adesso business. people. technology.

# Innovative software solutions for the medical technology of the future

www.adesso.ch/en

adesso

# How does software in medical devices need to change in order to enable digitalisation and disruptive business models?

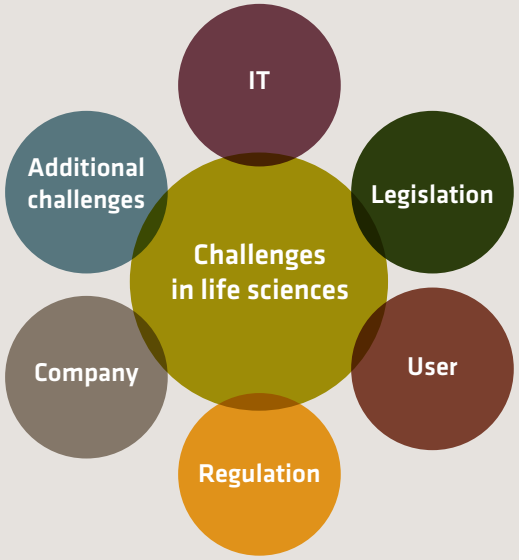
In order to answer this question, this white paper addresses the following topics:

- The challenges in the market
- The current challenges in the development of medical devices
- Ideas for innovative solutions
- Practical example: the virtual laboratory analyser
- Opportunities and requirements from a regulatory perspective

www.adesso.ch/en

# Introduction and the challenges in the market

From time to time, the disruptive business models of new players change entire industries in which companies have been successful for many decades according to proven procedures. Examples of this are Uber in the taxi and rental car sectors and Tesla in traditional automobile manufacturing. These disruptive business models were made possible by software and corresponding innovations.




We are currently seeing that the market for medical devices is subject to considerable changes both nationally and internationally. The resulting challenges in the life sciences market (medical technology, pharmaceuticals and diagnostics) are mainly generated by the digitalisation of medical technology and the overall progression of networking in the health care system. In addition, legislation is in a state of flux, as with the FDA Guidance Documents, for example. More and more medical devices that consist only of software, such as the 'App auf Rezept' (app on prescription), are finding their way onto the market.

In addition to healthcare professionals, patients are increasingly becoming the direct users of medical devices. This places additional demands on the user experience (UX). The Medical Device Regulation (MDR) and the IEC 62366 standard, for example, are significantly improving usability engineering – in other words, the ergonomics of the application.

We are seeing regulatory requirements becoming more comprehensive. In this regard, the new MDR and the IVDR are essential driving forces. In addition, people are also changing: time availability, as well as decentralised cooperation models, are increasingly becoming part of everyday life. Our society is becoming more often confronted with additional challenges that shape our lives and actions. This requires an increase in the rate of development, testing, and approval of medical devices and represents a challenge that demands pragmatic approaches from all parties involved.

In our white paper, we therefore present the opportunities that arise from these challenges as well as appropriate ideas for solutions. Software being part of medical devices is an essential success factor for future digital health applications.

**We hope you enjoy reading this white paper and look forward to hearing your feedback and discussing it with you.**

# Current challenges in the development of medical devices

We now want to take a closer look at the market challenges in the world of medical device manufacturers. New players are arriving on the market in areas that have so far been dominated by conventional and established manufacturers. Whether it's startups from the digital world or large corporations like Apple or Google, these companies have all discovered the healthcare market for themselves and bring their processes as well as their working methods and ways of thinking with them. Long development cycles – sometimes years long – are increasingly giving way to the agile mindset. Today, a solution must be quickly available and just as quickly adaptable to changing needs.

Neither the quality of medical devices nor patient safety may be affected by the rapid and flexible development of medical devices. In order to guarantee this, the current regulations must also be further developed and reviewed. New technologies, such as artificial intelligence (AI), are just as helpful here as the ever-increasing use of existing and ready-made software components. This applies not only to the development cycle of a medical device, but also during operation: to product monitoring, prompt repairs and the use of consumables. A further developed quality management system for the development and operation processes of medical devices is required in order to adequately deal with the associated device development risks.

