THINK TANK

Learning from health data use cases

Real-world challenges and enablers to the creation of the European Health Data Space

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Introduction

In the Communication on the European Strategy for Data, the European Commission set out its objectives to create the right environment in the European Union to allow digital health technologies to reach their full potential. In the health context, this includes supporting more person-centred care delivered through resilient and sustainable health systems, ultimately supporting citizens to make better choices for their health and well-being.

The digital health solutions needed to achieve this vision demand that data can be collected, stored, and accessed for direct use in the provision of care, and re-used for scientific research, for evidence-based policy making and for health system planning and administration. The European Health Data Space (EHDS) is envisaged as the vehicle for facilitating such use of appropriate and representative data for the benefit of citizens, along with other important contributing initiatives including GAIA-X and European Health Emergency Preparedness and Response Authority (HERA). The EHDS should provide a trusted mechanism for data access by healthcare providers, researchers and policy makers; as well as a channel for patients to grant access to their health data through data altruism.

A key step in building the EHDS is the creation of a governance framework that is adapted to the special characteristics of health data and the needs of the healthcare professionals, researchers and policy makers who wish to use health data. During the first half of 2021 the European Commission is inviting all stakeholders in the future EHDS to share their perspectives on the way in which the governance framework for the EHDS can best serve individuals' interests and rights, especially with regards to the goals of safely processing of sensitive personal health data while at the same time making it accessible for use in the wider public interest.

In this context, EIT Health has worked with four of its partners to explore the challenges they currently face in bringing digital health solutions to market, and draws on their experiences to outline recommendations for actions that the European Commission could take to address challenges in access, storage, use and re-use of health data.

The full realisation of digital health solutions into everyday care of patients and disease prevention requires more than access to data. It demands attention to new models of care reimbursement that account for care delivered remotely; it demands new legal relationships between the providers of digital health solutions and traditional care providers to allow for new models of shared liability, and it also demands new competencies and skill sets among the clinical and wider healthcare workforce. While these issues are all crucial to the full integration of digital health solutions into healthcare systems, they are not the subject matter of this report. In this report we focus only on the special challenges related to data, and the opportunity which the EHDS has to overcome such challenges.

The present report sets out the experience of four very different digital health solution providers, and uses their specific experiences – supplemented by reports from other EIT Health partners – to illustrate the current reality of accessing and using health data to develop and provide a digital health solution. The five case studies are described in further detail in the Annex, but in short, they comprise of:

1. DigiOnko
An app-based solution to support the digitisation of the patient journey in cancer care, from prevention throughout the full patient journey.

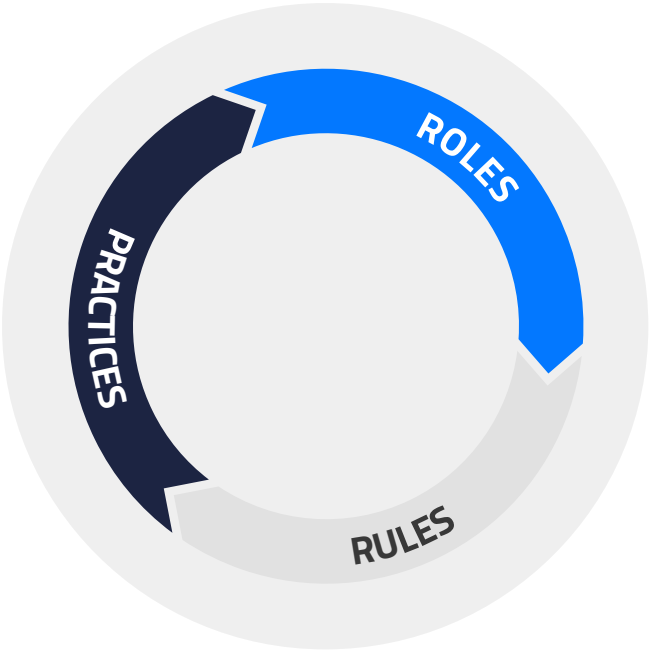
2. FibriCheck
A telecare tool that may be used both as a prescribed digital health solution within the healthcare system or as a consumer solution contracted directly between the citizen and the solution provider.

3. Bluemetrix
A data management and control solution to be used as a tool throughout the wider healthcare system to facilitate access to data.

4. New SkyCare
A solution to provide a pan-European virtual out-patient hospital supporting the patients and care providers through telemonitoring and remote medical assistance.

The case studies have allowed us to identify three broad categories of data related challenges that organisations are facing in the development and use of these solutions. These categories can be summarised as challenges related to the various roles held by different stakeholders in digital health; the range of regulations that apply to health data at multiple levels; and the policies and practices that exist within the organisations concerning data use which intersect with formal legal regulations and rules that apply to data processing.

The use cases explored have identified a wide range of interrelated challenges. Whilst categorised in the report, these three categories of challenges should not be viewed in isolation, as there are many overlapping areas.



However, the categorisation is used to help focus on some key challenges that the emerging EU legislation and the guidance that will be adopted to support the realisation of the European Health Data Space will have the opportunity to address.

An overview of challenges in roles, regulations and policies and practices

CHALLENGES RELATED TO **ROLES & RELATIONSHIPS**

The way in which data can be accessed and used is often defined by the role the user has in the healthcare system. A data user may be a healthcare professional, an employee within a healthcare provider organisation, an academic researcher, a business partner in the healthcare system (such as an insurer), a commercial provider of a solution, and of course the patient or citizen who may wish to use health data. Some of these players will have a commercial interest in the data, through direct revenue generation or as the holder of a fiduciary duty of care within a public healthcare system; while others will have non-commercial roles in the public sector, but will nonetheless be focussed on generating value from data.

These roles are not static. A healthcare professional may also at times be a researcher, a public health insurance body can also be a policy maker and a patient can be an active data provider when data are collected by a personal device or a passive data provider through an interaction with a healthcare professional. It is important to understand the nature of these roles, as the role a health data user assumes is key to the relationships they hold with the data subject and the data originator. Identifying and understanding these relationships is important as it impacts the regulations, policies and practices which have to be taken into account, as will be explored in the following sections.

When it comes to categorising these relationships, in some cases, the data subject and the data originator will be the same person, for example in a patient held app where the patient manually enters data or data are collected through an accelerometer or other tool. In other cases, other parties will be involved, such as a healthcare provider who generates laboratory results or images in the context of care provision. There can also be business-to-business relationships, such as when a healthcare provider contracts with a digital health solution provider for a service; however, that same provider may also have direct business-to-consumer relationships with respect to the same service. The legal requirements of the solution provider will not be the same within the two contexts, even though the data accessed may be the same. This creates complexities for the solution provider which can be complex to understand and manage.

