



**CENTER
SMART SERVICES**



Consortial Project

Smart MedTech Development

**Agile Development of Medical Technology
Products and Services**

Complexity
Management Academy

Smart MedTech Development

Motivation and challenges

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- Increasingly strict regulations such as The Medical Device Regulation (MDR) pose major challenges for medical technology companies in the development of new products and services: they require new methods, approaches and tools for development and approval.
- Shorter product lifecycles require faster development processes that include agile development methods. Appropriate organizational framework conditions must be created for these.

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- In global competition, differentiation is increasingly taking place through Smart Services, the development and market launch of which is a step that poses great challenges for producers of medical devices.
- The consortial project provides answers to the challenges mentioned above and shows how new development methods can be applied in the field of medical technology.

Your Benefits and Expenses

Benefits

- Gain expertise for the smart development of medical technology products and services.
- Assessment of your current development processes.
- Access to cross-industry best practice development approaches.
- Exchange of experience with the other consortium partners and successful practice companies.
- The design of the regulatory framework as well as the corresponding methods is based on your questions and challenges.
- Achieve a shorter time-to-market and maximum customer benefit by implementing the measures developed in the solution catalogue.

Expenses

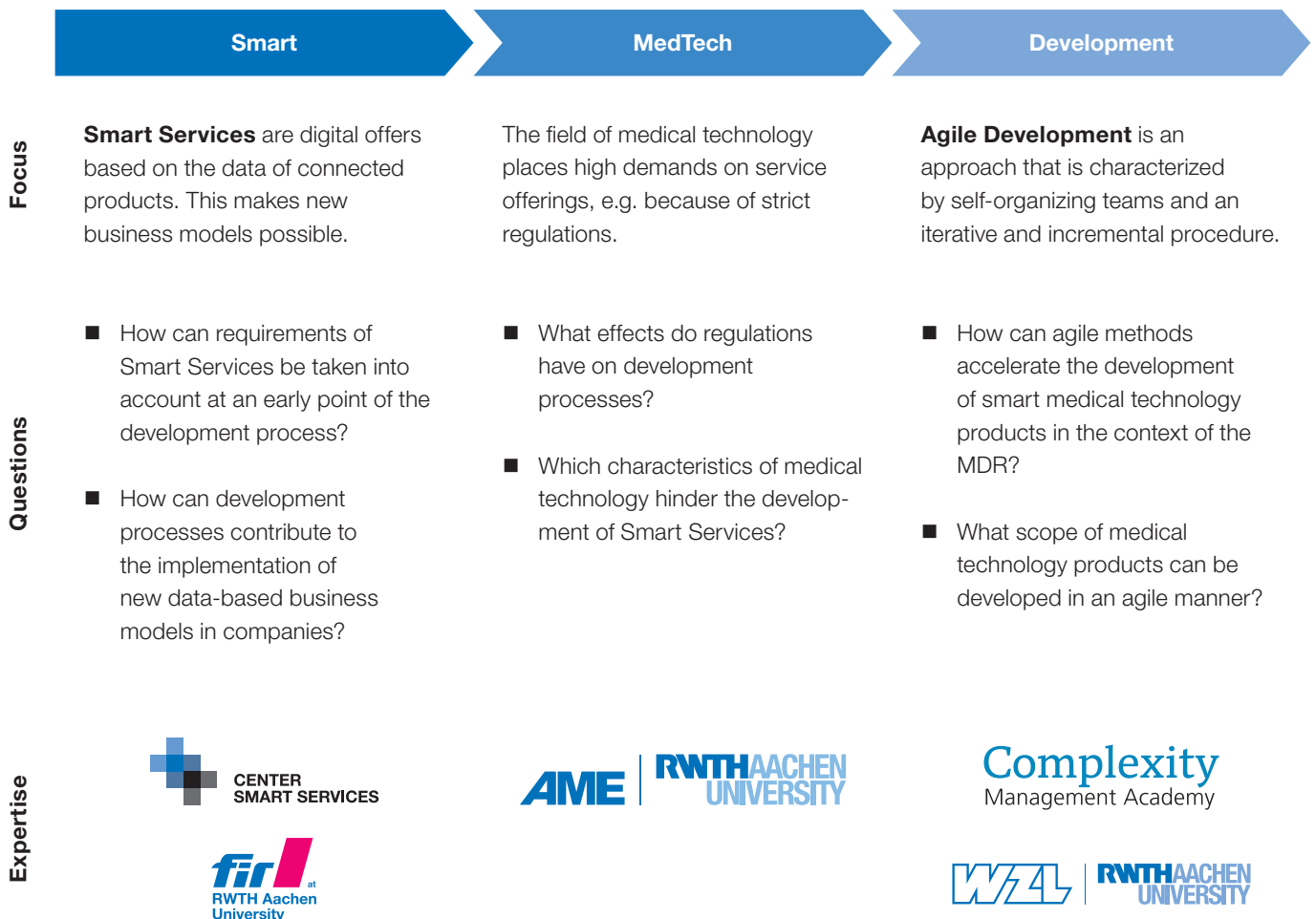
- The participation fee is 50.000,- € per company plus VAT.
- All expenses for the implementation and documentation of the project are included in the fee.
- The participation fee includes a one-day audit of your development in the topics agile development and development of Smart Services.
- You decide which current challenges and weak points of your own development and approval process you want to include in the project.