## Modern medical devices necessitate seamless collaboration

Recently, the interoperability of medical devices has become increasingly important. In an increasingly digitalised world, it is becoming more and more important that devices can communicate in different scenarios. Some examples of this are in the operating room, where an oximeter controls the oxygen supplied by a ventilator, and in a clinic, where test results are available to the physician immediately following a medical examination of a patient.

This trend is also evident in the increasing use of data from other external sources where patients document their vital signs, such as fitness trackers or apps. This enables physicians to make a diagnosis not only on the basis of individual test results, but also to take into account compliance with medication guidelines and other patient behaviour in their decision-making. These topics are essential components of the digitalisation of medical devices.

## Regulatory issues require special attention

The regulatory requirements are constantly increasing. In the European Union and Switzerland, this currently concerns the MDR and InVitro Diagnostics Regulation (IVDR) and their implementation in the development and operation of medical devices. But the regulatory requirements of the Asian market and in particular the huge sales opportunities in China – in addition to the FDA requirements from the USA – also keep the bar high.

# Ideas for innovative solutions

The development of medical devices, with software as an integral part, is an exciting and challenging process. How do you reach your goal after the usual approach? The selection of technologies for implementation takes place once the medical device's technical field of application has been defined and a specification created. Software plays a major role in more and more medical devices. Being an essential component of medical devices, software has an influence on the time to market and generates additional risks in product development. There are special quality assurance measures in place for software. In addition, all regulatory requirements must be met.

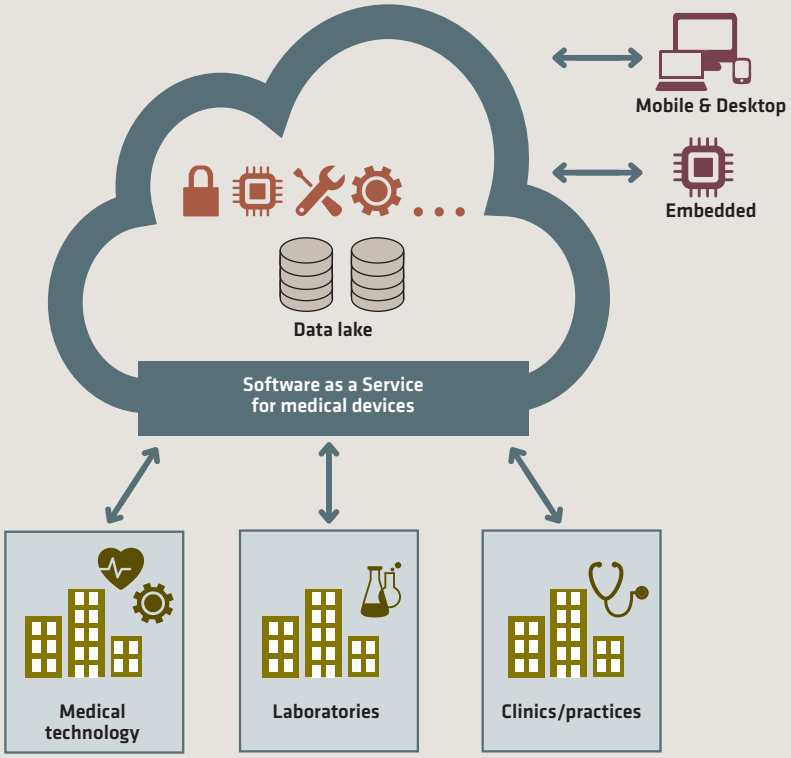
www.adesso.ch/en

## Reusing software components in medical devices

In order to take the above factors into account, you need a quality-assured software development process with regulatory documentation that is generated in parallel. This essential process takes time, which can extend the development time of medical devices.

This is where the first innovative solution comes into play: reusing software components in a medical device. The concepts of modularisation and reuse are widespread in the field of software development. A well-defined software component with a limited scope and clearly defined context, such as user administration or change logging, can be used as part of different systems or products. Such components, in particular, have relatively high safety requirements, which can be met through careful design and extensive quality control.