CHALLENGES RELATED TO **RULES & REGULATIONS**

As the roles of an individual and the relationships they hold change, the regulations and rules by which they are bound will also change. A particular challenge for any effective governance framework for the use of data is the accommodation of changing and ambiguous roles. The present governance framework in Europe applicable to the use of health data is largely defined by the GDPR. However, it is also impacted by a wide range of national legislation covering general data protection issues as well as health sector specific issues. In some countries, these rules exist at both national and regional or state level.

The experiences of the use cases, as well as a wide range of research, has shown that the fragmentation of the health data legal landscape creates significant challenges to data use and re-use, in particular when data use encounters new challenges associated with different geographies, institutions and medical practices and specialities.

CHALLENGES RELATED TO **POLICIES & PRACTICES**

While formal laws create the governance framework for the use of data, the organisation in which data are collected, processed, stored and used as part of everyday healthcare impose a further layer of governance. This comes via the policies and practices that are in place to regulate the way in which their staff and business partners can interact with the data for which they are legally responsible. This includes practices related to the data itself – data format, the way in which data are labelled, the languages in which data are captured (both human and machine) – as well as processes on how the data may be used – who has access rights, when may data be shared, how can data be amended or deleted.

Such policies and practices impact not only how data may be used and shared, but in many cases they also undermine the practical potential to use data. As organisational-specific policies and practices can vary, this presents challenges of interoperability – i.e. the ability of organisations to have clear and shared expectations for the format, labelling, languages and access rights for data. Technical, semantic, legal and operational interoperability must be ensured. If interoperability is not met, data remain effectively

Roles & Relationships:

Real-world examples, challenges and enablers

The uses cases set out in detail in the Annex demonstrate that almost all digital health solutions require a wide range of stakeholders across several organisations to work together. They typically involve several organisations, some with a commercial role in developing and providing the device and service, others with a public sector role in delivering healthcare. Insurers, both public and private, may be involved in reimbursing the cost of the service. Finally, the end users may include patients, citizens and healthcare professionals. This results in the existence of many different roles and relationships within the scope of one service. As mentioned earlier in this report, these roles and relationships are not static, and may change over time.

REAL-WORLD EXAMPLE: CITIZENS' RIGHTS (FIBRICHECK)

The app is loaded onto a patient-owned smart phone and activated by the patient. The patient generates a photoplethysmography (PPG) trace using the camera on the phone, which is then automatically analysed on the FibriCheck platform to detect cardiac arrythmias, including atrial fibrillation. The patient also provides contact data, demographic data and may also provide information on medication taken and other relevant factors. All the data are stored on the FibriCheck platform in identifiable format. The collection and processing of the healthcare data is based on the explicit consent of the patient in the context of a business-to-consumer relationship. The consent given by the patient is based on a policy that foresees re-use of the data in an anonymised format for research or commercialisation, but in the case of secondary research purposes only when additional explicit consent has been obtained.

In addition to this business-to-consumer relationship, FibriCheck may also be prescribed by a healthcare provider who can then access the PPG traces and other information provided by the patient to provide remote monitoring services. Thus within the FibriCheck context, two or even three relationships exist: the business-to-business relationship between FibriCheck and the healthcare provider, the relationship between the healthcare provider and the patient, and the business-to-consumer relationship between FibriCheck and the patient.

This creates particular challenges with the exercise of citizens' rights.

REAL-WORLD EXAMPLE: PATIENT CONSENT (DIGIONKO)

DigiOnko is designed to support breast cancer patients through their healthcare journey, from prevention, to diagnosis, treatment and long-term care. Data are collected at multiple points along this journey. Some are manually reported by the patient, some are automatically pulled from patient-held devices (e.g. sleep monitors) and some are automatically pulled from healthcare provider data stores (e.g. EHRs or lab results).

The app allows direct patient interaction with clinically held information such as medication plans, the integration of clinical information collected by the patient through monitoring tools, and direct interaction by healthcare providers with patient-held data. Data can also be aggregated for wider research use.

Within the scope of DigiOnko, there exists multiple categories of data, all with different owners, controllers and users. Some data are subject to clinical control, and some are integrated. This all creates particular challenges regarding patient consent.

REAL-WORLD EXAMPLE: MULTIPLE ROLES (NEW SKYCARE)

New SkyCare establishes a pan-European virtual out-patient support, allowing hospitals to support patients and care providers through telemonitoring and remote medical assistance. The patients use mobile apps to report measurements taken on consumer grade devices and sensors (weight, blood pressure & glucose measurements). The measurements are interpreted by a rule engine, and depending on the value, the rule engine sends tasks to the patient and/or medical service centre. Accordingly, within New SkyCare multiple categories of data are controlled and stored by the patients, hospitals, medical service centre, the platform provider and different sensor providers.

The decentralised storage of data provides additional challenges with execution of citizens' rights. It also has particular challenges with establishing responsibility for data ownership, quality and safety between the different partners.

REAL-WORLD EXAMPLE: DATA LAKES (BLUEMETRIX)

Bluemetrix design and build data lakes for healthcare authorities and operators across the EMEA and APAC regions. This involves bringing data sets from multiple sources into a data lake environment where the different data sets are combined to create one or more new data sets, which will have richer functionality and data attributes, thus allowing data scientists and clinicians to carry out AI/ML modelling on the data sets to help improve patient care and medical research.

Each of the source data sets will have their own governance and access policies controlling the use of this data, but the combined data sets created in the data lake may have different policies around governance and access. This can be particularly problematic when a small proportion of the data in a combined data set comes from a particular source for which the governance and access policies are in conflict with the policies on the combined data set.

Where the data lake has few data sources, manual workarounds can overcome the conflicts between policies. However, when there are hundreds of data sources feeding into the data lake, a manual workaround is not possible or feasible.

Challenges related to **roles & relationships**

Based on the real-world examples provided by our use cases, we can distil the following challenges related to roles and relationships:

CITIZENS' RIGHTS

Where data are held by more than one data controller, access requests by a data subject require a chain of actions and they cannot be fully complied with by one data controller. This creates complexity for both the data controllers and the data subject.

"When our service is used through a healthcare provider, we cannot support subject access requests (SARs), although we would like to be able to do so."
– FibriCheck

The differences and specificities in terms of data governance and access policies cause challenges when bringing data from different sources together, which are only amplified when the number of sources increase. Due to the lack of association of data policies to the actual data stored on the patient, it is difficult to manage data requests across multiple policies and owners.

"The existence of a minimal number of recommended categorisations for data policies, would simplify the integration of data from multiple sources and facilitating the combination and integration of more complex data sets."
– Bluemetrix

Where data are generated in a context which includes business-to-consumer, business-to-business and doctor/patient relationships – which is frequently the case in digital health care provision – challenges arise in complying with a request for data deletion as it does not apply in the same way across all the relationships.

