The DiGAs framework– a model for Europe?

Possible options for achieving a European System

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101017603

digital-strategy.ec.europa.eu/en/policies/eip-aha

Background

To be able to provide high level healthcare for the ageing population, we need to start using more digital solutions. Digital solutions need to have proven positive effects on healthcare, both in terms of medical and economic aspects. The Nordic countries have a national universal healthcare system in place, but the pathway to get medical devices reimbursed varies from country to country. At the roundtable we discussed the current reim-bursement system from a regulative authority, entrepreneurs, as well as from the user's perspective. Through collaboration, the fractioned Nordic- Baltic market could be increasingly attractive for healthcare innovation providers.

EIT Health in collaboration with the IN-4-AHA consortium invited stakeholders to discuss the best practices and challenges that we are facing in bringing digital devices to the Nordic and Baltic market. The event was set up in two sessions. First, the experiences from Germany, UK and the Nordic Interoperability Project were shared, and thereafter, a roundtable discussion between 15 stakeholders representing the Nordic countries and Estonia. The virtual event had around 30 listeners across Europe.

Aim of the roundtable discussions

The aim of the roundtable discussions is to shed light on the current status of digital health applications at a national and pan-European level and to answer the question of whether the German *Digital Health Care Act* can be a suitable model for other European countries. Based on the framework conditions and experiences in Germany, the *status quo* and the transfer-ability of the experiences to other European countries will be analysed. EIT Health have conducted round table meetings in Germany, France, Sweden and Spain to date, and other countries are in the pipeline.

Participants and practical aspect of the round table

We gathered 15 decision makers and opinion leaders from the following stakeholders from Sweden, Denmark, Finland, Norway and Estonia with introductory presentations from the UK and Germany:

- Developers, innovation marketers and competence centres within digital health applications
- Health insurance companies
- Service providers
- Regulatory authorities
- Market access- Health Technology Assessment bodies (HTA)
- Market access experts / consultants
- Healthcare experts

The roundtable participants were first given an overview about lessons from previous roundtables in the Nordics on accelerating innovation in healthcare by Erik Forsberg, previous Managing Director of EIT Health Scandinavia. Experiences from Germany on DiGA, were presented by Henrik Matthies, Managing Director, Federal Ministry of Health, Health Innovation Hub and experiences from the UK on bringing digital health applications to market by Tim Andrews, ORCHA. Thereafter, Anders Tunold-Hansen from the Nordic Interoperability Project gave overview about what has been already done under the Nordic cross-border N!P project. The first session with short pre-sentations was followed by a round table discussion on nine questions.

What is a DiGA per definition?

The German Federal Institute for Drugs and Medical Devices (BfArM) summarised in its guidelines what a DiGA is in the context of their regulation.

A DiGA is a medical device that has the following characteristics[2]:

- Medical device of risk class I or IIa (according to MDR or, under the transitional provisions, according to MDD)
- The main function of the DiGA is based on digital technologies
- The DiGA is not a digital application that merely serves to read or control a device; the medical purpose must be substantially achieved by the main digital function
- The DiGA supports the detection, monitoring, treatment or mitigation of disease or the detection, treatment, mitigation or compensation of injury or disability
- The DiGA is not for primary prevention
- The DiGA is shared by the patient or by the healthcare provider and patient, i.e., applications that are only used by the physician to treat patients ("office equipment") are not DiGA.

2 Adapted from Prof. Dr. Christian Johner: Das Digitale-Versorgung-Gesetz (DVG) – als Hersteller damit Geld verdienen? (johner-institut.de).

With a large ageing population with increasing medical needs, the use of digital solutions will become an important part of the future healthcare systems. The aim of this meeting is to develop validated and scalable methods for integrating digital healthcare apps (DIGAs) into the healthcare system. Several European countries are in the process of evaluating and developing novel frameworks for integrating DIGAs into local and national health systems.

Different stakeholders are contacted by developers and companies and need ways to proceed in a regulated way. The agenda is being discussed in different meetings and progress is being made by different stakeholders on how to introduce digital devices into the market, share data for the benefit of individuals, and to enhance the activity and participation of individuals using digital healthcare applications. In Finland for example, there are recommendation procedures in place for digital devices, and 16 different assessments are in the pipeline.

