

CUSTOMER STORY

## Softway Medical

# How Softway Medical achieves 300 people alignment and simplifies ISO 13485 compliance ?



- STRATEGIC ALIGNMENT AND ENTERPRISE-WIDE VISIBILITY



- CROSS-FUNCTIONAL TEAM COLLABORATION AND EFFECTIVENESS



- CONTINUOUS DELIVERY OF REGULATORY COMPLIANT APPLICATIONS

# Overview



## COMPANY

Softway Medical is a software provider and integrator delivering solutions to healthcare organizations. Softway Medical's customers are 1.200 radiology centers and 1.100 healthcare facilities, generating an income of €80 millions.

## CHRISTOPHE LETOURMY

Christophe Letourmy is Product Manager at Softway Medical.

**1 company vision**



**5 software Applications**



**700 stakeholders of wich 300 in R&D**



**Dispatched on 10 sites**



## CHALLENGE

- Modernizing legacy development tool set
- Scaling agile practice and synchronizing 300 stakeholders located on several sites
- Optimizing quality management system to make compliance auditing easier

## SOLUTION

- Plan "Tuleap Enterprise Expert », on-premises
- Subscription « Tuleap Open Roadmap »



With Tuleap, we achieve strategic alignment. This means we bring the actions of each team into line with our company's strategic objective.



| Christophe Letourmy, Product Manager and RA Leader at Softway Medical

# The double challenge of Agile Development and evolving Medical Compliance standards

## The situation at Softway Medical

The growth of the company brought out **with new challenges**:



**Organizational:** Softway Medical was growing with dozens of software development teams. How to synchronize 300 stakeholders, dispatched on several sites?



**Regulatory:** with the recent EU regulation in the medical compliance world, the number of applications of Softway Medical subject to regulation has increased from 1 Medical Device to more than 10 medical devices. How to optimise project management and quality processes to make compliance auditing easier?



**Technical:** how to manage not only one big historical software application but also many micro-services with interdependencies? Softway Medical has to both separate project environments while aligning them.

## Which tool to solve these challenges

As Softway Medical was expanding, they realized that their project management and toolset had to be modernized. They decided to change from IBM Rational because the tool was aging and not evolving anymore. IBM Rational was no longer meeting Softway Medical needs and requirements.

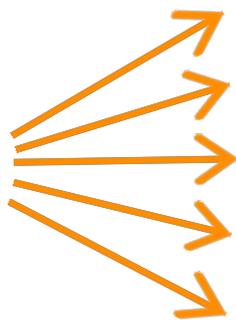
Software Medical had thus to find a new solution capable to achieve multiple challenges at the same time.

If nothing was done to improve the situation, Softway Medical would have gradually slowed down its innovation capacity. The company would not have been able to continuously deliver consistent improvements to its software products.

## The Solution with Tuleap

Softway Medical found that Tuleap was able to meet all the necessary requirements. After a few months of evaluation and proof of concept (POC), Tuleap was deployed on a large scale throughout the company .

**After only 2 months of deployment,** Tuleap had already been widely adopted by users.



- **215 projects in production**
- **322 active users**
- **9.648 artefacts**
- **159 tests executions**
- **239 Milestones and Sprints**

“ Tuleap provides freedom for our teams, and confidence for auditors.. it makes possible to accelerate the delivery of medical technology, and assert compliance with minimal effort. ”

| Christophe Letourmy, Product Manager and RA Leader at Softway Medical

## Moving from Agile at Team Level to Agile at Enterprise Level

For 10 years, development teams at Softway Medical have worked with an individual agile manner. In January 2020, it comes the challenge to make 30 squads (teams) work together. After being coached by an independent professional, it was clear it was time to move to agile at scale.