"Less than 0.1% patients ask to execute their right to be forgotten but trying to explain to them that they cannot exercise this request through us directly is time consuming and leads to frustrations."
– FibriCheck

"The lack of a consistent use of meta-data to identify data points within the data held on a given patient makes compliance with chapter 3 of the GDPR (rights of data subjects) challenging."
– Bluemetrix

The existence of multiple legal relationships and differing legal duties for different data controllers creates a lack of transparency towards the data subject and makes action for the data controller(s) difficult. This problem is exacerbated when some data are controlled by the patient who can delete data from an app but may not be able to delete the same data from the databases held in the healthcare system.

"We provide users with the tools to delete their data, but where the use of FibriCheck is prescribed by a HCP, this deletion cannot be completed as data is held within healthcare system databases as part of care provision and must be left unchanged."
– FibriCheck

Where data are held across several entities on different legal bases, full data portability is often impossible because it is not held by one data controller who can provide a copy of the full data set. The patient who wants to exercise their right to data portability may have to make several requests and will end up holding several data sets.

Passing on several data sets to a new service provider may be complex and may not be accepted by the new service provider.

"Patients sometimes approach us for access to their data, but we cannot provide access to data for which we are not data controller."
– FibriCheck

CONSENT TO DATA USE

Where the digital health solution supports a patient through several aspects of their journey through the health system, consent may be requested at each data collection point and by several different actors, as each may be required to demonstrate that they have acquired consent. This can be both confusing and irritating for patients, and is time consuming for care providers and other actors in the digital health solution.

"Patients are asked to consent too frequently; it irritates them and could even undermine trust."
– DigiOnko

In an offering with multiple hardware and software providers, the patient needs to provide consent to each provider and to the sharing of data between providers.

"Patients need to deal with multiple consents for the individual parts of the solution with different providers. This may be too complex and confusing. There is a risk that patients either do not consent at all, or consent without understanding how it all fits together. Both these situations are undesirable."
– New SkyCare

When the digital health solution includes both a business-to-consumer and a business-to-business relationship, data are collected based on consent in the former relationship while in the second it is generally collected on the legal basis of providing care. This can create a conflict in further duties that arise with respect to the data, in particular the right to data portability which is contingent on data being collected on the basis of consent or in pursuance of a contract.

"Due to the lack of a European Consent form patients need to be continually asked for the right to use their data."
– Bluemetrix

Consent for using data to provide care and consent for using data for research are separate consents. The need to inform the patient about the purpose for which data will be put in each research project in practice makes data use for a small company very difficult.

"Given that we are required to inform the user that we use the data in a specific research study, we would need to reidentify the users again to inform them. So, for us, it truly adds to the complexities of utilising data for research, and ultimately we very rarely do so outside of well-defined clinical studies in which informed consent is requested upfront."
– FibriCheck

DATA QUALITY AND SECURITY

Consumer grade devices do not need to adhere to the same safety and performance (data quality) criteria as medical grade devices. Differences in legislation among countries cause delays due to bureaucracy in reaching a common understanding and agreement and capture that in contracts and data processing agreements.

"The objective of patients using their own devices has been postponed to a later stage. Supporting 'BYOD' solutions is a time-consuming process because of the implications of regulations impacting upon healthcare. Harmonisation of EU regulations is a must in order to speed up innovation processes."
– New SkyCare

The movement of the point of care from the traditional care setting increasingly into the home setting creates novel challenges for data verification.

"Verifying data quality from multiple devices is a relatively straight forward technical problem to solve where it involves data that is generated by the device, as the key issues are to check that the device has not been hacked or the data tampered with. Verifying data created by the patient is more difficult as this may require Natural Language Processing modelling."
– Bluemetrix

In order for a care provider to be able to use a digital solution they need certainty about the quality of the data arising from other partners which will be integrated into the system, and the quality thresholds for each data item need to be checked.

"Undertaking quality assurance for data integrated into our system is hugely time consuming."
– DigiOnko

How can the EHDS address challenges related to **roles & relationships**?

The problem of multiple roles and relationships needs to be addressed within the governance framework for the EHDS, both at a legislative and operational level. The complex landscape of multiple roles and relationships explicitly acknowledged, and mechanisms should be developed to allow roles to change over time. The European Commission should consider the option of a standardised nomenclature for different roles and a common framework of responsibilities relating to different roles.

- Where multiple roles exist, there is a negative impact on the capacity of one data controller to meet subject access requests or requests for deletion of data. The EHDS should create a mechanism to allow simple co-operation between organisations so that data subjects can exercise their rights to subject access requests or requests for deletion of data with maximum ease.

- Where data are held across several data controllers, data portability is fragmented, and the patient will have trouble in truly being able to exercise this right. The EHDS should include a capacity for a patient to automate data portability through the EHDS.

- Under the current system, consent is required far too often. The EHDS should explore and integrate new models of consent that allow for the inclusion of the 'once only' principle into consent mechanisms wherever possible. New apps and IT tools should be developed to allow for dynamic consent in which the data subject can easily amend consent. The EHDS should consider creating a European Consent form with explicit meta-data explanations covering the majority of patient data use cases.

- In cases where the infrastructure for digital health services includes the use of tools (hardware and software) held by several parties, guidelines on data quality must be established whilst ensuring data security. The EHDS should explore the potential for certification of data quality from devices and software in the context of the Medical Devices Regulation.

Rules & Regulations:

Real-world examples, challenges and enablers

The use cases set out in the Annex demonstrate that any digital health solution is subject to a wide range of regulations, from EU level regulations such as the GDPR, MDR and (in due course) new legislation such as the Data Governance Act and the Data Act. However, digital health solutions also have to comply with a wide range of health sector-specific legislation at national and regional level, which can often impact on the way in which EU law is applied in practice. The use case actors have all reported a high level of frustration with the level of legal complexity, lack of legal certainty and very significant costs of time and labour to understand and navigate the complex regulatory environment for digital health solutions.

REAL-WORLD EXAMPLE: BAVARIAN HOSPITAL LAW AND PREMISES RESTRICTIONS (DIGIONKO)

DigiOnko is established within University Hospital Erlangen. Accordingly, when processing data, DigiOnko has to comply with the DSVGO (German GDPR) as well as regional laws applicable to Bavarian hospitals, the Bayerisches Krankenhausgesetz (BayKrG - Bavarian Hospital Law).

Article 27 of the BayKrG states that third party data service providers may only process patient data collected by the hospital if the hospital retains control over the data and is given authority to issue instructions to the data-processing employees of the third party. This has been interpreted by Bavarian hospitals to mean that patient data may only be processed or archived on premises belonging to the hospital.

This has resulted in a situation where DigiOnko and similar providers are very limited in what they can do with data and how they can collaborate with others. This poses particular challenges to any desire to develop AI algorithms to process health data, as it is difficult to have the necessary computing capabilities to support such research on the site of the hospital.

REAL-WORLD EXAMPLE: LACK OF CLARITY REGARDING MEMBER STATE GOVERNANCE FRAMEWORKS (DIGIONKO)

DigiOnko aims to develop multiple apps, some of which will hopefully become BfArM approved DiGAs, which would be a great step towards wide roll out in Germany. However, it is very hard to get good visibility of the governance frameworks of digital health solutions in other Member States.