For the development of medical devices, separate software components can be created with a software core that can be reused in different medical devices. Since every medical device has particular requirements for the software used, the software components – starting from a software core that is always the same – can be highly personalised to meet this goal. Reusing software components that are already quality-assured and tested by regulatory authorities reduces the time to market, costs and product risks.




## New opportunities thanks to cloud technologies

Scalability, availability, data analysis and interoperability of software components: these are the latest aspects of interest in terms of reusable software components in medical devices. These are components of the Software as a Service (SaaS) concept, in which software components are centralised services in the cloud. As with other forms of cloud computing, availability and scalability play a particularly important role. Examples of such software services are collaboration, e-mail, CRM, ERP and document management solutions. Users can access them via a browser.

The advantages of SaaS concepts is the wide range of mature and well-tested services that can be adapted to specific requirements and applications. Deployable on various types of end devices and operating systems, they provide the user with access to the application data they need, independent of the user's location. The centralised collection of data – including data from business processes, orders and medical devices – creates data pools that are the starting point for using artificial intelligence (AI) for business process optimisation and data analysis.

Using Software as a Service for medical devices (SaaS-MD) enables you to successfully meet the challenges described above in the field of medical devices. Software for the development of medical devices, either as a part of medical devices or as a standalone medical device, is provided in part or entirely as a service in the cloud. The services are developed and verified according to current medical device standards. They are connected to and used by medical devices, but also by local software systems (LIMS, HIS) and the medical device manufacturers' centralised maintenance systems. These include, for example, information systems, embedded software for medical devices and apps on mobile devices for additional processes or services related to medical devices.

## Modern networking solutions

Networking in the health care system is continuing to increase as part of general digitalisation initiatives within society. Providers of health services and medical devices are also currently developing interfaces for data exchange – for example, on the basis of the FHIR de-facto standard – and are making these available (for B2B). Apple and Google are the biggest players in the B2C market of 'health platforms'. Furthermore, users of mobile devices are willing to make their data available for scientific purposes. This means that in terms of consumers, more and more individual user data is becoming a means of payment in the network – naturally in compliance with legal data protection and data security requirements.

# Practical example: The virtual laboratory analyser

The medical device in this example is a laboratory analyser that can be used in a commercial laboratory or hospital environment. This instrument requires samples to be prepared in a conventional and mainly manual fashion. Patient data and additional information on the analytical procedure originate from the connected laboratory information management system (LIMS), which also receives the measurement results and passes them on to the subsequent reporting.

The analyser has a display and can be operated with touch functions. For example, simple settings can be adjusted on the device, instructions for replacing consumables (reagents) can be displayed and error or warning messages can be edited. The device's software and firmware are usually updated by a manufacturer's technical service specialist – either within the scope of maintenance cycles or in the case of malfunctions that cannot be eliminated by the user on site.

On the user side, a dedicated expert ensures that maintenance intervals are adhered to, consumables are ordered, necessary quality assurance measures are carried out and, finally, that the device deployment documentation is maintained manually in Office documents. The employee knows how the device is being used and whether capacities can still be provided on the analysis device.

## Reusing software components in laboratory analysers

These devices analyse the inserted samples according to previously defined procedures and thus determine the measurement results. A reusable analysis software component provides the software core with the component to execute the analysis procedure. Desired measurement steps, expected results and other parameters are individually entered as definitions into the analysis software component. This means that, as soon as device development begins, a component is built up which can be adapted to the device to be developed or individually extended by further analysis methods.

Another possibility for a reusable software component of the analysis device is connecting patient management with other devices – for example, to a laboratory information system (LIMS) via connectors. At its core, the component provides general patient management. This can be highly customised to meet the requirements of the laboratory analyser and the connected LIMS. The connectors for the interfaces to the LIMS are implemented on the basis of widely used data standards, for example, HL7 and FIHR, and enable an easy connection to other systems.

