

Result Report



Market access

German-Danish network for
innovation and
cooperation in healthcare



Interreg
Deutschland - Danmark



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Imprint

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Project management
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This result report presents a compilation on the key findings provided by the partners working in the work package:



Project management



Ideation process



Project communication & PR



Development process



German-Danish platform for
innovations in the health sector



Market access

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The Access & Acceleration project

The aim of the Access & Acceleration project is to provide an overview of the relevant players within the medical innovation sector in the German-Danish border region (*access*), and to signpost ways to speed up the cycle of medical innovation (*acceleration*). In the last three years, the Access & Acceleration project has examined both the fundamental barriers to market entry and the innovation process in the healthcare sector. The results were integrated into a digital platform where users from the clinical, academic and industrial sectors can find the skills to develop new ideas and create new products for the healthcare markets in Denmark and Germany. The partners participated in pilot projects, pursuing the innovation process from the ideation stage to testing and evaluation, right through to the prototype phase. All of the stages were also documented on the platform. The platform also contains examples of good cooperation between research institutions, hospitals and companies. A database linking regional stakeholders offers the opportunity for future cooperation and the further use of the platform even after the end of the project.

Project facts



March 2019 – March 2022



2.9 million Euros budget, thereof 1.7 million Euros funds



7 partner organisations from Denmark and Germany

Project aims

- ✓ strengthen cooperation between medical providers, companies and universities in the German-Danish region
- ✓ promoting the involvement of patients and healthcare professionals in the user-centred development of innovative services and technologies in the health sector
- ✓ increasing the innovative capacity of companies and supporting them in accessing cross-border markets

Project partners



Introduction to the challenges addressed

It is notoriously difficult to access the Danish and German markets for healthcare products with existing and new technological solutions. It is especially hard for SMEs that do not possess the necessary knowledge and market insight.

One of the main objectives of this work package was to create and provide access to an ecosystem in which members know the healthcare sectors and have clear market access strategies.

Involved in this work package were: Centre of Medical Technology (CIMT), The Maersk Mc-Kinney Møller Institute at the University of Southern Denmark (MMMI) and the Clinic for Orthopaedics and Trauma Surgery, University of Lübeck (UKSH). These partners have close contact to the clinic and companies. CIMT and UKSH are placed in the hospital whereas MMMI is specialised in health informatics and technology. Some of the partners have previously worked with ecosystems in the health sector, which involved research institutions, companies, consulting companies, start-ups among others.

To overcome these challenges, the project partners aimed at

- identifying market barriers, including regulatory standards, guidelines, health economic opportunities and (lack of) financial incentives,
- developing strategies for market access as well as tactics for innovative healthcare solutions,
- identifying opportunities to support processes for adaptation and dissemination of new technological solutions in the health and care sectors, and
- attracting health providers such as hospitals, general practitioners and municipalities in Denmark as well as health insurance providers in Germany to facilitate access to the market.

Within the Access & Acceleration project, the partners worked to reach these goals through three main activities:

- Improvement of the innovation dialogue for identifying market access barriers in Denmark and Germany;
- Development of strategies for access to markets in Denmark and Germany;
- Validation and dissemination of market access strategies.

Market access barriers in Germany and Denmark

Methods and activities

Firstly, the stakeholders and market access barriers were identified through interviews and workshops with actors from SMEs, consultants and researchers. Both interviews and workshops were performed in parallel on the Danish and German side of the border.

The interviews were conducted as semi-structured interviews by phone and were afterwards confirmed by mail. The interview questions were constructed with input from project partners from the hospital, university and the cluster organisations.

A semi-structured interview is a type of interview in which the interviewer asks predetermined questions, but can ask other questions if there occurs a possibility to gain more or deeper information from the interviewee. This method is used because the companies have different characteristics. The semi-structured interviews provided us with the opportunity to be more adaptable in the interview questions.

Some market access barriers were already pre-defined and listed in the interviews, but it was also possible for the interview participants to name others. The pre-defined market barriers were given by Welfare Tech which is a cluster organisation with close contact to companies and their challengers:

- Different laws and regulations
- Language barriers
- Different healthcare systems structure
- Different user needs
- Access to funding for internationalisation activities
- Access to qualified counselling
- Lack of knowledge of how the healthcare system is organised
- Different culture
- Difficulties in collaborating with Danish/German partners

The procedure of the workshop was based on the barriers (or challenges) mentioned in the interview guide. The workshop was divided into three stages:

1. Prioritise the challenges
2. Elaborate and discuss the top 3 challenges in groups

3. Presentation and plenum discussion on the challenges

The addressed market barrier was verified later in the project in a survey with the aim to identify barriers and strategies to overcome these.