DigiOnko app solutions will need to undergo country specific reimbursement processes and regulations one by one in the EU. Therefore, it will be time consuming and costly to spread developed and proven solutions to other EU member states, even if DigiOnko has invested significantly to show its solution has positive healthcare effects in order to meet the DiGA requirements for reimbursement. There is no clarity on how these assessments could be used in other countries. The application of new HTA rules in EU must address these issues.

REAL-WORLD EXAMPLE: FRAGMENTED REIMBURSEMENT LANDSCAPES (FIBRICHECK)

Broad adoption of digital health applications in a medical context without the right (financial) incentives is challenging. Different countries are trying to cope with this challenge in their own way, but this fragmentation of reimbursement landscapes makes achieving EU-wide reimbursement for new digital health solutions a very complex ask.

Country specifics will always be required as healthcare systems, national economies and populations are fundamentally different. However, a consolidated EU level assessment for digital health solutions would have the potential to considerably ease the route to market for small companies. Such EU level assessment would need to account for the specifics of digital health solutions and medical technologies.

REAL-WORLD EXAMPLE: VARYING RULES FOR VARYING DATA LEAD TO EXCESSIVE REQUESTS FOR PATIENT CONSENT (DIGIONKO)

The DigiOnko application is designed to support the patient throughout their whole journey. To facilitate this, it demands the inclusion of data from several data sources. To include such data within a central integrated solution such as DigiOnko, the rules applicable to each data set have to be applied. These rules vary significantly depending on the context in which the data were collected. In some cases, this will result in the patient being asked repeatedly for consent, or provided with an information notice several times, even in the course of a relatively simple and centralised journey.

REAL-WORLD EXAMPLE: CONFUSION REGARDING USE OF DATA FOR RESEARCH PURPOSES HINDERING HEALTH DATA RESEARCH (FIBRICHECK)

Use of data for research purposes is governed by Art 9(2)(j) and Art 89 of the GDPR. The application of these articles varies by Member State and rules are often not clearly communicated or understood by prospective users. Despite the fact that EDPB guidance has been issued, it remains an issue around which much confusion and uncertainty exists.

Given the complexities and challenges that have been caused by the GDPR and its implementation, it is usually unclear to end users which data can or cannot be used for research. This means that organisations such as FibriCheck find using data for research is usually very challenging leading to a lack of use of real life generated health data for research purposes (i.e. outside of well-defined clinical studies), to the detriment of advances in care.

Challenges related to **rules & regulations**

Based on the real-world examples provided by our use cases, we can distil the following challenges related to rules and regulations:

LEGAL LEGACY SYSTEMS

Sectoral legislation on data use is often out of date and is not fit for current digital health solutions or research.

"The challenges of federal and state law mean development is slowed down or even lost."
– DigiOnko

There is a big delay between introduction of new EU regulations (e.g. GDPR and EU MDR) and national implementation of laws, followed by the organisational interpretation of those laws.

"It takes so much time to get a common understanding and agreement (privacy, documentation, reporting, etc) which then need to be captured in contracts and data processing agreements. We spend more time on paperwork than on actual innovation."
– New SkyCare

LEGAL COMPLEXITY

Complex national level rules on data processing have been recently developed in many countries. In many cases the jurisprudence on the application of the law is still emerging.

"From a research perspective, our real-life generated dataset is of tremendous value both in our field but also in adjacent areas. However, there is a lack of clarity (and different opinions) that exist regarding how this data can be re-used in this setting, resulting in only limited use being made of valuable data for research outside traditional clinical studies."
– FibriCheck

Multiple layers of regulation and laws, many designed to function on a particular legal territory, make working across borders very complex.

"We have to adapt contracts all the time, for the same function we can be a data controller in one context and a data processor in another, it is costly and time consuming."
– FibriCheck

RE-USE OF DATA FOR RESEARCH

Where several data controllers hold data in the context of one digital health solution, different legal bases for using data may apply. This limits the capacity for data collected for care to be reused for research.

"Our hospital partners are asking questions about using data for secondary research, but as there is often no clear-cut legal answer regarding what is possible under which conditions, valuable data often remains unused."
– FibriCheck

When there is the involvement of multiple institutions and data which is not collected under an agreed privacy statement across institutions, retrospective analyses are highly complicated. This limits the usefulness of study data for future research.

"Healthcare innovation requires a balancing of the duties to the data subjects under the GDPR and the potential for data to be used to create sustainable and sophisticated patient care."
– DigiOnko

How can the EHDS address challenges related to **rules & regulations**?

- The European Commission should support Member States to address the legacy legislation challenges and ensure that legislation is suited to emerging and evolving digital health solutions. This could include sharing of experiences and best practices by countries that have recently adopted new legislation that impacts digital health, such as France and Germany.

- The European Commission should work in close partnership with EDPB and the new EDIB to identify the areas in which the application of EU level law has become fragmentated as a result of interaction with national law, in order to reduce fragmentation as much as possible.

- New EU level sector specific law, such as the planned EHDS legal framework, should specifically address the use of data for research both within and across borders, taking full account of the practical challenges of complying with multiple legal requirements.

- The interaction between the Medical Devices Regulation and national level legislation should be carefully mapped to highlight potential stumbling blocks that may impede the use of digital health solutions that are dependent on data use between several legal entities, including those in different jurisdictions.

- The European Commission should establish a European "fast track" for digital health solutions, looking to the experiences of different Member States, notably the DiGA example from Germany. This will help to support digital health innovation, improve patient care, treatment and diagnosis, and improve the resilience of healthcare systems.

- Digital health solutions which show a positive healthcare effect via a controlled study in one Member State, should be able to enter reimbursement schemes in other Member States. This would reduce the challenges of reimbursement, drive innovation, support healthcare systems and could develop the EU into the largest digital health market in the world.

Policies & Practices

Real-world examples, challenges and suggested enablers

The uses cases set out in the Annex include digital health solutions which may be delivered on the basis of a simple contractual relationship between a digital solution provider and a citizen, as well as those that may be provided in partnership with or as a service to a healthcare provider. The use cases demonstrate that as soon as a solution is delivered with or to a healthcare provider, a new set of challenges arise. Solution providers need to negotiate around the internal policies and practices which define how the solution may be used within the context of the wider organisational structure of the healthcare provider. Such policies and practices usually define the day to day use of digital health solutions and must be observed in addition to the formal legal requirements discussed above. The practices are often defined by the wider vision and mission of an organisation, and often set the overall tone towards digital health which impacts in a very real way how digital health solutions can be used 'on the ground'.

The vignettes below highlight some of the operational challenges that were experienced by the use case owners as they sought to work with hospitals and other health-care organisations to provide services.