## Opportunities from using cloud technologies on laboratory analysers

Let's assume that you would like to improve the point of care for diabetics and the laboratory analyser described enables the blood sugar value HbA1c to be measured in the long-term. Its aim is to provide doctors and medical staff with a method for checking whether a patient actually complies with the guidelines.

Some of the software, such as the device control, must still be developed individually. Other components, however, can be selected from the Software as a Service cloud portfolio. These include, for example, the module that evaluates the test, saves the results and transfers them to the cloud and the audit trail module that logs and stores every step performed on the device. With only minimal development effort, you will receive an individual solution tailored to your needs, with which you can start your validation activities promptly.

## The feedback round

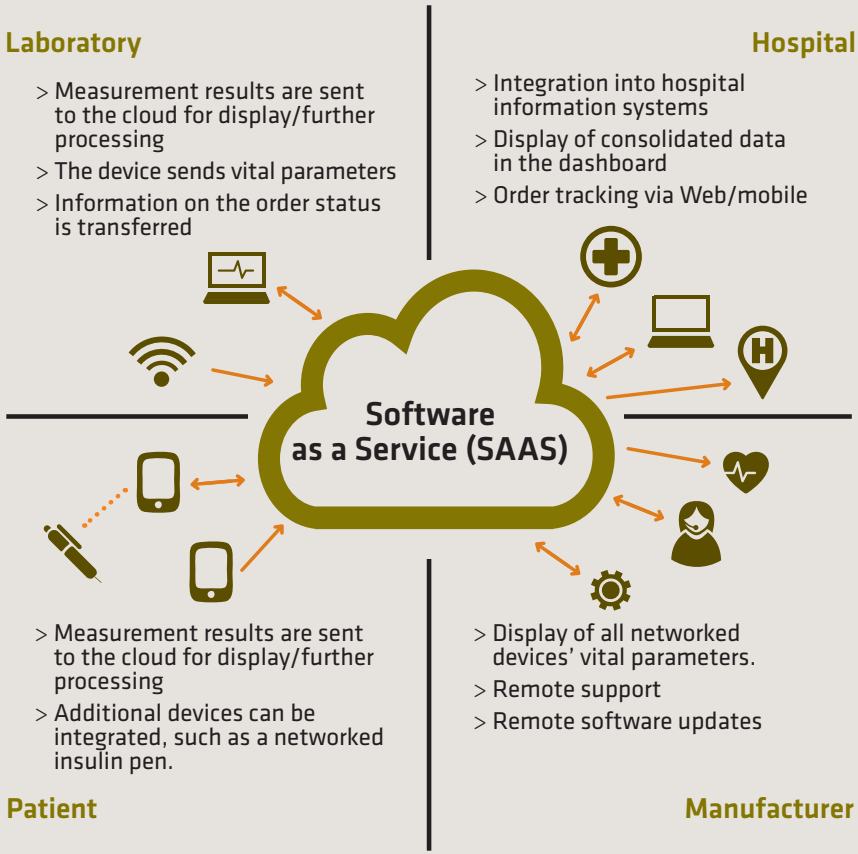
In order to receive early feedback, present your device, which is still undergoing validation, to the relevant doctors for testing. If you receive suggestions for improvement or if there are additional requirements, the implementation is carried out quickly and without much effort thanks to the flexibility that the Software as a Service concept offers. The integration service includes all common interfaces, for hospital, practice and laboratory information systems. This enables the consistent tracking of all incoming and outgoing laboratory orders. These can then be displayed and tracked in a Web app, for example.

## The expansion of marketing activities

Once the validation has been completed and the CE mark is issued, you can begin selling and expand your marketing activities. Imagine being at a trade show exhibiting your device, when you come into contact with a company that offers blood glucose measurements via a patch using an app. You realise that your ideas would complement each other perfectly. You then agree to consolidate the data from your device along with the blood glucose readings and provide it to your healthcare professional as a diabetes dashboard.

The Software as a Service cloud also offers the proper solution for this: by providing a 3rd-party integration service, the app can send data to the cloud for processing and presentation in an easy-to-use manner.

