

**CUSTOMER STORY**

# **Biofidelity, Genomic Technology Innovator, Selects Jama Connect® to Inject Efficiency and Adaptability into the Requirements and Test Management Process**

Biofidelity chooses Jama Connect to enhance the process previously managed manually with Jira and documents.



**Provides innovative technologies that unleash the potential of genomics for fast and accurate targeting and monitoring of cancer treatment**

**Headquartered in Cambridge, United Kingdom**

Biofidelity was founded in 2019 with the goal of enabling millions of lives to be transformed through access to vital information needed for accurate targeting and monitoring of treatments for cancer and other illnesses. They develop innovative molecular technologies that remove the noise from genomic data to make analysis simpler, faster, and more adaptable. Healthcare providers, laboratories, patients, and biopharma firms rely on Biofidelity solutions to provide only the information needed to enable swift decision-making and ensure the best possible outcomes.



Biofidelity's first product, Aspyre® Lung Reagents, is a research use only (RUO) product that enables simple, fast, and reliable detection of established biomarkers in tissue or blood for use in non-small cell lung cancer research. It includes the lab assay and turnkey cloud analysis software designed to be integrated into a customer's laboratory. The company's second product, Aspyre® Clinical Test for Lung, is a laboratory developed test (LDT) that clinicians use to submit tissue or blood specimens to Biofidelity's CAP-accredited, CLIA-certified lab for analysis with a quick two-day turnaround time from sample to result.

## CUSTOMER STORY OVERVIEW

### Challenges

Biofidelity's competitive edge is in developing products offering simplicity, speed, low failure rates, and sensitivity. As a startup beginning to scale, the company developed their products using a combination of general-purpose platforms, manually tracking requirements and tests, and checking traceability. Managing this information across several documents in separate systems required manual connections, leading to lack of formal traceability between tools. Additionally, while the team could view the history of changes and comments in Jira, there was no established process for reviewing and approving requirements. Significant effort was needed to correctly gather the approved content for release documentation.



No automated change control and review process for requirements and tests



Documentation preparation took seven to ten days every quarter



Needed to be ready to adapt to changes in regulatory environment

For each quarterly product release, the company needed to ensure that all actions were complete, and that all information was accurate. However, using Jira made it extremely challenging to consolidate and display all the requirements, test items, and their upstream and downstream relationships. Jira only provided a basic draft table of user needs for verification and left the validation process to be handled manually using a spreadsheet.

The resulting process of generating documents took seven to ten days each quarter. “When we were developing a release, we spent a lot of time creating a traceability matrix by hand in Excel. Trying to connect all the requirements and test item types that were separate in Jira was hugely time consuming,” said Adam French, Associate Director of Software & IT, Biofidelity.

Although mandatory FDA oversight of LDTs were originally slated for 2025, Biofidelity demonstrated foresight by recognizing the need to stay ahead of the evolving regulatory landscape. They took proactive steps to improve their product development processes to ensure they could demonstrate compliance.

The need for better processes was driven by the company’s aim to make Aspyre technology accessible to millions of people affected by cancer each year, which requires the ability to adapt to new target markets more quickly and easily.

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*Adam French*  
*Associate Director of Software & IT at Biofidelity*

## EVALUATION

**Alignment of requirements with Jira issues**

**Process for reviewing and approving requirements**

**Automation of requirements and tests change control**

**Faster generation of documentation**

The company initially set out to find a test management system. However, they quickly discovered that general purpose project management software, even with plugins, lacked features for requirements management, collaboration, and traceability. In searching for application lifecycle management systems for medical device development, they found Jama Connect, MatrixALM, and Visure Requirements.

After an evaluation involving the software development team, Jama Connect was chosen for its superior configuration, control and review of changes, and documentation capabilities. Jama Connect and its Software as a Medical Device (SaMD) framework offered flexibility and a depth of configuration that included templates and pre-configured out-of-the-box item types that closely aligned with the team’s existing Jira issues.



The team valued how Jama Connect offers efficient and reliable control over changes to requirements and tests through traceability. In Jama Connect, impact analysis identifies all upstream and downstreamtraced items affected by a change. Additionally, suspect links are automatically created after changes are made to designated fields, flagging all downstream requirements that may no longer be accurate, complete, or verified.

“Adding control of changes and relations between all item types was the most important thing for us. You can put relationships between Jira issues, but it doesn't give you the suspect link notification, review process, or control to check upstream and downstream items after you change a source item,” said Max Artomenko, Software Engineer, Biofidelity.



Aside from the Jama Connect product, there were two other reasons for the choice. The Jama Software team spent a significant amount of time answering and asking questions that went to the heart of what the Biofidelity team needed. In addition, a member of the software development team had previous practical experience of how Jama Connect could be effectively integrated into the software development process.

## OUTCOMES

With Jama Connect, Biofidelity has reduced documentation preparation time for each release from seven to ten days down to two to three days, a 33-50% reduction. More importantly than the time savings, the team remains confident that the information is correct and ready for FDA audits due to the automated traceability, suspect link notifications, and review processes in Jama Connect.

Jama Connect has standardized how and where all the different teams create and store content. That helps ensure the team is alerted when changes are made and manage changes to team makeup. “Most important for the company is to have one source of truth for all user needs relating to software and hardware requirements, even when the teams change,” said Artomenko.

Unlike in the past, the team can do its traceability analysis in Jama Connect at any moment, even during development. This provides greater control of changes that affect the state of software requirements.

The company successfully transitioned their issue types from Jira into Jama Connect item types and experienced improvements in managing them. The plan is to further expand the management of requirements and tests in Jama Connect by incorporating risk management using the FMEA item type, which is readily available in Jama Connect’s SaMD framework.



**Reduced documentation preparation time by 33 to 50%**



**Increased standardization and automation of requirements change control**



**Development process that's ready for dynamic regulatory landscape**



**Ability to expand into risk analysis and additional teams, products, and markets**



By shifting risk analysis from Excel to Jama Connect, the team anticipates gaining more efficient control over risks, including immediate ways to demonstrate that all risk items have mitigations that are implemented and tested.

While the software team was the first to use Jama Connect, additional R&D teams are evaluating Jama Connect to potentially manage their user needs, requirements, and tests for other related products. Jama Connect's support for reuse of existing requirements and tests could translate into faster development of new products and entry into new markets. "One of the key advantages of Jama Connect is that it improves our processes and makes it easier for us to move into new markets and adapt as regulations change," said French.

**“As we move into a regulated space in the future, we expect to be audited more frequently. With the help of Jama Connect's SaMD framework, we are getting ready to be able to demonstrate that the quality is there every time.**

*Adam French*  
*Associate Director of Software & IT at Biofidelity*



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, please visit us at [jamasoftware.com](https://jamasoftware.com).