REAL-WORLD EXAMPLE: BLUEMETRIX AS AN INNOVATIVE SOLUTION TO FRAGMENTED DATA POLICIES

Bluemetrix and its partnership with St. James's Hospital, Dublin and Children's Health Ireland aims to address the situation in which a data lake is created from many data sources. Each data originator has local processes, policies and practices which govern who may access data, how it may be used and how it may be shared. The policies in most cases are attached to the data, meaning they remain in force even when data are federated.

Bluemetrix is a data processing platform which addresses the ingestion of data into a data lake while allowing the continued compliance with the data source's original data processing governance requirements. This is an intensely complex issue which could be simplified by the addition of categorisations of data policies, thereby enabling organisations such as Bluemetrix to ensure compliance with a smaller number of categories, versus a vast number of organisational-specific policies.

Bluemetrix also addresses the challenge of the ethical requirement of undertaking population or cohort based research, while retaining the capacity to report incidental findings to specific patients by ensuring that data is pseudonymised for research through tokenisation, but re-identifiable if the research identifies a health risk to a particular data subject who can be alerted to the health risk.

REAL-WORLD EXAMPLE:
OFFERING AN INTEGRATED PATIENT-CENTRIC SOLUTION REQUIRES A BURDENSOME NEGOTIATION OF DATA QUALITY THRESHOLDS AND DATA ACCESS PROTOCOLS (DIGIONKO, FIBRICHECK)

Many digital health solutions demand that data are brought into a data platform from many diverse sources. DigiOnko draws on data uploaded directly by patients, data from diagnostic interventions and data from EHRs. This requires not only negotiating different data access protocols, but also checking the data quality thresholds for each particular piece of data within the service. This demands significant time investment from the solution developers.

FibriCheck echo this burden, noting that within their context integration of data sources is hugely time consuming and complex, demanding a high level of technical skill and the co-operation of the data controller as well as the health care professional.

REAL-WORLD EXAMPLE:
INTEGRATION OF PERSONALLY OWNED DEVICES HINDERED BY COMPLEX RESPONSIBILITY MATRIX (NEW SKYCARE)

New SkyCare is designed to provide a pan-European virtual out-patient hospital supporting the patients and care providers through telemonitoring and remote medical assistance. It is based on a medical service centre operating across borders (currently between the Netherlands and Sweden); allowing patients to use personal consumer grade devices, such as weighing scales and heartrate monitors while operating on an open platform available to accredited healthcare providers and patients. It is designed to work with many roles and different legal relationships. While aspects of this solution have worked well, the objective of allowing patients to 'bring your own device' has not been achieved. This is due the complexity of the regulatory implications of connecting any consumer grade device to a medically graded platform and integrating legal and operational responsibility for consumer grade devices not controlled by the healthcare provider.

Challenges related to **policies & practices** for data use

Based on the real-world examples provided by our use cases, we can distil the following challenges related to the internal policies and practices related to data use.

BUILDING TRUST WITH PATIENTS AND CARE PROVIDERS

To build trust patients need to be able to see who has accessed their data and what use it has been put to, including the value it has created.

"We have found that when patients can see how their data is used and the value of its use to society, their trust grows."
– Bluemetrix

LEGAL CERTAINTY FOR HEALTHCARE PROVIDERS

Healthcare is heavily regulated with many co-existing rules, this creates risk adversity and uptake hesitancy among many healthcare providers in using data arising from outside their own organisation and leads to a slow adoption of new technologies.

"Patients want the app and the support it provides; however, they are frustrated that old laws prevent its full roll out."
– DigiOnko

DATA INTEROPERABILITY

The practices of many healthcare providers do not yet include the routine collection of electronic and shareable health data.

"The reality is that many patients' records are still paper, getting their data into a system like ours is complex and often not possible."
– DigiOnko

The involvement of different parties, each with their respective requirements on technical, security and governance levels, means that integrations are complex and time consuming. Additionally, there is the need to educate parties about the process and technologies used.

"In our experience, the two most time-consuming aspects of healthcare data integration projects are as follows:

- *Complying with the technical & security requirements of internal ICT departments, which were not developed with cloud computing in mind.*
- *Agreeing with data controllers and processors on what level of governance automation is carried out on their data sets.*
- *The integration of the actual data sets and the automation of the governance is usually relatively straightforward – it is the explanation of how security and governance work in a cloud computing environment that can take time and require buy-in."*

– Bluemetrix

Data integration is costly and complex. Digital health will advance slowly unless this is addressed.

"It literally took us a year to integrate FibriCheck with one hospital as integration typically requires work on both sides and this is often underestimated."
– FibriCheck

PROCESS INTEROPERABILITY

The reality of working across organisations is very complex. From a technical perspective it is difficult to properly develop an integrated two-way system, which means that innovators are often prevented from receiving and sharing data with hospital systems. Linked to this, there is the (social) challenge of reluctance from physicians to collaborate/share hospital data with a solution such as FibriCheck.

"The application of processes between organisations must be streamlined, if not the costs of implementing digital health solutions may prohibit many small innovators from coming into the market."
– FibriCheck

A key challenge when creating data lakes is ensuring the data from the different sources complies with the different respective governance and access policies, which can differ greatly from data source to data source.

"In our opinion, the main roadblock to data integration revolves around the enforcement of existing governance and access policies over the data after it has been integrated with other data sources. If this problem can be solved or simplified, then it will be much easier for different organisations to share their data and integrate their data systems. The lack of guidelines or recommendations around meta-data for policies make it a challenging issue to untangle."
– Bluemetrix

LIABILITY FOR CLINICAL DECISIONS

Patients want to be able to use devices they own, but the liability and organisational implications, including device calibration, quality of data collected, and device maintenance, make this a very difficult step for healthcare providers to take.

"Hospital level responsibility makes personal device use almost impossible at present."
– New SkyCare

How can the EHDS address these challenges related to **policies & practices?**

The challenges highlighted in the context of practices and policies related to data use are intimately tied to the ways in which digital health stakeholders are internally organised. The action points highlighted below are formulated to address the ways in which the EHDS could address some aspects of these challenges, although they do not address all aspects of these challenges.

- Trust in the EHDS will be earned over time. However, transparency is paramount in order to build the basis for such trust amongst both data subjects and data users. The EHDS should include clear information on its purpose and models of operation addressed to different audiences according to their existing knowledge bases and needs.

- Trust in the EHDS by data users will depend on the quality of the data to be accessed. To build such trust, the EHDS should develop a robust system for certifying the quality of data, which includes transparency on how it was acquired and all aspects of its format.

- As the EHDS will depend on shareable data, the Commission should incentivise the use of standards to make health data Findable, Accessible, Interoperable and Reusable. The EHDS should include common guidelines on data meta-labelling to allow for data to be found and aligned to both the use requirements of organisations wishing to make use of it and the governance and access policies of data providers.