Now imagine that after some time you have sold a large number of devices and you would like to expand the analysis portfolio of your device. You have already developed the appropriate test and are now faced with the challenge of distributing the necessary software changes to the devices that are already in use. Thanks to the cloud-based architecture, you can automatically distribute the necessary updates to all connected devices and provide your customers with the latest software version.



## Constantly solving problems with continuous new developments

Let's go another step forward. Let's say you want to add an insulin pen to your device that logs the delivery and makes it available to your healthcare provider. Since the pen is controlled via an app anyway, connecting to the SaaS cloud is no problem: you have the option of synchronising the insulin pen's corresponding interfaces as well as the interfaces of other devices with the cloud, and displaying their data in a user-friendly way.

In addition to the many possibilities that arise during development with the help of Software as a Service, this method offers significant advantages in the operation and maintenance of your medical devices. Of course, it would be best if your customer had no problems with the device. However, since this is not always possible, your employees have the option of connecting to your customer's medical device and solving problems that arise together.

In addition, the vital parameters of the device in question can be recorded via a feedback channel and made available to you for maintenance. This enables you to identify at an early stage whether, for example, certain components of the medical device, such as lamps, have exhausted their service life and need to be replaced.

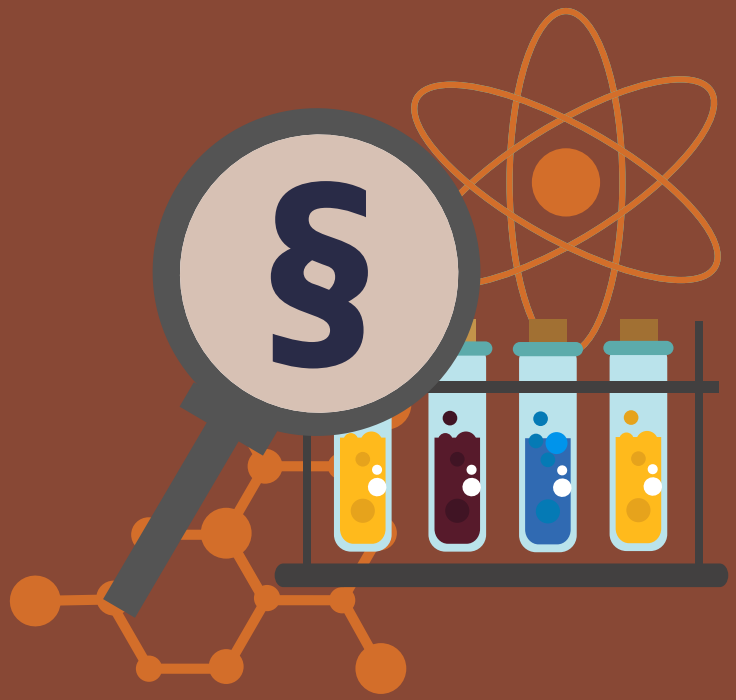
## Modern networking solutions

The B2B interfaces for medical devices are now fully developed. Prior to FHIR, HL7 was an all-encompassing and bulky format, which could not always guarantee perfect communication between interlocutors. Thanks to FHIR, which is now also available in version 4.0.1, it has become much easier to let systems interact with each other. The resources are made available thanks to RESTful services. The goal of a Software as a Service solution would be the combined usage of existing resources to provide an API that allows you to create high-quality services. Service layers emerge, which gradually take over higher-value tasks.

It is important to carry out digitalisation efficiently because, with each new service, the modular system is expanded to implement the next steps continuously and even more efficiently. Management tools that are required for the resulting residual APIs are also available as a cloud service – for example, https://apiary.io from Oracle.

The example of the laboratory analyser makes one thing clear: we make it possible for modern networked supply chains to automatically re-order consumables, provide clinics and practices with feedback on laboratory orders and transmit the results of analyses directly.

## Opportunities and requirements from a regulatory perspective




These new opportunities from the areas of IT technology and the associated methods demonstrate that you have the opportunity to use medical devices more efficiently and effectively in everyday life. However, these products are subject to comprehensive regulatory requirements, which also have an impact on the IT solutions used.

