

# Agile Success Stories in Healthcare

Build on Experiences and Lessons Learned

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# Summary

How can MedTech companies reconcile agile methods with regulatory requirements? What successes have already been achieved? And what experiences can organizations build on?

This white paper summarizes best practices and success factors that leading healthcare companies have reported from their transitions to Agile. It is based on published case studies from America, Europe, and Asia.

Key findings are:

- Agile has significant advantages over plan-based approaches previously used for medical device development
- The path to Agile is well-explored and safe
- Established agile practices comply with healthcare regulations

The sections of this white paper address the key objectives and benefits of Agile, how to approach agile adoption, and agile success factors. All recommendations are based on experiences from leading healthcare companies. The concluding section discusses possible limitations of Agile and the presented experiences, and it provides an outlook on important agile trends beyond development.

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# The Business Case of Agile in Healthcare

Healthcare companies have moved to agile development approaches because their previously established methodologies became inefficient and hard to manage. The transition to Agile may involve some challenges. However, Agile’s benefits are convincing. They are regarded as prerequisites for business success in dynamic markets.

## Motivation & Objectives

What has motivated leading healthcare companies to adopt agile development? Several organizations have published reports about their agile initiatives. Table 1 summarizes their motivations and objectives.

The three core aspects that appear in multiple objectives are:

- Time to market
- Customer value
- Team collaboration

Of course, quality and productivity also count and are expected to be improved further by the introduction of Agile methods.

Objectives	Reported in Case Studies			
Reduce time to market			[P]	[S]
Improve predictability of releases		[G]		[S]
Respond to customer requests or market needs more quickly	[A]	[G]	[P]	
Improve customer value			[P]	[S]
Improve quality			[P]	[S]
Increase productivity and reduce costs	[A]			[S]
Improve collaboration across functions		[G]	[P]	
Improve team alignment, collaboration, and motivation			[P]	[S]

The case studies are: [A] Abbott Laboratories [1][2] [G] GE Healthcare [3]  
 [P] Philips [4][5][6][7] [S] Siemens Healthineers [8][9]

Table 1: Objectives and motivations of agile initiatives at case study companies.

The case studies that this white paper is based on are from Abbott, GE, Philips, and Siemens. They report on agile initiatives that took place over all from 2003 to 2016. The GE and Siemens projects developed software products in the medical imaging domain [3][8]. Philips ran a larger initiative that included development of healthcare information systems and medical devices [4][7]. The Abbott case study is related to a combined hardware/software medical device [1].

## Achievements & Benefit

Throughout all case studies, the results of the agile initiatives fulfilled the companies' expectations. Many of these results match important benefits of Agile that the 2020 State of Agile Report identified [10] (see Box 1).

### **GE Healthcare: Early feedback, transparency, and accountability**

The GE Healthcare report was written within a year after the start of the initiative [3]. Its authors state: "While we've only just begun our journey, we've seen positive results already. Getting feedback early and frequently from customers has let us prioritize features correctly [...] We've seen much more transparency and accountability among our teams."

### **Philips: Speed, customer mindset, and quality**

Philips has conducted a large organization-wide agile transformation that included its healthcare businesses. The initiative started in 2014. Two years later, they have reported the following achievements [6]:

- Average release cycle time down from 18 months to 6 months
- A greater focus on the customer mindset
- Feature cycle time reduced from >240 to <100 days
- Sprint and PI deliveries on time, leading to "release on demand"
- Quality improvements—zero regressions in some business units

### **Siemens Healthineers: Transparency, efficiency, and customer feedback**

The Siemens Healthineers experience report provides a detailed picture of the development organization's internal mechanics [9]. A year after the Agile rollout began, the first large Scrum-based project with 20 teams was completed successfully: "Progress within the project was highly transparent from an early stage and we [reached] our planned milestones."