- Data integration and use demands skills that are not abundant in Europe. In order for the EHDS to be successful and supplied with high quality data, more healthcare providers need to be trained in data science. The European Commission should earmark funds from EU4Health and other budgets to support such training at EU level. The EHDS may want to make reference to certain levels of skills certification.

- Digital health creates new liability relationships between solution providers, users and patients. The European Commission should support Member States in exploring new models of liability sharing that more easily allows multiple actors to be involved in the provision on healthcare.

Conclusion

The use cases detailed in the Annex and highlighted in the above report demonstrate clearly that the innovators in digital health still face considerable challenges in using health data. The challenges are faced by all types of digital health innovators, including those in large well-established companies, new small businesses, and academic partners. The challenges explored above focus on the issues related to health data access and use which could be addressed in the EHDS. Those challenges however represented only one category of challenges, and do not represent the full picture of the complexity of developing and bringing a digital health product to market and integrating it into wider healthcare services.

The use case owners shared extensively on the wider issues, which include issues related to reimbursement of care using digital solutions; issues connected to the liability of cross organisational working which extend beyond issues of liability for data and data use; and issues related to wider challenges of interoperability, beyond the technical and semantic interoperability of data. These issues will also need to be addressed if broader digital health objectives are to be achieved. The report has therefore focused upon issues related to data access and use as foreseen in the EHDS.

The action points outlined above all focus on the need for close collaboration between all key stakeholders in the development of the EHDS to ensure that the risks of fragmentation of data governance issues that are well documented between countries can be overcome. This demands that the development of the EHDS is undertaken in close collaboration with all Member States, represented through the bodies that understand digital health well. This should include the eHealth Network, the partners of the TEHDAS Joint Action, as well as other EU level bodies with responsibility for data more generally including the European Data Protection Board, the European Data Protection Supervisor, and the Boards to be established under the Data Governance Act and the legislation on Artificial Intelligence. In addition, EU level bodies with direct interest in the use of health data should also be included, such as the ERN Board.

The work undertaken to address the challenges must also be accompanied by well-targeted communications materials that help each stakeholder group (patients, healthcare professionals, researchers, policy makers) understand the objectives of the EHDS and the way in which the planned governance measures will address their needs. Such materials may need to be supported by educational materials to ensure that a common European level of health data governance literacy can be achieved.

Finally, the experiences highlighted in the use cases demonstrate that certification of compliance with data governance requirements may be an important additional tool to support the development of trust in the EHDS. The use cases show that data controllers often demonstrate a very high level of risk avoidance when asked to share data with other users or to use data that comes from outside their own organisations. The requirements of the GDPR and other related legislation are stringent and the penalties high, and moreover healthcare professionals are bound by ethical and deontological codes which demand that they avoid possible harm to patients, including harm that may result from other people having access to personal data. Therefore, if certification schemes can be developed which ease some of the risk assessment burdens on the data protection officers and other responsible parties in hospitals and other care organisations, they may feel more supported in providing data to the EHDS and also in using data from the EHDS in the work they undertake.

Annex

Use case overviews

DIGIONKO

What is DigiOnko?

Based in Bavaria, Germany, DigiOnko is aiming to build a comprehensive, integrative digital care structure for all aspects of cancer care, using breast cancer as the initial proof of concept. The goal is to use digitisation to enable personalised precision medicine to improve prevention, early detection, treatment and avoidance of relapse in breast cancer. This encompasses:

- **Digitalisation of prevention**
  An integrated mobile and in-patient screening programme is foreseen to overcome some key hurdles in prevention – namely inclusion and participation of the broadest target populations.

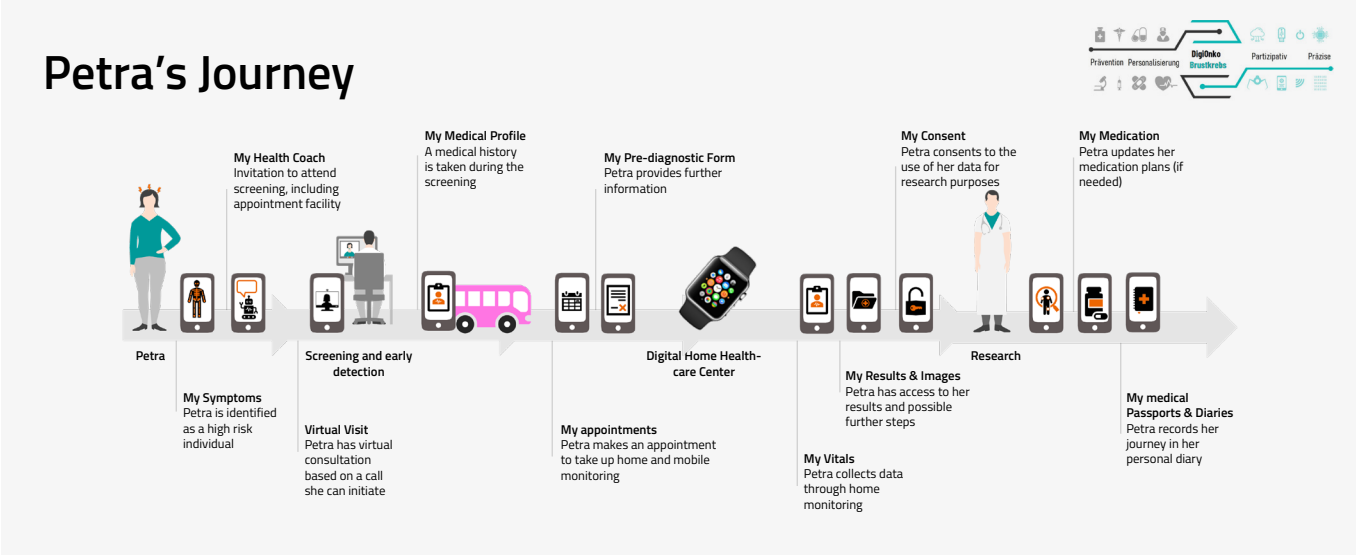
- **Use of medical home care and diagnostics**
  Transitioning care and diagnostics to the home setting where possible is a goal of the DigiOnko project, which aims to utilise existing technological progress to enable increased use of home care, saving patients visits to the doctor and enabling quick and accurate ECG, leukocyte and blood glucose measurements, genomic tests, side effect monitoring and quality of life assessment from home via a structured, digitised programme.

- **Implementation of health apps in the care concept**
  DigiOnko aims to integrate the use of disease-specific health apps to improve therapy management, health monitoring, patient-doctor communication, and improved quality of life.

- **Use of machine learning and artificial intelligence to analyse existing and collected data**
  Machine learning can simplify care, disease monitoring and improve care quality by using existing data. It can also uncover previously unknown and unsuspected scientific correlations. DigiOnko therefore aims to carry out extensive analyses with existing data that are already available or can be collected within the project framework to improve care pathways and contribute to a better understanding of correlations in breast cancer.