eit Health

Co-funded by the European Union

1 What are the main challenges in bringing digital health devices to the market?

- Handling reimbursements was considered a main challenge by several participants. Reimbursement models differ between countries. In Sweden, it is solely publicly financed in one way or the other, whereas, for example, in Germany health insurance companies also handle reimbursements. The Swedish reimbursement system is focused on outcome and tasks rather than technology, which has both advantages and disadvantages. In addition, the institution that pays is usually not the one benefitting the most.
- The DiGAs fast-track method is interesting, but the main challenge is clarifying the benefits, contributors, and payments in relation to the stakeholders.
- Clear information about accreditation and markets is needed. For small companies and start-ups, it is very important to have a clear understanding of what is necessary and beneficial for obtaining the approval as a DiGA. At present, it is sometimes perceived difficult to understand what is required to meet and exceed expectations.
- The recognition by central authorities that DiGAs are a new entity that must be approved and prescribed by the practitioners is necessary. In addition, we need to have a system in place to handle DiGAs.
- The hospital sector needs enough funding to buy digital solutions.
- The benefits from medical devices are distributed across the system. The payers, the clinicians and the patients all receive benefits from the digital solutions. The distribution of benefits is not always considered in the prescription decision. How can the motivation to pay be maintained if the payer does not see all the benefits?
- Digital solutions are not going to work without the acceptance from the healthcare professionals. They need to receive benefits from the use of DiGAs, for them to be fully accepted and integrated into the healthcare system. They should not only be involved in sending data to a centralised resource, but also being able to use the data gathered.
- Awareness and knowledge of the existence of digital health solutions, and how they compare to or complement traditional treatments. Maybe we should prepare guidance on how to compare different kind of treatments?
- Trust in the efficacy and safety of these digital devices is instrumental for a successful implementation in a clinical setting. This trust must be shared and distributed in the system to all stakeholders.
- Awareness of local prescription habits. Shared and clear processes concerning how to prescribe and use the DiGAs. It is not only an assessment and marketing issue, but digital devices also must be integrated into the local healthcare prescription procedures for patients, perhaps mimicking the prescription of drugs.

- Being proactive and handling risks on governance. What will be the legal and practical effects on the healthcare systems, when digital applications are increasingly being used?
- Returns on investments, financial benefits of digital applications are difficult to estimate. 42 scientific publications demonstrate economic benefits of digital health applications, but they are difficult to generalise from.
- The six DiGAs that are currently permanently listed in Germany, have all the evidence that their solutions are working, are at least as good as current alternatives in the healthcare system, as they are being very relatable. This can be a starting point for building trust in sceptical healthcare officials. Generally, in Germany, the amount of education necessary for doctors and nurses are underestimated. Many have a very vague understanding of what is needed.
- A structured form of training, from the doctors' point of view, needs to be developed. This has been evident in Germany.
- There is a need for a best practice routine that works in the short period of time (seven minutes) the physician has with the patients. This should be longitudinal and describe what happens months later when the patient returns, and the data is evaluated.

2 Does the current reimbursement system cover the patient's expenses in your country?

- **Denmark**: people pay themselves since the reimbursement does not cover the expenses. General practitioners sometimes recommend digital solutions, but this is on a random basis and largely depends on their knowledge. The current plan is to expand a pilot plan for digital applications to cover the entire country, but the Health Tech Hub Copenhagen is working toward expanding this plan more ambitiously and to make it more like DiGAs.
- **Estonia:** digital health devices are being used in some specific cases, for example, in the diabetes area, where apps are paid for by the government. But this is not the general case. However, several innovation programmes are investigating the benefits and costs of digital solutions. The benefits can be measured in many ways, both economical and for the patient in other ways like being able to do tests close to their home, saving huge amounts of time. The work has begun to build a framework for the use of digital solutions including reimbursements, quality assessments, and building competence and trust in DiGAs.
- **Sweden:** it is the Dental and Pharmaceutical Benefits Agency that is responsible for reimbursements. Regarding digital solutions it could be that applications are included in some cases, like in diabetes care.

eit Health
Co-funded by the European Union

3 Is your country ready to accept digital health devices that have been accepted for reimbursement in other EU countries?

In general, the opinion was that the countries are ready for discussions, but not ready to put it into practice yet. Technical aspects, regulations, organisational and educational aspects are not yet solved. Both market acceptance and reimbursement systems need to be in place. Medical devices in the EU have a common system and cannot be blocked, although their reimbursements are not harmonised within the EU. Any kind of Nordic or European initiative in this context will be a showcase on how to do this in an easy way. It is important for the companies to gain access to a viable market and for the patients to gain access to the digital health applications. It will take a long time if all countries discuss these issues on their own instead of working together.