Important Agile Benefits				
1. Ability to Manage Changing Priorities	70%		[G]	[S]
2. Project Visibility	64%		[G]	[S]
...				
4. Delivery Speed / Time to Market	60%	[A]	[P]	
5. Team Morale	59%	[A]		[S]
6. Increased Team Productivity	58%			[S]
...				
8. Project Predictability	50%		[P]	[S]
9. Software Quality	46%	[A]	[P]	
...				
13. Project Cost Reduction	26%	[A]		

Box 1: Benefits of Agile as reported in the 2020 State of Agile Report [10]: Rank, Benefit, Percentage of Respondents (relevant selection, “...” indicates omissions). The letters in brackets indicate the companies that have reported the respective benefit in their case studies: [A] Abbott Laboratories, [G] GE Healthcare, [P] Philips, [S] Siemens Healthineers.

Additional benefits included [8][9]:

- Team efficiency developed within expectations, although not as well as ideally expected.
- The teams’ learning curves were steep, and enormous amounts of know-how were transferred.
- Agile practices have made the search for wasted effort much more systematic, so that process complexity can continuously be reduced.
- Customer involvement and feedback is integrated closely into the development process, resulting in better prioritization of features and higher customer value.
- Teams perceive work as more interesting, show higher team spirit, and have reduced over-hours.

**Abbott Laboratories: Cost and time savings, quality, and team morale**

The first agile medical device development project at Abbott Laboratories showed the following advances over its non-agile predecessor [1][2]:

- Lower cost, shorter duration, higher quality
- Better, less prescriptive test cases
- Accommodated change
- Better work-life balance and team morale

The authors attribute the achievements largely to the iterative approach of the agile project. This led to early availability of working software, frequent evaluation and feedback, and higher levels of quality assurance.

# Agile Adoption Experiences

The case studies of agile adoption at leading healthcare companies analyzed for this white paper reveal several patterns that are common for most of these companies. They include typical timelines, a pilot-based phased approach, and a set of best practices.

## Timeline

How long did it take the case study companies to implement Agile? The reported time frames span from a bit less than a year (GE Healthcare) to four years (Siemens and Philips). The initiatives' scopes range from new product development project (Abbott) via development organizations of one business area (GE and Siemens) to multiple business areas (Philips).

### Agile implementation timelines in case study companies

The GE Healthcare case study focuses on the pilot project and the start of the rollout in its Imaging Solutions unit [3]. It could build on existing agile initiatives in joint-venture subsidiaries (cf. [11]) and acquisitions (cf. [12][13]).

The Siemens Healthineers [8][9] and Philips [4] case studies cover the start of the agile initiatives in smaller pilot settings to the main rollout phases into large, distributed organizations. The case study from Abbott Laboratories reports from Agile introduction into one larger project without additional rollout. It took about a year from preparations and training to the first internal product release.

### Three Core Phases: Pilot, rollout preparation, and rollout

The overall time frame breaks down into the following three main phases (see also Figure 1):

**Pilot of approx. six to nine months** (Abbott [1], GE [3], Siemens [8][9])

**A few months for overall rollout preparation**, including: (GE [3], Philips [4], Siemens [8][9])

- Attaining management commitment and support
- Planning and preparation of rollout activities
- Training of the organization affected by the rollout

**Main rollout phase of approx. six to eighteen months**, depending on size and heterogeneity of the organization, and on product size and complexity (Philips [4], Siemens [8][9])

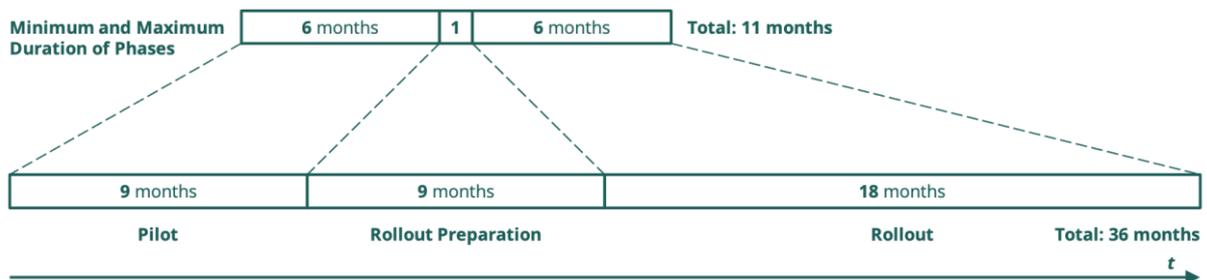


Figure 1: Minimum and maximum duration of phases of agile introduction at the case study companies.