Results

In both Denmark and Germany, five qualitative interviews were conducted with partners from different industries and institutions. In total, 20 participated in the workshops.

Main market access barriers identified through the interviews and workshop

1. Barriers regarding the Medical device regulation and national legislation

- Tender process and the high demand for evidence-based products cause problems [Danish company]
- The legislation and structure for the *Hilfsmittelverzeichnis* in Germany [Danish company]

2. Different structure of the healthcare system

- The legislation and structure for the *Hilfsmittelverzeichnis* in Germany [Danish company]
- In Denmark, there is an open innovation environment. However, Denmark struggles with scaling [Danish company].
- The German market is not interested in new innovative ideas because of how the reimbursement system works [Danish company]
- The different health care systems mean different financial incentives in terms of treating patients [Danish and German companies]

3. Market barriers related to language especially German companies pointed this as a barrier

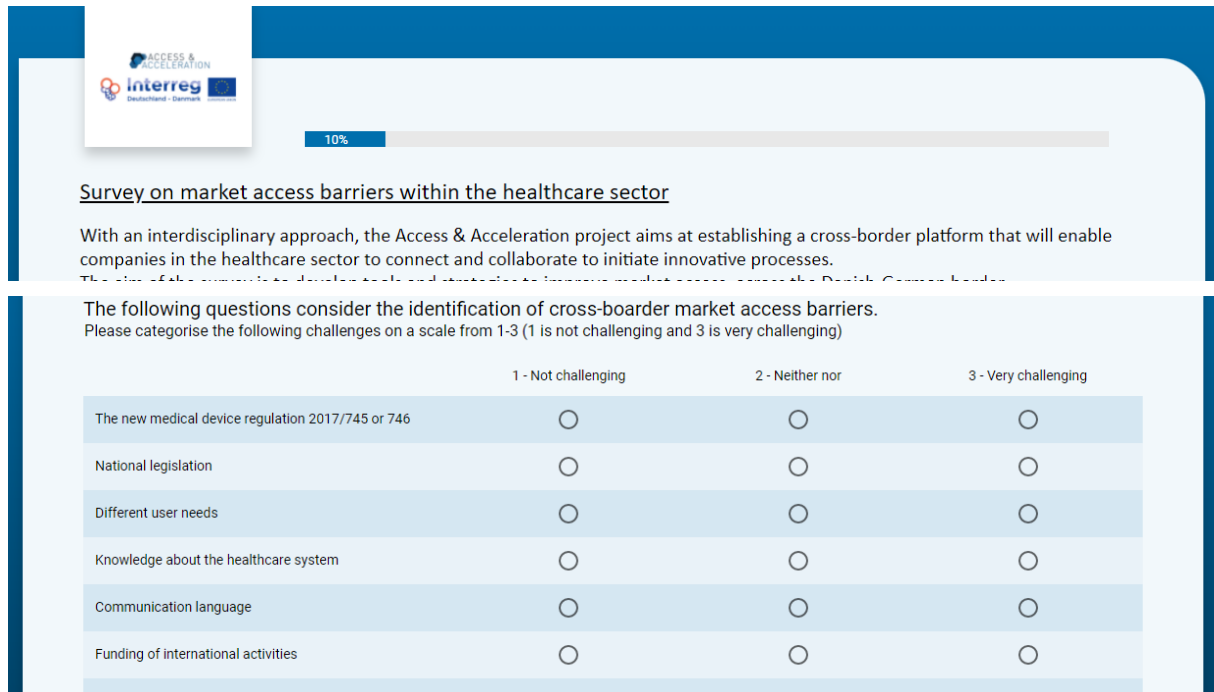
- Relevant information is only available in national language [Danish and German companies]
- Germans prefer to speak German [Danish company]
- Lack of knowledge on tender processes across borders [German company]
- Information and knowledge are in the national language [Danish and German companies]

In the workshops and interviews, the stakeholders addressed the large amount of information available, which can be a big disadvantage for small companies because it takes a lot of resources to go through all the information. Read more about the method and address market entry barriers in the *Report on market entry barriers* [2].

Roadmap to market

Methods and activities

To develop market access strategies, an online survey and desk research were conducted in an attempt to secure input from a wide range of partners from industry, research and public institutions to help define an overall methodology.



Survey on market access barriers within the healthcare sector

With an interdisciplinary approach, the Access & Acceleration project aims at establishing a cross-border platform that will enable companies in the healthcare sector to connect and collaborate to initiate innovative processes.