- The question of evaluation and implementation of DiGAs are two different questions of equal importance. Both are necessary and very important.
- The perceived difference of DiGAs sold either directly to the patients or to the healthcare system was also discussed. These are two totally different business models, where the digital applications are paid for by the patients or by the healthcare system respectively. And this might differ between countries for the same application, which might be a problem.
- The collected data might vary, or be considered to vary, in quality, depending on what kind of application was used to collect the data. This could also influence the handling, storing, sharing and usage of the data.
- The role of the active patient is growing in importance in terms of measuring the effects of different interventions or medications. In this aspect, the US is probably far ahead of the EU.
- In terms of market access, many companies and developers think of the US first, as it is a larger common market. For Europe, it will be extremely important to find common solutions and collaborations between countries, similar to how medical treatments are approved. This must happen, otherwise there is a concern that the patients will not be able to gain access to novel DiGAs.

4 What have been the main challenges in adopting and implementing the new regulations, and who are the most active stakeholders in driving developments going forward?

Sweden: The CE-labelling of medical devices is one challenge. Collaboration on reimbursement assessments in Europe is another. The Medial Devices Regulation (MDR) and the In Vitro Diagnostic Devices Regulation (IVDR) in Europe are linked to CE-labelling and reimbursements. The Swedish Medical Products Agency is one of the main stakeholders making sure the necessary guidance and infrastructure are in place for the application of these regulations. One of the most discussed parts of the infrastructure is the use of third-party assessment bodies.

After approval, gaining access and being able to market it to the healthcare system is the key. In order to achieve this creating collaborations, knowledge transfer, and awareness are important. And it makes sense that if a digital product has been approved in one EU country, it should be possible to use it in other member states too. This process would require trust and automation since it would require the transfer of some data and appropriate licences. It is a complex issue, but a key element for scaling.

UK: Creating a common European system like the one for medical devices can take a very long time to agree on. England has focused on sharing a regulatory infrastructure but keeping flexibility at a local level. Each local jurisdiction and healthcare system may then decide on their own implementation. Starting with a very practical approach by using and implementing certain specific applications is easier, and then creating the necessary framework for that. The NHS drives the active recovery programme for five million people waiting for surgery. This toolkit contains about 20 to 30 key products that are being implemented and using this as a strategy to start using the applications as soon as possible.

5 Do you believe that the DiGA regulation from Germany could be a basis for developing regulations in your country?

The DiGA fast-track system is very interesting and could be a fast way of getting the system going. It will be investigated by Estonia next year.

It is important to remember that when newer and better versions of a DiGA are developed, the new versions will need to have re-evaluation, and eventually the older versions will have to be removed or discarded somehow. There will be a constant evolution of DiGAs.

There is a common core between the DiGA fast-track, the Nordic review method, and the UK method. It may be that the way forward is that we will have only partly common assessment criteria but allowing some local adjustments.

Sweden: The current MDR and IVDR regulations are probably enough for the evaluation of DiGAs. The difficult part will probably be the marketing and incorporation into the regular healthcare system, whose processes will probably have to be updated to incorporate digital health systems. This might be quite difficult. If the DiGA fast-track system can assist with that, it would be valuable.

Denmark: It makes good sense to copy the DiGA system to speed up the process and have the same rules in many countries. From a start-up developer perspective, it is difficult to develop a product that follows certain rules in one country and other rules in another country. The more we can coordinate this the better. Also, from a patient perspective it enables easier access to DiGAs. We can see now that many start-up companies are moving to Germany and selling their digital solutions there, because Germany has moved in this direction, and German patients have exposure to many more digital solutions than patients in other countries. We will probably see the same development if we do the same in the Nordics.

eit Health
Co-funded by the European Union

6 Do you think we need to harmonise the digital health device market regulation, and if so, what are the next steps?

Yes, we have to make it easier, and we have to be aware of the fact that the Nordic Region is quite small. And the best digital innovations might not come from the largest corporations, they might come from small start-ups, and we need to make it easy for them to gain market access to use all the wisdom we have. Quality defined in one country should be the same quality defined in another country. We need a lot of discussions to clarify the jurisdictions and facilitate the harmonisation, but we must keep this high on the Nordic agenda. The industry must be active, because it is the industry that will first see the benefits of a common market for digital solutions. The benefit for the healthcare systems will also be realised, so that even small hospitals have access to the latest and best digital health devices, which require bigger markets to be financially viable.

The EU can rival the US as a market, and having a common agreement on quality is a must. The reimbursements are a broader discussion, which might be unrealistic for everyone to agree upon. But quality and market access should be harmonised and workable.

Countries also have different financial capabilities when it comes to re-imbursements, which can be seen in other areas, like oncology. But this is solvable, the first step is trying out some DiGA-inspired aspects, before taking bigger steps.

It should be remembered that some harmonised legislation is already in place, but maybe it is not interpreted in different ways in different countries.