## Pilot-Based Phased Approach

All analyzed case studies build their Agile introductions on pilot projects. Deitsch and Hughes [3] illustrate very well why such a pilot is important: "The objective for our pilot was to acquire scrum experience, understand how we could apply these techniques within our larger business (such as making it work within our Quality Management System), and to build confidence among team members and leadership that we could be successful."

### Phases: From initial experience gathering to continuous improvement

Overall, the case studies report the following phases of Agile introduction, as illustrated in Figure 2:

**Collect and analyze available Agile experience**, integrate already existing agile grassroots initiatives (Siemens [8][9], GE [3])

**Conduct pilot project**, including training of pilot team (Siemens [8][9], GE [3], Abbott [1], Philips [4])

**Plan and prepare rollout, train organization** affected by rollout, establish new agile team structures (Siemens [8][9], GE [3], Abbott [1], Philips [4])

**Start and manage rollout**, preferably in steps of increasing extent and keeping good control over events (GE [3], Siemens [6][7])

**Continuously improve and evolve** agile practices and organizational structures (Siemens [8][9], GE [3], Philips [4])



Figure 2: Typical phases of agile introduction. The three core phases are highlighted in dark.

# Agile Adoption Best Practice

Throughout their agile adoption initiatives, the case study companies have identified important lessons learned and best practices. They are summarized in Box 2. These best practices should be considered during every Agile transition.

In addition, the following three aspects are particularly important.

### Proceed step-by-step

The GE Healthcare report characterizes their gradual, step-by-step approach [3]: "We decided to launch our move to agile with one team. Then after that team was comfortable, roll it out to one site. And, finally, we could take it to all of our development sites globally."

### Cross-functional collaboration

A cross-functional perspective aims at involving IT and all relevant business functions into the agile initiative. All stakeholders shall receive

**Agile Adoption Best Practice**

- Build on previous experience
- Conduct thorough training in agile methods (e.g., Scrum)
- Attain executive commitment and support
- Establish team autonomy through self-organizing teams
- Prefer feature teams over component teams
- Involve the support of experienced agile coaches
- Conduct the rollout in a gradual, step-by-step manner
- Apply a cross-functional perspective

Box 2: Important best practices for agile adoption as identified by the case study companies.

suitable training. Philips emphasizes the importance of communication between all stakeholders, and about objectives and progress of the agile initiative [5].

### Core team drives Agile and compliance

There must be a core team that drives Agile introduction and provides support to the projects. This can be a team of internal and external coaches, or a central support team like the Agile Center of Excellence that Philips describes in its case study [4].

In the regulated healthcare domain it is also very important to involve the quality and regulatory team early on, and to keep strong bonds with them continuously (cf. GE case study [3]).

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# Agile Success Factors

What are the building blocks of agile success in the healthcare domain? This section presents important lessons learned that agile initiatives from leading healthcare companies have reported. They range from establishing solid agile workflows on team level, via specific measures for achieving regulatory compliance to automation and tool support.

## Team-Level Mechanics of Agile

The basis of every agile development is the management of team-level workflow. Most organizations choose the Scrum method as defined in the Scrum Guide [14]. It provides the methods needed for effective team coordination.

A report from Philips's agile initiative emphasizes that they systematically established Scrum as their "foundational core" of basic agile practices [5]. Also GE Healthcare, IDX Systems Corporation (later acquired by GE) [12][13], and Siemens Healthineers chose Scrum as their preferred agile method on team-level.

Omnyx, a joint venture subsidiary of GE Healthcare, has published an experience report that describes in detail why and how they "very early on [...] chose Agile (Scrum) as the approach to go about developing [their] product(s)" [11][15]. They "intentionally shaped the organization such that it was most conducive to Scrum, providing a fertile ground to build a strong agile culture." Their measures involved design of office space, establishing a suitable matrix organization, and maintaining a rhythm of steady iterative development cycles.

## Achieving Regulatory Compliance

For achieving regulatory compliance, agile case studies report that three practices and approaches are particularly relevant: Definition of Done, hybrid development, and Testing.