## The current regulatory framework

It is important to ensure the safety of patients. Therefore, when developing software for medical devices, in addition to the software development side, it is important to also carry out regulatory checks and perform verification and validation (V&V), which are described in the harmonised standards. Serious estimates reckon that an expenditure surcharge of 50 to 100 per cent for the defined processes of quality management and for the preparation of the documentation is required by the regulatory authorities.

In addition, the recently tightened legal provisions on data protection and information security must also be observed. Special rules apply to the personal data of patients in order to prevent negative effects caused by their publication or unobserved changes by third parties.

## Modern IT technologies in coordination with regulatory requirements

An important aspect of the aforementioned ideas for reusability is the handling of standard software in the development process. To exclude risks for medical devices, the off-the-shelf software (OTS) must be validated before use. Appropriate documents must be used to demonstrate their applicability to the specific situation. You can reduce the effort considerably through repeated usage. Finally, the documented tests for verification are made readily available and the tests for validation can be easily adapted.

## Quality assurance

If you want to use services from the cloud, the development must comply with standards and be supplemented by certified quality management. Using Software as a Service for medical devices (SaaS-MD) reduces the effort needed for technical documentation by allowing the service provider to create large parts – such as specifications, technical risks, architecture and software design – for these components on a one-off basis. As the legal manufacturer of these medical devices, these are copied into your medical device file. The tests for the verification of the services, however, are also carried out by the service provider. Predefined test cases can be provided in order to verify the integration, which you perform in your environment.

The GAMP5 guide divides software in the pharmaceutical industry into categories according to its complexity and the extent of its use. The idea behind this is that, for frequently used software components, the need for individual testing is reduced because errors are detected and published more quickly. SaaS-MD addresses this, reducing not only costs and development time, but also patient risk.

As the manufacturer of the medical device, in terms of its actual usage, you must carry out a supplier audit with the SaaS provider and check the quality management used there and its application. In addition, the tasks and responsibilities are defined in a service-level agreement (SLA).

## The technical documentation

To make the technical documentation for various medical devices available in the document formats of the medical device manufacturer, all relevant contents of the technical documentation in an application lifecycle management system (ALM) are stored by you. Since the documents are created in a modular fashion, you can select the content relevant to your device.

As a result, there will be no unwanted gaps in your documentation. Continuous traceability between the contents ensures that coherent information (specification, detailed design, technical risk and corresponding tests) is provided. The configuration management in ALM allows you to document the versions and specific configurations used in the medical devices.