7 If you are looking at the best practices of the digital health devices in your country, which of these best practices could be used by other countries in the Nordic Region, or across Europe?

According to ORCHA, UK (ORCHA is one of the largest sources of Digital-Health compliance, working to improve lives with the best digital health) there are five crucial steps to digital health integration:

1. Establish an effective accreditation and assessment process.
2. Consider distribution and dissemination processes, defining how to get the apps out and working.
3. Establish systems and processes that allow the healthcare system to use the applications the way they want.
4. Integrate digital health into core pathways and becoming part of the systems.
5. Find mechanisms for how to pay for them in a sustainable way.
6. All these parts need to work to make digital health applications a main-stream part of the healthcare system and accessible to the patients.

8 What parts should be developed together and what should be developed in the individual countries?

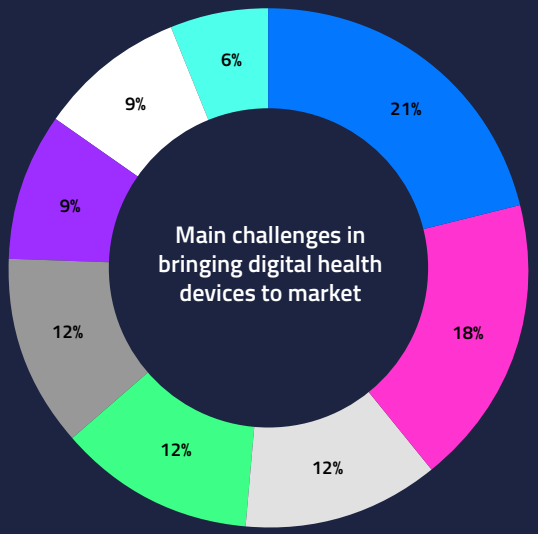
Everything should be done together, except from the reimbursement models. All the technical and data security could and should be done together in the Nordics, and probably as much as possible in the EU. But since the reimbursement models differ so much between countries that should be held separate.

If data is not accessible, it is not possible to integrate anything. For example, if people from Finland come to Estonia and need to buy their prescribed drugs, they are able to do it, but not yet in other countries.

Within the context of the European Health Data Space, Finland has made an example by creating a data intermediary for the re-use or secondary use of health data. A discussion about the possibility of reusing this data is welcomed, since data needs to move when people move. This also applies to research and the use of digital applications on the market. Data is probably the area that we should work closely together in.

9 What do you see as the three main challenges in bringing digital health devices to the market?

The attendees responded to the question through a multiple-choice poll. The outcome of the poll can be seen in the graph to the right.



21% Education and skills, particularly among healthcare providers

18% Collecting clinical and economical evidence to be reimbursed by the payer

12% Data interoperability (Integration from different sources)

12% Engagement of all needed stakeholders in order to develop a digital device

12% Mutual recognition of the ready to market solutions/positive healthcare effect by all member states

9% Quality of data input to digital solutions

9% Wide range of regulations – hard to follow

6% Complicated access to health data for solution validation

Participants

Name	Organisation
Chairs, Moderators and Advisers	
Liina Joller-Vahter (Chair)	IN-4-AHA consortium (Innovation4active and healthy ageing) / Estonia
Christina Bergstrand (Chair)	EIT Health Scandinavia / Sweden
Sara Lei (Moderator)	Karolinska Hospital / Sweden
Erik Forsberg	Managing Director, EIT Health Scandinavia
Henrik Matthies	Managing Director, Federal Ministry of Health, Health Innovation Hub / Germany
Tim Andrews	ORCHA / UK
Anders Tunold-Hanssen	N!P (Nordic Interoperability Project) / Norway
Ylva Tryselius	Medical Writer
Developers, innovation marketers and competence centres within digital health applications	
Jesper Grønbæk	Health Tech Hub Copenhagen / Denmark
Marie Gårdmark	RegSmart / Sweden
Hille Hinsberg	Proud Engineers / Estonia
Taavi Einaste	Nortal / Estonia
Regulatory Authorities	
Max Herulf	Swedish eHealth Agency
Helena Dzojic	Medical Products Agency / Sweden
Silja Elunurm	Ministry of Social Affairs / Estonia
Jari Haverinen	FinCCHTA / Oulu University Hospital, Finland
Jukka Lähesmaa	Ministry of Social Affairs and Health / Finland
Health Insurance Authority	
Karl-Henrik Peterson	Estonian Health Insurance Fund / Estonia

Co-funded by the European Union

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101017603

digital-strategy.ec.europa.eu/en/policies/eip-aha

eithealth.eu

innovation4ageing.eu