### Definition of Done

Definition of Done is the primary means for achieving regulatory compliance in agile development. The Definition of Done is a set of criteria that

each piece of work within an agile iteration must fulfill in order to become part of the iteration's product release. It is a core practice of Scrum [14].

The case studies from GE Healthcare and Siemens Healthineers point out how they use the Definition of Done. "Adherence to regulatory requirements is now largely a part of the doneness criteria that the Product Owner uses to accept features from the team" [8]. For instance, the Definition of Done mandates that in the case of high product risk, mitigation measures shall be built into the feature.

The GE Healthcare report points to the challenge that the additional quality and regulatory steps result in a large Definition of Done [3]. For this reason, agile organizations in healthcare should pay special attention to definition and management of their Definitions of Done [16].

#### Additional Information Sources

*Definition of Done* is described in more detail in an accompanying white paper:

Andreas Birk, "Agile best practice for medical device development: Manage compliance with Agile QMS," SWPM, Apr. 2021.

Find more information on *hybrid development* in another white paper:

Andreas Birk, "Approaching Agile in medical device development: Unlock the power of Agile in regulated environments," SWPM, Mar. 2021.

Access the white papers and related webinar recordings at <https://intland.com/unlocking-the-power-of-agile-in-medical-device-development/>

## Hybrid development

Hybrid development is the capability of combining agile and plan-driven development approaches. In regulated development it is often important to integrate traditional practices into the agile development workflow.

The authors of the GE Healthcare case study note: "Finally, we found that we can be agile, but the rigors of being in a regulated industry require us to operate a hybrid development model with more up-front planning and post-sprint testing than would be found in a pure agile environment." [3]

## Testing

Testing activities are often needed to implement the Definition of Done criteria imposed by regulatory constraints in healthcare. For this purpose, in the agile initiative at Siemens Healthineers, "each Scrum Team had at least one tester who was specially trained to plan and execute tests demanded by regulatory bodies" [9]. During the course of the agile rollout, this specialized knowledge had been transferred to the other team members.

## Requirements & Testing

Scrum does not prescribe nor mandate any specific technical development practices as they are needed for accomplishing requirements, architecture, or testing tasks. Most teams apply user stories as their central means for representing requirements [17][18]. Unit testing and acceptance testing are the main testing techniques used by agile projects [19][20].

### Agile requirements and product owner teams

Agile requirements activities are typically led by the role of the Product Owner as defined in the Scrum Guide [14]. The agile adoption case study from Siemens Healthineers describes how a hierarchical team of Product Owners, led by a central Chief Product Owner, effectively accomplishes the complex requirements tasks inherent in large healthcare products [8][9].

### Agile testing

The case studies from Abbott Laboratories and, again, Siemens Healthineers provide detailed information on various aspects of agile testing. The Abbott case describes how the team developed and refined its agile test case creation. It also explains the benefits of highly iterative testing [1].

The Siemens case study places some emphasis on describing their organizational structures and practices used for agile testing. These consist of three levels [9]: (1) Development-related testing in Scrum teams, (2) integration tests that are contributed by all teams into a central automated infrastructure, and (3) system testing conducted by a dedicated team.

## Test Automation

Agile development benefits much from automated testing practices. The Siemens Healthineers case study describes various aspects of test automation and illustrates its importance [9]:

- "Some developers now write new integration test cases and automate them, and are even busy automating existing test cases."
- "[System] Test cases are automated wherever it makes sense to do so. The non-functional tests have a higher rate of automation than the functional tests."

- "A suite of performance tests runs four times a day for all current code changes."
- "The performance tests [...] have radically reduced the number of performance issues that used to be revealed at later stages of testing."

## Tool Support

Effective tool support is essential for the success of agile product development in healthcare. Both the regulatory constraints and the nature of high-tech products make development particularly complex. Software tools that support agile development and application lifecycle management make it possible to master these complexities.

### Test automation

Obviously, test automation is one area where suitable tool infrastructure is needed [9]. It starts with unit testing in the development environment and ends with large performance testing setups and specialized hardware-in-the-loop test stands.