Project Goal



Benefit from a unique cooperation in the areas of Smart Services, Medical Technology Development and Agile Development on RWTH Aachen Campus.

The organizing institutes and companies of RWTH Aachen Campus combine unique expertise in the future topics “Smart Services”, “Agile Development Methods” and “Clinical issues for Medical Technology”.



Why it is worthwhile to consider the areas of Smart Services, Agile Development and MDR together in the development process:

Field Monitoring

When developing Smart Services in the field of medical technology, requirements of various Stakeholders must be taken into account at an early stage of the development process. A service must add value for the clinic, the doctors and the nursing staff.



Medical Device Regulation

Accelerated Development Cycles

Strict regulations such as the MDR have made development and approval processes more demanding. Agile development offers enormous savings potential through accelerated development cycles and shortened time-to-market.



Smart Services



Agile Development

Regular Releases

Because Smart Products are software-based, it is possible to roll out new features during the usage phase. To do this, an organization must be able to identify changing customer needs in order to feed them back into the development process.

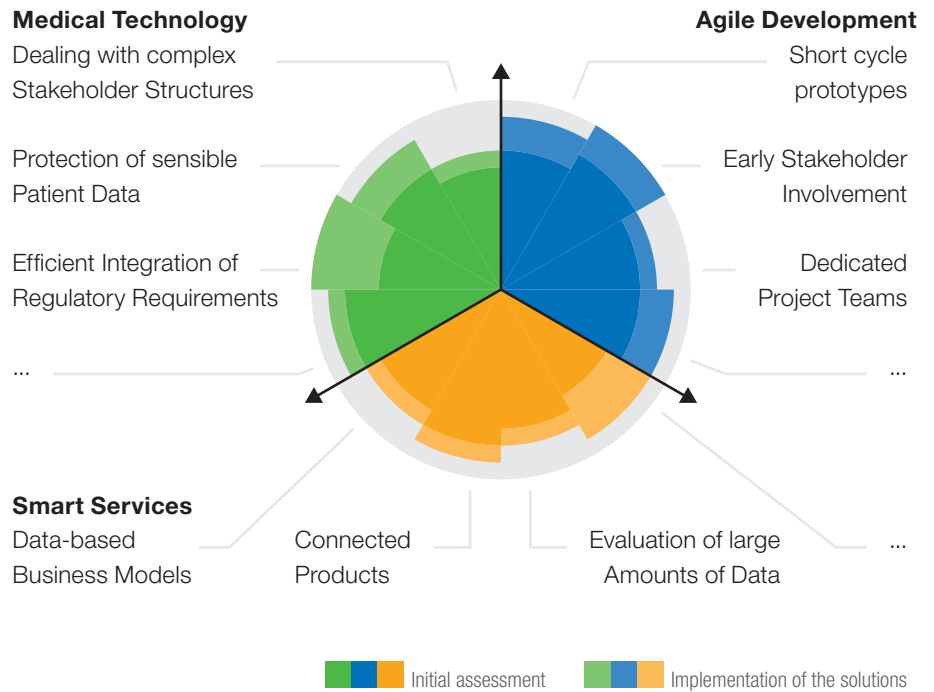


The Procedure

The Maturity Model

A regulatory framework including maturity levels in the areas of medical technology, agile development and Smart Services will be developed for this project. During an audit at the beginning of the project, the maturity level of the participants will be identified by using this framework.

- Comparison of the own maturity degree with other companies in the medical technology sector.
- Derivation of strengths and weaknesses of the organization with regard to the future topics of medical technology.
- Presentation of the status quo and a target state for the further development of the own development organization.



The Solution Catalogue

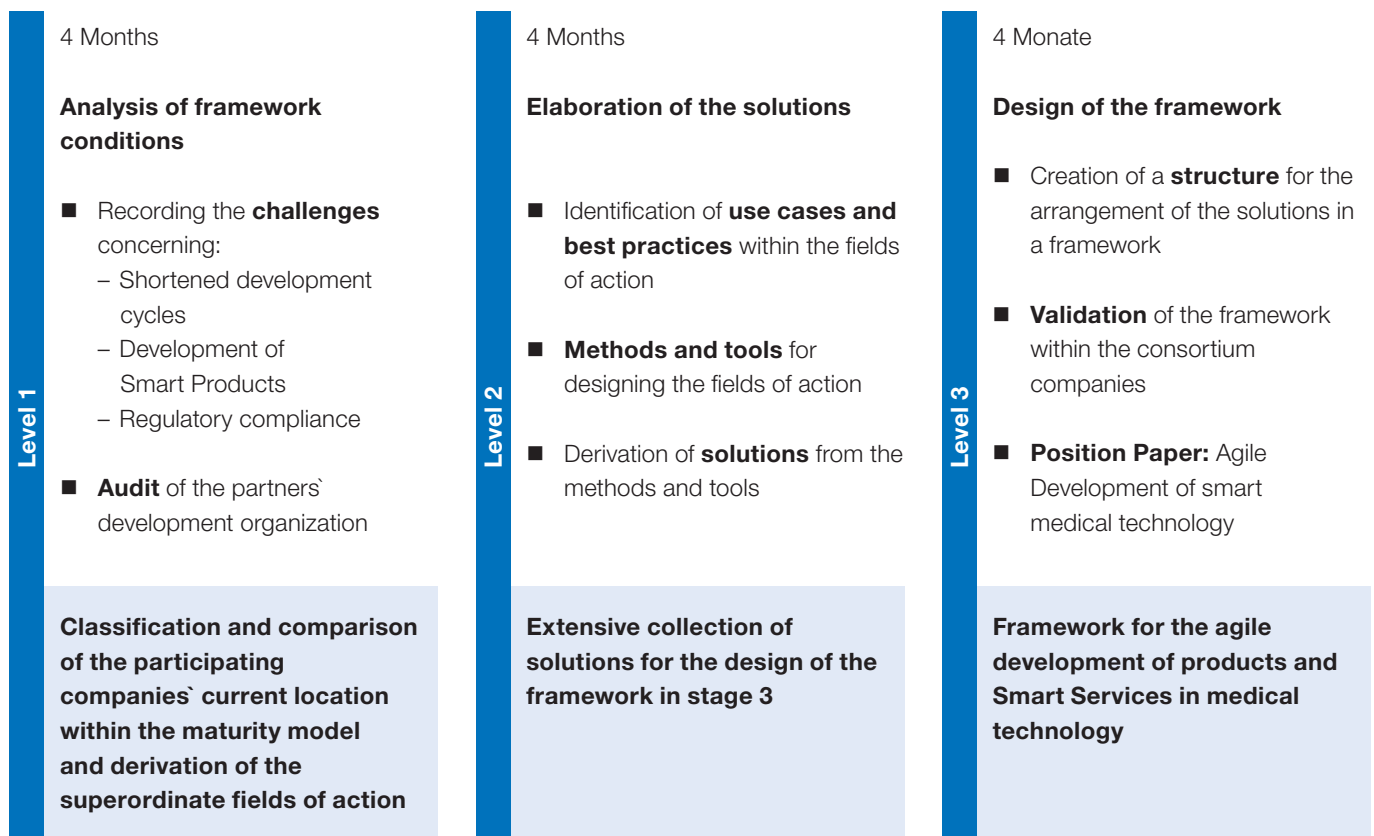
	Solutions	Area
Resources	IT Staff	Green, Blue, Orange
	Processes	Green, Blue, Grey
	...	
Information Systems	Connectivity	Green, Grey, Orange
	PLM Software	Green, Blue, Orange
	...	
Culture	Error Culture	Grey, Blue, Orange
	Innovation Drive	Green, Blue, Orange
	...	
Organizational Structure	Interdisciplinary Teams	Grey, Blue, Orange
	Service Sales	Grey, Orange
	...	