## Which framework for agile at scale?

“SAFe is a too rigid framework for us. We have rather built a home-made agile at scale approach inspired from SAFe, with the concepts that suits us fine”

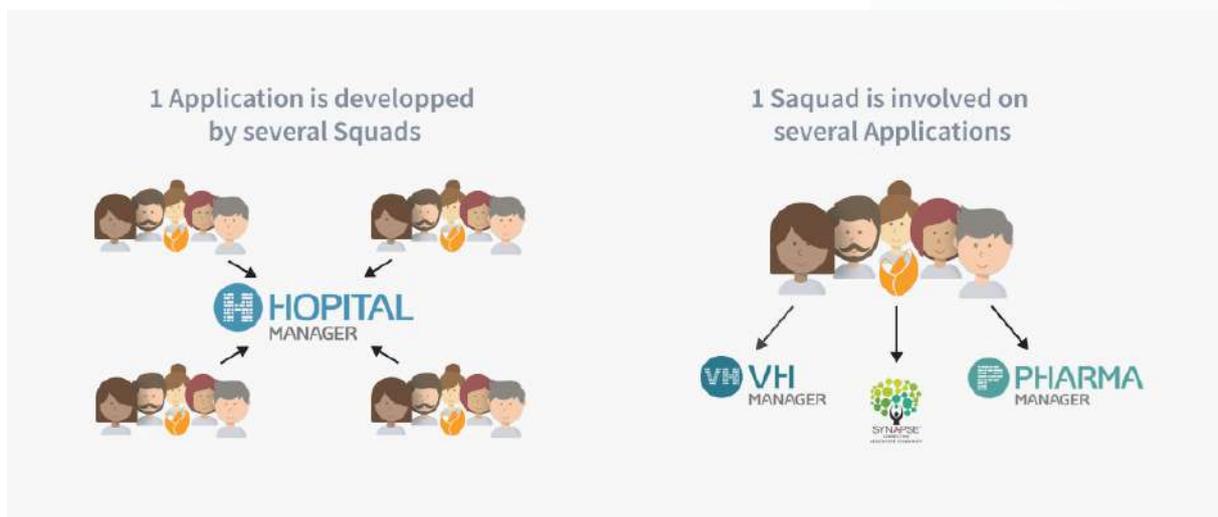
| Christophe Letourmy, chef de projet et responsable AR chez Softway Medical

### Softway Medical has kept the following approaches from SAFe® :

- Multiple levels of planning with specific goals
- Different paces of delivery
- Build incrementally with fast integrated cycles
- Organize around value with cross-functional teams

# Software Development Team Structure at Softway Medical

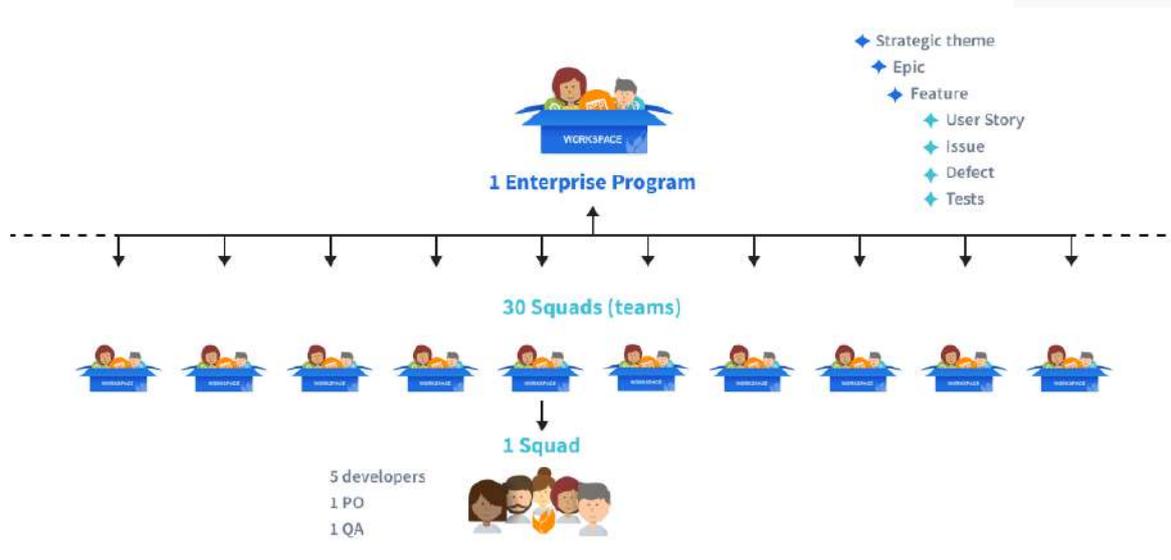
For the reorganization of the whole teams' work, this is how Softway Medical decided to orchestrate:



# Agile at scale at Softway Medical inspired from SAFe

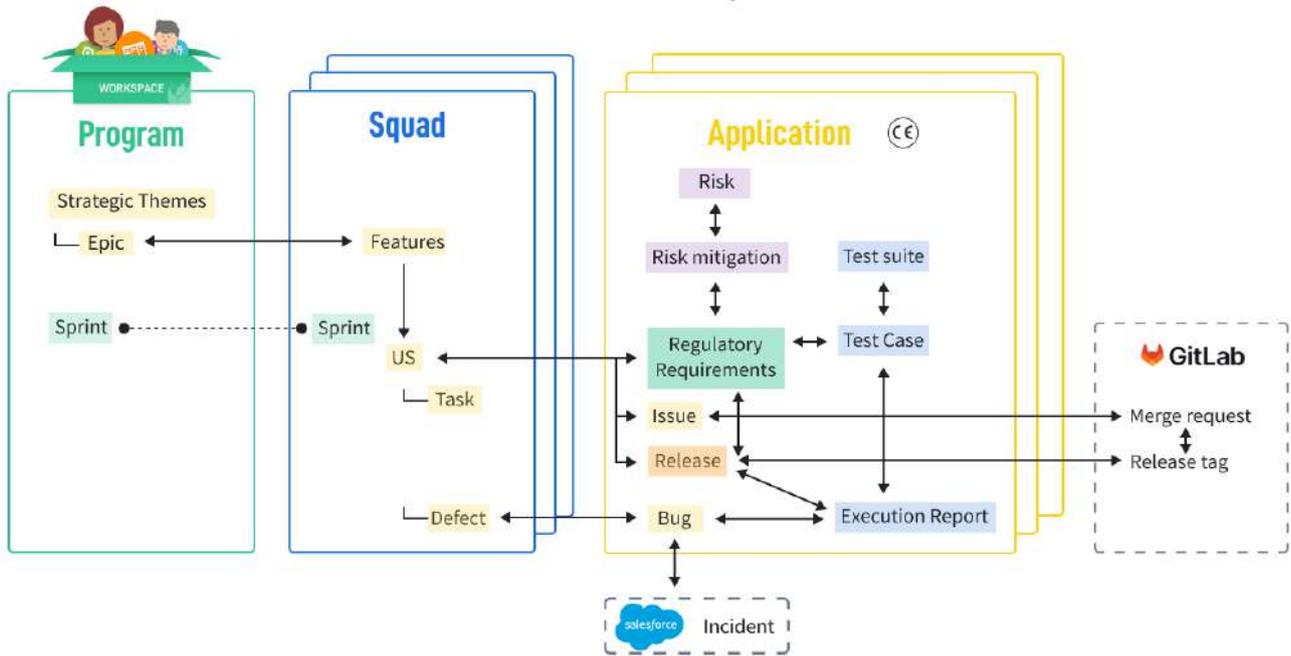
To make the 30-teams synchronization happen, Softway Medical created **3 types of collaborative workspaces in Tuleap**, with a hierarchy allowing work and iterations synchronizations.

- 1 workspace for the **Enterprise Program** sharing the company vision, the scope, and enabling to manage Strategic Themes, Epics and Features
- 30 workspaces for **Squad/Team** work, coordinated with the Enterprise Program, managing User Stories, Issues, Bugs, Issues and Defects. (Each Squad is made of 5 developers, 1 Product Owner and 1 Quality Engineer)
- Several workspaces for Softway Medical's **Software Applications**



## Synchronizing work and achieving full traceability

This workflow illustrates how work items are managed and linked back to each other, in each Tuleap workspace at Softway Medical. As you can see, all work items are tracked into Tuleap: the Top Management managing strategic items and giving the pace for delivery, the 30 Squads working on the Features, User Stories and Tasks and the 5 Application Products storing all regulatory requirements and tests.



### With Tuleap, Softway Medical reaches:

- synchronization of milestones (release and sprints) between the Program and the teams
- coordination of actions with consistent workflows
- real-time monitoring: the roadmap makes it easy to follow projects' progress

“ Tuleap ensures consistency and transparency. It provides us visibility into how well the teams are progressing toward meeting the enterprise objectives. ”

| Christophe Letourmy, chef de projet et responsable AR chez Softway Medical

For continuous integration and Git repositories, Gitlab is integrated with Tuleap that remains the central platform at Softway Medical.