### Test management

The Siemens Healthineers case study describes that test management tools had to be substituted in order to fit better with the specific demands of Agile [9]: Previously existing tooling was focused too much on centralized test management, while Agile calls for more distributed, team-based approaches.

### Requirements management and traceability

The Omnyx experience report describes how they established traceability in their requirements tool [11]. They mapped Product Requirements Specifications to derived Software Requirements Specifications and further to agile User Stories.

# Start into an Agile Future

What will the future of healthcare product development look like? Foremost, the future will be agile. Agile is best suited to deal with this highly competitive and demanding domain. The provided case studies demonstrate the benefits and that agile development really is viable.

In addition, Agile does not end at development. DevOps and continuous delivery transform system operations and customer relationships. Agile QMS offers new perspectives for rooting quality and compliance into our organizations.

## Agile is for Everyone

Most of the case studies presented in this white paper have been reported by software development organizations of large corporations. Does this imply that agile development in healthcare should be limited to such environments? The answer is clearly that Agile is suited for any type of development.

### Organizations of all sizes

First, Agile is for every size of organization. Case studies about agile initiatives often come from larger software organizations because these have typically been early adopters of Agile: They have the resources to investigate new trends early, and software development has been the origin of agile methods.

Among our case studies, Omnyx has many characteristics of a startup organization [11]. For startups and smaller companies in healthcare today, it is most common to use Agile from the outset (cf. [21]). This leaves medium-size enterprises with possibly the largest challenges for an agile transition. However, the rich body of accumulated experiences on how to approach an agile transition offers much practical advice and safe guardrails for every journey to Agile.

### Combined hardware/software development

Second, Agile is not for software only. The Abbott Laboratories case study represents the development of combined hardware/software medical devices [1]. The interfaces between software and hardware development can indeed offer some challenges for Agile. However, many companies

have managed these challenges already. Even hardware development can follow and benefit from agile methods (cf. [22][23][24]).

## DevOps & Continuous Delivery

Agile lays the foundation for advances beyond the direct context of development, in particular for DevOps and Continuous Delivery.

### Improve service quality and customer satisfaction

DevOps is an approach and a set of practices that combine software development (Dev) with IT Operations (Ops). It is based on and requires Agile. Among its benefits are higher service quality, proactive improvement of software-based services, and enabling Big Data applications.

Continuous Delivery is the ability to deliver software updates and new features with high speed and frequency, built on DevOps. Especially in the context of web-based software services, Continuous Delivery can improve product quality and customer satisfaction. It can even enable new software-based business models.

### BDD and User Story Mapping as enablers

Among the presented case studies of agile initiatives, two present roadmaps that include DevOps and Continuous Development as future objectives [9][4]. A recent report from Siemens Healthineers describes which agile practices they have established, like Behavior-Driven Development (BDD) and User Story Mapping, in order to enable and support Continuous Delivery [25].

## Agile QMS

Agile also has the potential to transform Quality Management Systems (QMS) and related measures for managing regulatory compliance. Important characteristics of an Agile QMS are:

- The Agile QMS is integrated throughout the entire organization
- Quality is rooted in development teams
- The Agile QMS is built on lean/agile practices instead of process control

## Lean QMS builds compliance incrementally

The Scaled Agile Framework SAFe® [26], which has driven the successful implementation of Agile at Philips, includes the practice of a Lean QMS [27] that fosters building compliance incrementally into the solution.

## Cornerstones of Agile QMS

Siemens has defined the following cornerstones of an Agile QMS [28]:

- Pervasive focus on customer and business value
- Personal engagement for quality
- Early testing for fast learning
- Real-time data and open systems
- Prevention, risk management, and systematic improvement
- Quality competence throughout the organization

These characteristics of an Agile QMS, like customer value, early testing, and organization-wide integration, are also the ingredients of the reported agile success stories of leading healthcare companies. So they not only transform development but also integrate development, quality, and compliance closer with each other.

### Additional Information

More details on *Agile QMS* are found in the accompanying white paper:

Andreas Birk, "Approaching Agile in medical device development: Unlock the power of Agile in regulated environments," SWPM, Mar. 2021.

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