



CUSTOMER STORY

Vave Health Migrates to Jama Connect® to Accelerate Development and FDA Clearance

After outgrowing their initial purchase of a requirements tool with limited capabilities, Vave Health chose Jama Connect® to automate and streamline their processes in order to maintain efficient release cadences, manage change, and ensure full verification and validation (V&V) coverage.

- Vave Health offers the world's most affordable wireless, ultra-portable ultrasound ecosystem at a low monthly cost
- Founded in 2014 in Santa Clara, California
- **Mission:** To change the paradigm of healthcare, starting with ultrasound
- **Recent Awards:** 2021 Good Design Awards Winner, 2021 Wood Pencil for Health Product Design Award from D&AD Awards, 2021 IDA Design Silver Award, 2021 Platinum Spark Award, 2021 International Design Excellence Award

Vave Health is committed to revolutionizing the physician-patient experience through innovative, industry-transforming technologies. Founded by a Stanford University Ph.D. with expertise in the miniaturization of imaging systems, Vave Health has developed a state-of-the-art, ultraportable solution that delivers cost-effective imaging at the point of care with a mission of making vital health technology accessible to all.

Their innovative handheld ultrasound device packs the ability to wirelessly connect with your Android or iOS smartphone or tablet.

Vave Health is changing the paradigm of healthcare, starting with ultrasound, and as a result of their innovations, the company has been awarded many prestigious design awards in recent years, including a 2021 Good Design Award.

CUSTOMER STORY OVERVIEW

After initially selecting Matrix Requirements, Vave Health found themselves constrained by the tool's limited functionality and were ready for a change. Following a requirements management market analysis, Jama Connect was selected and onboarded due to its ease of use and industry-leading functionality.

Now, with more confidence in their processes, the team can quickly and easily prepare for regulatory compliance, run parallel projects, identify gaps in coverage for V&V, and maintain a release cadence with ease.

CHALLENGES WITH MATRIX

- Reports, such as a traceability matrix, were taking too long to generate
- The steep learning curve caused most people to revert to working in Word and Excel
- Inability to develop parallel projects and reuse data between releases, contributed to duplicated work and slower-than-desired release cadence

SELECTION CRITERIA

- A solution that would scale with their growth
- Quick-to-adopt and easy-to-use
- Strong market presence
- Ease of data migration

OUTCOME + FUTURE

- Accelerate the release cadence from what previously took a couple weeks, down to a day or two
- Decrease generation of trace matrices from 30 days to one per project
- Scale development process with the ability to run multiple projects in parallel
- Maintain traceability and instantly identify coverage for verification and validation of requirements to respond to action items sooner in development

In the early days of Vave Health, the development team originally selected Matrix Requirements due to its low cost. While the tool was sufficient for managing their requirements in the preliminary stages of development, as the company began to scale, it became apparent that they needed a more mature, enterprise-grade solution with more robust capabilities.

The main challenges that Vave Health had which led them to seek out a new solution were:

- Reports, such as a traceability matrix, were taking too long to generate
- Steep learning curve caused most people to revert to working in Word and Excel
- Inability to develop parallel projects and reuse data between releases, contributed to duplicated work and slower-than-desired release cadence

As a small team, they did not have dedicated staff to manage requirements – it was a shared responsibility. With Matrix Requirements, the learning curve was so steep, only a few people were able to use it. Even then, it was used similarly to an Excel spreadsheet.

“Matrix Requirements was difficult to use, and it limited our ability to easily extract reports and quickly show traceability. The whole process just took too long,” said Craig Loomis, Vice President of Product at Vave Health.

“One of the deliverables in getting our product released is generating the trace matrix. With Matrix Requirements, it was very cumbersome,” said Sandhya Mitnala, Head of Quality and Regulatory at Vave Health. “We realized that something that should have taken one or two days, and managed through the project, took us almost a month. It was a very manual process.”

Additionally, as the team grew and the development work went from singular to multiple projects, the team ran into limitations using Matrix Requirements.

“One thing we didn’t initially think about when selecting Matrix Requirements was the ability to have multiple projects in motion at the same time,” said Loomis. “Although it was technically possible, there was no good way to extract the trace matrix and manage revisions across different projects at the same time in parallel!”