**The automatic end-to-end traceability provided by Tuleap avoids manual work which is generally a significant source of errors.** It also simplifies real-time traceability, as to always be ready for a compliance audit, and ensures that Softway Medical applications are highly qualitative.

## Three paces of work

Leveraging the flexibility of Tuleap, Softway Medical decided to **set up 3 paces of iterations:**



### Enterprise Pace

This 30-to-45-day iteration is driven by the Program, for the delivery of the historical software application (« Hôpital Manager »). Enterprise pace synchronizes the 30 development Squads. Once a month, all the company gathers around the Enterprise Program workspace to assess progress, review Epics, Features and KPIs, and even plan forthcoming iterations.



### Squad Pace

Each team releases after 15 days, at the end of their Sprint



### Micro-services

When this is possible, while remaining

# Ensuring Continuous Compliance for medical standards

Among other regulatory standards, Softway Medical has to ensure product compliance to two major medical norms:



ISO 13485 : Medical Devices - Quality Management Systems (QMS)



EC 62304 : Medical Device software – Software Lifecycle Processes

Tuleap helps quality teams at Softway Medical to manage compliance activities. Now, QA and testers trace and manage all product quality assurance tasks across the application lifecycle management process.

“ Thanks to Tuleap, we achieve an end-to-end traceability. This makes possible for developers to understand the context of a task and get all the history of a defect; and for Quality Managers, to integrate quality goals with day-to-day activities, and implement continuous compliance to accelerate regulatory audits. ”

| Christophe Letourmy, chef de projet et responsable AR chez Softway Medical

At Softway Medical, Quality Engineers are working closely with Development teammates. They have determined 3 types of validation, ("Definition of "done" in agile) Each increment checks and validates its "level" of conformity.

#### Definition of **Done of User Stories**, for the **Product Owner**.

1. Run Functional Tests
2. Merge
3. Check Acceptance criteria
4. Done

#### Definition of **Done of Requirements**, for the **Quality Manager**.

1. Run Automatic Tests
2. Run Non-regression tests
3. Check or complete the Compliance documentation
4. Done

#### Definition of **Done of Requirements**, for the **Release Manager**.

1. Check that all Tests have been run and passed
2. Check that the remaining bugs are not critical issues
3. Check or complete the Compliance documentation
4. Everything is done. He can release.

**Within this context, Tuleap enables Softway Medical to simplify their products verification and facilitates audits.** Quality Managers at Softway Medical can now demonstrate to auditors the incremental development approach and quality assurance strategy they deploy. Plus, exporting test campaigns and requirement matrix in the forms of documents, QA leads can provide proof of all items changes and how they build regulatory validation continuously.

## The results achieved by Softway Medical

***" After only 2 months in production of Tuleap, we went beyond our targets. "***

Tuleap has become the central and reference tool at Softway Medical company. Both the Top management and the Development teams are happy because they achieve their specific objectives.



# Enterprise Outcomes with Tuleap

## Company-wide visibility



The company's strategic vision and goals are now shared among all employees. Tuleap made company-wide transparency possible, gathering together all the company information and projects in one digital and visual space available to all.

## Team alignment



30 R&D teams now work in sync, sharing common objectives and activities progress through easy-to-follow dashboards and real-time chart.

## Facilitated compliance



Tuleap enforces the use of controlled processes to enable agility in full accordance to medical regulatory requirements. Actually, regulatory auditing is now easier because Tuleap helps get an end-to-end traceability, so that everything is tracked automatically with context and date, hence requiring minimal effort.

“ Tuleap has given freedom to our teams, and confidence to the auditors. ”

| Christophe Letourmy, chef de projet et responsable AR chez Softway Medical

## Teams Challenges with Tuleap

**Increase of team work** with shared workspaces, making it possible to know "who is doing what" and to identify bottlenecks. For example, with Tuleap's Kanban boards, teams keep track of work in the form of task cards, making it very easy to see where work items stack up. **Better understanding** of the product scope and development context of the work as Tuleap organizes artifacts and product management.

**Automation on the whole development stream** through the integration of development, test management and CI-CD tools.

**Decrease in errors** with advanced workflows and automations that guide people through their work step by step.

# Going Forward

**Discover Tuleap in action  
thanks to a demo**

**Request a demo**





[www.tuleap.org](http://www.tuleap.org)