How does DigiOnko work?

The holistic approach of DigiOnko can be seen via the graphic representation of a patient's journey:



How could the EHDS help improve the environment for DigiOnko?

Many aspects of the project are interlinked with the scope of the EHDS, as a key feature of DigiOnko is the digitisation of care and prevention pathways for better patient care. The following topics were identified as particularly relevant to the DigiOnko context:

- Access to data – challenges of common data structure, Findable, Accessible, Interoperable and Reusable data meta-tagging, and interoperable access infrastructure to facilitate re-use.
- Patient consent and control based on dynamic consent.
- Data Altruism – methods for data donation by patients.
- Data access for further research – permission, transparency, withdrawal of consent.

Stakeholders:

- Women's Health Clinic, University Hospital Erlangen (Leads: Prof. Dr. med. Peter A. Fasching, Prof. Dr. med. Beckmann & Prof. Dr. Björn Eskofier (Informatics))
- Medical Valley, Erlangen

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FIBRICHECK

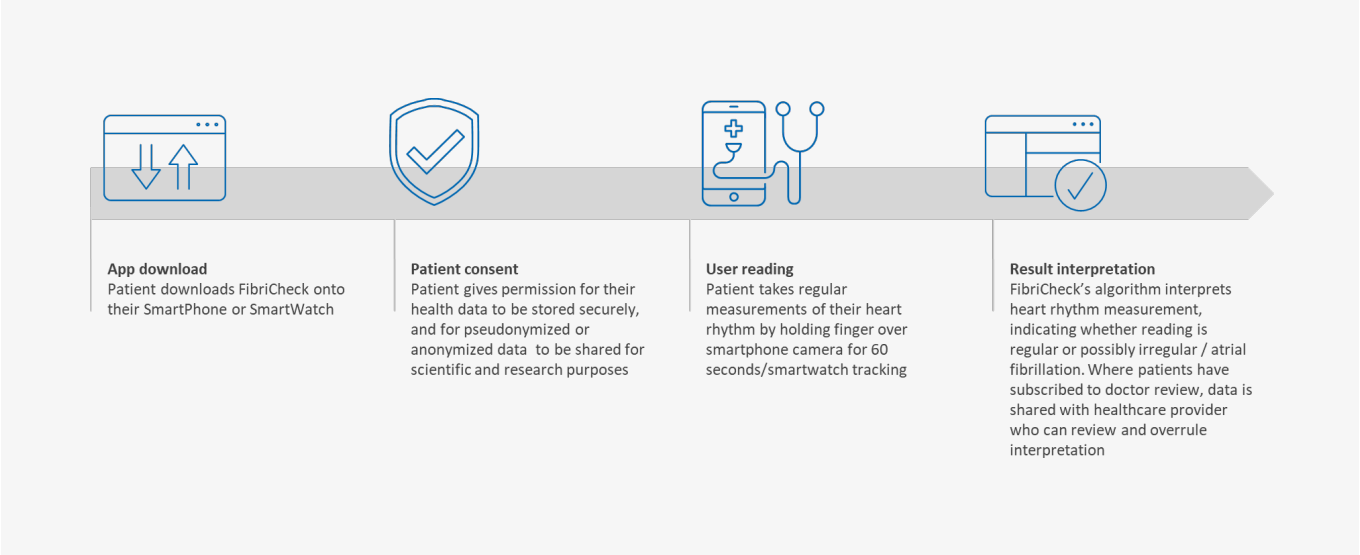
What is FibriCheck?

Based in Hasselt, Belgium, FibriCheck is a smartphone and smartwatch app targeting stroke prevention by enabling early detection of cardiac arrhythmias. With the mission of making healthcare widely available, affordable, and time/location-agnostic, FibriCheck uses clinically validated PPG technology and has proven clinical equivalence to single lead ECG devices.

Helping citizens globally, FibriCheck is medically certified as a CE-Class IIa medical device in Europe, has FDA clearance in the US and is TGA cleared in Australia.

How does FibriCheck work?

FibriCheck enables users to check their heart rhythm whenever and wherever, simply by using an app on their smartphone or smartwatch. A quick check-up is as easy as placing a finger on your smartphone camera for 60 seconds or opening the app on your smartwatch. Diagnosed patients can monitor their heart rhythm with FibriCheck from the comfort and safety of home, saving caregiver coordination and travel time to in-clinic visits.



By using an individual's own smartphone/smartwatch, FibriCheck have improved access to heart monitoring for over 650,000 people, who have performed over 5.5 million measurements. FibriCheck has helped detect over 60,000 arrhythmias (often innocent) – all without the need for extra hardware or visits to a healthcare centre. FibriCheck's algorithms have been extensively validated in clinical settings and large clinical trials in free-living conditions, demonstrating their state-of-the-art performance and proven equivalence with single lead ECG (electrocardiogram) devices.

How could the EHDS help improve the environment for FibriCheck?

FibriCheck has played a pioneering role in the field of digital health over the last 6 years and has gathered significant experience regarding the opportunities and barriers of using health data for the betterment of patient care.

Since the beginning of the pandemic, there have been tremendous gains in the delivery of effective remote care continuity. Together with leading clinical partners, FibriCheck launched a Europe-wide remote monitoring project: TeleCheck-AF. The success of this project represented a key turning point in the adoption of digital heart health, enabling over 40 clinical centres in 14 countries to deliver high-quality care despite pandemic restrictions. Replacing 95% of face-to-face visits, approximately 2,500 patients were monitored remotely through TeleCheck-AF, garnering recognition by medical societies, citation in multiple clinical studies and inclusion in clinical guidance.

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BLUEMETRIX

What is Bluemetrix?

Bluemetrix is a data automation and management solution which simplifies and expedites the integration of data from multiple data sources and deploys it in a data lake. They enable those in charge of data operations, data governance and self-service analytics or executives with accountability for data reporting to benefit from a single view of all data activity across an organisation.

The Bluemetrix use case focuses on their partnership with St. James's Hospital, Dublin and Children's Health Ireland, where they are working towards the development of a Data Safe Haven infrastructure, with a view to it being used to facilitate clinical research using the latest in AI and ML technology. This project will initially involve the integration of data from the EHR (Cerner) system in operation in the hospital, with data from Pathology, Radiology and other related healthcare systems installed on the hospital campus.

Over time, as the system matures, other data sources from outside of the campus facility will be integrated with the data in the Data Safe Haven, allowing for richer and more complex research to be carried out on the data.

While the data will be integrated initially from St. James's and Children's Hospitals, the plan is to make this integrated dataset available to researchers throughout Ireland. This will involve third party researchers accessing the data for their own research projects, which will mean that the data has to be available in a pseudonymised format.

How will this project work?

The data exists today in distinct silos throughout the organisation, and it is not possible to integrate or combine the data in a secure or simple manner using the existing systems. The sensitive nature of the data that is stored, also precludes the siloed data being made available as is to third party research institutions.