The maturity model points out deficits of the company with regard to the implementation of the future topics of medical technology, agile development and Smart Services. In order to enable the further development of the organization, generic solution modules are developed and combined with the fields of action of the maturity model. The solution modules relate to four areas: Resources, the information system, culture and organizational structure. They ensure comprehensive monitoring of the development organization. The detailed monitoring shows which future topic will benefit most from the implementation of the respective solution. By implementing all the solutions from the catalogue, your company is able to bring medical technology products and services faster to the market and in a more targeted manner.

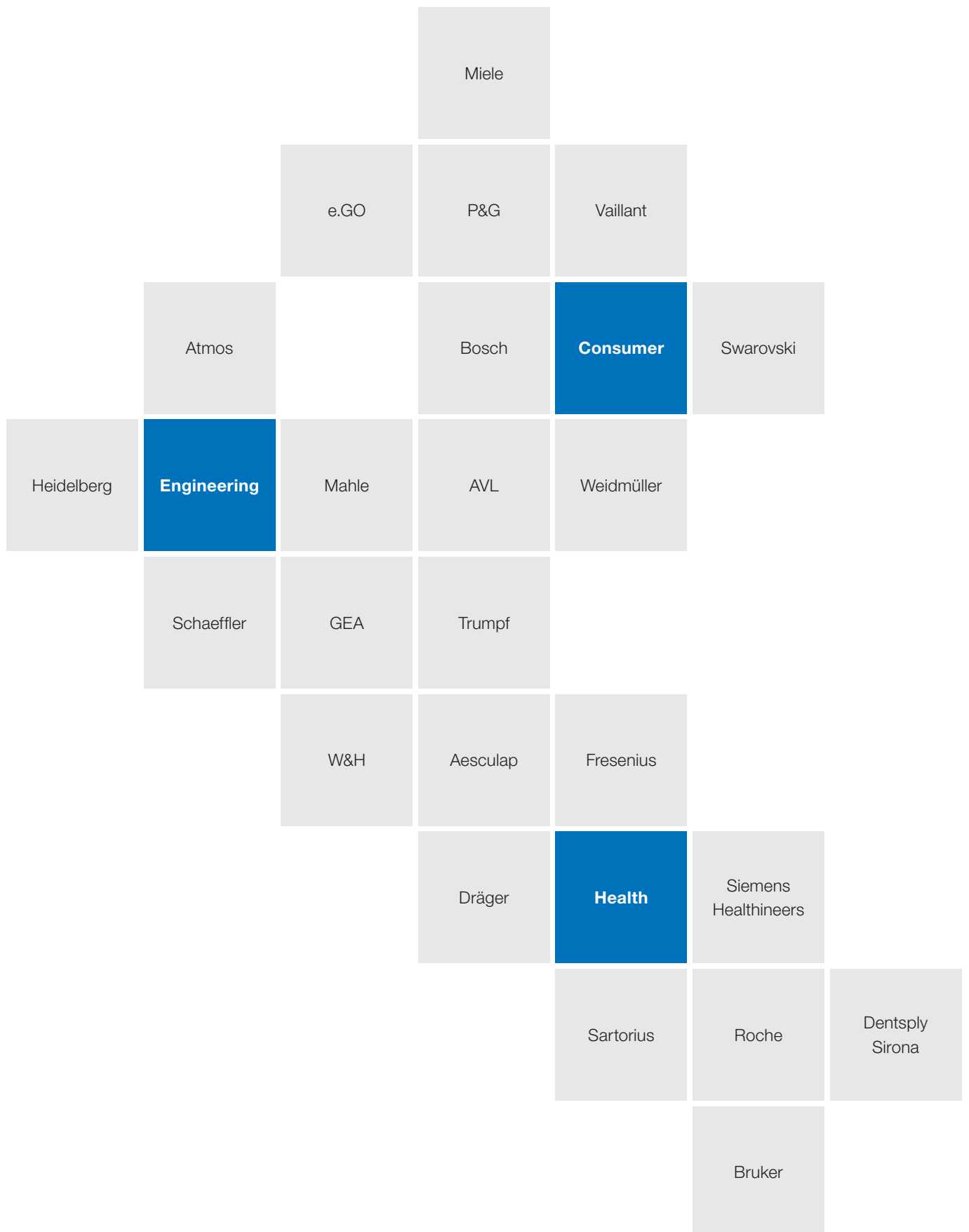
Time Schedule of the Consortium Project



Kick-off November 2020 **1. Review meeting** March 2021 **2. Review meeting** July 2021 **Finish** November 2021



References



Our Network of Experts



Center Smart Services

The Center Smart Services develops marketable data-based services together with its Center members. The Center portfolio addresses companies in the area of Mechanical and Plant Engineering and the Manufacturing Industry, who want to open up new business areas with Smart Services or use modern methods of data analysis (e.g. machine learning) to benefit from their data. The Center's services include the development and application of methods for the design of digital business models, further education offerings and industrial services for the introduction of digital business models in companies.

www.center-smart-services.com



FIR e. V. at RWTH Aachen

The FIR e. V. at RWTH Aachen was founded in 1953 and has 130 employees, including 55 scientists. The goal is to create a bridge between science and business in industrial management. Annually, 40 publicly funded projects and 60 projects with industrial customers are carried out at the FIR. Its competencies lie in Service Management, Information Management, Business Transformation and Production Management.