In order to overcome the limitations of their current tool, the team set out to find a solution that could meet their current needs and grow with them as they expanded in the market.

“The startup world is unique in that you’re trying to do so much more with fewer resources. Sometimes you do need to leverage technology to automate things that larger companies would be able to throw bodies at,” said Loomis.

When it came time to evaluate the available solutions in the marketplace, things moved quickly.

“From my experience working with Jama Software® at other companies, and my coworkers’ similar experiences, we wanted to move to a more automated solution and Jama Software was on everyone’s mind,” said Mitnala. “It was a very easy choice for us. All of the solutions we looked at, outside of Jama Connect®, were ruled out quickly,” shared Loomis.

During the evaluation process, the Vave Health team was able to access a sandbox account created specifically for them, so they could test out the solution to make sure it was the right fit. Because there were so many things already in motion, the team wanted to ensure that data migration would not be an issue, so they could keep moving quickly.

“Before we even signed a contract, we spent time in Jama Connect and had a lot of confidence in moving forward. We knew that our data would be migrated easily, and we wouldn’t be putting our projects at risk,” said Loomis.

Although Matrix Requirements supported some initial needs, the team knew that in order to derive the value they needed, it was time to up-level their tool for requirements management and systems engineering. The return on investment for Jama Connect, a robust, yet easy-to-use platform (which comprised the feature set and functionality they required) would increase efficiencies, simplify compliance, reduce risk, and ultimately speed time-to-market, paying dividends in the long run.

“As a startup, the one thing you must ensure is that you are able to move fast. You’re learning the market, you’re working against your competitors, and speed to market is critical. Especially where there are things that can be automated – that’s where you want to invest,” said Loomis.



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CRAIG LOOMIS

Vice President of Product,
Vave Health

Now, with more automated processes within Jama Connect, the team can focus on what matters – developing innovative, industry-transforming technologies.

“Jama Connect’s automation allows us to efficiently manage each release. The tool allows us to reduce manual processes involved in generating traceability and focus our efforts on reviews of the trace matrix. Efficiency and speed are critical in managing our software cadence and to be competitive in the marketplace,” said Mitnala.

After migrating to Jama Connect, Vave Health now can:

- Accelerate the release cadence from what previously took a couple weeks down to a day or two
- Decrease generation of trace matrices from 30 days to one per project
- Scale development process, with the ability to run multiple projects in parallel
- Maintain traceability and instantly identify coverage for verification and validation of requirements to respond to action items sooner in development

The Vave Health team leveraged Jama Software Professional Services to ensure that the onboarding process was smooth and simple.

“We’re still in the process of rolling out the tool, but Jama Software’s Professional Services team has been phenomenal. Jama Software has supported us with implementation of industry best practices questions in real-time,” said Mitnala. “The Jama Software team has been very responsive in providing us with resources, and giving us tips and tricks in implementing Jama Connect for a medical device startup.”

“Jama Connect allows us to identify lack of coverage for verification and validation of requirements, and we’re able to act on it immediately during the development process. The automation improves our product development process to achieve velocity and execute efficiently,” said Mitnala.



Working in the medical device industry means that complying with key industry standards is a major part of entering the market. And Jama Software is helping Vave Health make that process easier.

“Jama Software’s certification for IEC 62304 through TÜV SÜD is an added bonus. It provides confidence in the tool and the out-of-the-box templates provide us a good starting point to manage our development process,” said Mitnala.

When looking toward the future, the Vave Health team plans to integrate Jama Connect throughout their entire development process.

“We’re going to rely on Jama Connect for maintaining our release cadence and supporting us in terms of collaboration, focus efforts on review process, maintaining compliance, generating trace matrices more efficiently, and being able to maintain the matrices throughout the development process,” said Mitnala.

“It is really important for us to be able to collaborate in a better way and collect feedback from all stakeholders more efficiently,” added Loomis. “And with Jama Connect, we have that confidence.”



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SANDHYA MITNALA

Head of Quality and Regulatory
Vave Health



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. To learn more, visit us at: jamasoftware.com.