The building of a Data Safe Haven will allow all of the distinct data sets to be combined and integrated in one data repository. Bluemetrix will ensure the data is tokenised using Format Preserving Methods, so that anonymised data can be made available to researchers in a format which will allow them to create and run AI/Machine Learning models on the data. We will also simplify the building of the pipelines and automatically capture all governance activity from the pipelines, providing a Governance framework for the Data Owners to audit and validate what happens with their data.

Third party researchers and institutions can be given controlled access to the data, ensuring that at all stages they will only be able to access tokenised data, and no-PII/sensitive data will be made available to them. Typically this will result in third party researchers being able to access data in tables on the data lake, and to run AI/ML models using the AI/ML tools available on the data lake, so that the data at all times will remain within the data lake.

This project is intended to be a pillar project in the development of an Academic Health Science campus at St. James's Hospital. As the data is also to be made available to third party researchers across the island, it is envisaged that it will have a very positive effect on the level and scale of clinical research carried out in Ireland. Aggregation of patient data from multiple sources enables the creation of sufficiently large datasets for statistical and AI analysis, and the delivery of insights into diagnosis, prognosis, optimised therapy, and improved patient care.

How could the EHDS help improve the environment for Bluemetrix?

For the successful completion of the project, the following issues will need to be overcome:

Technical

- Access Policies: Secure access policies will have to be implemented across the datasets ingested and generated.
- Data Policies: The data policies governing the usage of the various data sets will have to be implemented and enforced.
- Encryption: All PII and Sensitive data will need to be encrypted as it is ingested into the safe haven.
- AI/ML Toolset: An AI/ML toolset will need to be put in place which allows access to researchers or different skill sets, while ensuring the most up to date AI/ML modelling can be carried out on the data.

Governance

- Data Access: The data owners/stewards are required to give permission for their data to be used and integrated into the Safe Haven.
- Audit: All activity that is carried out on the datasets needs to be recorded and auditable.
- Data Policies: The data policies governing the usage of the various data sets will have to be implemented and enforced.

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NEW SKYCARE

What is New SkyCare?

New SkyCare is an EIT Health project that aims to establish the first pan-European virtual hospital, supporting patients and care providers through telemonitoring and remote medical assistance. In New SkyCare health providers and payors in Sweden and the Netherlands, are working together with a multinational medical technology company to explore novel ways to provide care, leveraging opportunities offered by digital healthcare approaches.

The goal is (1) bringing care to the comfort of the patient's home, where they have access to their data and remote access to health professionals, and (2) relieving the pressure on health care providers by shifting the monitoring to a 24/7 Medical Service Centre, which contacts the patient and health providers when necessary.

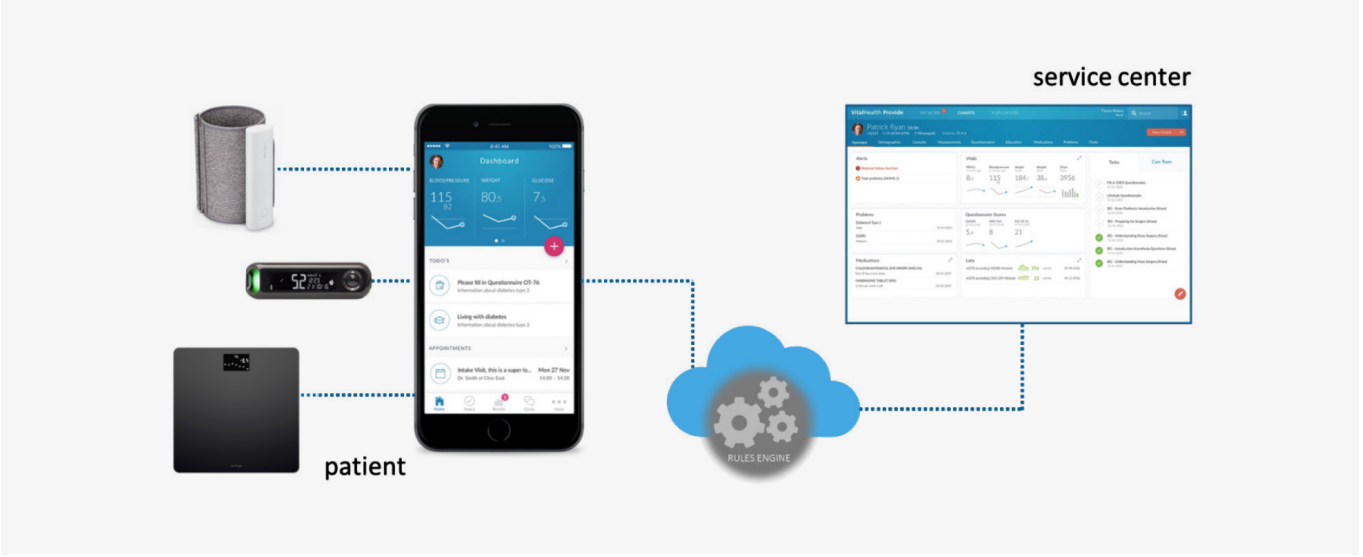
The three key features of the IT architecture of the open central platform are:

- **Connection** between patients and their existing eHealth tools (bring your own device) and the 24/7 Medical Service Centre
- **Analysis** (decision rules) of incoming measurement data
- **Views** (dashboards, task lists) for monitoring by the Medical Service Centre

The platform was classified as Class IIb Investigational Medical Device (2020). The implementation and technical documentation have been completed (2021). The project is now waiting for ethics approval for feasibility pilots; (1) monitoring of Diabetes Mellitus Type 2 patients in Erasmus MC in the Netherlands, and (2) monitoring Heart Failure patients in Karolinska Hospital Sweden.

How does New SkyCare work?

At enrolment, patients download the app on their smartphone and provide consent for the study. After enrolment, patients take regular measurement (e.g. blood pressure, blood glucose, weight). This data is interpreted by the rules engine of the associated care program. Depending on the measured value, the rule engine may schedule tasks for the patient and/or Medical Service Centre. Professionals (Medical Service Centre, Healthcare providers) have access to the New SkyCare web portal for professionals where they have access to patient measurements and monitoring tasks.



How could the EHDS help improve the environment for New SkyCare?

Within EHDS an important improvement towards the implementation and scalability of digital health solutions could be realised if European and national policymakers would make rules regarding health data use more consistent. The EHDS should be secure and provide mechanisms for consent, data access and governance, encryption and logging. The following EHDS properties are particularly relevant for New SkyCare.

- **Trust:** A health data space that is known, understood, and trusted by all partners should reduce lengthy discussions on project or collaboration-specific solutions.
- **Neutral zone:** Data sharing and analysis in a trusted "neutral zone", that is not owned by or located in the organisation of a specific partner.
- **Research:** A research environment where algorithms can be developed, linked to data sets (within consent) and validated.

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