

CUSTOMER STORY

Medimaps Accelerates FDA Submission of AI-Powered Software from Weeks to Hours with Jama Connect®

ABOUT MEDIMAPS

Medimaps is a leading MedTech company specializing in advanced bone microarchitecture analysis. Their flagship product, an AI-powered Software as a Medical Device (SaMD), helps clinicians to improve fracture risk assessment and osteoporosis management through innovative image-based algorithms.

CUSTOMER STORY OVERVIEW

As a pioneer in medical imaging and AI, Medimaps faced the challenge of managing complex requirements and maintaining compliance in a highly regulated industry. Their reliance on manual processes like Excel created inefficiencies and hindered collaboration.

By implementing Jama Connect, Medimaps transformed its workflows, enabling the rapid development of their AI-powered software. This move allowed the company to automate traceability, integrate with existing tools, and improve collaboration. As a result, they reduced FDA submission preparation time from over a week to just two or three hours, and greatly increased confidence in regulatory compliance.

WITH JAMA CONNECT, USERS EXPERIENCE:

- Automated traceability that reduces regulatory prep time from weeks to hours, taking the stress out of compliance, even with highly complex AI-driven software products.
- Seamless integrations with tools like Jira and GitLab that provide developers with immediate context to resolve defects efficiently.
- A reliable single source of truth that preserves design history and aligns cross-functional teams around a unified development process.

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Jean-Mathias Heraud, Senior Director of Software Development and IT

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CHALLENGES

Before implementing Jama Connect, Medimaps faced several challenges that hindered its ability to scale efficiently.

- **Unsustainable Manual Processes:** The team managed traceability manually across multiple Excel spreadsheets. As the AI-driven software grew in complexity, every change required updates in several places, making it incredibly difficult to guarantee consistency.
- **Resource Drain:** Manual documentation took developers away from their core work. "The team was spending more time validating documents than improving the product," shared Jean-Mathias Heraud, Senior Director of Software Development and IT at Medimaps.
- **Stressful Regulatory Submissions:** Preparing for audits often required over a week of fighting against different files and version control issues, leaving them without full confidence that their reports were accurate.

SOLUTION

Medimaps formed a committee to evaluate enterprise-level requirements management tools and selected Jama Connect over Polarion to build a reliable, collaborative framework specifically designed for regulated development.

Balanced Structure and Usability to Increase Collaboration

The platform provided a unique blend of power and intuitiveness that required almost no training for users. "[Jama Connect] really balanced between structure and usability," Heraud noted. "Everything was accessible not only to engineers but also to regulatory, clinical, and product teams. This cross-functional collaboration was essential for us."

Item-Based Management for Seamless Traceability

Medimaps transitioned to an item-based approach, ensuring traceability across system requirements, software and AI requirements, risk controls, and verification activities. This shift embedded traceability directly into the development culture.

"My advice is to not approach Jama Connect as a document replacement tool, but to approach it as a way to structure collaboration and to embed traceability in the development culture," Heraud said.

Robust Toolchain Integration

The company leveraged Jama Connect Interchange™ to sync with Jira. When a test fails in Jama Connect, the team logs a defect in Jira, automatically carrying over test protocols and execution steps. This gives developers immediate context to fix bugs while maintaining full traceability down to the specific lines of code in GitLab

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OUTCOMES

Since embedding Jama Connect into its operations, Medimaps has achieved remarkable improvements.

- **Accelerated Regulatory Reporting:** Generating reports for FDA submissions of AI-powered software went from a stressful, week-long ordeal to a simple, automated process taking just two or three hours. Heraud explained, "Before Jama Connect, preparing for FDA submissions was a nightmare. Now, with everything in one place, we can generate reports with just one click. It's a huge time saver and gives us complete confidence in the results."
- **Unwavering Confidence in Compliance:** The platform delivered essential peace of mind. Heraud emphasized, "With Jama Connect, we are totally confident. For us, it was probably more important than gaining a few days of work. It was the fact that it's reliable."
- **Enhanced Team Alignment:** With a single source of truth, Medimaps unified its engineering, regulatory, and clinical teams, ensuring everyone remains aligned on requirements throughout the development lifecycle. All teams can access the full project history, including past discussions and approvals, providing vital context.

Ready to see how **Jama Connect** can modernize your development process? Let's connect

ABOUT JAMA SOFTWARE

Jama Software is focused on accelerating product velocity with AI-driven development across multidisciplinary engineering organizations. Using Jama Connect, engineering organizations can now adopt AI-driven development while intelligently managing the complexity and compliance of parallel development, automated pipelines, and industry standards. Our rapidly growing customer base spans aerospace & defense, automotive, medtech & life sciences, semiconductor, industrial manufacturing, consumer electronics, infrastructure, robotics, and energy. For more information about Jama Connect services, please visit www.jamasoftware.com.