The following questions consider the identification of cross-border market access barriers. Please categorise the following challenges on a scale from 1-3 (1 is not challenging and 3 is very challenging)

	1 - Not challenging	2 - Neither nor	3 - Very challenging
The new medical device regulation 2017/745 or 746	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
National legislation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Different user needs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Knowledge about the healthcare system	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Communication language	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Funding of international activities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Figure 1: Survey on market access entry barriers

Aim of the survey was to verify the identified market entry barriers found earlier in the project and further investigate how to overcome these barriers. Aim of the desk research was to identify tools and strategies already available and open source on the internet.

Based on the barriers, strategies and information were combined in a detailed strategy report, made for addressing the challenges and solutions. The report is included on the roadmap, which you can find online at [the Access & Acceleration project website](#). The strategy report showed the complexity of the topics and indicated that the large barrier was to get an overview on the information available.

In the desk research, it was found that a large amount of information was available on the internet about getting access to other markets. Therefore, the aim of the tool/roadmap developed in Access & Acceleration was to provide SME with a good overview on useful information on how to start the journey of getting access to other markets. This was done with inspiration from similar tools with other topics like the

OPI- guide from Welfare Tech and Atea's overview of software in the healthcare sector (see Figure 2).



Figure 2: <https://www.atea.dk/brancher/sundhed-og-velfaerd>

Since usability was a high priority in the development, a usability test was both conducted as interviews and later on as a survey more focussing on the content.

Results

More than 300 Danish companies and more than 100 German companies were contacted for participation in the survey. Furthermore, a large number of institutions, business development associations and network partners were contacted as well to assist with finding participants for the survey. In total, 30 individuals from 27 different companies participated in the survey, most from micro-enterprises (n=15).

Four market barriers were identified:

1. The new medical device regulation 2017/745 or 746
2. Lack of knowledge about the healthcare system
3. Structure of the healthcare system
4. Funding of international activities

The language barriers were not verified (n=2) by the survey, but mostly addressed as a barrier in the German workshop and therefore deselected. Access to funding was more prominent and therefore included in the strategy.

The roadmap can be found at <https://www.accessinnovation.eu/roadmap.html>

The roadmap is structured by an interactive image showing the addressed barriers and works as a menu for the roadmap, (see Figure 3), a video is showing how to use the roadmap. For each barrier, possible actions are described with corresponding links to more detailed information. The relation between actions and links is shown with

illuminated links when the user scrolls the mouse over an action. (3) at last a detailed background information on the barrier. At the bottom of the roadmap the case studies and contact information is found.

For each identified market entry barrier, companies find tools on what actions they can take to overcome existing barriers. In addition to the measures, companies will find valuable links to

- webinars that provide guidance on the different problems,
- documents and illustrations that explain structures and processes in more detail,
- databases and portals that facilitate access to calls for tender or cluster intelligence,
- cooperation exchanges and networks to better discuss and solve problems with each other,
- web pages with more in-depth and further information, so that a topic can be examined from many different angles and the user can build up a broad knowledge for themselves.



Figure 2: Interactive introductory picture to the roadmap

1. How to comply with the European legislation?

In the section below the new medical device regulation is shortly described and we will provide you with information and tools that will help your company to solve the challenges:

- Understand and get an overview of the MDR/IVDR
- Share and get knowledge
- Get contacts for clinical investigation/collaboration
- Getting access to a notified body

Actions to comply with European legislations (MDR)

x

Note: Scroll the mouse over actions (bullet points) to see related links.

- Exchange experience with companies from your own network
- Register in cluster organisations
- Participate in a knowledge exchange through networking
- Organise workshops for knowledge exchange
- Appoint an adviser
- Found a special department
- Find and hire a specialist for the company
- Hire an external service provider
- [Obtain an overview of MDR, notified bodies and Eudamed](#)
- Participate in webinars

Networks

- [Find international partnership in Enterprise Europe Network](#)
- [Become a member of Medico Industrien \(DK\)](#)
- [Find the perfect network in Denmark \(DK\)](#)
- [Find your cluster in Germany](#)
- [Improve your network](#)

Information

- [Introduction to MDR \(Danish Medicines Agency\) \(DK\)](#)
- [Understand EUDAMED \(DE\)](#)

Tools

- [Get ready for the MDR \(factsheets\)](#)
- [Find a notified body in the NANDO database](#)
- [Participate in international matchmaking events and trade missions](#)

Webinar

- [Safe and performant Medical Devices for all \(EC webinar\)](#)
- [A Danish angel on the MDR \(DK\)](#)
- [Different angels on the worldwide regulatory process](#)
- [Webinars and lessons learnt by BSI](#)

Background information (MDR)

+

2. Understand the structure of the healthcare systems in Denmark and Germany

Figure 3: Screenshot of the information displayed for the identified barriers

The usability interview suggested changes to primarily make the roadmap less text heavy, and other adjustments. The survey showed subsequently that the user found the roadmap user friendly and useful.