## Error analysis and evaluation

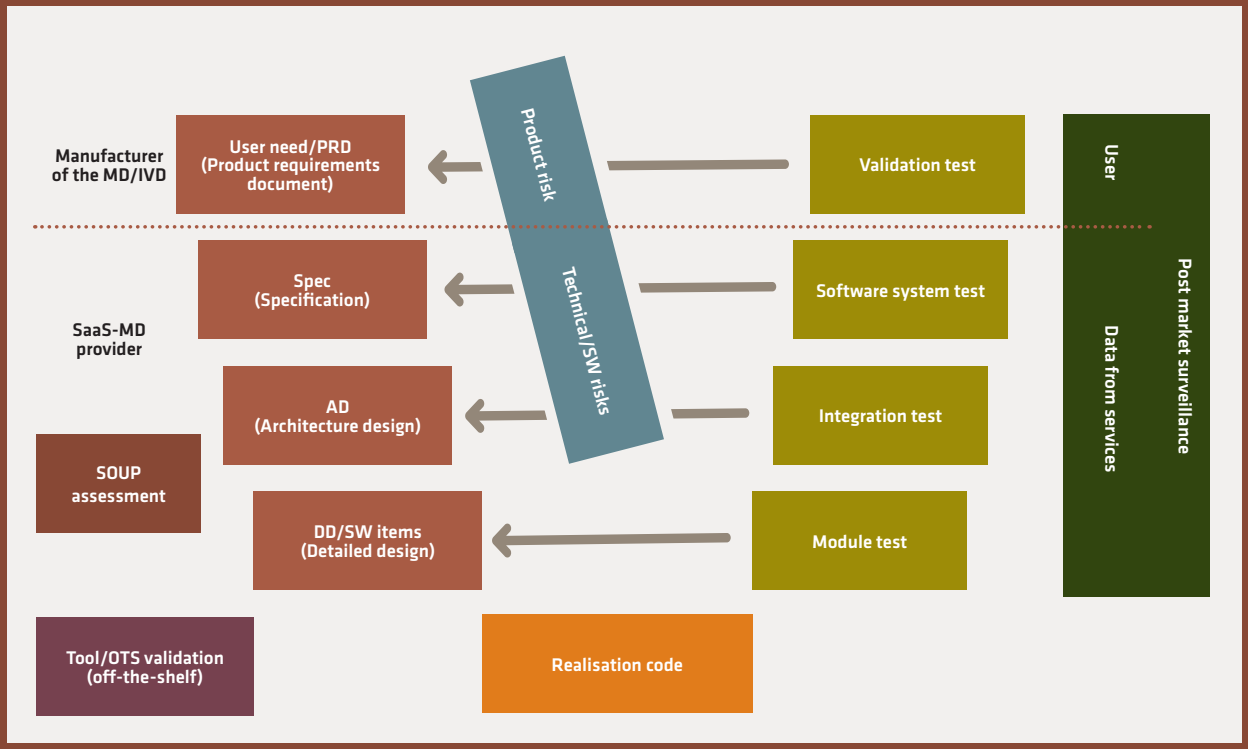
Meeting the additional requirements of MDR for post-market surveillance is made easier through the networking of the services with the centralised maintenance systems of the medical device manufacturers and continuous data transfer. This way, successful usage as well as errors that occur are centrally recorded and evaluated and thus availability is automatically tracked.

The service provider's medical technology experts ensure compliance with data protection and data integrity rules. Experience in the design and implementation of standard functionalities - such as audit trail, data security and user management - is also taken into account by other manufacturers of medical devices when using them for new medical devices. This results in a reduction in the error rate.

While both the assessment and the possible measures for risk management of development tools (OTS) and frameworks (SOUPs) represent a considerable effort for the individual medical device manufacturer, their use is centralised at the service provider. The services are not to be regarded as SOUP – they are ultimately developed according to the standards – but consist of frameworks and other components.

The tracking of possible errors and vulnerabilities is done centrally and is largely automated by security databases. Necessary adaptations and further developments are planned and implemented in a timely manner. You then decide on the application in your medical device after consulting your service provider. This means that the activities are divided between the SaaS-MD provider and you as the manufacturer/distributor. The same applies to the data transmitted by the devices. While the actions of the users are important, the technical data of the services used is an important source for the provider in order to continue developing the services.

Modern networking solutions and the fact that data is stored centrally enables your customers to also run parts of the medical device on mobile devices. Since there is no installation qualification (IQ) in the traditional sense, an intensive assessment of the possible risks is essential. To limit the influences of the terminal device, you must ensure that it is well encapsulated. Unexpected settings and responses of the user device could, for example, lead to an abort with a corresponding error message.




*Dividing up the regulatory activities and documents between the manufacturer of the medical device and the SaaS-MD provider*

## What happens next?

In the course of this white paper, you will have learnt what future software solutions for medical devices might look like and which content, technical and, above all, regulatory aspects must be taken into account.

What advantages result for manufacturers, distributors, suppliers or other parties involved from the opportunities in the further development of the medical product described above? In order to outline this, we would like to give you a brief description of the resulting new business models.

> **Pay per use:** your customers pay per use of the medical device. This could involve a billing model based on the number of tests performed and with possible discounts or benefits for higher usage.

> **Free to use, but give me your data:** your customers receive the medical device free of charge or at reduced cost. In return, you receive anonymised usage data from the device.

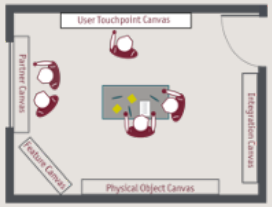
> **Functions on demand:** your customer can enable selected functions of your medical device immediately or at a later date, at short notice and individually – such as new methods of sample analysis. Billing is done individually for each enabled function.

