and used to manage requirements, tests, and risk based on its intuitive user interface, authoring, collaboration, reviews, and verification. Automated input of test results and flexible output in generating reports provide a tailor-fit to the company's needs.

OUTCOMES

With Jama Connect, the Onera team has experienced the following benefits:

- Faster iteration on requirements due to less time spent in alignment, review, and audit meetings
- Consistency of requirements, terminology, configurations, and documents for all teams affected by design changes
- Visibility into risk identifications and mitigations for internal and regulators' teams

Learn how [Jama Connect](#) helps medical device companies succeed with higher quality and faster time to market.

ABOUT JAMA SOFTWARE

Jama Software® is focused on maximizing innovation success in multidisciplinary engineering organizations. Numerous firsts for humanity in fields such as fuel cells, electrification, space, software-defined vehicles, surgical robotics, and more all rely on Jama Connect® requirements management software to minimize the risk of defects, rework, cost overruns, and recalls. Using Jama Connect, engineering organizations can now intelligently manage the development process by leveraging Live Traceability™ across best-of-breed tools to measurably improve outcomes. Our rapidly growing customer base spans the automotive, medical device, life sciences, semiconductor, aerospace & defense, industrial manufacturing, consumer electronics, financial services, and insurance industries. Visit jamasoftware.com to learn more.