Case studies on strategy application pilots

Methods and activities

To validate the developed strategies for market access, the work package aimed to test these strategies on two use cases. The results should be used to test the usability of the strategies and as basis to further spread the knowledge of the strategies and the roadmap.

The two pilots in the Access & Acceleration project functioned as the case study.

Semi-structured interviews were performed with Henrik Lindholm from Cambio and with Nils Reimers from Stryker. These interviews were transcribed and analysed and placed in a format of one page under the same headlines as the ones in the interview guide.

Results

Case study - Cambio

The case study was structured with first an introduction to the case study, then an introduction to the company (Cambio), information on their process and first steps when they decide to enter a new market, then their experience with some of the prominent market barriers, which tools they use to overcome this barrier, and finally the usefulness of the roadmap.

Henrik mentioned that one of the main barriers they meet is the fact that the healthcare system on new markets are structured very differently compared to the their existing market setup.

Further, he mentioned that the tool they primarily use is network.

He believes that the roadmap is a smart and useful tool for overcoming some of the basic barriers and that it is useful to have a kind of overview map helping to get better understanding of the 'mechanisms' in new markets regarding how healthcare is organised, how it is funded, main features of registration requirements for national bodies and authorities with more.

Case study - Stryker

The largest barrier Stryker faced at that time and what drove their market entry strategy was the level of regulation on medical devices. Ten years before, the European market was much easier to gain access to compared to the US market. Today, it is vice versa.

In terms of overcoming the barrier, Nils mentioned that they had focused a lot on getting their medical device approved on the US market in order to gather data to validate their technology. With clinical data they could prove to the European hospitals that their technology was safe and a viable solution.

Nils mentioned that the roadmap was a useful tool for overcoming some of the basic barriers in terms of registration and certificates.

Dissemination

In the final part of the project work package 6 has focused on disseminating the achievements and results of the work performed in the tasks.

Due to corona, we decided to share our results on a different way than described in the DOA. Instead of hosting knowledge sharing workshops we developed a flyer that we handed out on multiple conferences (WHINN, E-sundhedsobservatoriet, Medicoteknisk

Selskab Landsmøde). Furthermore, we participated in a Networking meeting for Danish companies wanting to enter the German companies hosted by the Danish Life Science Cluster (former Welfare Tech). Finally, we have made an article presenting results that we plan to publish in multiple newsletters and webpages.

Conclusion and perspective

In summary, there is no one perfect strategy for overcoming the various market entry barriers. Every company has different prerequisites and consequently needs a different strategy. Not every company that wants to enter the other market necessarily has to struggle with all the barriers mentioned in this document. The content of this work package has focused on identifying the most common barriers to entering new markets. To overcome these barriers, a digital roadmap to market has been developed to enable companies to access the information they need to develop a successful market entry strategy as easily as possible.

For each identified market entry barrier, companies find tools on what actions they can take to overcome existing barriers. In addition to the measures, companies will find valuable links to

- webinars that provide guidance on the different problems,
- documents and illustrations that explain structures and processes in more detail,
- databases and portals that facilitate access to calls for tender or cluster intelligence,
- cooperation exchanges and networks to better discuss and solve problems with each other,
- web pages with more in-depth and further information, so that a topic can be examined from many different angles and the user can build up a broad knowledge for themselves.

In the interviews and online surveys, it was repeatedly emphasised how extremely important and valuable a well-functioning network is. It facilitates the exchange of knowledge and ideally enables joint action and mutual support in the attempt to access the German or Danish market with their own innovative products.

To ensure usability, the developed strategies were validated through two case studies with Stryker and Cambio. Both case studies indicated that the roadmap was a useful tool and that contained the knowledge on the barriers and tools needed on a basic level.

The final part of the work package focused on disseminating the achievements of the project. The results concerning the knowledge on the different markets and how to overcome the barriers, specifically the roadmap reached the relevant target groups

which were companies aiming to access the German or Danish market and accelerate their process.

Results in a nutshell

- 10 companies included in interviews
- 4 defined market entry barriers
- A roadmap to improve overview on available data on useful information to facilitate market access: <https://www.accessinnovation.eu/roadmap.html>
- Two case studies address companies' journeys and how they could use the roadmap
- 49 participants in the workshops
- 3 knowledge sharing events
- 2 strategies reports

List of publications/references

1. One pager on market access barriers in Germany and Scandinavia, available in German and Danish
2. Report on market access barriers, available in English
3. Report on market access strategies, available in English
4. Roadmap on market access, available at <https://www.accessinnovation.eu/roadmap.html>
5. [Flyer on the roadmap](#)
6. Video as introduction to the roadmap, available at the [roadmap website](#)
7. Evaluation report on the roadmap and its usability, available in English