> **A personalised combination of the three mentioned models**

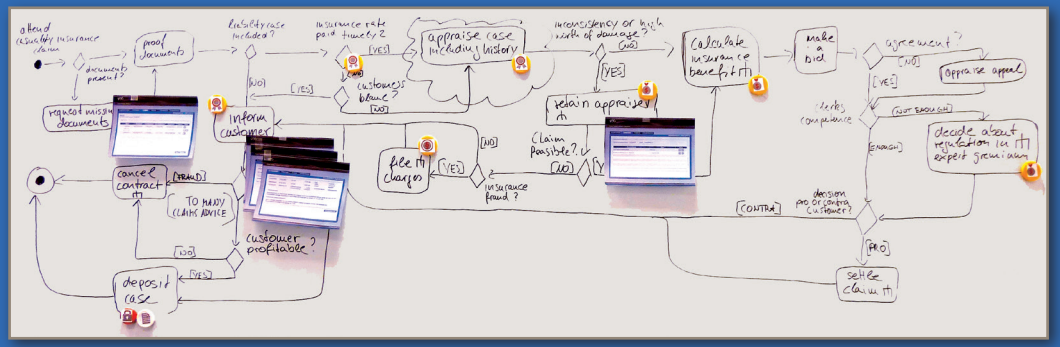
## Together we work out your digital solution

In the **Interaction Room: digitalisation**, we work with you to develop innovative software for your medical devices and show you the disruptive business models for your company.

The Interaction Room method was developed by the research institute paluno: The Ruhr Institute for Software Technology at the University of Duisburg-Essen.




The Interaction Room is a physical or virtual project room for the targeted support of communication between company management, product management, marketing, business departments and IT. The aim of the Interaction Room is to identify new or redesigned medical devices and their associated business models. The needs of all relevant internal and external target groups are taken into account.




The diverse methodological building blocks make the **Interaction Room: digitalisation** an ideal tool for efficiently developing innovative solutions for the next generation of your medical devices in a cross-functional team and making associated disruptive business models successful for the future.

### The Interaction Rooms method...

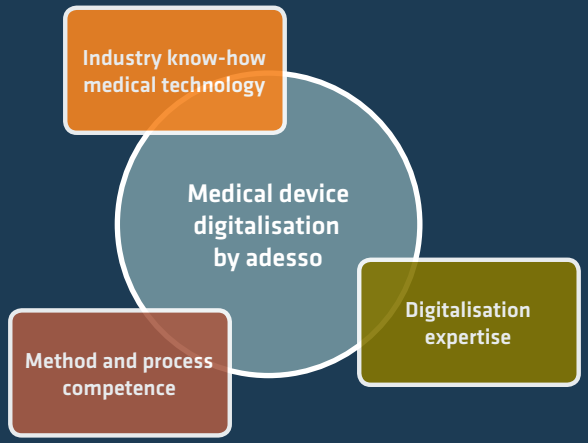
> ...enables the interactive exchange between groups to develop a common understanding and appreciation.

> ...creates dynamics by balancing departmental differences and delivering useful results.

> ...provides simple instruments, modern methods such as design thinking and a comprehensible set of rules, in order to identify and develop important ideas and topics at a glance.

**www.adesso.ch/en**

adesso business. people. technology.




adesso combines proven medical technology industry know-how from numerous successfully completed projects with the necessary methodological, process and regulatory competences.

In addition, our experts have extensive experience stemming from digitalisation projects in various industries.

**Would you like to know how we can provide you with support within this context? We look forward to hearing from you.**

**Lars Schmiedeberg**
adesso Schweiz AG | Manager Life Sciences
Telephone: +41 58 520 98 00
E-mail: lars.schmiedeberg@adesso.ch

**adesso Schweiz AG**
info@adesso.ch
www.adesso.ch/en

Zurich | Bern | Basel | Lausanne | Lugano