www.fir.rwth-aachen.de



Cardiovascular Technology of the Institute of Applied Medical Technology at RWTH Aachen University

The Cardiovascular Technology (CVE) teaching and research area of the Institute of Applied Medical Technology (AME) is the original nucleus of the Helmholtz Institute for Biomedical Engineering at RWTH Aachen University. Founded in 1971, today's research focuses on the development of new systems in the areas of cardiac and pulmonary support and heart valve replacement, as well as basic research in the areas of blood compatibility, numerical simulation and experimental testing.

www.ame.rwth-aachen.de

Complexity Management Academy

Complexity Management Academy

The Complexity Management Academy focuses on individual training in complexity management. In addition to the extensive range of open seminars and company-specific in-house seminars, the Complexity Community develops success patterns for tomorrow's complexity management and product development in a network of experts from a wide range of industries. With more than 50 partner companies, this network is unique in Europe and offers the ideal platform for the exchange of information on all current topics of complexity management and agile product development.

www.complexity-academy.com



Machine Tool Laboratory of RWTH Aachen University

The Machine Tool Laboratory (WZL) of RWTH Aachen University focuses on the entire range of production technology issues. The Innovation Management Department at WZL has many years of experience from numerous research and industrial projects in the field of complexity and development management. Especially in recent years, WZL gained valuable experience in the field of innovation management, including in the medical technology industry.

www.wzl.rwth-aachen.de

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P. 6: Nik MacMillan/unsplash.com

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